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WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

ORIGINAL: ENGLISH
DATE: NOVEMBER 30, 2018 ~~DECEMBER 15, 2017~~

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by the 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.

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 9001:2015

Summary of 2018 Updates

In April 2018, CIPO successful passed its first ISO Surveillance Audit. The audit did not find any non-conformities or situations that could lead to a non-conformity if left uncorrected. Of the 10 comments in the report, 8 good practices and 2 opportunities for improvement were identified.

Also in April 2018, CIPO launched its Patent Quality webpage http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04378.html containing its quality policy, objectives and standards. The content on this page will continue to grow and develop over time.

CIPO started analyzing the Client Contact Database (CCD) data from the Client Service Centre and the Online Feedback Mechanism data at a more granular level to enable better corrective and/or preventive action where appropriate as well as to better identify opportunities for improvement within its processes.

CIPO conducted Employee and Client Satisfaction surveys. The final report from the CIPO 2018 Client Satisfaction Survey was publicly released on September 26, 2018 http://www.ic.gc.ca/eic/site/112.nsf/eng/home.

In October 2018, CIPO welcomed a new Director General of Patents, Virginie Ethier.

CIPO is currently finalizing its first internal Annual Quality Report (2018) which will facilitate management review and the external auditing process.

Finally, CIPO will be offering Patent Quality webinars ("Patent Quality Conversations") for our stakeholders early next year and will be hosting the first CIPO Patent Quality Summit in February 2019.

~~In June 2017, CIPO's Patent Branch obtained ISO 9001:2015 certification.~~

~~The internal audit program was expanded to include a larger certified internal audit team and the number of audits conducted was increased. A risk based approach also incorporated into the 3 year process audit schedule, ensuring that processes identified as higher risk are audited more frequently.~~

1. LEADERSHIP AND POLICY

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

(a) The quality policy established by top management.

(b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.

(c) An organizational chart showing all those bodies and individuals responsible for the QMS.

~~The Quality Policy of the Patent Branch of CIPO~~CIPO Patent Branch Quality Policy:

The Patent Branch is committed to ensuring a consistent client experience that delivers quality patent products and services in an efficient and timely manner, creating certainty in the marketplace and stimulating innovation.

The quality management system ensures:

- That our quality objectives are met;
- That national products and services adhere to the requirements of the Patent Act and Rules;
- That international products and services adhere to the Patent Cooperation Treaty and Regulations;
- A better understanding of clients' needs and expectations; and

- Continual improvement of our processes to meet expectations on quality, cost, and timeliness.

