



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2014
EMA/564159/2014

Technical specifications for open invitation to tender

Procurement Procedure EMA-2014-49-AUD for provision of audit services

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Technical specifications for open invitation to tender

No. EMA/2014/49/AF-AUD

1. Title of the invitation to tender

This document contains the Technical Specifications for the Open Invitation to Tender no. EMA-2014-49-AUD for the provision of audit services.

The contract notice for this open tender has been published in the Official Journal of the European Union (OJEU) no. S 238 of 10 December.

2. Objectives and context of the invitation to tender

The European Medicines Agency ("the Agency") is a decentralised body of the European Union based in Canary Wharf in the Docklands area of London (E14). Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency was established in 1995 and operates under Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products. The Agency is an Agency of the European Union and has its own legal personality. The Agency's budget is subject to checks and audits by the Court of Auditors.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised marketing authorisation is valid in all European Union and EEA-EFTA states. The safety of medicines is monitored constantly by the Agency through a pharmacovigilance network.

The Agency also gives scientific advice and protocol assistance to companies for the development of new medicinal products. It published guidelines on quality, safety and efficacy testing requirements. A dedicated office provides special assistance to small and medium-sized enterprises (SMEs). Seven scientific committees, composed of members of all EU and EEA-EFTA states, some including patients' and doctors' representatives, conduct the main scientific work of the Agency.

The Agency conducts audits of its administrative and operational processes, accounts, procedures, projects, IT systems, governance, internal control and risk management systems.

This tender seeks to obtain specialist audit knowledge in the different topics that the Agency may audit in the next 4 years period.

The Agency has experienced growing demands in the last years to provide audit services to its management, stakeholders and Management Board, on an increasingly diverse range of topics, from pharmacovigilance to IT systems. This contract aims to assist the Agency meet these increased requirements by providing additional audit resources to support the internal audit function or by performing some of the audits under the responsibility of the head of Audit at the Agency.

The working language of the Agency is English.

3. Subject of the tender

The Agency considers that it may require assistance in the field of internal audit in all of the following topics:

3.1. System audits

The auditor produces an opinion based on reasonable assurance that relevant applicable systems/procedures are appropriate (in line with legal requirements) and complied with and the internal control and governance system in place allows the Agency to meet the defined objectives for those administrative and operational procedures.

System audits at the Agency can include among others, regulatory complex procedures (such as initial marketing authorisations for new drugs), governance aspects, horizontal procedures such records management or security of records, to administrative processes, mostly governed by the rules applicable to EU bodies.

3.2. IT systems audit

The objective of this audits is to provide reasonable assurance that an specific IT system or some areas of the Agency's IT systems are in compliance with the defined standards, policies or best practices set up as audit criteria.

The Agency's IT environment is complex and includes a number of secure systems and in-house developed applications for the coordination and secure transmission of data among the Agency, National Competent Authorities (NCAs), industry and other stakeholders.

3.3. Projects audit

The auditor provides an opinion on the performance and/or compliance of a project with the relevant project management methodology and with the aspects defined in project objectives.

Projects may be in the IT area, but also non-IT related, even if a small IT component is there.

3.4. Financial audits

The objective of these audits is to enable the auditor to express an opinion whether the financial statements are prepared, in all material respects, in accordance with an applicable financial reporting framework or specific financial procedures have been consistently applied to certain transactions.

3.5. Ad-hoc audits

Any other audit that must meet specific needs not listed above. This is designed to provide some flexibility in the framework contract and to allow the Agency to conduct specific audits on diverse topics, as necessary.

The initial duration of the framework contract will be one year from date of signature by the last of the contracting party, with the possibility of up to three extensions of one year each, making a maximum possible duration of four years. The Agency reserves the right not to renew the framework contract.

All audit services are to be provided in compliance with the relevant international audit standards and SOP/EMA/0025 (attached as Annex VII), describing the internal audit procedure at the Agency, as relevant.

The services will be carried out at the Agency's premises and/or the contractors' premises, depending on their nature.

4. Participation in the tender

4.1. Agreements on public procurement

Participation in the Agency's tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with Union in the field of public procurement under the conditions laid down in that agreement.

The Agency can therefore accept offers from and sign contracts with tenderers from the EU Member States, EEA countries and any other country which has an international agreement with the Union in the field of public procurement. The tender procedures of the Agency are not, however, open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA").

4.2. Subcontracting

If the tender envisages subcontracting any part of this contract, the following documents must be provided with the tender submission:

- (i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor.
- (ii) A letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the tenderer if it wins the contract and the extent of the resources that it will put at the tenderer's disposal for the performance of the contract.
- (iii) If requested under points 12, 13 and 14 any documents regarding the exclusion and/or selection criteria for any subcontractors.

If such documents are not provided, the Agency shall assume that the tenderer does not intend subcontracting.

5. Additional documentation available to tenderers

Further information about the work of the Agency can be obtained on its website:

<http://www.ema.europa.eu>.

6. Information visit

Not applicable

7. Variants

Not applicable

8. Estimated contract volume

The estimated value of the framework contract is €480,000, distributed in approximately 2-4 audits/year.

The Agency may exercise the option to increase the estimated contract value at a later stage via negotiated procedure with the successful tenderer in accordance with Article 134 (1) (f) of the Rules of Application of the general Financial Regulation¹.

9. Price

9.1. Currency of tender

Prices should be submitted in Euro. The costing sheet attached to these specifications as Annex I must be used to submit a tender.

Please note that any financial costing sheet must be submitted in separate binders or folders, which must be clearly labelled.

Tenders are reminded that they must be able to cover all the tasks defined in point 3 above.

Tenderers must provide unit prices for each expert profile specified in Annex IV. In particular, tenderers must provide unit prices for each expert profile according to whether the services are provided on the Agency's premises or at a different location.

These unit prices must be fixed and include all costs and expenditure incurred directly and indirectly by the contractor in the performance of the tasks. No separate travel and accommodation costs will be paid by the Agency, so these costs should be included in the unit prices.

9.2. All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include travel, subsistence etc). No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

9.3. Price revision

Prices submitted in response to this tender shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the contract.

From the beginning of the second year of performance of the contract, prices may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the contract became effective. Specific Contracts shall be concluded on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision.

This revision shall be determined by the trend in the European Index of Consumer Prices (EICP) published by the Statistical Office of the European Union in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (European Union index) (<http://epp.eurostat.ec.europa.eu>).

