

PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by CANADIAN INTELLECTUAL PROPERTY OFFICE(CIPO)

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.

ARTICLE I. 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

Normative reference for QMS: ISO 9001

ARTICLE II. 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.*

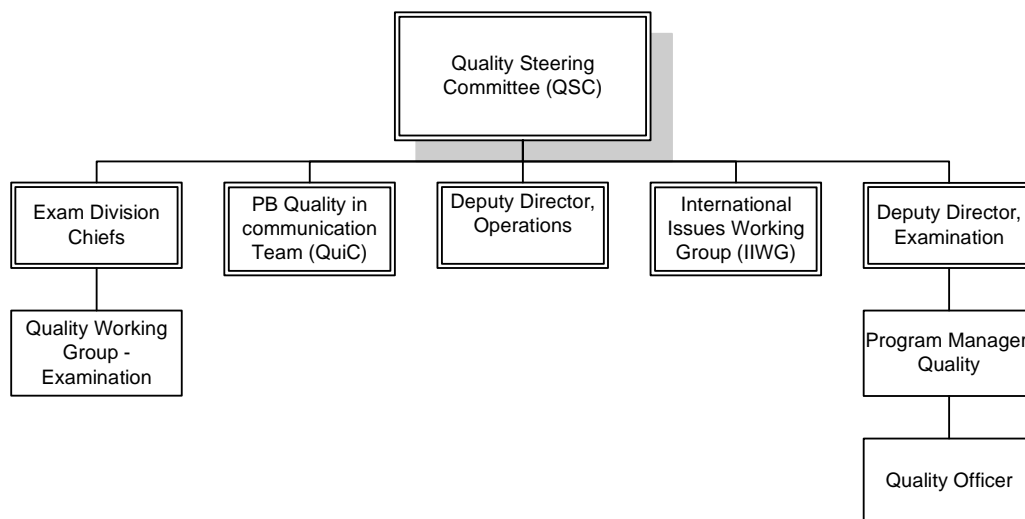
The Quality Policy of the Patent Branch of CIPO is defined as:

The Patent Branch is committed to a culture of excellence, underpinned by a Quality Management System. Individually and collectively we:

- Endeavor to meet our clients' needs and expectations while conforming with the Patent Act and Rules;
- Invest in communication and employee development so each and every one is instrumental in our success;
- Strive for consistency and continuously improve our processes, products and services

The Patent Branch (PB) intranet contains a listing of all the organizational units responsible for the implementation of the quality management system. Responsibilities in the Patent Branch Quality Management System (QMS) are illustrated in the following QMS organization chart. It should be noted that the Deputy Director, Examination is also part of the Examination Division Chiefs group. In addition, the Quality Steering Committee is formed of PB senior managers, including the Assistant Commissioner of Patents, Examination Division Chiefs and Deputy Directors.

QMS Reporting Structure



The Program Manager – Quality is a member of the Quality Steering Committee, and is responsible for the implementation and continuous improvement of the Quality Management System. The Manager reports on the functionality of the system and makes recommendations to senior management about improvement projects.

The Quality Steering Committee (QSC) is responsible for directing the implementation of the Quality Management System. It sets priorities, allocates resources and tasks, and ensures that

project timelines and objectives are met. In addition, it sets and monitors quality targets. The QSC is formed of senior management of the Branch, including the Assistant Commissioner of Patents, and the Program Manager – Quality.

The International Issues Working Group (IIWG) resolves issues related to international work (ISA/IPEA) and monitors processes in Examination and Operations. In addition, this group monitors nonconformities arising from transactions between different units and sections in the Branch. It also provides follow-up for any unresolved nonconformities, ensures that these are fixed, and that the results are communicated to employees as best practice. The Group is formed of Section Heads from across the Branch, including those in Operations performing international work and representatives from each Examination Division. Program Managers are invited occasionally, as required.

The Quality in Communication Group (QuiC) helps disseminate information across the Branch through formal and informal channels. It promotes and brings awareness to employees about Branch's activities in order to better engage employees. The Group is formed of employees from across the Branch, including Operations, Classification and Examination.

