WIPO

WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by BRAZILIAN NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY (INPI/BR)

> *The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.*
>
> *The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.*

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

> *In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.*
>
> *If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"*
>
> *For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"*
>
> *Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.*

All changes made from previous 2024 report are highlighted in Blue.

Quality Management System for International Search and Preliminary Examination consist basically of three components:

1. Quality standards for Search & Examination work: tools, systems, documented information, training, communication.

2. Quality Assurance: peer review, management review and quality control.

3. Quality review process.

The quality standards and practices are compliance with the standards and practices established by the PCT guidelines. Although the QMS in place is based upon ISO 9001:2015 principles, INPI/BR is not ISO 9001 certified.

The establishment of an internal Quality Assurance System for international search reports (ISR), written opinion (WOISA) and international preliminary examination reports (IPER) is set to assure compliance with PCT and Regulations, PCT administrative instructions, PCT International Search and Preliminary Examination guidelines, and other INPI internal guidelines and instructions.

Since 2022, INPI is in the process of planning and implementation of an automation solution (BPMS – Business Process Management Suite) for the Patent and PCT macroprocesses through the adoption of the business process management discipline and the acquisition of an automated system in order to improve efficiency, effectiveness and quality of its processes. The provider of this system was hired in 2024 and BPMS implementation will be gradual and should take place in the medium and long term, expected to end at the end of 2029.

In 2023, INPI has initiated the journey to implement a new reference model to improve and achieve excellence in INPI Management, that was part of INPI´s 2023 and 2024 Action Plan and INPI´s Strategic Plan 2023-2026. This reference is called Management Excellence Model® (MEG). MEG is a Brazilian Quality Model developed by the National Quality Foundation (FNQ) based on the Malcom Baldridge National Quality Award and others international models. This model aims to stimulate and support organizations in the country in the development and evolution of their management, so that they become sustainable, cooperative and generate value for society and other interested parties. It is based on 7 fundamentals of Excellence Commitment, Responsibility, Leadership, Systemic thinking, Processes, Innovation and Culture. And from the perspectives of 7 results (qualitative and quantitative indicators): economic-financial, environmental, social, customers and market, people, suppliers and products and processes. An organization is considered excellent when it meets in a balanced way, to all de fundamentals of Excellence and the results generated by them.

With the aim of knowing its adherence to this model, in 2023 INPI hired FNQ to perform a diagnosis on its maturity level. In 2024, INPI gave continuity in MEG´s implementation according to an action plan in order to achieve a higher score. The following activities were done: collect and consolidation of evidences to improve management maturity level and hiring of the second cycle of assisted self-assessment in order to obtain a new diagnosis of Management Maturity Level. In 2025, INPI hired the second cycle of assisted self-assessment and has almost doubled the score compared with 2023 results achieving the maturity level of almost 60%. In 2025, INPI also participated in the recognition process for the FNQ's Best in Management 2025 awards, being the first federal agency to participate in this recognition. It's expected to increase the maturity gradually until achieving the excellence level.

As part of this transformation into excellence, in 2025, INPI initiated the project of reviewing its Value Chain and process architecture with completion expected in the first quarter of 2026. The Value Chain is a model that offers a systemic and integrated view of organizational processes, showing how they are structured and interconnected and how they add value to the final product or service offered to the customers and others stakeholders. Among the premises for reviewing the Value Chain are: alignment with MEG Guidelines, INPI´s Strategic Plan and review of existing process and incorporation of new processes that are not reflected yet in the current Value Chain.

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.*

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

[Sample table, to be amended as necessary]

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according 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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
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	✓		
	(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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
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	✓		
			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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	✓		
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted	✓		
	(vi)		Records about 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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
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 QMS is applied by a Quality Group in Patent Board, which are responsible for carrying out the quality management system requirements and the quality review process.

The Working Groups of the areas under the PCT meet regularly with the top management in order to measure the effectiveness of the Quality Review process. These meetings serve as a basis for measuring, analyzing and interpreting the results of the examinations, updating guidelines, procedures and work instructions, detecting whether the user's needs are being met and identifying the points of possible improvements in the quality of services provided.