¹ Part 1, Title V of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

Revision shall be calculated in accordance with the following formula:

$$Ar = Ao * \frac{Ir}{Io}$$

Where

Ar = revised total amount

Ao = total amount in the original tender

Io = index for the month in which the validity of the tender expires

Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices

9.4. Costs involved in preparing and submitting a tender

The Agency will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

9.5. Period of validity of the tender

Tenderers must enclose a confirmation that the tender (including prices) is valid for six months from the final date for submission of the tender.

9.6. Protocol on the Privileges and Immunities of the European Union

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

10. Payment arrangements

A payment will be made for each audit conducted once all deliverables for that audit have been received and accepted by the Agency.

Payments under the Contract shall be executed only if the contractor has fulfilled all its contractual obligations by the date on which the invoice is submitted, including specified deliverables.

11. Contractual details

A draft framework contract is attached to these Technical Specifications as Annex VI. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of their tender response.

The Agency wishes to conclude a maximum of three framework contracts in priority order to provide audit services, as and when required, for an initial period of one year, followed by three possible renewals each of one year, making a maximum possible contract duration of four years. A framework

contract will establish the terms governing specific contracts to be awarded during a given period, in particular with regard to price.

Tenderers will be ranked and framework contracts awarded to the three highest ranking in priority order. Requests for specific services will be sent to the first priority contractor and only if it is unable to provide the services or reply within 10 working days of receipt of the request with a proposal, then the request for services will be sent to the second ranked contractor and, subsequently, to the third ranked contractor, as necessary.

The prices to be quoted in the replies to the Agency's request for services will be the price per profile established by each tenderer as per Annex I.

Signature of the framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through specific contracts is binding for the Agency.

Each specific contract will contain details of deliverables and timelines for particular services to be provided.

12. Exclusion criteria

All tenderers and subcontractors shall provide a declaration on their honour (see Annex II), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in this Annex.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex II before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender and to subcontractors.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the tenderer shall declare on its honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in its situation have occurred.

13. Selection criteria: financial and economic capacity

Requirements:

Tenderers must be in a stable financial position and have the economic and financial capacity to perform the contract.

Given the range of services that the Agency is expecting to be provided and the width of expertise requested, all tenderers must have an annual turnover in excess of € 360,000 for audit services, averaged over the past three years.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint tenders whereby a consolidated assessment shall be made) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amount, as indicated above and in the Official Journal notice, the on-going economic capacity will be assessed including financial independence and liquidity.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with the economic and financial capacity. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors.

If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested:

1. appropriate statements from banks or, where appropriate, evidence of relevant professional risk indemnity insurance;
2. financial statement for the last year for which accounts have been closed;
3. a statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last fiscal year;
4. if the tenderer relies on the capacities of other entities (e.g. a parent company), a written undertaking on the part of those entities confirming that they will place the resources necessary for performance of the contract at the disposal of the tenderer for the period of the contract. In such case the Agency may require that the successful tenderer(s) and such entities are jointly liable for the execution of the contract.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above in points 1, 2 and 3 if such evidence has been submitted to it for the purposes of another procurement procedure and if it still complies with the requirements of the Agency. If, for some exceptional reason which the contracting authority considers justified, the tenderer is unable to provide the documentation mentioned in points 1, 2 and 3, it may prove its economic and financial capacity by any other means which the contracting authority considers appropriate.

14. Selection criteria: technical and professional capacity

Requirements:

The criteria for this contract are:

- Authorisation of the tenderer to perform the contract under national law.
- Proof of enrolment in the relevant audit professional register, as prescribed in the country in which the tenderer is established.
- Experience and expertise in providing similar services on the topics described in point 3 to similar organisations and in all the different types of audits described under point 8.
- Suitably qualified staff for the different roles requested. Suitable qualifications would be Chartered Accountant, CIA, CISA or equivalent, depending on the nature of the audits to be undertaken. As the Agency will need services in a range of audits, it expects to receive profiles in the different audit areas. University degrees are required for all profiles, as described in Annex IV; university degrees in the subject matter being audited would be advantageous.
- Sufficient suitable qualified staff numbers to ensure delivery of services in case of changes of dates, staff leaving,... An average annual number of professional staff of at least 50, including financial and IT auditors is expected and should be included in the statement of the average manpower requested below.
- Evidence of having a formalised quality system in place, appropriately supervised by the relevant national body or similar.

Tenderers must meet all of the above requirements.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with these selection criteria. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors. For joint tenders the evaluation committee will assess the combined capacities of all members, including sub-contractors.

- Authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation of entry in the VAT register.
- Proof of enrolment in the relevant audit professional register, as prescribed in the country in which the tenderer is established.
- A list of the principal services related and most relevant to this invitation to tender provided in the past three years, with the sums, dates and recipients, public or private. All the types of audits described under point 8 should be mentioned.
- CVs for at least 5 experts in each of the profiles described in Annex IV (only 3 CVs are needed for the "specialist" profile and 2 CVs for the "partner" profile) that are proposed to work for the Agency's contract. The proposed profiles should demonstrate experience and expertise in auditing a diverse range of topics as described in point 3 of this document and experience in the regulatory framework applicable in EU institutions and bodies), as described in the list of the principal services provided in the past three years, as requested in the previous bullet point. The Curricula Vitae submitted must bear no indication of name or date of birth, only a number; a separate list should be included showing the association between these numbers and actual names.
- A statement of the average annual manpower and the number of managerial staff of the tenderer in the last three years.
- Certificates attesting compliance with quality standards, such as the ones required by the Institute of Chartered Accountants in England and Wales (ICAEW) or similar in the country where the tenderer is based.

15. Award criteria

The award criteria which will apply to this tender are as follows. The technical award criteria and price each account for 50% of the weighting which shall be used to determine contract award.

