POLICY/0001
EMEA/MB/355781/2007Rev.1

The European Medicines Agency's Integrated Quality Management System

1. Introduction and purpose

This policy describes the purpose and structure of EMEA's integrated quality management (IQM) system. It outlines the responsibilities of the key actors in the IQM system.

The maintenance of this policy is the responsibility of the IQM team leader.

2. Scope

This policy applies to all staff and all processes.

3. Definitions

AAC:	Audit Advisory Committee
ARM	Agency-wide risk management
Direction:	Direction implies control and guidance, as appropriate, to the needs of the organisation and does not preclude empowerment to any part of the organisation.
EMEA management:	the Executive Director and all levels of management
ICS:	Internal Control Standards
IQM:	Integrated Quality Management
ITIL:	Information Technology Infrastructure Library, is a frame work of best practice approaches which should facilitate the delivery of high quality IT services.
Middle management:	levels of management below top management
Stakeholders and partners:	Stakeholders and partners include all those who can be affected by the organisation's activities, products and services. Some stakeholders/partners may have a direct interest in the output of the agency, while others may be negatively impacted (e.g. in case of a negative opinion on a medicinal product). Equitably implies that the stakeholders' and partners' needs and expectations are balanced in a fair way. Examples of stakeholders include: patients, pharmaceutical industry, healthcare professionals, and staff. Examples of partners include: national competent authorities and the European Commission.
RUP	RUP stands for 'Rational Unified Process', an iteractive software development process framework. It has been adapted to the Agency's requirements under the name 'RUP@EMEA'
Top management:	the Executive Director and the first, top level of management.
IAC:	Internal Audit Capability, formerly known as IQM/Audit, EMEA's internal audit function

4. Policy statement

This policy is the highest-level description of the IQM system and sets out the framework for ensuring the efficacy and effectiveness of the system.

1. Mission Statement

The Mission statement of the European Medicines Agency is at the top of the quality management documentation hierarchy. The following quality policy and description of the quality management system outline how the agency intends to ensure the fulfilment of its mission in an efficient, effective and consistent way.

2. Quality Policy

The EMEA has decided to establish, document, implement, and maintain an Integrated Quality Management system[1] and continually improve its effectiveness, in line with the requirements of ISO 9001:2000, the regulatory framework, the Framework Financial Regulation[2], the EMEA's Financial Regulation[3], the internal control standards[4], and the Staff Regulations.

Integrated management is the understanding and effective direction of an organisation, resulting in the best possible management decisions, so that the needs and expectations of all stakeholders and partners are equitably satisfied by the best use of all resources.

To lead the European Medicines Agency towards high standards of performance and operate it successfully, it is necessary to manage the agency in a systematic and visible manner. Management is based on the following eight quality management principles:

1. Leadership
   Leaders establish unity of purpose and the direction of the agency and its activities. They create and maintain the internal environment in which people can become involved in achieving the European Medicines Agency's mission and objectives. Leaders are committed to ensuring that the EMEA's management system is developed, implemented and continually improved.
2. Involvement of people
   People at all levels are the essence of the agency and their involvement enables their abilities to be used to the benefit of the EMEA and its stakeholders and partners.
3. Stakeholder and partner focus
   The agency depends in part on its stakeholders and partners for input into its processes, while it provides services for others of them. It is able to do so thanks to internal and external stakeholders and partners constituting or providing its resources. The agency should therefore identify and understand current and future needs and requirements and should strive to meet and exceed stakeholders' and partners' expectations and balance its response to contradictory ones[5].
4. Process approach
   The desired results are achieved more efficiently when activities and related resources are managed as a process, i.e. as a chronological sequence of actions and decisions, which ultimately lead to an output.
5. System approach to management
   Identifying, understanding and managing inter-related processes as a system contributes to the effectiveness and efficiency of the agency in achieving its objectives.

[1] Hereinafter called (the) IQM system.
[2] (Commission Regulation (EC) No 2343/2002 on a Framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC) No 1605/2002 of 25 June 2002 on the financial regulation applicable to the general budget of the European Communities)
[3] Adopted by the Management Board on 10 June 2004.
[4] Adopted by the Management Board on 11 December 2008. Hereinafter called ICS.
[5] E.g., the public's and pharmaceutical industry's expectations may differ.

