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WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

REPORT ON QUALITY MANAGEMENT SYSTEMS

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

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

INAPI acknowledges the importance of a 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, significant changes have been implemented., ~~primarily through~~ Resolution Nº473/2013 of September 13th, 2012, ~~which~~ set~~s~~ out a new structure in the Institute, including the creation of the Institutional Strategy Department for advising the National Director in institutional strategic design; designing and managing a Management Control System, including the provision of a high quality service to the public; among others. The increasing importance of quality in services led to the creation of the User Services Division to further improve the quality of the services provided to the users by INAPI, as well as measure their satisfaction as a whole. Its approach includes giving information and assistance to users and applicants regarding patents, trademarks, and other IP-related subjects, with highly trained staff available to them both in our Offices and remotely by phone or web services. ~~Among others, 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. Along with the Institutional Strategy Department, a new User Services Division replaced the former Operations Division, aiming at improving the quality of services INAPI gives to its users with a comprehensive approach that covers information and assistance to users and applicants regarding patents, trademarks and other IP related subjects, where highly trained staff is available to them both in our Offices and remotely by phone or web services~~.

In 2014, INAPI worked on modifying its process documentation to fulfil the ISO 9001:2008 standard. ~~As a matter of fact, some~~This initiative gathered some units of the former~~the~~ Operations Division (namely archives and digitations) and some processes within PCT Department, namely the Receiving Office process, which ~~were~~were suitable candidates ~~chosen for being implemented to qualify for~~to obtain a certification under the ~~an~~ ISO 9001:2008 ~~certification~~standard. This process ended in November 2015, with the recognition of the fulfilment of the ISO standards, ~~therefore,~~and the grant of an ISO 9001:2008 certificate. After the certification, the natural step was starting the work on including our new PCT activities within its scope.

INAPI has improved and maintains a QMS based on the continuous improvement of its internal processes and the management and training of its staff. INAPI's QMS aims at preserving the effectiveness and continuous improvement of its processes and the organization as a whole. INAPI's QMS is based on the continuous improvement of the efficiency 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 essential methods to ensure effective operation and control of the processes.
- Ensure the availability of resources and the necessary information to support the functioning and follow up of the processes.
- Perform a process follow up, measure and analysis.
- Implementation of necessary actions to accomplish the planned ~~results~~ outcomes and the continuous improvement of the processes.

Due to the latter and aiming to fulfil the commitments established by INAPI in its Quality Policy on the implementation of the ISA/IPEA activities, the correspondent steps for an ISA/IPEA quality service were developed under the principles of the ISO 9001:2008 standard, in order to be included in the scope of an ISO certification. This planning facilitated the work of implementing the ISA/IPEA process as suitable for being included in the scope of the ISO certification, especially given the interest in certifying this particular process. ~~As a result of~~Given the good outcomes of this planning, the management review recommended the inclusion of the ISA/IPEA activities in the recertification under ISO 9001:2015, which was finally obtained in the first term of 2018, and then successfully ~~audited~~showing accomplishment of the standard after the audit process of 2021, ~~with~~obtaining only minor observations ~~in 2021~~.

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CERTIFICADO

Número SC-2972/21

REGISTRO NACIONAL Nº 12098

LGAI CHILE S.A.,
Certifica que el Sistema de Gestión de Calidad de la empresa:

Instituto Nacional de Propiedad Industrial
INAPI
RUT: 65.999.669-3
Av. Libertador Bernardo O´Higgins Nº 194, Piso 16, Santiago
Región Metropolitana de Santiago, Chile.

Para las actividades siguientes:

Servicios de Recepción, Verificación y Transmisión de Solicitudes internacionales de Patentes; Búsqueda Internacional sobre patentabilidad; y Examen Preliminar Internacional sobre patentabilidad en el marco del Tratado de Cooperación en Materia de Patentes (PCT)

Es conforme con los requisitos de la norma
ISO 9001:2015

Fecha de Otorgamiento Inicial: 28 de Mayo del 2018
Fecha de Otorgamiento de Renovación: 28 de Mayo del 2021
Fecha de Vencimiento: 27 de Mayo del 2024

Para Verificar validez del certificado tomar contacto telefónico al +56 (2) 2562 90 18 o vía e-mail a: certificacion@applus.com

SISTEMA NACIONAL DE ACREDITACION INN - CHILE

Carolina Troncoso Fernández
Directora de Certificación CHILE

El presente certificado se considera válido siempre que se cumplan todas las condiciones del contrato del cual este certificado forma parte

The certification under ISO 9001:2015 and the standardization all of our PCT procedures was of use to our Office once the service of International Search and Examination processes were broaden to applications filed in English for countries of Latin America and the Caribbean where the ISR, WO and IPRP are drafted in English if requested by the applicant.

It is relevant to point out that our recent role of ISA/IPEA contributed dearly to a national recognition where INAPI received an Award for its Excellence as a public service, where it was recognized as one of the three best public institutions in the country in 2016. This award ~~is focused~~focuses on the contribution ~~of the~~that public institutions may provide to citizens, improving their daily lives with the highest quality levels of service. Moreover, INAPI got this acknowledgement again after its work during 2018 and 2020. In that instance, further recognition of matters relating to our QMS influenced this achievement, thereby demonstrating our strong commitment ~~with~~ to quality of service and the improvement of our user~~s~~' experience.

In 2019, INAPI celebrated 10 years since adhering to the PCT. This celebration was carried out with the visit of officers representing WIPO and the SPTO, where different activities with the general public, universities, and agents took place. These meetings were addressed to discuss the advantages of the Treaty and to know the needs and users' expectations looking to improve the quality of services.

Over that year, some of the PCT documentation drafted by INAPI was revisited and evaluated taking into consideration ~~under the light of~~ the most frequent inquiries made by our users. As a result, some of these documents were updated. In particular, a new ”INAPI's PCT user's guide” was drafted and made available to the public in our web page, where this document discloses important information regarding the international search and preliminary examination activities, as well as important information regarding entering national phase.

As an overview of what happened in 2020, it is important to point out that the COVID-19 pandemic challenged every aspect of daily life, and the functioning of INAPI was not an exception to this new reality. Even though it was expected that this pandemic would be overcome by the end of 2020, the new strains forced everyone to extend the measures for assuring the safety of people around the world. INAPI was not an exception here.

-Therefore, in order to keep the staff safe and ensure the correct provision of our services to all our users, new measures to enable access to every staff member's computer station were taken, keeping all the necessary conditions to comply with the requirements of the Information Security Management System Standard. This action allowed our staff to work safely from home without neglecting everyday activities in order to keep INAPI's services ongoing like in everyday situations while remaining safe for our users to file their applications.

