

PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Nordic Patent Institute (NPI)

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each authority should then provide at least the information indicated in the descriptive boxes, under the following headings

Nordic Patent Institute (NPI) has established a Quality Management System in accordance with ISO 9001 standards. The system covers all services offered and consists of three levels. Level 1 describes the policy, goals and organisation of the Institute, level 2 contains procedures for handling of the QA system and level 3 contains the procedures for the daily operation of Nordic Patent Institute, including the association. NPI will request certification of its Quality Management System under the ISO 9001 standards in 2011.

Search and Preliminary examination of PCT applications is carried out by staff of the Danish and Norwegian patent offices on behalf of NPI. NPI has Service Level Agreements between NPI and the Danish Patent Office and the Norwegian Industrial Property Offices governing the work carried out on behalf of NPI in accordance with the PCT guidelines.

In this report, the NPI Quality Management System (herein after "NPI QMS") will therefore refer to both the internal NPI internal Quality Management System (as mentioned above) and the national quality systems in Denmark and in Norway, which both are certified under the ISO 9001 system.

The Service Level Agreements between NPI and the Danish Patent Office (DKPTO) and the Norwegian Industrial Property Offices (NIPO) specify exact requirements for the quality management system in the national patent offices of Denmark and Norway. The national quality systems in both Norway and Denmark, and the NPI quality system, are described and maintained in electronic form.

Since Iceland, as a member state of Nordic Patent Institute, does not perform any searches or examinations on behalf of NPI, the quality management system of NPI does not contain provisions concerning search and examination carried out by Iceland.

The NPI QMS generally consist of three components:

- a. Quality standards for Search & Examination work
- b. A quality management system including procedures, tools, manuals, training, competences, communication, procedures for measuring quality, etc.
- c. A review mechanism for monitoring compliance with quality standards

The quality standards and practices in the national quality systems and the embracing NPI quality system are harmonized with respect to any PCT work and are brought in full compliance with the standards and practices established by the PCT and applied by the EPO

1. LEADERSHIP AND POLICY

21.04 Confirm that the following are clearly documented, and that this documentation is available internally:

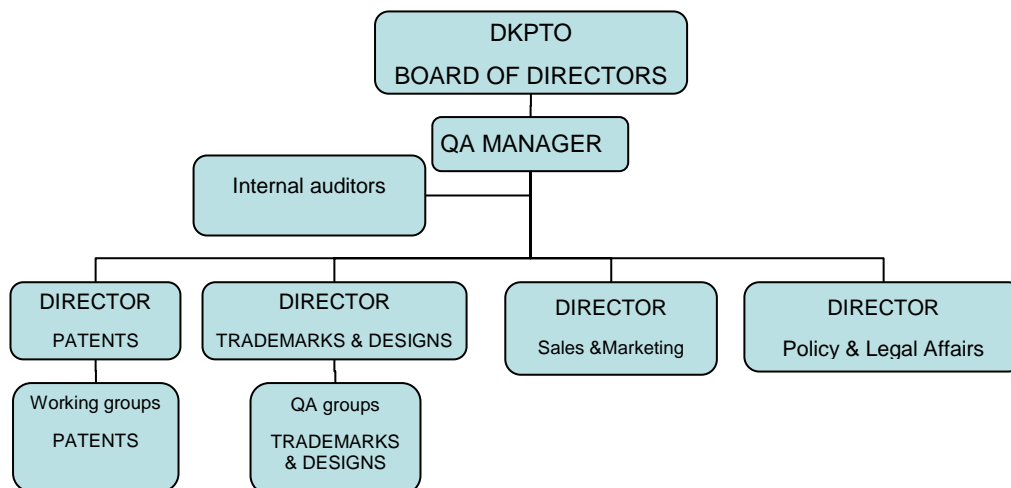
- (a) The quality policy established by top management.*
- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.*

NPI Quality policy is clearly described in Level 1 of the embracing NPI quality system as described above. It is defined in accordance with ISO 9001:2008 standards.

The Quality Management of the NPI is organised as shown in the figure below.

All members have well defined roles within quality control, training or quality management matters.

Danish Patent and Trademark Office (DKPTO) QM organizational chart:



DKPTO also has Quality Management System (QMS) certified according to ISO 9001:2008 within the areas of Patents and Trademarks, organized as indicated in the chart above. DKPTO became ISO certified in 2005.

The search and examination practice is harmonized between the national offices. A production group, comprising of members from NPI, NIPO, DKPTO and the Icelandic Patent Office and a harmonization group of examiners work constantly on ensuring the harmonization of the search and examination practice and the relevant quality documentation.

