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WORLD INTELLECTUAL PROPERTY ORGANIZATION
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**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

# MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PATENT COOPERATION TREATY (PCT)

## Thirteenth Session
## Geneva, May 3 to 5, 2006

QUALITY FRAMEWORK:
REPORTING ON QUALITY MANAGEMENT SYSTEMS

*Proposals submitted by the European Patent Office*

1. At its twelfth session, held in Geneva from December 12 to 16, 2005, the Meeting considered draft templates, proposed by the European Patent Office, for use by the International Authorities in reporting on their quality management systems in accordance with Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.

2. The Meeting's discussion of the templates (see document PCT/MIA/12/10, paragraphs 13 to 15) is outlined as follows:

> "13. The Meeting expressed its satisfaction with the general approach taken in the draft templates set out in document PCT/MIA/12/8 Add.1, agreed that further detailed work on them should be undertaken via the PCT/MIA electronic forum, and accepted the offer of the European Patent Office to lead and coordinate that further work. The Meeting agreed that detailed comments on the drafts should be provided by Authorities by the end of January 2006 in order to enable final drafts to be submitted for consideration by the Meeting at its next session, envisaged for May 2006, at which the Meeting would consider what should be included in a report to the PCT Assembly for consideration at its next session.
>
> "14. The Meeting also agreed that, once the templates had been finalized and agreed, the template intended for initial reporting should be used as the basis for the next reports prepared by each Authority.

"15. The European Patent Office also indicated its willingness to lead and coordinate future work on the more general matters set out in paragraph 7 of document PCT/MIA/12/8, noting that a uniform approach on all aspects of them would not necessarily be an appropriate or achievable objective."

3. Annexes I to V contain revised draft templates and related material submitted by the European Patent Office, as follows:

Annex I: T21-17: Proposed Template for Responses to PCT/GL/ISPE Chapter 21; Chapter 21.17 - Stage 1 Reporting

Annex II: T21-18: Proposed Template for Responses to PCT/GL/ISPE Chapter 21; Chapter 21.18 - Stage 2 reporting

Annex III: Summary of Submissions

Annex IV: Proposed Glossary of Terms for Quality Management under the PCT

Annex V: Draft Checklist

*4. The Meeting is invited to:*

*(i) discuss the proposed templates, glossary of terms and checklist; and*

*(ii) agree the nature and timing of future reports to the Assembly in accordance with Chapter 21 of the Guidelines.*

[Annexes follow]

ANNEX I

T21-17
PROPOSED TEMPLATE FOR RESPONSES TO PCT/GL/ISPE CHAPTER 21
CHAPTER 21.17 - STAGE 1 REPORTING

# REPORT UNDER CHAPTER 21.17

Each Authority should provide at least the information below, under the following headings:

## INTRODUCTION (Chapter 21.01 - 21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:

- Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.
- An organigram showing at least the organisational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.

## QUALITY MANAGEMENT SYSTEM (Chapter 21.03 - 21.09)

**Establishment and maintenance of QMS** (Chapter 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

a) Sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E).
b) Incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.

**Resources - infrastructure** (Chapter 21.05)

Provide information about the infrastructure in place which ensures the following:

a) Adequate quantity of search and examination (S&E) staff, including
   i) means for matching the quantity of S&E staff to the inflow of work
   ii) means for ensuring that recruited S&E staff have the necessary technical qualifications
   iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.
b) Adequate quantity and skills of administrative staff to support S&E
c) Provision of appropriate equipment and facilities to support S&E
d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34
e) Provision of up-to-date work manuals. These must include explanations of
   i) quality criteria and standards
   ii) descriptions of work procedures
   iii) instructions ensuring that the work procedures are adhered to.

f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and familiarity with work manuals.
g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

**Administration - procedures** (Chapter 21.06 a, b)

Provide information on those administrative procedures and control mechanisms which ensure the following:
a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.
b) Coping with fluctuations in demand and backlog management.

**Quality Assurance Procedures** (Chapter 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance with PCT/GL/ISPE are issued. In particular, provide information on:
a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.
b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.
c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including
    i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards
    ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.
d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

**Feedback arrangements** (Chapter 21.08)

Give information on arrangements to:
a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that
    i) deficient S&E work is corrected
    ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented
    iii) best practice is identified, disseminated and adopted.
b) Accommodate prompt feedback from WIPO, designated and elected offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

**Communication, Guidance and Responses to Users** (Chapter 21.06c, 21.09)

Give information on arrangements to:
a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.
c) Monitor and react to user needs and feedback, including:
    i) Measuring user satisfaction and perception
    ii) Handling complaints
    iii) Correcting deficiencies identified by users
    iv) Taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.
    v) Taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users.
    vi) Ensuring needs and legitimate expectations of users are met.

