PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Japan Patent Office

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

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 organisational chart showing all those bodies and individuals responsible for the QMS.
(a) The JPO has developed the "JPO's Vision" as a mission to be carried out, and make it public on the JPO's website.

(b) The Deputy Commissioner is in charge of supervising and sorting out important matters related to technologies for various operations examinations as well as for appeals and trials, and has a responsibility for the QMS.

(c) Organizational chart (Figure 1) is posted on the Quality Management Office's homepage on the intranet.

Figure 1 Organizational chart

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.
The JPO has maintained and improved the quality of patent examination through both (1) "Quality Control" performed for each patent application at each Art Unit and (2) "Quality Management" exercised from a cross-sectional point of view.

(1) "Quality Control" at each Art Unit

Each Art Unit at which applications of each technical field are examined strives to perform the "Quality Control" of examinations for proper examinations of individual cases based on examination guidelines by unifying application of the judgment standards between each examiner through consultations between several examiners, checks of the content by a director, etc.

(2) Cross-sectional "Quality Management"

Furthermore, the JPO sets a quality management system based on a concept of the quality management cycle (PDCA cycle) that is maintained mainly by the Quality Management Office and improves the examination quality at the JPO as a whole continuously. Under this concept, examination results are post-measured and analyzed objectively, and then the results are reflected on the implementation plan to maintain and improve examination quality.

To be specific, the Quality Management Office conducts the internal review on individual case by the third party in the JPO, collects User reviews, and analyzes related statistical information. In addition, these results of analyses are utilized for considerations on measures to improve examination quality by related sections, and the feedback is given to the Art Units for supporting the Quality Control at each Art Unit.

This Quality Management System is reviewed by the Deputy Commissioner. Through this review, the effectiveness of the QMS and the process of continual improvement progresses are ensured.
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.

(a)(b)

At the beginning of fiscal year, after the Deputy Commissioner's review, the handling target of examination including quality objective is formulated. And this quality objective is widely notified to staffs.

Through this notification, the JPO communicates to the staff the importance of meeting quality standard and compliance with the JPO's QMS.

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.

(a)
The Deputy Commissioner reviews human resources, physical resources and educational resources from a management point of view, if necessary, through the meeting being held one or two times a week.

(b)(c)
See 21.07

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).

(a)
In the meeting held one or two times a week, the Deputy Commissioner reviews the QMS activities, if necessary. In addition, a comprehensive review of the QMS activities is carried out at the end of fiscal year.

(b)(d)
Inputs for these reviews are as follows:

- Results of reviews of sampled cases (See 21.16(a))
- Statistical data related to quality (See 21.16 (b))
- Feedbacks from users (See 21.16(b))
- Corrective actions and preventive actions taken re. non-conformities discovered through the above
- Follow-up for corrective actions and preventive actions

(c)(e)
The results of these reviews are recorded in the meeting documents.
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.

(a)

In the JPO, patent examiners carry out search and examination. These patent examiners generally have a technical educational background from universities or colleges and have a bachelor's degree at least, and there also are examiners with master's degree or doctor's degree. The JPO recruits examiners from applicants who passed the first class national public servant recruitment examination, in the divisions of science and engineering or agriculture. The examination is ranked as the most difficult among national public servant recruitment examinations. Furthermore, the successful applicants undergo a character test and their nature is carefully evaluated.

English is one of the subjects in the first class national public servant recruitment examination. The JPO regards English ability as an essential element in recruitment of its staff. Moreover, assistant examiners are required to receive specified English language training course before they are promoted to examiners. They can also participate in training courses for other foreign languages such as French, German, Korean, Chinese, etc.

As a provisional measure to cope with further increasing backlogs, the JPO has employed highly specialized outside human resources as fixed-term examiners for five years. The JPO gave an examination, equivalent to the first class national public servant recruitment examination, to strictly evaluate their nature, and employed them.

As of FY2010, the JPO retains 1703 examiners in total (fixed-term examiners, 490).

