Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by the National Institute of Industrial Property (INAPI) of Chile.

> *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*

INAPI acknowledges the importance of Quality Management System (QMS) to ensure that all patent processing steps are completed in a timely and in a high quality manner. INAPI aims to maintain and improve its QMS as implemented during the ISA/IPEA application process according to chapter 21 of the PCT Search and Preliminary Examination Guidelines.

Since the appointment of INAPI as an ISA/IPEA and due to the new redefinition of institutional priorities, major changes have been implemented, especially through Resolution Nº473/2013 of September 13th, 2012, which sets out a new structure in the Institute. Among other, the former Department of Planning and Management Control, the Development Division and the Department of Continuous Improvement of Processes, were replaced by the new Institutional Strategy Department, in charge of supervising the

quality control policies. Together with the Institutional Strategy Department, a new Operations Division was created, in order to improve the processes, with its focus on giving a quality service to the user.

Nowadays, the Institutional Strategy Department is working on the improvement of the QMS, by reviewing the ISO 9001:2008 model and adapting our processes and procedures accordingly.

In this context, INAPI has implemented and maintains a QMS, which is based in the continuous improvement of its processes and the management and training of its staff. INAPI's QMS aims to maintain the effectiveness and continuous improvement of its processes and of the organization as a whole. INAPI's QMS is based on the continuous improvement of the effectiveness of the performance oriented to the clients. The following activities are carried on and verified:

- Identify the processes that are necessary for the QMS operation.
- Determine the sequence and interaction of the QMS processes.
- Determine the criteria and necessary methods to ensure the effective operation and the control of the processes.
- Ensure the availability of resources and the necessary information to support the operation and follow up of the processes.
- Perform a process follow up, measure and analysis.
- Implementation of necessary actions to accomplish the planned results and the continuous improvement of the processes.

Due to the latter and aiming to fulfill the commitments that INAPI has established through its Quality Policy regarding the implementation of the ISA/IPEA activities, a specific Quality Management System is being developed, specially designed for the processing of international applications under the PCT procedure, particularly focused on our ISA/IPEA role.

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.*

a) INAPI was created in 2009 as a decentralized institution technically and legally responsible for the care and management of industrial property services in Chile.

INAPI's mission is to develop the industrial property national system through the protection of the rights, the diffusion of knowledge and the encouragement of a balanced and comprehensive vision of Industrial Property, aiming to contribute to the economic and social development of Chile.

To achieve the above, INAPI is committed to permanently provide services of the highest quality, which is reflected in the organizational structure of INAPI, as well as in various initiatives aimed at that goal.

On October 10th 2013, Resolution N°1392 was published. This Resolution approves the quality policy for INAPI. This documentation was distributed among the staff via e-mail and it is also available in INAPI's web page.

Resolution N°1392 establishes that the development of a Quality Management System is under way, based on the continual improvement of its processes and in its staff's management and training.

This Resolution establishes that the quality policy of INAPI is based in the reliability and impartiality of the registration, management and promotion of the Industrial Property, with a high service standard for its

users, continual improvement of the processes and commitment of the staff. Because of the latter, INAPI's commitment is focused on:

- Managing the Industrial Property applications in an adequate and timely manner, according to the guidelines, laws and rules.
- Ensure a high level of satisfaction from users, through the management of their expectations and an effective response to their consultations and complaints.
- Continually develop the skills and proficiency of INAPI's staff, keeping a high motivation and commitment aiming to answering the requirements and the expectations of users.
- Developing an integral system of planning and control, by ensuring the fulfillment of the commitments that allow the identification of opportunities to improve processes.
- Continuously improve and enhance the efficiency and the effectiveness of the processes, which are incorporated in the scope of the QMS by means of measuring and giving feedback both to the users and the staff on process matters.

b) Top management delegated on Mr. Felipe Welch, Head of Institutional Strategy Department, as Quality Manager for the Institute through Resolution Nº1135/2013, which establishes a Quality Management Committee. Top management also published Resolution Nº1028/2013, designating Mrs. María Pilar Rivera as Head of Quality within the PCT Department.

