WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

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.~~During the year 2014, INAPI has been working on modifying its process documentation in order to fulfill the ISO 9001:2008 standard. As a matter of fact, some units of the Operations Division (namely archives and digitation) and some processes within PCT Department, namely the Receiving Office process were chosen to be implemented to qualify to an ISO 9001:2008 certification.

~~In this context,~~ INAPI has ~~implemented~~ improved and maintains a QMS, which is based in the continuous improvement of its internal 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, the activities which have been designed for a quality service as an ISA/IPEA were developed under the ISO 9001:2008 principles, in order to be included in the scope of a future ISO certification.~~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. Given the intention to remodel some of INAPI's activities for qualifying for an ISO 9001:2008 certification, this Quality Policy was reviewed and improved, as provided in Resolution 223/2014. This quality policy was disseminated among the staff by top management representative by means of meetings with all the Divisions of this institution. Along with this, the reviewed Quality Policy was made available to the staff through its uploading to the shared directory of INAPI's network for consultation purposes.

~~This Resolution~~ This new version of the Quality Policy 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 national and international guidelines, laws and rules.
• Knowing users perception regarding the provided service and keeping an effective communication in matters on consultations and complaining, to contribute to the improvement of our users' satisfaction
• Continuous improvement of the effectiveness of the processes incorporated in the scope of the Quality Management System based in Standard ISO 9001:2008.
• ~~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.~~
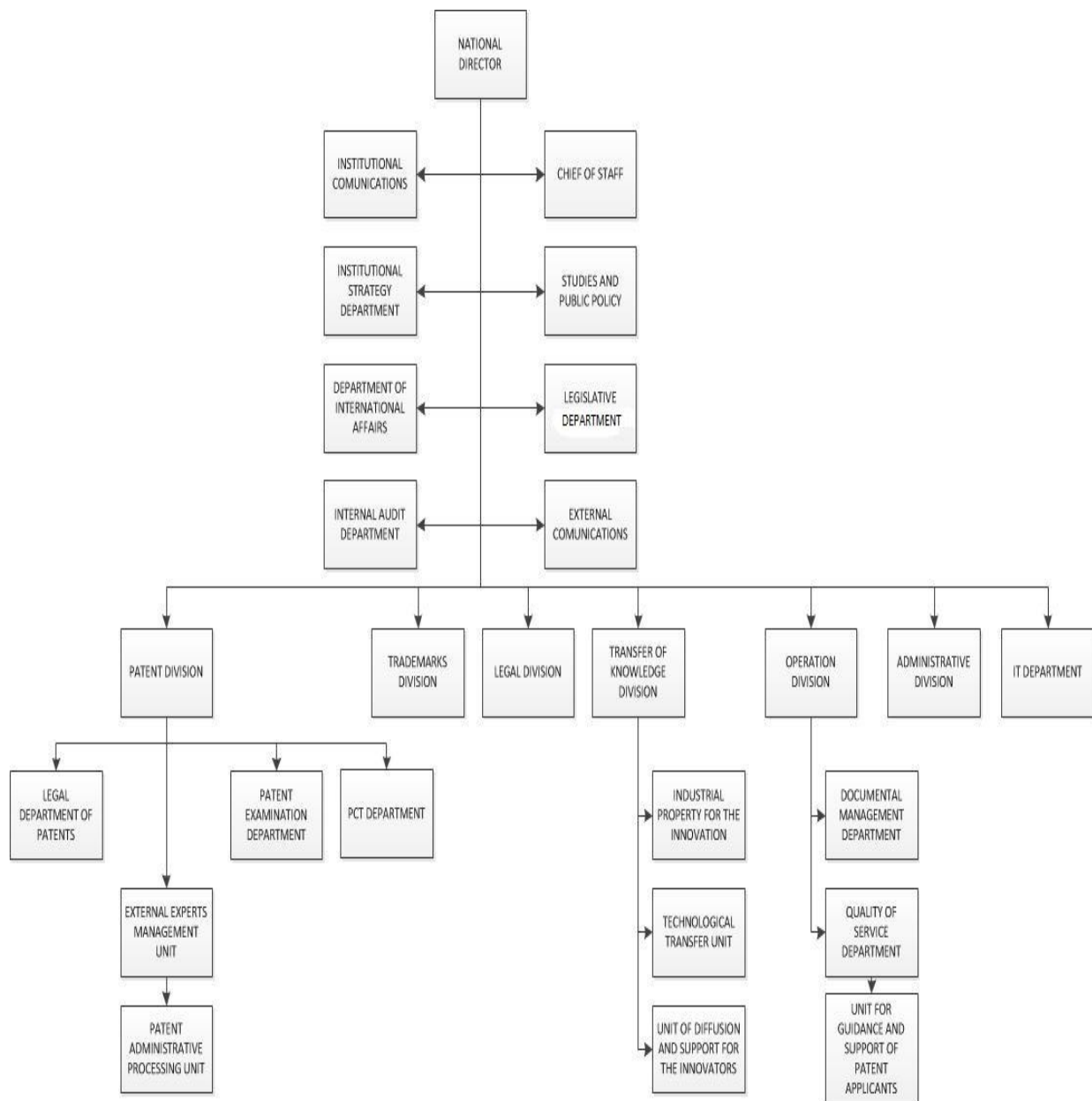
b) Top management delegated on Mr. Felipe Welch, Head of Institutional Strategy Department, as Quality Manager for the Institute through Resolution Nº1135/2013, which establishes a Quality Management Committee. Top management also published Resolution Nº1028/2013, designating Mrs. María Pilar Rivera 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.