21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements.

[Sample table, to be amended as necessary]

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	✓		
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	Organizational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓		
	(b)	Control of the continual improvement process	✓		
21.07	(a)	Communication of management about this standard to staff	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS in based on Chapter 21	✓		
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.17	✓		
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.14	(a)	System in place for monitoring resources required to deal with demand	✓		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channeling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.19		Established comm. with WIPO and desig. + elected offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed	✓		
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.22	(a)	Quality policy of the Authority and commitment to QMS	✓		
	(b)	Scope of QMS	✓		
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes	✓		
	(f)	a description of the interaction between the processes and the procedures of the QMS.	✓		
21.23	(a)	Records which documents are kept and where they are kept	✓		
	(b)	Records of results of management review	✓		
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits	✓		
	(i)	Records on actions taken re. non-conforming products	✓		
	(j)	Records on actions taken re. corrective actions	✓		
	(k)	Records on actions taken re. preventive actions	✓		
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(i) Recording of the databases consulted during search	✓		
		(ii) Recording of keywords, combination of words and truncations during search	✓		
		(iii) Recording of the languages used during search	✓		
		(iv) Recording of classes and combinations thereof consulted during search	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes	✓		
21.26-21.28		Additional information on further inputs to its internal reviews	✓		
21.29		Initial report called for by paragraph 21.19	✓		

21.06 Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:

- (a) the effectiveness of the QMS; and*
- (b) that the process of continual improvement progresses.*

a) The DKPTO has set up a QA-group consisting of a representative from the Board of Directors (board representative), a QA manager who reports to the Board of Directors and directors of the relevant divisions. The role of the board representative is to ensure the flow of information to the Board of Directors on such issues as improving the efficiency of the quality management system and processes, and the resources required to achieve this; to inform the board about evaluation results and to ensure that relevant minutes from board meetings are posted on the intranet and filed in Gefion (record management system).

The quality organisation of NIPO consists of the Quality Coordinator Team Group (KK), a body responsible for the QMS, managed by the Quality Manager. The Quality Manager reports directly to the General Director in matters regarding quality of our services and the QMS. A Quality Coordinator is appointed for each department.

b) The DKPTO has its own internal audit group made up of representatives from various divisions. All representatives report to the QA manager. (perform audits on the QMS of DKPTO)

At NIPO A Quality Assurance Group for each process, including Patents, is working and is responsible for the quality regarding processing patent application and S&E. The group has also the responsibility to organise and carry out internal audits and periodical quality controls by sampling. The QMS and the quality policy and the quality objectives are followed up by top management. Issues regarding processing applications and S&E are followed by Production Forum, where Quality Manager and the directors of all productions departments are involved.

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- (a) those of this standard; and*
- (b) complying with the Authority's QMS.*

See point 21.06.

21.08 Indicate how and when top management of the Authority or delegated officers:

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood throughout the respective Authority.*

The NPI Quality managing group (see organization chart in 21.04) analyses and monitors the performance of the QA system, quality objectives and assesses its conformity with Chapter 21 and ISO standards.

NIPO:

The management review is held yearly by the Top Management Group, chaired by the General Director. It is such planned to incorporate the results and the follow up matters in the next year activity plan. The agenda for the meeting includes following issues but is not limited to:

1. Status of follow-up actions from previous management review.

2. Evaluation of quality policy, quality objectives and risk management.
3. Non Conformities, Corrective and Preventative actions
4. Quality Control measurements – suitability, adequacy and effectiveness of the QMS and the periodical quality control results by sampling.
5. Personnel, resources, competence and employees satisfaction measurements
6. Customer Satisfaction Survey and Complains
7. Reports from internal audits
8. Reports from external audits (performed by the certification body)
9. Any other matters

DKPTO:

The DKPTO Board of Directors consists of a Director General and the two Deputy Director Generals. Board of Directors and the QA manager evaluate the QMS and need for resources twice a year. The basis for this meeting is a status report of the QMS including performance, results of quality objectives, internal and external audit reports, feed back from customers including complaints and suggestions for improvement etc.

