WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

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)

> *In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.*
>
> *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. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.*

Normative reference for QMS: ISO 9001:2015

202~~3~~2 Highlights

In March 202~~3~~2, CIPO was successful in its ISO 9001:2015 ~~Surveillance~~ Recertification Audit. No nonconformities were found in the audit. CIPO will have a ~~recertification~~ surveillance audit in ~~March~~ April 202~~4~~3.

Further, in March 2023, the new position "Deputy Director – Training, Quality and Service" was created. This position provides leadership and strategic direction for the continuous modernization, business transformation as well as process and service delivery improvements to enhance training, quality and service excellence initiatives for the branch. The QMS Reporting Structure has been updated

In April 2023, a new initiative whereby ePCT is consulted to identify applications with an ISR/WO-ISAs due in the next week or two was started. These are then verified in our InterApp system and either the Section Head of the examiner responsible for the report is contacted or, if an internal error is found, the error is fixed and the examination is accelerated. This system has led to a big improvement in timeliness at CIPO.

The Quality Control (QC) questions that CIPO uses in the QC of both Chapter I and Chapter II ~~reports~~ search and examination products were reviewed and ~~will be~~ updated in October 2023. Concurrently, the international QC tool used by Section Heads to enter the QC data was also updated.

Mandatory ~~R~~refresher ISA/IPEA training for Examiners and Section Heads have been prepared and will ~~take place~~be completed early 202~~4~~3. The training will consist of a series of six pre-recorded videos. Additionally, ~~an annotated form of the examination notes has been posted with the other~~ ISA/IPEA annotated forms as well as the ISA & IPEA Training and Reference Manual have been updated.

The launch of our Next Generation Patents (NGP) system will take place in 202~~4~~3. This system comprises a new client interface as well as a new employee system for National applications, replacing TechSource. Incorporating international processes into NGP will occur in a later phase.

1. LEADERSHIP AND POLICY

<div style="background-color: yellow">

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 specified by top management.*
>
> *(c)   An organizational chart showing all those bodies and individuals responsible for the QMS.*

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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

CIPO's Patent Branch quality policy and key quality objectives can be found on the CIPO Patent quality page (https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04378.html). Additionally, the quality policy and objectives can be found under Quality Management on the intranet (CIPOnet). The Quality Manual, also available on the intranet, contains the quality policy, the key quality objectives and more detailed/specific objectives that fall under the key quality objective categories.

CIPO's intranet (CIPOnet) contains a listing of all the organizational units responsible for the maintenance and continuous improvement of the quality management system. Responsibilities in CIPO'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~~The Patent Management Committee (PMC) is formed of the Patent Branch senior managers, including the Assistant Commissioner and Director General of Patents, Examination Division Directors, Director - Business and Strategic Affairs, Director - Patent Policy and International Affairs, Senior Director - Patent Services and Strategic Affairs, Deputy Director – Patent Training, Quality and Services, and Chair - Patent Appeal Board.

