

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

SUMMARY

The INPI-Br Quality Report has been substantively reviewed and updated from previous year.

Quality Management System for International Search and Preliminary Examination has been considerably improved along the past years.

In 2017 there was the establishment of the Executive Directorate (DIREX) in the Organization in substitution to the Vice-Presidency.

The Quality General-Coordination (CQUAL) started to report directly to the Executive Director and is responsible to coordinate together with the Quality Group inside the Patent Directorate the Quality Management System (QMS) for ISA&IPEA.

Generally, the INPI-Br QMS consist of three components:

- 1- Quality standards for Search & Examination work
2. Quality Assurance: procedures, tools, manuals, training, communication, procedures for measuring quality.
3. Audit and review mechanism for monitoring compliance with quality standards

The quality standards and practices are compliance with the standards and practices established by the PCT. However, INPI-Br is not ISO 9001 certified, although the QMS in place is based upon ISO 9001 principles.

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.

The INPI-Br has also increased its effective number of patent examiners to 332, at the end of December 2017, and it is expected to hire 163 more until 2020.

1. LEADERSHIP AND POLICY

21.04 Confirm that the following are clearly documented, and that this documentation is available internally:

- (a) The quality policy established by top management.*
- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.*

(a) The Quality Policy in INPI-Br is:

1. Strive for excellence in service delivery through continuous improvement of processes, to increase the satisfaction of citizens, users and customers.
2. Adopt a Quality Management System (QMS) that guarantees products and services in accordance with the standards established by the legislation in force and International Agreements and Treaties.
3. Improve and value human resources, adapting the infrastructure and work environment to the various activities, to ensure the development of competencies with excellence.

(b) The INPI-Br is headed by a President, an Executive Director and three others Directors, appointed in accordance with legislation. Appointments to positions in committee, roles and functions are made in accordance with current legislation.

The Quality General-Coordinator is the responsible to elaborate e conduct the QMS among the organization. The Coordinator acts as support to management on all levels to ensure the proper function of the QMS.

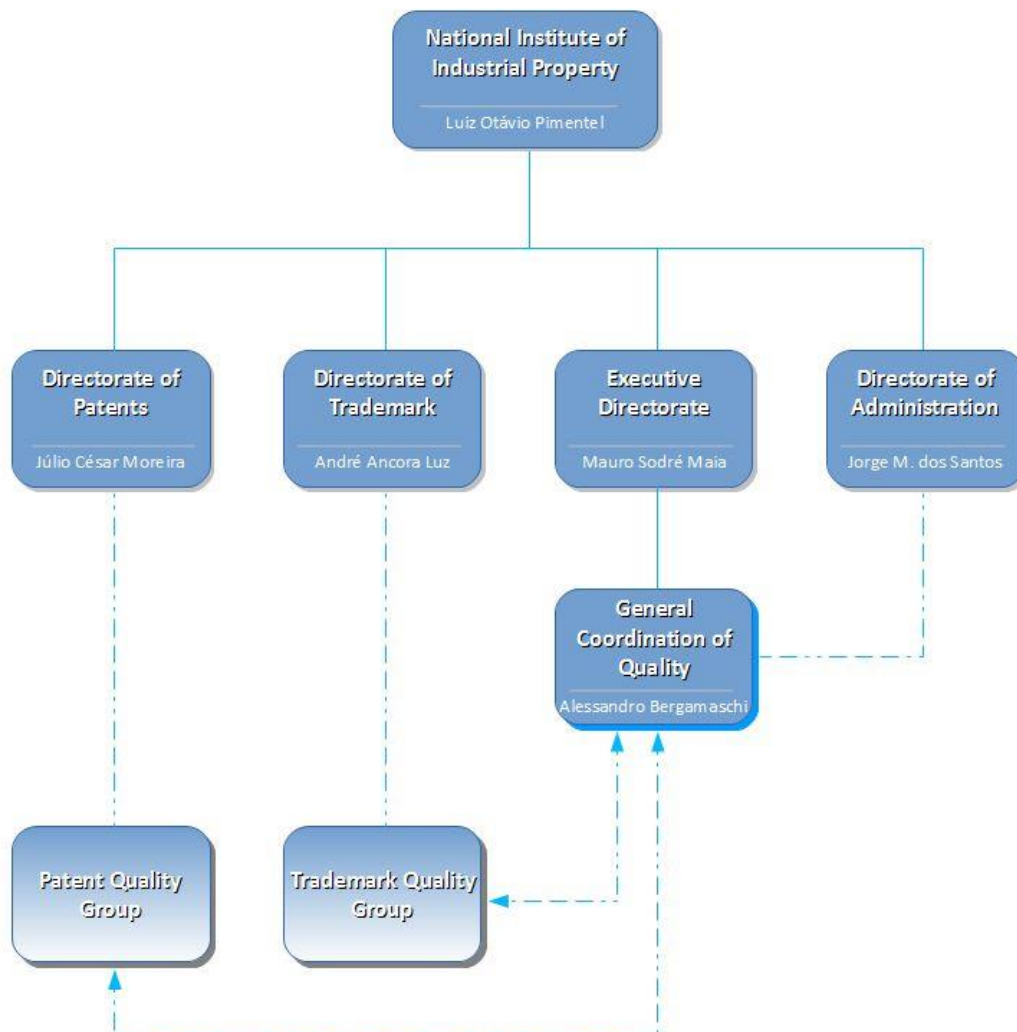
In the Patent Directorate there is a PCT Quality Group which is also responsible to define and standardize procedures, work instructions and all others activities of the Quality Management System (QMS) required by PCT and Regulations, Administrative Instructions, Receiving Office (RO) Guidelines, and PCT Search and Examination Guidelines.