**INTERNAL REVIEW (Chapter 21.10 - 21.15)**

**Chapter 21.10** specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Chapter 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Chapter 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are:

**Required Arrangements for Internal Review (Chapter 21.10)**

The Authority should show that arrangements are in place to ensure that:
a) An internal review is carried out to determine
    i) the extent to which a QMS complying with the model of Chapter 21 has been established.
    ii) the extent to which the Authority complies with the requirements of its QMS.
    iii) the extent to which the Authority complies with PCT/GL/ISPE
b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.
c) The internal review takes place at least once a year.

## OPTIONAL INFORMATION UNDER CHAPTER 21.17

**Guide to Internal Review Arrangements (Chapter 21.11 - 21.15)**

**Chapter 21.11** states that 21.12 - 21.15 are "proposed as a guide to the basic components of an internal review mechanism and reporting system", and are thus optional. However, by providing responses on the following points, the Authority will ensure that sufficient information on the provisions for Internal Review required by Chapter 21 is provided.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point a) under "Quality Assurance" above].
b) Arrangements providing information on the effectiveness, and the extent of implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.
c) Arrangements for compiling information received as feedback from users, including designated offices, elected offices, and applicants.
d) Arrangements for compiling information on actions for eliminating the causes of deficiencies, undertaken since the last review. This information arises from
    i) Corrective action, i.e. actions taken to eliminate the causes of deficiencies and prevent the deficiencies from recurring [e.g. point c) ii under "Quality Assurance" and point c) iv under "Communication, Guidance and Responses to Users" above].
    ii) Preventive action, i.e. actions taken to eliminate the causes of potential deficiencies and prevent the deficiencies from occurring [e.g. point c)v under "Communication, Guidance and Responses to Users" above].
e) Arrangements for providing information on follow-up action from previous reviews.
f) Arrangements for providing information relating to any other recommendations for improvement received from e.g. the MIA, external auditors.
g) Arrangements for internal review by Senior Management (c.f. Chapter 21.14) The Authority may show that the information is presented in such a way as to allow senior management to:
    i) Gain an objective appreciation of performance regarding compliance of S&E work with PCT/GL/ISPE and how it can be improved.
    ii) Gain an objective appreciation of performance regarding compliance with QMS requirements and how it can be improved.
    iii) Identify whether changes are needed and where they are needed.
    iv) Identify opportunities for improvement.
    v) Record decisions taken regarding the implementation of the improvements identified above, as a reference for future internal reviews.

[Annex II follows]

ANNEX II

T21-18
PROPOSED TEMPLATE FOR RESPONSES TO PCT/GL/ISPE CHAPTER 21
CHAPTER 21.18 - STAGE 2 REPORTING

This supplemental report relates to the QMS established by

(NAME OF AUTHORITY)

as set forth in our report under PCT/GL/ISPE section 21.17 on

(DATE OF LAST REPORT UNDER 21.17)

and as modified in the supplemental report(s) under PCT/GL/ISPE section 21.18 on

(DATE OF SUPPLEMENTAL REPORT(S) IN WHICH CHANGES WERE PREVIOUSLY INDICATED).

As a result of our most recent internal review under PCT/GL/ISPE sections 21.10-21.15, this Authority has made modifications to its QMS as discussed below.

The modifications are given with reference to the sections of the revised template for responses to PCT/GL/ISPE Chapter 21.17 to which the changes relate.

*(The Authority should describe any changes made to its QMS making reference to the specific sections of the template proposed by EPO to the MIA, dated April 2006 and entitled "Revised Template for Responses to PCT/GL/ISPE Chapter 21.17", and / or making reference to any supplemental report(s) under PCT/GL/ISPE section 21.18 compiled in accordance with the present document.*
*If no changes have been made to its QMS since the last report, the Authority should indicate such.)*

[Annex III follows]

ANNEX III

SUMMARY OF SUBMISSIONS

## Introduction

Chapter 21 imposes the obligation on IAs to provide reports on the establishment of a QMS according to points numbered 21.01 to 21.19. Responses to some of these points are most useful if formulated according to an agreed framework, so that a structured reporting approach is possible. These revised templates are intended to provide such a framework. They apply to the initial report under Stage 1 according to point 21.17, and the annual report according to point 21.18.