15.1. Technical evaluation

Tenders will be evaluated on the basis of the following award criteria:

- (1) methods and tools to be used to carry out the tasks (10 points) as described at point 3 of this document – the Agency expects a maximum of 3 one-side A4 pages on this issue -;
- (2) the mechanisms for ensuring continuity of service (10 points) - approximately 1 one-side A4 page expected -:
 - a. present the business continuity plan in place;
 - b. ensure that relevant information is shared and distributed amongst its staff;
 - c. procedures to ensure an appropriate hand-over of knowledge in the event of changes of staff

- (3) mechanisms for ensuring quality of the service provided (20 points) - approximately 3 one-side A4 pages expected -:
- a. a description of the quality controls that the tenderer would put in place on the delivery of the services whilst they are being performed.
 - b. the procedures for complaint management and resolution, including escalation procedures at higher level within the tenderer's organisation chart;
- (4) organisation of the team, coordination with the Agency and between members of the team (10 points, breakdown provided for a, b and c below) - approximately 2 one-side A4 pages expected -:
- a. description of the profile of the person who will act as project leader for the framework contract and his/her position in the organisation (2 points). In the event of a contract being awarded, the project leader will be the Agency's contact point, the sole interlocutor to whom it will address any requests. The project leader must provide the Agency with answers and solutions, as regards both the subject of the contract and organisational or administrative matters (including problems related to invoicing and payment), and implement them subject to the Agency's agreement. Therefore, he /she must be placed at the right level in the tenderer's organisation chart (partner, director, or similar). Please note that no CVs are to be submitted for this point;
 - b. personnel policy, management, information and training (3 points); particularly with regard to procedures for selecting CVs meeting the requested profiles, keeping staff informed about the audit;
 - c. working methods to identify and report conflicts of interest to the Agency (5 points). Therefore, each tender should clearly describe how the tenderer has organised itself in order to identify conflicts of interest easily and to report conflicts of interest to the Agency.

The figures in brackets indicate the maximum score that can be attributed to each individual criterion.

Tenders which do not obtain at least 50% of the maximum score for each award criterion and at least 60% of the overall score for all the criteria will not be admitted to the next stage of the evaluation procedure.

15.2. Financial evaluation

The price used to determine the tender which offers the best value for money will be the total price of the evaluation scenario stated in Annex I.

The evaluation scenario is based on the unit prices, per expert profile, depending on whether the services are to be provided on the Agency's premises or elsewhere, and takes account of the annual estimate of the total workload and of the division of the tasks into work done on the Agency's premises and elsewhere. The prices tendered however shall be the prices paid by the Agency per profile if a contract is awarded.

Tenderers' attention is drawn to the fact that the sole objective of the evaluation scenario is to provide a fair, non-discriminatory basis for comparing the financial bids.

Consequently, this evaluation scenario cannot under any circumstances be considered to constitute a commitment on the part of the Agency to conclude specific contracts for the related services and quantities, and cannot give rise to any right or legitimate expectation on the part of the contractor.

Prices must be expressed in euro (€). Prices should be quoted free of all duties, taxes and duties, including VAT (the Union is exempt from such charges under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union). As stated in point 9.2 above, prices must be inclusive of all costs involved in the performance of the contract and no expenses will be reimbursed separately by the Agency.

The award criteria for price shall be evaluated according to the following formula:

$$\frac{\text{Lowest price} \times 50}{\text{Tenderer's price}}$$

The tenderer's price shall be the grand total stated by the tenderer in Annex I.

Tenderers' attention is drawn to Article 151 of the Rules of Application of Regulation (EU, Euratom) No. 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union concerning abnormally low tenders.

15.3. Contract award

Three contracts will be awarded to the tenderers that offer the best value for money, namely those three highest scoring tenderers, after adding the points obtained in as per headings 15.1 and 15.2 above to two decimal places.

This total score (points as per heading 15.1 for technical award criteria + points as per heading 15.2 for price) will determine the tenderers that will be awarded the contract and the order of priority.

16. Tender to be submitted

In order to assess each tenderer according to the above-mentioned criteria, the following information must be submitted by the tenderer:

- A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
- An information sheet on the tenderer indicating:
 - the name and registered business address including telephone number, e-mail address and website address;
 - any other different current or previous trading name in the past three years;
 - the name and contact details of the person whom may be contacted with any queries regarding this tender;
 - the legal status of the tenderer;
 - if the tenderer is a company the company registration number, VAT registration number and date of incorporation;
 - if the tenderer is a member of a group of companies and, if so, the relationship between the tenderer and the ultimate holding company, the name and address of the holding company and its registration number, whether the ultimate holding company would be prepared to guarantee the liabilities in connection with this contract;
 - name of the persons authorised to sign contracts on behalf of the tenderer.

- Completed declaration in Annex II relating to Exclusion Criteria.
- Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above).
- Documentation requested to enable assessment of Award Criteria (point 15 above)
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- Confirmation of acceptance of the draft contract and terms and conditions of tender.
- Tenderers must enclose a confirmation that the tender (including prices) is valid for six months from the final date for submission of the tender.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.
- Tenderers are requested to make use of the checklist given in Annex III to ensure that no enclosure has been omitted in their tender.

Annexes

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Annex I

Costing sheet – Price list and financial evaluation scenario

This is provided as an Excel spreadsheet to be completed with the price per profile by the tenderer

Annex II

Exclusion criteria declaration upon honour and detail of supporting documentation required

It is MANDATORY to complete all parts highlighted in grey.

The undersigned (insert name of the signatory of this form):

☐ representing the following legal person: (only if the economic operator is a legal person)

full official name:

official legal form:

full official address:

VAT registration number:

OR

☐ in [his][her] own name (only if the economic operator is a natural person)

➤ declares that the above-mentioned legal person² is not in one of the following situations:

- a) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;
- c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;
- d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;
- e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the European Union's financial interests;
- f) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the European Union's budget.

➤ declares that the natural persons with power of representation, decision-making or control³ over the above-mentioned legal entity are not in the situations referred to in b) and e) above;

➤ declares that the above-mentioned legal person⁴:

² In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

³ This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

⁴ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

- g) has no conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure;

- acknowledges that the above-mentioned legal person⁵ may be subject to administrative and financial penalties⁶ if any of the declarations or information provided prove to be false.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

Date: _____ Signature of authorised representative: _____
 (Print name): _____
 Position in Company: _____
 Representing (name of tenderer): _____

⁵ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁶ As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

Annex III

Summary checklist of documents which tenderers must submit

1. Letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
2. Tender in one original paper copy with one copy of all documents on CD-ROM, containing the following elements:
 - Information sheet on the tenderer (as detailed in point 16 above).
 - Completed declaration in Annex II relating to Exclusion Criteria.
 - Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above).
 - Documentation requested to enable assessment of Award Criteria (point 15 above).
 - A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
 - Confirmation of acceptance of the draft contract and terms and conditions of tender.
 - Tenderers must enclose a confirmation that the tender (including prices) is valid for six months from the final date for submission of the tender.
 - An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
 - Documents as requested in relation to proposed subcontracting.
 - Tenders submitted by consortia or by groups of service providers *[or suppliers]* must indicate the role, title and experience of each member or of the group.
 - **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex I, and exclusive of VAT, signed by an authorised representative of the tenderer.