The Quality Working Group (QWG) is responsible for defining and standardizing work procedures in Examination. It establishes the quality standards for search and examination in the Branch. The Group is formed by Section Heads and Senior Examiners from each Examination Division, and is chaired by the Program Manager – Quality.

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.

| Chapter 21 requirement | | | Extent of compliance | | |
|------------------------|-----|--|----------------------|------|----|
| | | | full | part | no |
| 21.04 | (a) | Quality policy available | ✓ | | |
| | (b) | Identified roles and names for QMS responsibility | ✓ | | |
| | (c) | Organisational 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 | ✓ | | |
| | (b) | The PCT Guidelines are in line with the Authority's QMS | ✓ | | |
| 21.08 | (a) | Management reviews take place | ✓ | | |
| | (b) | Quality objectives are reviewed | ✓ | | |

| Chapter 21 requirement | | | Extent of compliance | | |
|------------------------|-----|--|----------------------|------|----|
| | | | full | part | no |
| | (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. | ✓ | | |
| 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 | ✓ | | |

| Chapter 21 requirement | | | Extent of compliance | | |
|------------------------|-----|---|----------------------|------|----|
| | | | full | part | no |
| | (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 | | ✓ | |
| 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 | ✓ | | |

| Chapter 21 requirement | | | Extent of compliance | | |
|------------------------|-----|---|----------------------|------|----|
| | | | full | part | no |
| | (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 effectiveness of the QMS is ensured by the Quality Steering Committee (QSC). This committee meets every 2 weeks where it reviews the progress of the quality program, approves documents and discusses quality related issues.
- (b) The PB-Program Manager – Quality ensures that the process of continual improvement progresses throughout the patent branch. This individual chairs many quality committees, tables issues for the QSC and follows up on quality initiatives to ensure that they are progressing as expected.

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) The management of CIPO communicates to staff the importance of meeting treaty and regulatory requirements through a variety of ways. Each examiner is made aware of the yearly production goals and priorities of examination by their supervisor once a year. These documents contain reference to our obligations under the PCT and put a high priority on maintaining a very high level of quality in our work. Additionally, the management approved quality standards for ISA/IPEA examination are largely informed by the PCT and Guidelines, such that compliance with these requirements is brought in at the base level of our work.

(b) As discussed above, each examiner reviews and commits to yearly production goals as well as the priorities of examination for our work. Maintaining an excellent level of quality is a requirement of these annual commitments. Also, the Assistant Commissioner of Patents continually raises our QMS objectives a topic during regular meetings with employees and also through the month Patent Branch Newsletter.

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 senior management of CIPO meets annually to update the 5-year strategic plan for the Canadian Intellectual Property Office. During this meeting the specific objectives, service standards and goals of Patent Branch are analyzed and adjustments are made to ensure that appropriate resources are available.
- (b) – (c) Patent Branch reviews the quality objectives for the organization on a yearly basis, these objectives form a key part of each employee's yearly performance review and their goals for the subsequent year. Each employee is made aware of their specific quality objectives and priorities at their yearly performance evaluation and mid-year performance review.

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).*

Internal review at PB does not take place as one central activity but is distributed around many yearly activities. The Quality Steering Committee (QSC) is composed of Patent Branch's top management and this committee meets every two weeks and reviews corrective and preventative action requests (as needed), customer feedback, recommendations (both internal and external) and QC/QA results (quarterly) and internal audit data (a measure of effectiveness, twice each year). The QSC also approves all yearly reviews/revisions to mappings and work instructions and any other quality related documentation.

In this manner PB provides a continual management review of the QMS, rather than as a single activity. This approach is considered more effective as Patent Branch is still in the process of updating its National QMS and thus many overlapping systems are being reviewed and improved regularly. More frequent management input and review into the QMS is considered essential.

Section 2.02 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.*

Patent Branch has almost 400 examiners trained to examine national and international examination. The examiners are divided over 4 examination divisions in the following numbers:

| Division | Supervisors | Examiners |
|---|--------------------|------------------|
| Mechanical | 9 | 88 |
| Chemistry (including general chemistry and organic chemistry) | 9 | 106 |
| Electrical | 8 | 93 |
| Biochemistry | 5 | 59 |

Patent examiners are highly qualified and highly trained employees. The training for all new examiners is rigorous as they start their career with an intensive three-month classroom program before joining their section under the supervision of a Section Head and mentored by a senior examiner. They return to the classroom for a month of advanced training at the end of their first year and spend their second year perfecting and honing their skills before completing their apprenticeship.