6. Continual improvement
   Continual improvement of the EMEA's overall performance should be a permanent objective.
7. Factual approach to decision making
   Effective decisions are based on the analysis of data and information to establish (underlying) facts.
8. Mutually beneficial supplier relationship
   The agency and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

3. EMEA's IQM System

To apply successfully its IQM system, the agency shall:

- identify and document the processes needed for the IQM system and key processes critical for the realisation of the quality policy, mission and strategy and their application throughout the organisation (ICS no. 8),
- determine and document the sequence and interaction of these processes (ICS no. 8),
- determine, document, analyse and evaluate the risks related to these processes and introduce and implement control measures to terminate or mitigate the risks (ICS no. 6),
- determine and document criteria and methods needed to ensure that both the operation and control of these processes are effective (ICS no. 15, 16),
- ensure that internal controls cover the policies and procedures established, documented, implemented and maintained by management. This is to ensure the economic, efficient, and effective achievement of the EMEA's objectives, the adherence to external rules, management policies and regulations, the safeguarding of assets and information, the prevention and detection of fraud and error, and the quality of accounting records and the timely production of reliable financial and management information (ICS no. 5, 8, 12, 13 and 16),
- ensure the allocation of appropriate resources and the availability of information necessary to support the operation and monitoring of these processes, allocate available resources according to the prioritisation resulting from the above risk analysis, and document and communicate the risks related to the unavailability of adequate resources for the operation and mitigation of risks (ICS nos. 3, 4, 6, 12 and 13),
- implement actions necessary to achieve the planned results and continual improvement of these processes (ICS no. 9).

4. Documentation of EMEA's IQM System[6]

The agency's Executive Director, with the approval of the Management Board, defines the strategy, business plan and work priorities and documents them in the agency's work programme. The activities carried out, the resulting output, compliance with internal control requirements, and the performance are documented in the agency's annual activity report. Results are measured by performance indicators to show how well key processes are carried out (ICS no. 5, 9, 12 and 15).

It shall be defined and documented how the requirements for quality will be met. Quality planning and work planning in each sector and unit (incl. Directorate) shall be consistent with all other requirements of the agency's IQM system. Quality and work planning shall be documented in a format to suit the agency's method of operation (ICS no. 5, 8 and 12).

The agency shall ensure that the IQM system documentation is understood, implemented, and maintained at all levels in the organisation. To this extent a user-friendly system is developed to ensure that the correct document is available at the correct issue, at the right place, and at the right time (ICS no. 8, 11 and 12).

[6] For guidance on the structure of the documentation, see point 16 below.

Documents required by the IQM system shall be controlled. A documented procedure is established to define the controls needed to:

- approve documents for adequacy prior to issue,
- review and update as necessary and re-approve documents,
- ensure that changes and the current revision status of documents are identified,
- ensure that relevant versions of applicable documents are available at point of use,
- ensure that documents remain legible and readily identifiable,
- ensure that documents of external origin are identified and their distribution controlled,
- prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose.

Records established and maintained provide evidence of compliance with regulations, conformity with requirements and the internal control standards, and the effective operation of the IQM system (ICS no. 8).

A documented procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records (ICS no. 11).

A documented procedure defines the rules for public access to EMEA documents and determines the various categories of documents, e.g. public, restricted, and confidential (ICS no. 12).

5. EMEA Management Responsibility (ICS no. 9)

5.1 Management Commitment

EMEA management provides evidence of its commitment to the development and implementation of the IQM system and continually improving its effectiveness by:

- communicating to the organisation (agency staff and agency partners) the importance of meeting regulatory requirements and stakeholders' and partners' needs and expectations, and the importance of the effectiveness of the IQM system (ICS no. 2 and 12),
- establishing and updating the agency's mission statement and quality management system, thereby ensuring the implementation of the principles of corporate governance (ICS no. 1),
- ensuring the implementation of the internal control standards, as required by the framework financial regulation,
- ensuring that measurable quality objectives, consistent with the quality policy, are established for the agency and at relevant functions and levels within the organisation (ICS no. 5),
- ensuring compliance with environmental legislation and continued commitment to the Agency's environmental policy,
- ensuring that responsibilities and authorities are defined, documented and communicated within the EMEA (ICS no. 7 and 12),
- ensuring that the planning is carried out in order to meet requirements as well as quality objectives, and that the integrity of the IQM system is maintained when changes are planned and implemented (ICS no. 5),
- conducting management reviews (ICS no. 15),
- ensuring the allocation of appropriate resources (ICS no. 3).