END

Annex IV

Description of the minimum requirements (profiles) for staff proposed by tenderers for the performance of the tasks covered by the contracts

INTRODUCTION

The following minimum qualifications and other conditions (profiles) are required for the staff proposed by tenderers who may be called on to perform the tasks to which this procedure refers.

Information supplied concerning the requirements set for each profile:

- Studies: Description of the minimum educational qualifications required for the profile
- Knowledge and skills: List of the minimum knowledge and skills required for the profile in question
- Experience: Minimum experience required for the profile

The list of profiles is as follows:

- Audit assistant
- Audit senior
- Audit manager
- Audit specialist
- Partner

In particular, it should be recalled that, in line with point 14 of the specification, for each expert profile in question the tenderer must provide at least five experts who meet all the minimum requirements set out below to perform the tasks to which the tender refers in its point 3.

For the profiles of specialist, however, at least three experts who meet the minimum requirements must be proposed and at least two experts for the partner profile.

Detailed CVs must be provided in all cases, using the model CV in Annex V to the specifications.

DESCRIPTION OF THE PROFILES

Audit assistant	
Education and professional qualifications	• University degree or equivalent professional qualification in the area
Knowledge and skills	• Sound knowledge of audit, governance, internal control and risk management • Good drafting and written presentation skills • Good knowledge of office automation software (MS Word, Excel, Powerpoint or equivalent) • Excellent knowledge of written and spoken English
Professional experience	At least three years' relevant experience, with at least one year in internal or external audit

Audit senior	
Education and professional qualifications	• University degree or equivalent professional qualification in the area
Knowledge and skills	• Good knowledge of audit standards, techniques and methodologies • Good knowledge of governance, especially within international organisations • Good knowledge of internal control, especially of the framework applicable at EU institutions and agencies (COSO based) • Sound knowledge of internal control methods and best international practices in international administrations and/or organisations • Good knowledge of the theory and practice of risk management • Excellent drafting and written presentation skills • Good knowledge of office automation software (MS Word, Excel, Powerpoint or equivalent) • Excellent knowledge of written and spoken English
Professional experience	At least five years of relevant experience, with at least two years in internal or external audit

Audit manager	
Education and professional qualifications	• University degree or equivalent professional qualification in the area
Knowledge and skills	• Good managerial skills • Excellent knowledge of audit standards, techniques and methodologies, and specifically of the international standards (IPPF) issued by the Institute of Internal Auditors (IIA) • Excellent knowledge of governance, especially within international organisations • Excellent knowledge of the theory and practice of internal control, especially of the framework applicable at EU institutions and agencies (COSO based) • Good knowledge of methods of internal control and best international practices in international administrations and/or organisations • Excellent knowledge of the theory and practice of risk management • Excellent drafting and written presentation skills • Good knowledge of office automation software (MS Word, Excel, Powerpoint or

Audit manager	
	- equivalent) • Excellent knowledge of written and spoken English
Professional experience	At least five years' relevant experience, with at least four years in audit and at least two years in team management

Audit specialist	
Education and professional qualifications	• University degree or equivalent professional qualification in the area
Knowledge and skills	• Good knowledge of audit techniques and methodologies • Sound knowledge of governance, the theory of internal control and risk management • Excellent knowledge and practical experience of a specific domain such as procurement, IT systems, IT security, statistics, regulatory environment in which the Agency operates, etc. • Good drafting and written presentation skills • Good knowledge of office automation software (MS Word, Excel, Powerpoint or equivalent) • Excellent knowledge of written and spoken English
Professional experience	At least four years' relevant experience in audit, specifically in the area of specialisation

Partner	
Education and professional qualifications	• University degree or equivalent professional qualification in the area
Knowledge and skills	• Excellent managerial skills • Excellent knowledge of audit standards, techniques and methodologies, and specifically of the international standards (IPPF) issued by the Institute of Internal Auditors (IIA) • Excellent knowledge of governance, especially international organisations and the EU environment • Excellent knowledge of the theory and practice of internal control, especially of the COSO-based framework applicable at EU institutions and agencies • Excellent knowledge of methods of internal control and best international practices in international administrations and/or organisations • Excellent knowledge of the theory and practice of risk management, including best international practices • Excellent drafting and presentation skills • Good knowledge of office automation

Partner	
	software (MS Word, Excel, Powerpoint or equivalent) • Excellent knowledge of written and spoken English
Professional experience	At least 15 years' relevant experience, with at least ten years in audit and at least five years in team management

Annex V

Model CV

PERSONAL INFORMATION

No personal information is to be included here.
Please include a number and a separate list linking the CV's numbers to the names.

PROFESSIONAL EXPERIENCE

[Add separate entries for each experience. Start from the most recent.]

Replace with dates (from - to)

Occupation or position held or mission relevant to the profile

Employer, if possible including website

Main activities and responsibilities

EDUCATION AND PROFESSIONAL QUALIFICATIONS

[Add separate entries for each course. Start from the most recent.]

Replace with dates (from - to)

Qualification awarded

Education or training organisation's name, town and country where it is located

Principal subjects covered or skills acquired

PERSONAL SKILLS

Mother tongue(s)

Specify with mother tongue(s)

Other language(s)

Specify other languages and level (basic, average, excellent)

Communication skills

Describe the experience and/or qualifications demonstrating drafting and presentation skills

**Organisational / managerial
skills**

Describe the management and team leadership experience and skills, if applicable

Computer skills

Describe the experience and/or qualifications demonstrating good knowledge of office software (Word, Excel, Powerpoint or equivalent) . You may wish to specify in what context they were acquired.

ADDITIONAL INFORMATION

Publications	Include any additional information relevant to the functions to be performed.
Presentations	
Projects	
Conferences	
Seminars	
Honours and awards	
Memberships	

Annex VI

Draft framework contract

Annex VII

SOP/EMA/0025 Audit programmes and internal audits conducted by the Audit Advisory Function



Standard operating procedure

Title: Audit programmes and internal audits conducted by the Audit Advisory Function		
Status: PUBLIC		Document no.: SOP/EMA/0025
Lead author	Approver	Effective date: 29/07/2014
Name: Edit Weidlich	Name: Guido Rasi	Review date: 29/07/2017
Signature: On file	Signature: On file	Supersedes: SOP/EMA/0025 (19-MAY-11)
Date: 29/07/2014	Date: 29/07/2014	TrackWise record no.: 4087

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, and its Implementing Rules;
 - Relevant regulations in the fields of human and veterinary medicines;
 - The International Standards for the Professional Practice of Internal Auditing of the Institute of Internal Auditors;
 - The 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;
- 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

This SOP reflects the recent changes in the Financial Regulation.