The Quality Manager is responsible for the implementation and continuous improvement of the Quality Management System. On the other hand, the Head of Quality of the PCT Department will be in charge of INAPI's quality and best practices regarding the PCT requirements on the processing of international applications.

c) As shown in the chart below INAPI is headed by the National Director, who is assisted in his work by a group of professional advisors to the National Directorate, mainly in areas of policy. INAPI has two main business areas: the Trademarks and the Patents Divisions[1]. The latter's structure is composed of the different technical areas of examination and by a group of officials dedicated to provide guidance to users. This internal organization allows addressing analysis and examination without neglecting advice and guidance to users of the system, whether they are inventors, universities, research centers or law firms.

The Patent Division also has a special PCT Department, created through Resolution Nº 991/2013. This Department is in charge of organizing within INAPI, all work related to the proper use and implementation of the treaty. This unit will be responsible for processing and managing all applications received as ISA/IPEA. The Head of the PCT Department was designated through the Resolution Nº 1028/2013. This position is currently held by Mr. Henry Crew.

---

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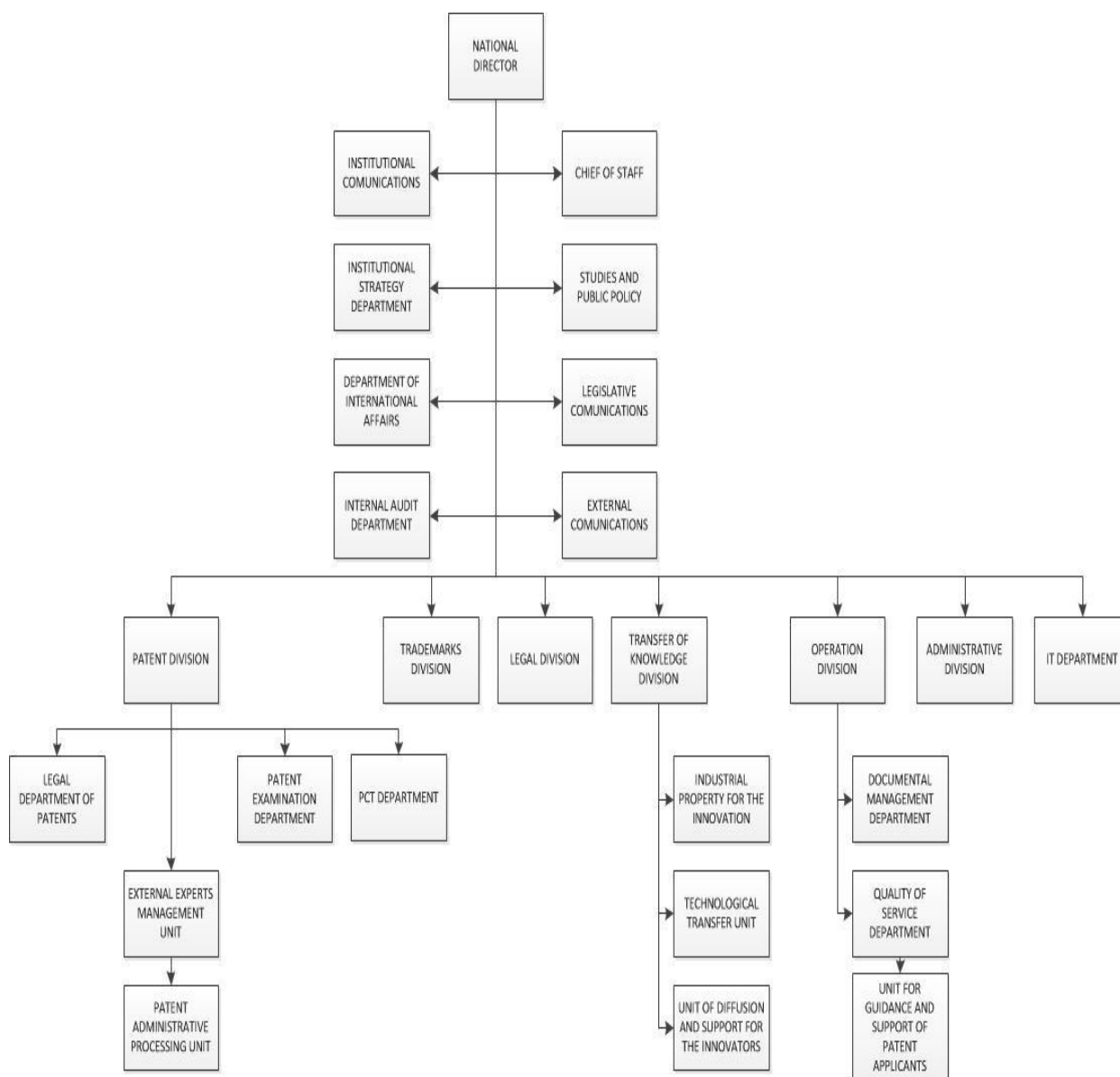
21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements.)

