EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Audit programmes and internal audits conducted by the Audit Advisory Function		
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1. Purpose

The purpose of this SOP is:

- to describe the procedure for the internal audit engagement process (including planning, conduct, communication, contradictory procedure, quality assessment, final report, action plan and any follow-up actions) conducted in line with:
  - Financial Regulation applicable to the Budget of the European Medicines Agency, as adopted by the Management Board;
  - Relevant legislation in the fields of human and veterinary medicines;
  - The International Standards for the Professional Practice of Internal Auditing of the Institute of Internal Auditors;
  - AF-AUD's Code of Ethics;
  - The Internal Audit Charter of the European Medicines Agency approved by the Management Board;
  - European Medicines Agency Audit Manual;
- to outline the procedure for establishing the auditors' risk assessment and assurance map;
- to outline the procedure for establishing the audit strategy and annual audit programme for year N+1 for internal audit activities within the European Medicines Agency;
- to ensure that the rolling programme for years N+2 and N+3 is maintained;
- to ensure that Trackwise procedure for the annual audit programme is used consistently and correctly;

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- to outline the procedure for establishing the Annual Audit Report;

It applies to all internal audits conducted at the European Medicines Agency, including audits conducted with outsourced resources under the direct lead of a member of the Audit Function (e.g. IT audits, EC framework contract) and follow-up audits respectively.

This SOP is not applicable to audits conducted by the Internal Audit Service of the European Commission and by the Court of Auditors.

2. Scope

This SOP applies to all the Agency, and especially the Audit Function, auditee management and auditees.

3. Responsibilities

It is the responsibility of the Head of Audit to ensure adherence to this procedure in particular to complete all work with due professional care, objectivity and according to the relevant professional standards.

It is the responsibility of the Executive Director and auditee management to ensure adherence to this procedure, in particular that:

- the objective of the engagement all information and documents relevant for the scope and objective of the audit are provided in time;
- all contradictory procedures are performed within the established deadlines;
- management's improvement action plan is prepared and effectively implemented or that senior management has accepted the risk of not taking action and that this is properly communicated in writing;
- appropriate attention is given to addressing any recommendations raised by the auditors.

All staff audited in line with this SOP must follow the rules defined herein and help ensure the smooth running of an audit.

The Management Board will be informed on the audit findings and recommendations and on the status of implementation of improvement actions for issued recommendations in line with the relevant provisions.

4. Changes since last revision

The SOP has been updated to formalize processes which are taken into consideration during the audit process, especially the requirements of the new Data Protection legislation applicable to EMA (EU DPR), effective as of 11 December 2018.

There have been other changes in the AF-AUD audit charter and the Code of Ethics however these changes have not affected this SOP.

5. Documents needed for this SOP

All the below documents/templates can be found on the:

x-drive:\Auditpractices\Checklistsandtemplates

- Audit Plan template
- Audit Report template
- Guideline to complete internal audit reports
- Audit Feedback questionnaire
- Contradictory Procedure template
- Annual Audit Report template
- Checklist for Reviewing Audit Reports for validators
- SOP/EMA/0121 - How to conduct a procurement procedure: available on the public EMA webpage.

6. Related documents

- Regulation (EC) No 726/2004, as amended.
- Financial Regulation applicable to the budget of the European Medicines Agency Applicable from 1 July 2019, Adopted by the MB on 13 June 2019.
- Financial Regulation applicable to the General EU Budget Art 118, 9.
- The International Standards for the Professional Practice of Internal Auditing of the Institute of Internal Auditors.
- The Code of Ethics.
- EMA Risk Register.
- The Internal Audit Charter of the European Medicines Agency, as adopted by the Management Board.
- European Medicines Agency Internal Audit Manual.
- User manual for tracking internal audits, recommendations and actions in Trackwise.
- Memo on grading of findings.