[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	✓		
	(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	✓	✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓	✓	
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓	✓	
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓	✓	
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓	✓	
21.14	(a)	System in place for monitoring resources required to deal with demand		✓	
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓	✓	
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓	✓	
	(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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(d)	Indication where and how the Authority makes its quality objectives publicly available			✓
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	✓	✓	

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

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

(a)   the effectiveness of the QMS; and

(b)   that the process of continual improvement progresses.

a) The 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.

In addition to what it was stated above, the work that was done for implementing some procedures accordingly to the ISO 9001:2008 standard led the Institutional Strategy Department to develop and document several procedures in order to ensure the effectiveness of the QMS.

Particularly, for purposes of the QMS, INAPI's top management will be constituted by the National Director, the Deputy Director for the Legal Division, the Chief of the Administration and Finances Division, the Deputy Director for the IT, the Deputy Director for the Operations Division and the Head of the Institutional Strategy Department, who, jointly to the management representative, are in charge of performing an at least annual review to the QMS to verify the proper execution of the activities intended to the compliance of the QMS objectives.

INAPI has defined, established and scheduled several tools for analysis and measurement, leading to the continuous improvement of the activities such as management of non-conformities, corrective and preventive actions, satisfaction surveys for clients/users/beneficiaries, audits, complaints and suggestions and management reviews, with the purpose of demonstrating the service conformity, and ensure and continuously improve the effectiveness of the QMS.

b) In order to assess the adequacy of the QMS, the quality objectives are measured by means of determining the level of compliance of the commitments and indicators lying in the institutional control panel, where the goals and periodicity of measurement are set. This panel also gathers all the monitoring

data with the purpose of ensuring the effectiveness of the QMS. The data is collected by the process owners who inform the Head of Quality to process the information and to evaluate actions in response to the current scenario.

Regarding the business areas in general, eEvery 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.

a) Heads of units within the Patents Division 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.

b) Concerning the QMS, the management representative holds regular meetings with all the staff, aiming to communicate the importance of the system and the requirements given by the treaty and its rules as external documents along with the requirements given by the standard and the proper way to fulfill these requirements.

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 workeding on the definition of its specific quality objectives for each business area, where the Patents Division developed the first quality objectives for the ISA activities. After those objectives are completely defined, we intend to perform and an annual review of them will be performed from 2015 as well as the management reviews in order to ensure the availability of appropriate resources and the continuing suitability and effectiveness of the QMS.

a)   As it is stated in the Quality Manual, top management of INAPI conducts management reviews at least once every 12 months. It is during these management reviews where top management determines and allocates the necessary resources for the operation of the QMS, in order to implant, maintain and

continuously improve the effectiveness of the processes and to achieve the client/user/beneficiary satisfaction, by fulfilling their requests.

The entry information for these reviews are, among others, the internal audits reports, the performance of the internal processes and conformity of the service, status of the corrective and preventive actions and any change which could change the QMS.

b)   Quality Policy as well as Quality Objectives are considered as the entry information for the management review, hence they shall be reviewed at least once every 12 months by top management where they might be improved, if necessary.

c)   The Quality Objectives are communicated to the staff by the management representative who reinforces the importance of these objectives. These objectives are also available in a shared directory in INAPI's servers where they can be consulted by any staff member concerned.

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.~~

a)   As it was already stated, an annual review shall be conducted by top management in order to assess the efficiency of the QMS and to adjust the system in order to improve it continuously. Under this framework, PCT quality procedures will also be reviewed and adjusted as necessary. This activity will be starting next year given that operation as ISA/IPEA has recently been launched and the data is not yet sufficient to conduct a complete review.

b)   Regarding the compliance with what is indicated in Chapter 21, specific quality controls have been designed for the ISA/IPEA activities, including the review of the Search Reports and Preliminary Examination in several levels such as supervisors and PCT Department. There, the minimum quality standard is fundamentally based on what it is stated in the Treaty, the Rules and the Guidelines, observing complete compliance of this standard. The reviews are comprehensive of formal and substantive examination, wherein the relevant information collected is recorded by the reviewers and analyzed by the PCT Department for quality and continuous improvement purposes.

c)   to e) All the information concerning QMS reviews and internal reviews is recorded. Particularly, regarding the internal quality review for ISA/IPEA activities, the information is managed by the PCT Department. The quality controls were designed in order to be clear, objective and straightforward and therefore, transparent for any staff member requiring information related to this process. It also considers the information regarding recommendations on how to improve the results and the follow-up of the corrective or preventive actions detected throughout the steps of the search and examination process.