QMS Reporting Structure
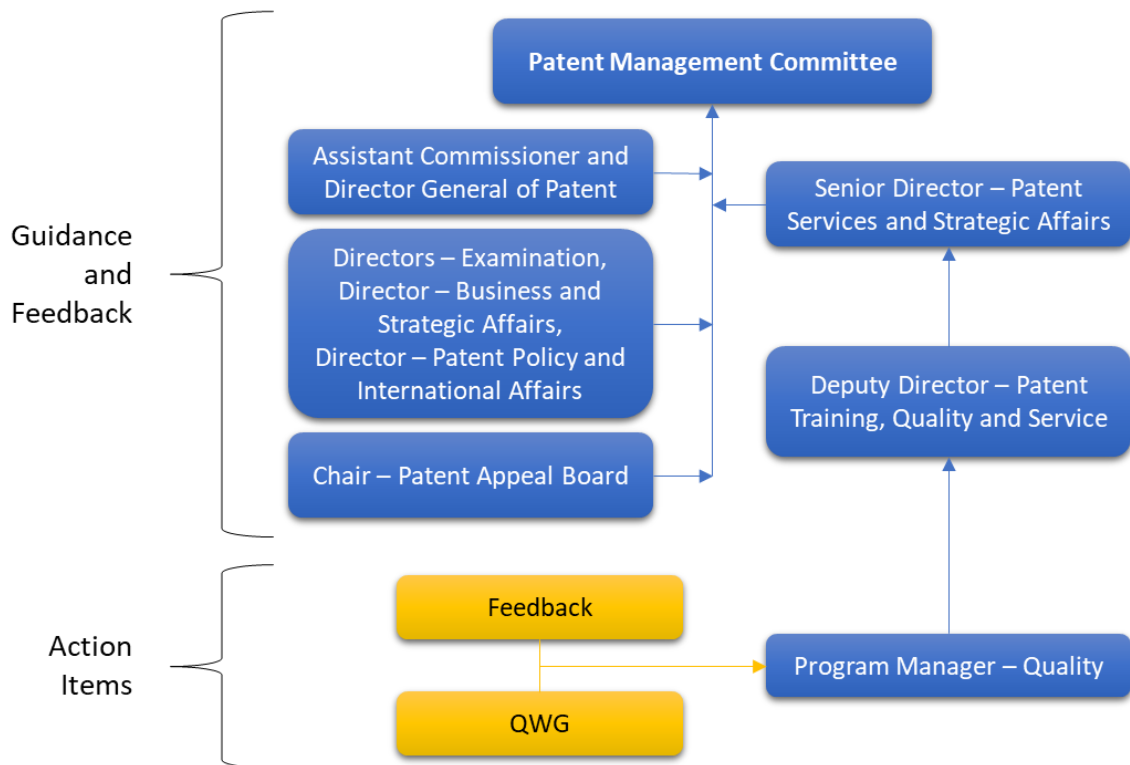
The Patent Management Committee (PMC) is responsible for directing the maintenance and continuous improvement of the Quality Management System. It sets priorities, allocates resources and tasks, and ensures that project timelines and objectives are met. In addition, it sets and monitors quality targets. The PMC is formed of senior management of the Branch, including the Assistant Commissioner and Director General of Patents.

Senior Director – Patent Services and Strategic Affairs 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.

Deputy Director – Training, Quality and Service is a position that was created in March of 2023 with the aim of better preparing Patent Branch for ongoing and upcoming modernization initiatives and in view of leading Patent Branch towards a more agile, client centered organization that will better support Patent Branch's ability to deliver on its priorities: our people, our clients and innovation. This position provides leadership and strategic direction for the continuous modernization, business transformation as well as process and service delivery improvements to enhance training, quality and service excellence initiatives for the branch.

The Program Manager – Quality is responsible for the maintenance 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 Manager brings quality-related items to the Patent Management Committee on an as-needed basis. The Manager also presents the Annual Patent Quality Report to the PMC.

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. This group also contributes to quality-related projects and initiatives. The Group is formed by Section Heads and Examiners from each Examination Division as well as representatives from Operations and Patent IT. It is chaired by the Program Manager – Quality.

The Operations Mapping Team used to form a part of the Quality Team but in an effort to improve the efficiency of Operations process mappings, the Operations Mapping Team has been moved to the Operations group. This allows mapping officers a better understanding of how operations processes are being conducted and to update information in a more timely fashion. **Mapping Teams** include an Examination Mapping Review Group (EMRG) and an Operations Mapping Review Group (OMRG). The OMRG consists of mapping officers in the Operations sector. There is one mapping officer for each of the main Operations area. The second **Mapping Team**, the **Examination Mapping Review Group** (EMRG) led by the Practice Team, creates and/or updates mappings (process flows) and work instructions for the national and international examination and classification processes. The EMRG consists of examiners and supervisors (Section Heads), one of which is the chair. Members are replaced with other examiners and supervisors periodically and/or as needed. All operations and examination/classification mappings are created in MS Visio and their associated work instructions are created in MS Word. The mappings and work instructions are then combined into pdf documents that are then placed on CIPO's intranet (CIPOnet).

> *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 to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) comply with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according to paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			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 technical 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	✓		
		(b)	for the documentation of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b)	Instructions to follow work procedures accurately and they are kept up-to-date.	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(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, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(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	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of 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)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. nonconforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(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	✓		
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews	✓		
21.31			Initial report called for by paragraph 21.31	✓		

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 Patent Management Committee (PMC). This committee meets weekly. The Deputy Director – Training, Quality and Service attends the PMC on a regular basis. Quality-related items are brought to PMC monthly or on an as-needed basis by the Program Manager – Quality in order to review the progress of the quality program, define priorities, approve documents and discuss quality-related issues.

