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SUBJECT: Draft Standard for a European Quality Management System

DRAWN UP BY: Chair of the Working Party on the European Quality System

ADDRESSEES: Administrative Council (for decision)

SUMMARY

This document presents the results of the Working Party on the European Quality System to date.

In finalising the draft European Quality Management System standard (Annex 1 to the current document), the Working Party concluded that a number of issues raised during the meetings require discussion and decision by the Administrative Council.

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I. INTRODUCTION

As noted in the Summary of decisions of the 106th meeting of the Administrative Council meeting in The Hague in June 2006 (CA/97/06, paragraph 3.5)

> "A Working Party shall be set up with the mandate and terms of reference outlined in CA/122/06."

Following an indicative vote, a majority of the delegations agreed that the participants in such Working Party chaired by Ms Alison BRIMELOW (GB) would be: DK, DE, ES, FR, CZ, RO, GR, NL, PT + UNICE and epi.

Two workshops were held in July and August 2006. All Member States were invited to send delegates to attend one of the two workshops. These served primarily to review and to compare existing Quality Management Systems (QMS) implemented by national offices and provided an opportunity to make proposals for the future work of the Working Party.

Following the workshops the EQS Working Party met three times in the last half of 2006. Additionally, an enlarged meeting was held in January 2007, to which all Member states were invited to send delegates. The enlarged meeting provided all Member States with an opportunity to provide input and make a final review of the draft standard. The meeting also provided an opportunity to establish for the Council any essential and unresolved issues.

The current document sets out the text of the Standard for a European Quality Management System (EQMS) supported by the EQS Working Party and a majority of the delegates represented at the enlarged meeting, and presents a number of issues for decision by the Council.

II. EUROPEAN QUALITY MANAGEMENT SYSTEM - THE STANDARD

A. SECTIONS OF THE EQMS DRAFT STANDARD SUPPORTED DURING THE ENLARGED WORKING PARTY MEETING

The following sections of the draft standard for the EQMS were supported by Member States during the enlarged meeting:

- Section 1. Leadership and Policy
- Section 2. Management of Resources

- Section 4. Quality Assurance
- Section 6. Internal Review Mechanisms (based on Quality Data)
- Section 8. Inter-Office Communication
- Section 9. Documentation
- Section 10. Extent of Information on the Search Process
- Section 11. Minimum Requirements on the Standards of the Search Results

B. SECTIONS OF THE EQMS DRAFT STANDARD THAT CONTAIN UNRESOLVED ISSUES

The EQMS standard (Annex 1 to the current document) is that supported by the majority of Member States during the enlarged meeting.

The following sections require discussion and decision by the Council.

a) Section 3. Management of Administrative Workload

Some Member States were of the opinion that this section of the standard should go further than define a generic requirement that each office should have "appropriate control mechanisms regarding fluctuations in demand and backlog management." Their position was that common time limit and backlog targets should be established for all participating offices. Other Member States were of the opinion that this might present an over ambitious objective, particularly for the initial phase of development of an EQMS standard.

b) Section 5. Two-way Communication between Offices and their respective Users

The current draft of the standard requires participating offices to make their quality goals publicly available. Some delegates were of the opinion that participating offices should also publish their achievement against the published goals. A review of current practice by national offices reveals a wide range of quality goals and measurements of achievement. Some delegates supported further investigation into existing national offices' objectives and measurements of achievements before requiring participating offices to publishing achievement data.

c) Section 7. Independent Review Mechanism

Two diverging views were expressed during the enlarged meeting on whether the standard should prescribe an independent audit of the each office's QMS against the EQMS standard. A clear majority is in favour, seeing the process as imperative for reasons of credibility and to give confidence in the system. A small number of delegates saw potential conflicts with national legislation. The view was expressed that an independent audit might create pressure on the system for the EPO to automatically recognize the results of NPO search work from particular offices "certified" by an independent auditor to be compliant with the EQMS. It was stressed that automatic recognition must be avoided, particularly in the absence of clear (search) product standards, in order to avoid a slow but certain decline in the output of the system.

Further reflections on the independent review mechanism are included under paragraph V below.

III. THE NATURE AND ROLE OF THE EUROPEAN QUALITY BOARD

The delegates attending the enlarged meeting of the Working Party expressed strong support for the concept of a European Quality Board (EQB). The majority of delegates support such a body reporting directly to the Council.