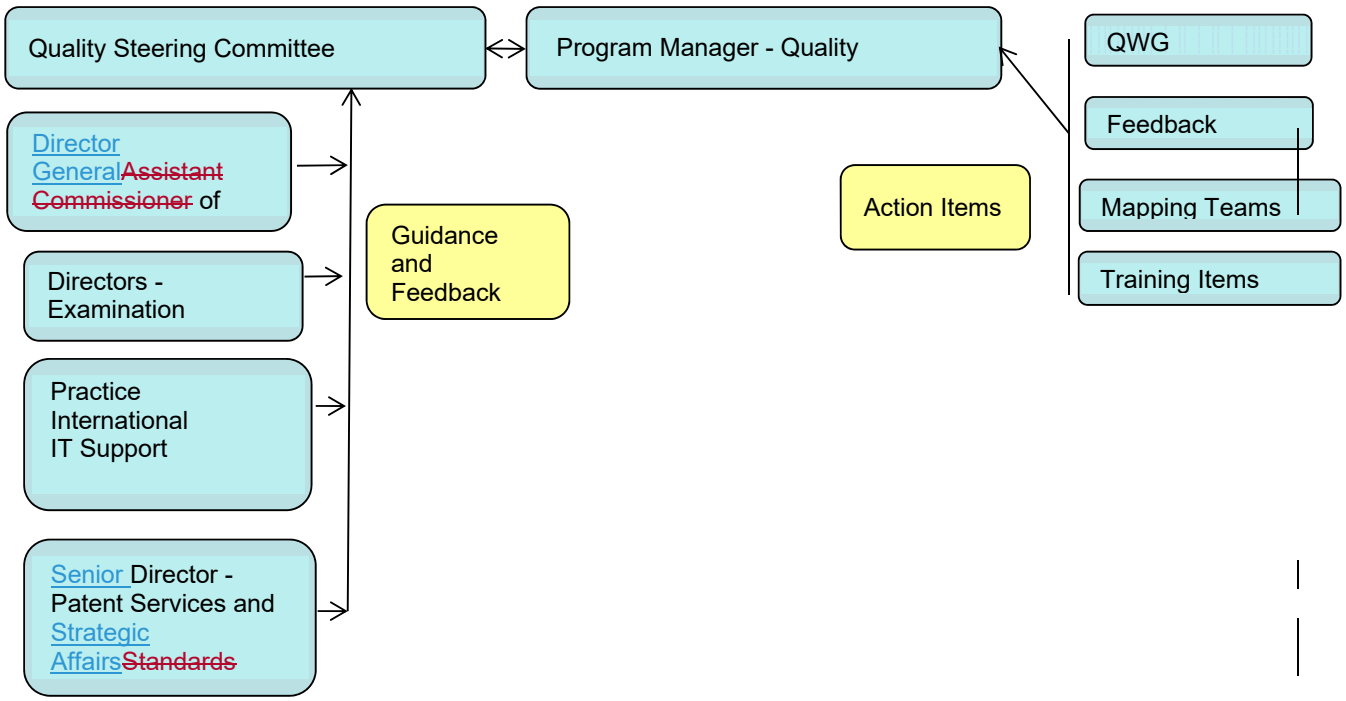
Responsible management of the quality management system assures oversight, strategic direction and stewardship fostering a culture of excellence, inclusiveness, employee engagement and development.

Our key quality objectives are:

- Quality
- Timeliness
- Efficiency

The Patent BranchCIPO's (PB) intranet (CIPOnet) contains a listing of all the organizational units responsible for the implementation of the quality management system. Responsibilities in the Patent BranchCIPO's 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 Directors group. In addition, the Quality Steering Committee is formed of the Patent Branch senior managers, including the Director GeneralAssistant Commissioner of Patents, Examination Division Directors, Senior Director - Patent Services and Strategic Affairsandards and the Director - Business and Strategic Affairs

QMS Reporting Structure



The Program Manager – Quality is a member and the chair 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 Director General Assistant Commissioner of Patents, and the Program Manager – Quality.

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.

Senior Director – Patent Services and Strategic Affairs Standards is responsible for all of Patent Branch operations, as well as being the direct manager of the Quality, Training and IT programs and the Business and Strategic Affairs group. This centralization allows for improved co-ordination between projects and resources.

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)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives throughout the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS in based on Chapter 21	✓		
			determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.24	✓		
		(e)	recording the results	✓		
21.10			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains tech. qualifications to S&E in all technical fields	✓		
		(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	for the documentation records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation accord. to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(b)	Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a)	Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(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	✓		
21.11	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(i)		Internal quality assurance system for self assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.14		(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	✓		
21.15	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	✓		
	(iii)		Clear and concise guidance on the S&E process for the user	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iv)		Indication where and how the Authority makes its quality objectives publicly available	✓		
21.16			Established communication with WIPO and designated and elected Offices	✓		
21.17			QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.18		(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	✓		
21.19	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		the documented processes are carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		a description of the interaction between the processes and the procedures of the QMS.	✓		
21.20	(i)		Records which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Evidence of conformity of processes	✓		
	(v)		Results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Record of data allowing individual work to be tracked	✓		
	(viii)		Record of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.21	(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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(v)		Recording of a listing of all search statements used in databases consulted	✓		
	(vi)		Records about other information relevant to the search	✓		
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.22			Report on its own internal review processes	✓		
21.23-21.25			Additional information on further inputs to its internal reviews	✓		
21.26			Initial report called for by paragraph 21.26	✓		

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 to 4 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 Ppatent Bbranch. 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 Director General of Patents continually raises our QMS objectives as a topic during regular meetings with employees and also through the monthly Patent Branch Newsletter. Further, all Patent Branch employees complete mandatory QMS awareness training yearly, which includes a review of the quality policy, objectives and how each employee fits with the Authority'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 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 the Patent Branch are analyzed and adjustments are made to ensure that appropriate resources are available.

