

An Annex to the Infection Prevention and Control Program Standard



April 2017





Auditing the Infection Prevention and Control (IPAC) Program

An Annex to the IPAC Program Standard

by the IPAC Canada Working Group for the IPAC Program Standard and IPAC Program-wide Audit Tool (PAT[®])

Copyright 2016 IPAC Canada/PCI Canada

IPAC CANADA: Auditing the IPAC Program

PAT[©] Working Group

Co-Chairs:

Karen Clinker MEd BScN CIC CCOHN/CM Infection Control Consultant – Northwestern Ontario (2006-2014) Public Health Ontario Dryden, Ontario

Members:

Brenda Dyck BScN Infection Prevention and Control Consultant Winnipeg, Manitoba

Jim Gauthier MLT CIC Senior Clinical Advisor, Infection Prevention Sealed Air Diversey Care Kingston, Ontario

Bernice Heinrichs RN MN CIC Infection Control Professional Standards and Projects Team Alberta Health Services Edmonton, Alberta Shirley McDonald ART CIC IPAC Consultant/Medical Writer (2005-2014) Ontario Agency for Health Protection and Promotion & Public Health Ontario Bath, Ontario

Karen Hope MSc BSc Director IPC – Calgary Zone Alberta Health Services Calgary, Alberta

Ramona Rodrigues RN BSc MSc(A) CIC ICS-PCI FAPIC Manager, Infection Prevention and Control Service – Adult Sites McGill University Health Centre Montréal, Québec

Marion Yetman MN BN RN CIC Provincial Infection Control Nurse Specialist (2006-2015) Government of Newfoundland/Labrador -Department of Health & Community Services St. John's, Newfoundland

Acknowledgements

The authors wish to thank IPAC Canada for facilitating the development of this *IPAC Program Audit Tool* (*PAT*[®]) Annex to the *IPAC Program Standard*. Thanks also to the Canadian Agency for Drugs and Technologies in Health (CADTH) for valuable training of committee members in critical appraisal of the medical literature and other technical support.

Suggested Citation

Infection Prevention and Control (IPAC) Canada. Auditing the infection prevention and control (IPAC) program. An annex to the IPAC program standard. 2017April. Available at: https://ipac-canada.org/photos/custom/pdf/Audit_Annex.pdf.

Supplement

An annex describing the methodology used to produce the *IPAC Program Standard* and *IPAC Program Audit Tool (PAT[®])* together with the literature search strategy, critical appraisal and stakeholder review process, is available at: https://ipac-canada.org/photos/custom/pdf/Supplement.pdf.

Table of Contents

AUD	Л	TING T	HE IPAC PROGRAM	. 5
1		Wн	at is an IPAC Program Audit?	.5
2		Aud	IT CRITERIA FOR THE IPAC PROGRAM AUDIT	6
	ź	2.1	IPAC Risk Identification	.7
	ź	2.2	IPAC Risk Grading	10
	ź	2.3	IPAC Risk Weighting	10
3		THE	AUDITOR	11
	3	3.1 Au	ditor Competence and Abilities	11
	3	3.2 Au	diting Theory	12
	3	3.3 IP/	AC Auditor Selection	12
4		THE	Audit Plan	13
	4	4.1 Est	ablishing an Audit Plan	13
	4	1.2 Au	dit Sampling	13
	4	4.3 Ga	thering Audit Evidence	14
	4	1.4 Au	dit Findings Integrity	15
5		Step	'S IN THE AUDIT PROCESS	15
	5	5.1	Planning and Preparing for the Audit	15
	5	5.2	Conducting the IPAC Program Audit	18
	5	5.3	Scoring the Audit	23
	5	5.4	Reporting on the Audit	24
A	BB	REVIAT	IONS	28
G	LC	SSARY	OF TERMS	28
APP	EN		A: AUDIT SAMPLING	30
APP	E١	NDIX B	: SCORING THE IPAC PROGRAM AUDIT	32
	(Qualito	ative Scoring	32
	(Quanti	itative Scoring	32
	(Qualita	ative vs. Quantitative Scoring	33
REF	ER	ENCE	S	34

Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization 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 (IIA)

1. What is an IPAC Program Audit?

An infection prevention and control (IPAC) program audit is a comprehensive and objective evaluation of the design and effectiveness of a health care organization's IPAC program against an approved standard. The audit "adds value" to IPAC practice as a whole, specifically to patient and staff safety outcomes. Evaluating the IPAC program allows an organization to¹:

- obtain valuable input from staff, management and others within the organization on the comprehensiveness, reliability and functionality of the IPAC program; and
- review each individual component of the IPAC program to determine how well the program is being implemented.

In recent years, IPAC programs have become increasingly part of achieving and supporting the staff and patient safety goals of their organization. The requirement for auditing IPAC practice in health care and measuring the implementation of IPAC protocols and procedures has become a critical component to achieve these goals. Government agencies that develop IPAC guidelines,² accreditation bodies³ and staff health and safety associations have highlighted the value of audit tools.

Data derived from audits can be used to direct the IPAC program's annual goals and objectives and assist in meeting the needs of the organization in relation to IPAC standards and safer health care practices. The infection control professional (ICP) who undertakes audits will act as a role model and change agent.⁴

The audit process fills the gap between policy and practice. Stages in this process include:

- setting IPAC program auditing criteria based on the IPAC program standard;
- providing structured training for auditors;
- testing IPAC practice against these criteria ("the audit");
- providing results and constructive feedback to those audited;
- correcting IPAC practice where it falls short; and
- re-auditing to ensure that the IPAC program standards continue to be met.

Modification of practice and subsequent demonstration of improvement in IPAC outcomes 'closes' the audit 'loop'. This cycle is repeated until the chosen criteria are fulfilled and outcomes are satisfactory.⁵

During an audit, the auditor (person performing the audit) and auditee (site/department/area being audited) are partners in this continual improvement process. An IPAC program audit will benefit the organization best when used in a positive manner:

- Audits should be proactive rather than reactive.
- Audits are a means for problem solving, not for laying blame.
- Audits identify program strengths and opportunities for improvement.
- Audits result in continuous improvement of processes.
- Audit findings should add value to the auditee's quality improvement programs.
- Audits monitor for consistency across all aspects of the process.
- Audits promote/enhance the organization's IPAC culture and employee awareness of IPAC protocols and procedures.

2. Audit Criteria for the IPAC Program Audit

The criteria of an IPAC program audit are the indicators that the auditor will observe and evaluate against the IPAC program standard.

A criterion is 'a systematically developed statement that can be used to assess the appropriateness of specific healthcare decisions, services and outcomes'.⁶

Audit program auditing criteria are classified as structure, process or outcome⁷:

- Structure criteria refer to the availability and organization of resources, including products (e.g., provision of alcohol-based hand rub at point-of-care; availability of IPAC guidelines for each procedure).
- Process criteria refer to what is done with the organization's resources (e.g., compliance with hand hygiene protocols; IPAC practice follows organizational guidelines).
- Outcome criteria measure the effect of the activities on staff and on the patient (e.g., infection rates).

In the past, IPAC activities have focused primarily on outcome audits (e.g., surveillance activities aimed at generating infection rates). Measuring structure or process criteria that have been proven to affect outcome may be a more cost-effective and sensitive measure of the quality of care.⁸

The audit criteria that have been chosen for the *IPAC Program Audit Tool (PAT[©])* are based on the *IPAC Program Standard* developed by IPAC Canada (available at: http://ipac-canada.org/photos/custom/pdf/IPAC_PROGRAM_STANDARD_2016.pdf).