A. FUTURE ROLES FOR THE EUROPEAN QUALITY BOARD

The following list sets out the issues that delegates attending the enlarged meeting see as falling within the responsibilities of the EQB:

- to prepare annual reports to the AC;
- to give substance to communication between participating MS;
- to prepare proposals for the operation of the EQMS;
- to work out recommendations, forms, and checklists;
- to promote the dissemination of “best practice”;
- to validate the (national) independent auditors.

B. COMPOSITION OF THE EUROPEAN QUALITY BOARD

The following proposals were made for the composition of the EQB:

- Proposal 1: EPO (1 representative), B28 (1 representative), users (2 representatives), an external independent chairman (from industry) acknowledged as a quality expert;

- Proposal 2: A tripartite structure including all Member States (as per WPTI), the EPO, and users (as observers), with a restricted Working Party;

- Proposal 3: The continuation of the existing Working Party

- Proposal 4: A limited tripartite group with Member State representation on a rotational basis

IV. THE FUTURE WORK OF THE EUROPEAN QUALITY SYSTEM WORKING PARTY IN 2007 BEYOND THE EQMS

The future work of the EQS Working Party, if in fact the Council should decide to retain such a body at all, depends to some extent on the composition of the EQB. With a restricted EQB, a Working Party would be needed to further develop additional components of the EQS and to perform some of the tasks set out above.

There was support from all delegates for commencing work on product standards, and Member States have been requested to provide examples of these, with an indication of how compliance is measured. The EQS secretariat will catalogue Member States' input and make them available to all Member States. This work could form the basis for future work of an EQS Working Party.

There was agreement that the Working Party should concentrate on strategic issues faced by the system.

V. INDEPENDENT AUDITING OF OFFICES AGAINST THE EQMS STANDARD

As indicated above, a clear majority of delegates favour independent review. It is noted that offices having QMS' certified to ISO9001 have been and are subjected to such independent reviews on a regular basis. The current draft of the EQMS (Section 7) foresees an initial report by each participating office describing what it has done to implement a QMS based on the EQMS Standard (self-verification), followed at a later date by a review performed by an independent auditor.

This would lead to a tiered level of verification of achievement of each office's QMS, namely offices that are:

- ISO 9001 certified
- EQMS certified
- EQMS self-verified

It may be of interest to the Council to assign to each level of compliance a set of tasks in the context of the European Patent Network (EPN) that offices may participate in.

VI. DECISIONS REQUESTED

With regard to:

A. DRAFT STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM - SECTION 3: MANAGEMENT OF ADMINISTRATIVE WORKLOAD

The Administrative Council is requested to decide on whether Section 3 of the draft Standard should be:

- maintained in its current form, or
- amended to include a reference to common time limit and backlog targets

B. DRAFT STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM - SECTION 5: TWO-WAY COMMUNICATION BETWEEN OFFICES AND THEIR RESPECTIVE USERS

The Administrative Council is requested to decide on whether Section 5 of the draft Standard should be:

- maintained in its current form, or
- amended to include a requirement that participating offices should publish their achievements as measured against the published goals

C. DRAFT STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM - SECTION 7: INDEPENDENT REVIEW MECHANISM

The Administrative Council is requested to decide on whether Section 7 of the draft Standard should be:

- maintained in its current form, or
- The paragraph with the reference to an audit by an independent auditor at planned intervals should be deleted

D. DRAFT STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM

The Administrative Council is requested to approve the European Quality Management System Standard as set out in Annex 1 of the current document with the changes adopted under VI. A, VI. B and VI. C, above, if any.

E. THE EUROPEAN QUALITY BOARD

The Administrative Council is requested to approve the formation of a European Quality Board, and to decide on its composition, namely whether the EQB should be comprised of:

- The EPO (1 representative), B28 (1 representative), users (2 representatives), an external independent chairman (from industry) acknowledged as a quality expert;
- A tripartite structure including all Member States (as per WPTI), the EPO, and users (as observers), with a restricted Working Party;
- The continuation of the existing Working Party
- A limited tripartite group with Member State representation on a rotational basis

F. THE FUTURE WORK OF THE EUROPEAN QUALITY SYSTEM WORKING PARTY IN 2007 BEYOND THE EQMS

The Administrative Council is requested to decide whether the European Quality System Working Party should continue its work, to further develop additional components of the EQS, in particular to investigate how to proceed with product quality standards.