Also, in 2020 other measures for simplifying the filing of PCT international applications were taken. During the yearly review of the QMS and taking into consideration the most common commentaries of INAPI's users, a new payment system was developed, where this system enables the payment of fees with a credit card. This initiative has been vastly welcomed by the applicants since it saves much time for them.

On the other hand, significant work was conducted to encourage online filing via ePCT by the applicants. In that regard, INAPI and WIPO arranged public webinars for applicants to learn more about this tool from a practical ~~approach~~perspective. After that, a user's manual in Spanish was drafted, which was revised by WIPO Officers. This new manual was successfully released and helped our users to have a better understanding when using ePCT ~~when filing~~to file an application as well as fulfilling any Authority's requirements. It also enabled our users to file online, and as a result of this awareness-raising, a 100% online filing in INAPI as a RO was achieved ~~on~~ in 2021 which had a minimal decrease~~d~~ in 2022 to ~~a~~ 98%. Nonetheless, the online filing rate rose again to 100% in 2023. It is important to point out that our regional reality significantly differs from other regions where online filing is a common activity,~~;~~ contrary to what actually happens in our region, since~~hence p~~ paper filing is an established costume among Latin-American applicants. Moreover, there are some national Offices within our region that do not allow online filing due to their national legislation, with all the processing issues that this restriction implies, both for applicants and any RO, ISA, and (eventually) IPEA appointed by the applicant. Moreover, there are Offices that do not take full advantage of the program or simply do not use it properly regarding some operations that involve ISA/IPEA, or IB activities, affecting the planning of their work. Therefore, INAPI ~~is~~ keeps on working to~~in~~ encourage~~ing~~ online filing in every public PCT-related activity as well as point out the advantages of going paperless in PCT processes.

It is well known that Chile has been facing social disturbances as from 18. October 2020; where the protests usually center and take place near INAPI's institutional building. Due to the latter, the building suffered damage from fire on two different occasions and staff was unable to go to the Office to work. Nevertheless, INAPI was adequately prepared and was able to ensure the proper attention to its users by reacting fast enough to habilitate remote access to its officers in order to continue work with no significant changes in the procedures and keeping the quality of service that always provides to the users.

Notwithstanding the ongoing COVID situation, INAPI worked consistently on improving its quality goals during 2022, focusing on shortening processing times for international PCT patent applications by breaking down different aspects of both the filed applications and the use of time. Concerning the applications and the quality of their contents in terms of the necessary information for obtaining a clear and strong document, INAPI worked on offering applicants new tools to learn how to properly file an application. Thereto, a new patent drafting training course was carried out jointly with WIPO, which had a great demand by many different user profiles. In addition to this, INAPI joined to WIPO's Inventor Assistance Program (IAP), which raised much interest in inventors wanting to be sponsored by an IP agent for filing a patent application, selecting five inventors who are being guided into filing their patent application in INAPI as a result of this first version. ~~Considering the level of success of both initiatives work is being done in order to launch new editions of them in the nearest future.~~Given the successful outcomes of this summoning in terms of the number of candidates wanting to participate in these activities, a second version of the IAP and of the patent drafting training took place in 2023, and new versions are to be launched from 2024 onwards.

Regarding the use of time, the collection of statistical data is enough to measure an average processing time in several steps of the international search process, thereby reinforcing certain matters that might need to be addressed, such as the extension of the searching ~~of documents~~process itself and the number of ~~selected~~ cited documents in the ~~prior art~~ISR, giving us a hint of improvement opportunities ~~in the use of~~for using time in a more effective way. Moreover, to help avoiding usual formal ~~usual~~ mistakes when filling out the PCT forms, the PCT Department staff worked in said forms in order to adapt them to restrain typical mistakes such as leaving certain boxes unmarked in page one of either ~~the form~~ PCT/ISA/210 or PCT/ISA/237 forms when filling out the correspondent box in the form. ~~It is expected that this will help shortening the quality control process by avoiding the reprocessing of forms with formal errors.~~After one year using this adapted forms, the number of forms needing corrections decreased compared with previous years.

~~Likewise, during 2022~~ Law No. 21,355 ~~came into force~~, which modifies Law No. 19,039 on Industrial Property in Chile, modernizing the IP legislation of our country in order to facilitate innovation. ~~This law~~ establishes a new framework for improving IP, especially within national practice. ~~, where, for example, p~~Provisional patent applications are now allowed and ~~where~~ PCT applicants entering the National Phase in Chile (as long as they have selected INAPI as ISA/IPEA) may be eligible for certain ~~rate~~ fee reductions, if they meet the particular requirements established therein.

Finally, after updating ~~this year the~~ INAPI's national patent examination guidelines ~~were updated~~ and ~~a~~ launching the new version of the Guidelines ~~was launched~~, the Patents Division developed some tutorial videos for better understanding the exclusions or patentability as well as introducing users to new technologies, such as computer-implemented inventions and the exclusions linked with such technologies. Concerning green patents, in 2023, INAPI launched a green patents program that aims to shorten the processing time in about 30% in applications that develop green technologies to have a positive impact on the environment.

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 specified 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 underway, 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 representatives through meetings with all the Divisions. Along with this, the reviewed Quality Policy was made available to the team through its uploading to the shared directory of INAPI's network for consultation purposes.

This new version of the Quality Policy establishes that the quality policy of INAPI is based on the reliability and impartiality of the registration, management and promotion of the Industrial Property, with a high service standard for its users and interested parts, continual improvement of the processes and commitment of the staff. Because of the latter, INAPI's commitment is focused on:

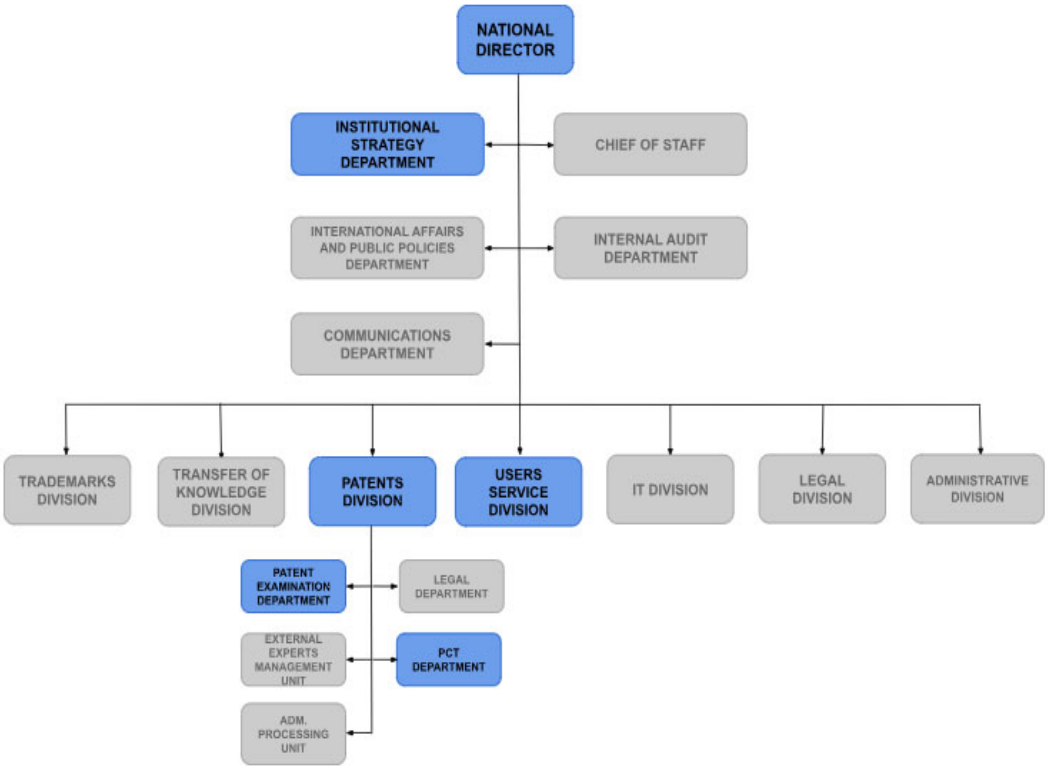
- Managing the Industrial Property applications in an adequate and timely manner, according to the national and international guidelines, laws and rules.
- Knowing users and interested parts perception regarding the provided service and keeping effective communication in matters on consultations, suggestions and complaints, to contribute to the improvement of our users' and interested parts' satisfaction.
- Continuous improvement of the effectiveness of the processes incorporated in the scope of the Quality Management System.
- Continually develop the skills and proficiency of INAPI's staff, keeping a high motivation and commitment aiming to answer the requirements and the expectations of users.

b) Top management delegated on Mr. Felipe Welch, Head of Institutional Strategy Department, the position of Quality Manager for the Institute through Resolution Nº1135/2013, which establishes a Quality Management Committee. Top management also published Resolution Nº1028/2013, designating Ms. María Pilar Rivera as Head of Quality at 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 is 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 by a group of professional advisors to the National Directorate, mainly in policy areas. INAPI has ~~two~~ three main business areas: the Trademarks Division, ~~and~~the Transfer of Knowledge Division, and the Patents Division~~s~~. The latter's structure is composed of the different technical areas of examination and by a group of officials dedicated to guiding 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 all work related to the proper use and implementation of the treaty in INAPI. This unit is 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. Mr. Henry Crew currently holds this position.



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	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		

		(d)	using input incl. information according paragraph 21.24	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		

		(b)	which maintains technical qualifications to S&E in all technical fields	✓		
		(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b)	Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a)	Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	✓		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		

21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		

	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	✓		
	(iii)		Clear and concise guidance on the S&E process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes			
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		

	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		

	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	✓		
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted	✓		
	(vi)		Records about other information relevant to the search	✓		
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews	✓		
21.31			Initial report called for by paragraph 21.31	✓		

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

a) The 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 service, the Internal Audit Department has an important role assisting 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 mostly preventive. The Internal Audit Department is responsible for proposing policies, programs and control measures for strengthening the institutional management and safeguarding resources assigned to INAPI.

In addition to the above-stated, the work done for implementing some procedures accordingly to the ISO standard led the Institutional Strategy Department to develop and document several procedures in order to ensure the effectiveness of the QMS.

Notably, for purposes of the QMS, INAPI's top management ~~will be~~is 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, and the Head of the Institutional Strategy Department. All of them, 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. This aims at demonstrating the service conformity, and ensures and continuously improves the effectiveness of the QMS.

b) In order to assess the adequacy of the QMS, top management performs a yearly review for the sake of evaluating the outcomes of the involved processes after the adjustments made the fore year in response to any observation, improvement opportunity, or non-conformity raised for said processes from own or external follow-ups. This review includes, among other activities, analysing the outcomes of the indicators linked to the quality objectives. Therefore, top management reviews~~the quality objectives are measured, determining~~ the level of compliance of the commitments and quality indicators lying in the institutional control panel, which contains information about the goals and periodicity of measurement, as well as all the monitoring data to ensure the effectiveness of the QMS.~~.~~ Process owners collect this data and report it for inclusion in the panel. This information is then compared with previous years data to evaluate if any improvement can be attributable to the adjustments made to overcome any findings detected in the former period, and then plan possible improvements, implement them, check their results in the next top management review, and then make the necessary changes (PCDA cycle).
~~This panel also gathers all the monitoring data to ensure 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, every Head of Section (i. e., Patents and Trademarks Division, Transfer of Knowledge) is responsible for the continuous improvement of their area of work. They give feedback to the Institutional Strategy Department for them to review the processes, analyze and evaluate the results, and propose and develop strategies and actions for the processes needing to be improved.

The Quality Management Committee reports directly to the National Director on matters regarding the 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.

Besides all of the above, the ISO 9001:2015 standard has included risk management as one of the main requirements to be fulfilled. This discipline by itself guarantees continuous surveillance and the actions to be taken in order to minimize the impact of risks in the operations under certification. It is for this particular reason that there is an implicit and ongoing control of the progress of the continual improvement.

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. There, any news on the Treaty and regulatory requirements are communicated, as it is information about the handling of quality standards and the quality system.

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

Along with the meetings, the PCT periodically ~~microsite contains~~monitors all the relevant information regarding PCT (the Treaty, Rules, and ~~the new~~ Guidelines, among others). If there should be any update on any of these documents, the process owner updates the documented information list by correcting the version number, date, and new location of the document, if applicable. All these contents are available to the Examination Department and PCT staff. Any news regarding PCT requirements is posted on this site.

b) Concerning the alignment between the QMS and the PCT Guidelines, 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 criteria given in the standard and the proper way to fulfil these requirements. The Quality Manual includes an Annex linking the QMS with the PCT Guidelines. This manual is embedded in our QMS site and is open for consultation to all staff members involved.

21.08 Indicate how and when top management of the Authority or delegated officers:

(a) conducts management reviews and ensures the availability of appropriate resources;

(b) reviews quality objectives; and

(c) ensures that the quality objectives are communicated and understood by the relevant staff at the respective Authority.

