


VERSION NO. 1	MANUAL TITLE <b>QUALITY MANUAL</b>	DOCUMENT NO. <b>QM 13.2</b>
	DOCUMENT NAME  <b>INTERNAL QUALITY AUDIT</b>	REVISION NO. <b>0</b>
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## 1.0 OBJECTIVES

- 1.1 To ensure that PSHSS continuously operates in accordance with the specified policies, procedures and external requirements in meeting institutional goals and objectives.
- 1.2 To ensure that improvements to the quality management system are identified, implemented and suitable to achieve objectives.

## 2.0 SCOPE

This procedure includes planning, execution, reporting and follow-up of an internal quality audit (IQA).


## 3.0 POLICIES

- 3.1 The IQA shall be conducted at least once a year or as deemed appropriate by the QMR. The IQA schedule shall be prepared by the Lead Auditor and approved by the QMR.
- 3.2 The IQA shall be scheduled based on the complexity and the observed performance of the area.
- 3.3 Responsibility

An IQA team, headed by a Lead Auditor, shall be duly appointed by the Executive Director under the Office of the Executive Director (OED), and by the Campus Director at the campus level, to undertake a quality management system audit. The Internal Quality Auditors (IQAs) that form the IQA team must possess the following characteristics:

- Adept at the elements of ISO 9001:2015;
- Adequately trained to perform IQAs; and
- Have no direct responsibility in the areas being audited.



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### 3.4 QMR's Responsibilities


- Reviews the IQA plan;
- Reviews the corrective action/s and opportunities for improvement/s based on the IQA Report submitted;
- Audits the IQA process.

### 3.5 Lead Auditor's Responsibilities

- Prepares an IQA plan with the institution's manuals as basis for planning the audit. The plan shall include:
  - The office which will be audited;
  - The list of auditors who will compose the IQA Team and the particular auditor who will conduct the individual audit (The number of auditors depends upon the size of the area to be audited.); and
  - The date and duration in which the actual audit shall be performed;
- Coordinates with the Head concerned and agrees on the day to perform the audit;
- Be responsible for all phases of the audit. He shall be given authority to make final decisions regarding the conduct of the audit and any audit observations;
- Assists in the selection of IQAs to form the IQA Team;
- Plans the audit, prepares working documents and briefs the IQA Team;
- Reviews the documentation on existing quality management system activities to determine their adequacy;
- Consolidates all audit findings and observations and prepares IQA Report;
- Reports critical nonconformities to the auditee immediately;
- Reports any major obstacles encountered in performing the audit;
- Reports to the auditee on the audit results clearly, conclusively, and without undue delay; and
- Conducts the opening and closing meeting, as necessary.



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### 3.6 IQA Team Responsibilities

- Supports the Lead Auditor;
- Communicates and clarifies audit requirements;
- Performs the audit using checklists;
- Checks with the Head or his/her authorized representative at the end of each office's audit if he/she agrees with the facts and non-conformities found in the audit;
- Prepares the Corrective Action Request (CAR) form for nonconformities, and Opportunities For Improvement (OFI) form for suggestions for improvements as appropriate;
- Reports the audit results;
- Remains alert to any indications of evidence that can influence the audit results and possibly require more extensive auditing; and
- Acts in an ethical and professional manner at all times.

### 3.7 Auditee's Responsibilities

- Understands the purpose of the IQA;
- Determines the scope of the audit such as what quality management system standard or documented information should be audited;
- Cooperates with the IQAs to permit the audit objectives to be achieved; and
- Receives the IQA Report and addresses any CAR or OFI received on a timely manner.

### 3.8 Conduct of the Internal Quality Audit


#### 3.8.1 IQA Plan

The IQA plan shall be prepared by the Lead Auditor and shall be approved by the QMR. It should be communicated to the auditors and auditee. It should be designed to be flexible in order to permit changes based on information gathered during the audit, and to permit effective use of resources. The plan should include:

- The audit objectives and scope;



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- Identification of IQA Team members and assignments;
- The date and place where the audit is to be conducted;
- Identification of the organizational units to be audited;
- The expected time and duration for each major audit activity;
- The schedule of meetings to be held with auditee;
- References to be used by the IQA Team; and
- Date of IQA reporting or closing meeting.