7. Definitions

Day: working day, excluding weekends, Agency's holidays, business disasters

IIA: Institute of Internal Auditors

IQMCo: Integrated Quality Management Coordinator

ED: Executive Director

DED: Deputy Executive Director

EXB: Executive Board

Head of AF-AUD: Head of Advisory Function – Audit

HoDiv – Head of Division

HoDep – Head of Department

HoTF – Head of Task Force

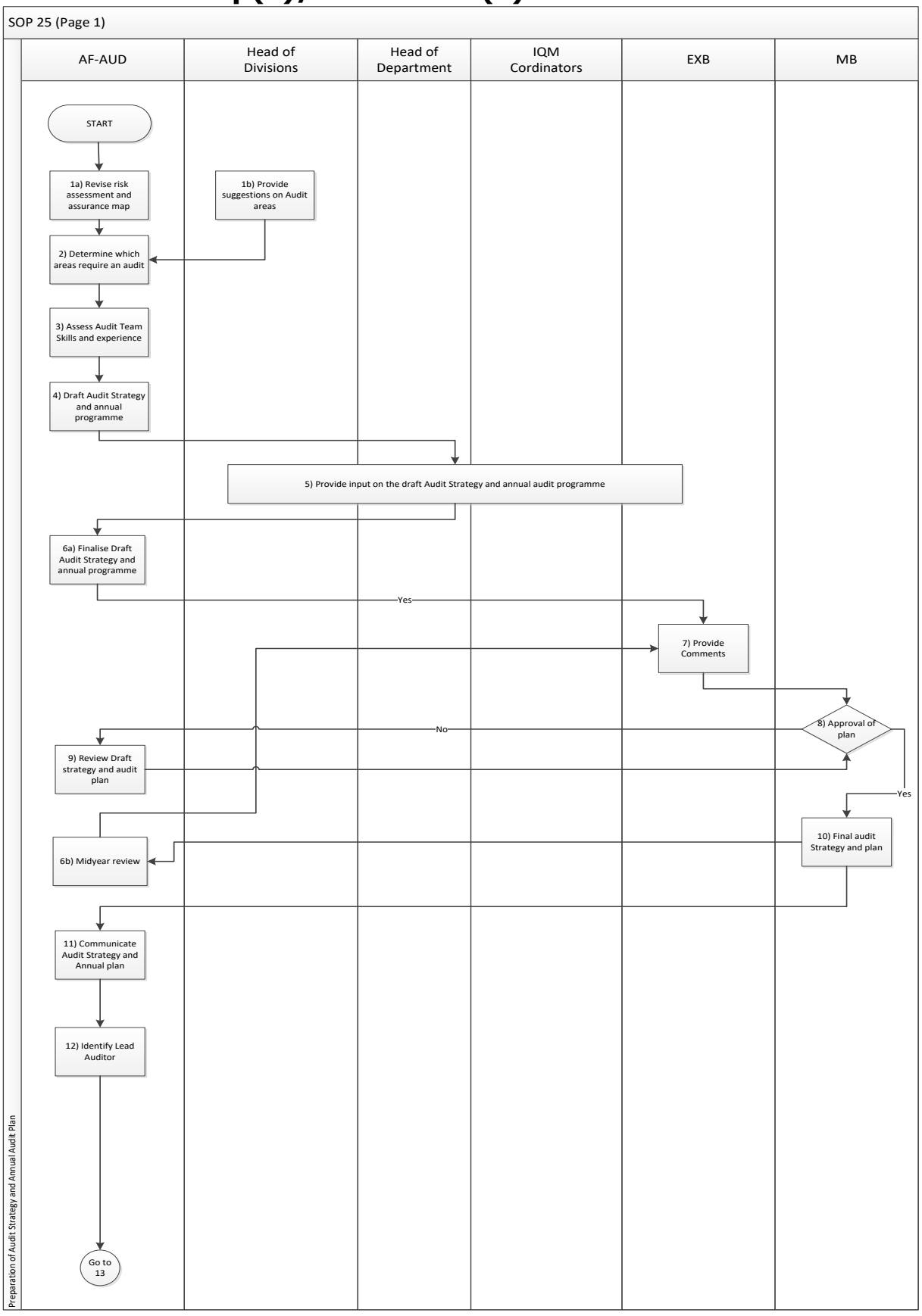
IAP(s): improvement action plan(s)