Audit criteria/standards are⁹:

- measurable;
- observable by the auditor;
- evidence-based;

- explicit (visible) vs. implicit (implied/understood);
- related to important aspects of care; and
- linked to health outcomes which are clear, influenced by process and occur within a short period.

2.1 IPAC Risk Identification

Risks are threats or negative outcomes that can be expected to occur if a particular procedure or practice is not performed or is performed incorrectly. When developing IPAC audit tool criteria, risk answers the question, "What is harmed by a deficiency if the criterion is not met?" See Table 1 for examples of IPAC risks associated with different types of health care organizations.

Health Care Organization	Audit Criterion Deficiency	Possible Result of Deficiency
Acute Care	Failure to reprocess semi-critical and critical medical devices according to manufacturer's directions and best practices	Acquisition of post-operative infection
Long-term Care	Failure to clean and disinfect commodes between residents	Spread of C. difficile
Community/Home Care	Failure to sterilize foot care instruments	Foot infection, acquisition of bloodborne infection
Ambulatory/Clinic Care	Failure to provide masks to coughing patients	Acquisition of influenza by other patients and staff
Prehospital Care	Failure to perform hand hygiene according to best practices	Spread of infections between patients and health care providers
Occupational Health	Improper discard of used needle	Staff needlestick, acquisition of bloodborne infection

Table 1: Examples of audit criteria deficiencies in different health care organizations

Once IPAC risks are identified and audit criteria/standards established, each of the audit criteria should be graded as to the **likelihood** of risk/infection occurring if the criterion is not met, as well as the **impact** of the risk/infection to the patient, staff or the organization. A weighted score is then developed based on the grading, and this score can be used to assess the overall severity of the deficiency as well as guide action plans and timelines to deal with the deficiency. A deficiency with a high score will require more immediate action than will one with a very low score. See Figure 1 for the steps in this process.



Figure 1: Steps in the development of IPAC audit tool criteria

IPAC risks may be identified from¹⁰:

- prior audit results;
- industry surveys and benchmarking (e.g., surveillance);
- outcome measurements (e.g., morbidity, mortality, increased length-of-stay related to infection);
- litigation related to infection;
- failed workplace safety inspections; and
- workplace accident insurance claims (e.g., infection resulting from needlestick injury).

A risk framework may be used to identify IPAC risks in the organization,¹⁰ for example:

- Exposure Analysis: effects of physical (e.g., sharps) or human (e.g., communicable disease) risks;
- Environmental Analysis: effects on processes and changes in the external and internal environments, including:
 - physical environment (site, location, weather, terrain, access);
 - economic environment (budget, finances);
 - government regulations (policies, regulations, standards);
 - suppliers (product manufacturers, product suppliers, contractors); and
 - technology (e.g., single-use medical devices).
- Threat Analysis: effects of natural disasters or pandemics on the IPAC system.

Another type of risk framework may be seen in Table 2, with IPAC risks grouped by patient risks, organizational risks and staff risks.

Table 2: A risk framework for identifying IPAC risks in a health care organization

Patient Risks

Will deficiency result in harm to patients?

What is the extent of harm?

Types of patient harm:

- infection
- higher morbidity and mortality
- excess length of stay
- extra procedures (e.g., additional surgery)

What is highest risk?

- certain patient populations (e.g., oncology)
- certain types of care (e.g., surgery)
- certain types of activity (e.g., reprocessing)
- business risks that impact on operations of organization (e.g., increased length of stay)

Organization/Facility Risks

Will deficiency result in harm to the facility?

What is the extent of harm?

Types of facility harm:

- increased cost due to infection
- litigation
- operations (e.g., damage to facility)
- outbreaks
- closures
- recalls
- interruption of service (e.g., flooding)
- reputation, loss of confidence in facility
- delays in admission, transfer, discharge
- increased ER wait times
- treatment, procedures and surgery
- delays in consults and referrals
- care and service accessibility
- failed health inspections

What is highest risk?

- regulatory requirements (e.g., environmental impact or contamination)
- business risks that impact on operations of organization (e.g., increased ER wait times)

Staff/Contractor Risks

Will deficiency result in harm to staff?

What is the extent of harm?

Types of staff harm:

- staff infections and sick time/absenteeism
- workplace insurance claims
- increased fear in staff to care for high risk patients and subsequent union action (e.g., Severe Acute Respiratory Syndrome -SARS)

What is highest risk?

- certain patient populations (e.g., mental health)
- certain types of care (e.g., needlesticks)
- certain types of activity (e.g., outbreaks)
- regulatory requirements (e.g., handling of biohazardous material, occupational health)

IPAC CANADA: Auditing the IPAC Program

2.2 IPAC Risk Grading

Grading or measuring risk is not a precise science.

Grading or measuring risk is not a precise science and is difficult because of its intangible nature. Often a quick qualitative grading (high, medium, low) is most effective. Because risk is difficult to measure directly, the use of observable and/or measurable risk factors are often used in audits.¹⁰ Combined together, a set of risk factors can effectively result in better conceptualization of a particular risk, allowing it to be more easily measured.

When selecting the risk factors that are to be used, the **likelihood** of the risk occurring and the potential **impact** of the risk need to be considered. Choose several factors to represent important aspects of the auditable unit(s) risks. These factors should vary within each auditable unit from conditions of low risk to high risk.

The *PAT*[©] working group has graded each of the IPAC program standards using a consensus model. For a summary of how these values were achieved, see the *PAT*[©] *Supplement*, which may be found at: www.ipac-canada.org/photos/custom/pdf/Supplement.pdf.

2.3 IPAC Risk Weighting

Assigning weight to risk factors is a subjective process.¹⁰ Weights are allocated to the chosen risk factors based on an evaluation of the consequences that the risk factor has on patients, staff or the organization, using a sliding scale (e.g., two to eight points). This scale represents the strength of the risk factors in the area or department being audited.

Judgement must be used to determine the weight a particular risk factor should have in relation to other risk factors. Assigning weight can be done by the auditor or by a group using a consensus tool such as the Delphi Technique.¹¹

The same grading might not be applicable to a particular risk factor in all audited areas. For example, environmental cleaning within the operating room would carry a higher weight than would environmental cleaning in office spaces.

The PAT[©] working group has weighted each of the IPAC program standards based on their risk grading and uses these values when scoring the PAT[©]. For a summary of how these values were achieved, see the *PAT[©] Supplement*, which may be found at: www.ipac-canada.org/photos/custom/pdf/Supplement.pdf.

3. The Auditor

Internal auditors have to be independent people who provide an independent, objective and constructive view.

Chartered Institute of Internal Auditors

An auditor is an individual trained to conduct an audit. **Internal auditors** are employed by the organization that they audit. **External auditors** may or may not be employed by the organization they audit (e.g., auditor from another facility within a multi-facility organization, or an outside consultant hired or requested to do an audit by the facility).

3.1 Auditor Competence and Abilities

To be effective, the organization must have qualified, skilled and experienced staff performing internal audits. Individuals chosen to perform audits should exhibit certain fundamental character strengths¹²:

- Integrity the foundation of professionalism;
- Fair presentation the obligation to report truthfully and accurately;
- Due professional care the application of diligence and judgement in auditing;
- Confidentiality security of information;
- Independence the basis for the impartiality of the audit and objectivity of the audit conclusions; and
- Evidence-based approach the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

The auditor must also possess the following^{5, 12}:

- good verbal and written communication skills;
- time management skills (prompt attendance, ability to keep to a schedule);
- adequate training prior to the audit (e.g., prepared for what to look for in terms of the audit evidence via interview, observation and documentation review);
- knowledge and understanding of the criteria of the audit tool (e.g., IPAC knowledge, knowledge of legislated requirements, specialized knowledge of the area to be audited and all aspects of the audit tool and auditing process to be used);
- observation skills (e.g., ability to observe and assess practice);
- thorough investigative skills (e.g., cognitive, verbal, listening);
- good interpersonal skills (e.g., ability to encourage appropriate deficiency resolution);
- ability to analyze data; and
- engaging presentation skills.

