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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.

This report has been prepared as a comprehensive and detailed presentation of INAPI's Quality Management System for the processing of international PCT applications. In this context, and rather than limiting the scope to updates and developments from the past year, it was decided to issue a document presented in a clean format, without tracking marks. Accordingly, the activities undertaken during 2025 are summarized in the introductory section.

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.

I. INAPI and its Quality Management System:

INAPI was established in 2009 as a decentralized institution with technical and legal responsibility for the administration and management of industrial property services in Chile. Since its inception, the institution has demonstrated a steadfast commitment to raising public awareness regarding the value of citizens' creations and their protection. Accordingly, INAPI's mission is to develop the national industrial property system through rights protection, knowledge dissemination, and the promotion of a balanced and comprehensive vision of industrial property, thereby contributing to Chile's economic and social development.

To fulfill this mission, INAPI is committed to delivering services of the highest quality by maintaining an appropriate organizational structure and implementing a wide range of initiatives directed toward this objective, among other measures.

The commitment to quality is reflected in the redefinition of INAPI's institutional priorities, including the decision to design and implement a Quality Management System aimed at delivering high-quality service to the public. This commitment was formalized through INAPI's Quality Policy, approved by Resolution No. 1392 on October 10, 2013. The resolution disclosed the development of a Quality Management System based on the principles of continual process improvement and staff management and training.

Subsequently, in 2014, to advance the quality of its services, INAPI undertook the refurbishment of several processes, including those of the Receiving Office within the PCT system, with the objective of certifying them under the ISO 9001:2008 standard. These processes successfully obtained certification in November 2015.

Further demonstrating its dedication to quality, INAPI's Top Management resolved to expand the certification scope to include all PCT International Phase processes, specifically the ISA/IPEA activities, for the renewal under the ISO 9001:2015 standard. This renewal incorporated new features such as risk management among others. The ISO 9001:2015 certification was granted in 2018 and has been continuously maintained since, with no non-conformities identified during annual external audits.

The certification under ISO 9001:2015 and the standardization of all PCT procedures have proven valuable to the Office, particularly as the scope of International Search and Examination services expanded to include applications filed in English from Latin American and Caribbean countries. In these cases, the International Search Report (ISR), Written Opinion (WO), and International Preliminary Report on Patentability (IPRP) are drafted in English upon the applicant's request.

It is important to highlight that INAPI's recent role as an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) significantly contributed to national recognition when INAPI was awarded for Excellence as a Public Service. In 2016, INAPI was recognized as one of the three best public institutions in Chile. This award emphasizes the contribution of public institutions to citizens by enhancing their daily lives through the highest quality levels of service. Furthermore, INAPI received this distinction again in recognition of its work during 2018 and 2020. In these instances, particular acknowledgment was given to aspects related to our Quality Management System, underscoring our strong commitment to service quality and continuous improvement of the user experience.

Over the last 5 years, INAPI consistently advanced its quality objectives, with a focus on reducing processing times for international PCT patent applications by analyzing various aspects of both the applications received and time usage. Regarding the quality of applications and the completeness of the information required to create clear and robust documents, INAPI introduced new resources to assist applicants in properly filing their applications. To this end, patent drafting training courses have been conducted jointly with WIPO, attracting significant participation from diverse user groups.

Additionally, INAPI has joined WIPO's Inventor Assistance Program (IAP), which has attracted significant interest from inventors seeking sponsorship from intellectual property agents to support the filing of patent applications. Owing to the positive response and high demand, annual editions of the IAP and related patent

drafting training have been conducted. To date, 32 candidates have applied to the IAP, with 16 selected by the National Screening Board, resulting in the filing of 8 patent applications and the grant of 2 patents.

Meanwhile, the patent drafting workshop called applicants from across Latin America, targeting a specialized group capable of acting as multiplier agents within their communities, thus disseminating patent processing knowledge across scientific and entrepreneurial networks. Facilitators welcomed an increased number of participants by year, resulting in highly successful workshops.

Regarding time management, statistical data collection has enabled measurement of average processing durations at various stages of the international search procedure, highlighting areas for potential improvement such as extending the search process itself and managing the number of documents cited in the International Search Report. To reduce common formal errors in PCT form submissions, the PCT Department staff revised relevant forms, particularly the PCT/ISA/210 and PCT/ISA/237, to help prevent omissions such as unchecked boxes on the first page. After one year of using these modified forms, the incidence of forms requiring corrections has decreased compared to previous years.

In 2022, Law N°21,355, an amendment to Law N°19,039 on Industrial Property in Chile, modernizes the country's IP legislation to better facilitate innovation. Among other provisions, it allows for provisional patent application filings and grants certain fee reductions to PCT applicants entering the National Phase in Chile—provided they have selected INAPI as their ISA/IPEA and meet the specified criteria.

Following the update and release of INAPI's national patent examination guidelines, the Patents Division produced tutorial videos aimed at clarifying exclusion criteria and patentability requirements, including guidance on emerging technologies such as computer-implemented inventions and related exclusions. In 2023, INAPI launched a green patents program designed to expedite processing times by approximately 30% for applications focused on environmentally beneficial technologies.

Among the accomplishments noted, INAPI has been designated as an eligible ISA/IPEA by 14 Latin American countries and the Caribbean, selected to conduct international preliminary searches for more than 2,950 PCT applications and issuing over 2,650 International Search Reports and Written Opinions in both Spanish and English. The annual volume of applications has stabilized at approximately 300 per year.

According to data from the WIPO Statistics Data Center, INAPI's role as an ISA has contributed to the growth of PCT filings in Latin America and the Caribbean. This trend is particularly evident at the Receiving Office in Chile, where filings have steadily increased, except in 2021, when the COVID-19 pandemic caused a temporary decline due to worldwide lockdowns and reduced funding for research and development affecting entrepreneurs and researchers alike.

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During 2025, the Patents and IT Divisions have collaborated closely, concentrating their efforts on establishing the necessary measures to commence the transition from PDF patent publications to XML format. To date, the Office has successfully prepared and formatted INAPI's Authority File and begun issuing new patents directly in XML format, conforming to the ST.36 standard. These results have been submitted to WIPO and INPI-Br for cross-validation, which yielded positive outcomes. INAPI is therefore confident in its full compliance with the objectives set by the PCT Minimum Documentation Task Force, thereby ensuring the availability of published patents in XML format for all interested parties from January 1, 2026, onwards.

In parallel, the teams have initiated the development of workflows aimed at optimizing data quality and consistency across different publication stages. Special attention has been given to metadata accuracy, schema validation, and the automation of conversion processes to minimize manual intervention. Looking ahead, INAPI plans to further integrate these processes into its patent management systems, enhancing interoperability with international databases and contributing to a more transparent and efficient dissemination of patent information.

II.2 Timeliness

One of the primary objectives of the PCT International Search Report (ISR) submission at INAPI is to provide the outcomes of the international search, together with the Written Opinion of the International Searching Authority (WO/ISA), in a timely manner. This allows applicants sufficient time to make informed decisions regarding their intellectual property strategy prior to the publication of the application in Patentscope. Accordingly, key indicators within INAPI's Quality Management System are associated with the timeliness of ISA report issuance, aiming not only to meet legal deadlines but to deliver this essential information as early as possible, even for applications that do not claim priority. Throughout 2025, the Patent Examination Department has prioritized issuing ISRs and WO/ISAs for non-priority applications without delay, maintaining parity with reports for applications with priority claims. This concerted effort has led to a positive impact on timeliness key indicators compared to 2024 performance. In 2025, more than 55% of Search Reports and their Written Opinions have been submitted at least one month prior to the respective due dates. This advancement is expected to alleviate examiner workload and improve the management of their various responsibilities.

II.3 Strengthening IP awareness and knowledge beyond Santiago (capital city of Chile)

INAPI conducted a diagnostic evaluation to assess the level of public awareness across the country regarding the fundamental concepts of Intellectual Property and the benefits of safeguarding creations through IP rights. The evaluation revealed that both individuals and enterprises possess limited knowledge in this area, with those located outside the Metropolitan Region being comparatively less familiar with such rights. This lack of awareness is reflected in the filing patterns for trademarks and patents: fewer than one-third of trademark applications originate from outside the Metropolitan Region, while patent applications from other regions account for only around 43% of national filings. Furthermore, the study highlighted limited access to patent information and documentation among potential IP system users outside Santiago.