The procedure for establishing the audit strategy and annual audit programme for internal audit activities within the European Medicines Agency (former SOP/EMA/0024 Establishment of the European Medicines Agency's audit strategy) and the process for producing the Annual Audit report has been incorporated in this SOP.

5. Documents needed for this SOP

All the below documents/templates can be found on the x-drive:\Templates\Others\Audits:

- 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

6. Related documents

- [Regulation \(EC\) No 726/2004](#), as amended.
- [Financial Regulation](#) applicable to the budget of the European Medicines Agency as adopted by the Management Board, as adopted by the Management Board on 15 January 2014.
- [Regulation](#) of the European Medicines Agency laying down detailed rules for the implementation of certain provisions of the Financial Regulation for the Agency as adopted by the Management Board on 20 March 2014.
- The [International Standards](#) for the Professional Practice of Internal Auditing of the Institute of Internal Auditors.
- The [Code of Ethics](#).
- The [Internal Audit Charter](#) of the European Medicines Agency, as adopted by the Management Board on 12 June 2014.
- 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

EEB: Executive Board

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

HoDiv – Head of Division

HoDep – Head of Department

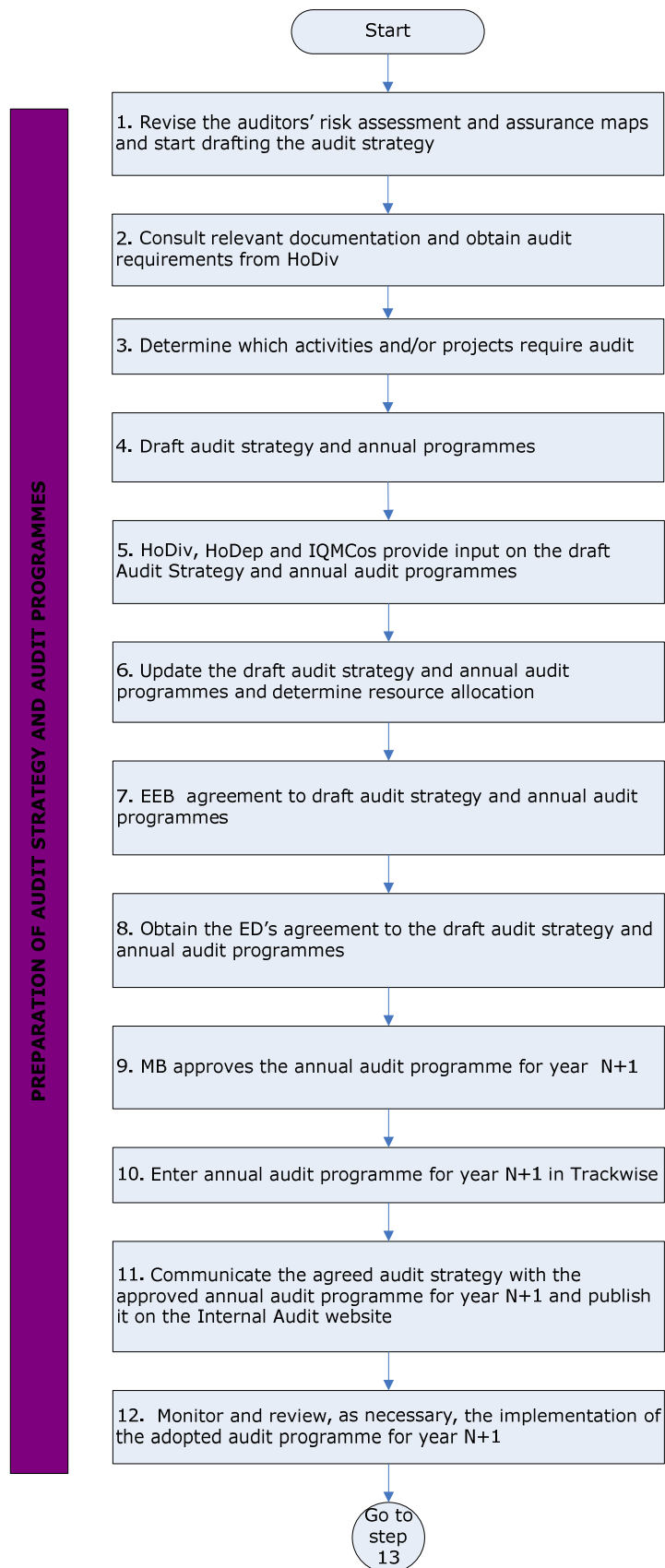
IAP(s): improvement action plan(s)