Top management shall:

- establish and maintain an adequate internal control system and an internal audit function in accordance with the framework financial regulation (ICS no. 14, 15 and 16), and establish and maintain an Audit Advisory Committee in accordance with the AAC's Terms of Reference,
- ensure the appointment of an IQM adviser (head of the internal audit capability).

5.2 Management Review (ICS no. 15)

Top management shall review the agency's IQM system yearly as part of the review and reporting cycle.

The purpose of the management review is to ensure continuous improvement and the continued suitability, adequacy, and effectiveness of the IQM system.

The input to the annual management review consists of the measurements, monitoring results, and analysis of process performance and output, as described in the SOP governing the management review.

The output from the management review contributes to the input for the annual planning and reporting cycle and contributes information for the decision-making on the allocation of staff and financial resources. The AAC shall be informed of the outcome of the management review and assess and advise on the conclusions.

5.3 Agency-wide Risk Management – ARM (ICS no. 16)

EMEA management show their commitment to the implementation of internal control standard no. 16 by the adoption of an agency-wide risk management strategy as an integral part of the IQM system. The risk management strategy and the internal control standards require an annual risk assessment. The outcome of the annual agency-wide risk management (ARM) cycle is reported in the annual activity report and provides input to the strategic business and budget process. The ARM Manual provides further details on the processes involved.

5.4 Resource Management (ICS no. 3 and 5)

Top management shall determine and ensure the allocation of appropriate resources to:

- implement and maintain the IQM system and continually improve its effectiveness,
- enhance stakeholder and partner satisfaction by meeting and exceeding their needs and expectations.

5.5 People (ICS no. 3, 4 and 7)

Human resources contributing to the agency's processes shall be competent, as evidenced by their personal strengths, appropriate education, training, skills and experience.

- management determines the necessary competence for personnel performing work affecting the quality of the agency's output. Human resource plans are aligned with policy and strategy, the organisational structure, and the framework of key processes. Staff resources are planned, managed, and improved.
- management provides training or takes other actions to satisfy these needs. Staff's knowledge (transferable and implicit knowledge of each individual) and competencies are identified, developed and sustained.
- the effectiveness of training or other actions is evaluated.
- management ensures that its personnel and partners are aware of the relevance and importance of their activities.
- records of education, training, skills and experience are maintained by the agency.
- management ensures that drive and motivation are encouraged and performance is rewarded as feasible.

5.6 Infrastructure

EMEA management determines, provides and maintains the infrastructure needed to achieve compliance with regulations and conformity to output requirements. For this, management will take into account environmental legislation and the agency's environmental policy. Infrastructure includes, as applicable:

- buildings, workspace and associated utilities,
- process equipment (both hardware and software),
- support services (such as transport and communication).

5.7 Work Environment

EMEA management determines and manages the work environment needs in order to achieve compliance with regulations, including environmental legislation and the agency's environmental policy, and conformity to output requirements.

Creation of a suitable work environment, as a combination of human and physical factors, should include considerations of:

- creative work methods and opportunities for greater involvement to realise the potential of people in the organisation (ICS no. 3 and 4),
- creating an environment where drive and motivation are encouraged and rewards are given by management for work well done, and this should be acknowledged fully and publicly,
- safety rules and guidance, including the use of protective equipment,
- office environment, e.g. ergonomics, workplace location, facilities for people in the organisation, heat, humidity, light, airflow, and hygiene, cleanliness, noise, vibration and pollution.

5.8 Information (ICS no. 12)

EMEA management should treat data as a fundamental resource for conversion into information and for the continual development of the agency's knowledge (knowledge database). Such a database is essential for making factual decisions and can stimulate innovation. In order to manage information the EMEA should:

- identify its information needs,
- identify and access internal and external sources of information,
- convert information into knowledge of use to the agency,
- use the data, information, and knowledge to define strategies and set and meet objectives,
- ensure appropriate security and confidentiality,
- evaluate the benefits derived from the use of this information in order to improve the management of information and knowledge.