Recognizing the need to expand IP understanding and strengthen the management and use of IP rights across all Chilean regions, INAPI established strategic objectives aimed at improving service accessibility and promoting regional engagement with the intellectual property system. To advance these goals, the institution secured over USD 2 million in public funding to enhance the availability and use of IP rights nationwide, reinforce INAPI's internal capacities, and deepen collaboration with regional innovation ecosystems. Key initiatives include:

- Developing an open-access IP web platform for patent information, launching a pilot project collaboratively with three regions to identify and address specific technical challenges.
- Creating a web platform for CATIs (Technology and Innovation Support Centers) to enhance outreach and connectivity with local communities.
- Conducting IP training and targeted promotional activities across regions through digital marketing strategies.
- Designing an integrated platform to centralize all of INAPI's services in a single access point, with personalized navigation tailored to different types of users.

To date, some of these initiatives have been evaluated, and concrete actions are currently being planned and advanced, including:

- Coordination for the appraisal and analysis of regional technical needs in collaboration with an already established working group;
- Development of a dashboard to collect and display identified technical needs in situ;
- Prioritization of the identified needs;
- Search and technological surveillance of IP rights assets to identify appropriate solutions;
- A pilot project for a platform addressing the evaluated needs, open to all enterprises and regional stakeholders, aimed at validating the platform's utility and measuring its impact;
- Assessment of the feasibility of contracting services to produce 20 videos for INAPI to strengthen promotion and knowledge of Industrial Property among users, broadening outreach and refining technical understanding of IP rights processing; these videos are intended for dissemination through social media and institutional platforms;

- Contracting services for the design, implementation, and management of digital marketing campaigns targeting regional users to promote INAPI's tools and services, including workshops, online training, and consultancy.

II.4 Cooperation with other IP Offices

In 2023, INAPI and the European Patent Office (EPO) signed a new Agreement for technical and strategic cooperation focused on data exchange and the high-quality, effective promotion of intellectual property systems. This Agreement aims to ensure efficient patent examination processes, facilitate continuous improvement of international patent systems, and promote innovation and bilateral trade between Europe and Chile.

A key objective of the Agreement is to enhance the quality of the patent examination process. To this end, INAPI will exchange information and practices, and also will receive training, tools, and technical support from the EPO, and both Offices will benefit from each other's prior work. The Agreement also includes establishing regular exchanges of patent data to improve patent examination quality for both parties. Additionally, activities aimed at improving the patent system will be conducted not only for staff members but also to raise awareness of the advantages of the IP system for local innovators and the global user community.

Since the signing of the Agreement, INAPI and the EPO have engaged in regular collaboration to share best practices and advance a jointly designed roadmap established in 2024 for a two-year period spanning 2025–2026. To date, meetings have been held to discuss search and examination quality, identify improvement opportunities, and determine appropriate tools to expedite the examination process by leveraging EPO work results. Concurrently, IT teams have collaborated on technical cooperation concerning patent data exchange, reviewing the flow of Chilean patent information and working to improve the completeness and quality of front file data.

In support of awareness-raising efforts, INAPI and the EPO jointly organized an online international seminar in November covering the Patent Cooperation Treaty (PCT) and the European Unitary Patent.

Additionally, in 2023, INAPI joined WIPO's International Cooperation for Patent Examination (ICE) program as a donor Office, a pro-bono initiative designed to enhance the efficiency of patent examination in developing countries with limited substantive examination capacity by facilitating the preparation of search and examination reports through participating donor Offices. Under this program, INAPI has served as a donor Office for Trinidad and Tobago and Panama and stands ready to continue supporting patent offices in Latin America for this purpose. Moreover, aligned with this efficiency objective, similar activities were carried out between INAPI and the Dominican Republic under a bilateral cooperation agreement between the two Offices.

II.5 AI Advances

Since 2016, INAPI has actively pursued the implementation of Artificial Intelligence (AI) technologies. The global interest in AI has steadily increased due to its growing relevance and impact across numerous technical fields, a trend expected to continue for the foreseeable future. In response, the Chilean Government established and subsequently updated a National Artificial Intelligence Policy (in 2021 and 2024, respectively). This policy provides a national strategic framework guiding AI development and adoption within the public sector, structured around three core axes:

- **Enabling Factors:** Focusing on talent development, technological infrastructure, and data management;
- **Development and Adoption:** Emphasizing research, innovation, technology transfer, entrepreneurship, and the integration of AI across various sectors, fostering collaboration among academia, and public and private sectors to enhance productivity and modernize the State;
- **Governance and Ethics:** Centered on establishing clear regulatory frameworks, protecting fundamental rights, ensuring transparency, and promoting international cooperation to define common standards.

Complementing this, guidelines for AI tool usage in the Chilean public sector underscore the importance of developing AI systems that prioritize individual benefits, respect all fundamental rights, and are secure, reliable, inclusive, and sustainable.

In recent years, INAPI has implemented AI solutions to improve its internal processes. This journey began with the development of an image search tool for trademarks in collaboration with the University of Chile. In 2024, AI applications within the Trademarks Division advanced further with the creation of a generative AI application to assist in product and service classification under the Nice system. This application accelerates and enhances the review of classifications, proposes alternative coverage options, and verifies class assignments. The solution achieved an accuracy rate of 98% in automated classifications and increased senior examiner productivity by 33%. A version tailored for external users is under development and expected to launch in 2025.

AI is also leveraged in gender-related initiatives, particularly in identifying inventor gender to generate and publish statistics on female participation in the industrial property system, as part of INAPI's periodic gender reports.

During the development and deployment of these AI tools, the responsible team recognized the necessity for a robust regulatory framework to ensure responsible and effective AI use in the Office, aligned with the National AI Policy. Consequently, in 2025, INAPI designed an AI Strategy that will be launched shortly. This strategy is founded on collaboration involving public entities, international organizations, private sector partners, academia, and civil society to guarantee a comprehensive and participatory approach. The strategy aligns with principles of innovation and sustainable development, contributing to a secure and equitable digital ecosystem.

The AI strategic framework is organized around five key pillars:

63 **Governance and Ethical Framework** focused on ensuring the responsible development and deployment of AI systems, safeguarding user rights, and protecting data privacy.

- Establishment of an institutional AI Committee.
- Implementation of clear policies for the ethical and responsible use of AI.
- Development of data security and privacy protocols.
- Promotion of human oversight in all AI-assisted decision-making processes.

73 **Infrastructure and Technical Capabilities** aimed at building a robust technological foundation to support the efficient implementation of AI-based solutions.

- Adoption of a comprehensive data governance model.
- Modernization of systems and platforms for enhanced interoperability.
- Deployment of advanced data processing and analysis tools.
- Integration of AI with existing systems such as IPAS and SGP.

83 **Talent and Culture Development** designed to foster continuous staff training, facilitate organizational change management, and promote a culture of innovation.

- Continuous training programs for staff in AI technologies and methodologies.
- Promotion of an institutional culture centered on innovation and adaptability.
- Incorporation of AI specialists into multidisciplinary teams.
- Encouragement of interdepartmental collaboration to share knowledge and best practices.

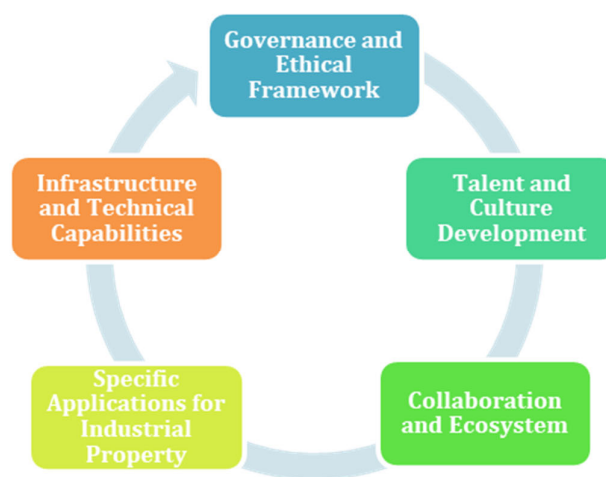
93 **Specific Applications for Industrial Property** focused on enhancing both internal efficiency and public service delivery through the application of AI-driven tools.

- Implementation of AI solutions for patent registration.
- Application of AI technologies in trademark registration processes.
- Development of AI systems to support INAPI's function as a judicial authority.

- Automation of administrative and procedural tasks.
- Deployment of AI-powered tools for user support and guidance.

: 3 **Collaboration and Ecosystem Development** dedicated to building and strengthening strategic partnerships with key actors in the innovation and technology ecosystem.