    (b)   The Program Manager – Quality ensures that the process of continual improvement progresses throughout the Patent Branch. This individual chairs the Quality Working Group, tables issues for the PMC and follows up on quality initiatives to ensure that they are progressing as expected. The Program Manager has the strategic role of maintaining and continually improving quality at PB and recommends what priorities should be done.

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 and Director General of Patents continually raises our QMS objectives as a topic during regular meetings with employees. Further, new 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 as part of the onboarding program. The QMS awareness training is also available to all PB employees who are invited to consult it periodically.

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 by the relevant staff at the respective Authority.

(a) The senior management of CIPO meets annually to update the 5-year strategic plan (https://ised-isde.canada.ca/site/canadian-intellectual-property-office/sites/default/files/attachments/2023/CIPOCS-1884_Business_Strategy-eng.pdf) 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) CIPO 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 midyear 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 21.27-21.30:

(a)   at least once per year (cf. paragraph 21.27);

(b)   in accordance with the minimum scope of such reviews as set out in Section 9, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

(c)   in an objective and transparent way (cf. paragraph 21.27);

(d)   using input including information according to paragraphs 21.29 (ii)-(vi);

(e)   recording the results (cf. paragraph 21.30).

Internal review at CIPO does not take place as one central activity but is distributed around many yearly activities. The Patent Management Committee (PMC) is composed of Patent Branch's top management and this committee meets weekly. Quality-related items are brought to PMC on an ~~monthly or~~ as-needed basis. A once-a-year review of the entire QMS is performed. This review includes a review of corrective and preventative action requests, customer feedback, recommendations (both internal and external), QC results and internal audit data (a measure of effectiveness). The PMC also approves all revisions to current quality-related documentation, such as quality standards, as well as any new quality-related documentation as required.

In this manner 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 are considered essential. The output of management reviews include decisions and actions related to opportunities for improvement, any need for changes to the quality management review and resource needs.

> *21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.*

Top management at CIPO promotes practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

2.   RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

(i)   (a) understand issues that affect its ability to achieve intended results of the QMS, and

(b) understand the needs and expectations of interested parties;

(ii)   identify risks and opportunities related to the performance of the QMS as a basis for planning;

(iii)   plan and implement actions to address risks and opportunities;

(iv)   check the effectiveness of the actions taken; and

(v)   continuously update risks and opportunities.

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

(i)

(a) To understand issues that affect its ability to achieve the intended results of the QMS:

The Patent Branch uses a variety of tools and methods to understand the organization and its context. The primary tools for this are CIPO's Business Plans and CIPO's Five-Year Business Strategy. The business plans outline the initiatives and activities that will position the organization to deliver on the priorities established in the Business Strategy. The Business Strategy takes into consideration external and internal factors such as regulatory, legal, technological, market, international, and national. The Business Strategy is widely consulted throughout government and by clients and stakeholders. CIPO's Risk Management plan includes Patent Branch's risks and proposed mitigation strategies.

The Patent Branch does further analysis during strategic planning sessions. The sessions are an opportunity for senior management to evaluate the branch, in light of the issues and trends raised and to identify risks and opportunities for action. Documentation of strategic planning retreats at the branch and corporate level is maintained.

The Patent Branch Quality group continually evaluates the ability of the Quality Management System to achieve its intended results. This takes the form of weekly or

biweekly meetings where progress is monitored, shortcomings are discussed, and solutions are brainstormed.

(b) To understand the needs and expectations of interested parties:

There are several channels through which the Patent Branch determines the needs and expectations of interested parties. This includes:

- Ongoing National customer satisfaction survey "Patent Product Evaluation"
- 2019 Patent Quality Summit
- CIPO Patent Quality Conversation webinars
- Patent Practice (2PC) meetings with agents
- Online Feedback Mechanism (OFM)
- Internal Feedback Mechanism – Great Ideas Database (GID)
- CIPO's Public Service Employee Survey (PSES)
- CIPO Service Excellence Employee Survey
- CIPO Client Satisfaction Survey
- Industrial Training Visits (ITV)
- IT Modernization (ITM) Usability Testing and User Acceptance testing
- National Entry Request (NER) online solution questionnaire
- Patent quality metrics page and CIPO Quality Dashboards – questionnaires

The ITV program was initiated in Patent Branch in 2018 to provide examiners with technical training in their art through on-site visits with Canadian companies. The first ITV took place in October 2018, which saw several examiners from the Mechanical division visiting Toronto-area companies involved in medical technology research. It allows the office to build partnerships with companies. Industrial Training Visits which had been put on hold because of the pandemic, are once again available.