(b)–(c) CIPOPatent 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. In addition to this, the quality objectives are published in the quality manual – available in the CIPO intranet – and posters stating the quality objectives are displayed throughout CIPO.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

(a) at least once per year (cf. paragraph 21.22);

(b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));

(c) in an objective and transparent way (cf. paragraph 21.22);

(d) using input including information according to paragraphs 21.24 (ii)-(vi);

(e) recording the results (cf. paragraph 21.25).

Internal review at PB CIPO 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 to four 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 current quality related documentation, such as quality standards, as well as any new quality related documentation.

In this manner PB CIPO provides a continual management review of the QMS, rather than as a single activity. This approach is considered more effective as the Patent Branch continuously

develops and improves its QMS and ensures the maintenance of its ISO 9001 certification. More frequent management input and review into the QMS is considered essential.

2. RESOURCES

21.10 Explanatory note: The granting of ISA/IPEA 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 below, should provide this assurance.

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff:

sufficient to deal with the inflow of work;

which maintains the technical qualifications to search and examine in the required technical fields; and

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.

(ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:

at a level to support the technically qualified staff and facilitate the search and examination process, and

for the documentation of records.

The Patent Branch has over 360 examiners trained to examine national and international examination. The examiners are divided over 5 examination divisions in the following numbers:

Division	Supervisors	Examiners
Mechanical	8	99105
General Chemistry	4	4844
Organic Chemistry	5	59
Electrical	9	101
BiochemistryBiotechnology	5	5957
		366

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 is ongoing targeted training and development available for all patent examiners and administration personnel throughout the year. CIPO's patent examiner continuous training program was outlined in an article entitled "The Canadian Patent Examiner Continuous Training Program" published in World Patent Information (Volume 39, December 2014, Pages 73-74). In 2016, CIPO put in place a Strategy for continuous training entitled "Continuing Education Strategy for Patent Examiners".

Examination staff's technical qualifications are maintained and monitored regularly by management. In 2017, the Patent Office put in place a Strategy for continuous training entitled "Continuing Education Strategy for Patent Examiners". In addition, a Learning and Development Plan (LDP) is created by each employee and reviewed by supervisors twice yearly. There is a series ofare mandatory training courses each that an employee is required to take during aevery year. , aAdditionally, employees can take extra courses for personal and professional development. Also, regular attendance at conferences and tradeshows related to an examiner's technical field is supported and encouraged by management. There is also the Patent Examination Technical Seminars (PETS) initiative, where the OfficeCIPO invites technical speakers to come and present their research in the Patent Branch, for the benefit of many examiners. Another initiative to enhance examiners' expertise is the introduction of industrial visits allowing examiners to visit industrial sites and perfect their knowledge. A comprehensive paper on Patent Branch's training program has been published and is entitled "Patent Examiner Continuous Training Program – A Framework" by Marc De Vleeschauwer. This paper as well as the Strategy for continuous training can be accessed at http://opicnet.ic.gc.ca/eic/site/487.nsf/eng/h_ne02056.html.