(b)

Part of staff at of office work and management divisions is examiners from Patent Examination Divisions, and they sufficiently know about PCT system. Other staff also has received appropriate trainings on the whole PCT system, search/examination process, and contents of operations.
## 21.12 Material resources:

<table>
<thead>
<tr>
<th>(a)</th>
<th>Describe the infrastructure in place to ensure that</th>
</tr>
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<tbody>
<tr>
<td>(i)</td>
<td>appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;</td>
</tr>
<tr>
<td>(ii)</td>
<td>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.</td>
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<table>
<thead>
<tr>
<th>(b)</th>
<th>Describe how instructions</th>
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<tbody>
<tr>
<td>(i)</td>
<td>to help staff understand and adhere to the quality criteria and standards, and</td>
</tr>
<tr>
<td>(ii)</td>
<td>to follow work procedures accurately and consistently</td>
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</tbody>
</table>

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

(a) Resources include a system for effectively executing searches of prior art documents such as minimum documentation, and a drafting system for implementing international searches and international preliminary examinations. These resources are extremely important for examiners to perform their task, and are periodically updated, and are upgraded upon their request when needed. Technical support is also extended to examiners so that the best operating conditions are continuously maintained.

With searches for a prior art, the JPO has developed its own system, which searches not only through IPC or Full text in Japanese and English but also through commercial Web such as STN and JDreamII, which can be executed by a single PC terminal for examiners. Access to Japanese and foreign patent documents, as well as NPL (Non Patent Literature), is possible from this terminal. For retrieval of foreign patent documents, search using IPC, ECLA and USPC is possible.

There are many search systems originally developed by the JPO. They include: the F-term system (which is based on classification with multiple viewpoints) and the FI system (which is the IPC fine-tuned by the JPO). Therefore, examiners can choose an appropriate search tool according to the content of an application.

The following is a concrete description of the F-term system: Under the F-term system, about 2,600 technical groups (theme codes) are defined; and for about 1,800 technical groups, "terms" which are multiple viewpoint classifications suitable for each technical group are assigned. Persons with profound knowledge of both technology and patents have previously analyzed the Japanese patent and utility model documents and have assigned an appropriate "terms". Therefore, with the F-term system a more precise search is available than searches by using key words, etc. In addition, F-term, FI, IPC and key words can be used simultaneously so that a quick and extremely precise search is executed. With respect to NPL about computer software and NPL about intensively competitive field or advanced technical field that are unable to be searched by commercial database, the JPO has developed its own database. Computer software terms like F-term are assigned to the documents on the computer software database so it is possible to search a document with these terms.

Furthermore, a search formula used in searches and a document set obtained by the search formula can be automatically recorded, search know-how can be shared among examiners.

When an examiner establishes International Search Reports or International Preliminary Examination Reports, report preparation support by drafting system has been realized. Especially, innovations to prevent drafting mistakes, such as mounting of functions to permit simultaneous drafting of necessary documents, a function of automatic import of bibliographic matters to drafting documents, a checking functions for input contents, etc are
provided. Moreover, electronic management and electronic approval procedure for PCT applications are realized.

The office management divisions analyze the functions and the performance of the information systems and the systems are reviewed every year. Measures for their improvement are designed to meet the requirements of examiners, in order to provide comfortable environments where the examiners can execute the highest quality searches and preliminary examinations with maximum efficiency.

(ii)

The JPO possesses a substantial amount of documentation, mainly comprising patent documents. With respect to Patent documents, the JPO along with the National Center for Industrial Property Information and Training possesses all official gazettes corresponding to minimum documentation, and the JPO's examiners are able to utilize these gazettes (For most part of the official gazettes of the minimum documentation, examiners are free to access those documents from their terminals). For NPL, the JPO is able to utilize published magazines and commercial on-line databases including JDreamII etc., thus, it secures to access a wide range of NPL, making it possible to meet the requirements for minimum documentation.

(b)(i)(ii)

- "PCT International Search and Preliminary Examination Guidelines"

English and Japanese versions are provided for examiners in the form of paper media. This can be available through the intranet.

- Manuals for internal practices

Basic practices for examiners to carry out international searches and preliminary examinations are documented in internal manuals. These are distributed to examiners in the form of paper media. It can be referred to through the intranet. These internal manuals comprehensively describe matters from criterion of judgment for international searches and preliminary examinations to procedures on internal system. They are based on rules and regulations such as the Treaty, the Regulations and the Guidelines and the operational procedure of the internal system (PCT-RO).