[Sample table, to be amended as necessary]

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	✓		
	(b)	Identified roles and names for QMS responsibility	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(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)	(i) determine the extent to which the QMS in based on Chapter 21			✓
		(ii) determine the extent to which S&E complies with PCT Guidelines		✓	
	(c)	an objective and transparent way		✓	
	(d)	using input incl. information according paragraph 21.17		✓	
	(e)	recording the results			✓
21.10		Assurance to monitor and adapt to actual workload		✓	
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work		✓	
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E		✓	
		(ii) Ensuring documentation accord. to Rule 34		✓	
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.		✓	
21.13		(i) L&D program to ensure and maintain necessary skills in S&E		✓	
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.		✓	
21.14	(a)	System in place for monitoring resources required to deal with demand		✓	
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E		✓	
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports		✓	
	(b)	Control mech. regarding fluctuations in demand and backlog		✓	
21.16	(a)	Internal quality assurance system for self assessment		✓	
		(i) for compliance with S&E Guidelines		✓	
		(ii) for channeling feedback to staff		✓	
	(b)	A system for measurement of data and reporting for continuous improvement		✓	
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work		✓	
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints		✓	
		(ii) Appropriate system for taking preventive/corrective actions		✓	
		(i) Appropriate system for offering feedback to users		✓	
	(b)	(i) A procedure for monitoring user satisfaction & perception		✓	
		(ii) A procedure for ensuring their legitimate needs and expectations are met		✓	
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available			✓

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.19		Established communication with WIPO and designated and elected Offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)		✓	
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed			✓
	(b)	Media available to support the Quality Manual			✓
	(c)	Document control measures are taken			✓
21.22	(a)	Quality policy of the Authority and commitment to QMS		✓	
	(b)	Scope of QMS		✓	
	(c)	Organizational structure and responsibilities		✓	
	(d)	the documented processes are carried out in the Authority		✓	
	(e)	Resources available to carry out processes		✓	
	(f)	a description of the interaction between the processes and the procedures of the QMS.		✓	
21.23	(a)	Records which documents are kept and where they are kept		✓	
	(b)	Records of results of management review		✓	
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes			✓
	(e)	Results of reviews of requirements relating to products		✓	
	(f)	Records of the S&E process carried out on each application		✓	
	(g)	Record of data allowing individual work to be tracked		✓	
	(h)	Record of QMS audits			✓
	(i)	Records on actions taken re. non-conforming products			✓
	(j)	Records on actions taken re. corrective actions			✓
	(k)	Records on actions taken re. preventive actions			✓
	(l)	Records referring to search process documentation		✓	
21.24	(a)	(i) Recording of the databases consulted during search		✓	
		(ii) Recording of keywords, combination of words and truncations during search			✓
		(iii) Recording of the languages used during search		✓	
		(iv) Recording of classes and combinations thereof consulted during search		✓	

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(b)	Records about other information relevant to the search				✓
	(c)	(i) Records about limitation of search and its justification			✓	
		(ii) Records about lack of clarity of the claims			✓	
		(iii) Records about lack of unity			✓	
21.25		Report on its own internal review processes				✓
21.26-21.28		Additional information on further inputs to its internal reviews				✓
21.29		Initial report called for by paragraph 21.19		✓		

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

> *(a)   the effectiveness of the QMS; and*

> *(b)   that the process of continual improvement progresses.*

a) The Quality Management Committee is in charge of ensuring the effectiveness of the QMS. This Committee reviews the progress of the quality program, discusses and approves the documents and quality related issues.