While Patent BranchCIPO 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 Policy and International Affairs division. This division is summarized below:

Division	**Work units**
Patent Policy and International Affairs	Manager – Patent Policy - 5 officers Program Manager - International (PCT-PPH) - 1 project coordinator Program Manager - International (IPC, CPC, VG) Program Manager - International (PLT, Group B+) Acting Program Manager - Examination Practice - 2 project coordinators

The Patent Examination division is also supported by Patent Services and Standards DivisionStrategic Affairs (PSSAD) Division. This division has over 140 130 employees distributed in several work units. The following table identifies the main work units (some are outside of PSSAD):

Incoming Correspondence Unit (ICU)	Outgoing Correspondence Unit
Formalities and Assignments	Maintenance fees and Agent Renewal Registry
Optical Character Recognition (OCR) zone	PCT (national phase entry)
Mail Room	PCT (international)

Patent Business Intelligence and Information Management Services (PBIIMS)	Examination support
Training	Patent IT Systems
Quality	

The PCT International Unit has highly skilled administrative personnel comprising one acting Section Head and 5 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.

CIPOPatent 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 and Sequence Listing.

Material resources:

(iii) Describe the infrastructure in place to ensure that appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

(iv) Describe the infrastructure in place to ensure that 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.

(v) Describe how instructions:

to help staff understand and adhere to the quality criteria and standards; and;

to follow work procedures accurately and consistently

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

(iii) In conjunction with the former Enterprise Solutions Branch (ESB), the Patent Branch has CIPO 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 BranchCIPO 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 MS Word 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.

The preparation of all correspondence is aided by the use of standardized paragraphs which are pre-programmed into each interface and developed in-house. The "Standardized Clauses" developed by the MIA were incorporated into the aforementioned paragraphs. This enhances the consistency of our international products and assists employees in efficiently preparing their work.

(iv) In addition to the Canadian collection being available electronically as well other IPOs' collections also being available online, patent examiners have access to one commercial patent database to support search and examination work. This database is Questel Orbit. CIPO entered into a contract with Questel in 2014. Questel meets the minimum patent document standards set out by the PCT and is available to the entire examination corps.

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, IEEE, GENESEQ and Scopus.

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

A master list of all internal and external documents is maintained by PB's the CIPO'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.

Patent Examination Quality Standards, including Quality Standards for National and International Patent Classification and International Search and Preliminary Examination, are published on the CIPO Patent Quality page as well as on CIPO's intranet. The Quality Standards are updated and reviewed yearly by the QSC.
In 2011, CIPO released quality standards for our then classification division. These standards define how the classification examiners:

- Facilitate the retrieval of Canadian patent documents through the use of the IPC,
- Contribute to the proper work flow of the office by assigning the First (F) symbol which is used for routing; and
- Contribute to the efficient operation of the Patent Office by making searches more efficient and reliable.

Training resources:

(vi) Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

acquire and maintain the necessary experience and skills; and

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 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 at least 6about 9 months, employees are given International Search and Examination training. After successful completion of these courses, the employees begin examining international applications within their art queuestechnical fields, under the supervision of the trainer and the section head. After one year in the office, employees take additional courses directed toward jurisprudence and advanced examination.

Additionally, for all employees, a Continuous Training Program is in place to encourage ongoing training throughout the year. Examiners are required to attend certain mandatory training, while being able to add extra optional training as they see fit. Examiners are encouraged to stay abreast of their technology areas through the training programs and initiatives. All examination related training matters are handled by the Program Manager - Patent Examination Training. In 20167, CIPOthe Patent Office put in place a Strategy for continuous training entitled "Continuing Education Strategy for Patent Examiners".

Within the continuous training program, examiners receive mandatory refresher ISA/IPEA training and all employees have access to the ISA/IPEA training manual online. This manual is regularly revised to keep current with CIPOPatent Branch's practice. Annotated forms, which provide examiners with information and concrete examples on how to complete the various ISA/IPEA forms, can be found on our intranet.

The ISA/IPEA training materials also provide instruction on what CIPOPB'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.

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

As discussed above, the computerized processing system InterApp serves as a system for managing the entire process of handling international applications. Within this system, CIPO 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 is given further training to ensure that there is always someone available to handle fluctuations in workload in Operations. WIPO-provided training is also requested when the need presents itself. Such training took place in the fall of 2018.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.11 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:

(i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and

(ii) 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 workloads 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.