5.9 Partnerships and Suppliers

EMEA management should maintain optimal relationships with partners (e.g. EU-partnership, national competent authorities) to promote and facilitate communication with the aim of mutually improving the effectiveness and efficiency of processes that create value.

When appropriate and in compliance with regulations, and if such partnerships add value to the agency, partnerships with suppliers should be established[7],.

Partners/suppliers should be encouraged to implement programmes for continual improvement of performance and to participate in other joint improvement initiatives, such as benchmarking.

5.10 Natural Resources (ICS no. 10)

Consideration should be given to the availability of natural resources (e.g. used for heating) that can influence the performance of the EMEA. While such resources are often out of the direct control of the agency, they can have significant positive or negative effects on its results. The agency should have plans, or contingency plans, to ensure the availability or replacement of these resources in order to prevent or minimise negative effects on the performance of the organisation. Plans and contingency plans should comply with environmental legislation and the agency's environmental policy.

[7] Examples of suppliers include: European Directorate for the Quality of Medicines (EDQM), the Translation Centre for the Bodies of the European Union. Other suppliers may be private companies/contractors with whom a long-term business relationship is established.

5.11 Financial Resources and Procurement

The Framework Financial Regulation, the EMEA Financial Regulation, the Implementing Rules to the Financial Regulation, and the Internal Control Standards shall apply. The agency shall ensure that the purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product (output) realisation or the final product (output).

The agency shall evaluate and select suppliers based on their ability to supply their product(s) in accordance with the financial regulations applicable. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained according to the financial regulation. (ICS no. 14).

6. The European Medicines Agency's Tasks/Services (Output/Products)

The agency shall plan and develop the processes needed for the realisation of its tasks/services (output/product). Planning of the realisation of its tasks/services shall be consistent with the requirements of the other processes of the IQM system (ICS no. 8).

In planning the realisation of its product/output the EMEA shall determine the following, as appropriate:

- quality objectives and (regulatory, stakeholder/partner and other) requirements for the output (ICS no. 5);
- the need to establish processes, documents, and to provide resources specific to the planned task/service (output/product) (ICS no. 8);
- required verification, validation, monitoring, inspection (quality control, compliance) and test activities specific to the task/service (output/product) and the criteria for task/service (output/product) acceptance (e.g. deliverable part of a framework contract) (ICS no. 9);
- records needed to provide evidence that the realisation processes and the resulting output/product meet requirements (documented evidence) ICS no. 8 and 11).

Note: a document specifying the processes of the IQM system and the resources to be applied to a specific output/product, project or contract can be referred to as a quality plan The agency may also apply requirements for design and development planning, inputs, outputs, review, verification, validation and change control to the development of product realisation processes.

7. Stakeholder and Partner Related Processes (ICS no. 8)

Regulations apply to EMEA's key processes, and timeframes and compliance/conformity is a requirement. For other processes/services related to customers and other interested parties the requirements related to the product/service requested and/or expected shall be determined and reviewed prior to the agency's commitment to supply the product/service to the customer and other interested party. The agency shall ensure that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved,
- the agency has the ability to meet the defined requirements.

Documented evidence of the review and arising actions shall be maintained.

The EMEA shall determine and implement effective arrangements for communicating with customers in relation to:

- product information,
- enquiries, contracts or order handling, including amendments,
- customer feedback, including customer complaints.

8. Design and Development

Design and development planning, input and output pertains, *i.a.*, to processes related to guidance documents for the stakeholders and partners, the agency's website, software development, offices, meeting rooms, forms and templates (designed, e.g., with the aim to ensure user friendliness, completeness or consistency). Design and development should be in line with ISO 9001:2000 and ISO 10006:2003 (QMS-Guidelines for Quality Management in projects) and other ISO standards and guidelines, where applicable.

To ensure a structured and consistent approach to IT software development, EMEA has adopted RUP. Likewise, the adoption and implementation of ITIL intends to ensure a high quality of service provided by the IT Service Desk.

9. Stakeholder and Partner Related Property[8]

The EMEA shall exercise care with stakeholders' and partners' property while it is under the agency's control or being used by the organisation. The agency shall identify, verify, protect and safeguard customer property provided for use, assessment, or incorporation into the agency's output. If any stakeholder's or partner's property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the stakeholder/partner and records maintained.