In 2022, the Great Ideas Database (GID) was launched, replacing the existing internal feedback mechanism "The Patent Branch Suggestion Box". It is a new employee feedback mechanism that makes it easier to capture employees' great ideas and innovative suggestions regarding patents. It is a repository of great ideas and suggestions that is simple to use and accessible to all employees.

Service Level Agreements (SLAs) are also used to determine the expected quality and timeframe to process requests from providers, allowing the Patent Branch to establish clear service standards.

CIPO has service standards which are communicated to our stakeholders and performance targets for our internal management.

(ii) to identify risks and opportunities related to the performance of the QMS as a basis for planning:

CIPO identifies risks and opportunities through project activities, through submissions to the PB Suggestion BoxGreat ideas Database, through annual Internal and External Audit Program activities or via interactions with interested parties. Risks may come to light as issues with processes, training, human resources, policy, IT, office practice or quality. These topics are raised at various PB management committee meetings.

The Patent Branch documents risks and opportunities on a continuous basis using a variety of mechanisms. Risks and opportunities identified through internal audit activities are recorded in individual audit reports and the Internal Audit Summary Report. IT projects generally document risks in project risk registers, project charters and in project close out reports. Finally, risks may also be recorded in PMC, Patent Practice Committee (2PC), and Patent Policy Practice Committee (3PC) meeting minutes.

Corporate and branch risk profiles and registers are maintained.

(iii) to plan and implement actions to address risks and opportunities:

Risks are reviewed and actioned by PB management governance committees on a continuous basis as opposed to annually. For example, risks identified through quality projects are reviewed and actioned regularly by the quality team. The PMC reviews and assigns action items for risks identified during annual internal audit activities and these are reviewed by the PMC. Any non-compliances, non-conformities and/or opportunities for improvement identified in the internal audit are kept in a master sheet along with actions taken to address each. Risks are further prioritized in the audit report based on identified impact and probability. IT project risks are reviewed and actioned monthly at project meetings and project governance committee meetings. Risks associated with practice are addressed at the Patent, Policy and Practice Committee.

Risks identified in the corporate risk profile are reviewed annually at PMC and quarterly at the corporate level Senior Executive Committee. In all cases, depending on the nature of the risk (the probability, impact and proximity), appropriate mitigations are put in place and incorporated into the mitigation strategy. In addition, projects are prioritized in consideration of the risks identified.

This approach of continually identifying, reviewing and updating its risks and opportunities allows the Patent Branch to immediately apply the lessons learned from its previous actions to address risk and opportunities.

Identification and mitigation of risks may lead to improvements in processes. This could include small changes, requiring only notification or minor training updates, or they could be large changes requiring new processes, or large end to end Continuous Improvement projects.

Opportunities are addressed by collecting information, benchmarking against other IPO offices, conducting pilot projects to explore possible benefits or launching Business Improvement projects to improve performance of an entire value stream. A PB Performance Improvement Plan is maintained.

The QMS documents the risks and opportunities in the form of strategic considerations in project close out reports. These reports generally identify what went well, what needs to be changed, and provide a framework for lessons learned moving forward. Hence, the reports act as an inventory of lessons learned and are consulted prior to commencing a similar project in the future.

The QMS plans actions to address risks and opportunities. The plan includes escalating the risk or opportunity to the relevant authority such as the ~~Project Manager,~~ Program Manager - Quality, Deputy Director - Training, Quality and Service or ~~Supervisor~~Senior Director. The relevant authority collects information on the identified threat or opportunity such as who raised the risk, when it was raised, category of risk, description of the risk, impact of the risk, possible response to the risk and risk action.

The actions on the risks and opportunities are integrated and implemented in the Quality Management System processes. For instance, as described above, the risk or opportunity is diverted to a management group specializing in said risk or opportunity. This ensures that the information related to the threats and opportunities is communicated both within the project and externally to stakeholders.

(v) check the effectiveness of the actions taken:

Risks identified in the corporate risk profile are reviewed annually at PMC and quarterly at the corporate level Senior Executive Committee. In addition, the mitigation strategy is reviewed in order to assess whether risks have been properly addressed and/or mitigated.