It's worth mentioning that within INAPI's permanent policy of providing the highest quality of service, the Internal Audit Department has a main role, since its main objective is to assist the National Director in the design and implementation of plans aimed at reviewing and examining the administrative and financial management of INAPI. The work performed by this Department is essentially preventive. The Internal Audit Department is responsible for proposing policies, programs and control measures for strengthening the institutional management and safeguarding resources that have been assigned to INAPI.

b) Every Head of Section (i. e., Patents and Trademarks Division, Transfer of Knowledge) is in charge of the continuous improvement of their own area of work by giving feedback to the Institutional Strategy Department in order for this Division to review the processes, analyze the results, evaluate them and propose and develop strategies and actions in those processes which need to be improved.

The Quality Management Committee reports directly to the National Director on matters regarding quality of service and the QMS. Besides that, it is stated that the Internal Audit Unit will be a part of the Quality Management Committee, only for purposes of fulfilling the compliance of the surveillance of the rules that regulate the QMS in INAPI.

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.*

Heads of units have regular meetings with the examiners and administrative staff to inform on the evolution of their work. In those meetings the information about treaty and regulatory requirements is communicated, as well as information on how quality standards and quality system are being handled.

The Head of the Patent Examination Coordination Department (DEP) and the staff of the PCT Department regularly send information to all the staff of the Patents Division on all the important issues such as the evolution of indicators, new procedures or whatever information is relevant for the work of the Patent Division staff.

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

Aiming to fulfill the Strategic Priorities for 2013-2015, INAPI has a strategic plan, which was communicated to the different units as part of the institutional alignment plan. INAPI's Quality Policy defines the commitments that were taken in order to grant a quality service. Therefore, after the implementation of the Quality Management Committee (QMC) and the approval of the Quality Policy, INAPI is working on the definition of its specific quality objectives for each business area. After those objectives are completely defined, we intend to perform an annual review of them as well as the management reviews in order to ensure the availability of appropriate resources and the continuing suitability and effectiveness of the QMS.

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

(a)   at least once per year (cf. paragraph 21.25);

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

(i)   to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));

(ii)   to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));

(c)   in an objective and transparent way (cf. paragraph 21.25);

(d)   using input including information according to paragraphs 21.27 (b)-(f);

(e)   recording the results (cf. paragraph 21.28).

According to what has been stated so far in this report, INAPI is currently working on defining a PCT QMS, aiming to fulfill the commitments that INAPI has established through its Quality Policy regarding to the implementation of the ISA/IPEA activities. Given that INAPI is not yet operative as an ISA/IPEA, there hasn't been an internal review of this PCT QMS. Nevertheless, once INAPI starts being operational as an ISA/IPEA, the intent is that an internal review will be conducted at least once a year, as it is stated in the institutional QMS, which has been completed. As for the PCT QMS, its implementation considers as a fundamental principle the alignment with what it is stated in the Search and Preliminary Examination Guidelines, specially regarding what is established on Chapter 21. Once this QMS is fully operative, at least an annual internal review on this matter will be performed. This review should be performed both by the Quality Committee and the PCT Department. The results of that revision shall be recorded and kept as a feedback for the measures to be taken in order to continuously improve the system.

2. RESOURCES

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

21.11 Human resources:

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

(i) sufficient to deal with the inflow of work;

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

(iii) which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated

is maintained and adapted to changes in workload.

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

(i) at a level to support the technically qualified staff and facilitate the search and examination process;

(ii) for the documentation of records.

a) Within its structure and internal organization, INAPI's Patent Division has a mixed system for searching and examining patent applications and utility models.

The system of analysis comprises a team of highly qualified professionals who are responsible for determining whether the applications meet the requirements for patents to be granted. The system is composed of two groups of experts:

1) **External experts**: The work of the experts is specifically regulated by the Industrial Property Law (Law Nº19.039) and its Regulations. According to these, INAPI's National Director has to asses their suitability for examination and their permanence or removal from the Register of Experts.

External experts work under the direct supervision of the Unit of Experts Management of INAPI's Patent Division, which is in charge of the register and its update. Their work consists on issuing expert reports, analogous to the search and written opinions of the PCT. Regarding the results of the search and examination processes, these experts are supervised technically by a group of **examiners**.

2) **Internal experts (examiners)**: The examiners are members of the Patent Examination Department of INAPI's Patent Division, and are responsible for evaluating whether the expert's work meets the criteria and guidelines set by the institution for the analysis of patentability. Examiners are also responsible for delivering a final recommendation on the patentability of applications to the National Director. The work of the Examiners is under constant evaluation of the technical staff in each technical area and with technical examiners meetings in order to harmonize criteria.