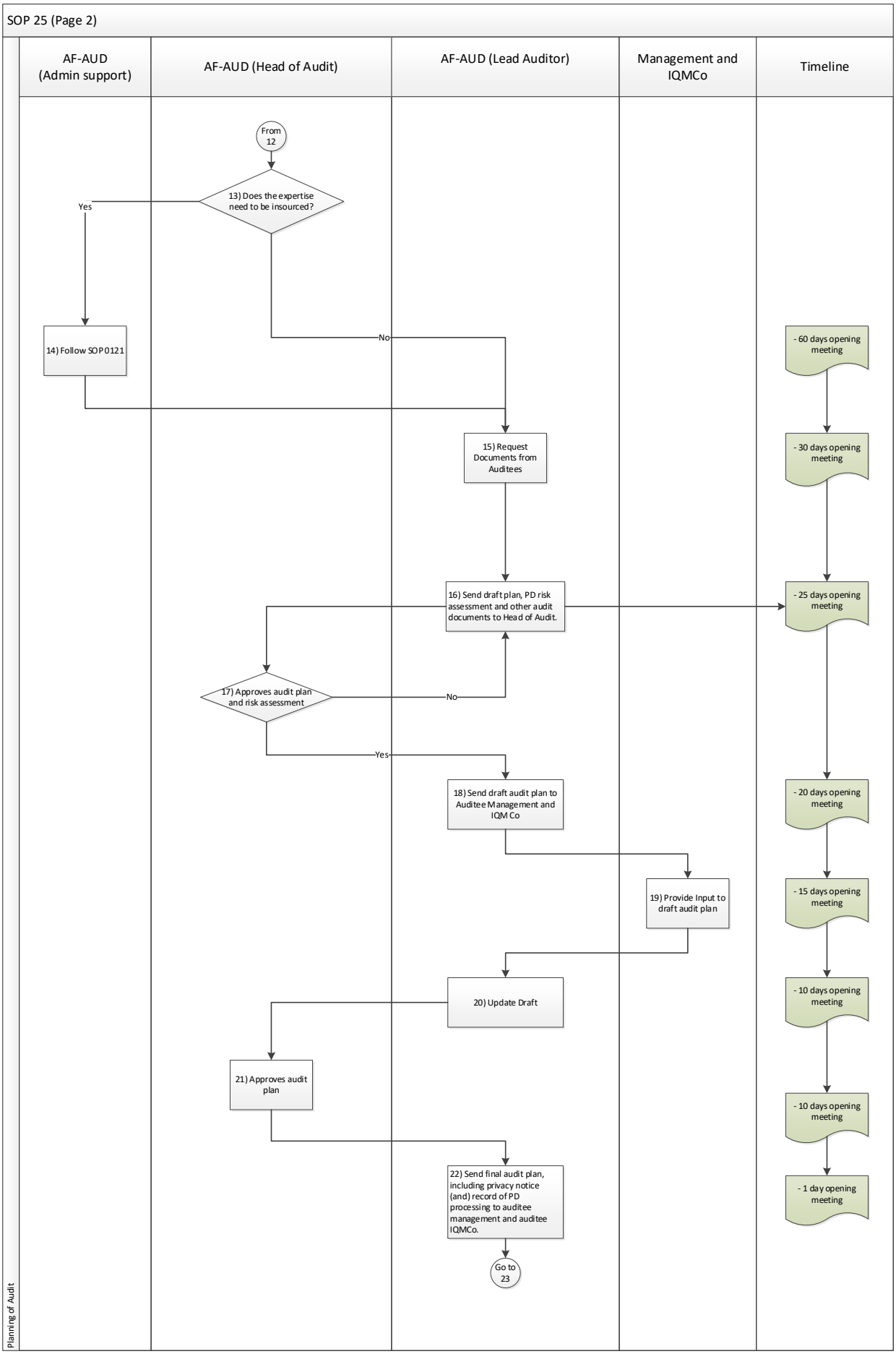
MB – Management Board

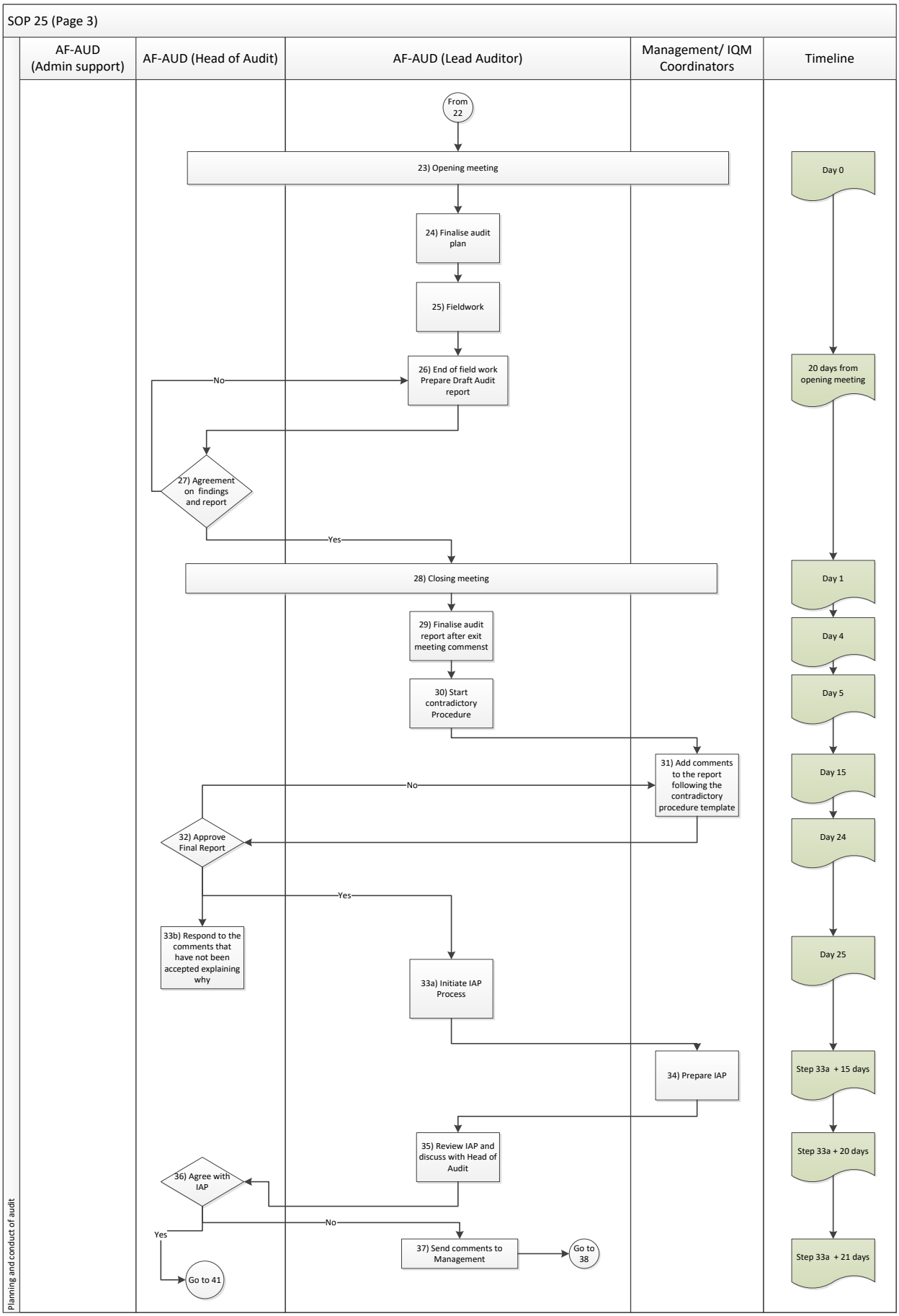
TW: TrackWise (The Agency’s electronic audit tracking management system)