Aiming to fulfil the Strategic Priorities for 2016-2018, INAPI communicated a strategic plan to the different units as part of the institutional alignment plan. INAPI's Quality Policy defines the commitments taken to grant a quality service. This strategic plan includes the initiative of assessing the feasibility of including the ISA/IPEA processes within the ISO certification and the readjustment to the standard ISO 9001:2015. This last goal was accomplished on May 2018, when the certification under the ISO 9001:2015 was obtained, broadening its scope to include our ISA/IPEA activities. After implementing the Quality Management Committee (QMC) and the approval of the Quality Policy, INAPI worked on defining its specific quality objectives for the business areas. In that regard, the Patents Division developed quality objectives for ISA activities, performing an annual review thereof since 2015. A new Institutional Strategy plan for the 2020-2022 period, was drafted by several staff members in 2020, including examiners and quality officers. This plan considers several strategic initiatives among which PCT activities are included: patent quality and Chilean patent applications internationalization. Different and multidisciplinary specialized teams worked in various initiatives to improve quality in our processes in order to get a more comprehensive view of different sections' work and how they impact other areas. This activity also helped other staff members have an external approach to possible solutions for everyday challenges.

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 is, 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.

As a result of the ~~last~~ 2020 Management Review ~~(2020)~~, all PCT processes were reviewed, and the Institutional Strategy Department worked on drafting new flowcharts for all RO, ISA and IPEA processes. This activity led to the development of a PCT improvement plan, where several opportunities for improvement were identified and for which action plans were generated. The plan was implemented in april 2021. Since then, minor corrections and adjustments were carried out on these flowcharts as a response to findings disclosed in internal and/or external audit reports, as agreed during the correspondent management reviews.

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.

Since 2016, either the responsible of processes under ISO certification or an involved member of the particular Department communicates the quality objectives to every Department of the Organization in order to make it closer and more familiar to the staff, making them aware of their contribution in the fulfilment of them.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

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

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

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

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

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

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

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

a) As it was stated, an annual review is conducted by top management in order to assess the efficiency of the QMS and to adjust the system to continuously improve it. This review takes place shortly after a yearly internal audit takes place, in accordance with ISO 9001:2015 standard requirement 9.2. This audit is comprehensive and thorough for all QMS processes. Under this framework, PCT quality procedures are also being regularly reviewed and adjusted as necessary.

b) Regarding compliance with what is indicated in Chapter 21 and the extent to which the QMS is based on, our system was designed to fulfil the requirements of ISO 9001:2008 standard, later adjusted to ISO 9001:2015 criteria. This design was made without neglecting the main points necessary to comply as ISA/IPEA; therefore, it is based on Chapter 21 as the certification demonstrates. INAPI is engaged to achieving high-quality standards, and, in this sense, specific quality controls have been designed for the

ISA/IPEA activities, including the review of the Search Reports and Preliminary Examination on 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 for~~of~~ formal and substantive examination quality criteria fulfilment, 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 data is managed by the PCT Department. The quality controls were designed to be clear, objective and straightforward and, therefore, transparent for any staff member requiring information related to this process. It also considers information regarding recommendations on how to improve the results and the follow-up of corrective or preventive actions detected throughout the steps of the search and examination process.

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

Given ~~the fact that~~ INAPI's ~~is certified under~~ ISO 9001:2015 standard certification, QMS yearly management reviews include a context analysis, leading staff to evaluate opportunities and risks detected in the previous year, looking for ways to keep them into consideration or discard those not falling into this category given the eventual changes of said context. This analysis also allows for detecting or reassessing new opportunities and risks for the period. Moreover, risk management is a compulsory ~~requirement that has to be fulfilled~~requirement under the ISO 9001:2015 standard. ~~It is for that purpose that~~To that purpose, INAPI works under a governmental technical document based on the ISO 31000 standard and the ERM-COSO II methodology; therefore, all risks, including those linked to the conformity of international search and examination, are handled under this framework and are included in the institutional risk matrix.

2. RISK-BASED PRACTICES

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

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

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

21.13 Arrangements for establishing risk-based practices

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

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

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

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

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

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

(v) continuously update risks and opportunities.

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

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

As pointed out before, our guidelines for risk-based practices are ruled by the ISO 31000 standard, in particular the dispositions of the Chilean guidelines NCh-ISO 31000:2012 (Risk Management- Principles and Orientations)Nch ISA 31010:2013 (Risk Management- Risk evaluation techniques) NCh-Guide ISO 73:2012 (Risk Management- vocabulary), and NCh-ISO 31004:2014 (Risk Management- Orientation for implementing ISO 31000).

i) INAPI's top management acknowledges the existence of inner and outer factors that may affect its ability to achieve the planned outcomes in its QMS. In this context, a SWOT (Strengths; Weaknesses; Opportunities and Threatens) analysis is conducted at least once every 12 months to identify inner and outer forces, opportunities and risks ~~in order~~ to focalize strategic actions to influence them.

Concerning the needs and expectations of interested parties, a thorough analysis ~~was~~ is periodically carried out to identify these parties and their expectations. Furthermore, our methodology states that inner and outer interested parties are to be informed and consulted. This updating is made via Management reports, which are made available to these parties either through INAPI's webpage or meetings. In addition to these reports and consultations, further information is gathered from our user satisfaction surveys to collect relevant data about their expectations of the content of the forms and their utility, as well as any information that can arise in the periodical meetings INAPI holds with their most representative users and interested parties in order to hear their opinion about INAPI's services.

ii) Our guidelines establish a methodology for identifying, analyzing and valuing risks and opportunities that may affect the attainment of the institutional strategic objectives. The process of reviewing the pertinence and value of said risks is conducted at least once a year and includes all the process within the QMS scope.

The opportunities are identified for every process included in the QMS through identification of events that may produce positive effects, according to what is stated in COSO II.

Concerning risks, those are considered as the events that may affect the objective's achievement negatively.

The risks are identified using a consequence/probability matrix, which allows combining consequence and probability classifications in order to establish a risk level or risk classification. This matrix enables hierarchically organizing the risks, their origins, or the way they are to be treated, all based on the risk level. These risks are also classified according to their source (inner/outer) and the kind of risk according to what is stated in a table in the document. Once the risks are identified, they are included in the institutional strategic risk matrix.

iii) and iv) After the risks and opportunities are correctly identified and organized, controls are developed and designed to address such risks. To this end, our guidelines state that it is necessary to determine whether or not the residual risk level is tolerable in order to decide what option to take regarding every risk. The processes included in the QMS consider taking actions aimed at reducing the probability of occurrence of the risk or reducing the consequences. Once these actions are correctly decided, they are included in the institutional risk strategy matrix, where they are rated in terms of probability and impact, delivering the severity of the risk and the necessity to address it or not. All this information is used to determine the level of exposure to the risk.

The level of exposure to the risk determines whether or not an action plan is required to treat it. These plans are documented in a spreadsheet, along with the action plan monitoring. The action plan monitoring allows the following-up of the effectiveness of the actions taken.

v) It is considered that all risks and opportunities are to be checked in the top management review. During ~~2022~~2023, all risks were re evaluated by the officers in charge of risk management within each Division in order to update the ranking of the most relevant risks and the action plans for these risks. Given that the current situation is different from the one at the end of ~~2021~~2022, the exposure level to risks dramatically changed, which consequently led to updating the risk matrix for the next period.