All patent examiners receive an initial four days of training on the PCT International Search and Preliminary Examination processes and requirements. In addition, there are ongoing targeted training and development available for all patent examiners and administration personnel.

Examination staff's technical qualifications are maintained and monitored regularly by management. This is accomplished through Personal Learning Plans (PLP). PLPs are created by each employee and reviewed by supervisors twice yearly. There is a minimum level of training each employee is required to take during a year, this includes mandatory courses as well as employee directed personal and professional development. Additionally, regular attendance at conferences and tradeshow related to an examiner's technical field is supported and encouraged by management.

While Patent Branch accepts both French and English patent applications, the French applications represent only 3-4% of our PCT applications. Currently 10-15% of examiners possess bilingual capabilities. The current levels and training of examination staff is more than sufficient to deal with the flow of International Applications. Additionally, patent examination is supported by the Patent Administrative Policy, Classification and International Affairs division. This division is summarized below:

| Division | Work units |
|--|--|
| Patent Administrative Policy, Classification and International Affairs | 1 unit in classification 5 officers 2 program manager (responsible for ISA/IPEA) |

The Patent Branch is also supported by Patent Operations. This division has over 160 employees distributed in several work units. The following table identifies the main work units:

| | |
|--|----------------------------|
| Mail sorting and image scanning | Assignment |
| Formalities | Maintenance fees |
| Optical Character Recognition (OCR) zone | PCT (national phase entry) |
| File preparation | PCT (international) |
| Patent Data Quality Services | Examination support I |
| | Examination support II |

The PCT International Unit has highly skilled administrative personnel comprising one Section Head, two Mail Clerks and 10 International PCT Analysts responsible for PCT work in the Receiving Office and in the International Searching and Examining Authorities. This group has also been trained to support the examination staff and facilitate the international search and examination process.

Patent Branch has established procedures and work instructions to be used by the examiners and the PCT Analysts. Detailed checklists have also been established. Some examples of the procedures created are: Checking the Request, Checking PCT Mail, Classification, Check Demand, Refund, Generate Notice, Process Fee, QC scan, Receive Search Copy, Scan PCT Mail, Search and Establish Opinion, Sequence Listing.

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.

- (a) (i) In conjunction with the Informatics Services Branch (ISB), the Patent Branch has developed a modern and efficient system entitled InterApp to handle the prosecution of international applications electronically. The software has been developed in C++ and includes various modules. Two of the main modules are a workflow management system, and a document management system. The document management system permits the Patent Branch to electronically stamp the application with various modifications/corrections and stores them in a db2 database.

All applications are scanned upon receipt in TIFF T6G4 black and white 300 dpi formats. Notices are currently prepared in WordPerfect using mail merge templates and are converted to TIFF and stored in the system once printed (no scanning of notices).

The multi-user system allows many people to view the same application concurrently. Examiners can view/print applications, prepare notices and save their notices in the system. Quality Control steps are part of the workflow, so once an International Search report and Written Opinion (ISR/WO) are prepared, a task is created to enable the Section Head to review these documents. Once the QC is complete, the PCT International Unit receives a task to print and mail the documents. The PCT Analyst performs a further QC before the documents are converted to TIFF using a special printer driver.

(ii) In addition to the Canadian collection being available electronically as well other IPOs' collections also being available online, patent examiners have access to two commercial patent databases to support search and examination work. The first database is EPOQUE provided by the European Patent Office. EPOQUE was first implemented at CIPO in 2009 and meets the minimum documentation standards set out by the PCT and is available to the entire examination corps.

Additionally, in 2010 Patent Branch also entered into a contract with LexisNexis to have access to TotalPatent for all examiners. This online database provides an additional resource to support search and examination work. TotalPatent also meets PCT minimum documentation standards.

Additionally, the CIPO Resource Centre (CRC) offers global access to strategic technical and business information including access to multiple periodicals via the CRC electronic resources and other Canadian libraries.