The risks identified through internal and external audits are reviewed regularly. The actions taken to address the risks are assessed for effectiveness in the next internal and external audit. If the action taken did not fully address the risk, the remaining risk will be identified and reprioritized in the audit report.

Following the implementation of a project, a review of what went well, what did not go well, what opportunities were sized upon and what opportunities were missed is done by all involved it the project. Through this activity, lessons learned are then captured to improve and inform further project planning.

(vi) to continuously update risks and opportunities:

Top management continually determines and addresses the risks and opportunities that can affect the conformity of products and services and the ability to enhance customer satisfaction.

Risks and opportunities are updated as well through regular audit activities.

A Patent Branch Risk Profile is maintained.

3. RESOURCES

The Patent Branch has over 400 examiners trained to examine national and international applications. CIPO is in the process of hiring additional patent examiners.

The examiners are divided over 5 examination divisions in the following numbers:

Division	Supervisors (Section Heads)	Examiners
Mechanical	9	131~~120~~
General Chemistry	4	~~53~~56
Organic Chemistry	5	6~~80~~
Electrical	9	113~~5~~
Biotechnology	5	70~~68~~
Total	32	43~~816~~

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 patent 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 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 addition, a Learning and Development Plan (LDP) is created by each employee and reviewed by supervisors twice yearly. There are mandatory training courses that an employee is required to take every year. Additionally, 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 CIPO invites technical speakers to come and present their research 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.

While CIPO accepts both French and English patent applications, 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 are 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
	    • 6~~7~~ Policy Officers
	    •
	
	~~Acting~~ Program Manager - International ~~(PCT-PPH)~~
	    • 1~~2~~ Project Coordinator
	    •
	
	Program Manager - International (PPH)
	    • 1 Project Coordinator
	
	Program Manager - International (IPC, CPC, VG)
	
	Program Manager - International (PLT, Group B+)
	~~1 Acting Project Coordinator~~
	
	Program Manager - Examination Practice
	    • 3~~2~~ Project Coordinators

The Patent Examination division is also supported by Patent Services and Strategic Affairs (PSSA) Division. This division has approximately 120 employees distributed in several work units.

The following table identifies the main work units (some are outside of PSSA):

Incoming Correspondence Unit (ICU)	Outgoing Correspondence Unit (OCU)
Formalities and Assignments	Maintenance Fees and Agent Renewal Registry
PCT (international)	PCT (national phase entry)
Mail Room	Desktop Publishing

Patent Business Intelligence and Information Management Services (PBIIMS) & Patent IT Systems (PITS)	Examination Support
Quality	Training

The PCT International Unit has highly skilled administrative personnel comprising one Team Leader and 6 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.

CIPO 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, 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), CIPO developed a modern and efficient system entitled InterApp to handle the prosecution of international applications electronically. Two of the main modules are a workflow management system, and a document management system. The document management system permits CIPO 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. Clients have the option to retrieve the documents in electronic format via Canada epost Connect™. epost Connect is a digital delivery platform that facilitates sending and receiving

confidential messages and documents with one or multiple recipients. It enables seamless, secure collaboration with clients through one common platform.

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, which was renewed in 2020. Questel meets the minimum patent document standards set out by the PCT and is available to the entire examination corps. CIPO maintains many branch-specific tools to supplement searching such as GenomeQuest and STN.

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. In 2019, the database was migrated to an enterprise search platform which enhanced search capabilities. CIPO's non-patent literature (NPL) 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. Specifically developed for CIPO is a library Discovery Tool which can be used to search many non-patent literature e-resources at once. Our NPL collections also meet the PCT Minimum Documentation.

(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's intranet in both English and French. These publications are all assigned to an owner and follow CIPO's procedure for control of documents for updates.

Documents are stored in an Information Management (IM) system (GCdocs), the Canadian government's content management solution, which has replaced the use of shared drives to significantly improve the way the government manages electronic records. GCdocs ensures the identification and description of documented information by the use of metadata that is self-generated by the GCdocs system, i.e., date, author, format and a unique identification number. GCdocs also facilitates version control. An Information Management (IM) Analyst provides GCdocs support and guidance for Patent Branch.

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 as required by the PMC.

