1.0 PURPOSE

This procedure established the method of internal audit to be planned, implemented and reported to meet the requirements of ISO 9001:2015 standard and to ensure the effectiveness of the Quality Management System (QMS). This includes in determining the compliance and non-compliance of elements in the quality system.

2.0 SCOPE

This procedure applies to all activities and processes related to internal audits described in the ATMSB quality manual and procedure including policies and work instructions affecting the quality of audited work.

3.0 RESPONSIBILITY

3.1 The Quality Assurance Department shall be responsible for:

a) Inform Top Management (TM)/ respective Head of Department (HOD)/ Management Representative (MR) on the upcoming audit
b) Forming an internal audit team
c) The preparation of the audit plan, audit criteria and notification to departments involved
d) Briefing the audit team members
e) Reporting the audit results for Management Review
f) Documenting the audit reports and the observations
g) Retain documented information as evidence of the implementation of the audit programme and the audit results.

3.2 The Internal Quality Auditors shall be responsible for:

a) Carrying out the audit according to the audit plan and on departments that are not directly under his/her responsibility.
b) Reporting non-conformities from audit.
c) Promote area for improvement based on audit findings
d) Reporting the audit results to the TM/HOD.
e) Follow-up on the implementation and effectiveness of corrective actions.

3.3 TM/ respective HOD

a) Ensure full cooperation and facilities are provided during audit session.
b) Shall respond to the audit findings within **14 working days** and take necessary corrective and corrective actions.

4.0 PROCEDURE

4.1 Audit Initiation

4.1.1 Based on the company Process Map, the Lead Auditor (LA) shall prepare/update yearly Internal Audit schedule/programme covers the relevant areas (departments/sections) and processes to be audited at the end of the year.

4.1.2 The Audit schedule (criteria) shall be prepared **annually** and will cover all elements of the quality system or plan.

4.1.3 The internal quality audit shall be conducted **twice a year** by qualified and trained auditors. The interval between audits of any particular system should **not exceed 12 months.**

4.1.4 An Internal Audit Team, (IAT) shall be formed with approval from the TM. The auditors that assigned shall independent of the areas to be audited and has no direct responsibility to that area.

4.1.5 An audit plan shall be planned, and taking into consideration the following:

a) Objective and importance of the audit
b) Scope of the audit
c) Audit Criteria
d) Audit team
e) Timetable of the events
f) Areas to be audited
g) Personnel to be present
h) The sequence of audit based on audit trail
i) Results of previous audit

4.1.6 After the audit teams have been selected, the designated Lead Auditor (LA) shall prepare a written audit plan to the TM/HOD and auditee of the area to be audited **at least two (2) weeks** before commencing the audit.

4.2 Audit Execution

4.2.1 The assigned Lead Auditor (LA) in the Internal Audit Team (IAT) shall be chaired on the opening meeting on the first day of the IQA.

4.2.2 During the audit, the auditors shall conduct the audit based on the following methodology.

a) Review relevant procedures/documents
b) Interview the auditee on the practices against documented procedures/support documents;
c) Observe the relevant practice/processes;
d) Check the relevant records as evidences of implementation

4.2.3 Any audit evidence or audit findings made during the audit shall be recorded by the auditor in the Audit Checklists

4.2.4 If there is any finding during audit, the auditor shall explain the findings to the auditee and seek their agreement (if possible) on the acceptance on the non-compliances which tentatively to be raised.

4.2.5 Finding from the Internal Quality Audit shall be recorded in the Corrective Action Report (CAR) and shall be issued to the respective auditees.

4.2.5.1 Definition of

(a) Major Nonconformance
- ISO clauses not addressed
- Entire Operation Procedures/ Quality Manual (QM) not implemented
- A high percentage of the same minor nonconformance detected and is recurring.

(b) Minor Nonconformance
- Single lapse that can be corrected almost immediately
- Does not affect effectiveness of the quality system

(c) Observation
- Recommendation made for improvement. The same observation raised on the subsequent audit can be categorized as minor non-conformances.

4.3 Audit Report

4.3.1 Based on the audit notes/checklist, the auditor shall categorize the audit findings as either observations or non-compliance (NC) at the end of the audit.

4.3.2 The auditor shall review with the Lead Auditor to confirm the findings to be categorized as NC or observations.

4.3.3 Once the non-compliance has been confirmed, the LA shall record the non-compliance and observation into the CAR form.