4. QUALITY ASSURANCE

21.12 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, including the use of any checklists to verify reports before their issue or for monitoring the quality standard as part of a post-issue review process:

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) 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.

(iii) 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 CIPOthe 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 (ISR, WO and IPRPs). Quality of examination work is evaluated through two distinct formalized processes. The first is Quality Control (QC), which is an on-going activity that occurs during the

examination process. QC data is analyzed semi-annually and reports are presented to QSC. The second is Quality Assurance (QA), which happens subsequently and occurs during specified periods of time. The output of both these processes is a collection of statistical data which is analyzed quarterlyQA is performed and analyzed every 2 years.

Quality Ccontrol is performed by supervisors, who carry out reviews for adherence to established quality standards of search and examination by answering a standard set of questions. This control is randomly sampled at a minimum level of 1025%, 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/hertheir supervisor are corrected. Supervisors are responsible for ensuring that any systemic or major issues are reported to the appropriate authority. Examiners and supervisors have access to a history of all previous QC actions and can review them through an online database.

Supervisors were trained to conduct Quality Control on sampled ISA and IPEA reports using data collection questions in the International Quality Control and Quality Assurance Program. Each question measures conformity with the CIPO Quality Standards for International Examination. All identified non-compliance must be explained with a specific comment.

Quality Aassurance is performed by a single examiners on a sample of work which has already been completed by our internal processes and transmitted to our client(s). The QA occurs over a short period of time each quarter, so that data can be analyzed, root causes treated and training adjusted prior the next quarter's QA taking place. This is termed internally as a 'batch' approach and the QA and data analysis is repeated .every 2 years.

QA is done following a standardized method and permits sharing of expertise. QA examiners appraise the original examiners' decisions for adherence to the Patent Office's CIPO's search and examination standards. QA examiners are selected from each examination division for a given term and are given training., and mMembership is rotated to allow for involvement of all examiners in QA.
QA is sampled randomly at a minimum level of 10% of all examined ISAs, and data are collected for analysis and identification of areas of improvement. QA examiners are responsible for raising systemic or major issues warranting a corrective action to the appropriate authority.

The resultant QC data from both these processes is analyzed semi-annually and the resultant QA data is analyzed upon completion of the QA cycle. 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 6 categories consisting of 31 criteria that are applied to each application under review. The categories are search strategy and examination notes, search restrictions, ISR and WO-ISA formalities, novelty, inventive step and industrial applicability, observations Box No. VII and Box No. VIII of WO-ISA, and timeliness. 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 QC data analysis are presented to the Quality Steering Committee every 6 months. Reports and recommendations on QA data analysis are presented to the Committee after each QA cycle.

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 CIPO 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 PB Quality Team or International (PCT-PPH) which evaluate 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.

(a) All Quality Standards are reviewed and updated annually.

(b) An update to the system of measurement and collection of quality data from CIPOPatent Branch's examination division has been implemented. This update improves the questions which are used to collect data for our QC and QA activities based upon earlier data analysis. Improvements include streamlining questions, removal of low error rate topics, expanding other questions to include more varied possible responses. Additionally, new features allow staff to have better access to results of QC and QA carried out on their work.

(c) A new checklist was added to InterApp for Chapter I applications to remind examiners to double check a few important items in their CIPO Examination Notes, ISR and WO-ISA before QC and/or mailing. The checklist focuses on the most common errors and omissions reported in the CIPO Quality Assurance (QA) exercise completed in 2016. Examiners use this checklist as a reminder to double check certain aspects of their work and ensure that the work submitted conforms to quality standards. Analysis of recent QC data indicates that the checklist has been successful at lowering non-conformance rates in many of the related categories.

5. COMMUNICATION

Inter-Authority communication:

21.13 Explanatory note: Each Authority should provide for effective communication with other Authorities.

(Note: This point is informative. No response is required by the template to paragraph 21.13)

21.14 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)

Marie Quinn, P. Eng., Patent Branch Program Manager for Quality.