## Comments received on original templates

In revising these templates, the EPO has taken on board the **comments received from IAs** as discussed during the 12th session of the MIA (see PCT/MIA/12/10, paragraphs 13-16). Comments were received from JPO, USPTO, Rospatent (Russia), CIPO (Canada), IP Australia and SPRO (Sweden).

The majority of these comments reflected a need for explanation of what kind of response is required to the various headings and numbered points.

- **CIPO** requested a glossary defining all terms (see Annex IV); pointed out that Ch.21 requires a report on compliance with the rest of the guidelines as well as Ch.21, and asked how this should be done; requested examples to clarify this and other points; and commented that there are overlaps in the items covered under different titles, which should be resolved.
- **IP Australia** considered the original templates T21-17 and T21-18 to be good starting points, but are happy to consider improvements suggested by other authorities; are in favour of retaining a reference to established QMS methodology e.g. ISO 9000; and suggested that a comprehensive report using T21-17 should be produced at regular intervals, say every 5 years.
- **JPO** pointed out that Ch.21 does not call for information relating to a "recognised normative reference" for a QMS, so including this in the templates is not justified; requested examples, especially under 21.5; and suggested combining the responses to 21.7 and 21.8 under a single heading.
- **Rospatent** understood that the templates do not replace Ch.21, but are intended to provide headings for future reports, referring to and explaining the headings of Ch.21; suggested some further breakdown of headings and subheadings; pointed out that some items referred to in template points 21.1-21.4 seem superfluous; called for the IA to report exactly which parameters relating to quality are being controlled (e.g. time limits, completeness of citations, checks of examiner's opinions), under section 21.3; and requested consistent use and definition of various terms (e.g. "system", "procedures", "arrangements", "department", "organisational unit").
- **SPRO** supported the templates as presented
- **USPTO** agreed with the concept of templates in general; suggested that sections 21.1, 21.2 and 21.4 of T21-17 be deleted, as the wording of Ch.21 does not call for reporting on these points; raised a similar objection to sections 21.10-21.15 relating to internal review, taking the view that Ch.21 requires reporting only on the QMS (points 21.03-21.09) and not the Internal Review (points 21.10-21.15); suggested the requirement for an Organigram be made optional; supported IP Australia in its suggestion to report under T21-17 every

5 years; and provided two revised versions of the templates, with T21-17 truncated as indicated above and T21-18 greatly simplified.

**Response to comments received from IAs**

The EPO understands the USPTO view that a **report under 21.17** should not provide details of the Internal Review process to which points 21.10-21.15 refer. However, EPO considers that at least the internal review arrangements described in 21.10 are an integral part of the QMS required by Chapter 21, for the following reasons:

1. The "Internal Review" section of Ch.21, given by points 21.10 - 21.15, provides the structure for internal reviews reported under 21.18. If it were left out of the template, the Authority would have no guidance on how to perform the subsequent annual reviews. It seems important that, in setting up and reporting a QMS under 21.17, the Authority is guided by the template itself as to the elements which must be in place in order to perform subsequent reviews.
2. The EPO considers that no IA can expect to be compliant with Chapter 21 if its QMS does not include the internal review arrangements specified in 21.10. The QMS should therefore explicitly include the arrangements for internal review necessary to comply with Ch.21, and these arrangements should be clear from the initial report under 21.17
3. In the EPO's view, the wording of Chapter 21 is sometimes contradictory and vague, so that it is difficult to rely on a strict interpretation of specific passages. Nonetheless the EPO position is that the wording of Chapter 21, e.g. point 21.03, implies that the "Internal Review" section of Chapter 21 is part of the QMS, and should therefore be covered by a report under 21.17.

Regarding the internal review arrangements, in response to the US comments, the EPO considers that point 21.10 provides the obligatory requirements for these. Point 21.11, on the other hand, states that the following points (21.12 - 21.15) are "proposed as a guide" and are therefore not obligatory. The revised 21.17 template reflects this, and covers points 21.12 - 21.15 in an optional part.

In order to accommodate the **USPTO position on reporting under 21.17,** EPO proposes that only a description of the arrangements for internal review, as specified by point 21.10, and not a report on the internal review process, should be included in the report under **section 21.17**. This should be clear from the revised version of the template for 21.17.