> *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 about 9 months, employees are given International Search and Examination training. After successful completion of these lectures, the employees begin examining international applications within their technical 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 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 - Training. In 2016, CIPO put in place a Strategy for continuous training entitled "Continuing Education Strategy for Patent Examiners".

As mentioned above, 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 CIPO invites technical speakers to come and present their research for the benefit of many examiners. Another initiative to enhance examiners' expertise is the ~~introduction of~~ industrial training visits program allowing examiners to visit industrial sites and perfect their knowledge.

~~Exceptionally during~~Since the COVID-19 pandemic, all patent examiner training has been offered virtually. Both the qualification and continuous training programs have continued to be offered to examiners virtually, mostly utilizing MS Teams as a training platform. Examiners have also been communicated various scientific seminars and conferences, which are open to the public and accessible online, to maintain their technical training.~~, while~~ Ttradeshows, PETS and Industry visits, which hadve been put on hold because of the pandemic ~~until in-person training and visits become available again~~, are once again available.

Within the continuous training program, examiners receive mandatory refresher ISA/IPEA training and all employees have access to the ISA/IPEA training and reference manual online. This manual is regularly revised to keep current with CIPO's practice. Annotated forms, which provide examiners with information and concrete examples on how to complete the various ISA/IPEA forms and well as CIPO Examination Notes including search details, documentation and strategy, can be found on our intranet.

The ISA/IPEA training materials also provide instruction on what CIPO'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 these 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 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 who are part of the same examination "pool", which includes a section of IPC codes that represent an area of common subject matter. This allows Section Heads of their sections to manage temporary fluctuations in work load or employee availability.

In 2023, a new initiative whereby ePCT is consulted to identify applications with an ISR/WO-ISAs due in the next week or two was started. These are then verified in our InterApp system and either the Section Head of the examiner responsible for the report is contacted or, if an internal error is found, the error is fixed and the examination is accelerated. This system has led to a big improvement in timeliness at CIPO.

In order to ensure that the 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.

4.   MANAGEMENT OF ADMINISTRATIVE WORKLOAD

> *21.16 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.

5. QUALITY ASSURANCE

21.17 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality 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.

International Eexamination work at CIPO is underpinned by its International Search and Examination Standards. These Standards take into account internal and external clients' needs, and incorporate the requirements of the PCT International Search and Preliminary 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 a Quality Control (QC) program, which is an ongoing activity that occurs during the examination process. QC data is analyzed annually and reports are presented to PMC during the annual quality review as well as communicated to the examiner community through Examiner Bulletins.

Quality Control 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 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 their 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 Program. Each question measures conformity with the CIPO's Quality Standards for International Search and Examination StandardsCIPO Quality Standards for International Examination. All identified non-complianceconformity must be explained with a specific comment.

The resultant QC data is analyzed annually. The data consists of a series of statements which are evaluated by the supervisor as being met or not met on each application. These statements are derived from the quality standards. There are 6 categories consisting of 31 27 criteria for Chapter I (26 after a mid-year update) and 15 for Chapter II applications 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 PMC.

Processes to monitor and measure the performance of the QMS include a Control of Nonconformity Procedure which was implemented so that nonconformities can be identified and documented, and so that a long-term solution can be implemented. Any process that doesn't work as expected should be identified, in particular transaction errors between Classification, Examination, PCT International Unit and Scanning (i.e., cross-unit non-conformities). Cross-unit non-conformities are issues which result from international phase procedures not being followed and which issues would not be captured in any other reporting mechanism, such as quality control forms. ~~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, 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 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 Control of Nonconformity Procedure ~~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 Internal Audit.

To report a non-conformity, an email is sent to the Program Manager – International (PCT) via the PCT Practice mailbox. The PCT Practice group will assist in rectifying the error and will track the non-conformities in a spreadsheet.

(a) All Quality Standards are reviewed and updated as required.

(b) An update to the system of measurement and collection of quality data from CIPO's examination division has been implemented. This update improves the questions which are used to collect data for our QC 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, an update of the QC tool was made in order to limit the number of incomplete QC results and new features were modified to allow ~~staff~~ examiners to have better access to results of QC carried out on their work.

(c) A checklist is used in 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 QC data indicates that the checklist has been successful at lowering non-conformance rates in many of the related categories.

6.   COMMUNICATION

> *Inter-Authority communication:*
>
> *21.18 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 21.18)*
>
> *21.19 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)

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Communication and guidance to users:

21.20 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.