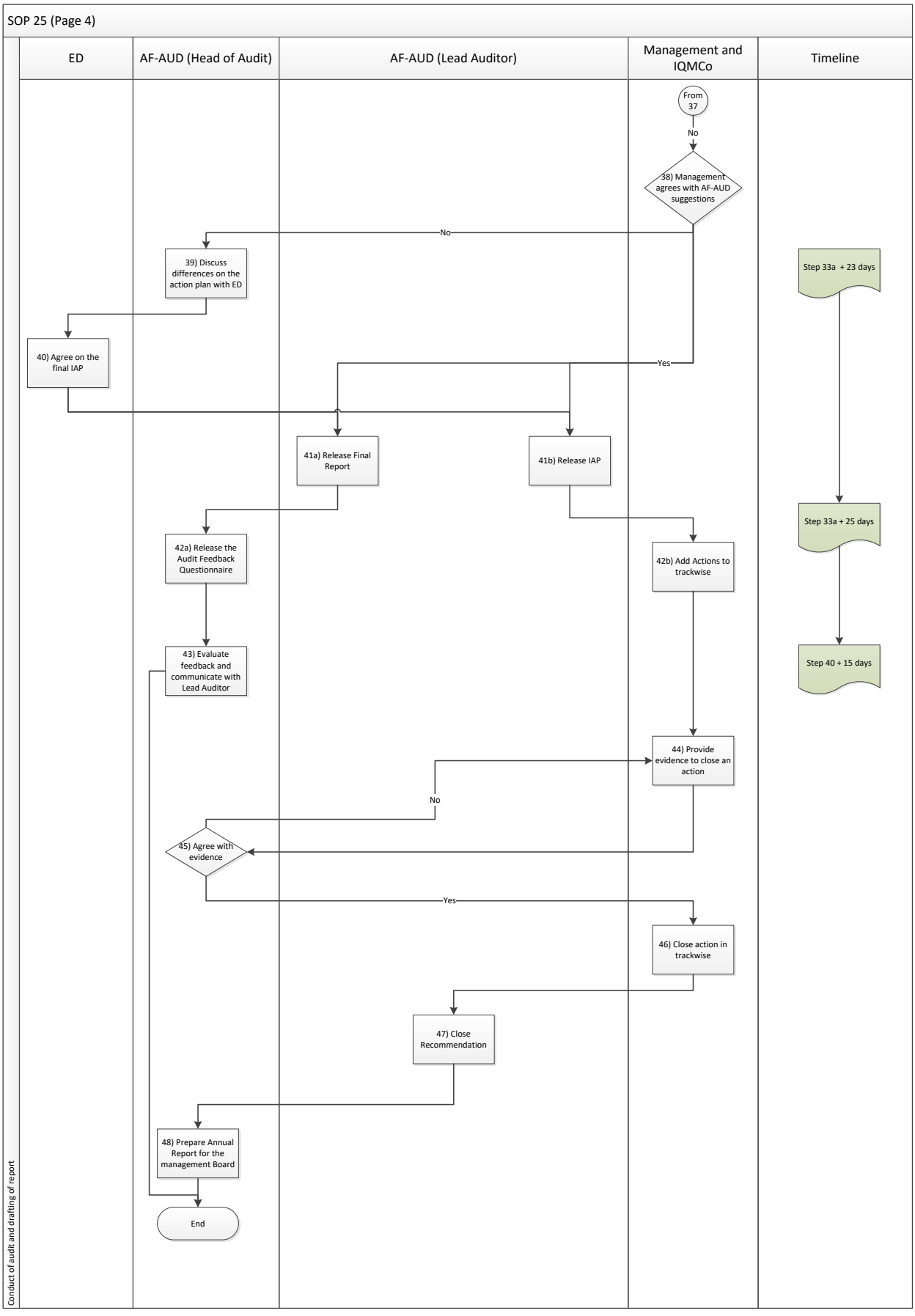
For the main definitions refer to Glossary as per the Internal Audit Manual