Moreover, the Canadian internal patent database was completely remodeled in 2008 to include an enhanced GUI interface with added functionalities. CIPO's non-patent literature collections are continually augmented, and include comprehensive coverage from reputed journals, publications and databases, such as the American Chemical Society, Knovel and Scopus.

(b) (i , ii) Instructions for employees to understand and adhere to the quality criteria, standards as well as work instructions and process mappings are all published on Patent Branch's website in both English and French. These publications are all assigned to an owner and follow PB's procedure for control of documents for updates.

In addition, a master list of all internal and external documents is maintained by PB's administration department. This list provides information on names of authors/owners, document location and dependencies, as well as expected revision dates. Authors and

owners are responsible for regularly updating and disseminating information to appropriate staff members.

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.*

Upon initial recruitment new patent examiners undergo a rigorous three month classroom training course. When complete the examiners then are paired with a senior examiner who acts as a coach and trainer for the next two years. All work the new employee does is reviewed and monitored by the trainer. After being in the office for a year new employees take additional courses directed toward jurisprudence, advanced examination and International Search and Examination. After successful completion of these courses, the employees begin examining international applications within their art queues, under the supervision of the trainer and the section head.

Additionally, for all employees, an enhanced Continuous Training Program was effected in 2009 to institute a point system for all training completed by examiners during a fiscal year. Examiners are required to meet a minimum point score per year, specifically in areas related to intellectual property and science and technology. The training point system allows examiners and supervisors to track training completed and determine future training needs. All training matters are handled by the Program Manager - Patent Examination Training.

Within the continuous training program, all examination staff receive mandatory refresher ISA/IPEA training and all employees have access to the ISA/IPEA training manual both in hardcopy and online. This manual is regularly revised to keep current with Patent Branch's practice. The manual includes a section on annotated forms was added to provide examiners with information and concrete examples on how to complete the various ISA/IPEA forms.

The ISA/IPEA training materials also provide instruction on what PB's quality criteria and standards are and how they are evaluated on international search and examination work. Examiners' awareness that their work is subject to this criteria and the importance of compliance is reinforced in the yearly goals and objectives assigned to each examiner.

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*

As discussed above the computerized processing system InterApp serves a system for managing the entire process of handling international applications. Within this system, Patent Branch has implemented a control mechanism that ensures that users are aware and properly apportion resources to deal with all applications in a timely manner.

Each stage of the task is colour coded to enable users to quickly determine when a time limit will expire. There is an automatic process when a task is beyond the predetermined time limit where, if further action must be taken, another task is generated. A weekly query is run to determine the

necessary action for affected applications. These affected applications are brought to the attention of senior staff members who take the appropriate action (i.e. contact the applicant/agent by phone, facsimile or send the appropriate notice).

Within patent examination, section heads (the supervisors of all the examination units) are able to inspect and monitor the work queues of each employee to ensure that files are being worked on in a timely manner and in accordance with the appropriate practices. Section heads are also able to reassign work among the employees of their sections to manage temporary fluctuations in work load or employee availability.

In order to ensure that expected turn-around times are maintained in the operations division, each new staff member receives basic training from experienced PCT analysts, as well as guidelines to follow. As experience is gained with each specific task (e.g. Receiving Office for new applications), the analyst or mail clerk is given further training to ensure that there is always someone available to handle fluctuations in workload in Operations.

Section 2.03 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.

The computer processing system InterApp described above operates the same for administrative tasks as well as examination tasks. Support staff have work queues with all assigned tasks and deadlines shown. Supervisors are able to review work and reassign tasks to balance work loads as needed. All sub-stages in the process of processing the application are governed by separate deadlines to ensure that each sub-step is completed in a timely manner and the application moves through the system efficiently.

Section 2.04 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.

Examination work at the Patent Office is underpinned by its International Search and Examination Standards. These Standards take into account internal and external clients' needs, and incorporate requirements of the PCT Search and Examination Guidelines. These standards then dictate the types of criteria which are used to evaluate examination work. Quality of examination work is evaluated through two distinct formalized processes. The first is Quality Control (QC), which occurs during the examination process. The second is Quality Assurance (QA), which happens subsequently. The output of both these processes is a collection of statistical data which is analyzed quarterly.