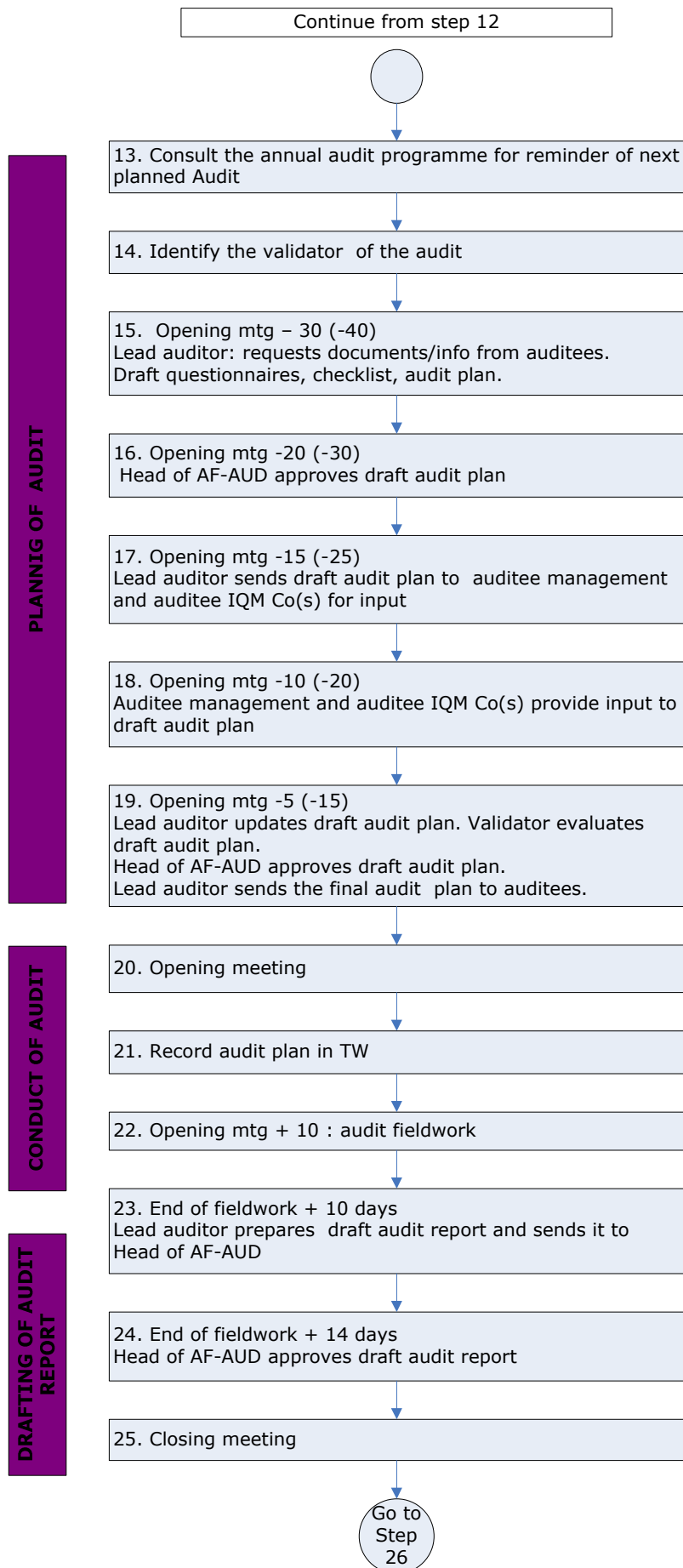
MB – Management Board

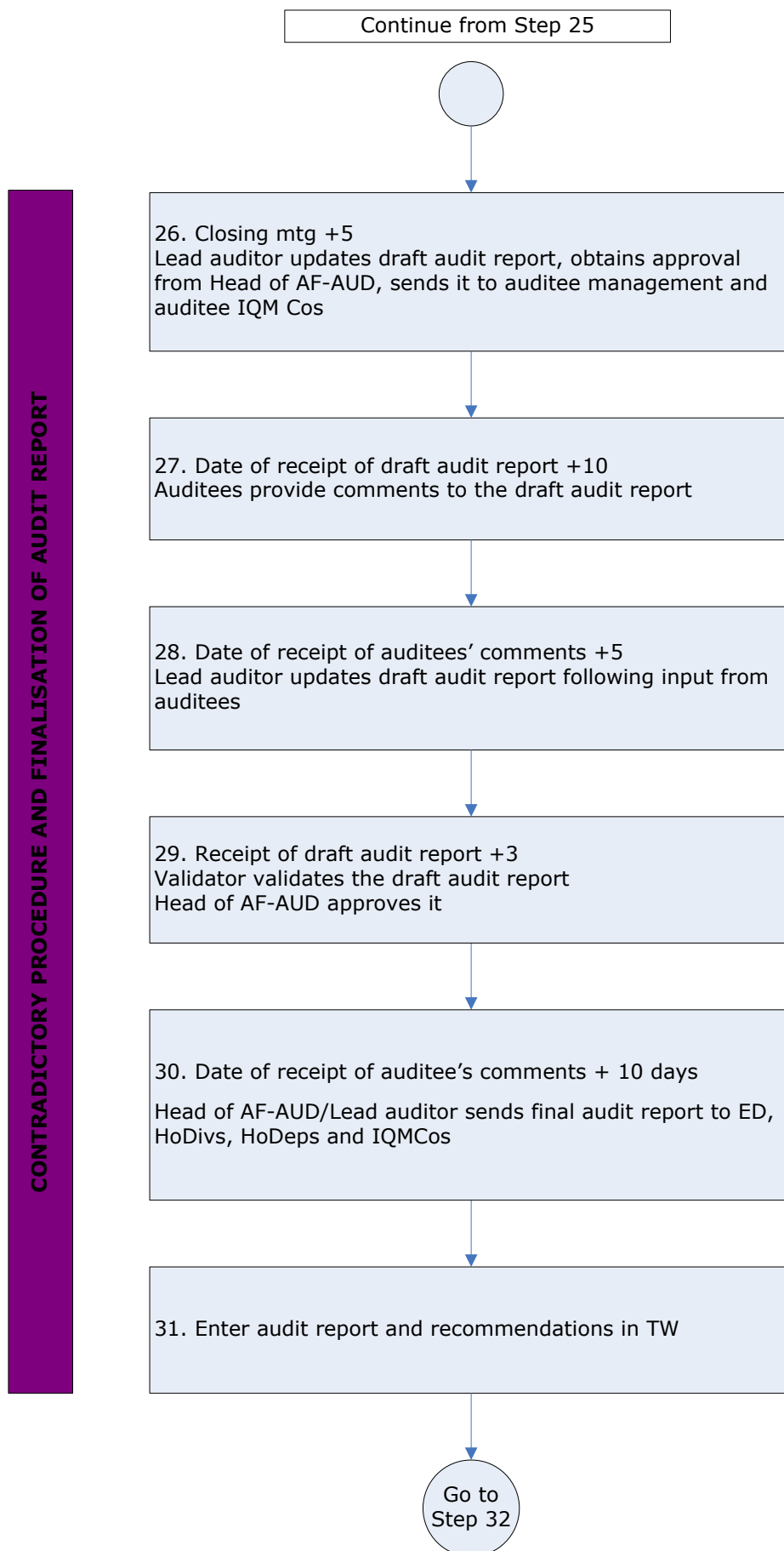
TW: TrackWise (The Agency's electronic audit tracking management system)