The Quality General Coordination has the responsibility to conduct customer's survey to detect if their expectations and satisfaction are met. An improvement plan is done with the survey results.

(b) INPI/BR seeks to continually improve the effectiveness of the QMS through a variety of mechanisms, including:

- defining and revising quality objectives,
- measuring quality objectives against minimum performance undertakings,
- measuring customer's satisfaction,
- performing corrective and preventive actions,
- conducting management reviews,
- complying with the quality policy statement,
- reviewing documented information periodically,
- providing periodic training of the personnel,
- applying the risk and process approaches.

> **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-b) The Top Management promotes regular meetings and events where it communicates to its staff the importance of meeting the requirements of this standard and compliance with QMS requirements. Moreover, this communication is also done through e-mail, intranet and internet *and* workshops.

The INPI/BR Strategic Plan 2023-2026, the Annual Action Plan and its quality objectives, performance indicator, goals, projects and strategic objectives were widely reported throughout the organization and to

its customers and made available at INPI´s website: https://www.gov.br/inpi/pt-br/governanca/planejamento-estrategico

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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.

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(a-c) The Top Management meets at least once a month in the Committees' meeting to follow and review the organization objectives, quality goals and the Annual Action Plan accomplishment.

The Internal Governance Committee (CGI), is the highest level Committee of governance, management of integrity, strategic planning, de-bureaucracy, monitoring and evaluation, and risk management within the Institute. It has consultative and deliberative function. In addition to other competencies, the committee is responsible for institutionalizing the strategic planning process of INPI; establish strategic guidelines, objectives, initiatives and indicators; to lead and institutionalize governance structures, strategy, integrity, risks, quality management and internal controls appropriate to the development of the continuous improvement, to promote the integration of risk management into the strategic planning and business process management at all levels of the Institute, to monitor the implementation and evaluate the results of the actions planned; periodically review the institutional strategy and the Quality Management System; undertake actions to find the means and resources sufficient and necessary to execute and sustain the projects related to the institutional strategy; to establish, at its discretion, subcommittees or working groups for advisory subjects of its competence.

The main decision and corrective actions decided by the Committee are spread-out towards the respective managers and processes may be reviewed.

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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).

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(a) The QMS is continuously monitored by the Quality General Coordination and through the Quality Group and PCT Coordination.

(b)-(c) The extent of compliance of search and examination work with the PCT Guidelines is based on the review of work from the Examiners prior to issue the reports, and also on the review of work sampled after publication. There is a specific and trained group of Patent examiners available to work with PCT (ISA&IPEA) processes. The review findings are reported to the Examiner and to the head of the technical division of their respective examination unit. Reports are regularly provided to the Patent Managers – General Coordinators and Quality Coordination on the extent to which work complies with INPI Quality Standards. Internal quality audits are planned to be carried out on the processes used to ensure their

compliance with INPI/BR Quality Management System, Chapter 21 and the PCT Guidelines and other internal regulations.

 (d) – (e) At the end of each year, CQUAL meets with PCT management to review and discuss about the reports submitted to WIPO and subjects related to QMS. This review assesses how well the system is performing, what can be improved and whether it is meeting the policy and objectives set for it.

> *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.*

Due to the strong Brazilian legislation, INPI/BR must be in compliance with Risk Management process and, therefore, regularly promotes practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed. Item 2 describes how INPI/BR handles Risk Management.

2.   RISK-BASED PRACTICES

> *21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.*
>
> *21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.*
>
> *(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).*
>
> *21.13 Arrangements for establishing risk-based practices*
>
> > *Provide information on the arrangements that your Authority has made to:*
> >
> > *(i)   (a) understand issues that affect its ability to achieve intended results of the QMS, and*
> >
> > > *(b) understand the needs and expectations of interested parties;*
> >
> > *(ii)   identify risks and opportunities related to the performance of the QMS as a basis for planning;*
> >
> > *(iii)   plan and implement actions to address risks and opportunities;*
> >
> > *(iv)   check the effectiveness of the actions taken; and*
> >
> > *(v)   continuously update risks and opportunities.*
>
> *21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.*
>
> *(Note: This point is informative. No response is required by the template to paragraph 21.14).*