8. Process ma p(s)/ flow chart(s)




SOP 25 (Page 2)
AF-AUD (Admin support)
AF-AUD (Head of Audit)
AF-AUD (Lead Auditor)
Management and IQMCo
Timeline
From 12
13) Does the expertise need to be insourced?
Yes
No
14) Follow SOP 0121
15) Request Documents from Auditees
16) Send draft plan, PD risk assessment and other audit documents to Head of Audit.
17) Approves audit plan and risk assessment
No
Yes
18) Send draft audit plan to Auditee Management and IQM Co
19) Provide Input to draft audit plan
20) Update Draft
21) Approves audit plan
22) Send final audit plan, including privacy notice (and) record of PD processing to auditee management and auditee IQMCo.
Go to 23
- 60 days opening meeting
- 30 days opening meeting
- 25 days opening meeting
- 20 days opening meeting
- 15 days opening meeting
- 10 days opening meeting
- 10 days opening meeting
- 1 day opening meeting
Planning of Audit


SOP 25 (Page 3)
AF-AUD (Admin support)
AF-AUD (Head of Audit)
AF-AUD (Lead Auditor)
Management/ IQM Coordinators
Timeline
Planning and conduct of audit
From 22
23) Opening meeting
24) Finalise audit plan
25) Fieldwork
26) End of field work Prepare Draft Audit report
No
27) Agreement on findings and report
Yes
28) Closing meeting
29) Finalise audit report after exit meeting commenst
30) Start contradictory Procedure
31) Add comments to the report following the contradictory procedure template
No
32) Approve Final Report
Yes
33b) Respond to the comments that have not been accepted explaining why
33a) Initiate IAP Process
34) Prepare IAP
35) Review IAP and discuss with Head of Audit
36) Agree with IAP
No
Yes
37) Send comments to Management
Go to 38
Go to 41
Day 0
20 days from opening meeting
Day 1
Day 4
Day 5
Day 15
Day 24
Day 25
Step 33a + 15 days
Step 33a + 20 days
Step 33a + 21 days


SOP 25 (Page 4)
ED
AF-AUD (Head of Audit)
AF-AUD (Lead Auditor)
Management and IQMCo
Timeline
From 37
No
38) Management agrees with AF-AUD suggestions
No
Yes
39) Discuss differences on the action plan with ED
40) Agree on the final IAP
41a) Release Final Report
41b) Release IAP
42a) Release the Audit Feedback Questionnaire
42b) Add Actions to trackwise
43) Evaluate feedback and communicate with Lead Auditor
44) Provide evidence to close an action
No
45) Agree with evidence
Yes
46) Close action in trackwise
47) Close Recommendation
48) Prepare Annual Report for the management Board
End
Step 33a + 23 days
Step 33a + 25 days
Step 40 + 15 days
Conduct of audit and drafting of report

9. Procedure

Step	Action	Responsibility
	Preparation of Audit Strategy and audit programmes	
1	a) Each Year in August, review the auditors' risk assessment and assurance maps. The audit strategy (which includes the audit programme for year N+1 and rolling programme of audits for year N+2 and N+3) should begin being drafted. b) Provide information on the audit requirements in all operational and support areas	AF-AUD HoDiv and DED
2	Determine which activities and/or projects require audit.	AF-AUD
3	Assess the Audit Team and determine if the team possesses' adequate skills, knowledge and experience to lead the audit activities.	AF-AUD
4	Draft the audit strategy, annual audit programme for N+1 and rolling audit programme for year N+2 and N+3.	AF-AUD
5	The Executive Board, HoDiv, HoDep and IQMCo provide input to the draft Audit Strategy, annual audit programme for N+1 and rolling audit programme for year N+2 and N+3.	EXB HoDep and IQMCo
6	a) Complete draft audit strategy and annual programme based on input provided. b) Midyear review drafted based on previous consultations and input provided by stakeholders.	AF-AUD AF-AUD
7	The Executive Board discusses and endorses on the updated draft audit strategy, audit programme for year N+1 and rolling programme for year N+2 and N+3. Comments are provided on the audit strategy and annual programme.	EXB
8	MB approves the annual audit programme for year N+1 If not approved go to step 9. If approved go to step 10	MB
9	Review audit plan based on previous recommendations from MB then repeat step 8.	AF-AUD
10	Finalise audit strategy, annual audit programme for N+1 and rolling audit programme for year N+2 and N+3	MB
11	Communicate the agreed audit strategy, annual audit programme for N+1 and rolling audit programme for year N+2 and N+3. Notify year N+1 to Heads of Division, Heads of Department and IQMCo. Publish it on the Internal Audit website.	AF-AUD
12	Identify lead auditor for each audit carried out in year N+1.	AF-AUD