The status report and the results of the quality objectives are presented on the Intranet, and the results are presented in the patent department on internal meetings

QA meetings are held four times per year. The QA meetings are attended by the members of the QA group, see 21.06. The basis for decision making at these meetings is derived from internal audit reports, from the regular quality control, from initiated proposals for improvement as well as e.g. reports from customer visits.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:

- (a) *at least once per year (cf. paragraph 21.25);*
- (b) *in accordance with the minimum scope of such reviews as set out in Section 8, namely:*
 - (i) *to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));*
 - (ii) *to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));*
- (c) *in an objective and transparent way (cf. paragraph 21.25);*
- (d) *using input including information according to paragraphs 21.27 (b)-(f);*
- (e) *recording the results (cf. paragraph 21.28).*

NIPO:

Internal audits are carried out at least ones a year and the quality group for the Patent process has the responsibility to organize and perform the audits. For each audit, there are established specific areas of activity, including S&E and compliance with the PCT Guidelines. Follow-up actions, corrective and improving activities are presented for the management and all personnel, and the status for improvement actions is followed by the management and the Quality Group. The effectiveness of corrective actions is periodically evaluated by the management.

DKPTO:

See here point 21.08

The quality measurements are based upon the PCT guidelines. Internal and external audits are performed through out the year.

QA-meetings discuss among other things the following :

1. Follow-up from previous reviews and actions taken.
2. Results from internal audits
3. Input from the quality groups incl. performance
4. Feedback from customers
5. Status on corrective actions
6. Status on suggestions for improvements
7. External audit results
8. Output from the top management evaluation including: Evaluation of the QMS, policy, quality objectives.

Every report is monitored on the Intranet and filed in Gefion (record management system).

2. Resources

21.10 Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

- (a) Provide information about the infrastructure in place to ensure that a quantity of staff:*
 - (i) sufficient to deal with the inflow of work;*
 - (ii) which maintains the technical qualifications to search and examine in the required technical fields; and*
 - (iii) which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated*
is maintained and adapted to changes in workload.
- (b) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:*
 - (i) at a level to support the technically qualified staff and facilitate the search and examination process;*
 - (ii) for the documentation of records.*

The NPI Board and management continuously monitor and discuss the demand for resources to insure the quantity of staff can deal with the inflow of work.

Furthermore the management of the national offices assure control over workload changes and qualified personnel at all time.

Maintenance of the technical qualifications to search and examine in the technical fields is assured by:

1. A precise recruiting program, where appropriate skills and qualifications are required.
2. An extensive introductory and training program for qualification as examiner.

Similar programs are established for the administrative staff.

21.12 Material resources:

- (a) *Describe the infrastructure in place to ensure that*
 - (i) *appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
 - (ii) *at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.*
- (b) *Describe how instructions*
 - (i) *to help staff understand and adhere to the quality criteria and standards, and*
 - (ii) *to follow work procedures accurately and consistently*

are documented, provided to staff, kept up-to-date and adapted when necessary.

NPI has a modern IT infrastructure, and IT-tools used by the examiners and other staff of the national offices to support the search and examination process are of high and modern standard. This includes workflow based IT-case processing systems and access to the most comprehensive databases for search purposes.

Searches are mainly conducted online by using the same databases and search systems as used by the EPO. The most important databases are EPODOC, WPI, PAJ and INSPEC accessed via the EPOQUE search tool. Other important document databases are accessed for instance via Dialog and STN. Examiners also use full text databases in various languages and other databases containing articles and other non-patent literature

The collection of patent documents and other publications in paper form is very comprehensive and is used whenever appropriate.

NPI has full access to PCT-minimum as referred to in Rule 34.

All examiners have online access to PCT Guidelines and PCT Regulations. Both NIPO and DKPTO have extensive manuals for all parts of the patent process, including in particular guidelines with respect to search, examination and communication with applicants available electronically. Permanent working groups specifically dedicated to improvement of tools and procedures, quality control, and initiation of corrective action in response to feedback from the quality control have also been established.

21.13 Training resources:

- Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:*
- (i) *acquire and maintain the necessary experience and skills; and*
 - (ii) *are fully aware of the importance of complying with the quality criteria and standards.*

See 21.11.

21.14 Oversight over resources:

Describe the system in place for continuously monitoring and identifying the resources required:

- (a) to deal with demand; and*
- (b) comply with the quality standards for search and examination*

See 21.11.

3. Management of administrative workload

21.15 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:

- (a) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
- (b) Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

NPI uses uPDate as an internal electronic handling system. All information regarding a case/application is recorded in this system. Internal time limits are entered and a reminder is automatically send to the examiner to start the examination at each step in the process.

The director of each technical team is constantly monitoring the workload of each employee to help plan and distribute the workload properly.

4. Quality assurance

21.16 The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:

- (a) An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:
 - (i) for compliance with these Search and Examination Guidelines;*
 - (ii) for channelling feedback to staff.**
- (b) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*
- (c) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

Quality measurements are performed each month according to the Guidelines.

In case of mistakes information is given on internal team meetings.