To provide a better understanding on the issues that affect INPI to achieve intended results and objectives of the QMS, the Risk Management Division from the Quality General Coordination of INPI is periodically offering advices, materials and training on INPI´s Risk Management Manual and Database to the patent examiners involved at the PCT's process as well as to others INPI´s units and interested parties. All the risks mapped in PCT and QMS process, as well other processes, are recorded and monitored on a database called AGATHA provided by the Ministry of Planning with the purpose to manage and control the

risks identified in the process. Additionally, regular meetings are conducted with INPI units to provide guidance and support on risk management issues. It´s also adopted the practice to keep in touch with several offices to understand their challenges and implemented solutions, exchanging knowledge and experiences. In 2022 it was developed and launched with the partnership of another governmental organization, a Business Intelligence tool to help the top management, managers and risk owners in the process of monitoring all INPI's risks and action plans. This BI tool is being periodically optimized and can be accessed through the INPI's internal company network.

The picture below shows an overview of one of the dashboards with a general view of INPI´s risks spread in all INPI`s macroprocess:

In order to understand the needs and expectations of INPI units and interested parties, we collect some relevant information conducting user satisfaction surveys, holding meetings with interested parties and also from the inputs we receive from ours online users service channels.

To identify risks and opportunities related to the performance of the QMS as a basis for planning, training programs in risk management and process mapping are provided on regular basis, as well as periodicals process reviews and its redesign (if necessary), in order to identify, analyze and valuing risks.

INPI´s risk documentation guidelines are composed by the Risk Management Manual and Policy. The methodology to manage risks is defined in the Risk Management Manual. The methodology has as its basic premise the risk assessment within the organizational processes, and is supported by guidelines of the ABNT NBR ISO 31000:2018 standard.

According to this methodology, process owners evaluate the risks, by identifying consequence/probability matrix, in order to establish a risk level. Next, they define responses to risks and, eventually, establish control measures, aiming to modify the level of risks, always seeking to reduce them. Once these actions are properly approved by the risk managers and top management, they are included in the institutional risk database (AGATHA), and the action plan is monitored by the Risk Management Division and by the Committee in order to check its effectiveness.

At any time, risk managers can review any information on risks' database or through the BI tool mentioned above as part of the monitoring process and in order to check whether the actions are being effective as well there are any changes in the context or process related to the risk. As mentioned in item 21.08 there is also an advisory and deliberative forum, the Internal Governance Committee in charge of the leadership and supervision of the most critical risk management and internal controls implementation as well as other assignments.

INPI adopts "The Three Lines" model, where the process owner is the first line of defense in risk management, the Risk Management Division and the Internal Governance Committee are the second line of defense, and the Internal Audit is the third.

Each of these three "lines" plays a distinct role within the organization's wider governance framework, aiming to check the effectiveness of the actions taken.

The risks and opportunities are considered during the strategic and corporate plan and also a context issues analysis is conduct (which includes an updated SWOT analysis) in every new risk management process to ensure a continuously update risks and opportunities.

Risk Management Process adopted by INPI is described below:

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.

INPI/BR is constantly providing resources needed to deliver desired outcomes including the maintenance and improvement of the quality management system.

The current staff (technical and administrative) is adequate to deal with the inflow of work and deliver the search and examination process in the established deadlines.

Some regular actions are described as bellow:

- ✓ providing training in industrial property and in foreign languages;
- ✓ graduating masters and doctors at the INPI/BR Academy of Industrial Property;
- ✓ training team leaders,
- ✓ flexible conditions of work for examiners who are in view of obtaining the Doctor title;
- ✓ improved facilities and material resources;
- ✓ deployment of new IT systems to support the examination and administrative service;
- ✓ teleworking (home office) modality: Currently there are a total of 306 examiners working on patent examination, of which 264 are teleworking. The goal is a productivity average of 130% for the participants in the full teleworking and 120% of partial teleworking respectively 30% and 20% higher than examiners not in teleworking working where it is expected a productivity of 100%, The examiners achieved an average examination productivity of 146,45 % for the full teleworking program and 133,21 % for the partial program during the period from January to October 2025. This increase was very positive for INPI exam production results and customers satisfaction.