3.2 Auditing Theory

The auditor should have a good understanding of auditing theory (i.e., the reason for conducting an audit and the audit methodology to be used).

A written procedure (audit plan) is developed to define the responsibilities and requirements for planning and conducting the audit, establish which records are required for review and report results. The selection of trained auditor(s) and conduct of the audit ensures objectivity and impartiality of the audit process.

The auditor reviews the audit criteria to ensures that he/she understands the requirements necessary for the criteria to meet the established IPAC standard. The auditor is aware of validation techniques that will provide audit evidence that the criteria conform to the standard (see Section 4.3, *Gathering Audit Evidence*).

The auditor understands the scoring requirements of the audit and is prepared to explain this to the auditee, including how the criteria are weighted (see Section 2.3, *IPAC Risk Weighting*).

3.3 IPAC Auditor Selection

IPAC auditors are selected based on their knowledge of the IPAC requirements of the area to be audited, familiarity with the area to be audited, or other factors. Where a health care organizaton has multiple sites, an auditor based at one site could audit another site. The auditor(s) will complete the full auditing process, including pre-and post audit meetings, audit documentation and communication of the final audit report in a timely manner.

The number of auditors recommended to carry out a specific audit will vary depending on the size of the area being audited and the number of staff working in the organization (Table 3).¹³

Number of Staff	Recommended Number of Auditors
Less than 50	2
50 - 149	3
150 - 249	4
250 - 349	5
350 +	6+

Table 3: Recommended number of auditors based on staff numbers

From: Alberta Municipal Health and Safety Association: COR Training

The trained auditor will objectively gather information, validate the facts and then compare them to the standards used to measure IPAC practices. The primary goal is to help improve the IPAC program. The auditor must ask specific questions and obtain knowledge about the organization/service provider.⁵

An IPAC auditor does not necessarily need to be an infection control professional. For example, a dialysis nurse might be better suited to audit IPAC practices in a dialysis unit. In highly specialized organizations, obtaining IPAC expertise to assist in the auditing process should be considered.

An IPAC auditor does not necessarily need to be an infection control professional.

4. The Audit Plan

4.1 Establishing an Audit Plan

A written audit plan will outline the format and structure of the internal audit and should be presented at the pre-audit meeting. The audit plan contains the following components¹⁴:

- pre-audit meeting;
- audit date(s);
- location of audit (e.g., site/department/area);
- audit objectives (i.e., why is the audit being done?);
- audit scope (i.e., full audit or a portion of the audit?);
- auditor(s) contact names/phone numbers/email addresses;
- auditee(s);
- audit methodology (i.e., how will the audit be conducted?);
- audit time-table or schedule;
- method of reporting audit results;
- information regarding safety (e.g., are there special requirements for auditor to follow during tours, such as personal protective equipment?);
- any other relevant information pertaining to the audit; and
- post-audit meeting date.

4.2 Audit Sampling

4.2.1 AUDITING MULTIPLE WORK SITES

For organizations that have multiple work sites, the number of work sites included in the audit must be representative of the overall operations of the organization. Work sites include all places where staff employed by the organization carry on work. The number of work sites included in the scope of the audit must also meet established minimums, as indicated in Table 4.^{15, 16}

Table 4: Minimum number of work sites to be included in an audit

Number of Work Sites	Minimum Number Included in Audit
1 – 2 sites	All sites
3 – 4 sites	At least 2 sites
5 – 8 sites	At least 3 sites
9 – 30 sites	1/3 of all sites

From: Alberta Municipal Health and Safety Association: COR Training; and Alberta Forest Products Association: Audit Protocols

4.2.2 **CHOOSING A REPRESENTATIVE SAMPLE OF STAFF**

Accessing a representative sample of the organization's staff to interview will result in higher accuracy of results and reduction of bias¹⁷ when completing the audit.¹⁴ All units and staffing levels of the organization must be reflected in the sample to ensure that it is representative of the size and complexity of the organization.¹⁵ To be "representative" the interview sample must consider all of the following variables:

- Length of Service includes a cross-section of everyone from new hires to experienced staff.
- **Department** includes staff from all departments in the organization.
- Staffing Level includes a cross-section of staff from every staffing level, management to . workers, including part-time and casual. When the audit scope encompasses more than one work site, include a sampling of personnel from each work site included in the scope of the audit.
- Work Shifts include a sampling of staff from all shifts.

If the organization is small and time permits, as many people as possible should be interviewed during the staff interview and observational tour components of the audit. If the organization is large, staff should be chosen according to statistical criteria to ensure that the interview sample is representative of the size of the organization. Sample size calculations may be used to determine the minimum number of staff interviews that are required based on the total number of staff in the organization.

See Appendix A for recommended number of staff to interview based on facility size using sample size calculations.

4.3 Gathering Audit Evidence

For each of the IPAC audit criteria (i.e., IPAC program standards), the auditor determines whether the organization conforms to the standard or does not conform to the standard. This audit evidence comprises records, statements of fact or other information which are relevant to the audit criteria/standards, are verifiable and will validate (or "prove") the audit result.

There are three established methods to generate audit evidence and validate audit results¹⁴:

does not conform to a standard. **Documentation**: What written materials are necessary

The auditor uses audit

evidence to determine

organization conforms

to an IPAC standard or

whether the

- to validate the results? For more information and a list of written records that may be used for the Document Review, see Section 5.2.1, Review Health Care Organization's Documentation and Records.
- Interview: What questions must be asked to validate the results? Interviews may be formal (i.e., scheduled and structured) or informal (e.g., ad hoc during the observational tour). For more information on conducting staff interviews, see Section 5.2.2, Staff Interviews and Knowledge Assessment.
- **Observation**: What directly observed practices will validate the results? For more information on conducting observational tours, see Section 5.2.3, Site/Department/Area Observations.

4.4 Audit Findings Integrity

The integrity of the audit findings rests upon the audit evidence that the auditor has gathered during the audit. The audit findings can be challenged by the auditee if audit evidence is weak.¹²

5. Steps in the Audit Process

The audit should follow a planned sequence of events, as illustrated in Figure 2.

5.1 Planning and Preparing for the Audit

Pre-audit preparation is essential to the success of the audit process.⁵ The following are the pre-audit planning and preparation steps that should be considered prior to conducting an IPAC audit:

5.1.1. PRE-AUDIT PREPARATION

Prior to meeting with the site/department/area that is to be audited, there should be communication between the auditor and auditee to determine the following:

- Establish audit date(s) and schedule.
- Select specific area(s) to be audited and the scope of the audit (e.g., patient care areas only).
- Provide a list of documents required for review prior to, or during, the audit (e.g., IPAC manual, organizational chart with names of key individuals and contact information). A facility map might be necessary if auditing different sites from the same organization, if the auditor is unfamiliar with the site being audited.
- Suggest key participants to be in attendance at pre-audit meeting.
- Determine approximate number of employees to be interviewed during the audit so this can be provided in the Audit Plan and addressed at the pre-audit meeting. (See Section 4.2.2, *Choosing a Representative Sample of Staff*, and <u>Appendix A</u>, *Audit Sampling*).
- Establish supplies and workspace required by the auditor.