Patent Standards and Strategic Affairs Division
Contact details:

Marie Quinn, P. Eng
Program Manager, Quality
Canadian Intellectual Property Office
Industry CanadaInnovation, Science and Economic Development
50 Victoria Street, Gatineau QC K1A OC9

Marie.Quinn@canada.ca
Telephone 819-635-8532
Facsimile 819-994-1989
Government of Canada

(a) This is the joint responsibility of the Program Manager for Quality: Marie Quinn (see contact info above) as well as theand (c)

Elaine A. Hellyer, P. Eng., Program Manager - International (PCT-PPH): Elaine A. Hellyer (see contact information below).

Elaine A. Hellyer, P.Eng.
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Communication and guidance to users:

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

(i) An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and

offering feedback to users.

(ii) A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

(iii) 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.

(iv) An indication of where and how the Authority makes its quality objectives publicly available for the users.

(i) Client complaints are handled directly via the CIPO Cclient Sservice Ccenter (CSC), where customers can directly speak with a CIPO representative, using 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. This 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.

CIPO has started analyzing the Client Contact Database (CCD) data from the CSC and the OFM data at a more granular level to enable better corrective and/or preventive action where appropriate. This analysis is performed semi-annually.

As described above, the corrective action/preventative action program is available to employees. This program uses an internal issue tracking software JIRA. JIRA permits non-conformities to be identified and tracked systematically and routed to the appropriate resource and it is in wide use throughout CIPOPatent Branch.

(i) CIPO 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.

(ii)

(iii)(ii) A joint consultation committee between CIPOPatent Branch management and Intellectual Property Institute of Canada (IPIC) patent agents, the Patent Practice Committee CIPO-IPIC (2PC), 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 2PC.

On December 1, 2015 the Patent Branch launched an ongoing Patent Evaluation Survey to our clients. This survey collects data on client's perception of quality and timeliness of service as well as inviting them to compare the work of CIPO to other IPOs. Finally, the survey gathers information on client's awareness of CIPO's OFM and on the responsiveness of PB employees to phone inquiries. Clients will be are invited to participate in the survey whenever receiving national examination actions such as examination reports or notices of allowance. The QSC willThe Patent Branch analyzes the results of the survey regularly and act on the necessary changes. The high level results of client responses are expected to be relevant to international practice as well.

In 2018, CIPO conducted Employee and Client Satisfaction surveys. The final report from the CIPO 2018 Client Satisfaction Survey was publicly released on September 26, 2018 http://www.ic.gc.ca/eic/site/112.nsf/eng/home. CIPO is currently putting together an action plan to address any concerns or opportunities for improvement that have been identified. These surveys will be repeated every 3 years.

(iv)(iii) 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.

(v)(iv) CIPOPatent Branch will published its quality objectives externally on CIPO's Website in Aprilearly 2018 on its new Patent Quality page http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04378.html.. The objectives are also available internally for employees on our intranet and in our Quality Manual. Additionally, CIPOPatent Branch has publishedpublishes its Quality Standards for International Search and Preliminary Examination on theour Quality Pagewebsite for all users to access. These standards are broken in to sixfour sections: Subject matter, Search, Application Formalities, 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 these standardse 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.

21.16 Communication with WIPO and designated and elected Offices:

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

The Ppatent Bbranch Program Manager - International (PCT-PPH) 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 Program Manager - International (PCT-PPH) 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.

6. DOCUMENTATION

21.17 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 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

21.18 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) A Qquality Mmanual that takes into account Chapter 21 of the guidelines of the PCT and ISO 9001:2015 requirements has been prepared and distributed to patent employees. The manual provides an overview of the quality policy, quality objectives, quality initiatives, organizational roles, responsibilities, and authorities. The manual is a working document and will beis updated when changes to the Quality Management System are planned and implemented.

(b) The Quality Manual is published in CIPO's intranet and can be accessed by all staff.