(i) Patent Examiners

- ✓ As a minimum requirement for recruitment, all patent examiners must possess the title of Master of Science and have English or Spanish language skills. As soon as they are selected, they immediately enter professional training courses in specific skills tests. After ~6 months of training, the examiners start to exercise examination procedures, training "on the job" mentoring for ~18 months. The patent examiners also participate in the exercise of technical courses and events in their specific fields, promoted by INPI/BR or by other entities, for purposes of technical improvement in their areas. Currently, approximately 65%

of examiners have the title of Doctor of Science.

✓ Among the applied requirements for receiving documentation, referenced in Rule 34, INPI/BR can receive PCT applications in three different languages, which are Portuguese, English and Spanish.

Administrative Staff

✓ The administrative staff is trained to conduct formal examinations and international administrative procedures of the PCT, as well as to control, verifiy and registration of applications filed under the PCT.

(ii) Appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained. As mentioned in the Introduction of this report, a new System (BPMS) is being developed to improve the process efficiency and effectiveness enabling the automation of different tasks currently performed manually including performance measurement and management activities reducing significantly manual interventions and workload.

Material resources:

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

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

(v)   Describe how instructions:

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

to follow work procedures accurately and consistently

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

(iii-iv) The INPI/BR often reviews facilities and technological resources. Such review includes:

✓ acquisition of new computers with up-to-date common setup, workstation and chairs to accommodate the new examiners. Updating software for basic usage, extension of contracts on patent search databases and developing software resources for online control of all work and registration of examinations, including statistical data, information, issuing forms, and quality indicators. The workstations have electronic dictionaries and translators specifically to work in technical support.

✓ implementation of a new System (BPMS) as mentioned in the Introduction of this report. Currently, patents flow (including national patents) uses 14 integrated systems to support search and examination process and the implementation of BPMS aims to incorporate 7 systems inside BPMS suite and to enable integration with 7 remaining systems enabling information and data centralization in one place and making the information up to date and available in all systems. This system will also enable to manage requests for international search and international preliminary examination, assignment of examiners, deadline's controls and several others functionalities.

✓ The minimum documentation, referenced in Rule 34, is available, accessible and kept ready for search and examination purposes. All documentation is now stored on electronic media.

Each examiner work with 2 monitors and has access to the Internet and to search databases such as STNext (Chemical Abstracts Service – CAS); IEEEXplore (IEEE, through EBSCO BRASIL); Derwent

Innovation (Clarivate Analytics LLC), including Global Patent Data, DWPI, CPI Manual Codes and INSPEC; and Sequence Base, including GENESEQ (Clarivate Analytics LLC).

In March 2022, INPI started a pilot project to fill out the ISA/IPEA forms directly in the ePCT in XML format, with a small number of examiners (21). As a result of this project, since March 1st, 2023 the ePCT became the only tool used by all examiners to fill out the forms for the PCT international phase.

Since September 2025, INPI has established that the Receiving Office may only accept international applications and related post-filing documents in electronic format or by electronic means (applying to the Receiving Office, ISA and IPEA under Rule 89bis.1(d-bis)). Therefore, the entire international phase of the PCT application in Brazil is conducted exclusively through ePCT.

(v) The basic procedures of service relating to the PCT, as the Treaty, the Regulations and Guidelines are available in English and Treaty and the Regulations translated into Portuguese, in both printed and electronic formats, and are released on the occasion of trainings conducted. All the forms and templates for the Search and Examination are automatically available in the patent system (SISCAP) in the three supported languages (Portuguese, English and Spanish).

As part of QMS maintenance, in 2025 PCT Coordination has kept the amount of 83 processes flow developed with the partnership of an external consultancy, 203 work instructions, 2 procedures and 30 forms regarding activities from the receiving office, international search and preliminary examination processes. All these documents were widely communicated and the patent examiners involved with PCT processes were trained.

Patent Examiners that have been trained in the procedures of the PCT in a more extensive work, participate in mentoring, discussing questions and guiding in the most difficulty cases.

Work instructions, procedures, process flows and forms are reviewed within maximum three years or whenever necessary, new procedures and work instructions are developed in order to ensure greater consistency and adherence to customers' need and to obtain more efficiency.