There should be a clear, preferably documented, reason for conducting the audit as this will need to be communicated to the site/department/area manager in the pre-audit meeting (e.g., auditing in order to develop an action plan for the IPAC program as part of an overall operational plan, or auditing as part of the ongoing quality improvement program).



Figure 2: Steps in the audit process

5.1.3. PRE-AUDIT MEETING WITH SITE/DEPARTMENT/AREA

Prior to conducting the audit, the auditor(s) advises the site/department/area manager that a formal audit of their work area is to be conducted and a meeting is arranged to provide a brief review of the audit process and develop an audit plan.¹⁸ The auditor discusses the entire audit process with management and with selected staff representatives.¹⁹

The pre-audit meeting is attended by the auditor(s), auditee and others impacted by the audit, such as area managers, Quality Manager, IPAC department manager/lead, etc. This meeting can take place prior to the date of the audit (preferable) or on the audit date itself. Discussion should include the purpose of the audit, what will be happening during the audit and expected outcomes. Minutes may be recorded. Individuals who attend the pre-audit meeting should also attend the post-audit meeting.

The audit process identifies new risks, analyses risks against established norms and effectively implements risk management activities. Key elements of this process are communication and consultation. An interactive exchange of information between the IPAC team, management, health care workers and other partners provides the basis for increased awareness of the importance of IPAC practices, identification of risks before they arise and prompt management of risks as they occur.²⁰ Questions should be invited and it is important to ensure confidentiality of shared information.

The auditor(s) should provide written auditing materials to those present at the pre-audit meeting to reinforce what was communicated in the meeting, and to "de-mystify" what will be required during the audit itself, thereby assisting individuals to prepare for the audit.

Examples of information that can be provided at the pre-audit meeting include:

- contact information of the auditors and key site/department/area individuals;
- interview questions the auditing questions should not be a surprise to those interviewed and pre-knowledge of the auditing questions will help get the individual better prepared for the audit;
- documents that will need to be reviewed audits run much more smoothly if the required documentation (e.g., policy manuals) is readily available at the time of the audit;
- forms for scheduling of staff according to the pre-determined dates and times of the audit;
- details on the positions and number of staff to be interviewed (e.g., how many managers, front-line staff, contracted staff);
- responsibilities of key individuals (i.e., auditors and site staff) during the audit process; and
- requirements for the auditor with respect to dress code, personal protective equipment or safety equipment that may be needed during the observational portion of the audit.

It is the auditee's responsibility to ensure that all staff, documents and records are ready to facilitate the audit evidence gathering.^{12, 14}

5.1.4. ORGANIZATION FAMILIARIZATION AND INFORMATION SHARING

One of the major phases of pre-audit preparation is familiarization with the organization and its specific characteristics. Some organization characteristics that are important to assess include:

- size (e.g., small, medium, large) and whether it has a centralized and/or decentralized structure (e.g., one large facility and/or dispersed or satellite sites);
- the nature of the health care services being delivered (e.g., acute care, long-term care, rehabilitative care, high risk and high cost health care service delivery activities) and the related IPAC issues that may occur;
- the resources available to meet the IPAC program needs;
- potential barriers and enablers that can affect IPAC program delivery; and
- organizational structure and reporting relationships.

Much of this organizational information should be provided to the auditor(s) when a decision to conduct the audit is made. This information will assist the auditor(s) to better prepare for the audit.

A brief escorted tour of a site/department/area will assist area staff and the auditor(s) to become acquainted prior to the audit taking place and should identify any further questions that need to be answered. This brief tour can be done ahead of the audit taking place or just before the actual audit begins.

5.1.5. AUDITOR PREPARATION ACTIVITIES

Auditors must respect the dress codes, personal protective equipment and safety procedures of the area they are auditing. Auditors must ensure they are prepared for the audit by becoming familiar with:

- the auditing process itself and related IPAC audit tools and forms;
- all information provided by the site/department/area being audited; and
- necessary items to bring with them for the audit (e.g., audit standard, audit checklists and forms, schedules, calculator) needed in the completion of the audit.

Once these steps have been completed, the audit may be administered.

5.2 Conducting the IPAC Program Audit

To best measure structure, process and outcome criteria, the auditing process must utilize the components of documentation review, interviews and direct observation.

5.2.1. REVIEW ORGANIZATION'S DOCUMENTATION AND RECORDS

The **Document Review** ensures that written IPAC guidelines are in place for each clinical procedure and practice and that these guidelines are current, acceptable and practical. If the health care organization's guidelines are inadequate, shortcomings should be addressed and rectified before the audit proceeds.⁵ Authoritative guidelines are readily available to inform the development of the IPAC program's protocols and procedures, produced by organizations such as the Public Health Agency of Canada or provincial Departments of Health, as well as IPAC Canada's *IPAC Program Standard*.²⁰

The Document Review is used for initial verification of audit findings. Some of the information will be obtained from documents that directly or indirectly contribute data that can be used as a basis for determining compliance with the IPAC program standards. Written or printed records may also be used to validate audit evidence (e.g., recorded sterilizer parameters may be used to validate effective sterilization of medical equipment).

Document review tends to be a long and complex process. For document review, the auditor should²¹:

- Focus the document review on the objectives of the audit tool.
- Request that staff indicate where the information is found in the requested documents. Review by a person unfamiliar with the local documentation system may be tedious and fruitless. The auditor must be explicit about his/her needs.
- Request documentation for the required audit element. For example, to determine if IPAC training activities have occurred, the auditor avoids a request for "committee minutes", since the information may not be found there. A better document to review might be staff attendance records for IPAC-related in-services. The IPAC Canada PAT[®] Auditor Workbook provides a list of suggested documents to review for each of the IPAC program standards.

Refer to Table 5 for a list of documents that may be used to verify IPAC program audit results.

Table 5: Types of documents used for IPAC audit document review

Types of documentation that may provide verification of IPAC audit results¹²:

- IPAC program administration records (e.g., goals and objectives, annual report, action plans, IPAC strategic plan, IPAC operational plan, IPAC protocols and procedures, IPAC manual, SWOT analyses, accreditation reports)
- Organizational records (e.g., mission/vision/values statements, organizational goals, policies, protocols, procedures, departmental manuals, preparedness guides, organizational charts, strategic plan, operational plan, annual report, accreditation reports)
- Communications records (e.g., memos, media reports, publications, promotional materials, signage, posters, newsletters, bulletins, electronic information messaging systems, websites)

Types of documentation that may provide verification of IPAC audit results ¹² :			
	Meeting records (e.g., minutes, terms of reference)		
	Assessment records (e.g., program needs assessments, stakeholder consultations, patient surveys, post-discharge questionnaires, staff surveys/focus groups, town halls, suggestion boxes, ombudsman reports, patient complaints related to IPAC program)		
	Human resource management records (e.g., staff performance appraisal forms, staff self-audit forms, job descriptions, work contracts, contractor agreements, attendance management programs, post-exposure follow-up protocols)		
-	Quality improvement records (e.g., sterilization indicator records, IPAC- related incident investigations, such as blood and body fluid exposures, audit action plans for improvement)		
-	Audit records (e.g., process audit records, outcome audit records, antibiotic usage records, inspection records, tabletop/drill reports, action plans)		
-	Purchasing records (e.g., purchasing and procurement records that include IPAC considerations, records of loaned/ leased medical equipment, product trials/evaluations)		
	Education and training records (e.g., staff training records, IPAC program educational materials, attendance records, evaluation forms, course certificates, education awareness campaign materials, brochures, pre/post-test results, self-audits, "just in time" training records, orientation materials, patient/visitor education materials)		
	Surveillance records (e.g., laboratory reports/data links, line listing forms, outbreak reports, risk assessments, IPAC software and statistical resources, surveillance reports)		

5.2.2. STAFF INTERVIEWS AND KNOWLEDGE ASSESSMENT

Prior to any observations in the workplace, there should be an assessment of staff knowledge regarding the application of IPAC standards while carrying out their duties. The auditor may collect this information with formal *Staff Interviews*, with a questionnaire or from ad hoc staff questioning during the observational tour.^{5, 19} The advantage to questioning staff directly is that the interviewer can adjust and expand questions according to the answers derived, to get a better sense of how (or whether) an IPAC standard has been implemented. Staff are advised that all interview records are confidential and will be destroyed once the report has been completed.