ANNEX 1 STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM

A Common Quality Framework for the European Patent Office and the National Patent Offices of the Member States of the European Patent Organisation

STANDARD FOR THE EUROPEAN QUALITY MANAGEMENT SYSTEM

DRAFTED BY THE EQS WORKING PARTY

January 2007

Preamble

This document sets out a standard for a European Quality Management System (EQMS) which aims to provide a foundation for the patent offices participating in the European Patent Network (EPN) - the European Patent Office (EPO) and National Patent Offices of the Member States of the European Patent Organisation (NPOs) – to achieve convergence and continuous improvement in the quality of their products and services.

This document defines the minimum requirements of the EQMS that each participating office shall implement within the framework of the EPN as a first step to a European Quality System (EQS). It sets out basic requirements with regard to:

1. Leadership and Policy
2. Management of Resources
3. Management of Administrative Workload
4. Quality Assurance
5. Two-way Communication between Offices and their respective Users
6. Internal Review Mechanisms (based on Quality Data)
7. Independent Review Mechanism
8. Inter-Office Communication
9. Documentation
10. Extent of Information on the Search Process
11. Minimum Requirements on the Standards of the Search Results

In the following text, "the office" refers to all offices implementing the current standard.

SECTION 1: LEADERSHIP AND POLICY

Top management of the office is responsible for the development and implementation of a Quality Management System (QMS) and for ensuring its compatibility with the EQMS requirements. Top management shall establish a quality policy and ensure the effectiveness of the QMS. It shall ensure that the process of continual improvement progresses. It shall delegate responsibilities for the QMS and document these in an organisational chart.

Top management of the office shall communicate to its staff the importance of meeting statutory and regulatory requirements including those of this standard.

Top management of the office shall conduct management reviews and ensure the availability of appropriate resources. It shall regularly review quality objectives and ensure that they are communicated and understood throughout the respective office.

Top Management of the office shall support the European Patent Network by maintaining appropriate links with each other participating office in order to allow for an exchange of experiences within the EPN and to promote best practice amongst all participating offices.

SECTION 2: MANAGEMENT OF RESOURCES

The office shall be able to accommodate changes in workload and shall have an appropriate infrastructure to support the search and examination process and to enable staff to comply with instructions.

The office shall establish the following resources and infrastructure:

1. A system for continuously monitoring and identifying the resources required to deal with workload;

2. A quantity of examiners sufficient to deal with the inflow of work each with a diploma of completed studies at university level or - in exceptional cases - equivalent professional experience;

3. An effective training and development program for all examiners to ensure that they acquire and maintain the necessary experience and skills and are fully aware of the importance of following work procedures accurately and consistently;

4. Appropriately trained and skilled administrative staff to support the examiners and facilitate the work done in the office;

5. Comprehensive and up-to-date work instructions to help staff understand and adhere to work procedures accurately and consistently;

6. Appropriate equipment and facilities, such as IT hardware and software, to support the work done in the respective office;

7. Access to appropriate search documentation properly arranged for search and examination purposes.

SECTION 3: MANAGEMENT OF ADMINISTRATIVE WORKLOAD

The office shall have in place the following minimum practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification:

1. Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective office; and

2. Appropriate control mechanisms regarding fluctuations in demand and backlog management.

SECTION 4: QUALITY ASSURANCE

The office shall have quality assurance procedures which ensure timely issue of the products it offers (such as search and examination reports) compliant with documented work procedures and instructions to all staff. Such procedures shall include:

1. An effective internal quality assurance system for assessment, involving verification, validation and monitoring of products (e.g. searches and examination work) for compliance with instructions to staff and channelling feedback to them;

2. A system for verifying the effectiveness of actions taken to address deficiencies and to prevent issues from recurring; and

3. An effective system for ensuring the continuous improvement of the established processes

SECTION 5: TWO-WAY COMMUNICATION BETWEEN OFFICES AND THEIR RESPECTIVE USERS

The office shall have in place a system for measuring, monitoring and using customer feedback including at least the following elements:

1. An appropriate system for handling complaints and making corrections, and taking corrective and/or preventative action where appropriate and offering feedback to users

2. A procedure for measuring and monitoring user satisfaction and perception and for ensuring their legitimate needs and expectations are met.

The office shall make its goals in terms of quality publicly available for the users.

SECTION 6: INTERNAL REVIEW MECHANISM BASED ON QUALITY DATA

Top management of the office shall ensure that a review of the office's QMS is undertaken at planned intervals to ensure the QMS' continuing suitability, adequacy and effectiveness.