10. Measurement, Analysis and Improvement (ICS no. 5, 8, 9, 14 and 15)

The agency shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- to demonstrate compliance with regulations, conformity with requirements and/or specifications,
- to ensure conformity with the IQM system,
- to improve continually the effectiveness of the IQM system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Top management ensures that effective and efficient methods are used to identify areas for improvement of the performance of the IQM system[9]. Measurement and monitoring of stakeholder and/or partner satisfaction shall be based on a review of customer-related information.

11. Monitoring and Measurement of Processes (cf. ICS no. 8 and 14)

The agency shall apply suitable methods for monitoring and, where applicable, measurement of the processes of the IQM system. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and/or corrective action shall be taken, as appropriate, to ensure conformity to the product and/or compliance with the regulations, including required time schedules. See also point 15. Improvement.

12. Monitoring and Measurement of Product/Output (ICS no. 8 and 14)

The agency shall, in line with regulations, monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements.

Documented evidence of the monitoring and measurement, as well as the conformity/compliance status, shall be kept. Records shall indicate the person(s) authorising release of the product[10].

[8] Customer property can include intellectual property and proprietary information.
[9] Examples include: satisfaction or motivation questionnaires, internal audits, financial measurements, and self-assessment.
[10] E.g. press release, opinion, and reply to a request for regulatory or scientific information or explanation.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer or other interested party.

13. Control of Non-conforming Product/Output (cf. ICS no. 8 and 14)

The agency shall ensure that a product[11] which does not conform to requirements is identified and controlled to prevent its unintended use, release or delivery. The controls and related responsibilities and authorities for dealing with a non-conforming product[12] shall be defined in a documented procedure. Records about non-conforming product and subsequent actions taken shall be maintained[13] (ICS nos. 13, 18, 20, and 24).

When a non-conforming product is detected after delivery or use has started, the agency shall take action appropriate to the effects, or potential effects, of the non-conformity.

14. Analysis of Data (cf. ICS no. 5, 12 and 14)

The agency shall determine, collect, and analyse appropriate data to demonstrate the suitability and effectiveness of the IQM system and to evaluate where continual improvement of the effectiveness of the IQM system can be made. This shall include data generated as a result of monitoring[14] and measurement and from other sources (e.g. surveys). The analysis shall serve as input to the annual management review.

The analysis of data shall provide information relating to

- stakeholder/partner satisfaction
- conformity to product (output) requirements
- characteristics and trends of processes and products including opportunities for preventive and improvement action, risk analysis and mitigation,
- suppliers.

15. Improvement (ICS no. 5 and14)

15.1 Continual improvement

The agency shall continually improve the effectiveness of the IQM system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective, preventive and improvement actions and management review.

15.2 Corrective and Preventive Actions

The agency shall take action to eliminate the cause of (potential) non-conformity/non-compliance/risk in order to prevent occurrence/recurrence. Corrective and preventive actions shall be appropriate to the effects of the (potential) non-conformity/non-compliance/risk encountered.

A documented procedure shall be established to define requirements for

- reviewing (potential) non-conformities (including customer complaints) and determining their causes,
- evaluating the need for action to prevent occurrence/recurrence of non-conformities
- determining and implementing action needed,
- records of the results of action taken, and
- reviewing (corrective) action taken.

[11] Usually a document, e.g. a press release, EPAR, certificate or centralised product opinion.
[12] E.g the controls in place to prevent the publication of confidential information on the external website.
[13] This could also pertain to withdrawal of a medicinal product batch in case of product quality defects.
[14] E.g. key performance indicators and internal audits.

To provide a structure for improvement activities, top management should define and implement a process for continual improvement that can be applied to realisation and support processes and activities.

Such a process for continual improvement should be used as a tool for improving the agency's internal and interface effectiveness and efficiency, as well as to improve the satisfaction of customers and other interested parties.

Management should support improvements in the form of small-step ongoing activities[15] integral to existing processes as well as breakthrough opportunities, in order to gain maximum benefit for the agency and its interested parties.

15.3 Internal Audit (ICS no. 16 and financial regulation, Art. 71)

Internal audits ensure compliance with the IQM system and are the responsibility of the EMEA's internal audit capability.