Step	Action	Responsibility
	Planning of Audit	
13	Decide if for an audit, expertise needs to be insourced (Framework contract) . If yes, and the framework contract needs to be used go to step 14. If the audit is conducted by EMA auditors go to step 15.	Head of AF-AUD
14	Opening Meeting -60 days Follow SOP/EMA/0121 to insource auditors (framework contract).	AF-AUD (Admin Support)
15	Opening meeting -30 days Request information and/or documents from the auditee management and IQMCo.	AF-AUD Lead Auditor
16	Opening meeting -25 days Send draft audit plan, checklists, surveys and/or questionnaires and assessment of private data risk to Head of Audit and backup on electronic document management system.	AF-AUD Lead Auditor
17	Review and decide if to approve draft audit plan and risk assessment If not approved repeat step 16. If approved go to step 18.	Head of AF-AUD
18	Opening meeting -20 days Send draft audit plan to auditee management and auditee IQMCo for input.	AF-AUD Lead Auditor
19	Opening meeting -15 days Provide input in order to finalise audit plan on the basis of that scope, objective and samples of engagement.	Management and IQMCo
20	Opening meeting -10 days Consider the comments/input from auditee management and auditee IQMCo. Update draft audit plan.	AF-AUD Lead Auditor
21	Opening meeting -10 days Approve draft audit plan	Head of AF-AUD

22	Opening meeting -1 day Send final audit plan, including privacy notice (and) record of personal data processing to auditee management and auditee IQMCo.	AF-AUD Lead Auditor
	Planning and conduct of audit	
23	Opening Meeting	Head of AF-AUD, AF-AUD Lead Auditor, Management/ IQMCo
24	Consider auditee input from opening meeting. Finalise audit plan.	AF-AUD Lead Auditor
25	Fieldwork (5 days or 10 days from opening meeting) • Follow the checklists and questionnaires developed and ensure all steps described are covered. • Complete and record all working documents/ questionnaires. • Discuss potential issues through appropriate channels; including those detected which may fall outside the original scope of the audit. If necessary, inform ED/auditee management and auditee IQMCo of any major issues as and when they are detected. • Collect evidence to document all findings detected. • Finalise audit working papers and cross-referencing of audit evidence. • Finalise the Checklist for Reviewing Audit Observation Worksheets and Supporting Evidence and the Checklist for Reviewing Working Papers. • For any documentation received in paper, copies are filed in audit master file; electronic documents are filed in the Agency's electronic document management system in the relevant audit folder.	AF-AUD Lead Auditor
26	End of fieldwork + 20 days Prepare preliminary Draft Audit Report • Prepare a preliminary Draft Audit Report ensuring that recommendations are properly graded. • Report should be saved in the appropriate folder in the electronic document management system. • Circulate it for review/input among audit team members. • Use guideline to complete internal audit reports.	AF-AUD Lead Auditor