Quality control is performed by supervisors, who carry out reviews for adherence to established quality standards of search and examination. This control is randomly sampled at 25%, and data are collected for analysis and identification of areas of improvement. Examiners may also be provided with direct feedback following a review of a file, and are responsible for ensuring that all issues raised by his/her supervisor are corrected. Supervisors are responsible for ensuring that any systemic or major issues are reported to the appropriate authority.

Quality assurance is performed by a team of two examiners and a supervisor who can provide oversight of QA work, as required. The team ensures unbiased assessment of examiners' work, while allowing standardized QA performance and sharing of expertise. QA examiners appraise examiners' decisions for adherence to the Patent Office's search and examination standards.

Should disagreement ensue between QA examiners, the supervisor is empowered to make a final decision. QA examiners are selected from each examination division for a given term, and membership is rotated to allow for involvement of all examiners in QA. QA is sampled randomly at 10%, and data are collected for analysis and identification of areas of improvement. QA teams are responsible for raising systemic or major issues warranting a corrective action to the appropriate authority.

The resultant data from both these processes is analyzed quarterly. The data consists of a series of statements which are evaluated by the supervisor or quality assurance examiner as being met or not met on each application. These statements are derived from the quality standards. Currently, there are 32 criteria which are applied to each application under review. Of these criteria, 15 are considered major criteria (those having serious consequences on the accuracy or clarity of the document under review) and 17 are considered minor criteria (those where errors do not result in the document under review being inaccurate or unable to be understood). Thresholds have been set for the acceptable error rate under each criterion and action has been taken to ensure that training and resources are adapted to meet and reduce error rates. Reports and recommendations on data analysis are presented to the Quality Steering Committee every 3 months.

Processes to monitor and measure the performance of the QMS include a cross-unit nonconformity procedure, where cross-unit issues are reported and corrections are carried out accordingly. Data arising from this procedure are collected regularly for analysis and continual improvement. Results of this procedure and any corrections are communicated regularly to employees at staff meetings.

Additionally, PB also has a Corrective/Preventative Action procedure. This is linked to the procedure for Cross-Unit Nonconformity, which allows any staff member to raise issues at any time within a process for correction to appropriate authorities. All issues and corrections are recorded for later review by the International Issues Working Group (IIWG), which evaluates the seriousness of issues and requests for corrective actions as required. Only issues or potential issues which are deemed serious enter the Procedure for Corrective and Preventive Action. Senior management is responsible for assigning resources to address corrective action requests and arranging follow-ups to ensure measures taken were appropriate and effective.

The Corrective and Preventive Action Procedure may also be called upon to resolve issues arising from customer complaints, employees' feedback, data analysis on Quality Control (QC) and Quality Assurance (QA) and Internal Audit.

Section 2.05 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.*

(a) and (b) Isabelle Robert, (Acting) Patent Branch Program Manager for Quality.

Contact details:

Isabelle Robert, ing.

Section head G3

Canadian Intellectual Property Office

Industry Canada

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- (c) This is the joint responsibility of the (Acting) Program Manager for Quality: Isabelle Robert (see contact info above) as well as the Program Manager for International (PCT): Kathleen Murphy (see contact information below).

Kathleen Murphy

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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) Client complaints are handled directly via the CIPO client service center, where customers can directly speak with a CIPO representative, the CIPO general enquiry telephone line where client service specialists can respond to general enquires or redirect calls to the appropriate party. Also, CIPO's Online Feedback Mechanism (OFM) (<http://www.ic.gc.ca/cipo/internet.nsf/comp-eng?readform>) provides an online form for users to submit comments, complaints or compliments to CIPO staff. Responses are returned to clients within 3 business days.

As described above the corrective action/preventative action program is available to employees. Issues raised through this mechanism are handled by the International Issues Working Group (IIWG).

(b) (i) CIPO has been conducting a biennial National Client Satisfaction Survey since 2001. The survey results have provided CIPO with great insight into the needs of its clients as well as their prevailing levels of satisfaction with respect to the products and services provided. This allows CIPO to further understand trends in the data year over year, pertaining specifically to the responses for patent applicants. The subsequent analysis is focused in large part on differences in satisfaction levels over time. Comparisons are made between the results for patent applicants and those for CIPO at large.