Regarding the search and examination activities, the **Patent Examination Department**, conformed by the examiners and the **Unit of Experts Management** are responsible of doing a continuous evaluation on the performance of our external experts and also of defining the improvement necessities. Furthermore, they monitor the fulfilling of the legal deadlines for issuing the experts reports and keep an updated record on the information that is related to the performance of the experts and examiners in the national phase.

In particular, regarding the examination procedure, INAPI has a working system that is focalized in achieving quality searches and examination. Indeed, the examination procedure of the applications comprises a first step in which the external experts are in charge of performing the search and the substantive examination, where the results of that work are then analyzed by the examiners. Thereby the search and examination work is carried out jointly by the Patent Examination Department and the Unit of Experts Management.

Every year the Office carries on its annual review and report and puts in its future plan the need for further training for the staff and the need to employ new examiners in different fields of technology. After that, there will be an intensive training to prepare the staff examination. Besides, the Office provides training courses for improving the staff's language skills, not only for the new employees, but for the whole staff as well. As for the training courses, and given the fact that searches are to be more exhaustive as an ISA, new searching trainings are being planned in order for the examiners to accomplish the best level required for an Authority.

Currently there are 180 staff members in INAPI and 79 external experts. The search and examination team consists of 102 professionals who are proficient in the patent examination reports, in all technical areas. The internal Examination Department Structure considers 5 technical areas, namely: Pharmaceuticals, Industrial Chemistry, Biotechnology, Mechanical and Electrics, hence allowing INAPI to cover all the technical areas. This number is expected to be increased in the near future, as new professionals will be recruited to accomplish new challenges. In this regard, external experts have just been incorporated and are to begin the training program. This increases the staff in 10%, approximately.

The annual training program that it is yearly conducted in INAPI considers both the technical and lingual training for the examiners. These considerations allow INAPI's technical staff to maintain both technical and language qualifications, mainly in the English language, although some examiners have knowledge of the German and French language. Indeed, all of our experts, both internal and external have at minimum an intermediate level of English, and of those, 40% have an advanced level of this language.

Also, almost 50% of this technical staff has postgraduate studies, the majority of which have masters degrees and PhDs in their respective technical areas.

With regard to professional experience, about 45% of our team has at least 10 years of experience in conducting search and examination patentability reports.

b) The Patents Division comprises a Processing Administration Unit, which is conformed by administrative staff. The purpose of this unit is to support the Patents Division in the management and handling of the administrative work. This staff has both experience and knowledge of the PCT system.

21.12 Material resources:

   (a)   Describe the infrastructure in place to ensure that:

   (i)   appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

   (ii)   at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.

   (b)   Describe how instructions

   (i)   to help staff understand and adhere to the quality criteria and standards; and;

   (ii)   to follow work procedures accurately and consistently

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

Every examiner is equipped with a workstation consisting of a computer with an access to databases and Internet. INAPI is constantly updating these computers in order to have access to the latest technology and facilitate the searching procedure through faster and more efficient equipment.

INAPI provides an access to internal and external databases for every examiner, and now we are working to accomplish the requirements of Rule 34 PCT. Indeed, since INAPI was appointed as an ISA/IPEA, there have been improvements regarding databases and search engines that are now available. Apart from the free searching databases such as Espacenet, Google Patents, INAPI, Patentscope, the USPTO, JPO and some others Patent Office's databases, contracts have been signed to have access to searching platforms, namely STN and Proquest Dialog, which provide access to over 200 databases in all technical fields. Also, an agreement has been established with other government institutions in order to have access to more than 1000 scientific publications through the BEIC program. This program allows searching in scientific publications such as Oxford University Press, Elsevier, AAAS, American Chemical Society, Annual Reviews, Nature, Springer Links and Wiley-Blackwell. Nevertheless, INAPI keeps on assessing databases that could be useful for our searches.

All the staff has access to the PCT, the Chilean industrial property law, to treaties and conventions, to the Guidelines and the internal instructions via our computer systems and on paper.

The procedures specifically related to the Quality Management System (QMS) are in preparation. As for the PCT procedures, a joint work with the Institutional Strategy Department is being conducted. The aim of this work is to map and document the processes and procedures that rule the PCT work in the international phase. At this point, the documentation of the functions of INAPI as a Receiving Office, which is available on request to all the staff members, went under review and the corrected version has just been released. A similar path is going under construction with the mapping and documenting of ISA/IPEA processes, looking forward to having it available as soon as possible.