Regarding the **USPTO position on reporting under 21.18**, i.e. that "section 21.18 of the Guidelines only requires the Authority to report on any changes it has made to its QMS based on its internal review, but not on the specifics of the review itself", the EPO has adopted the USPTO suggestion for a simplified 21.18 template. This refers explicitly to the new 21.17 template, and reflects only the changes made to the QMS as a result of the annual review. Nonetheless, the EPO believes that IA's may learn from each other by reporting on the results of the internal review as well, and proposes to encourage IA's to report the results on a voluntary basis.

The EPO strongly supports the **proposal of IP Australia** for an initial report under 21.17, followed by further comprehensive reports under 21.17 produced at regular intervals, say every five years.

**Revised templates**

The EPO has re-worked the templates in response to all comments received (See Annexes I and II).
The **revised templates** are discussed below.

Since the original template repeated much of the wording of Ch.21 itself, it was decided to provide more of a self-explanatory guide as to how to interpret the requirements of Ch.21, rather than provide a template strictly based on the wording and numbering of that chapter.

The reworked versions of T21.17 and T21.18 do not strictly follow the numbering and order of the Ch.21 requirements, but rather seek to provide logically formulated templates, the responses to which will ensure that the necessary requirements of the QMS framework described in Ch.21 are reported on correctly and in a consistent manner.

The EPO also notes that the optional points 21.12 to 21.15 could be covered to some extent by responses already given to 21.07, 21.08 and 21.09, and has structured the "Internal Review" section of the templates accordingly.

**Deviations from the format of Chapter 21** are as follows:

Chapter 21.06 a) and b) are taken to refer to administrative procedures. Point 21.06 c) has been shifted to the response to 21.09, as it seems more appropriate under the heading "Communication and Guidance to Users". EPO believes this is in line with comments received from CIPO, JPO and Rospatent.

The heading "Communication and Guidance to Users" of 21.09 has been expanded to include this aspect of feedback from users.

**Compliance Table**

The EPO has drafted a table to assist IAs to determine their level of compliance with Chapter 21 (see Annex V).

[Annex IV follows]

ANNEX IV

# PROPOSED GLOSSARY OF TERMS FOR QUALITY MANAGEMENT UNDER THE PCT

Note: some terms defined below relate to activities underpinning search and examination work, and may have different meanings compared to the same term used in accepted QMS models e.g. ISO 9000. These are denoted by an asterisk *. Wherever possible, the definitions are made compatible with generally accepted interpretations.

The column headed "Reference" gives the source of the definition in the corresponding row, including, in brackets, indications relating to ISO standards where available and where they could be of interest.

Terms and definitions in this glossary correspond to those used in the EPO QMS.

| Term | Definition | Reference |
|---|---|---|
| **conformity** | fulfilment of a requirement | ISO 9000 (3.6.1) conformity |
| **continual improvement** | recurring activity to increase the ability to fulfil requirements | ISO 9000 (3.2.13) management |
| **correction** | action to eliminate a detected nonconformity<br>NOTE 1: A correction can be made in conjunction with a corrective action<br>NOTE 2: A correction can be, for example, rework or repair | ISO 9000 (3.6.6) conformity |
| **corrective action** | action to eliminate the cause of a detected nonconformity or other undesirable situation<br>NOTE 1: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.<br>NOTE 2:<br>- "corrective action" may involve changes, such as in procedures and systems, to achieve quality improvement at any stage.<br>- "correction" refers to repair, rework or adjustment and relates to action taken to deal with an existing nonconformity. | ISO 9000 (3.6.5) conformity |
| **management review** | formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives<br>NOTE 1: Management review may include review of the quality policy.<br>NOTE 2: Quality audit results are one of the possible inputs to management review. | EPO QMS, BASED ON ISO 8402 (3.9) system |