CIPO also provides clients an Online Feedback Mechanism (OFM). Feedback provides a valuable source of client information that can be of great value when identifying service improvements that meet customer needs. Clients have an opportunity to comment on the application process, examination process the Canadian Patent Database and/or any other services provided.

(b) (ii) A joint consultation committee between Patent Branch management and Intellectual Property Institute of Canada (IPIC) patent agents. The Joint Liaison Committee (JLC) provides an opportunity for the exchange of information between the profession and CIPO in order to effectively address client concerns. Regular monitoring of the overview of the patents feedback received via the Online Feedback Mechanism from CIPO's external website is also shared with the JLC.

The Client Engagement & Partner Relations section is responsible for engaging internal and external clients in the planning and delivery of new e-business solutions. They are also responsible for ensuring that e-business solutions will be adopted by external clients, acting on their behalf to conduct user acceptance testing of new web applications and system changes. We also monitor client-facing web databases for usage and quality.

(c) Guidance on the entire PCT application process can be found on the CIPO website (http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr02598.html). This address contains a detailed kit for all first time users to get a quick and thorough introduction to the PCT system and to gain an understanding of how and when to file a PCT application in Canada. This kit is reproduced from the WIPO publication PCT Applicant's Guide. Links are also included to more detailed PCT information found on the WIPO website.

Furthermore, the International Affairs section of the CIPO website (http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr02414.html) provides a detailed breakdown of all the various ways in which CIPO participates in the worldwide IP system.

(d) Patent Branch has published its Quality Standards for International Search and Preliminary Examination and on our website for all users to access. These standards are broken in to four sections: Search, Examination, Communication and Timeliness/Efficiency. The standards can be accessed at the following internet address: <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr02693.html> . The overall goal of the Quality Standards is to ensure that all aspects of our products are of such a high quality level so as to be useful to our clients.

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

The patent branch program manager for PCT/International and the section head of PCT International Unit are jointly responsible for communications with WIPO and designated and elected offices. Systematic issues and high level changes are directed to the program manager who ensures that all staff are aware of the issues and that any changes to procedures are carried out. The PCT program manager also regularly attends WIPO meetings. Lower level issues, or those dealing with a specific application are directed to the Section Head of PCT International who follows up promptly.

Section 2.06 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.*

Currently, Patent Branch has not published a Quality Manual and distributed it to all employees. The manual exists in only draft form but has been reviewed by top management. The manual has not been released at this time because the QMS for national examination is still undergoing development, and thus a published Quality Manual has been deferred until the necessary information about our National processes can be added.

However, the Intranet for Patent Branch contains a dedicated Quality Section which is updated with the majority of the documents which would compose a Quality Manual. This includes mappings, work instructions for all international examination processes, international quality standards, quality control criteria and guidelines, data collection and analysis. All documents mentioned above are subject to version control (including version numbering and revision schedules) and are assigned a document owner who assumes responsibility.

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 Management portion of the Patent Branch intranet contains:

- (a) A clearly articulated quality policy as well as a copy of the quality objectives of Patent Branch.
- (b) The documents which define the scope of the QMS are not updated on our intranet site and no list of exclusions is currently available. The reasoning for this is that Patent Branch is currently in the process of updating its National QMS and since many of the elements and committees overlap between International and National the scope and exclusions are still in a state of development.

- (c) The CIPO/PB management team and descriptions of the roles of all the groups associated with the Quality Management System.
- (d) All processes and procedures within the PCT International operations and examination units are documented in mappings and work instructions. The process of continually updating and reviewing these documents is ongoing. All process mappings and work instructions are posted on our intranet site where they are available to employees. Additionally, training is offered from time to time whenever new processes or significant updates occur.
- (e) The mappings and work instructions for all International QMS processes and procedures also contain a detailed instruction on which resources are available and how they can be accessed. If a particular step in a process relies upon the use of an associated resource, the instructions on how to access that resource and properly utilize it are also documented.
- (f) Patent Branch is still in the process of completely updating its QMS for national examination work. Since many of the support systems and committees overlap for both International and National QMS we have not completely documented the interaction between the processes and the procedures of the QMS. These interactions are laid out in general terms in the 'terms of reference' which is defined for each Quality Committee or group, however these terms have not been recently updated or organized in a comprehensive manner.