The interview portion is used to gather information that cannot be directly observed, such as organizational items. A range of interviews are carried out, encompassing individuals from all levels of the organization. Questions are asked in a manner that relates to the individual's job or role and the interviewee is encouraged to expand on their answers with more information as needed.^{1, 22} Telephone interviews are particularly useful for interviewing busy managers and supervisors.

The interviews for the audit must be representative of both the size and the complexity of the health care organization being audited. Interviewees are selected by the auditor (this may be done in consultation with the employer). For more information about choosing staff for interviews, see Section 4.2.2, *Choosing a Representative Sample of Staff*.

Responses from interviewees are either positive or negative, and give an overall indication of what is working well and what is an area of concern in the organization. Some of the interview questions require auditor judgement and a range of points may be awarded.¹ Interview questions should be flexible in content and style in order to suit the individual begin interviewed.²² When more than one individual is interviewed, at least 70% of responses must be positive for the standard to be considered to be met.^{1, 23}

Interview questions should be flexible in content and style and tailored to the individual being interviewed.

The process of interviewing may comprise three types of interviews²¹:

- 1. **Pre-audit interview** is conducted with the departmental director and/or senior management, who may or may not be accompanied by other staff. The purpose of this interview is to meet those who will accompany the interviewer, to become familiar with the area(s) being audited, to address potential barriers and to set a time for a final meeting.
- 2. **Staff interview** is conducted with staff (including contractors, employees, physicians, volunteers) who perform different activities in the health care organization. The purpose of this interview is to obtain specific information related to IPAC standards from those carrying on activities in the health care organization.
- 3. **Post-audit interview** is conducted with the departmental director and/or senior management, to report the main findings of the audit.

General facts relating to staff interviews include²⁴:

- Use interviews in addition to documentation to verify findings.
- Establish where interviews should take place and time frames to follow.
- Ensure that confidentiality is maintained.
- Be prepared to listen.
- Frame questions in a manner that makes sense to the interviewee. The interviewer may need to re-word questions to suit the knowledge base and skill set of the person being interviewed.
- Determine if accurate answers might be difficult to obtain due to the likelihood of social desirability bias.²²
- Be prepared to manage the interview (e.g., know how to deal with hostility, reluctance etc.).
- Interview all levels of personnel (e.g., staff, supervisor, manager).
- Interview the staff responsible for each task.
- Corroborate interview evidence by:
 - asking questions: inquire about task details;
 - observing actual task: watch the task being done;
 - checking records: confirm if task done is consistent with the documented procedure; cross check with what records reveal; and

• follow the audit trail: sequence of process steps.

Staff interviews are conducted with those who perform different activities in the health care organization. The objective is to obtain specific information related to the IPAC standards. In order to make the most of these interviews, the following are recommended²¹:

- The interviewer should always be accompanied by a professional from the health care organization.
- There should be an initial interview with the person in charge of the unit or activity. A meeting with staff working under this individual should be held only with his/her consent.
- Introductions are made and the reason for the interview is explained.
- The interviewer explains to the interviewee what information is required.

5.2.3. SITE/DEPARTMENT/AREA OBSERVATIONS

The Observational Tour is not an inspection that looks for specific infection-related risks, rather it is a review designed to identify strengths, weaknesses and opportunities for improvement.

Evaluation and verification of many of the IPAC program standards is based on observing how IPACrelated activities are conducted. This assessment can be done by directly observing practice.

The **Observational Tour**, depending on the size of the area to be audited, may comprise two components:

- escorted tour to get a basic overview of the site/department/area; and
- in-depth Observational Tour to complete the audit tool, examine records and interview staff.

The Observational Tour is a critical part of the overall audit.²⁴ The auditor will objectively gather information by directly observing practice, validate the observations and then compare them to the IPAC program standards.⁵ The tour is not an inspection, but a fact-finding mission. Auditors question staff during the tour and note further questions that may need to be asked later of key individuals. Clarification may be requested if the auditor does not understand the answer to a question. In some cases, written manuals and other materials may need to be reviewed to confirm or validate answers or observed actions. Should a further review of written materials/manuals be required to corroborate an observation, the auditor will note this.

Designated, knowledgeable staff may accompany the auditor during the Observational Tour. The auditor will question staff during the tour and note further questions that may need to be asked later of key individuals. The auditor is permitted to visit controlled areas (e.g., isolation rooms) and must be provided with appropriate protective equipment to do so.

Observational tours are relatively simple, but time-consuming. Developing an audit calendar for planning the audit cycle may be useful from a time management perspective. Decisions on what

standards to audit and which clinical area(s) to visit will be reflected in the calendar. Over time, all areas and all standards will be audited as part of an ongoing process.²⁰

If the auditor observes failure to comply with techniques or inappropriate practices, it is important to take note and possibly mention it at the final meeting. However, this does not necessarily mean that it represents a trend unless the practice is repeated.²¹ If a substandard deficiency situation is detected that warrants work stoppage, the auditor takes this action and informs the manager immediately (e.g., construction without proper hoarding; unacceptable sterilization processes or practices used for reprocessing medical equipment).

5.2.4. AUDIT TOOL DOCUMENTATION

While audit details are still fresh for the auditor, all audit tool documentation should be completed as thoroughly as possible prior to providing a verbal report. Audit findings fall into two categories:

- Conformance: Based on the audit evidence, the observed finding conforms to the audit criteria; and
- Non-conformance: Based on the audit evidence, the observed finding does not conform to the audit criteria.

The auditor(s) should provide an overall synopsis comprising both achievements (provided first) and deficiencies (provided last) at the post-audit meeting. General opportunities for improvement or potential nonconformity may also be included.

5.3 Scoring the Audit

There are two types of scoring: qualitative and quantitative. Refer to <u>Appendix B</u>, Scoring the IPAC Program Audit, for information on scoring types.

The final scores for the audit are ideally presented in the final report to be provided to the audited site/ department/area after all audit information is reviewed by the auditor(s). It is not uncommon during an audit for auditors to request further audit-related information from the organization to accurately score the audit tool. As a result, scores obtained during the audit itself may change with the review of this requested information.

An IPAC program audit is a work in progress, leading to continuous improvement.

If a particular IPAC program standard does not apply to the health care organization, there is should be an option to report "Not Applicable".

Auditing the IPAC program is a work in progress. There is no pass or fail score, rather the health care organization strives to improve their score on subsequent audits, after addressing deficiencies, leading to continuous improvement.

5.4 Reporting on the Audit

At the end of the audit, the auditor should provide both an initial verbal report and a final written report in a timely manner to the auditee. These last two steps complete the audit cycle to 'close the loop'.²⁰

5.4.1. INITIAL AUDIT REPORT DOCUMENTATION

Rapid analysis of data and generation of timely reports are essential to improvement. Data are most useful when the time between data collection and reporting is short.²⁵ Summarizing deficiencies captured by an audit that are not immediately addressed during the audit and sharing these with stakeholders affected by the audit are essential before an action plan is formulated.²⁰

The initial audit report documentation is used to provide a **verbal** report to the facility/site at the completion of the audit.