### 3.8.2 Opening Meeting

The following are to be discussed in the opening meeting:

- Introduce the members of the IQA Team to the auditees;
- The purpose and scope/agenda of audit;
- Safety and other regulatory requirements as required;
- Clarification on other matters must be settled before the audit takes place.

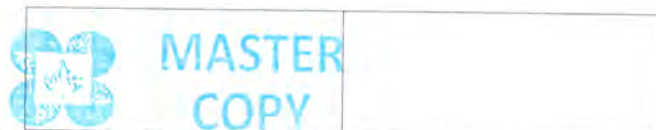
A formal opening meeting is not required for an IQA. It will be conducted if deemed necessary by the Lead Auditor.


### 3.8.3 Audit Execution

3.8.3.1 Evidence should be collected through interviews, examination of documented information, and observation of activities and conditions in the areas of concern. Pieces of evidence suggesting nonconformities should be noted if they seem significant, even though not covered by checklist, and should be investigated.

3.8.3.2 The auditors will perform the IQA using the audit checklist as well as the documented information as guides.

3.8.3.3 The auditors can use different types of questions which are as follows:



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- Open questions that encourage the auditee to talk in order to gather information.
- Probing questions - follow-up questions with the intention of zeroing in on gathered information. It is also the focusing phase of the interview.
- Closed questions are usually used to establish a final point on the gathered information. Normally answered by "yes or no", it is the final phase of the interview.

3.8.3.4 The auditors will observe the following conduct during the IQA.

- Objectiveness
- Punctuality
- Courteousness
- Politeness
- Respect for protocols
- Respect for confidentiality
- Respect for valid restrictions
- Exercise of fairness
- Works within his defined authority
- Avoids arguments
- Criticizes in a constructive way


3.8.3.5 The Internal Quality Auditors' performance will be evaluated by the lead auditor and the lead auditor by the QMR.

### 3.8.4 Reporting of Findings

#### 3.8.4.1 Audit Findings

All audit findings should be documented. After all activities have been audited, the IQA Team should review all of their findings to determine whether they are to be reported as nonconformities or as observations. The IQA Team



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should then ensure that these are documented in a clear, concise manner through the use of the Corrective Action Request (CAR) form and Opportunities For Improvement (OFI) form. Audit findings should likewise be supported by objective evidence.


3.8.4.2 The auditors shall classify findings as:

- Nonconformity
  - Failure to comply with a procedure, a quality management system requirement, or statutory and regulatory requirement.
  - A breakdown of an element of ISO 9001:2015.
- Observation
  - A statement of fact made during an audit and substantiated by objective evidence that may reflect positively or negatively on the quality management system. Though it is not booked as nonconformity, it calls management's attention to an area that requires improvement/action lest it be elevated to a nonconformity in future internal quality audits.
  - These findings shall be supported by objective pieces of evidence.
  - Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or the existence and implementation of a quality management system element which is based on observation, measurement or test and which can be verified.

3.8.4.3 The auditors documented information shall include the following:

- Office or area audited;



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- Date of the audit;
- Details of non-conformance observed;
- Objective evidence supporting non-conformance;
- Referencing of audited document; and
- Name(s) of person(s) the findings was verified/discussed.

3.8.4.4 The auditors shall have a consolidation meeting. Agenda includes:

- Review of findings;
- Consolidation of all findings;
- Groupings and tabulation of all findings;
- Classification of findings;
- Analysis of findings; and
- Preparation of CARs and OFIs.


3.8.4.5 The Lead Auditor shall prepare a standard IQA Report, which includes the following:

- Date of audit;
- Audit scope;
- Objectives;
- References used;
- IQA Team;
- Audit time table; and
- Summary of findings.

3.8.4.6 The auditors shall follow a code of conduct in the manner of reporting as stated in this document.

- The report should be concise but factual;
- The findings should be within the scope of audit;
- The report should reflect professionalism;



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- The report should not show bias by the individual auditor;
- The findings should be substantiated by objective evidence;
- The report should be presented in a constructive manner; and
- The report should present a true and fair view of the system implementation.