3. RESOURCES

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

Human resources:

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

sufficient to deal with the inflow of work;

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

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

i) 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 regulated by the Industrial Property Law (Law Nº19.039) and its Regulations. According to these, INAPI's National Director has to assess their suitability for examination and their permanence or removal from the Expert's Register.

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 of 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**.

During 2023, a new commission composed of experts, both internal and external, started working on reviewing and updating, if necessary, quality practices, aiming to improve the quality of our national examination tasks to level them up to what is actually required in our international role as an Authority.

2) **Internal experts (examiners)**: The examiners are members of the Patent Examination Department of INAPI's Patent Division. They 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 examiners meetings to harmonize criteria.

Regarding the search and examination activities, the **Patent Examination Department**, formed by the examiners, and the **Unit of Experts Management,** are responsible for doing a continuous evaluation of 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 examinations. Indeed, the examination procedure of applications comprises a first step in which the external experts are in charge of performing the search and the substantive examination, where their work results are 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 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 team as well. As for the training courses, and given the fact that searches are to be more exhaustive as an ISA, new searching training is being planned for the examiners to accomplish the best level required for an Authority.

Currently, there are 179 staff members in INAPI and 103 external experts. The search and examination team consists of 127 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. In 2019 new professionals were incorporated and began the training program. As part of the managing plan for changes in the examiners' workload, new participants were trained to absorb fluctuations in a continuously rising demand. Hence, examiners of several technical areas not involved in PCT activities worked along with more experienced examiners in new applications filed, thereby acquiring more experience for facing the international searching tasks, helping to lighten the workload of the staff. The unfortunate events of 2020 did not allow INAPI to consider new recruitments for that purpose. This situation extended for 2022, nevertheless, some examiners were selected to take over technical areas where the workload was bigger than in others and therefore collaborate processing applications within their technical expertise with good outcomes, lowering the workload of their fellow

colleagues. As some examiners retired, new examiners were recruited and trained to take over PCT international search and examination.

The annual training program ~~that is yearly~~ conducted in INAPI considers both the technical and lingual training for the examiners. These considerations allow INAPI's professional staff to maintain both technical and language qualifications, mainly in the English language, although some examiners are skilled in the German and French language. Indeed, all of our experts, both internal and external, have at least an intermediate level of English, and 80% of them have an advanced level of this language.

~~Also, a~~Almost 50% of the technical staff has postgraduate studies, the majority of which have Masters Degrees and PhDs in their respective technical areas.

Concerning professional experience, over ~~50~~70% of our team has at least 10 years of experience in conducting search and examination patentability reports.

As a part of the improvement plan designed in 2020, one of the measures taken for improving PCT processes, especially ISA/IPEA activities, was developing a plan for handling examiners' sick leave.

ii) The Patents Division comprises a Processing Administration Unit~~, which is~~ formed by administrative staff. The purpose of this unit is supporting the Patents Division in the management and handling of the administrative work. Experience and knowledge of the PCT system is required for these officers.

As for the PCT activities, the staff of the PCT Department ~~was~~ has increased over the last years by incorporating ~~administrative~~clerical officers to the staff. This~~, which~~, along with the customized management software (SGA), allow documenting records more efficiently in case of significant changes in workload. ~~The administrative~~The staff training ~~staff was trained~~focused on diminishing repetitive mistakes made when ~~to take~~filling out ~~over~~ many PCT forms and ~~provide~~ providing assistance in uploading the files to the SGA, thereby giving room for managing work in a better way.

As a part of the improvement plan designed in 2020, one measure identified for improving PCT processes was developing peer training for other staff members who are not directly involved in PCT activities to become skilled in the PCT processes, and help improving the operational continuity of those processes, if needed.

Material resources:

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

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

(v) Describe how instructions:

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

to follow work procedures accurately and consistently

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

Every examiner is equipped with a workstation consisting of a computer with access to databases and the Internet. INAPI is continually updating these computers to have access to the latest technology and facilitate the searching procedure through faster and more efficient equipment and internet connectivity. This equipment complies with all the requirements to support all search and examination processes. IT is responsible for continuously updating the examiners' equipment and relevant software to ensure the right continuity of services, having the best tools to comply with the search and examination tasks. This task became crucial once the home office was implemented. This working modality also pushed forward the provision of laptops able to give examiners access INAPI VPNs.

Besides the renewal of the equipment as mentioned above, a PCT management customized software for processing international applications (SGA) was developed to facilitate and give guidance to the examiners when conducting the search and examination during the ISA activities. As it has been said, this software handles not only the Receiving Office activities, but also the ISA/IPEA activities, indicating the necessary steps in every stage of the procedures, 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, which simplifies and accelerates the process. A second version of the SGA was released ~~last~~ in August 2016, including improvements for more manageable and neater use. New improvements were released in 2017, which have been afterwards adjusted to suit the examiners' work in a better way. These improvements include some functionalities that allow better control of the examiners' tasks as well as a more accurate following-up of them. They also allowed improving the control register. An expert team continuously analizes and work on adapting the SGA workflows representing the ISA and IPEA activities in order to achieve greater efficiency in the use of this system. While the adjustments for ISA activities are still underway, the IPEA SGA workflow was reviewed and improved; and as from December 2021 examiners can use it when working on an IPEA request. These improvements have been of great help when working on IPEA activities, making this process more fluent and straightforward.

For continuous improvement reasons, IT staff developed a PCT financial management module that interacts with the SGA in what is concerned with the payment and handling of fees. As said above, this module improved the efficiency of the fees management and, therefore, is of great use to manage even more closely our timeliness as an ISA. In addition to the latter, during the 2020-2021 period, INAPI joined the WIPO Fee Transfer Service, which improved our efficiency in terms of monitoring the payment of applications where INAPI acts as ISA, hence allowing to have even better handling of timeliness when delivering ISRs and WO/ISAs in due time.

INAPI provides access to internal and external databases for every examiner. Apart from free searching databases such as Espacenet, Google Patents, INAPI, Patentscope, and some other Patent Office's databases, contracts have been signed to access searching platforms, namely STN (including a sequence search module), Derwent innovation (formerly known as Thomson Innovation) and Proquest Dialog. Together, they provide access to over 200 databases in all technical fields. EPOQUE Net is being used in its full access mode since 2015. Also, an agreement has been established with other government institutions 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, treaties and conventions, to the Guidelines and the internal instructions via our computer systems and on paper.

Over 2013-2014 the PCT Department, along with the Institutional Strategy Department, designed the flowcharts for both Receiving Office and ISA/IPEA procedures and the documents where all these procedures are documented. The specific document and diagram for the ISA/IPEA activities were approved and made available for all the relevant staff. During 2016, the flowcharts for RO and ISA procedures were simplified according to the SIPOC methodology, to have a more straightforward and neater way to explain and understand both procedures.