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 18~~90~~ staff members in INAPI and ~~79~~ 87 external experts. The search and examination team consists of 1~~100~~02 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~~70% 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 and internet connectivity. In this regards, all PC stations in both the Examination and PCT Department were renewed, including new and bigger screens, in order to facilitate the examination process. This equipment gathers the necessary requirements to support all search and examination process.

Besides of the aforementioned renewal of the equipments, a PCT management custom software for processing international applications (SGA) has been developed in order to facilitate and give guidance to the examiners when conducting the search and examination during the ISA activities. This is the first version of an administrative management software for PCT applications, which not only handles the Receiving Office activities, but also the ISA activities, by means of indicating the necessary steps in every stage of the ISA procedure, among other activities such as management of timeliness. This software also allows the storage and retrieval of international PCT applications and all the related documentation, what simplifies and accelerates the process.

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. Over the year 2014 contracts for new databases have been signed, specifically Thomson Innovation, IEEE and GenomeQuest. In addition to this, INAPI began the trial period for Epoquenet .

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.

Over the last year, PCT Department along with the Institutional Strategy Department, designed the flowcharts for both Receiving Office and ISA procedures and the documents where all these procedures are documented. The specific document and flowchart for the ISA activities were approved and made available for all the relevant staff. Besides, an examination manual was specifically designed for the ISA activities in order to guide examiners when conducting search and examination. This manual has also been approved and made available to the examiners for them to consult it whenever they need to.

According to the ISO standard, every change in any of these documents has to be approved by the Deputy Director for the Patents and uploaded to the shared folder, replacing its latest version, which ought to be destroyed. The change shall be communicated to the relevant staff by email. 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, where they 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 high 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 period of ISA/IPEA activities, following last year activities, a program was designed which required the collaboration of other offices to deepen and strengthen the already acquired staff skills. Hence, 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 and IP Australia 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.

In order to acquire the necessary expertise to manage the search and examination process as a whole in terms of administrative procedures and quality controls, there were specific trainings conducted by ILPO and IP Australia.

All these programs also consider emphasize the importance of fulfilling the minimum quality standards in S&E, therefore, in addition to the other Authorities collaboration, seminars were organized for the staff to learn about PCT WIPO activities and the importance of the quality criteria as Searching and Preliminary Examination Authority, where WIPO experts gave their view and opinions on this topic.

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.*

a)   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.

b)   Concerning the fulfillment of quality standards, several quality controls have been established, where in the search and examination work is reviewed by the supervisors and the PCT Department. This mechanism allows monitoring the quality of the work and the development of preventive and corrective actions, which shall be followed-up in order to take the appropriate actions and also identify the necessary resources to comply with these activities.

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.

a)   With the purpose of delivering a high quality product, INAPI developed quality mechanisms for ensuring both product quality and timeliness in its delivery. Concerning timeliness, the aforementioned developed custom software (SGA) was specifically designed to keep track of the time spent in each activity and also to display the time remaining until the due date for every activity is met. This information will be periodically retrieved and processed by the PCT Department in order to manage the activities which must be completed before delivering the Search and Examination report, according with specific follow-up mechanisms designed for these purposes.

b)   Regarding the fluctuations in demand and backlog, the responsibility lies within the Patent Examination Department, where supervisors are requested to assign and evaluate the current workload on the examiners before the appointment of an examiner for searching and preliminary examination purposes. Therefore, the Patent Examination Department provides the necessary information for managing any fluctuation in the examiners workload and for dealing with backlog issues.

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.*

a) 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 on 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.

As a result of the implementation process, an internal quality assurance system was specifically designed for ISA/IPEA activities. This system considers the review of the entirety of the reports submitted by examiners before sending them to the applicant. Every report shall be approved by a supervisor by means of the fulfillment of specific checklists which are comprehensive for assessing compliance of what it is stated in the S&E guidelines, including search strategy documentation. The compliance of every aspect mentioned in the checklist is mandatory for delivering the report to the PCT Department to be submitted to the applicant and to the IB in a later stage. The system also considers the provision of the review results to the PCT Department in order to keep records examiner which allows monitoring every examiner's activity. Based on the level of fulfillment of compliance with checklists, the examiner may be subjected to a training activity or, on the contrary, their reports may be subjected to a random sample provided the expert shows an outstanding quality level during a certain period. All the findings within an evaluation period are communicated to the examiner. If the findings are of common occurrence, they are discussed in general meetings in order to correct said practice among all the relevant members of the staff.