5. Communication

21.17 Inter-Authority communication:

Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- (a) helping identify and disseminate best practice among Authorities;*
- (b) fostering continual improvement; and*
- (c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

Mr. Grétar Ingi Grétarsson, Vice-director of NPI as head of the NPI Quality management group is the designated contact for this purpose on behalf of Nordic Patent Institute.

21.18 Communication and guidance to users:

Describe the system in place for monitoring and using customer feedback including at least the following elements:

- (a) An appropriate system for
 - (i) handling complaints and making corrections;*
 - (ii) taking corrective and/or preventative action where appropriate; and*
 - (iii) offering feedback to users.**
- (b) A procedure for:
 - (i) monitoring user satisfaction and perception; and*
 - (ii) for ensuring their legitimate needs and expectations are met.**
- (c) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.*
- (d) An indication of where and how the Authority makes its quality objectives publicly available for the users.*

Measuring user satisfaction and perception, handling of complaints, correcting deficiencies identified by the users, taking correcting actions, preventive acting and ensuring that needs and expectations of the users are all handled according to the ISO 9001:2000 system.

Furthermore NPI provides comprehensive information and guidance to the users in English through the NPI website and the websites of the participating national offices in their languages.

21.19 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with WIPO and designated and elected offices. In particular describe how the Authority ensures that WIPO feedback is promptly evaluated and addressed

Communication from WIPO is handled by the NPI Vice-director or by the PCT units of the national offices, according to which type of communication is given.

NPI Vice-director also participates in the relevant WIPO meetings.

6. Documentation

21.20 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).

(Note: This point is informative. No response is required by the template to paragraph 21.20)

21.21 The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

- (a) the documents making up a Quality Manual that have been prepared and distributed;*
- (b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*
- (c) document control measures taken e.g. version numbering, access to latest version.*

The quality manuals are accessible to all staff on the Intranet (see also 21.12).

All procedures described in the ISO 9001:2008 standard including version numbering and access to the latest version are followed.

21.22 Indicate whether the documents making up the Quality Manual include the following:

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (b) the scope of the QMS, including details of and justification for any exclusions;*
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (d) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;*
- (e) the resources available for carrying out the processes and implementing the procedures; and*
- (f) a description of the interaction between the processes and the procedures of the QMS.*

21.23 *Indicate which types of records the Authority maintains, such as:*

- (a) a definition of which documents are kept and where they are kept;*
- (b) results of management review;*
- (c) training, skills and experience of personnel;*
- (d) evidence of conformity of processes, resulting products and services in terms of quality standards;*
- (e) results of reviews of requirements relating to products;*
- (f) the search and examination processes carried out on each application;*
- (g) data allowing individual work to be tracked and traced;*
- (h) records of QMS audits;*
- (i) actions taken re. non-conforming products, e.g. examples of corrections;*
- (j) actions taken re. corrective action;*
- (k) actions taken re. preventative action; and*
- (l) search process documentation as set out in Section 7.*

A definition of which documents are kept and where they are kept is found in the individual QM systems.

Most of the records are maintained in an internal website (intranet) but some of the records are due to their nature stored and maintained elsewhere.

Human Resources departments of the national offices store and maintain records on training, skills and experience of personnel.

Evidence of conformity of processes, resulting products and services in terms of quality standards and results of reviews of requirements relating to products Internal electronically in the patent department are filed in the internal record management systems of each office.

The search and examination processes carried out on each application data allowing individual work to be tracked and traced are filed in uPDate on the actual case.

7. Search process documentation

21.24 *For internal purposes the Authority should document its search process.*

The Authority should indicate

- (a) *which of the following are included in this record:*
 - (i) *the databases consulted (patent and non patent literature);*
 - (ii) *the keywords, combinations of words and truncations used;*
 - (iii) *the language(s) in which the search was carried out;*
 - (iv) *the classes and class combinations searched, at least according to the IPC or equivalent;*
 - (v) *a listing of all search statements used in the databases consulted.*
- (b) *which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.*

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)
- (c) *which special cases are documented and whether records are kept denoting any:*
 - (i) *limitation of search and its justification*
 - (ii) *lack of clarity of the claims; and*
 - (iii) *lack of unity.*

All the aforementioned information is filed in uPDate under each individual case.

8. Internal review

21.25 *Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.*

21.26-21.28 *These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes*

Internal reviews are a formalized part of ISO 9001 and hence the DKPTO and NIPO already have internal reviews at least twice a year.

In addition to the internal reviews, an independent external review will take place at least annually by an external certification company.

9. Arrangements for Authorities to Report to the MIA

21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.

[End of document]