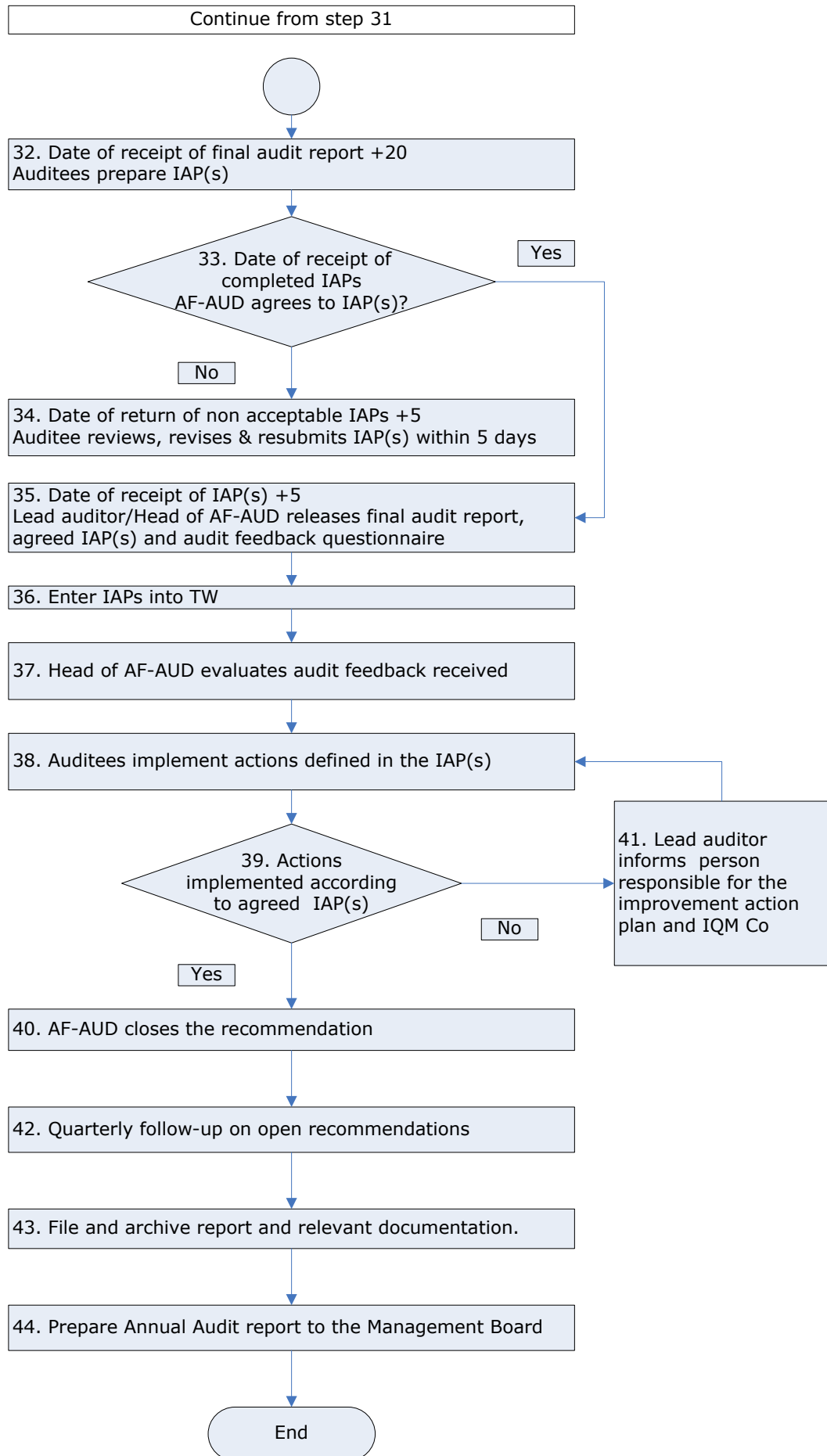
For the main definitions refer to Glossary as per the Internal Audit Manual.

8. Process map(s)/ flow chart(s)









9. Procedure

Step	Action	Responsibility
Preparation of Audit Strategy and audit programmes		
1.	In June of each year revise the auditors' risk assessment and assurance maps and start drafting the audit strategy (which includes the audit programme for year N+1 and rolling programme of audits for year N+2 and N+3).	AF-AUD
2.	Consult: • legal requirements; • audit programme of years N-1 and rolling programme for years N, N+1 and N+2; • outcomes of audits conducted in years N-1 and N, • risk assessment performed by the Agency's management and the IAS; • assurance maps; • the programme of the ECA, IAS and all other audit programmes; • the Agency's work programme for new areas of activity and processes; • the annual activity report of the Agency, including: related comments by the MB; any relevant reservation and the authorising officer's declaration of assurance (ED's); • the European Parliament's comments on discharge. Provide information on the audit requirements in all the operational and support areas.	AF-AUD HoDiv
3.	Determine which activities and/or projects require audit.	Head of 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.	HoDiv, HoDep and IQMCos provide input to the draft Audit Strategy, annual audit programme for N+1 and rolling audit programme for year N+2 and N+3.	HoDiv, HoDep and IQMCos
6.	Update the draft audit strategy, audit programme for year N+1 and rolling audit programme for year N+2 and N+3 and determine resource allocation.	Head of AF-AUD
7.	The Executive Group discusses and agrees on the updated draft audit strategy, audit programme for year N+1 and rolling programme for year N+2 and N+3.	EEB

8.	Discuss draft audit strategy, annual audit programme for year N+1 and rolling programme for year N+2 and N+3 with the Executive Director (ED) before the end of year N and obtain the ED's agreement to the audit strategy, annual audit programme for year N+1 and audit rolling programme for year N+2 and N+3.	Head of AF-AUD
9.	MB approves the annual audit programme for year N+1	MB
10.	Enter annual audit programme for year N+1 in Trackwise	AF-AUD
11.	Communicate the agreed audit strategy with the approved annual audit programme for year N+1 to Heads of Division, Heads of Department and IQMCos and publish it on the Internal Audit website.	Head of AF-AUD
12.	Monitor and review, as necessary, the implementation of the adopted audit programme for year N+1.	Head of AF-AUD
Planning of each audit		
13.	- Consult the annual audit programme for reminder of the next audit. - Identify the external and internal legislative background of audited processes.	Lead auditor
14.	Identify the validator who will be responsible for the review of the audit.	Head of AF-AUD
15.	Opening meeting -30 days (Opening meeting -40 days in case of outsourced contracted auditors or involvement of committees): - Request information and/or documents from the auditee management and IQM co-ordinator(s). - Prepare the Engagement Risk Assessment. - Use Documenting and Engagement Risk Assessment template. - Start preparation of the audit plan, checklists and questionnaires. - Use Audit Plan template. - Distribute tasks among audit team members. - Prepare audit plan, checklists and/or questionnaires and save in electronic document management system.	Lead auditor
16.	Opening meeting -20 days (Opening meeting -30 days in case of outsourced contracted auditors or involvement of committees): - Send the draft audit plan, checklist and questionnaires to Head of AF-AUD and get approval. - Send opening and closing meeting requests with minimum 30 days in advance.	Lead auditor