The internal review arrangements shall determine the extent to which the office has established its QMS based on the EQMS requirements and the extent to which it is complying with said requirements.

The reviews shall be objective and transparent so as to demonstrate whether or not said requirements are being applied consistently and effectively and shall be undertaken at least once a year.

The input to each review shall include information on:

1. Conformity with the office's QMS requirements;

2. Conformity with the EQMS requirements;

3. The effectiveness of the office's QMS itself and its processes;

4. Any corrective and/or preventative action taken to eliminate any cause of non-compliance;

5. Any follow-up action from previous reviews;

6. Feedback from and to users;

7. Feedback from other offices;

8. Recommendations for improvement;

9. Relevant decisions of national courts and Boards of Appeal, where appropriate.

The output from the internal review mechanism shall be analysed by the office to determine to what extent the office's QMS requirements and to what extent the EQMS requirements are being met. The results of the internal review shall be presented to top management within the office so that it can gain an objective appreciation of performance against the office's QMS and the EQMS requirements, and identify opportunities for improvement and where changes are needed.

SECTION 7: INDEPENDENT REVIEW MECHANISM

The office shall submit an initial report to an EQS Quality Body, describing what it has done to implement a QMS based on the requirements set out in this standard. This will help identify and disseminate best practice among offices.

After the initial report, the office shall arrange a QMS audit by an independent auditor at planned intervals defined by the EQS Quality Body to determine whether its quality management system:

1. Conforms to the requirements of the EQMS;

2. Is effectively implemented and maintained, and

3. Ensures that lessons learned are identified and actions are taken for continuous improvement.

The results of the QMS audit shall be reported to the EQS Quality Body without delay immediately after the review.

The EQS Quality Body will report annually to the Administrative Council of the European Patent Organisation.

SECTION 8: INTER-OFFICE COMMUNICATION

To help identify and disseminate best practice among offices and foster continual improvement, the office shall provide for effective communication with other participating offices to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The office shall nominate and make known to other participating offices the name of a quality contact person.

SECTION 9: DOCUMENTATION

The QMS of the office needs to be clearly described and implemented so that all processes in the office and the resulting products and services can be monitored, controlled, and checked for conformity.

Therefore, the office shall provide a reference for its staff and management in the form of a Quality Manual, which documents all the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In the manual it is to be indicated where instructions on the procedures to be followed may be found.

The following items are considered to be the minimum content for a Quality Manual:

1. The quality policy of the office including a clear statement of commitment to the QMS from top management;

2. The scope of the QMS, including details of and justification for any exclusions;

3. The organisational structure of the office and the responsibilities of each of its departments;

4. The documented processes carried out in the office such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;

5. The resources available for carrying out the processes and implementing the procedures; and

6. A description of the interaction between the processes and the procedures of the QMS.

It is necessary that the following records are kept:

1. A definition of which documents are kept and where they are kept
2. Results of management review;
3. Training, skills and experience of personnel;
4. Evidence of conformity of processes, resulting products and services in terms of quality standards;
5. Results of reviews of requirements relating to products;
6. Evaluations of suppliers;
7. The search and examination processes carried out on each application;
8. Data allowing individual work to be tracked and traced;
9. Records of QMS audits;
10. Authorisation of release of product;
11. Actions taken re. non-conforming product, e.g. correction;
12. Actions taken re. corrective action; and
13. Actions taken re. preventative action

SECTION 10: EXTENT OF INFORMATION ON THE SEARCH PROCESS

For internal purposes the office shall document its search process including at least:

1. The databases consulted (patent and non patent literature);

2. The keywords, combinations of words and truncations used;

3. The language(s) in which the search was carried out;

4. The classes and class combinations searched, at least according to the IPC; and

5. A listing of all search statements used in the databases consulted.

Each office shall further document for internal purposes special cases such as:

1. Limitation of search and its justification;

2. Lack of clarity of the claims; and

3. Lack of unity.

SECTION 11: MINIMUM REQUIREMENTS OF THE STANDARDS OF THE SEARCH RESULTS

The office shall present its search result in a format including at least:

1. The application number;

2. The classification (IPC) of the invention and classification where the search was carried out according to Section 504 of the Administrative Instructions under the Patent Cooperation Treaty;

3. The cited documents; and

4. A clear indication of which passages in the cited documents are relevant for which claims, in accordance with or at least equivalent to sections 505 to 508 of the Administrative Instructions under the Patent Cooperation Treaty.