- Strengthening cooperation with WIPO and others intellectual property offices.
- Establishing partnerships with universities and higher education institutions.
- Active participation in international innovation and AI networks.
- Building linkages with the private sector to promote technological synergy.
- Coordination with other public institutions to foster cross-sectoral AI initiatives.



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The forthcoming stages of this strategy aim to strengthen Chile's leadership in technological transformation by promoting the responsible use of Artificial Intelligence to achieve sustainable and equitable societal development. A key focus of the strategy is the development of specialized intellectual property tools. In the context of the patent process, the primary objective is to utilize AI to optimize each phase, including application filing, search, and examination. This initiative is designed to accelerate processing times while enhancing access to information for the benefit of both users and patent examiners. Furthermore, this optimization and ongoing monitoring will generate valuable data to identify opportunities for improvement and advance patent processing quality, thereby meeting the expectations of relevant stakeholders.

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) At the initial stage of designing and implementing INAPI's Quality Management System, the Office published Resolution No. 1392 on October 10, 2013, which approved the Quality Policy as an integral element of the system's development. This policy is grounded in the principles of continual process improvement and effective staff management and training. The document was disseminated to all staff via email and made accessible on INAPI's website. Subsequently, the Quality Policy was reviewed and

enhanced as outlined in Resolution No. 223/2014. Representatives of top management conducted meetings across all Divisions to inform and clarify the content and objectives of the policy to all personnel. The updated policy was also published on both the institutional website and the QMS microsite, which hosts all relevant information related to the system, including the list of documented information and associated records.

The revised Quality Policy articulates that INAPI's quality commitment is founded on the reliability and impartiality in the registration, management, and promotion of industrial property, accompanied by high service standards for users and stakeholders, ongoing process improvement, and staff dedication. Accordingly, INAPI's commitment focuses on:

- Managing industrial property applications efficiently and within established timeframes, in accordance with national and international guidelines, laws, and regulations.
- Understanding the perceptions of users and stakeholders regarding the services provided, and maintaining effective communication concerning inquiries, suggestions, and complaints, to enhance overall satisfaction.
- Continuously improving the effectiveness of processes encompassed within the Quality Management System's scope.
- Consistently developing the skills and expertise of INAPI's staff, while fostering strong motivation and commitment to meet users' requirements and expectations.

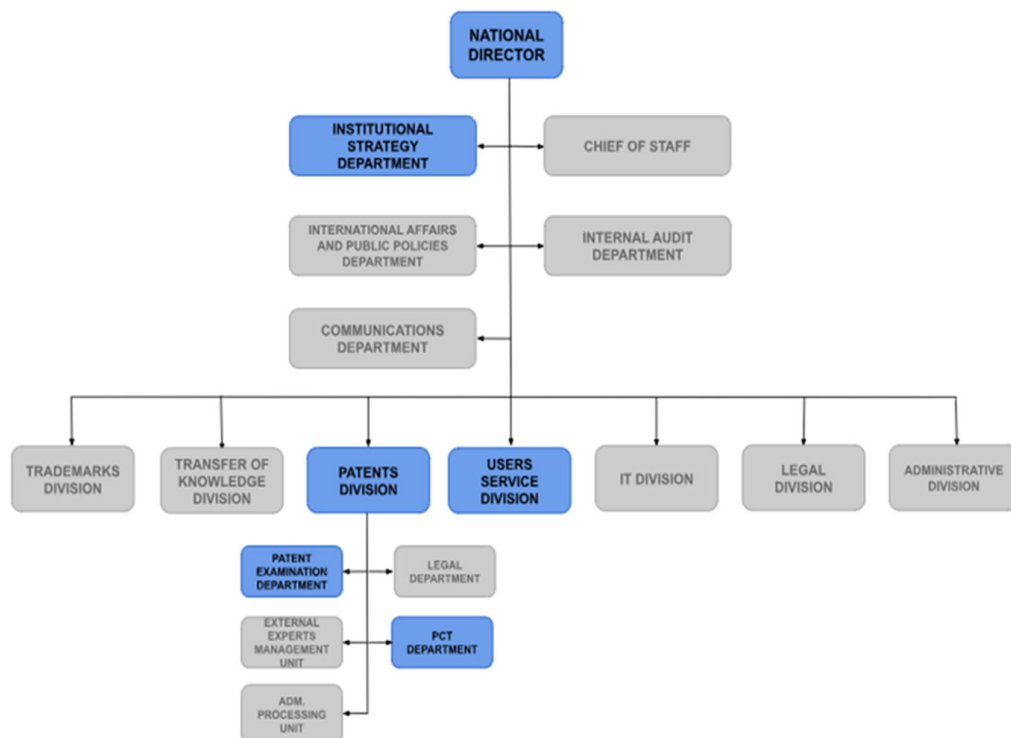
- (b) By Resolution N° 1135/2013, top management delegated Mr. Felipe Welch, Head of the Institutional Strategy Department, as the Quality Manager of the Institute and established a Quality Management Committee. In addition, top management issued Resolution N° 1028/2013, appointing Ms. María Pilar Rivera as Head of Quality within the PCT Department.

At the initial stage, the Quality Manager held responsibility for the implementation and continual enhancement of the Quality Management System. Meanwhile, the Head of Quality of the PCT Department was in charge of overseeing INAPI's adherence to quality standards and best practices specific to the requirements for processing international applications under the PCT. However, to fully leverage the benefits of operating under the ISO 9000 standard—particularly regarding continuous improvement and more precise monitoring of process outcomes—top management resolved to strengthen the role of the PCT process coordinators. Consequently, both the Quality Manager and the Head of Quality of the PCT Department were appointed as QMS coordinators, jointly responsible for the system's continual improvement.

In accordance with paragraph 5.3 of the ISO 9001:2015 standard, INAPI also designated process owners, assigning this role to the Heads of Departments responsible for operative and support processes (including PCT processes, Acquisitions, Human Resources, and IT Systems Development). Additionally, Internal Auditors were defined to conduct annual internal audits of the Quality Management System.

- (c) As illustrated in the organizational chart below, INAPI is led by the National Director, who is supported by a team of professional advisors primarily specializing in policy matters. INAPI's operations are organized into three main business areas: the Trademarks Division, the Transfer of Knowledge Division, and the Patents Division. The Patents Division comprises various technical examination units alongside a dedicated group of officials responsible for providing user guidance. This structure ensures that patent analysis and examination are conducted rigorously while offering comprehensive advice and support to system users, including inventors, universities, research centers, and law firms.

The Patents Division also encompasses the PCT Department, established under Resolution N° 991/2013, charged with organizing and overseeing all activities related to the effective implementation of the PCT within INAPI. This unit manages the processing of all applications submitted under INAPI's role as a Receiving Office (RO), International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA). The Head of the PCT Department, appointed by Resolution N° 1028/2013, is currently Mr. Henry Crew.



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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
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 to paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains technical qualifications to search and examine in all technical fields	✓		
	(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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(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 and information on the search and examination process for the user	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21		(a)	Established communication with the International Bureau	✓		
		(b)	Established communication with 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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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 limitation of search and its justification	✓		
	(vii)		Records about lack of clarity of the claims	✓		
	(viii)		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, composed of the National Director, the Deputy Director of the Legal Division, the Chief of the Administration and Finances Division, the Deputy Director for IT, and the Head of the Institutional Strategy Department, holds primary responsibility for ensuring the effectiveness of the Quality Management System (QMS). The Committee's duties include reviewing the progress of the quality program, discussing and approving quality-related documents and issues, and conducting an annual review of the QMS to verify the proper execution of activities aligned with the compliance of QMS objectives. Moreover, in line with INAPI's ongoing commitment to delivering the highest quality services, the Internal Audit Department plays a vital role by assisting the National Director in designing and implementing plans for reviewing and evaluating the administrative and financial management of the Institute. The audit function is predominantly preventive, with the Internal Audit Department responsible for proposing policies, programs, and control measures to strengthen institutional management and safeguard INAPI's allocated resources.

Additionally, in fulfilling ISO standard requirements, the Institutional Strategy Department has developed and documented several procedures to ensure the QMS's effectiveness. INAPI has defined, established, and scheduled multiple tools for analysis and measurement to drive continuous improvement. These tools include managing non-conformities, corrective and preventive actions, client/user/beneficiary satisfaction surveys, audits, complaints and suggestions handling, and management reviews. These efforts collectively aim to demonstrate service conformity while ensuring and continually enhancing the QMS's effectiveness.