17.	Opening meeting -15 days (Opening meeting –25 days in case of outsourced contracted auditors or involvement of committees):	Lead auditor
	• Send the draft audit plan to auditee management and auditee IQM co-ordinator for their input. Ask feedback within 5 days. Initiate discussion in order to finalise risk assessment and on the basis of that scope, objective and samples of engagement. • Complete the Checklist for Reviewing with Auditee Management Audit Objectives and Criteria Statements template.	
18.	Opening meeting -10 days (Opening meeting –20 days in case of outsourced contracted auditors or involvement of committees):	Auditee management & IQM co-ordinator
	• Provide lead auditor with comments/input on the draft audit plan / questionnaires. • Provide any additional documents relevant for the audit.	
19.	Opening meeting -5 days (Opening meeting –15 days in case of outsourced contracted auditors or involvement of committees):	Lead auditor & audit team
	• Consider the comments/input from auditee management and auditee IQM co-ordinator. • Finalise the audit plan with validator. • Obtain approval from Head of AF-AUD for final audit plan, checklists and questionnaires. • Send the final audit plan to auditee management and auditee IQM co-ordinator(s).	Lead auditor
Conduct of audit		
20.	Opening meeting:	Head of AF-AUD & lead auditor & audit team & auditee management & IQM co-ordinator
	• Discuss the audit plan including the objectives and scope, and consider any additional input auditee management may have. • Discuss the audit methodology, the communication between audit team and auditee, the possibility of interim closing meetings, and confirm the date and time of closing meeting. • Record the names of the participants and note any information given in addition to documentation already provided.	
21.	Record audit plan in TW.	AF-AUD assistant

22.	Opening meeting + up to 10 subsequent field work days: - Follow the checklists and questionnaires developed and make sure that all steps described are covered. - Ensure working documents/ questionnaires are properly completed and recorded. - Discuss any potential issues with the lead auditor; including those detected which may fall outside the original scope of the audit. If necessary, inform ED/auditee management and auditee IQM coordinator 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.	Lead auditor & audit team AF-AUD Assistant
Drafting of audit report		
23.	End of fieldwork + 10 days: - 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. - Send preliminary draft audit report to validator and Head of AF-AUD for review and approval.	Lead auditor & audit team
24.	End of fieldwork + 14 days - 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.	Validator/Head of AF-AUD

25.	Closing meeting: end of fieldwork + 15 days	Head of AF-AUD + lead auditor + audit team + auditee management + auditee ICMCo
	• Hold the closing meeting. • Present the conclusions and recommendations following the audit. • Discuss the draft audit report and comments/ suggestions that auditee may have. • Outline the process to be followed and deadlines to be respected.	
Contradictory procedure and finalisation of audit report		
26.	Closing meeting +5 days: draft audit report	Lead auditor
	• Update the draft audit report according to the discussions and evidence received from the closing meeting. • Send to Head of AF-AUD for comments and approval. • Send the draft audit report to auditee management and all IQM co-ordinator(s) for their comments, including the Contradictory Procedure template.	
27.	Date of receipt of audit draft report +10 days:	Auditee management& IQM co-ordination team
	• Review the draft audit report. • Complete and return Contradictory Procedure form.	
28.	Date of receipt of auditee's comments + 5 days:	Lead auditor & audit team
	• Audit team addresses comments raised by auditee management, decide whether to amend the draft report and records reply to comments in the contradictory procedure template. • Lead auditor updates accordingly the draft audit report and sends it to the Head of AF-AUD. • Initiate contradictory discussion for cross agency recommendations if required. • Checklist for Quality Assurance Review prepared and sent TO Head of AF-AUD/validator together with the draft report.	
29.	Receipt of draft audit report + 3 days:	Validator/Head of AF-AUD
	• Validates the draft audit report and completes the Checklist for Quality Assurance Review. • Approval of draft audit report by Head of AF-AUD: final audit report.	

30.	Date of receipt of auditee's comments + 10 days	Head of AF-AUD & Lead auditor
	- Send the approved and validated final audit report to ED, Heads of Division, Heads of Department and IQM co-ordinator(s). - Attach the completed Contradictory Procedure form, including the replies from AF-AUD.	
31.	Enter audit report and recommendations in Trackwise	AF-AUD
Drafting of IAP		
32.	Date of receipt of final audit report + 20 days:	Auditee management & IQM co-ordinator(s)
	- Draft IAP(s), with indication of start and end date of completion, person responsible., - Use Improvement Action Plan (IAPs) template. - If recommendations are not accepted auditee 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.	
33.	Date of receipt of completed IAPs +5 days:	Lead auditor & audit team
	- Analyse IAP(s). - If IAP(s) is (are) found acceptable, go to step 35. - 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 34.	
34.	Date of return of non-acceptable IAP(s) +5 days:	Auditee management & IQM co-ordinator
	- Revise non-acceptable IAP(s) and define new actions and deadline(s); - Send the reviewed IAP(s) to the audit team.	
Release of final audit report and IAP		
35.	Date of receipt of IAP(s) +5 days:	Head of AF-AUD & Lead auditor
	- Release the final audit report with accepted IAP(s) and the completed Contradictory Procedure form to ED, Heads of Division and Department, all IQM co-ordinators(s). - Send the Audit Feedback questionnaire to auditees for completion.	
36.	Enter improvement actions into TrackWise	IQMCos
37.	Evaluates audit feedback received.	Head of AF-AUD
Implementation of IAP		

38.	- Auditee management implements the actions within deadline(s) indicated in IAP. - Continuous monitoring of actions taken. - Any amendments to the actions (e.g. date due changes, action details changes) must be agreed and approved by the relevant manager and the Head of AF-AUD.	Auditee management & auditee IQMCos
39.	- Review the action(s) taken. - Decide whether the action(s) address or not the recommendations - If yes, go to step 40 - If not, go to step 41	AF-AUD assistant Lead auditor & audit team
40.	Close recommendation. Go to step 42.	Lead auditor
41.	Inform person responsible for the implementation of the improvement action and the IQMCo and go to step 38.	Lead auditor
42.	Quarterly follow-up on open recommendations. Once all recommendations are completed, the internal audit record will be assessed and recorded as closed or/and follow up audit is planned.	AF-AUD assistant
43.	File and archive audit report, recommendation/s and all supporting documents.	AF-AUD assistant
Annual Audit Report		
44.	Prepare the Annual Audit report to the Management Board, as requested by art. 84.1 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.

All documents should be considered confidential and for internal use of auditees and AF-AUD only.