(c) Documents such as mappings, work instructions for all international examination processes, international quality standards, quality control criteria and guidelines, data collection and analysis are subject to version control (including version numbering and revision schedules) and are assigned a document owner who assumes responsibility.

In addition to the Quality Manual, the CIPO's Intranet for Patent Branch contains a dedicated Quality Section which is updated with the majority of the documents which are presented in our Quality Manual.

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

(i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;

(ii) the scope of the QMS, including details of and justification for any exclusions;

(iii) the organizational structure of the Authority and the responsibilities of each of its departments;

(iv) 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;

(v) the resources available for carrying out the processes and implementing the procedures; and

(vi) a description of the interaction between the processes and the procedures of the QMS.

The Quality Manual contains:

(i) aA clearly articulated quality policy as well as the quality objectives of Patent Branch;.

(ii) tThe scope of the QMS;.

(iii) The quality manual contains a description of the CIPO/PB management team and descriptions of the roles of all the groups associated with the Quality Management System;.

(iv) references to the documented processes All processes and procedures within the PCT International operations and examination units. These processes and procedures 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. In 2011, these mappings were expanded to include all classification processes. This project was completed in 2016, and all processes in Ppatent Bbranch related to the processing of patent applications and grants for national and international examination are now documented and updated bi-annuallyevery 2 years;.

(v) the resources available for carrying out the processes and implementing the procedures. 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. In 2014 an extensive project was launched to map all of operations support processes. The operations support processes have now been mapped and are reviewed on a bi-annual basisevery 2 years; and.

(vi) a description of the interaction between the processes and the procedures of the QMS. The Patent Branch has determined the processes and procedures needed for the quality management system and their application throughout the organization to generate the necessary products and services. For each process, the Patent Branch has documented the mappings and work instructions for the sub-processes within said process to describe the interactions between the processes and the procedures. The inputs required and the outputs expected from each sub-process are indicated in the Process Definition section of the cover page of the mappings. The sequence and interactions of the processes and their sub-processes are based on the workflow as defined in TechSource (national applications) and InterApp (international applications). Additionally, the mappings and work instructions define the tasks, sequence of tasks, inputs, and outputs for a given sub-process

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

(i) a definition of which documents are kept and where they are kept;

(ii) results of management review;

(iii) training, skills and experience of personnel;

(iv) evidence of conformity of processes, resulting products and services in terms of quality standards;

(v) results of reviews of requirements relating to products;

(vi) the search and examination processes carried out on each application;

(vii) data allowing individual work to be tracked and traced;

(viii) records of QMS audits;

(ix) actions taken re. non-conforming products, e.g. examples of corrections;

(x) actions taken re. corrective action;

(xi) actions taken re. preventative action; and

(xii) search process documentation as set out in Section 7.

(i) As discussed above, CIPOPB maintains a database of all controlled documents, with revision history and document owner. All documents are now stored in an Information Management (IM) system, the Canadian government's new content management solution, which has replaced the use of shared drives to significantly improve the way the government manages electronic records. All official documents intended to be shared internally are stored on the PBCIPO's intranet. 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 also stored on the IM systemour network server.

(ii) See (i).

(iii) All employees of the Patent Branch have a Learning and Development Plan (LDP). 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 LDPs are archived to build a learning history for each employee.

(iv) Conformity of processes to our standards are recorded in the Patent Branch's Internal Audit results.

(v) Quarterly Quality Control/Quality Assurance results are stored on our network drive in an Access database and in the IM system and analysis is performed semiannually for QC and every 2 years for QA.

(vi) 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 must store search strings and search histories in this file. An update in December 2012 improved this search record. Greater clarity was introduced into the form and more detailed search information is now captured.

a. In 2013, CIPO began publishing search records with our ISR/WOs. These published records can be found on PatentScope.

(vii)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.