- (b) Concerning business areas overall, each Head of Section (e.g., Patents and Trademarks Division, Transfer of Knowledge Division) is accountable for the continuous improvement within their respective domains. These leaders provide feedback to the Institutional Strategy Department, which is tasked with reviewing processes, analyzing and evaluating results, and proposing strategies and actions to enhance processes requiring improvement.

The Quality Management Committee reports directly to the National Director on matters related to service quality and the QMS. Additionally, the Internal Audit Unit participates in the Quality Management Committee solely to ensure compliance with regulatory oversight requirements governing the QMS at INAPI. The Internal Audit Unit also participates in the annual internal audit process for QMS, with both the Head of the Unit, along with an Officer of the Legal Division having received specific lead auditor training in accordance with the ISO 9001:2015 framework.

To assess the adequacy of the Quality Management System, top management conducts an annual review to evaluate the outcomes of involved processes following adjustments made the previous year in response to observations, improvement opportunities, or non-conformities identified through internal or external follow-ups. This review encompasses, among other activities, findings, if any, of both internal and external audits to the QMS conducted within the reporting period, alongside analysis of key indicators outcomes linked to the quality objectives. Accordingly, top management examines the level of compliance with commitments and quality indicators presented in the institutional control panel, which documents goals, measurement periodicity, and comprehensive monitoring data to ensure the QMS's effectiveness. Process owners collect and incorporate data into the control panel, enabling systematic comparison with previous years to determine whether observed improvements are attributable to previously implemented modifications. This evidence-based approach supports subsequent planning, implementation, evaluation in the next top management review, and, where necessary, further modifications in accordance with the Plan-Do-Check-Act (PDCA) cycle.

Moreover, the ISO 9001:2015 standard introduced risk management as a key requirement, fostering continuous monitoring and the implementation of actions to mitigate risks that may impact certified operations. This framework inherently supports ongoing oversight and progress of continual improvement initiatives.

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 hold regular meetings with examiners and administrative staff to provide feedback on the evolution of key indicators. Additionally, updates regarding the Treaty and regulatory requirements are communicated, alongside information about quality standards and the Quality Management System. Any necessary remarks concerning common errors identified during quality assessments of reports, and the required corrections to ensure compliance with quality and legal standards, are also addressed. Furthermore, the Head of the Patent Examination Department (DEP) and the staff of the PCT Department regularly disseminate information to all personnel within the Patents Division, covering critical topics such as indicator trends, new procedures, and other relevant updates pertinent to their work.

In addition to these meetings, the PCT Department periodically monitors all relevant materials related to the PCT, including the Treaty, Rules, and Guidelines. When updates occur, the process owner revises the documented information list by updating the version number, date, and if applicable, the new document location. These materials are accessible to both the Examination Department and PCT staff. Any announcements regarding PCT requirements are promptly posted on this platform.

- (b) To ensure alignment between the Quality Management System and the PCT Guidelines, the QMS coordinators conduct regular meetings with staff to emphasize the importance of the QMS and the requirements established by the Treaty and its rules as external reference documents. These sessions

also cover the criteria specified in the ISO standard and the appropriate methods to satisfy these requirements. The Quality Manual contains an annex linking the QMS with the PCT Guidelines and is integrated within the QMS site, accessible for consultation by 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.*

- (a) In accordance with the requirements of ISO 9001:2015, the Quality Manual stipulates that INAPI's top management shall conduct at least one management review every 12 months. This review is scheduled shortly after the completion of the annual internal audit, typically in the last fortnight of April, to ensure that all relevant information regarding the Quality Management System's performance during the year under review is available. Among the inputs for these reviews are the internal and external audit reports; reports from process owners detailing the performance of internal processes and service conformity, including the resources necessary to maintain continuous operations efficiently and effectively; the status of corrective and preventive actions identified within the period; and any other pertinent information related to the QMS. This comprehensive data enables top management to determine and allocate the resources required to implement, maintain, and continuously enhance process effectiveness and achieve client/user/beneficiary satisfaction by meeting their expectations.
- (b) The Quality Policy and Quality Objectives constitute essential input for the annual top management review; thus, they must be reviewed at least once every 12 months alongside all other information gathered on the QMS's annual performance. These objectives may be reassessed and adjusted, if necessary, in light of internal and external issues identified for the forthcoming period.
- (c) The management representative disseminates the Quality Objectives to all staff through general meetings, the Office intranet, and email communications, thereby reinforcing their importance. These objectives are also publicly available on the Office's website and within the shared directory on INAPI's servers for staff access. To further emphasize the significance of these objectives and the value of each staff member's contribution, since 2016, process owners and involved team members have communicated the Quality Objectives directly to each Department within the Organization. This approach fosters closer engagement and awareness among staff regarding the importance and impact of their roles within the Quality Management System.

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 previously indicated, an annual review is conducted by top management to evaluate the effectiveness of the Quality Management System and make necessary adjustments to ensure its continual improvement. This review is held shortly after the annual internal audit, in compliance with the ISO 9001:2015 standard requirement 9.2. The internal audit is comprehensive and thorough, encompassing all QMS processes. Within this framework, PCT quality procedures are also regularly reviewed and updated as necessary.

- (b) With respect to compliance with Chapter 21 and the degree to which the Quality Management System adheres to it, our system was initially designed to meet the ISO 9001:2008 standard requirements and subsequently aligned with the ISO 9001:2015 criteria. This design duly incorporates key elements essential for compliance as an ISA/IPEA, ensuring adherence to Chapter 21, as evidenced by the certification. INAPI is committed to achieving high-quality standards, reflected in the implementation of specific quality controls for ISA/IPEA activities, which include multi-level reviews of Search Reports and Preliminary Examinations conducted by supervisors and the PCT Department. The minimum quality standards are principally grounded in the provisions of the Treaty, Rules, and Guidelines, with full compliance rigorously observed. These reviews thoroughly assess both formal and substantive examination criteria, with relevant findings documented by reviewers and analyzed by the PCT Department for quality assurance and continuous improvement purposes.
- (c) - (e) All relevant information pertaining to QMS reviews and internal evaluations is meticulously documented. Specifically, data related to internal quality reviews of ISA/IPEA activities is managed by the PCT Department. The quality control measures are designed to be clear, objective, and straightforward, thereby ensuring transparency for any staff member seeking information on the process. These controls also encompass recommendations for result improvements and monitor the implementation of corrective or preventive actions identified throughout the search and examination processes.

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 INAPI's ISO 9001:2015 certification, the annual Quality Management System management reviews include a context analysis that prompts staff to evaluate opportunities and risks identified in the preceding year. This evaluation considers whether to maintain or dismiss these factors based on changes in the internal and external context. The analysis also facilitates the identification or reassessment of new opportunities and risks for the upcoming period. Furthermore, risk management is a mandatory requirement under the ISO 9001:2015 standard. To this end, INAPI operates in accordance with a governmental technical framework based on the ISO 31000 standard and the ERM-COSO II methodology. Consequently, all risks—including those related to the conformity of international search and examination activities—are managed within this framework and incorporated into 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 place 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 previously noted, our guidelines for risk-based practices are governed by the ISO 31000 standard, specifically referencing the Chilean norms NCh-ISO 31000:2012 (Risk Management—Principles and Guidelines), NCh ISA 31010:2013 (Risk Management—Risk Assessment Techniques), NCh-Guide ISO 73:2012 (Risk Management—Vocabulary), and NCh-ISO 31004:2014 (Risk Management—Guidance for Implementing ISO 31000).

- (i) INAPI's top management recognizes the presence of internal and external factors that may affect its capacity to achieve the intended outcomes of its Quality Management System. In this context, a SWOT analysis (Strengths, Weaknesses, Opportunities, and Threats) is conducted at least once every 12 months to identify internal and external forces, opportunities, and risks, thereby focusing strategic actions to address them.

Regarding the needs and expectations of interested parties, a comprehensive periodic analysis is performed to identify these parties and their expectations. Our methodology further requires that internal and external interested parties be informed and consulted. This communication is conducted through Management reports, which are made accessible via INAPI's website or through meetings. In addition to these reports and consultations, further data is collected through user satisfaction surveys, which gather pertinent information regarding form content and usability, as well as feedback emerging from periodic meetings held by the Patents Division with its primary users and stakeholders to discuss INAPI's patent services.

- (ii) Our guidelines establish a methodology for identifying, analyzing, and evaluating risks and opportunities that may impact the achievement of institutional strategic objectives. A review of the relevance and significance of these risks takes place at least once per year and encompasses all processes within the QMS scope.