4.3.4 Auditees shall take the correction and corrective action and reply to the Lead Auditor **within two (2) weeks** from date of issuance of non-conformance detected.

4.3.5 The Lead Auditor shall assign an auditor to verify the implementation of the corrective action to ensure that corrective actions are carried out effectively.

4.3.6 The Lead Auditor shall compile and summarize the findings and report such findings during the closing meeting.

4.3.7 All the audit report will be numbered as UU/IQA0V/WW/XX/YY, example, ATMSB/IQA01/2020/01

UU	Company Name	ATMSB
IQA0V	Session of audit	IQA01, IQA02, etc.
WW	Year of audit	2020,2021, etc.
XX	Sequence number of audit (starting 01)	01, 02, 03, etc.
YY	Location of Audit	ATMHQ; GHCD, etc

Notes: Clause 4.3.7 only applies to Internal Quality Audit by the Quality Audit Department only.

4.3.8 The LA/auditor shall forward the copy of audit report and CAR (if any) to the auditee

4.3.9 The number of CAR and status of corrective action taken shall be reviewed during Management Review meeting.

4.4 **Special Audit**

4.4.1 Special audits can be initiated by the TM/Manager subject to the below conditions:

a) Sudden increase of client complaints
b) Changes in the organization structure
c) Other quality related issues

4.4.2 When receiving the CAR, TM/HOD of the audited area upon receiving the CAR shall on timely basis conduct the investigation for the root cause of the NC, initiate timely correction and corrective action to eliminate the non-conformity and their causes, recording the investigation results and correction and corrective action onto the CAR form as per **Corrective Action Procedures** **(Refer PM 03 Corrective Action Procedures)**

4.4.3 Upon replying of CAR by the TM/HOD, the Lead Auditor/shall conduct a follow up audit or a review on the effectiveness of the corrective action taken as per the **Corrective Action Procedures** **(Refer PM 03 Corrective Action Procedures)**

4.4.4 The auditor needs to identify a suitable date to conduct an audit to verify its implementation and effectiveness of the proposed correction and corrective action.

4.4.5 A new CAR shall be raised if the correction and corrective action has not been performed or is found to be ineffective. To identify the re-issued CAR is by its reference number.

4.5 **Corrective Action Request (CAR) Numbering System**

4.5.1 All the CAR issued will be numbered as UU/IQA0V/WW/XX/Y/NCRZZ, example, ATMSB/IQA01/2020/01/ATMHQ/NCR01

UU	Company Name	ATMSB
IQA0V	Session of audit	IQA01, IQA02, etc.
WW	Year of audit	2020,2021, etc.
XX	Sequence number of audit (starting 01)	01, 02, 03, etc.
YY	Location of Audit	ATMHQ; GHCD, etc
NCRZZ/ OBSZZ	Sequence number of number NCR (starting 01)	01, 02, 03, etc.

Notes: Clause 4.5.1 only applies to Internal Quality Audit by the Quality Audit Department only.

4.5.2 For the re-issued CAR, the new number will be recorded as UU/IQA0V/WW/XX/Y/NCRZZ(a),where all the reference numbers remain the same except for the addition of an identification (lowercase) at the end, starting with '(a)', example, ATMSB/IQA01/2020/01/ATMHQ/NCR01(a)

Original issuance	ATMSB/IQA01/2020/01/NCR01
First re-issue	ATMSB/IQA01/2020/01/NCR01(a)
Second re-issue	ATMSB/IQA01/2020/01/NCR01(b)
Third re-issue	ATMSB/IQA01/2020/01/NCR01(c)

Notes: Clause 4.5.2 only applies to Internal Quality Audit by the Quality Audit Department only.