In addition to this, the current practice involves meetings aimed to develop a search strategy among three examiners of the same technical field, in order to have different points of view and make the search more comprehensive during this first stage.

Finally, after the report is submitted to the PCT Department, it goes through a final formal review which ensures the proper issuance of the report by checking formalities related to what is stated in the S&E guidelines.

b) As it was previously stated, the Quality Assurance Mechanism includes the use of specific databases which record the result from the quality reviews and therefore the level of fulfillment of every examiner regarding ISA/IPEA activities. This registry allows the identification of findings and also detection of non-conformities, with the proposed preventive or corrective actions in order to follow the result of implementing these actions to correct the practice and continuously improvement.

c) The internal quality system for ISA/IPEA activities considers a procedure for correcting and amending any flaw raised during the product quality control. This includes the record of any non-conformity raised during the review which allows the development of preventive or corrective actions. The result of the implementation of these actions will be monitored in order to evaluate the effectiveness of actions taken in the long term.

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 afterof 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.

Over the last year customer's satisfaction surveys were designed to evaluate the RO activities. This survey will also apply for the ISA/IPEA activities once the initial reports are submitted. This is a closed survey, which gives room to the applicant for indicating the points of interests in which is considered there could be room for improvement.

Besides of the above, INAPI's website was reviewed and improved in terms of allowing a direct access to the user to all the activities and information related to PCT. Also a new and specific e-mail address for PCT consultations (pct@inapi.cl) was created, where applicants, agents and stakeholders can raise observations, queries and compliments regarding whatever PCT related issue.

> *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 operatingis 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.

Given the work done in terms of adapting some internal processes in order to qualify for an ISO 9001:2008 certification, a Quality Manual has been internally prepared. This manual is the master document for the functioning of the processes under the scope of the intended certification. This is a controlled document and it will be managed and controlled according to what it is indicated in the specific procedure for this matter. The documentation supporting the QMS includes the quality policy, quality objectives, processes' flow charts, operative procedures and the correspondent processes and registration documents. All this documentation is available to the staff members through a public internal server for consultation, if required.

Concerning PCT issues, particularly ISA/IPEA activities, an Examination Manual for ISA activities was distributed among examiners. This manual describes all the examiners related tasks and indications on how to fill out the main forms. This manual is also a controlled document and is available through the internal server.

A specific document control procedure was elaborated and documented. This document indicates all the necessary steps for changing an existing document after a necessity to do so is detected. Every controlled document shall have a title, an specific code in order to determine whether it refers to records, instructions or procedures, a version number, a revision history, disclaimer and the validity date.

It was pointed out that the obsolete copies of every document ought to be destroyed.

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

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

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

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

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

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

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

The Quality Policy, the scope of QMS, the organizational structure of the members of staff under its scope and their responsibilities, as well as the documented processes under the scope, resources and description of interactions are covered by what it is pointed out in the Quality Manual.

Although the Quality Manual currently does not make reference to the documented processes for search and examination procedures, those documents (e.g., Examination Manual under ISA scope) are available to the examiners and it is intended to include them in a newer version of the Quality Manual.

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.

Among the records which ought to be kept by this authority, the following are available:

- The documents control procedure clearly indicates, by means of a reference to an inner database, which records are to be kept and where should they be kept.
- The Quality Manual refers to the evidence of conformity of the processes under the framework of Registry Control, with an specific procedure for this purposes.
- The results of the, at least, yearly management review which are kept in the Institutional Strategy Department.
- Records on the CV, experience, trainings and skills of personnel are kept in the Human Resources Department.
- The SGA software that was developed for PCT activities allows tracking and tracing the individual work of every actor along the PCT international phase procedure for quality measures purposes.
- Every QMS audit activity shall be recorded, according to what is stated in the Quality Manual.
- According to the designed procedure for quality assessment during the ISA activities, every non-conformity and preventive or corrective action must be recorded in the databases
- When running a search, examiners are required to document the search strategy and submit this document according to what is stated in the Examination Manual.

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.

Concerning the searching procedure during the ISA stage, Examiners are required to document the databases that were consulted, their search statements, including keywords, truncations and their combinations, language and classes and subclasses. Any other important information regarding the search shall be recorded as well.

The current designed document for registering the search procedure also includes room for documenting the limitation of the search and lack of unity as well as a significant lack of clarity.

This document shall be uploaded to be included in the SGA software for PCT activities.

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.~~

All the relevant information was already indicated in the body of this report.

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]