Opportunities within each QMS process are identified as events with potential positive effects, as defined by COSO II, while risks are viewed as events that may adversely affect the attainment of objectives.

Risks are assessed using a consequence/probability matrix, which combines classifications of consequence and probability to establish a risk level or risk classification. This matrix facilitates hierarchical organization of risks, their origins, and treatment approaches based on their level of risk. Risks are also categorized by their source (internal/external) and type according to criteria presented in the relevant documentation. Upon identification, risks are incorporated into the institutional strategic risk matrix.

- (iii) and (iv) Once risks and opportunities are properly identified and structured, corresponding controls are developed and implemented to address them. Our guidelines require determination of whether the residual risk level is acceptable to inform decision-making regarding each risk. Processes within the QMS include actions directed towards reducing either the probability of risk occurrence or the potential consequences. Approved actions are documented within the institutional risk strategy matrix, where risks are evaluated in terms of probability and impact, yielding a severity rating that guides the necessity for treatment. This information serves to define the organization's overall risk exposure.

The determined risk exposure level dictates whether an action plan is required. These plans are formally recorded in a spreadsheet along with ongoing monitoring mechanisms to track the effectiveness of implemented measures.

- (v) All risks and opportunities are subject to review during the top management review, where each officer responsible for risk management across Divisions evaluates the preceding period's risk assessment to update the ranking of the most significant risks and their associated action plans. Following the 2023 risk matrix update, no substantial changes in internal or external factors warranted reassessment of risk exposure or classification levels for PCT processes; consequently, the primary risks and corresponding action plans remain unchanged.

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; and which maintains the technical qualifications to search and examine in the required technical fields; 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) INAPI's Patent Division employs a hybrid system for the search and examination of patent applications and utility models. Highly qualified professionals carry out searches of the state of the art and assess whether applications meet the minimal legal and technical requirements necessary for patent grant. The system consists of two groups of experts:

1. External experts, whose activities are governed by the Industrial Property Law (Law N° 19.039) and its Regulations. INAPI's National Director evaluates their suitability for examination work and determines their inclusion or removal from the Expert Register. These experts are responsible for issuing reports on patentability, which are similar to the International Search Reports (ISR) and Written Opinions (WO) issued under the PCT.

Patent Examiners provide technical supervision of the experts' activities and verify the compliance of the search and examination reports related to patentability. The external experts operate under the direct supervision of the INAPI Patent Division's External Expert Management Unit, which manages the Expert Register and oversees its updates. Together with the Patent Examination Department (DEP), this Unit is responsible for the ongoing evaluation of external experts' performance, their training necessities, and the identification of areas for improvement. Additionally, they monitor adherence to legal deadlines for the issuance of expert reports and maintain comprehensive, current records related to expert performance in the national phase.

Since 2023, a committee composed of external experts and patent Examiners has been revising and, if necessary, updating quality practices to improve the national examination processes and align them with the requirements of our role as an International Search and Preliminary Examining Authority. This committee has achieved significant enhancements in the quality control of substantive examinations. As a primary outcome of joint efforts with an external governmental laboratory, a new quality control mechanism for domestic patent applications was drafted and is currently being tested as a pilot project.

Specifically concerning the examination procedure, INAPI operates a system focused on achieving high-quality searches and examinations. The examination process for domestic applications begins with external experts conducting the search and substantive examination. Their work is subsequently analyzed by the patent examiners. Thus, the search and examination tasks are collaboratively performed by the Patent Examination Department and the Unit of Experts Management.

2. Examiners (internal experts) serve as members of the Patent Examination Department within INAPI's Patent Division and hold responsibility for assessing whether the work of external experts meets the institution's established criteria and guidelines for patentability analysis. In addition, examiners are tasked with providing a final recommendation regarding the patentability of applications, which is submitted to the National Director for decision. The work performed by examiners is subject to ongoing evaluation by the technical leadership in each field, and regular meetings are convened among examiners to harmonize criteria and ensure consistency in the application of standards.

Regarding technical qualifications and the need to expand the examination staff, INAPI conducts an annual review and prepares a report that evaluates requirements for further training and the recruitment of new examiners across diverse technological disciplines. Based on these findings, intensive training programs are delivered to ensure examination staff are equipped to meet current and emerging demands. Language training courses are also provided to both new hires and existing staff in order to enhance overall proficiency. Furthermore, recognizing the necessity for more comprehensive searches in its capacity as an International Searching Authority, INAPI is developing new search training initiatives for examiners to ensure conformity with the highest standards expected of the Authority.

Currently, INAPI employs 181 staff members and engages 87 external experts. The search and examination team comprises 107 professionals proficient in drafting patent examination reports across all technical domains. The internal Examination Department is organized into five technical areas: Pharmaceuticals, Industrial Chemistry, Biotechnology, Mechanical, and Electrical Engineering, thus enabling comprehensive coverage of all relevant technical fields. Furthermore, it has examiners responsible for the substantive examination of industrial designs. As part of a workload management strategy addressing the rising demand, in 2024-2025 new participants were recruited and trained to accommodate fluctuations such as retirements and resignations. Examiners from several technical areas not yet engaged in PCT activities collaborated with more experienced examiners on new PCT applications, thereby gaining experience to support international search duties and alleviate staff workload, and assuming responsibilities in PCT international search and examination activities. Due to the budget restraints mandated by the Ministry of Finance over the previous years, some examiners were reassigned to technical areas with higher workloads to assist with application processing within their expertise, effectively reducing the burden on colleagues.

Nearly 50% of INAPI's technical staff possess postgraduate qualifications, with the majority holding Master's degrees or PhDs in their respective technical domains. Furthermore, the professional examination team brings extensive experience to their roles, with over 70% of its members having at least a decade of expertise in conducting search and examination reports on patentability. Despite this high level of qualification and experience, INAPI implements an annual training program for examiners to ensure the ongoing maintenance of their technical proficiency and to keep them abreast of new developments across all relevant technical fields. This approach enables examiners to properly evaluate the state of the art for applications seeking protection for innovative technologies, including emerging areas such as applied artificial intelligence. These measures not only sustain the technical competence of the examination team but also support adaptability in managing changes in workload by encouraging collaboration across different, yet related, technical specialties.

(ii) The Patents Division includes a Processing Administration Unit (UPA), staffed by administrative personnel responsible for managing and handling the administrative aspects of patent and utility model applications. These officers are required to have experience and knowledge of the PCT system.

In relation to PCT activities, the PCT Department staff has expanded in recent years through the recruitment of clerical officers. This increase, combined with the use of customized management software (SGA, described in the following section of this report), has enhanced the efficiency of record-keeping, particularly during periods of significant workload fluctuations. Staff training has focused on reducing common errors in completing numerous PCT forms and providing assistance with uploading files to the SGA system, thereby improving overall work management.

As part of the improvement plan initiated in 2020, one key measure was the development of peer training programs to equip staff members not directly involved in PCT activities with the necessary skills to support PCT processes, thus enhancing operational continuity where required.

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, two screens to ease the reading and handling of documents while examining an application, and access to databases and the Internet. INAPI continuously updates these computers to incorporate the latest technology, facilitating the search process through faster and more efficient equipment and internet connectivity. This hardware and software infrastructure complies with all necessary requirements to support search and examination procedures effectively. The IT department is responsible for maintaining and updating the examiners' equipment and relevant software to ensure service continuity and equip staff with the best tools for conducting their tasks. This responsibility has become especially critical following the implementation of the remote work modality, which also prompted the provision of laptops enabling examiners to access INAPI's VPNs.

In addition to hardware and software updates, a customized PCT management software, called SGA, was developed to streamline the processing of international applications. This software facilitates and guides examiners during search and examination activities related to ISA and IPEA roles. As previously mentioned, the software manages not only the activities of the Receiving Office but also the ISA/IPEA procedures, outlining the necessary steps at each stage and including modules for managing timelines. SGA also

supports the storage and retrieval of international PCT applications and their related documentation, simplifying and accelerating examination procedures. A second version of SGA was released in August 2016, incorporating improvements for more manageable and user-friendly operation. Further enhancements were introduced in 2017 and subsequent years, including functionalities that allow better control of examiner tasks and improved follow-up capabilities. These improvements also contributed to the refinement of the control registry. A dedicated team continually analyzes and adjusts the workflows within SGA to enhance operational efficiency in ISA and IPEA activities. While adjustments for ISA workflows are ongoing, the SGA workflow for IPEA was reviewed and improved, allowing examiners to utilize it from December 2021, resulting in a more streamlined and effective process.