- Computer System Operations Manuals

These can be referred through the intranet.

- Useful Information to Improve Quality

Useful information to improve quality is seen at the site of the Quality Management Office on the intranet.

All of the above instructions can be obtained from the Portal Site of Examination Department on the intranet. The site of the Quality Management Office is linked from the Portal Site. These documentations are updated if necessary.
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.

Course training

An officer recruited by the JPO is required to attend three training courses and pass the examinations for each course before becoming an examiner. Total hours of three courses are 250 hours. Lecturers for this training program include university professors, lawyers and examiners. The training programs include training in the international regulations, together with related rules including the Patent Cooperation Treaty, the contents of PCT International Search and Preliminary Guidelines and practices of international search and preliminary examination.

OJT by supervising examiners

An officer recruited by the JPO is trained to execute examination as an assistant examiner for basically four years under the guidance of the supervising examiner.

Technical training, Visits to businesses, Internship, Studying in domestic universities and overseas universities

In order to acquire the knowledge of cutting edge high level technologies, examiners are given opportunities such as attending technological trainings, visiting to businesses, internship and studying in domestic universities and overseas universities.

Language training

Opportunities to receive training in English and other foreign languages are also given according to need.

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

(a)(b)

According to the forecast for workload prepared by office work and management division, maintenance and improvement plans for necessary resources are established to deal with demand and to comply with quality standards.

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.
Upon receipt of a PCT application, an administration schedule sheet is formed in order to keep to the schedule for preparation of the ISR and IPER for each application. This schedule, in consideration of the time limit stipulated in the PCT and the period required for procedure in the JPO, contains timing required to keep every time limit (time limit for establishing invitation to pay additional fees, notification of decision on protest, ISR, IPER etc.) in a sheet of paper, and it is distributed to examiners along with a PCT application to contribute to schedule management.

An electronic management system for PCT applications has been established and schedule management can electronically be carried out.

Directors carry out term control for PCT applications in each art unit, using these schedule sheet and electronic management system.

(b)
- Short-term fluctuations in demand and backlog
  In order not to impartially assign a great many jobs to particular examiners and not to delay the procedure, multiple numbers of examiners in charge are assigned in the same classification. Also, a director can adjust the service volume for each examiner in charge as necessary.

- Medium-to long-term fluctuations in demand and backlog
  Medium-to long-term fluctuations are dealt with appropriately by means of changes in examiners’ assuming technical fields or transfer, etc.

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.

The quality of content of international searches and international preliminary examinations has been maintained and enhanced by checks carried out by a director or a person delegated by the director for all cases, or by consultations with other examiners.

In addition, staff in a office work and management division checks whether there are errors in bibliographic and formality items in the International Search Report and International Preliminary Examination Report prepared by examiners before sending them to International Bureau or Applicants.
Furthermore, samples are extracted from cases that have been sent to applicants and the each case is reviewed by the third party in the JPO. This review is managed mainly by the Quality Management Office. This review includes the point to be checked whether or not the case complies with the International Search and International Preliminary Examination Guidelines. Analyses of the review are utilized for considerations on measures to improve examination quality by related sections, and the feedback is given to the Art Units to support the Quality Control at each Art Unit.

(b) The Quality Management Office acquires various statistical data related to quality. In addition, it collects comments from users. The information is utilized for considerations on measures to improve examination quality by related sections, and the feedback is given to the Art Units for supporting the Quality Control at each Art Unit.

(c) When some sort of problems is found in search and examination results, information is provided for related sections, said section carries out investigating the problem and making plans for corrections of defects and prevention of reoccurrence of the problem. The improvement plan is informed to each art unit and examiner widely and implemented. The Quality Management Office performs ongoing evaluations for the effectiveness of the improvement plan.

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.