> *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.*

(vi) The INPI/BR maintains regularly training for examiners, searching and examination procedures, among others. The need, frequency and content of these training programs are reviewed annually in the Annual Training Program.

INPI/BR has a Training Center equipped with classrooms for training new and current examiners. All classrooms have computers so that the examiners can access INPI/BR Search Data Bases and simulate examination. INPI/BR has an integrated communication platform (AVAYA) to enable distance trainings and meetings and there´s also the possibility to use others videoconference platforms (such as Zoom, Google Meets, etc).

By regular trainings and speeches the examiners are kept aware of the importance to be compliance with exams criteria and quality standards.

Besides the regular trainings INPI/BR is currently seeking for partnerships with other IP Offices worldwide in order to share best practices and experiences.

> *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.*

(vii) Requests for international search and international preliminary examination under the PCT are recorded and controlled through an internal electronic system – SISCAP. Each new request is identified and updated constantly. The SISCAP system informs automatically the deadline for submission of reports, ensuring the proper demand for services.

The head of each technical division, which acts as examiner supervisor, assigns the request to a ISA/IPEA examiner. The examiner is responsible to monitor the deadline and to issue the examination report. After the examination and the peer review, when necessary, the report is sent to the supervisor for substantive verification. After supervisor performs the verification, the report is then sent to PCT division for a final quality inspection. If reports are compliance with standards, they are sent to applicant and WIPO. If not, the PCT division returns back the report with the problem found requesting the examiner to correct it. Only after all quality standards are met, the request is sent to applicants.

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.*

(i) Requests for international search and international preliminary examination are monitored by the internal electronic system: SISCAP.

The SISCAP system has an automatic mechanism that shows the time remaining to issue the reports, on the registration page or handling of this request.

After completing the forms in ePCT, the examiner uploads a copy of them to SISCAP, which continues to be the system responsible for managing the examiners' workload and for forwarding them to the formal and technical quality review.

(ii) The PCT General Coordinator and the Head of PCT Division are responsible for monitoring and controlling the application fluctuations and possible delays.

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-iii) INPI/BR established an internal Quality Assurance System for international search reports (ISR), written opinion (WOISA), and international preliminary examination reports (IPER) involving the evaluation of administrative work in RO, verification of compliance with PCT administrative instructions, PCT Reception Office (RO), Guidelines, PCT International Search and Preliminary Examination Guidelines and other INPI internal guidelines and instructions.

The quality assurance system establishes the following steps of verification at ISA and IPEA stages:

1. **Self-checking by examiner**: when conducting the examination, the examiner fills out checklists for each international application covering the steps at the ISA and IPEA stages. The examiner is responsible to monitor the deadline and to submit the examination report to the supervisor for substantive verification.

2. **Verification of substantive examination**: The Heads of the technical divisions verify the reports issued by the examiners that mainly cover subjects related to the search and patentability requirements, before issuing the ISR and the WOISA. After supervisor performs the quality check, the request is then sent to PCT division for formal quality inspection.

A new search strategy review process has been adopted since 2020, when the examiner finds only documents of the general state of the art (only "A" documents). This process includes the figure of a "partner searcher" who will check the search strategy established by the first examiner and, if necessary, make changes to the strategy and a new research. Thus, with the interaction between the two examiners, there has been an increase in the quality and confidence of the totally positive reports issued.

3. **Formality examination checking**: The PCT division staff performs a formality checking on all PCT forms (100%) to be sent to the applicant and IB, inspecting the integrity and consistency of the details in the forms. If reports are compliance with quality standards, the reports are sent to applicants and WIPO. If not, the PCT division returns back the report with the non-conformity found requesting for change. Only after all quality standards are met that the request is sent to applicants.

In 2023, the PCT Coordination began a pilot project to review the quality of the examination of PCT applications in which INPI acted as International Authority (ISA and IPEA). This review is based on a sample calculated according to the annual batch of ISA and IPEA reports for the period under analysis. The sampling is based on ISO 5426:1985 requirements. The batch of products eligible for review was composed of the final product delivered by INPI as International Authority after its submission to the applicant. In addition to this new procedure, product quality criteria for ISR and IPER reports were also developed, as well as forms for recording review results. These criteria were distributed in 3 Categories according to the severity of non-conformity. Each Category is composed of criteria that is subdivided in attributes. As a result, 9 criteria related to the PCT application exam were addressed in the form with 41 objective questions (attributes), aimed at exam compliance, published work instructions, PCT Rules and Articles and the Guide. This pilot was ended in 2024 with the report containing the review results and indication of opportunities for improvement in the process and procedures according the reviewer's feedback.