	• Send preliminary Draft Audit Report to validator and Head of AF-AUD for review and approval.	
27	Closing meeting - 1 Agreement on findings and report • Receive, validate and approve the preliminary draft audit report. • Use the Checklist for Reviewing Audit Reports for validators. • Send the preliminary draft report to auditee management. If agreement is not reached repeat step 26. If agreement continue to step 28	Head of AF-AUD
28	Closing Meeting day 1	Head of AF-AUD, AF-AUD Lead Auditor, Management/ IQMCo
29	Closing meeting +4 days: Finalise audit report taking into consideration input from auditees raised during closing meeting.	AF-AUD Lead Auditor
30	Closing meeting +5 days: Start contradictory procedure by sending Management and IQMCo template.	AF-AUD Lead Auditor
31	Closing meeting +15 days: Add comments to the report following the contradictory procedure template • Review the draft audit report. • Complete and return Contradictory Procedure form.	Management/ IQMCo
32	Closing meeting + 24 days: Approve final report • Validates the audit report and completes the Checklist for Quality Assurance Review. • Approval of audit report by Head of AF-AUD: final audit report. If not approved repeat step 31 If approved go to step 33.	Head of AF-AUD
33	Closing meeting : +25 days a) Initiate IAP Process • Draft IAP(s), with indication of start and end date of completion, person responsible.	AF-AUD Lead Auditor

	• Use Improvement Action Plan (IAPs) template. If recommendations are not accepted management should state reasons, suggest alternatives and accept the risk. Extensions might be granted on written request only. No extension shall be granted for critical recommendations but for cases when a reasonable justification is provided and following a consensus of Head of AF-AUD and ED. b) Respond to the comments that have not been accepted during the contradictory explaining why	
34	Date of IAPs process initiated +15 days: Prepare IAP and send to lead auditor for review	Management/ IQMCo
35	Date of IAPs process initiated +20 days: Review IAP(s) submitted by auditee management and IQMCo and discuss with Head of Audit	AF-AUD Lead Auditor
36	Date of IAPs process initiated +20 days: Agree with IAP • If IAP(s) is (are) found acceptable, go to step 38. • If IAP(s) is (are) not found acceptable, state reason(s), suggest alternatives(s), if possible, and return IAP(s) to auditee management for action. Continue with step 37.	Head of AF-AUD
37	Date of IAPs process initiated +21 days Send comments to auditee management • Revise non-acceptable IAP(s) and define new actions and deadline(s); • Send the reviewed IAP(s) to audit team.	AF-AUD Lead Auditor
38	Management agree with AF-AUD suggestions If no agreement go to step 39. If agreement go to step 41.	Management and IQMCo
39	Date of IAPs process initiated +23 days: Discuss differences with management of the action plan with the ED	Head of AF-AUD
40	Agree on the final IAP(s) to address recommendations.	ED
41	Date of IAPs process initiated +25 days: a) Release the final audit report with b) accepted IAP(s) and the completed Contradictory Procedure form to ED, DED, Heads of Division and Department, all IQMCo.	AF-AUD Lead Auditor

42	Date of IAPs process initiated +25 days: 42a) Release audit feedback questionnaire	Head of AF-AUD
	42b) Enter improvement actions into TrackWise	Management and IQMCo
43	Date of finalising IAP(s) +15 days: Evaluate feedback obtained from questionnaire and communicate results with lead auditor	Head of AF-AUD
44	Auditee management implements the actions within deadline(s) indicated in IAP and provides evidence to close action.	Management and IQMCo
45	Review the action(s) taken. Decide whether the action(s) address or not the recommendations If yes, go to step 46 If not, repeat step 44	Head of AF-AUD
46	Close action in TW	IQMCo
47	Once all actions are closed, the recommendation should be closed within TW	AF-AUD Lead Auditor
48	Prepare the Annual Audit report to the Management Board, as requested by art. 80.1 of the Agency's Financial Regulation, on the basis of the audits conducted during the given year, including all IAPs during that period and send it to the MB for information. This report should be sent at the time that the Annual Activity Report is submitted to the Management Board.	Head of AF-AUD

10. Records

Audit reports and all audit related records (audit plans, checklists, questionnaires, working papers, handwritten notes, documents sent by auditee management, etc.) are to be kept in the Agency's electronic document management system in the relevant folder: Cabinet/06 Corporate Governance/06.6 Audit/Internal Audit/Annual Audit Programme/YYYY.

Based on Financial Regulation applicable to the General EU Budget Art 118, 9 "The reports and findings of the internal auditor, as well as the report of the institution, shall be accessible to the public only after validation by the internal auditor of the action taken for their implementation". All other working papers should be considered confidential and for internal use of auditees and AF-AUD only.