An administrative management software for the PCT applications is under development.

Finally, INAPI's Examination Guidelines have just been published after a review period, in which the technical staff, the Legislative Department and applicants, through a public consultation, were asked to give their opinion and remarks regarding this document. These guidelines, which are in line with those stated in the PCT International Search and Preliminary Examination Guidelines, were developed with the purpose of harmonizing criteria and set a quality standard for the examination process. This document will be under continuous review, in order to keep it up-to-date.

21.13 Training resources:

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

(i)   acquire and maintain the necessary experience and skills; and

(ii)   are fully aware of the importance of complying with the quality criteria and standards.

With the purpose of maintaining the searching and examination skills of the staff within a level of quality which complies with the best practices, an annual training program is designed and reviewed at least once a year, according to the qualifications of the team and the specific needs that are to be covered. These training programs include, among other, language, technical subjects and examination reinforcements through on line courses. As for the implementation of ISA/IPEA activities, there has been some close collaboration with other Authorities in order to learn the best practices regarding the examiner's work in this field. In this regard the USPTO and CIPO have provided our examiners with training programs on searching, aiming to conduct the International Search and establish a Search Report, and on elaborating the Written Opinions and International Preliminary Examination Report.

The process of incorporating new professionals starts by identifying needs in technical areas and building a profile for the post. Then a public application process is conducted which concludes with the selection of candidates. These candidates are subject to a comprehensive training and selection that is divided in two stages: first an "induction", focused on providing general knowledge and expertise with regards to patents and industrial property. For this stage, INAPI normally works in cooperation with other Offices. A second stage corresponds to the training itself. During this period the candidate works under the guidance of experts at INAPI, conducting examination of actual patent applications.

The entire process is overseen by the heads of the technical areas of the Department of Examination who finally evaluate the performance and capacity of the candidates, selecting those which meet the requirements set by INAPI.

Finally, once candidates are accepted as part of INAPI, each selected candidate has an assigned tutor that supervises and provides support when preparing their first reports. Tutoring is held for one year with different supervisors within the same technical area. The performance of new professionals is assessed every four months. If after a year (or earlier), the candidate demonstrates the development of skills and abilities necessary to perform search and examination reports, he may start working independently. The purpose of this process is that, within an 18 month period, all new experts must be prepared for search and examination without the supervision of a tutor, taking in to account the law, regulations and the Guidelines.

The process of recruitment and training has been developed and designed so as not to affect the productivity of the Office. This has been reflected in the fast reduction of pending applications over the past years.

21.14 Oversight over resources:

> *Describe the system in place for continuously monitoring and identifying the resources required:*
>
> *(a)   to deal with demand; and*
>
> *(b)   comply with the quality standards for search and examination.*

As it was stated above, every Head of Section (i. e., Patents and Trademarks Division) is in charge of the continuous improvement of their own area of work by giving feedback to the Institutional Strategy Department in order for this Division to review the processes, analyze the results, evaluate them and propose and develop strategies and actions in those processes which need to be improved.

Regarding the PCT Department, due to the PCT QMS that is being developed, one of the main tasks is the definition of both the continuous improvement mechanisms and the responsible of monitoring and identifying the resources that are required for those purposes.

3.   MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

Since INAPI hasn't started working as an ISA/IPEA, no specific control mechanism is available at the moment. Nevertheless, INAPI is aware of the importance of having these sorts of control mechanisms in order to ensure the timeliness as an Authority, hence the development plan includes the design and implementation of an electronic control mechanism that overviews the individual timeframe of an application once it has entered to the ISR and WO or IPER process. It is also intended that this program will give feedback to take the necessary actions regarding fluctuations in demand and backlog management. However, a management program is currently available for measuring the timeliness in the national phase, which allows the heads of the technical areas to have the proper information on the examiners work. This tool provides a control mechanism that identifies the workload of each examiner, by which the Head of the technical section can distribute the workload according to the demand.