To implement this new post-delivery product quality review procedure, the development of an automation system is underway to carry out the quality review process more efficiently. The system will consist of 3 modules: parameter recording, sampling, conformity assessment and also a management panel that will show the key process indicators and results. Parameter recording module was delivered in September 2023 and conformity assessment in February 2024. Sampling module is under development with completion forecast in the end of 2025. After the implementation of sampling module and the management panel, this review process will become part of routine.

6.   COMMUNICATION

Inter-Authority communication:

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

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

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

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

(b)   fostering continual improvement; and

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

(a-c) Alessandro Bunn Bergamaschi: Quality General Coordinator.
Tel: +55 21 99837-7836 – email: alessandro.bergamaschi@inpi.gov.br

Gisela Aparecida Silva Nogueira: PCT General Coordinator
Tel: +55 24 98823-2380– email: gisela@inpi.gov.br

Communication and guidance to users:

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

(i)   An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and

offering feedback to users.

(ii)   A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

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

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

(i) There are several communication channels available for a direct contact with applicants or their respective representatives:

✓   telephone,

- ✓ personal interview or meeting
- ✓ e-mail
- ✓ "Integrated service platform: system (web system available at INPI webpage: https://www.gov.br/inpi/pt-br/plataforma-integrada-de-atendimento divided on 4 levels: pre-service, field service, problem solving service and service in new solutions. Each level offers different ways of contact, such as: INPI Chatbot, INPI "Conecta todos" (connect all) platform, Contact us, Comex service, Ombudsman's customer service, Citizen information service and Telepresential service where, through the appropriate section, everyone can open a case and make a complaint or praise, send suggestions, request information, receive instructions about procedures, request telepresential service, etc.)

Applicants and/or Legal Representatives may also apply for a personal interview or meeting with the Patent Examiner, as long as it is requested with prior notice. All patent examiners are well trained and prepared to provide applicants/legal representatives the necessary consultancy regarding their queries.

(ii) After the forms (ISR, WOISA, IPER) are sent to the applicant and IB, a survey is sent to the applicant email with questions related to that specific application, regarding satisfaction and perception.

In 2025, new guidelines and targets were implemented to monitor user's satisfaction. The types of surveys were:

- Qualitative Research: Semi-structured and individual interviews with applicant or common representatives (natural or legal person without intermediaries) or agent duly authorized by the applicant.

- Quantitative Research: Survey, using an online form, with questionnaires sent to applicant or common representatives (natural or legal person without intermediaries) or agent duly authorized by the applicant.

(iii) Guidance to applicants on Intellectual Property, including information on the search and examination process is provided by various means, such as the INPI/BR Website (https://www.gov.br/inpi/en/services/patents) and some training seminars organized in Cooperation with WIPO. It was also developed by INPI/BR a User's Guideline to explain how to file patent applications through the PCT System. The WIPO Tutorial Videos in Portuguese are available at youtube (https://www.youtube.com/watch?v=7Le0PDP68XQ), where users and applicants can find all the necessary information regarding the PCT, PCT application, etc.

INPI/BR website is frequently updated to give information concerning notices, announcements, events, as well as courses and activities related to Intellectual Property. Also, all the important information related to the Institute is made available, including a session about most frequently asked questions (FAQ) related to different areas of INPI/BR, as well as all Brazilian laws and normative acts referred to Industrial Property.

The INPI/BR service chart was updated in 2025 and is available on https://www.gov.br/pt-br/orgaos/instituto-nacional-da-propriedade-industrial

All the information related to Quality processes (Quality and Risk Policy methodologies, dashboards and frameworks) are available in INPI/BR website in the following links:

https://www.gov.br/inpi/pt-br/governanca/gestao-da-qualidade

All the information related to Patent Cooperation Treaty – PCT (International and National Phase) are available in INPI/BR website in the following link: Tratado de Cooperação em matéria de Patentes (PCT) — Instituto Nacional da Propriedade Industrial (www.gov.br)

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 between WIPO and the designated and elected office at the INPI/BR is carried out by the PCT Division. It will forward all feedbacks from WIPO to the management and / or to the head of the involved technical department or to the patent examiners concerned.