Indicate where and how the Authority makes its quality objectives publicly available for the users.

(i)   Client complaints are handled directly via the CIPO Client Service Center (CSC) 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 5~~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 now analyzes 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~~ A corrective action/preventative action mechanism~~program~~ is available to employees to track internal IT issues, including data correction. ~~This program uses an internal issue tracking using software JIRA.~~ This mechanism uses SharePoint and permits non-conformities to be identified and tracked systematically ~~and~~ as well as routed to the appropriate resource for action.

(ii) A joint consultation committee between CIPO 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 the 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 clients' awareness of CIPO's OFM and on the responsiveness of PB employees to phone enquiries. Clients are invited to participate in the survey whenever receiving national examination actions such as

examination reports. The 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 put together an action plan to address any concerns or opportunities for improvement that have been identified. These surveys were intended to be repeated every 3 years, but the next survey, delayed due to the pandemic, was conducted in 2022. The final report from the CIPO 2022 Client Satisfaction Survey was publicly released on November 16, 2022, https://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/innovation_science_economic_development_canada/2022/098-21-e/Report-POR098-21.pdf. The next survey should take place in 2025.

(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.

(iv)   CIPO publishes its quality objectives externally on its Patent Quality page https://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, CIPO publishes its Quality Standards for International Search and Preliminary Examination on the Quality Page. These standards are broken into six sections: Subject matter, Search, Application Formalities, Examination, Communication and Timeliness. The overall goal of these 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. In December of 2020, CIPO launched its Patent quality metrics page http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04824.html.

> *21.21 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 Patent Branch Program Manager - International (PCT PPH) and the Team Leader of the 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 Team Leader of PCT International who follows up promptly.

7.   DOCUMENTATION

(a) A Quality Manual 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 is 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, CIPO's Intranet contains a dedicated Quality Section which is updated with the majority of the documents which are presented in our Quality Manual. In addition, there is a Quality wiki page accessible to all employees that includes additional quality information such as QC reports, internal audit reports, search record reports and patent quality events/outreach.

The Quality Manual contains:

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

(ii) the scope of the QMS;

(iii) 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 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 whenever new processes or significant updates occur;

(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 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; and

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

> *21.25 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. nonconforming 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 8.*

(i) As discussed above, all documents are stored in an Information Management (IM) system, the Canadian government's 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 CIPO's intranet. There is no separate management review outside of the internal audit and normal management oversight provided by the PMC. The minutes of the PMC meetings are also stored on the IM system.

(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~~Reports.

(v) Quality Control results are stored in an Access database and in the IM system and analysis is performed annually for QC.

(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. 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.

(viii) All audit results are stored in the IM system. All audit documentation, including tools, templates and reports, are available internally to employees on the internal wiki page.

(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).

8.   SEARCH PROCESS DOCUMENTATION

21.26 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 criteria where Section Heads respond to whether the unity or clarity issues were properly responded to by the examiner. As this criterion is part of the QC, it is subjected to data analysis regularly and trends can be identified.

These records are included with the ISR and WO on PATENTSCOPE.

9.   INTERNAL REVIEW

21.27 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.

21.28-21.30 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.

An internal review at CIPO is not articulated in a separate activity. All QMS-related documents are reviewed and updated as required. This includes the Quality Manual, examination standards, QC/QA tools, as well as training manuals and support documentation. Furthermore, internal process audits are carried out within CIPO yearly according to a 4 or 5 year calendar in which PCT processes are inspected for conformity with established procedures. System audits are carried out yearly. 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 PMC and deficiencies or recommendations are acted upon.

In March 2017, CIPO Patent Branch obtained ISO 9001:2015 certification. In March 2020, CIPO was successful in its ISO 9001:2015 re-certification. The latest re-certification audit has been conducted in March 2023. The re-certification audit did not find any non-conformities.

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 CIPO Patent Branch.

The audit program includes an audit schedule for all processes of the Patent Branch and provisions for impromptu audits at management request. The process audit schedule includes a risk-based approach, increasing the frequency of audits for processes identified as higher risk. Process audits are performed annually according to a 4 or 5 year schedule for all processes within the Quality Management System for ISA/IPEA. A modification to the audit schedule to take in consideration the process changes as a result of the implementation of the Patent Law Treaty was approved by PMC in 2019. 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.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). 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.

[End of document]