5.0 APPLICABLE CLAUSE

9.2 Internal Audit

6.0 QUALITY RECORDS

No.	Title of Records	Person In Charge (PIC)	Retention Period (Year)
1	Internal Audit Schedule	QA	7
2	Internal Audit Checklist	QA	7
3	Internal Audit Report	QA	7
4	Corrective Action Request Form	QA	7

DOCUMENT AMENDMENT REGISTER

NO	DATE	REASON	CHAPTER	VERSION
1	26/05/2000	Initial Release	All	1.1
2	04/09/2000	Procedure is amended to indicate that a concerns form is to be filled for the process of corrective action. NCR Ref CERT 072/00-3/04	All	2.0
3	11/06/2002	Procedure updated to be in-line with ISO 9001:2000	All	2.1
4	01/11/2005	IQA shall be coordinated by QAE from ACSB	All	2.2
5	02/01/2008	Document Authorization : Management Representative - DGM	All	2.3
6	30/06/2009	i) Procedure updated to be in line with ISO 9001:2008 ii) Quality Assurance Executive changed to Lead Auditor	All 4.1.2 to 4.1.5	2.4
7	01/06/2010	Change NCR to Corrective Action Request 6.3 Change Nonconformance Report to Audit Summary Report	4.2.3 4.3.1 4.3.3 5.0	2.5
8	30/04/2014	Procedure updated to be in-line with ISO 9001:2008 requirements.	4.1.1 4.1.4 4.1.5 4.1.6	2.6
9	15/07/2015	- The statement added by qualified and trained auditors - Internal Audit Schedule shall be prepared annually. - Audit program is changed to Audit Plan	4.1.1 4.1.3 4.1.4	2.7
10	23/03/2018	Procedure updated to be in-line with ISO 9001:2015. Amendment; - Revision No. changes to Version No. as agreed in the 4th ISO New Standard Transition meeting. - New format for Quality Records table.	All 5.0	2.8
11	26/07/2018	Procedure updated to be in-line with ISO 9001:2015.	3.2	2.9

NO	DATE	REASON	CHAPTER	VERSION
12	8/03/2021	Remove: - Clause 1.1 ensure documented procedures are being followed. - Clause 1.2 To determine the effectiveness of the Quality Management System (QMS). - Clause 1.3 plan for the Internal Quality Audits (IQA). - Clause 1.4 To identify opportunities for improvement - Clause 2.1 Compliance of the Company's Quality System to ISO 9001:2015. - Clause 4.1.3 Internal Audit Schedule shall be prepared annually. - ….. The audit plan shall be distributed to all HODs…..” - Auditor shall prepare an Internal Audit Report based on the audit findings, any CARs shall be issued to the HOD two working days after the audit. - The Lead Auditor shall compile and summarize the findings and report such findings during the closing meeting. - Record “Internal ~~Quality~~ Audit Report” Added: - Clause 1.0 “This procedure established the method of internal audit to be planned, implemented and reported to meet the requirements of ISO 9001:2015 standard and to ensure the effectiveness of the Quality Management System (QMS). This includes in determining the compliance and non-compliance of elements in the quality system.” Clause 2.0 “This procedure applies to all activities and processes related to internal audits described in the ATMSB quality manual and procedure including policies and work instructions affecting the quality of audited work.” - Clause 3.1 “….Top Management (TM)/ respective Head of Department (HOD)/ (MR)…..”	1.1 1.2 1.3 1.4 2.1 4.1.3 4.1.6 4.2.6 4.2.7 6.0 1.0 2.0 3.1 (a)/3.2 (d)/ 3.3	2.10

NO	DATE	REASON	CHAPTER	VERSION
		- "….audit criteria…." - Retain documented information as evidence of the implementation of the audit programme and the audit results - Promote area for improvement based on audit findings - "…..corrective and….." - "Based on the company Process Map, the Lead Auditor (LA) shall prepare/update yearly Internal Audit schedule/programme covers the relevant areas (departments/sections) and processes to be audited at the end of the year." - "The Audit schedule (criteria) shall be prepared **annually** and will cover all elements of the quality system or plan. - "…..The interval between audits of any particular system should **not exceed 12 months**…… - "After the audit teams have been selected, the designated Lead Auditor (LA) shall prepare a written audit plan to the TM/HOD and auditee of the area to be audited **at least two (2) weeks"** - "….(LA)… Internal Audit Team…..on…" - During the audit, the auditors shall conduct the audit based on the following methodology. a) Review relevant procedures/documents b) Interview the auditee on the practices against documented procedures/support documents; c) Observe the relevant practice/processes; d) Check the relevant records as evidences of implementation - "Any audit evidence or audit…… shall be recorded by the auditor….. Audit…." - "If there is any finding during audit, the auditor shall explain the findings to the auditee and seek their agreement (if possible) on the acceptance on the non-compliances which tentatively to be raised"	3.1 (b) 3.1 (g) 3.1 (c) 3.3 (b) 4.1.1 4.1.2 4.1.3 4.1.6 4.2.1 4.2.2 4.2.3 4.2.4	