In case that a delay is detected, this situation is communicated to the professional and at the same time measures are taken in order to relief the workload that this expert has, so that these conducts can be corrected to avoid new delays and to prevent their occurrence. The record of the delays in which an expert has incurred relating to the workload that the professional has assumed in a certain lapse of time is used as a measuring parameter for the subsequent assignment of new applications for these experts, in order to ensure an optimal workload that guarantees timeliness.

4. QUALITY ASSURANCE

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

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

(i)   for compliance with these Search and Examination Guidelines;

(ii)   for channeling feedback to staff.

(b)   A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.

(c)   A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

The national phase practice includes stages that are related to a quality assurance system in the examination process. For example, prior to give the recommendation on the granting or refusal of the application, the examination reports are reviewed by an examiner in order to verify the compliance of the criteria that is established both in the national law and its regulations and also the Examination Guidelines. Indeed, the Patent Examination Department (DEP), which groups the examiners of all technical areas, is responsible for the ongoing assessment of performance of the experts and the identification of possible improvements. In this regards, the DEP collects and gives feedback to the staff on common misinterpretations of the Guidelines or recurrent mistakes that have to be corrected in order to achieve a good quality service.

As for the ISA/IPEA implementation, checklists will be developed for self assessment of the reports. It is also intended that the work of the examiner will be supervised by the Head of the technical section and then validated by the Head of the DEP for this Supervisor to send it over to the PCT Department for a last formal revision in this Unit.

With the purpose of ensuring the continuous improvement of the processes, the Institutional Strategy Department delivers on a weekly base a Management Report of the work of the different units of INAPI. Regarding to the DEP, the report indicates the performance of each individual examiner in terms of due dates based on the status of the application. This report is delivered to the Head of the DEP, who sends it to each Head of Technical Section in order for them to manage the workload and the schedule of each examiner within the particular technical section. This report is generated directly from the IPAS program, which assigns different status to the application, depending on the stage in which it lies in the process. This Management Report is a useful tool for taking corrective and preventive actions and, therefore, works as a system for verifying the effectiveness of the actions that have already been taken, for example, reducing processing times or reducing backlog. Further tools will be developed specially for the ISA/IPEA work in INAPI.

5.   Communication

21.17 Inter-Authority communication:

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

(a)   helping identify and disseminate best practice among Authorities;

(b)   fostering continual improvement; and

(c)   providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The contact person appointed by Top Management for these purposes (a-c) is Mrs. María Pilar Rivera, Head of Quality of the PCT Department, who can be contacted through the email address mrivera@inapi.cl. In case Mrs. Rivera is unable to attend, Mrs. Viviana Troncoso, Head of the Mechanical, Electronics and Industrial Designs is to be contacted through the email address vtroncoso@inapi.cl.

21.18 Communication and guidance to users:

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

(a)   An appropriate system for

(i)   handling complaints and making corrections;

(ii)   taking corrective and/or preventative action where appropriate; and

(iii)   offering feedback to users.

(b)   A procedure for:

(i)   monitoring user satisfaction and perception; and

(ii)   for ensuring their legitimate needs and expectations are met.

(c)   Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.

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

INAPI gives great importance to the opinions of our users and sees in them an opportunity to identify areas for improvement in relation to the service provided. In this sense, and in compliance with paragraph 21.18 of the Guidelines for International Search and Preliminary Examination of the PCT, the Operations Division has a special Unit of Guidance and Support to patent applicants, which directly depends on the Quality of Service Department. Highly qualified professionals whose role is to advise users on matters relating to patents, either in the stage prior to the filing and during processing, integrate this unit. Orientation is given personally or through different channels, such as information specially designed for this purpose on INAPI's website, user guides, frequently asked questions and/or the e-mail account inapi@inapi.cl.

INAPI's commitment is to respond to all comments and questions within 48 hours of receipt. All requests for information received are collected electronically, which allows for tracking and reporting as well as for statistical analysis, all useful tools for measuring user satisfaction and perception.

In regards to the communication with the users, the policy of the PCT Department is to have a direct communication with the applicants, where all the questions and requests can be made directly to the staff of this Department.

Currently, surveys on the PCT system are being designed in order to have a view on the perception of the users in this matter.

> **21.19 Communication with WIPO and designated and elected Offices:**
>
> *Describe how the Authority provides for effective communication with WIPO and designated and elected offices. In particular describe how the Authority ensures that WIPO feedback is promptly evaluated and addressed.*

The communications with WIPO, the other Authorities and the Designed and Elected Offices is coordinated by the PCT Department by e-mail, mail and direct phone calls.