Besides, an examination manual was specifically designed for 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. However, given the recent changes in the International Search and Examination Guidelines, a second version is being drafted, which will also include the standardized clauses approved by the IB and all of the Authorities, among some new topics discussed and approved at the QSG and MIA meetings. Said clauses are currently being used by the examiners.

According to ISO standard, changes in any document have to be approved by the Deputy Director for the Patents and uploaded to the shared folder, replacing its latest version, which has to be destroyed. The change shall be communicated to the relevant staff by email.

Finally, INAPI's Examination Guidelines are in line with those stated in the PCT International Search and Preliminary Examination Guidelines, where they were developed to harmonize criteria and set a quality

standard for the examination process. Moreover, ~~in order~~ to align PCT requirements regarding patent examination, INAPI's national patent examination guidelines were reviewed and updated, aiming at aligning~~e~~ all examiners' work during the national process, as well as give a more standardized process for applicants and interested parts to understand and be familiarized with when it comes to reading the analysis included within the national search reports. The new version of these Guidelines was published in 2022 ~~thorough~~in INAPI's website.

Considering that accuracy of data is an important issue to be addressed and that the current discussions about the availability of text-searchable machine-readable contents as well as extracting and publishing data, particularly adapting to the new requirements that the PCT Minimum Documentation Task Force is currently promoting and targeting for achieving by 2026, INAPI focused part of its resources on moving forward with the transition to XML. Therefore, in 2023, INAPIs Patent Division, along with our IT division and WIPO Officers, have been consistently working to use IPAS, our national patent management system provided by WIPO, as a tool for providing all new patent documentation in XML format, hence complying with said new requirements as an ISA for making our patent documentation available in text-searchable machine-readable form.

Training resources:

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

acquire and maintain the necessary experience and skills; and

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

An annual training program is designed and reviewed at least once a year to maintain the staff's searching and examination skills within a high level of quality and complying with the best practices, according to the qualifications of the team and the specific needs that are to be covered. These training programs include, among others, language, technical subjects and examination reinforcements through online courses. Some Examiners have visited other Offices for training activities, ~~namely in France,~~such as ~~Korea,~~ Japan, ~~Brazil~~ and WIPO training activities according to its yearly training program for our region, among others.

Given the 2020 contingency, all training programs were conducted remotely. Concerning these activities, INAPI was part of a Pilot Training Program on computer-implemented inventions for Central America and the Dominican Republic, where INAPI's examiners took part as tutors or observers. Concerning 2021, some examiners are taking part as tutors in an Advanced Online Training for Patent Examiners in the Latin American Region on the Examination of Biotechnological Inventions, arranged by WIPO, which ended in January 2022. Further Advanced Online Training Activities on Biotechnological, Pharmaceuticals, and Computer-Implemented Inventions were both lectured and attended by our examiners in 2022 and 2023. Likewise, INAPI examiners participated as both students and tutors in several training activities organized by WIPO and other IP Offices that took place in 2022 and 2023. In addition, several training activities on search databases updating by our databases providers took place during the period. This is done at least once every year.

~~Given the 2020 contingency, all training programs were remotely conducted. Concerning these activities, INAPI was part of a Pilot Training Program on computer-implemented inventions for Central America and the Dominican Republic, where INAPI's examiners took part as tutors or observers. Concerning 2021, some examiners are taking part as tutors in an Advanced Online Training For Patent Examiners In The Latin American Region On The Examination Of Biotechnological Inventions, arranged by WIPO, which ends in January 2022. Likewise, in 2022 INAPI examiners participated both as students and as tutors in various training activities organized by WIPO or other IP Offices, such as the online PCT International Search and Preliminary Examination Guidelines and practice Seminar organized by WIPO and EPO for ISAs in the Latin America region, the Advanced Online Course for the Examination of Inventions in Chemical Pharmaceuticals for Latin America, also organized by WIPO and in which INAPI examiners were tutors, and the second stage of the training program that INAPI gave to examiners from the IP Office of Trinidad & Tobago, among other activities. In addition, several training activities in use updating were~~

~~organized with our database providers, which is done periodically every year. In addition, various training activities on updating their use were organized with our database providers, which is done periodically every year.~~

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 subjected to comprehensive training and selection that is divided into two stages: first, an "induction", focused on providing general knowledge and expertise with regards to patents and industrial property. ~~For~~ At this stage, INAPI usually works ~~typically~~ in cooperation with other Offices. The~~A~~ second stage corresponds to the training itself. During this period, the candidate works under the guidance of experts at INAPI, examining 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 who 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~~ while 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~~ evaluated 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 or she~~they may start working independently. The purpose of this process is that, within 18 months, all new experts ~~must be~~are prepared for conducting search and examination without the supervision of a tutor, taking into account the law, regulations and the Guidelines.

In order to improve the efficiency of this training process, there is an initiative of formalizing our training program and making it replicable for further training in the future, giving a common base, more transparent and straightforward for evaluating the participants. This program will also include reinforcing training for more experienced examiners. As a part of the improvement plan designed in 2020, another measure identified for improving PCT processes was reassessing the examiners' training and improvement program. To this end, a new training plan is was developed and implemented in April 2021.

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

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

As previously discussed, Heads of Sections of the Patents and Trademarks Division are in charge of the continuous improvement of their work area. They give feedback to the Institutional Strategy Department for this Department to review processes, analyze results, evaluate them and propose and develop strategies and actions in those processes needing improvements.

As ~~it is~~ explained further~~in the next point~~, a tool for monitoring the workload is available, where the relevant data ~~about the person responsible~~concerning the examiners time managing activities for PCT searching and examination, as well as the applications appointed to each one of them, is extracted from the SGA. This tool allows the assessment of the workload of every professional participating in the searching process, hence making ~~it~~ possible to deal with the flows in demand without neglecting quality in the process and assuring the required timeliness. Over 2023, some adjustments and refining of the data extraction criteria were conducted to have a more accurate picture of the current situation of each examiner regarding actual PCT workload.

Concerning the fulfilment of quality standards, several quality controls have been established, wherein 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 to take the appropriate actions and also identify the necessary resources to comply with these activities. Indeed, there are process indicators linked to the percentage of PCT/ISA/210 and PCT/ISA/237 forms that need to be reprocessed after being evaluated by the quality control responsible. This indicator allows identifying recurrent errors and taking actions to raise awareness on them to avoid further occurrences.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

(ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

a) To deliver 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 action is met. This information will be periodically retrieved and processed by the PCT Department to manage the activities which must be completed before delivering the Search and Examination report, according to specific follow-up mechanisms designed for these purposes.