5.4.2. THE VERBAL REPORT

At the completion of the audit and prior to leaving the area, the auditor gives an initial verbal report to the clinician/manager in charge of the area being audited, outlining any areas of concern as well as identifying good practice.²⁰

The auditor communicates the following audit findings at this informal post-audit meeting:

- Briefly present relevant audit evidence to highlight key commendable practices of the auditee.
- Briefly present relevant audit evidence to highlight key deficiencies that require attention.
- Highlight any urgent deficiencies that require immediate attention.

5.4.3. THE WRITTEN REPORT

A written report on the audit is developed and given to the area clinician/manager for action within one week of completing the audit at the post-audit meeting.

In order to complete the final written audit report and identify deficient areas requiring action, it is necessary for the auditor(s) to ensure that all audit-related documentation, interview and observation records are thoroughly reviewed in order to finalize all audit reporting requirements. The auditor(s) may use a standardized IPAC program audit summary report format²⁰ to clearly identify and score IPAC program achievements and identify deficiency areas requiring action.

The audit summary report²⁰:

- should have a professional appearance (e.g., typed, not hand written);
- states the time period during which the audit(s) occurred;
- states the area(s) audited and overall impression of the audit;
- describes the audit process used (e.g., review of documents, interviews with staff, observational tours in the area);
- breaks down interview sampling by level and position of staff interviewed;
- includes positive highlights as well as negative findings;

- nonconformity findings are supported by relevant audit evidence;
- identifies strengths and opportunities for improvement; and
- highlights any area that requires immediate response (i.e., if not corrected, the situation will have a negative impact on patient care or on staff safety).

A well-written report guides decision-makers in the corrective action(s) required to address deficiencies. A separate report may be prepared for each audit area, or a single report might be completed for all audits done within a given time period.²⁰

Questions should be encouraged and criteria that do not conform to IPAC standards must be supported by relevant audit evidence. Discussion should centre on actions to deal with non-conformances. The auditor may offer assistance in addressing deficiencies if the organization desires this, and if the auditor has expertise in the area and time to be involved further.

IPAC Canada provides standardized report formats for the auditor to use following an IPAC program audit. Refer to the *PAT[®]* Auditor Workbook to obtain forms (available at: https://ipac-canada.org/photos/custom/pdf/PAT_Workbook.pdf).

5.4.4. POST-AUDIT MEETING

The auditor meets with the manager and selected staff from the audited area within a week of completing the audit to discuss the summary report and corrective action(s). Involving the manager and selected staff from the audited area assists the manager in understanding the importance of the deficiency and helps to gain his/her support and input on how best to address the deficiency. Using this process helps to foster 'buy-in' and accountability from others towards closing the loop on audit deficiencies.²⁰ The same attendees that were at the pre-audit meeting should also be present at the post-audit meeting.

The auditee is also provided with the following information at a formal post-audit meeting:

- the completed audit tool with scoring and notes;
- the audit report identifying strengths and opportunities for improvement;
- results of staff interviews by level and position of employee interviewed (anonymous information only); and
- auditor justification for interview and site sampling.

The final audit report is presented and the audit findings are communicated by the auditor. Relevant audit evidence is presented to highlight key commendable practices as well as key deficiencies that require attention. Urgent deficiencies that require immediate attention are discussed and the auditor may offer assistance in addressing these deficiencies, if desired.

There should be open discussion regarding next steps and questions are invited by the auditor. The auditee is responsible for making immediate corrections to any detected nonconformities, as requested by the auditor and to expedite the corrective action process.¹⁴ Minutes of the post-audit meeting may be recorded for reference.

5.4.5. ACTION PLAN FOR IMPROVEMENT

A meeting with stakeholders to develop an action plan for improvement will ensure departmental commitment to the action plan, address the implications of deficiencies and suggest timelines for completion.²⁰

The action plan and the timelines for resolution of deficiencies must be realistic and appropriate. The impact of deficiencies on staff and patient safety will inform the action plan in terms of sequencing, level of involvement and timeline for resolution²⁰:

- Sequencing is the prioritization of corrective actions based on the level of risk identified for the deficiency. Deficiencies that have the greatest negative impact on patient care or staff safety and are most likely to re-occur if not corrected (i.e., high or critical risk) will be first in the sequence for corrective action.
- Level of involvement is based on the risk level of the deficiency and may be an important factor in the successful resolution of the problem. Deficiencies with a higher level of risk are addressed by senior administration in a timely manner.
- Timeline for resolution and the urgency of follow-up will depend on the level of risk and the resources available to the facility. If a critical or high risk deficiency is identified (i.e., continuation of the deficient practice will result in severe outcomes, such as an outbreak or death), the practice is stopped immediately, senior management is notified and the issue is resolved.

5.4.6. CLOSING THE LOOP AND RE-AUDITING

Auditing can be a costly process and it does not "add value" to the organization if audit deficiencies that are identified in the audit are not addressed. Unresolved deficiencies may make support for further auditing a challenge if senior management does not see a cost/benefit for the organization.

Following the audit, modification of practice and subsequent demonstration of improvement in practice through re-auditing 'closes' the audit 'loop' (Figure 3). This cycle is repeated until the chosen criteria are fulfilled, outcomes are satisfactory and deficiencies are addressed.²⁰

Most auditing in health care is incomplete in that the audit loop is not 'closed'. *Closing the loop* means that once an audit is completed and changes are advised or recommendations are made as a result of the audit, the effects of those changes are measured by re-auditing.⁸ Re-auditing can assess whether compliance scores are improving following remedial action(s) in order to evaluate the success of the action(s).

Re-auditing may also be used to assess the impact of multiple IPAC interventions on outcomes when combined with outcome surveillance (e.g., measuring infection rates prior to the audit and following recommended interventions). Re-auditing should be repeated until the chosen criteria are fulfilled or practice is acceptable.²⁶

Often the prolonged nature of the audit cycle may make closing the loop difficult, particularly for items that may not be resolved completely within one month of the audit (e.g., items requiring construction, capital expenditures or significant resources, increased staffing levels, outside consultant review). In these cases, the facility/site must have a process to ensure tracking and follow-up of the item until it is adequately addressed. Every effort should be made to ensure that audit deficiencies are addressed.





Abbreviations

- ER Emergency Room
- ICP Infection Control Professional
- IPAC Infection Prevention and Control
- PAT Program Audit Tool
- SARS Severe Acute Respiratory Syndrome
- SWOT Strengths, Weaknesses, Opportunities and Threats

Glossary of Terms

Audit: See IPAC Program Audit.

Audit Conclusion: The outcome of an audit provided by the audit team after consideration of the audit objectives and all audit findings.

Audit Criterion/Criteria: The measurable and weighted components of the IPAC standard.

Audit Evidence: Records, statements of fact or other information which are relevant to the audit criteria and are verifiable.

Audit Findings: Results of the evaluation of the collected audit evidence against the audit criteria.

Audit Sampling: Selection and evaluation of a sample of items from a population of audit relevance such that the auditor expects the sample to be representative of the population and thus likely to provide a reasonable basis for conclusions about the population.

Auditor: An individual trained to conduct an audit. An auditor must also have skills and knowledge appropriate to the area in which he/she is conducting the audit.

Auditee: The health care organization, department, area or individual(s) being audited.

Confidence Level: A measure of the reliability of a result. It is expressed as a percentage and represents how often the true percentage of the population who would pick an answer lies within a given margin of error (or confidence interval).