To further improve operational efficiency, IT staff developed a specialized PCT financial management module integrated with SGA for fee processing. This module has enhanced fee management efficiency and supports closer monitoring of timeliness in ISA activities. Moreover, during the 2020-2021 period, INAPI joined the WIPO Fee Transfer Service, which significantly improved the monitoring and management of fees for applications where INAPI acts as an ISA, aiding in timely delivery of ISRs and WO/ISAs.

INAPI provides examiners with access to internal and external databases. These include free online platforms such as Espacenet, Google Patents, INAPI's own database, Patentscope, and other Patent Office databases. In addition, contracts have been signed to access multiple proprietary platforms, including STN (with a sequence search module), Derwent Innovation (formerly Thomson Innovation), and ProQuest Dialog, providing access to over 200 databases covering all technical fields. Since 2015, full access to EPOQUE Net has been available. As the deployment of EPOQUE is scheduled for December 31, 2025, and it will be replaced by the ANSERA-based SEARCH (AbS) platform, INAPI's examiners have been participating in training sessions to familiarize themselves with this new system. Additionally, INAPI and the European Patent Office have conducted meetings to explore and establish the most appropriate mechanisms to ensure the optimal and most efficient use of this emerging tool. Further, through an agreement with the National Research and Development Agency (ANID), INAPI has access to the full text of nearly 5,000 scientific and technological journals in electronic format across 99 disciplinary areas through the Electronic Library of Scientific Information (BEIC), which includes sources such as Oxford University Press, Elsevier, the American Chemical Society, Annual Reviews, Nature, Springer, Science Magazine and Wiley. The cost of this platform exceeded US\$12 million in 2024. INAPI continues to assess additional databases that might enhance its searching capabilities.

All staff have access to relevant legal and procedural documentation, including the PCT, the Chilean Industrial Property Law, treaties, conventions, guidelines, and internal instructions, available via computer systems or printed copies.

Between 2013 and 2014, the PCT Department and the Institutional Strategy Department designed flowcharts for both Receiving Office and ISA/IPEA procedures, along with associated documentation. The specific flowcharts for ISA/IPEA activities were approved and disseminated among relevant staff. In 2016, these flowcharts were simplified following the SIPOC methodology to improve clarity and understanding of the procedures.

An examination manual, specifically developed to guide examiners conducting search and examination activities within the ISA framework, is available for examiners' consultation. Examiners are now expected to use the Standardized Clauses as part of their practice.

In accordance with ISO standards, any document modifications must be approved by the Deputy Director for Patents and uploaded to the shared folder, replacing previous versions which are subsequently destroyed. Changes are communicated to staff via email.

Finally, INAPI's Examination Guidelines align with those established in the PCT International Search and Preliminary Examination Guidelines, promoting harmonized criteria and quality standards for examination. To ensure consistency with PCT requirements, the national patent examination guidelines were reviewed and updated, aiming to standardize examiner procedures, facilitate understanding among applicants, and align national practices with international standards. The new version was published on INAPI's website in 2022.

Recognizing the importance of data accuracy and evolving requirements such as text-searchable machine-readable formats, especially those promoted by the PCT Minimum Documentation Task Force for 2026, INAPI has dedicated resources to transitioning to XML. Since 2023, INAPI's Patent Division, in collaboration with WIPO and the IT department, has been working to adopt IPAS, WIPO's national patent management system, to provide all new patent documentation in XML format and comply with the latest international standards. Therefore, the PCT Department, the Processing Administration Unit (UPA), the Deputy Director for Patents, and the IT Division have prioritized this transition over the past two years. They are working collaboratively to implement all necessary features to ensure that any patent published from January 1, 2026, will be available as a full-text searchable document under the ST.36 standard and properly stored in a repository accessible to any interested authority for consultation and retrieval. The cross-certification verifying compliance with these requirements was successfully conducted with INPI-Br, thereby confirming that the first objective of the Task Force has been accomplished. Concerning the backfile, both the IT Division and the Processing Administration Unit (UPA) have, throughout 2025, been actively working toward the 2036 milestone by converting existing patents and utility models from PDF text format to XML. They have also developed and are executing a planned roadmap that includes collecting and verifying the status of paper and PDF (image) documents in preparation for their transformation.

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 per year to maintain the staff's high-level skills in search and examination, ensuring compliance with best practices in accordance with the team's qualifications and specific needs. These training programs encompass, among others, language courses, technical subjects, and examination reinforcement through online courses. Some examiners have participated in training activities abroad, such as in Japan, and have attended WIPO-organized training courses aligned with its yearly regional training program, among others.

Due to the contingency in 2020, all training activities were conducted remotely. During this period, INAPI participated as part of a Pilot Training Program on computer-implemented inventions for Central America and the Dominican Republic, where INAPI examiners served as tutors or observers. For 2021, some examiners participated as tutors in an Advanced Online Training for Patent Examiners in the Latin American Region on the Examination of Biotechnological Inventions, organized by WIPO, which concluded in January 2022. Further online training activities on biotechnological, pharmaceutical, and computer-implemented inventions have been conducted from 2022 onward, with examiners participating both as students and tutors in sessions organized by WIPO and other IP offices. Additionally, several training sessions on searching databases, provided by our database suppliers, have been held annually to update examiners on the latest tools and resources.

The process of integrating new professionals begins with the identification of needs in specific technical areas and the development of a corresponding profile for the position. A public application process follows, culminating in the selection of candidates who undergo comprehensive training divided into two stages. The first stage, "induction," provides general knowledge and foundational expertise in patents and industrial property, often in collaboration with other offices. The second stage involves actual training under the supervision of a patents Examiner, where candidates evaluate real patent applications. This stage lasts between 12-18 months.

This entire process is overseen by the heads of the technical areas within the Department of Examination, who assess the candidates' performance and capacity, selecting those who meet INAPI's standards. Once accepted, each candidate is assigned a tutor responsible for guiding and supporting them in preparing their initial reports. Tutoring extends for one year, with supervision from different mentors within the same technical area. Performance is evaluated every four months; if, after this period, the candidate demonstrates sufficient skills and knowledge, they may work independently. The goal is for all new

examiners to become proficient in conducting search and examination activities without supervision within 18 months, in accordance with the law, regulations, and guidelines.

To enhance the efficiency of this training process, an initiative has been undertaken to formalize and standardize the training program, facilitating future replication. This program aims to establish a common, transparent, and straightforward framework for evaluating participant performance. It also includes reinforcement training for more experienced examiners. As part of the improvement plan developed in 2020, a reassessment of the examiner training and development program was carried out and a new training plan was implemented in April 2021.

The recruitment and training systems have been designed to ensure continuity in productivity, reflecting a rapid reduction of pending applications over recent 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 noted, the Heads of Sections within the Patents and Trademarks Division are responsible for the continuous improvement of their respective work areas. They provide feedback to the Institutional Strategy Department, which reviews processes, analyzes and evaluates results, and proposes strategies and actions to enhance those processes requiring improvement.

A workload monitoring tool is available that extracts relevant data from the SGA concerning examiners' time allocation for PCT search and examination activities, as well as the number of applications assigned to each examiner. This tool facilitates the assessment of individual workload, enabling management to balance demand flows without compromising processing quality or required timeliness. During 2023, adjustments and refinements were made to the data extraction criteria to provide a more accurate understanding of each examiner's current PCT workload.

To ensure compliance with quality standards, several quality control mechanisms have been established, whereby supervisors and the PCT Department review search and examination work. This system supports monitoring work quality and the development of preventive and corrective measures. These actions are tracked to ensure appropriate follow-up and to identify necessary resources for compliance. Notably, process indicators monitor the percentage of PCT/ISA/210 and PCT/ISA/237 forms requiring reprocessing following evaluation by quality control personnel. This indicator enables the identification of recurring errors and supports targeted awareness initiatives aimed at preventing future 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 ensure the delivery of a high-quality product, INAPI has developed quality mechanisms that guarantee both product quality and timeliness. Regarding timeliness, the custom software (SGA) previously described was designed specifically to track the time spent on each activity and to display the remaining time until the due date for every action. The PCT Department periodically retrieves and processes this information to manage the activities that must be completed before issuing the Search and Examination report, following specific monitoring mechanisms created for this purpose.