The objective of risk-based internal auditing is to evaluate and contribute to the improvement of risk management, control and governance systems.

The internal audit process is a management tool for independent assessment of any designated process or activity, the compliance with existing requirements and the effectiveness and efficiency of the agency.

Audit work is conducted in line with the Code of Ethics and International Standards for the Professional Practice of Internal Auditing (Institute of Internal Auditors, IIA), and in accordance with ISO 19011:2002 Guidelines for Quality and/or Environmental Management Systems auditing. This guidance is extended to apply to internal audits as required by the financial regulations applicable to the EMEA and may apply to other types of audits. Any audit work adheres to the principles of the guidance document: Charter/Policy for Internal Audit Capabilities (IAC) in EU Regulatory Agencies.

Internal auditing is an independent activity designed to add value and improve the agency's operations. Internal auditors should be objective in the performance of their work. The internal audit activity should be free from interference in determining the scope of internal auditing, performing work, and communicating results. Internal auditing assists the agency in accomplishing its objectives by bringing to bear a systematic approach to evaluating and improving the effectiveness of risk management, control, and governance processes.

Internal audits are conducted at planned intervals to determine whether the IQM system

- conforms to the planned arrangements, applicable regulations, including the financial regulations, the requirements of ISO 9001: 2000, the Internal Control Standards and other standards, and to the IQM system requirements established by the agency,
- is effectively implemented and maintained.

A risk-based audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits and risk assessments, undertaken at least annually. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The head of the internal audit capability co-ordinates the internal audits conducted and reports to the Executive Director and the Audit Advisory Committee on the performance of the IQM system and any need for improvement.

[15] E.g. Kaizen's concept of continuous improvement or the plan-do-check-act circle.

The head of the IAC, irrespective of other responsibilities, has the responsibility of ensuring that the processes needed for the IQM system are established, implemented, and maintained. This is achieved by providing advice to management and coaching on the architecture and the implementation of the IQM system. The head of the IAC reports to the Executive Director and the Audit Advisory Committee on the performance of the IQM system and any need for improvement, ensures the promotion of awareness of stakeholders' and partners' needs and expectations throughout the organisation, and liaises with partners on matters related to the IQM system (including benchmarking).

The European Commission's Internal Audit Service and the Court of Auditors operate independently of the European Medicines Agency's internal audit activity. They oversee assurance engagements for the functions, systems and processes for which the head of the IAC is responsible, as documented in the job description.

Internal auditors should possess the knowledge, skills, and other competencies needed to perform their individual responsibilities. The internal audit capability collectively should possess or obtain the knowledge, skills and other competencies needed to perform its responsibilities.

The head of the IACshould manage the internal audit activity effectively to ensure that it adds value to the organisation. The head of the IAC should communicate the internal audit programme, resource requirements and significant changes to the Executive Director, top management, the Management Board and the Audit Advisory Committee for review and, if appropriate, for approval. The head of the IAC should also communicate the impact of resource limitations. The head of the IAC should share information and co-ordinate activities with other internal and external providers of relevant assurance and consulting services to ensure proper coverage and minimise duplication of efforts.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in standard operating procedures (SOPs) and work instructions (WINs).

Management responsible for the area, systems and processes being audited shall ensure that actions are taken without undue delay to implement improvement action plans addressing opportunities for improvement. Follow-up actions shall include the verification of the actions taken and the reporting of verification results.

Internal audit reporting may include evidence of excellent performance in order to provide opportunities for recognition by management, motivation of people, and benchmarking purposes.

15.4 Key Roles and Functions

All staff are potential IQM actors and should contribute to the system's implementation and continual improvement.

The key actors' specific responsibilities, with appropriate details and references to the IQM system description should be included in job descriptions, job profiles, and other documents where relevant.

Top management's key IQM tasks and responsibilities are outlined under point 5 above, in the Internal Control Standards and Financial Regulations and Implementing Rules to the Financial Regulation, and in the ARM Manual. Further details are included in their job descriptions.

Middle management's key IQM tasks and responsibilities within their respective area are outlined under point 5 above, in the ARM Manual and in their job descriptions. They include:

- oversight, implementation and maintenance of all elements of the IQM system, including but not limited to: internal control standards and agency-wide risk management,
- ensuring compliance with all elements of the IQM system,

- contributing to the annual management review, including the review of internal control arrangements,
- ensuring that responsibilities and authorities are defined, documented and communicated,
- oversight and management of any sector IQM and risk co-ordinator.