| Term | Definition | Reference |
|---|---|---|
| **management system** | system to establish a policy and objectives and to achieve those objectives<br>NOTE: A management system of an organization can include different management systems, such as a quality management system or a financial management system. | ISO 9000 (3.2.2) management |
| **nonconformity** | non-fulfilment of a requirement | ISO 9000 (3.6.2) conformity |
| **preventive action** | action to eliminate the cause of a potential nonconformity or other undesirable potential situation<br>NOTE 1: There can be more than one cause for a potential nonconformity.<br>NOTE 2: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence. | ISO 9000 (3.6.4) conformity |
| **quality** | degree to which a set of inherent characteristics fulfils requirements<br>NOTE 1: The term “quality” can be used with adjectives such as poor, good or excellent.<br>NOTE 2: “Inherent” as opposed to “assigned”, means existing in something, especially as a permanent characteristic. | ISO 9000 (3.1.1) quality |
| **quality assurance (QA)** | part of quality management focused on providing confidence that quality requirements will be fulfilled | ISO 9000 (3.2.11) management |
| | NOTE 1: There are both internal and external purposes for quality assurance:<br>a) in internal quality assurance: quality assurance within an organization provides confidence to top management and other internal users;<br>b) external quality assurance: in contractual or other situations, quality assurance pro-vides confidence to external users. | EPO QMS based on ISO-8402 (3.5) system |
| **quality assurance scheme *** | systems and structures in place for providing quality assurance | EPO QMS |
| **quality management (QM)** | coordinated activities to direct and control an organisation with regard to quality<br>NOTE: Direction and control with regard to quality generally includes i.a. establishment of the quality policy and quality objectives quality control and quality assurance. | ISO 9000 (3.2.8) management |
| **quality management system (QMS)** | management system to direct and control an organisation with regard to quality | ISO 9000 (3.2.3) management |

| Term | Definition | Reference |
|---|---|---|
| **quality manual** | document specifying the quality management system of an organisation. NOTE: Quality manuals can vary in detail and format to suit the size and complexity of an individual organization. | ISO 9000 (3.7.4) documentation |
| **quality policy** | overall intentions and direction of an organisation related to quality, as formally expressed by top management<br>NOTE 1: Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of quality objectives | ISO 9000 (3.2.4) management |
| **quality standard *** | formulation of a requirement in terms of measurable performance | EPO QMS |
| **quality system** | organisational structure, procedures, processes and resources needed to implement quality management.<br>The quality system of an organisation is designed primarily to satisfy the internal managerial needs of the organisation. | EPO QMS BASED ON ISO 8402 (3.6) system |
| **record** | document stating results achieved or providing evidence of activities performed<br>NOTE 1: Records can be used, for example, to document traceability and to provide evidence of verification, preventive action and corrective action | ISO 9000 (3.7.6) documentation |
| **release** | permission to proceed to the next stage of a process | ISO 9000 (3.6.13) conformity |
| **repair** | a type of correction or action on a nonconforming product to make it acceptable for the intended use<br>NOTE 1: Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance.<br>NOTE 2: Unlike rework, repair can affect or change parts of the nonconforming product. | ISO 9000 (3.6.9) conformity |
| **requirement** | need or expectation of users, that is stated, generally implied or obligatory. | EPO QMS ISO 9000 (3.1.2) quality |

| Term | Definition | Reference |
|---|---|---|
| **review** | activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives<br>NOTE: Review can also include the determination of efficiency or effectiveness.<br>EXAMPLE: Management review, design and development review, review of user requirements and nonconformity review. | ISO 9000 (3.8.7) examination |
| **rework** | a type of correction or action taken on a nonconforming product to make it conform to the requirements<br>NOTE: Unlike rework, repair can affect or change parts of the nonconforming product. | ISO 9000 (3.6.7) conformity |
| **top management** | person or group of people who directs and controls an organisation at the highest level | ISO 9000 (3.2.7) management |

[Annex V follows]