Confidence Interval: Measures how much error may be tolerated at a given confidence level. A lower margin of error requires a larger sample size. This is also known as *margin of error* or *degree of precision*.

Conformance: Based on the audit evidence, the observed finding conforms to the audit criteria.

Criterion/Criteria: See Audit Criterion/Criteria.

Document Review: Part of an audit, designed to determine if a health care organization has current and accessible processes, policies, protocols and procedures in place and the adequacy and quality of records and documentation.

External Audit: An audit carried out by an outside agency (e.g., Accreditation Canada).

Internal Audit: An audit carried out by individuals who work within the health care organization.

IPAC Program Audit: A comprehensive and objective evaluation of the design and effectiveness of a health care organization's IPAC program against an approved standard.

Non-conformance: Based on the audit evidence, the observed finding does not conform to the audit criteria.

Observational Tour: Part of an IPAC audit, designed to allow an auditor to watch tasks being done and observe and verify specific conditions within a health care organization.

Population: The number of people from which the random audit sample is chosen.

Site Familiarization: Part of an audit, a brief escorted tour or discussion to allow the auditor to become familiar with the facility and any areas where special caution is required.

Staff Interview: Part of an audit, an approved, validated method used to gather and verify information about a health care organization's IPAC program by those impacted by that system. Includes formal discussion using standard, measurable questions or a questionnaire, delivered in-person or by phone.

Stratified Sample: A selection of people from the population based on characteristics that they have in common. For example, when auditing the use and reprocessing of endoscopy devices, the sample population might be all those who use, handle and reprocess endoscopy devices. This is also known as *quota sampling*.

Validation: The determination that evidence exists to verify that the audit tool criterion/standard has been met.

APPENDIX A: Audit Sampling

Statistical audit sampling helps ensure a high confidence level of compliance for the larger population when a smaller population is statistically sampled. It is the representativeness of a sample that allows the auditor to generalise the findings to the wider population. The larger a sample size, the more likely it is that a finding or result is not due to chance.

Audit sampling is used when the entire staff population cannot be audited. The audit sample is representative of the entire staff population and is likely to provide a reasonable basis for conclusions about the population as a whole. Audit sampling and the calculations below are best used for Staff Interviews where the questions asked require a "yes" or "no" type of response.

Several statistical parameters are used in calculating sample size:

- The confidence level is a measure of the reliability of a result. It is expressed as a percentage and represents how often the true percentage of the population who would pick an answer lies within a given margin of error (or confidence interval). The 95% confidence level means you can be 95% certain; the 99% confidence level means you can be 99% certain. A higher confidence level requires a larger sample size. The most commonly used confidence level is 95%.²⁷
- The confidence interval (also called margin of error or degree of precision) measures how much error may be tolerated at a given confidence level. For example, if you use a confidence interval of 4 and 47% percent of your sample picks an answer you can be "sure" that if you had asked the question of the entire relevant population between 43% (47-4) and 51% (47+4) would have picked that answer.²⁷ A lower margin of error requires a larger sample size.

When you put the confidence level and the confidence interval together, you can say that you are 95% sure that the true percentage of the population is between 43% and 51%. The wider the confidence interval you are willing to accept, the more certain you can be that the whole population answers would be within that range.²⁷

- The **population** is the number of people from which the random audit sample is chosen.
- A stratified sample is a selection of people from the population based on characteristics that they have in common. The characteristics used to stratify should be related to the measurement of interest.²⁸ For example, when auditing the use and reprocessing of endoscopy devices, the sample population might be all those who use, handle and reprocess endoscopy devices. This is also known as *quota sampling*.²⁹

The following formula and figures are based on Berenson's *Basic Business Statistics: Concepts and Applications*, 12th Edition:³⁰

For a finite (i.e., answer is "yes" or "no") sample, the uncertainty, or confidence interval, of a measurement at the 95% confidence level can be stated as:

$$\varepsilon = 1.96\sqrt{\frac{p(1-p)}{n}\frac{N-n}{N}}$$

where: ε = confidence interval (i.e., measurement uncertainty)

N = total population (i.e., total staff)

n = survey population (i.e., subsample of the total staff)

p = measurement (i.e., fraction of surveyed people to answer "yes" or "no")

If we require that the measurement uncertainty is less than ε , at the 95% confidence level, then the required survey size can be written as:



The application of this formula to a population in health care results in the recommended numbers of staff needed to be interviewed to result in a representative sample of the entire population, as indicated in Table 6.

Table 6: Minimum number of staff to be interviewed in an audit sample

Total Staff Population/ No. Staff in Stratified Sample	Minimum No. of Staff to be Interviewed with Confidence Interval = 5% (% of population)	Minimum No. of Staff to be Interviewed with Confidence Interval = 10% (% of population)
<10	ALL (100%)	ALL
11-20	ALL (100%)	10-17 (87%)
21-30	20-28 (94%)	17-23 (80%)
31-40	29-36 (92%)	23-28 (73%)
41-50	37-44 (90%)	29-33 (68%)
51-75	45-63 (86%)	33-42 (60%)
76-100	63-79 (81%)	42-49 (52%)
101-150	80-108 (75%)	49-58 (43%)
151-200	108-132 (69%)	59-65 (35%)
201-300	132-169 (61%)	65-73 (28%)
301-400	169-196 (52%)	73-77 (22%)
401-500	196-217 (46%)	77-81 (18%)
501-1000	218-278 (34%)	81-88 (11%)
1001-2000	278-323 (20%)	88-92 (6%)
2001-4000	323-351 (11%)	92-94 (3%)

IPAC CANADA: Auditing the IPAC Program

APPENDIX B: Scoring the IPAC Program Audit

Auditing the IPAC program is a work in progress. There is no pass or fail score, rather the health care organization strives to improve their score on subsequent audits after addressing deficiencies, leading to continuous improvement.

There are two methods for scoring an audit - **qualitative** and **quantitative**. Generally, most audits carried out in health care are scored using a qualitative method, as found with the audits provided in IPAC Canada's Audit Toolkit.

Qualitative Scoring

Qualitative scoring applies a simple Yes/No response when auditing a standard. If all of the audit criteria that constitute a positive finding (document review), response (interview) or observation (observational tour) are met, then the response is YES. If any of the audit criteria are not met, the response is NO.

The total score is:

<u>Number of YES responses</u> x 100 = % of standards that have been met

Number of standards audited

Quantitative Scoring

Quantitative scoring considers the **risk weight** of each standard in relation to the negative effects to patients, staff and the organization if the standard is not met.

Each standard has been extensively reviewed and graded according to its:

- a. likelihood of risk if the standard is not met, and
- b. impact of that risk.

Using a matrix, a risk weight has been assigned to the standard and this weight is used to develop the scoring value for the standard. If a standard is not met, the score is zero. If a standard is met, it is scored with the assigned point value for that standard, based on the risk weight of the standard. Refer to *Auditing the Infection Prevention and Control (IPAC) Program* and *PAT[®] Supplement* for details regarding the development of risk weights for IPAC Canada's program standards.

The total score achieved can be converted to a percentage of the total available points. Standards that have higher risk weights will have a greater impact on the total score than will low weight standards.

When developing action plans and interventions based on the results of the IPAC program audit, standards that have not been met and that have the highest risk weight should be addressed first, as they will have the greatest negative impact to the organization.