To maximize the benefits of this software, an additional tool was developed to extract data from SGA and process it into management information, such as the number of PCT applications at various stages and the length of time applications remain in queue. This data allows for the identification of applications experiencing excessive delays and indicates measures necessary to expedite their processing, thereby ensuring timely delivery. As noted previously, this tool underwent verification in 2023, with ongoing efforts to enhance its accuracy in detecting and filtering active applications while excluding those already completed.

b) Concerning fluctuations in demand and backlog management, responsibility rests with the Patent Examination Department. Supervisors are tasked with assessing and assigning the current workload among examiners before allocating applications for search and preliminary examination. Consequently, the Patent Examination Department provides essential information to manage workload variations and address backlog issues effectively.

The tool referenced in section a) also provides workload data for each examiner engaged in ISA/IPEA processes. This insight offers an overview of examiner availability during significant demand fluctuations and facilitates optimal assignment of examination tasks.

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 incorporates stages related to a quality assurance system within the examination process. For example, before recommending the grant or refusal of an application, examination reports undergo review by an examiner to verify compliance with criteria established in national law, its regulations, and the Examination Guidelines. The Patent Examination Department (DEP), which encompasses examiners across all technical fields, is responsible for the continuous assessment of expert performance and identification of potential improvements. In this regard, the DEP collects feedback on common misinterpretations of the Guidelines or recurrent errors that must be corrected to maintain excellent service quality.

To support continuous process improvement, the Institutional Strategy Department issues a weekly Management Report detailing the activities of INAPI's various units. For the DEP, this report shows each examiner's performance concerning due dates based on the application's current status. The report is sent to the DEP Head, who disseminates it to the Heads of Technical Sections to manage workload and scheduling for examiners within their respective sections. This report is generated directly from the IPAS system, which assigns application statuses according to their process stage. The Management Report serves as an effective tool for corrective and preventive measures and functions as a system to verify the effectiveness of such actions, for example, in reducing processing times or backlog. These reports are also utilized by the heads of departments within the Patents Division during their weekly meetings, serving as valuable information to identify and discuss potential improvements for the Division.

An internal quality assurance system has been specifically designed for ISA/IPEA activities as part of this implementation. This system requires the review of all reports submitted by examiners prior to dispatch to applicants. Technical Supervisors of the DEP approve each report by verifying a comprehensive checklist

designed to assess compliance with the Search and Examination (S&E) Guidelines and, where feasible, include search strategy documentation. Fulfillment of all checklist items is mandatory before the report can be submitted to the PCT Department. The PCT Department subsequently conducts a formal review of the report format prior to submission to the applicant and the International Bureau. The system also ensures that review results are communicated back to the PCT Department, maintaining records that enable monitoring of each examiner's activities. Depending on checklist compliance levels, examiners may either be assigned training activities or, conversely, their reports may be subject to random sampling, provided consistent high-quality performance is demonstrated over time. All findings within an evaluation period are communicated to the examiners, and cases of frequent non-compliance are discussed in general meetings to promote corrective practices among staff.

Finally, after submission to the PCT Department, all reports undergo a final formal review to ensure proper issuance by verifying formality compliance as stipulated in the S&E Guidelines. This review is conducted using a formal checklist.

ii) As previously mentioned, the Quality Assurance Mechanism includes specific databases that record outcomes from quality reviews, thus documenting the level of compliance for each examiner involved in ISA/IPEA activities. This registry facilitates identification of findings and detection of non-conformities, alongside the recording of proposed preventive or corrective actions to monitor their implementation and effectiveness for continuous improvement.

iii) The internal quality system for ISA/IPEA activities incorporates a procedure to correct and amend any defects identified during product quality control. This procedure mandates recording any non-conformity detected during review, enabling the development of preventive or corrective measures. The implementation of these measures is subsequently monitored to assess their long-term effectiveness.

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 mriviera@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 places great importance on the opinions of its users, viewing them as valuable opportunities to identify areas for service improvement. In this regard, and in compliance with paragraph 21.20 of the Guidelines for International Search and Preliminary Examination under the PCT, the User Services Division includes a dedicated Unit of Guidance and Support for patent applicants. This unit is staffed by highly qualified professionals who advise users on patent-related matters, both prior to filing and throughout the processing stages. Guidance is provided in person or via different channels, including dedicated information on INAPI's website, user guides, frequently asked questions, and the email address inapi@inapi.cl.

To enhance the efficiency of collecting user interactions with INAPI regarding guidance and support, and to prevent duplication of work related to user requests or inquiries, this year the User Service Division implemented Zoho Desk, an application designed to centralize all requests through omni-channel assistance. The initial phase focused on using Zoho Desk to centralize and manage institutional email and official chat requests, establishing a structured system for ticketing and reporting. It is anticipated that the range of communication channels integrated into the application will expand, including specific email addresses such as pct@inapi.cl, thereby maintaining direct interaction with PCT applicants during the PCT International Phase—a feature highly valued by these applicants.

INAPI is committed to responding to all comments, suggestions, complaints, and questions within 48 hours of receipt. All information requests are collected electronically, enabling tracking, reporting, and statistical analysis—valuable tools for measuring user satisfaction and perception.

Communication policy within the PCT Department emphasizes direct interaction with applicants, allowing questions and requests to be addressed by staff members directly.

Customer satisfaction surveys are sent to applicants to evaluate Receiving Office (RO) activities for each application filed at INAPI once the RO process concludes. A separate survey is distributed monthly for ISA/IPEA activities to gather feedback on the quality and utility of the International Search Report (ISR) and Written Opinion (WO). These closed surveys allow applicants to highlight areas of interest, identifying potential improvements. Additionally, INAPI conducts annual meetings with prominent representatives and agents to obtain feedback, address their needs, and implement necessary service enhancements. Feedback from these stakeholders regarding PCT international application management—as both RO and ISA/IPEA—has been highly positive, with consensus that INAPI delivers effective, efficient, and high-quality service, supported by open communication channels and courteous, knowledgeable assistance from PCT Department staff.

Furthermore, Resolution N° 687, dated November 16, 2011, established the Civil Society Council, comprised of at least five ad-honorem non-profit civil society representatives connected to policies, services, programs, or plans executed by INAPI. This consultative and self-governing body contributes

experience and insight, offering opinions and feedback on issues related to Industrial Property and INAPI's operations, regularly including quality and PCT matters. The Council convenes at least annually and is composed of representatives from agent groups, universities, inventors, enterprises, and others.

INAPI's website has also been reviewed and improved to provide direct user access to PCT-related activities and information. A dedicated email address for PCT inquiries (pct@inapi.cl) allows applicants, agents, and stakeholders to submit observations, questions, and compliments related to any PCT matter.

Additional information on quality—such as quality objectives and the quality commitment letter—is accessible through INAPI's website.

To enhance transparency regarding PCT activities, an online statistical tool, developed to cover all PCT applications in the international phase (INAPI acting as RO, ISA, and IPEA), is available on INAPI's website for any interested users to consult statistics such as the number of applications filed per year, technical areas of applications, ISA elections, and the RO where ISA applications were filed, among other data. PCT statistics have also been incorporated within the PCT section on INAPI's website.

The PCT Department developed and regularly updates the "INAPI's PCT User Guide," an electronic document outlining the principal aspects of the PCT International Phase, as well as introductory elements of the PCT National Phase for applications filed at INAPI. This guide focuses on the processing of PCT applications from their filing at INAPI as a Receiving Office, through actions following the payment of PCT fees, the drafting and submission of the International Search Report (ISR) and Written Opinion (WO/ISA), international publication, and the International Preliminary Examination Report (IPER) process. It also details the applicant's options after ISR submission, including filing Amendments under Article 19, Modifications under Article 34, withdrawal of the international application, among others. The guide's latest update expanded coverage by incorporating information not previously addressed and responded to common user inquiries related to both PCT international and national phases. This updated guide has been published on INAPI's website and integrated into all PCT-related activities in subsequent years. Additionally, the PCT Department has introduced a FAQ section on the website to address frequently asked questions. To further support INAPI's users and facilitate the initial steps of the PCT International Phase, significant efforts were undertaken in 2021 to promote the use of ePCT for online filing. In this context, INAPI and WIPO organized public webinars to provide applicants with practical instruction on the use of this tool. Subsequently, a user manual in Spanish was prepared and reviewed by WIPO officials. The release of this manual proved highly effective, enabling users to better understand the ePCT platform, file applications online, and fulfill the requirements of relevant authorities.