~~In order~~ To take the most of this software, a ~~new~~ tool was also developed. This tool extracts data from the SGA, processing it to show management information, such as the number of PCT applications in a particular stage and the residence time of the applications. This data allows the identification of the applications ~~which~~that have stayed queued a longer time, and, if necessary, indicates what measures should be taken to speed up the process for them and thereby ensure timeliness. As pointed out before, in 2023, this tool was checked and improvement work is underway to make it more accurate in detecting and filtering applications under process and disregarding those that were completed.

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.

The tool pointed out in a) also gives information on the workload for each examiner participating in the ISA/IPEA process. In this way, it provides an overview of the availability of examiners in case of significant fluctuations in demand and aids the best assignment for examiners.

5. QUALITY ASSURANCE

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

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

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

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

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

i) The national phase practice includes stages that are related to a quality assurance system in the examination process. For example, before recommending grant or refusal of the application, the examination reports are reviewed by an examiner to verify compliance of the criteria established in the national law, 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 the performance of the experts and the identification of possible improvements. In this regard, 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 an excellent quality service.

To ensure the continuous improvement of the processes, the Institutional Strategy Department delivers on a weekly base a Management Report on the work of the different units of INAPI. Regarding the DEP, the report indicates the performance of each examiner in terms of due dates based on the application's status. This report is delivered to the DEP Head, who sends it to each Head of Technical Section 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 a different status to the application, depending on their stage 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. It considers the review of the entirety of the reports submitted by examiners before sending them to the applicant. Every report is approved by a supervisor by means of the fulfilment of specific checklists, which are comprehensive for assessing compliance of what is stated in the S&E guidelines, and it is expected that it will include search strategy documentation, whenever possible. Compliance of all aspects mentioned in the checklist is mandatory for delivering the report to the PCT Department. This Department will run a formal review of the form before submitting it to the applicant and the IB in a later stage. The system also considers the provision of the review results to the PCT Department to keep records that allow monitoring every examiner's activity. Based on the level of fulfilment 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 specific period. All the findings within an evaluation period will be communicated to the examiner. If the findings are of frequent occurrence, they shall be discussed in general meetings to correct said practice among all the relevant members of the staff.

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. This review is done by filling a checklist of formalities.

ii) As it was previously stated, the Quality Assurance Mechanism includes the use of specific databases that record the result from the quality reviews and, therefore, the level of fulfilment 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 to follow the result of implementing these actions to correct the practice and continuous improvement.

iii) The internal quality system for ISA/IPEA activities considers a procedure for correcting and amending any flaw detected during the product quality control. This procedure 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 to evaluate the effectiveness of actions taken in the long term.

6. COMMUNICATION

Inter-Authority communication:

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

(Note: This point is informative. No response is required by the template to paragraph 21.18)

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

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

(b) fostering continual improvement; and

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

The contact person appointed by Top Management for these purposes (a-c) is Ms. María Pilar Rivera, Head of Quality of the PCT Department, who can be contacted through the email address mrivera@inapi.cl.

Communication and guidance to users:

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

(i) An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and

offering feedback to users.

(ii) A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

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

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

INAPI gives great importance to the opinions of our users and sees in them an opportunity to identify areas for improvement concerning the service provided. In this sense, and in compliance with paragraph 21.20 of the Guidelines for International Search and Preliminary Examination of the PCT, the User Services Division has a particular Unit of Guidance and Support to patent applicants. Highly qualified professionals whose role is to advise users on matters relating to patents, either in the stage before the filing and during processing, conform 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, or the e-mail account inapi@inapi.cl.

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

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

A customer satisfaction survey is being sent to the applicants in order to evaluate the RO activities for each application filed in INAPI as receiving Office and where the RO process for the particular application came to an end. Another survey was designed for ISA/IPEA activities. This survey is being sent to the applicants monthly, to receive feedback on the utility and quality of the ISR and WO. These are closed surveys, which give room to the applicant to indicate the points of interest and, therefore, identify where could be room for improvement. In addition to this, INAPI has been conducting a yearly meeting with part of the most reputed representatives and agents to get their feedback, attend to their necessities and make the necessary adjustments for improving our quality service to the customer.

Besides the latter, Resolution N°687, dated November 16th, 2011, creates the Civil Society Council, composed of at least five non-profit civil society representatives (who work ad-honorem) related to policies, services, programs, or plans carried out by INAPI. It is a consultative, self-governing authority that contributes from their experience and knowledge giving their opinion and feedback to our institution in subjects regarding Industrial Property and INAPI's functioning, among which quality and PCT matters have been constantly included. This Council gathers at least once a year, and it is formed by representatives of agents, universities, inventors and enterprises, among others.

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

Further information on quality, such as quality objectives and the commitment letter on quality, are available through INAPI's web site.

In order to further enhance the transparency of the PCT activities, a new online statistical tool for all PCT applications in the international phase (INAPI acting as RO, ISA and IPEA) was developed. This tool ~~("INAPI Analiza")~~ was uploaded on our web site for any interested user to visit it for consultations regarding the number of applications filed per year, technical areas of the applications, election of ISAs, the RO where our ISA applications were filed, among others. PCT statistics have also been included in the PCT section of the INAPIs web site.

Over 2019, our “INAPI's PCT user guide” was updated to cover information not originally considered. This update includes the addition of ISA/IPEA relevant information and topics of our users' everyday consultation, both for PCT international and national phases. This updated guide was uploaded to our institutional website for user consultation and has been introduced in every PCT activity taking place over the last couple of years. In addition to this improvement, PCT Department also made available to the users a new FAQ section on INAPI’s website to clarify our users’ most frequently asked questions and inquiries.

In 2023, Resolution 255/2023, creating the User Quality Service and Experience Committee, was published. This Committee advises on matters regarding INAPI's service quality policy, including improving the users perception of the Institute, making staff members aware of the need to provide a service of quality to our users, and advising Top Management on these matters, among others.

Given that the outcomes of the ISA surveys revealed that our users are not quite acquainted with patents language, INAPI and WIPO have jointly organized a patent drafting program for patent users. In 2021 the first online version of this program was launched, which was perceived as a valuable program according

to the participants. ~~A second~~Further versions of the program took place in 2022 and 2023~~ and we are currently discussing the possibility of developing a new training within 2023~~. With this program, INAPI aims at improving the quality of the contents of the international applications, since at it has been repeatedly pointed out by when studying applications to draft a search strategy, there are many excellent and apparently innovative inventions that can not be ~~analyzed~~analysed due to the lack of clarity of their contents. Hence, this program may be a key to unlock this particular difficulty, thereby encouraging the protection of new creations by more innovators not willing to use PI tools because of these entry barriers. Considering the success of the announcement and the number of people wanting to take part in the program, new versions are considered for the coming years, starting in 2024.