Qualitative vs. Quantitative Scoring

The following example illustrates the difference between qualitative and quantitative scoring:

An organization audits the following four standards from the IPAC Program Standard:

- Std. 11. An IPAC education program shall be provided annually, and periodically as required, to all staff working in the health care organization. [LOW RISK] SCORE = 3 if standard is met, SCORE = 0 if standard is not met.
- Std. 12. IPAC education shall meet the IPAC program priorities of the health care organization. [MODERATE RISK] SCORE = 4 if standard is met, SCORE = 0 if standard is not met.
- Std. 31. Hand hygiene education shall be provided to all individuals working in the health care organization. [HIGH RISK] SCORE = 5 if standard is met, SCORE = 0 if standard is not met.
- Std. 19. The health care organization shall have an IPAC surveillance program that addresses the organization's population-at-risk. [EXTREME RISK] SCORE = 6 if standard is met, SCORE = 0 if standard is not met.

RESULTS:

The total achievable score if all four standards are met is 18 out of 18 (100%).

Scenario 1: After auditing, results indicate that Standards # 13 and 14 (lowest risk standards) are not met but Standards # 33 and 21 (highest risk standards) are met. The quantitative score is 11 out of 18, for a percentage value of 61%. If only a qualitative approach is used, the score would be 50% (two out of four standards met).

Scenario 2: After auditing, results indicate that Standards #13 and 14 (lowest risk standards) are met but Standards # 33 and 21 (highest risk standards) are not met. The score is 7 out of 18, for a percentage value of 39%. If only a qualitative approach is used, the score would be 50% (two out of four standards met).

In the above examples, when only a qualitative method is used for scoring, both scenarios have the same result – 50%. However, when a quantitative method is used, the score is higher for scenario #1 (61% for scenario #1 vs. 39% for scenario #2). The organization thus achieves a better score when standards carrying the highest risk are achieved.

It is clear that using a quantitative approach that incorporates weighting of the standards will yield much more useful information than using a qualitative approach, indicating deficiencies that have the most impact on the organization and guiding improvement scheduling so that the standards with the most impact may be identified and acted upon first.

IPAC Canada's *IPAC Program Audit Tool (PAT[©])* is scored using a quantitative approach. Each of the IPAC program standards have been assigned a risk score based on their risk grade and risk weight.

References

- 1. Alberta Employment and Immigration. Audit Instrument Package. July 1, 2009.
- Provincial Infectious Diseases Advisory Committee (PIDAC). Best Practices for Infection Prevention and Control Programs in Ontario In All Health Care Settings 2012 [cited July 24, 2013]; Available from:

http://www.publichealthontario.ca/en/eRepository/BP_IPAC_Ontario_HCSettings_2012.pdf.

- 3. Accreditation Canada. Qmentum Program: Infection Prevention and Control Standards. 2013 [cited September 21, 2014]; Available from: http://www.accreditation.ca/infection-preventionand-control.
- 4. Millward S. Using Infection Control (IC) Link Practitioners to audit IC standards in the Independent Healthcare sector and provide robust evidence of practice. J Hosp Infect. 2006;64 Suppl 1:S91.
- 5. Bialachowski A, Clinker K, LeBlanc M, McDonald S. The audit process: Part I. Pre-audit preparation. Can J Infect Control. 2010 Spring;25(1):68-70.
- 6. Institute of Medicine. Guidelines for clinical practice: from development to use. Washington, DC: National Academic Press; 1992.
- 7. Bialachowski A, Clinker K, LeBlanc M, McDonald S. The audit process: Part II. Setting the Audit Criteria. Can J Infect Control. 2010 Summer;25(2):109-11.
- 8. Hay A. Audit in infection control. J Hosp Infect. 2006 Mar;62(3):270-7.
- 9. National Institute for Clinical Excellence. Principles for best practice in clinical audit. Oxford: Radcliffe Medical Press. 2002.
- 10. Miles E, Jazaie R. Internal Audit Risk Assessment and Audit Planning. Moss-Adams L.L.P. Certified Public Accountants/Business Consultants. May 6, 2011. 2011.
- 11. Dalkey N, Helmer O. An Experimental Application of the Delphi Method to the use of experts. Management Science. 1963;9(3):458-67.
- 12. ISO 9001:2008 Internal Auditor Training. 2008 [cited November 13, 2014]; Available from: www.iso9001consultant.org.
- 13. Alberta Municipal Health and Safety Association. COR Training. Number of Auditors based on Employee Numbers. [cited May 13, 2015]; Available from: http://www.amhsa.net/cor-auditing/large-employer-cor/cor-training/.
- 14. International Organization for Standardization. ISO 9001:2008 Quality Management Systems. 2008 [cited November 13, 2014]; Available from: http://www.iso.org/iso/home.html.
- 15. Alberta Municipal Health and Safety Association. COR Training. Table 1: 2010 Audit Sampling Criteria. 2010 [cited May 13, 2015].
- 16. Alberta Forest Products Association: Audit Protocols. Criteria for Determining a Representative Interview Sample. 2011 [cited December 12, 2016]; Available from: http://albertaforestproducts.ca/wp-content/uploads/2016/03/Sampling-Guide-20160415.pdf.
- 17. World Health Organization. Essential Medicines and Health Products Information Portal. Bias in Sampling. [cited May 13, 2015]; Available from: http://apps.who.int/medicinedocs/en/d/Js6169e/7.5.html.
- 18. Bryce EA, Scharf S, Walker M, Walsh A. The infection control audit: the standardized audit as a tool for change. Am J Infect Control. 2007 May;35(4):271-83.
- 19. Workplace Safety and Insurance Board (WSIB) of Ontario. Workwell Core Health and Safety Audit. June 2011.
- 20. Bialachowski A, Clinker K, LeBlanc M, McDonald S. The audit process: Part III. Closing the Loop. Can J Infect Control. 2010 Fall;25(3):161-5.
- 21. Pan American Health Organization. Rapid Evaluation Guide for Hospital Programs for Prevention and Control of Nosocomial Infections. Washington, D.C.2011 [cited February 1, 2016]; 2nd edition:[Available from:

http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=22319&Itemid =.

- 22. Woodward CA, Chambers LW. Guide to Questionnaire Construction and Question Writing. Ottawa, Ontario: The Canadian Public Health Association; 2012. p. 1-34.
- 23. The International Society for Quality in Health Care (ISQua). Guidelines and Principles for the Development of Health and Social Care Standards. 2015 [cited March 30, 2017]; 4th edition:[Available from: http://www.isqua.org/accreditation-iap/reference-materials.
- 24. Operational Excellence Consulting. Managing Effective Quality Audits. 2013 [cited November 13, 2014]; Available from: http://www.slideshare.net/flevydocs/managing-effective-quality-audits.
- 25. Nadzam DM, Soule BM. Performance Measures. APIC Text of Infection Control and Epidemiology. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc.; 2009.
- 26. French GL. Closing the loop: audit in infection control. J Hosp Infect. 1993 Aug;24(4):301-8.
- 27. Creative Research Systems: the Survey System. Sample Size Calculator. [cited May 13, 2015]; Available from: http://www.surveysystem.com/sscalc.htm.
- 28. Dawson B, Trapp RG, Dawson-Saunders B. Basic & clinical biostatistics. 2nd ed. Norwalk, Conn.: Appleton & Lange; 1994.
- 29. Fox N., Hunn A., and Mathers N. Sampling and sample size calculation. The NIHR RDS for the East Midlands / Yorkshire & the Humber 2009. [cited April 7, 2017]; Available from: http://www.webpages.uidaho.edu/ed571/571-Modules/M3/NIHS-Sampling Sample_Size_calculation.pdf.
- 30. Berenson ML, Levine DM, Krehbiel TC. Basic Business Statistics: Concepts and Applications. 12th Edition ed: Prentice Hall; 2011.