As a notable outcome of these awareness-raising initiatives, since 2021, nearly 100% of PCT international applications using INAPI as Receiving Office have been filed through ePCT. This achievement is especially significant considering the regional context, where, unlike other regions, paper filing remains a customary practice among many Latin American applicants. Additionally, there are national offices within the region that, due to local regulations, do not permit online filing—posing challenges for both applicants and Offices acting as Receiving Office (RO), International Searching Authority (ISA), or International Preliminary Examining Authority (IPEA). Furthermore, some offices are unable to fully utilize ePCT, or do not apply it appropriately for certain operations involving ISA/IPEA or IB activities, which can negatively impact workflow planning. In light of these challenges, INAPI continues to promote online filing in all public PCT-related activities, emphasizing the advantages of paperless processing within PCT procedures.

In 2023, INAPI published Resolution 255/2023, creating the User Quality Service and Experience Committee. This Committee advises on matters related to INAPI's service quality policy, works to enhance user perception of the Institute, raises staff awareness of the importance of providing quality service, and advises top management accordingly.

Recognizing that ISA survey results indicated users were not fully familiar with patent language, INAPI and WIPO jointly organized a patent drafting program for users. The first online version launched in 2021 received positive feedback from participants, with subsequent editions held in 2022, 2023, 2024, and 2025. The program aims to improve the quality of international applications, addressing difficulties examiners face when drafting search strategies due to unclear contents in some applications. By lowering these barriers, more innovators may be encouraged to use intellectual property tools. Given the program's popularity, further editions are planned.

INAPI also continues to offer its inventor and entrepreneur support program, INAPI Running, which provides specialized intellectual property knowledge and strategic guidance. The Patents Division participates by lecturing on patent rights and mentoring applicants interested in filing patent applications, including those using the PCT system.

In 2022, INAPI joined the Inventors' Assistance Program (IAP), which connects financially constrained entrepreneurs with volunteer IP agents in Chile who draft patent applications pro bono. This initiative enhances INAPI's role as a promoter of innovation and intellectual property benefits. New editions launched in 2023, 2024, and a new appointment call in 2025, which remains open permanently for the applicants to participate. The selected candidates are currently collaborating with their volunteers on application development, while some of the first beneficiaries of the Program succeeded in obtaining a granted patent.

Furthermore, during 2023 and 2024, organized seminars focusing on INAPI's ISA/IPEA role and USPTO procedures for the PCT National Phase. In 2022, WIPO Director General Mr. Daren Tang visited INAPI, during which multiple initiatives were announced to encourage entrepreneurs, innovators, and developers to utilize intellectual property as a tool for protection and development. These initiatives support the post-COVID ecosystem recovery. One announcement was the creation of the country's first Intellectual Property Training Academy. In August 2023, INAPI and WIPO co-hosted the first in-person PCT seminar since the COVID pandemic, featuring full attendance despite online transmission.

In 2024, INAPI celebrated its 10th anniversary as an operational ISA/IPEA. Accordingly, in October 2024, INAPI and WIPO jointly hosted the Annual Regional Meeting of PCT Latin American Offices, which addressed various aspects related to quality processing and quality management within PCT procedures. Participants included representatives from Latin American PCT member states, as well as delegates from the USPTO and the SPTO. During that week, on October 23, 2024, INAPI held a commemorative ceremony where WIPO's National Inventor Recognition was awarded to a university professor and researcher noted for significant advances in nanotechnology, and to a Chilean company that achieved notable improvements in securing mining operations by protecting their developments through the filing of PCT international applications.

In November 2025, as part of their Agreement, INAPI and the EPO jointly organized an online international seminar in November covering the Patent Cooperation Treaty (PCT) and the European Unitary Patent.

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.

Communication with WIPO, other Authorities, and designated and elected Offices is coordinated by the PCT Department through email, mail, and direct phone calls.

WIPO Circulars and related documents are received by the Head of the PCT Department, who then disseminates them to other relevant staff members, including the Deputy Director for the Patents Division, the Heads of the DEP and the International Affairs Department, and the National Director.

INAPI operates using the e-PCT system, which enables the electronic transmission of applications to WIPO and their electronic filing 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.*

In light of efforts to adapt certain internal processes for ISO 9001:2008 certification, INAPI prepared a Quality Manual serving as the master document governing the operation of processes within the certification scope. This manual is a controlled document, managed in accordance with a specific procedure. Supporting QMS documentation includes the quality policy, quality objectives, process flowcharts, operative procedures, and corresponding process and record documents. All such documentation is accessible to staff members via an internal server for consultation as needed. In 2017, INAPI pursued re-certification under the ISO 9001:2015 standard, resulting in updates to some documentation to address new requirements. This documented information is available to staff through a dedicated Google site designed for this purpose, which consolidates extensive information about PCT processes and INAPI's QMS, including the Quality Manual, quality policy and objectives, process maps, strategic and operational processes, and other relevant materials.

Regarding PCT-related matters, particularly ISA/IPEA activities, an Examination Manual for ISA activities was distributed to examiners. This manual details the tasks related to examiners and provides guidance on completing key forms. It is also a controlled document available on the internal server.

A specific procedure for document control was developed and documented, detailing all necessary steps for revising existing documents upon identification of needed changes. Each controlled document must include a title, a specific code indicating whether it pertains to records, instructions, or procedures, a version number, revision history, disclaimer, and validity date.

It is mandated that obsolete copies of all documents be destroyed to prevent their unintended use.

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, along with the corresponding statement from Top Management, the scope of the Quality Management System (QMS), the organizational structure of staff within its scope and their responsibilities, as well as the documented processes, resources, and descriptions of interactions among these processes, are detailed in the Quality Manual and accessible via the internal Google site. The Manual specifies that the institution's organizational structure and departmental responsibilities are documented on INAPI's website. Currently, the Quality Manual does not include the documented processes for search and examination procedures; however, these documents—such as the Examination Manual under the ISA scope—are available to examiners and are planned to be incorporated into a future, fully reviewed, and updated version of the Quality Manual.

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 maintained by this Authority, the following are available:

- A documented information list has been created and is accessible on our Google microsite. This document specifies the location, format, and storage details of each record, among other relevant information.
- To achieve certification and comply with the new requirements of ISO 9001:2015, all documentation underwent review and evaluation. It was concluded that maintaining a specific procedure to evidence process conformity was unnecessary. Nonetheless, a process exists for this purpose, and compliance of processes, products, and services is appropriately recorded.

- Results from at least annual management reviews are retained by the Institutional Strategy Department and made available via the internal Google site.
- Personnel records, including CVs, experience, training, and skills, are maintained by the Human Resources Department.
- The SGA software developed for PCT activities enables tracking and tracing individual contributions throughout the PCT international phase procedure for quality control purposes. This software contains all information related to each ISR, WO/ISA, and IPEA product drafted by examiners, including completed checklists used to assess product conformity with quality standards and every step of each search and examination process for each application.
- All Quality Management System audit activities are documented in accordance with the Quality Manual and made available via the internal Google site.
- INAPI has established, planned, and implemented processes for follow-up, measurement, analysis, and evaluation to assess both the performance and effectiveness of its QMS. The outcomes of analyses and assessments of final products (ISR, WO, and IPRP) are used to evaluate product conformity, user satisfaction, and QMS performance and effectiveness. These results also assess the efficient implementation of planned activities, the effectiveness of risk and opportunity management actions, external supplier performance, and identify areas for QMS improvement.
- Regarding actions on non-conforming products, the SGA maintains records of all corrections made to products failing quality control. Such forms are returned to examiners for correction before submission to users. INAPI controls all non-conformities, including complaints, and takes corrective actions accordingly. A defined process manages non-conformities and corrective actions, supported by a registry stored on the Google microsite.
- When conducting searches, examiners are required to document the search strategy, and it is anticipated that this documentation will be submitted as stipulated 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, search documentation is recorded within the examination report itself, including consulted databases, languages used, classes and subclasses reviewed, justification and any limitations of the search, as well as notes regarding lack of clarity in claims, unity of invention and the evaluation of all the patentability requirements.

Regarding the searching procedure during the ISA stage, a template was created prompting examiners to document the databases consulted, search statements including keywords, truncations, combinations

used, languages, and classes and subclasses considered. Any additional relevant information pertaining to the search must also be recorded. Presently, this template is completed and uploaded into the SGA system at the corresponding stage of the search and examination process by the professional responsible for drafting the International Search Report (ISR) and the associated Written Opinion.

The document designed for registering the search procedure also provides sections for noting search limitations, issues of unity, and 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]