3.8.4.7 The auditors shall submit copies of the CAR/s and OFI/s to the auditee concerned.

3.8.4.8 The IQA report shall be retained as documented information by the QMSO.

### 3.8.5 Closing Meeting

- The lead auditor shall preside over the closing meeting with the QMR and auditees/Heads;
- The lead auditor shall reiterate the scope and purpose of the audit and the reference standards they used during the audit;
- The auditors shall report their findings and observations;
- The time scale on the corrective actions and opportunities for improvements is agreed upon, if applicable; and
- All queries and clarifications are resolved.

## 3.9 IQA Report


The Lead Auditor shall issue a formal IQA Report to the QMR. The IQA Report will discuss findings and list possible improvement opportunities that shall be taken up during the Management Review Meeting.

## 3.10 Corrective Actions, Opportunities for Improvement, and Follow-Up

3.10.1 The auditor shall only be responsible for identifying the nonconformities and observations.



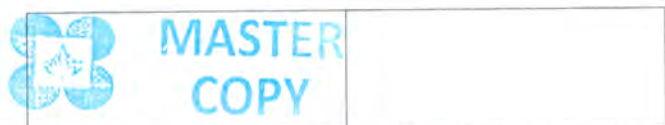



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- 3.10.2 The auditee shall be responsible for correcting the reported nonconformities and observations.
- 3.10.3 Corrections, corrective actions, and opportunities for improvements shall be reviewed and approved for adequacy prior to implementation.
- 3.10.4 Approved corrections, corrective actions, and opportunities for improvements implementations shall be based on the agreed time scale.
- 3.10.5 A follow-up audit shall be made by the auditor if nonconformities still exist. This is done to ensure that the corrective actions are in place. The follow-up dates will be agreed upon by the auditor and the auditee.
- 3.10.6 Results of corrections, corrective actions, and opportunities for improvements are verified and monitored for effectiveness.

### 3.11 Closure of Findings

The QMR/QMSO shall meet with the auditors and take overall responsibility for follow-up activities of audit results with the auditees. Follow up action will not be considered complete/closed until all corrections, corrective actions, and opportunities for improvements have been implemented and the status has been reported to the Lead Auditor.




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#### 4.0 PROCEDURES

Responsibility	Activity
Lead Auditor	1. Prepares the IQA Schedule for the year and have it approved by the QMR.
	2. Prepares the IQA Plan prior to the scheduled IQA and forwards to the QMR.
QMR	3. Reviews and approves the IQA Plan.
Lead Auditor	4. Conducts the Opening Meeting, if deemed necessary.
IQA Team	5. Reviews the quality management system manual and procedures.
	6. Prepares Audit Checklists, as needed.
	7. Conducts the audit.
	8. Accomplishes CAR for nonconformities, or OFI for observations found.
	9. Gathers objective pieces of evidence to support findings, if applicable.
	10. Discusses the findings with auditee for root cause analysis and agrees on date of completion on correction and corrective action/opportunities for improvement.
	11. Submits all CARs/OFIs to the Lead Auditor.
Lead Auditor	12. Updates the CAR Status Log and OFI Status Log.
	13. Consolidates findings with the IQA Team.



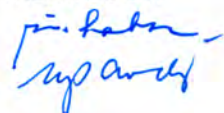
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Responsibility	Activity
Lead Auditor	14. Prepares and submits the IQA Report to the QMR. 15. Presents the findings during the Closing Meeting, which can be during the management review meeting.
IQA Team	16. Conducts follow-up audit for corrections, corrective actions and opportunities for improvements taken.
QMR	17. Closes the CAR/OFI.
Lead Auditor/QMR	18. Updates the CAR Status Log/OFI Status Log.

## 5.0 LIST OF FORMS AND REPORTS

- 5.1 Forms
  - 5.1.1 IQA Schedule
  - 5.1.2 Corrective Action Request Form
  - 5.1.3 Opportunities For Improvement Form
  - 5.1.4 CAR Status Log
  - 5.1.5 OFI Status Log
  - 5.1.6 IQA Auditor Performance Evaluation Form
- 5.2 Reports
  - 5.2.1 IQA Report

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