This communication with WIPO and designated and elected offices are done mainly by e-mail. The feedback given by WIPO and the offices are evaluated and treated by the PCT General Coordinator and, if necessary, it is redirected to a specific technical division.

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.

(a-b) INPI/BR has developed a variety of documentation to support the QMS. These include the Strategic Plan, Quality Policy, Process Management Manual, Risk Management Manual and Policy, Document Standardization System Manual, Guidelines for Search and Examination, Search and Examination procedures and working instructions, Quality Examination Review Procedure, Process Flows and other documents necessary for planning, reporting, operating and controlling processes and ensure the standardization of activities with clear assignment of responsibilities.

The documentation is available on different media such as INPI's BR portal https://www.gov.br/inpi/en, INPI/BR Intranet and INPI DRIVE (a web-based cloud storage), SISCAP system and provision of staff with a central source of information on how INPI/BR manage its processes in order to assure quality.

(c) The Process Management Manual and Document Standardization System Manual provide to all staff the correct procedures for process mapping and document control, including proper version numbering, identification, distribution, storage, access to latest version, responsibilities of the personnel, etc.

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 QMS covers the criteria under 21.24 (i) to (vi).

(i)-(ii) The Quality Policy document includes a clear statement of commitment to the QMS from top management.

(iii) The organizational structure and the responsibilities of each of its departments is described by a Brazilian Specific law (President act – Decree nº 11.207 issued on September 2022) and is available on INPI/BR website (https://www.gov.br/inpi/pt-br/acesso-a-informacao/institucional/estrutura-organizacional) and in the following link: https://www.planalto.gov.br/ccivil_03/_Ato2019-2022/2022/Decreto/D11207.htm#art7

(iv) The documented processes carried out in INPI/BR such as search, examination, publication and support process are available on INPI DRIVE so that all staff and examiners are able to see. There is a total of 83 processes flows in different levels mapped for PCT macroprocess, being 45 AS IS and 38 TO BE.

(v-vi) The Quality General Coordinator together with the PCT General Coordinator and Patent Quality Group organize all process implementation necessary to run QMS. INPI employs the process approach to develop, implement and improve efficiency of QMS. The responsibility for mapping the processes competes to PCT Unit which may request support from CQUAL which is INPI´s Process Office. As long as changes are made in the processes, a critical review is made on the documentation in order to ensure that procedures in place are aligned with the process flows established.

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.*

(i) All the internal documents related to PCT macroprocess are managed in accordance with the Document Standardization System Manual, provided by the Quality General Coordination and kept in INPI DRIVE. The records are kept in the network directory.

(ii) Top Management meets at least once a month to follow and review the organization objectives, quality goals and the Action Plan accomplishment. The main decision and corrective actions decided by the Management are cascaded to the respective managers and processes may be reviewed. Every month is published on INPI/BR Intranet the main results and goals achieved on the previous month.

(iii) Training records, skills and experience, as well as the retraining of the staff involved in the ISA/IPEA process, are kept in the Human Resources General Coordination.

(iv-v) All evidences are stored on SISCAP system for quality analysis purpose and auditing. Reports are issued on quality activities.

(vi-vii) SISCAP system tracks and storages all work done on the search and examination process.

(viii) The results of QMS Audits are stored under the responsibility of Quality General Coordination.

(ix-xi) All action taken to correct and prevent nonconformity are stored in SISCAP and passed on internally to the head of divisions.

(xii) Guidelines for Search and Examination at the Patent Board are uploaded on SISCAP system and are also available on INPI/BR Intranet.

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.

The search process documentation is stored in the record for each Search/Examination. The examiners are required to complete a form for all search and examination and the results are uploaded on SISCAP. It contains at least a "History List" of the search process, containing all used parameters a) i) to v). If it is necessary, the Examiner can append additional information regarding the search process, for example those indicated in paragraphs b) and c).

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.

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]