ANNEX V

DRAFT CHECKLIST

# COMPLIANCE SUMMARY TABLE - REPORT UNDER CHAPTER 21.17

| 21-17 Template Heading | Yes | Uc* | No |
|---|---|---|---|
| **INTRODUCTION (Chapter 21.01 - 21.02)** | | | |
| Recognised normative reference (optional) | | | |
| Organigram (optional) | | | |
| **QUALITY MANAGEMENT SYSTEM (Chapter 21.03 - 21.09)** | | | |
| **Establishment of QMS (Chapter 21.03) setting out:** | | | |
| a) basic reqs. for resources, admin. procedures, f/back & comm. for S&E | | | |
| b) QA scheme to monitor compliance with basic reqs., PCT/GL/ISPE | | | |
| **Resources - infrastructure (Chapter 21.05)** | | | |
| a) Quantity of S&E staff - means to: | | | |
| i) match quantity of staff to inflow of work | | | |
| ii) ensure required technical qualifications of recruited staff | | | |
| iii) ensure support for recruited staff re. language requirements of Rule 34 | | | |
| b) Means ensuring quantity and skills of Administrative staff | | | |
| c) Means ensuring appropriate S&E equipment and facilities | | | |
| d) Means ensuring Rule 34 minimum documentation | | | |
| e) Up-to-date work manuals including | | | |
| i) explanations of quality criteria and standards | | | |
| ii) descriptions of work procedures | | | |
| iii) instructions ensuring work procedures are followed. | | | |
| f) Training to ensure skills and familiarity with manuals | | | |
| g) Monitor, identify non-staff resource needs to meet demand & Quality Stds. | | | |
| **Administration - procedures (Chapter 21.06 a, b)** | | | |
| a) for timeliness of S&E related work to PCT/GL/ISPE quality standards | | | |
| b) for coping with demand fluctuation and backlog | | | |
| **Quality Assurance procedures (Chapter 21.07)** | | | |
| a) Verifiy, validate, monitor compliance with PCT/GL/ISPE, feedback to staff | | | |
| b) Measure, record, monitor, analyse QMS for conformity | | | |
| c) Checking effectiveness of actions re. deficient S&E work | | | |
| i) effective elimination, correction, release authorisation | | | |
| ii) effectively identifying causes, preventing recurrence | | | |
| d) Continuous improvement procedures for S&E processes | | | |

| 21-17 Template Heading | Yes | Uc* | No |
|---|---|---|---|
| **QUALITY MANAGEMENT SYSTEM (Chapter 21.03 - 21.09) - continued** | | | |
| **Feedback arrangements (Chapter 21.08)** | | | |
| a) Feedback given to staff re. compliance of S&E work so that: | | | |
| i) deficient S&E work is corrected | | | |
| ii) corrective action is identified and implemented | | | |
| iii) best practice is identified, disseminated and adopted | | | |
| b) Channel feedback from WIPO & designated / elected offices; so that: | | | |
| systemic issues noted by these bodies are evaluated and addressed | | | |
| **Communication, Guidance, Responses to Users (Chapter 21.06c, 21.09)** | | | |
| a) Channels for enquiries and applicant↔examiner communication | | | |
| b) Concise and comprehensive guidance and information to users | | | |
| c) Monitoring and reacting to user needs and feedback, including: | | | |
| i) measuring user satisfaction and perception | | | |
| ii) Handling complaints | | | |
| iii) correcting deficiencies identified by users | | | |
| iv) taking corrective action in response to issues identified by users | | | |
| v) taking preventive action in response to issues identified by users | | | |
| vi) ensuring needs and legitimate expectations of users are met | | | |
| | | | |
| **INTERNAL REVIEW (Chapter 21.10 - 21.15)** | | | |
| **Required Arrangements for Internal Review (Chapter 21.10)** | | | |
| a) Internal review is carried out to determine | | | |
| i) extent to which a QMS complying with Chapter 21 has been established. | | | |
| ii) extent to which Authority complies with the requirements of its QMS | | | |
| iii) extent to which the Authority complies with PCT/GL/ISPE | | | |
| b) Internal review shows if reqs. of QMS, GL applied consistently, effectively | | | |
| c) Internal review takes place at least once a year. | | | |

| **21-17 Template Heading** | **Yes** | **Uc*** | **No** |
|---|---|---|---|
| **INTERNAL REVIEW (Chapter 21.10 - 21.15) - continued** | | | |
| **Optional Guide to Internal Review Arrangements (Chapter 21.11 - 21.15)** | | | |
| a) Arrangements for information regarding conformity of S&E work | | | |
| b) Arrangements for info. on effectiveness of the QMS and its processes | | | |
| c) Arrangements for info. received as feedback from users | | | |
| d) Arr. for info. on actions eliminating causes/potential causes of deficiencies | | | |
| e) Arrangements for info. on follow-up action from previous reviews | | | |
| f) Arrangements for info. on other recommendations for improvement | | | |
| g) Management review (Chapter 21.14) so that senior management: | | | |
| i) sees extent of compliance with PCT/GL/ISPE and areas to improve | | | |
| ii) sees extent of compliance re. QMS requirements, areas to improve | | | |
| iii) can identify where and what changes are needed | | | |
| iv) can identify opportunities for improvement | | | |
| v) can record decisions taken re. identified changes and improvements. | | | |

* Uc - Under Construction

[End of Annex V and of document]