~~(vii)~~(viii) In 2018~~5~~ an updated ~~revised~~ audit template was approved by the QSC and all audit results are now stored ~~with the lead auditor and the Program Manager, Quality~~in the IM system. All audit documentation, including tools, templates and reports, are available internally to employees on the internal wiki page.

~~(viii)~~(ix), (x) and (xi) All non-conformities, corrective and preventative actions are tracked and logged through the same online interface.

(xii) This was discussed above in (vi).

7. SEARCH PROCESS DOCUMENTATION

21.21 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:

(vi) limitation of search and its justification

(vii) lack of clarity of the claims; and

(viii) 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 databases, keywords (in each language searched) and classes used. Examiners must also populate the forms with search histories and search strings as appropriate. The form is saved and stored with the international application.

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.

In December 2012, CIPO updated this search record to make some improvements and necessary changes. The new search record has greater structure and clarity and makes the storage of search strings mandatory.

In the interest of saving examiner time, some fields were removed from the search record. This included:

Closest Prior Art: There is no longer a requirement for the examiner to make a record of the closest prior art. This was removed because a similar discussion was already captured in Box V of the WO.

Stopping Search: There is no requirement for the examiner to document the rationale for stopping the search. Over time, this field was found to be unnecessary as the reasons for stopping the search typically broke down under either ' relevant art found for all claims ' or 'time/search strategy exhausted'. These reasons can be readily assumed by a review of the rest of the search record and the ISR and WO.

In 2013, the search record was amended as stated above to become a more thorough record of search activities undertaken. These records are included with the ISR and WO on PatentScope.

8. INTERNAL REVIEW

21.22 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.

21.23-21.25 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 the Qquality Mmanual, examination standards, QC/QA tools, as well as training manuals and support documentation. Furthermore, internal process and system audits are carried out within Patent BranchCIPO twice yearly (once a year for process audits and once a year for systems audits) according to a 43 year calendar and in which PCT processes are inspected for conformity with established procedures. Corrective and Preventative actions are taken throughout the year as issues are raised and when identified in the audit findings.

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

In 2008, the Patent Branch hired an external auditor to carry out the audit of the ISA/IPEA Quality Management System for compliance to ISO 9001:2008. Issues raised by the external auditor were addressed. Upon completion and integration of our National QMS a second external audit was conducted. In 2014, an ISO Gap analysis was conducted on the whole of CIPO (including ISA/IPEA QMS) and confirmed that progress toward ISO 9001:2008/2015 in Patent Branch has been good. In MarchJune 2017, CIPO Patent Branch obtained ISO 9001:2015 certification. This rigorous process of ensuring conformity amounts to an annual review of our management system, and will be repeated annually to ensure that the branch maintains certification. The next external audit, an ISO 9001:2015 A1 surveillance audit, will be conducted in March 2018.In April 2018, CIPO successful passed its first ISO Surveillance Audit. The audit did not find any non-conformities or situations that could lead to a non-conformity if left uncorrected. Of the 10 comments in the report, 8 good practices and 2 opportunities for

improvement were identified. The next external audit, another surveillance audit, will take place in March 2019.

Management is committed to continuously improving the Quality Management System and, has taken appropriate measures to ensure its effectiveness, and the maintenance of its ISO 9001 certification.

Internal Audit

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

The audit program includes an audit schedule for all processes of the Patent Office Branch and provisions for impromptu audits at management request. The process audit schedule was updated and approved by QSC in 2017 to include a risk-based approach, increasing the frequency of audits for processes identified as higher risk. Process audits are performed annually according to a 43 year schedule for all processes within the Quality Management System for ISA/IPEA. These process audits focus on assessing the adequacy and awareness of the processes and of the relevant documentation and controls. They include a review of all relevant statistics and QC data, a review of all relevant documents, a review of the processes themselves and a SWOT (strengths, weaknesses, opportunities and threats) analysis. System audits are performed annually on the Quality Management System itself to ensure compliance to requirements and effectiveness. Risks and opportunities for improvement are also identified and appropriate follow-up is conducted.

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 and/or lead the process audits.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

[End of document]