As another measure for improving the quality of the drafting of the patents, INAPi keeps imparting its inventors' and entrepreneurs' support program, called INAPI Running. This program seeks to advise and guide applicants regarding more specific IP knowledge and strategies. The Patents Division takes part in this program, lecturing about Patent Rights and mentoring applicants who want to file patents, including the use of the PCT system.

It is also important to point out that during 2022 INAPI joined the Inventors' Assistance Program (IAP) initiative. IAP links entrepreneurs with insufficient funding but wanting to protect their creations with volunteers within the IP agents in Chile who take the selected creations to draft, ad-honorem, the correspondent patent application for these entrepreneurs. This initiative allows INAPI to be a promotion organ for innovation and IP benefits spreading voice. A second version of the program was launched in 2023, and the selected candidates are currently working along with their volunteers to develop their applications.

Additionally, INAPI and the USPTO jointly organized a seminar~~ium~~ about PCT, focusing in INAPI's role as an ISA/IPEA and the process at the USPTO when entering PCT National Phase. During 2022, WIPO Director General, Mr. Daren Tang visited INAPI. During Mr. Tang's visit, INAPI announced several initiatives to encourage entrepreneurs, innovators, developers, among others to use IP as both a protection and developing tool for their processes, inventions and innovations. These in~~n~~itiatives aim at facilitating the post-COVID ~~covid~~ entrepreneurship ecosystem recovery. One of these announcements was the creation of the first Intellectual Property Training Academy in our country. In august 2023, INAPI and OMPI jointly organized the first in-person PCT seminar since the COVID pandemic, with a full venue regardless of the available online transmission.

21.21 Communication with WIPO and designated and elected Offices:

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

The communications with WIPO, the other Authorities and the Designed and Elected Offices are 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.

INAPI is operating with the e-PCT system, which allows electronic transmission of applications to WIPO, as well as electronic filing of the applications by applicants.

7. DOCUMENTATION

21.22 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 by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a) the documents making up the reference that have been prepared and distributed;

(b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and

(c) document control measures taken e.g. version numbering, access to latest version.

Given the work done in terms of adapting some internal processes to qualify for an ISO 9001:2008 certification, a Quality Manual was prepared. This manual is the master document for the functioning of the processes under the scope of the intended certification. It is a controlled document, managed and controlled according to what is indicated in a specific procedure. 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 an internal server for consultation if required. In 2017 INAPI worked on re-certification under the ISO 9001:2015 standard; therefore, some of this documentation was changed due to the new requirements for this standard. However, all the documented information is available to our staff members via a Google site, specially designed for this matter. The site gathers a vast quantity of information about the PCT processes and our QMS, including our Quality Manual, quality policy and objectives, processes map, our strategic and operation processes, among any other information of interest.

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. Currently, it is going under revision in order to release a second version.

A specific document control procedure was elaborated and documented. This document indicates all necessary steps for changing an existing document after a necessity to do so is detected. Every controlled document shall have a title, a specific code 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 have to be destroyed.

21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

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

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

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

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

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

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

The Quality Policy with the correspondent statement from Top Management, 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 between those processes are covered by what is pointed out in the Quality Manual and the available information in our internal Google site. It is stated in this Manual that the institution's organizational structure and the responsibilities of each of its departments are documented in INAPI's website. The Quality Manual currently does not refer to the documented processes for search and examination procedures. However, those documents (e.g., Examination Manual under ISA scope) are available to examiners and are intended to include them in a newer version of the Quality Manual once wholly reviewed and updated.

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

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

(ii) results of management review;

(iii) training, skills and experience of personnel;

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

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

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

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

(viii) records of QMS audits;

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

(x) actions taken re. corrective action;

(xi) actions taken re. preventative action; and

(xii) search process documentation as set out in Section 8.

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

• A list of the documented information was created and made available in our Google microsite. This document describes their location, format, where they are to be kept, among other information.
• In order to obtain the certification and adapt to the ISO 9001:2015 standard new requirements, all documentation was reviewed and evaluated. As a result, it was considered that there was no need for maintaining a specific procedure for evidencing the conformity of the processes. However, there is a process for that purpose, and the compliance of processes, products and services is properly registered.

• The results of the, at least, yearly management review which are kept in the Institutional Strategy Department and it is made available in our internal Google site
• Records on the CV, experience, training 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 with the PCT international phase procedure for quality measures purposes. Therefore, this software contains all the information related to every ISR WO/ISA and IPEA products that are drafted by our examiners, including every properly filled-out checklist, to evaluate the conformity of the product in terms of quality standards and every step of every search and examination process for each application
• Every QMS audit activity shall be recorded, according to what is stated in the Quality Manual.
• INAPI has determined, planned and implemented the necessary follow-up, measuring, analysis and evaluation processes for evaluating both performance and efficacy of its QMS. The outcomes of the process of analysis and assessment of the final products (ISR, WO and IPRP) are used to evaluate the conformity of these products, the satisfaction level of the user, performance and efficacy of the QMS. They are also used to assess if what was planned was efficiently implemented, the effectiveness of actions taken to manage risks and opportunities, the performance of external suppliers and the need for improvements in the QMS.
As for the actions taken regarding non-conforming products, the SGA holds all the information of corrections made on every product that didn't comply with the quality control process. Those forms are returned to the examiner for their correction before their submission to the user. Regarding non-conformities and corrective actions, every non-conformity is to be controlled by INAPI (complaining included) and corrective actions for it are taken. There is a process in place for managing non-conformities and corrective actions, and a registry of non-conformities and corrective actions which are stored in our Google microsite.
• When running a search, examiners are requested to document the search strategy and it is expected that shortly this document is to be submitted according to what is stated in the Examination Manual.

8. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

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

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

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

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

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

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

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

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

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

(vi) limitation of search and its justification

(vii) lack of clarity of the claims; and

(viii) lack of unity.

In the national phase, the search documentation is registered in the examination report itself, such as the consulted databases, the used languages, consulted classes and subclasses, justification and limitation of search, if any, and also records about lack of clarity of claims and unity of the invention. However, to

fulfil the requirements of the international standards as ISA/IPEA, a new procedure for searching documentation is being developed, which will be in harmony with the PCT Guidelines and the agreements that are to be taken in the MIA. The new forms are already being used and included in the national phase customized software for drafting reports.

Concerning the searching procedure during the ISA stage, a template was created and Examiners were requested to document the databases that were consulted, their search statements, including keywords, truncations and their combinations, language and classes and subclasses. Any other relevant information regarding the search has to be recorded as well. Currently, this template is filled-out and uploaded in the SGA in the correspondent stage during the search and examination process by the professional responsible for drafting the ISR and its written opinion.

The currently 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.

9. INTERNAL REVIEW

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

21.28-21.30 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

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

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting.

[End of document]