NO	DATE	REASON	CHAPTER	VERSION
		- "Finding from the Internal Quality Audit shall be recorded in the……"	4.2.5	
		- "Based on the audit notes/checklist, the auditor shall categories the audit findings as either observations or non-compliance (NC) at the end of the audit"	4.3.1	
		- "The auditor shall review with the Lead Auditor to confirm the findings to be categorized as NC or observations."	4.3.2	
		- "Once the non-compliance has been confirmed, the LA shall record the non-compliance and observation into the CAR form."	4.3.3	
		- "…..**within…..**"	4.3.4	
		- **"**The Lead Auditor shall compile and summarize the findings and report such findings during the closing meeting."	4.3.6	
		- "All the audit report will be numbered as UU/IQA0V/WW/XX/YY example, ATMSB/IQA01/2020/01 UU — Company Name — ATMSB IQA0V — Session of audit — IQA01, IQA02, etc. WW — Year of audit — 2020,2021, etc. XX — Sequence number of audit (starting 01) — 01, 02, 03, etc. YY — Location of Audit — ATMHQ; GHCD, etc	4.3.7	
		Notes: Clause 4.3.7 only applicable for Internal Audit from QA Department	4.3.8 4.3.9	
		- "The LA/auditor shall forward the copy of audit report and CAR (if any) to the auditee"	4.4	
		- "……during…."	4.4.1 (a-c)	
		- **Special Audit**		
		- Special audits can be initiated by the TM/Manager subject to the below conditions: a) Sudden increase of client complaints b) Changes in the organization structure c) Other quality related issues		

NO	DATE	REASON	CHAPTER	VERSION
		- "When receiving the CAR, TM/HOD of the audited area upon receiving the CAR shall on timely basis conduct the investigation for the root cause of the NC, initiate timely correction and corrective action to eliminate the non-conformity and their causes, recording the investigation results and correction and corrective action onto the CAR form as per **Corrective Action Procedures (Refer PM 03 Corrective Action Procedures)"**	4.4.2	
		- "Upon replying of CAR by the TM/HOD, the Lead Auditor/shall conduct a follow up audit or a review on the effectiveness of the corrective action taken as per the **Corrective Action Procedures (Refer PM 03 Corrective Action Procedures)"**	4.4.3	
		- The auditor need to identify a suitable date to conduct an audit to verify its implementation and effectivenss of the proposed correction and corrective action.	4.4.4	
		- A new CAR shall be raised if the correction and corrective action has not been performed or is found to be ineffective. To identify the re-issued CAR is by its reference number.	4.4.5	
		- **Corrective Action Request (CAR) Numbering System**	4.5	
		- All the CAR issued will be numbered as UU/IQA0V/WW/XX/Y/NCRZZ, example, ATMSB/IQA01/2020/01/ATMHQ/NCR01	4.5.1	
		UU — Company Name — ATMSB IQA0V — Session of audit — IQA01, IQA02, etc. WW — Year of audit — 2020,2021, etc. XX — Sequence number of audit (starting 01) — 01, 02, 03, etc. YY — Location of Audit — ATMHQ; GHCD, etc NCRZZ/ OBSZZ — Sequence number of number NCR (starting 01) — 01, 02, 03, etc. Notes: Clause 4.5.2 only applicable for Internal Audit from QA Department		

NO	DATE	REASON	CHAPTER	VERSION
		- For the re-issued CAR, the new number will be recorded as UU/IQA0V/WW/XX/Y/NCRZZ(a),where all the reference numbers remain the same except for the addition of an identification (lowercase) at the end, starting with '(a)', example, ATMSB/IQA01/2020/01/ATMHQ/NCR01(a) Original issuance ATMSB/IQA01/2020/01/NCR01 First re-issue ATMSB/IQA01/2020/01/NCR01(a) Second re-issue ATMSB/IQA01/2020/01/NCR01(b) Third re-issue ATMSB/IQA01/2020/01/NCR01(c) Notes: Clause 4.5.2 only applicable for Internal Audit from QA Department	4.5.2	