WIPO Circulars and documents are directed to the Head of the PCT Department who communicates them to other members of the staff, namely the Deputy Director for the Patents Division, the Heads of the DEP and the International Affairs Department and the National Director.

This year INAPI began operating with the e-PCT system, which allows the electronic transmission of applications to WIPO.

6.   DOCUMENTATION

> *21.20 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).*
>
> *(Note: This point is informative. No response is required by the template to paragraph 21.20)*
>
> *21.21 The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.*
>
> *For the purposes of this report indicate:*
>
> *(a)   the documents making up a Quality Manual that have been prepared and distributed;*
>
> *(b)   the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*
>
> *(c)   document control measures taken e.g. version numbering, access to latest version.*

Although INAPI has a Quality Policy and a QMS, currently there is no Quality Manual for this Authority. The Institutional Strategy Department in jointly work with the PCT Department has scheduled the setting up of the documents that will be part of the Quality Manual, in order to have them ready by 2014. It is intended that this document will be going through periodic reviews, with clearly established version numbering in case of changes. INAPI is aware of the importance of keeping previous editions for following up purpose, so, a procedure regarding this aspect will be set up.

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

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

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

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

(d) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;

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

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

Though to this date INAPI doesn't have a Quality Manual, there are specific documents that regulate the following issues:

- Resolution Nº 1135/2013 establishes a Quality Manager for INAPI, a Quality Committee and the responsibilities of every member of this Committee regarding quality issues.
- Resolution Nº 1392/2013 establishes the quality policy of INAPI and includes a statement of commitment to the QMS from top management. This Resolution also indicates the scope of the QMS.

The Quality Manual will also include the organizational structure of INAPI, which is available in the web site of the institution. Furthermore, it is intended that this manual will also include the documented processes that are being currently documented for the PCT Department by the Institutional Strategy Department along with the description of the interaction between the processes and procedures of the QMS.

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

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

(b) results of management review;

(c) training, skills and experience of personnel;

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

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

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

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

(h) records of QMS audits;

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

(j) actions taken re. corrective action;

(k) actions taken re. preventative action; and

(l) search process documentation as set out in Section 7

As INAPI is in the process of implementation to become an operative ISA/IPEA, the staff is working in the registration of all the pertinent documentation on the quality and the QMS. Nevertheless, some records are already available, such as:

- Documents related to training, skills and experience of personnel are available in the Human Resources Department.
- The Institutional Strategy Department keeps records of results of management reviews.
- The records of the S&E process that have been carried out are held by each examiner.
- Record of data of the individual work of every examiner is held by the Institutional Strategy Department and by the Head of the Examination Department of the Patents Division.
- The Institutional Strategy Department and the Head of the Examination Department of the Patents Division submit the reports regarding to management review and requirements related to products to the Deputy Director for Patents.

7.   SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

(a)   which of the following are included in this record:

(i)   the databases consulted (patent and non patent literature);

(ii)   the keywords, combinations of words and truncations used;

(iii)   the language(s) in which the search was carried out;

(iv)   the classes and class combinations searched, at least according to the IPC or equivalent;

(v)   a listing of all search statements used in the databases consulted.

(b)   which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

(c)   which special cases are documented and whether records are kept denoting any:

(i)   limitation of search and its justification

(ii)   lack of clarity of the claims; and

(iii)   lack of unity.

In the national phase, the documentation of the search is registered in the examination report itself, such as the databases that have been consulted, the languages that have been used, classes and subclasses consulted, justification and limitation of search, if any, and also records about lack of clarity of claims and unity of the invention. However, in order to fulfill the requirements of the international standards as an ISA/IPEA, in case of a request for international search, a new procedure for the searching documentation will be developed, which will be in harmony with the PCT Guidelines and the agreements that are to be taken in the MIA.

8. INTERNAL REVIEW

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

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

One of the main activities of the Institutional Strategy Department is to conduct at least a yearly review of INAPI's QMS. In concordance to the latter, the PCT QMS that is under development will also be reviewed at least once a year, specially focused on verifying the compliance with what is stated in the Report on Quality Management Systems, which is to be annually submitted by the Authorities.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.29 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.29, and supplementary annual reports in accordance with paragraph 21.30. 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]