IQM co-ordinators' key IQM tasks and responsibilities within their respective units/sectors are detailed in the document "The role of an IQM Co-ordinator" (EMEA/442069/2006, as amended) and in their job descriptions. They include

- assist their unit/sector in the implementation and maintenance of the IQM system, e.g. through follow-up on audits, improvement actions, maintenance of SOPs and work instructions,
- ensure that awareness of the IQM system is maintained and improved, e.g. through training of colleagues,
- act as liaison between own unit/sector and the rest of EMEA, including IAC

Risk co-ordinators' key IQM tasks and responsibilities are detailed in the ARM manual and in their job descriptions. They include:

- maintenance of the risk register,
- provision of guidance and information on the ARM process

The key tasks and responsibilities of IAC, EMEA's Internal Audit Capability, are described under point 15 above.

16. Structure of the Documented IQM System and IQM Manual

A documented management system should serve the EMEA. The nature and extent of the documentation should satisfy contractual, statutory and regulatory requirements, and the needs and expectations of stakeholders and partners, and should be appropriate to the agency.

Documentation may be in any form or medium suitable for the needs of the organisation, but must be controlled (ISO 9001:2000 4.2 Documentation requirements). Access by EMEA staff, and if appropriate agency partners, to the effective documents should be easy and at all times (correct issue, at the right place, at the right time) to ensure consistency of agency processes and output (ICS no. 8 and 11 and rules for the implementation of Council Regulation (EC) 1647/2003 on access to EMEA documents).

The IQM system documentation needs to be integrated and reflect the interrelated processes. Access at one point should allow navigation to all parts of the documented system. Superseded documentation needs to be retained in the historical archives to allow reconstruction of previously effective processes and related documentation (the EMEA policy on document retention).

The structure of the agency's IQM documentation is hierarchical, in line with ISO 9001:2000 4.2.1.

- 1st, the highest, level: the agency's IQM system description, including the quality policy and the mission statement,
- 2nd level: policies/executive decisions, Internal Control Standards (ICS),
- 3rd level: documented procedures (they define who, what, and when), process maps and descriptions of the processes in standard operating procedures (SOPs), addressing vertical as well as horizontal (cross-functional) processes within the EMEA and its committees and working groups,
- 4th level: work instructions (defining how the tasks are completed - down to the functional level of the process and of the tasks being completed),
- 5th level: templates (tools) essential for the processes to perform them in a standardised way,

- 6th level: documents resulting from the process and needing to be controlled and stored in accordance with relevant agency policies and SOPs[16].

5. Related documents

EMEA Standards for Internal Control (Code of Financial Conduct)
The EMEA Code of Conduct

6. Changes since last revision

Reference is made to the revised internal control standards (ICS) where relevant.
Reference is made to the guidance document: Charter/Policy for Internal Audit Capabilities (IAC) in EU Regulatory Agencies under Point 15.3.
A summary of the tasks and responsibilities of the main IQM actors has been included under point 15.4.
IQM/Audit has been changed to IAC throughout
IQM adviser has been changed to head of IAC throughout
The mission statement has been replaced by a general reference to the mission statement.
Definitions have been moved from footnotes to section 3. Definitions.

- This revised quality policy, replacing EMEA/MB/355781/2007 endorsed by the Management Board on 13 December 2007 and
- The structure of the European Medicines Agency's IQM system documentation as documented in this policy,

Endorsed by the Management Board on 5 March 2009

Approved by:

Function	Name	Signature	Date
Executive Director	Thomas Lönngren	*On file*	06-Mar-09
Head of Unit	Patrick Le Courtois	*On file*	06-Mar-09
Head of Unit	David Mackay	*On file*	06-Mar-09
Head of Unit	Andreas Pott	*On file*	06-Mar-09
Head of Unit	Hans-Georg Wagner	*On file*	06-Mar-09
Head of Unit	Noël Wathion	*On file*	06-Mar-09

[16] Tools in use, such as the completed risk register, which contains the evidence of the yearly risk assessment, are at the 6th level (i.e. the output level). The internal audit programme and the tracking system, also a tool in use, is another example of 6th level documentation.