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) As discussed above PB maintains a database of all controlled documents, with revision history and document owner. All official documents are stored on the PB intranet.
- (b) There is no separate management review outside of the internal audit and normal management oversight provided by the QSC. The minutes of the QSC meetings are stored on our network server.
- (c) All employees of Patent Branch have a Personal Learning Plan (PLP). These plans are stored electronically and contain a list of all the education and training the employees have

taken in the year. This includes mandatory training as well as optional or professional development training. Previous year's PLPs are archived to build a learning history for each employee.

- (d) Conformity of processes to our standards are recorded in the form of results for PB's Internal Audit results.
- (e) Quarterly Quality Control/Quality Assurance results are stored on our network drive analysis is performed quarterly.
- (f) All International examination applications are stored with an accompanying file of examination notes. This file contains a record of all the classifications, keywords and databases searched. The examiner can optionally store search strings and search histories in this file.
- (g) As discussed above the production tracking program InterApp stores all tasks performed on a file as well as the employee who actioned that task. It is possible to track individual employee work through this program.
- (h) A formal system of storing the results of QMS audits is being researched, in the interim the results are stored with the lead auditor and the program manager of Quality.
- (i), (j) and (k) All non-conformities, corrective and preventative actions are tracked and logged through the same online interface. The IIWG who is responsible these types of tasks maintains a record of all actions taken.
- (l) This was discussed above in (f).

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.*

Throughout the process of examination of an international application the examiner is also required to document the search process using the "Examination Notes" form. This form contains fields for the examiner to input the all databases, keywords (in each language searched) and classes used. Examiners may also populate the forms with search histories and search strings as appropriate. The form is saved and stored with the international application.

In addition to the above fields, examiners also indicate the inventive concept(s) which has been identified in the application, they list all the relevant documents found and write a description of the closest prior art. Finally, examiners complete the form by indicated their rationale for stopping the search. These fields assist both the examiner and the reviewing in ensuring that a comprehensive search and examination has taken place. By summarizing the closest document and articulating the inventive concept and rationale for stopping search the examiner demonstrates that they have completed the entire process of search and are ready to fill in the PCT forms. This information is also highly useful when transferring the case between examiners, performing a quality check or when national examination commences.

The "Examination Notes" forms do not require that information about clarity of the claims or lack of unity be recorded. However, such information is captured in the QC/QA criteria where section heads and quality assurance examiners respond to whether the unity or clarity issues were properly responded to by the examiner. As this criterion is part of the QC/QA it is subjected to data analysis regularly and trends can be identified.

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 review at CIPO is not articulated in a separate activity. All QMS related documents are reviewed on a yearly basis and updated as required. This includes examination standards, QC/QA tools, process mappings and work instructions, as well as training manuals and support documentation. Furthermore, internal audits are carried out within Patent Branch twice yearly and PCT processes are inspected for conformity with established procedures. Corrective and Preventative actions are taken throughout the year as issues are raised.

All data resulting from these review arrangements is presented to the Quality Steering Committee (QSC) throughout the year and deficiencies or recommendations are acted upon.

Additionally, in 2008 Patent Branch hired an external auditor carry out the audit of the ISA/IPEA Quality Management System for compliance to ISO 9001:2008. Issues raised by the external auditor have been addressed. Upon completion and integration of our National QMS a second external audit may be conducted.

Management is committed to continuously improving the Quality Management System and has taken appropriate measures to ensure its effectiveness and compliance to ISO 9001:2008.

Internal Audit

CIPO's Internal Audit program is headed by the Program Manager – Quality, and delivered by 18 professionally-trained internal auditors, representing all departments within the Patent Branch of the Canadian Intellectual Property Office.

The audit program includes an audit schedule for all processes of the Patent Office and provisions for impromptu audits at management request. Audits are performed annually for all processes within the Quality Management System for ISA/IPEA and on the Quality Management System itself to ensure compliance to requirements and effectiveness.

Internal auditors undertake intensive ISO quality audit training provided by a certified consulting firm. In addition, several auditors were further trained as lead auditors in order to conduct quality system audits.

a. 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.

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