(As of October 31, 2010)

➢ International Affairs Division
Kenji Shimada (Mr) (Deputy Director)
Norie Umemura (Ms)

➢ Administrative Affairs Division, Examination Standards Office (Specially on (a))
Reeko Imamura (Ms) (Director)
Tomoya Yanagisawa (Mr) (Deputy Director)
Masafumi Shimizu (Mr) (Assistant Director)

➢ Administrative Affairs Division, Quality Management Office (Specially on (b) & (c))
Masahiro Hiratsuka (Mr) (Director)
Kenichi Matsunaga (Mr) (Deputy Director)
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.

(a)
The name and phone number of a JPO examiner are listed in the international search report and the international preliminary examination report drafted by the examiner. By this, the means for bilateral communications between applicants and examiners is provided.

In addition, the Quality Management Office receives comments from users. The information provided to the Quality Management Office is utilized for the improvement of quality.

In all cases, corrective and preventive actions are taken where appropriate.

(b)
The Quality Management Office has been carrying out questionnaire survey to monitor user satisfaction and perception.

In addition, in order to grasp users' needs, the JPO holds periodical meetings with the associations of applicants and patent attorneys. Moreover, in order to hear direct opinions and requirements from major applicants, the JPO has been holding meetings with business executives, managers of intellectual property department and the Commissioner, the Deputy Commissioner, Director-Generals, directors, general administration sections.

(c)
The information on PCT international application is collectively described at one place to make it easy for reference (http://www.jpo.go.jp/index/kokusai_shutugan.html). This webpage includes information about not only the PCT Guidelines, the PCT (Treaty) and PCT Regulations but also application procedures.

In addition, user's guides on international search and preliminary examination are published annually, and related workshops are held throughout Japan. These guides can be obtained through the above web site.
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.

Communications with WIPO, designated and elected Offices on quality, shall be assumed by the International Affairs Division, the Examination Standards Office, and the Quality Management Office (see 21.17).

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.

(a)

The Quality Manual constitutes multiple documentations and includes instructions pointed out in 21.12 (b). In addition, it includes the documents pointed out in 21.22.

(b)

All documents can be obtained through the intranet. Part of them is provided in the form of paper media as pointed out in 21.12(b).

(c)

The documents of the latest version are always available through the intranet.
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.

The Quality Manual includes the following matters.

(a)

The "JPO's Vision" as a mission to be performed by the JPO is prepared.

(b)

The scope of QMS is described on the Quality Management Office's homepage on the intranet, introducing as work products established at the international search and international preliminary examination stages.

(c)

The organizational structure of the JPO is described on the Quality Management Office's homepage on the intranet. (see 21.04 (c))

(d)

The instructions of processes carried out in the JPO can be obtained from the Portal Site of Examination Department. Part of the instructions is provided in the form of paper media (see 21.12(b)). Information about processes for the QMS is available in the Quality Management Office's homepage on the intranet.

(e)

The information on documents utilizable for prior art search, the information on the system of search, drafting, etc., and the information on trainings can be referred to through the intranet.

(f)

The figure that illustrates the interaction between the processes and the procedures of the QMS can be referred in the Quality Management Office's homepage on the intranet. (Figure 2) (see 21.06)
### 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. |

(b) The management review regarding the availability of resources, etc. has properly been conducted in the meeting chaired by the Deputy Commissioner, and the results are documented.

(d)(e) The review for the samples extracted from the PCT work products are conducted and reviewed as to whether they comply with the quality standards (see 21.16(a)). The results are documented and reported to staffs.

(f)(g) Processes of international searches and preliminary examinations are electronically recorded in the management system. These records can be referred online and it makes possible to track and trace the process of individual work.

(j)(k) When problems are found, corrective and preventive actions are considered in related sections. The result of consideration is notified to staffs after compiling in a document.

(l) Part of the search processes is recorded in a search system developed by the JPO.
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; online 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.

When an examiner uses the search system developed by the JPO, the information (i)–(v) is automatically recorded in this system. In addition, according to manuals for internal practices, as far as the case searched with other database than that for the JPO, at least the information (i) (or that of (ii) in certain instances) is recorded in the search report.

The information on viewed documents is automatically recorded in the system when using the search system developed by the JPO.

When corresponding to (i) – (iii), that fact is all recorded in the search report.
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.

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]