Executive Director: Mauro Sodre Maia

Quality General Coordinator: Alessandro Bunn Bergamaschi

Patent Director: Julio Cesar Castelo Branco Reis Moreira

(c) Organizational Charts



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.).

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives throughout the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS in based on Chapter 21	✓		
			determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.24	✓		
		(e)	recording the results	✓		
21.10			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 tech. qualifications to S&E in all technical fields	✓		
		(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation records	✓		

Chapter 21 requirement			Extent of compliance			
			full	part	no	
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation accord. to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act accord. 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	✓		
21.11	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(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	✓		
21.14		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.15	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception		✓	
		(b)	A procedure for ensuring their legitimate needs and expectations are met		✓	
	(iii)		Clear and concise guidance on the S&E process for the user	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(iv)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.16		Established communication with WIPO and designated and elected Offices	✓		
21.17		QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.18	(a)	Documents making up the Quality Manual have been prepared and distributed	✓		
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.19	(i)	Quality policy of the Authority and commitment to QMS	✓		
	(ii)	Scope of QMS	✓		
	(iii)	Organizational structure and responsibilities	✓		
	(iv)	the documented processes are carried out in the Authority	✓		
	(v)	Resources available to carry out processes and implementing the procedures	✓		
	(vi)	a description of the interaction between the processes and the procedures of the QMS.	✓		
21.20	(i)	Records 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)	Evidence of conformity of processes	✓		
	(v)	Results of reviews of requirements relating to products	✓		
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record 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	✓		
21.21	(i)	Recording of the databases consulted during search	✓		
	(ii)	Recording of keywords, combination of words and truncations during search		✓	
	(iii)	Recording of the languages used during search		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(iv)	Recording of classes and combinations thereof consulted during search		✓	
	(v)	Recording of a listing of all search statements used in databases consulted		✓	
	(vi)	Records about other information relevant to the search		✓	
	(vii)	Records about limitation of search and its justification		✓	
	(viii)	Records about lack of clarity of the claims	✓		
	(ix)	Records about lack of unity	✓		
21.22		Report on its own internal review processes	✓		
21.23-21.25		Additional information on further inputs to its internal reviews	✓		
21.26		Initial report called for by paragraph 21.26	✓		

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 working groups in Patent Directorate, which are responsible for carrying out the quality requirements and Quality Assurance processes.

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

(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
- performing corrective and preventive actions
- conducting management reviews
- complying with the quality policy statement.

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 the precepts of the QMS. Moreover, this communication is also done through e-mail, intranet and internet. The administration also includes training in their communication materials of the QMS.

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

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood throughout the respective Authority.*

(a-c) The Top Management meet at least once a month to follow and review the organization objectives, quality goals and the annual Plan of Action accomplishment.

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

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));
to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));*
- (c) in an objective and transparent way (cf. paragraph 21.22);*
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.25).*

(a) The QMS is continuously monitored corporately by the CQUAL and through the Quality Groups in the Directorate of Patent. A formal management review is undertaken every week as well as monthly INPI-Br Meeting Board. The review assesses how well the system is performing, what can be improved and whether it is meeting the policy and objectives set for it.

(b) The extent of compliance of search and examination work with the PCT Guidelines is based on the review of work from each Examiner. The PCT International Division performs reviews against the standard requirements (Check List of the examination). The review findings are reported to the Examiner and to the head of the technical division of their respective examination unit.

(c) Reports are regularly provided to the Senior Management of the Patent Groups on the extent to which work complies with the quality assurance process. The quality assurance process includes requirements relating to search and examination. Internal quality audits are also carried out on the processes and procedures used to ensure their compliance with INPI-Br

Quality Management System, Chapter 21 and the PCT Guidelines and other internal regulations.

(d) At the end of each year, CQUAL meets with PCT management to review and discuss about the reports submitted to WIPO.

2. RESOURCES

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

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work;

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

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

The Executive Director along with Director of Administration provides resources needed to deliver desired outcomes including the maintenance and improvement of the quality management system. The Executives of each of the Groups along with their respective leadership teams provide resources needed to meet customer requirements within their areas of responsibility

Although the operational capability of the INPI-Br, at the time it received the title of ISA&IPEA, was already enough to meet the demand imposed by this new mission, action has been taken since then to maintain and even expand this condition in their several aspects. Such arrangements are reflected in actions as those below:

- ✓ hiring new examiners and administrative staff participate in studies and perform other activities assigned by the PCT General Coordination.
- ✓ providing training in industrial property and in foreign languages;
- ✓ implementation of post-graduate course on industrial property;
- ✓ 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;
- ✓ expansion of its Quality Management System (QMS), making it increasingly able to assess and guide the appropriate action to maintain a continuous improvement of products and services offered by the INPI-Br.

- ✓ Teleworking (Home office): in 2017, 100 patent examiners started Teleworking at Home and increased the examination productivity around 40%.

(i) Patent Examiners

- ✓ The INPI-Br has expanded its human capacity to manage examination procedures in a quicker and more reliable fashion. At the end of 2017 INPI-Br had 332 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, about 30% of examiners already have the title of Doctor of Science and about another 20% are in the process of obtaining this title.

- ✓ Among the applied requirements are the conditions for receiving documentation, referenced in Rule 34, including the languages supported by the Institute for receipt of PCT applications, 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 effect control, verification and registration of applications filed under the PCT. They are officials with experience and knowledge in the Administration in Industrial Property, in respect of the PCT, some of whom are trained in English and Spanish.

(ii) Appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained.

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 has invested to better equip the facilities with technological resources, and human resources already mentioned. Among the technological highlights are:

- ✓ acquisition of new computers with up-to-date common setup, tables 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.

- ✓ 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 EpoqueNet and Clarivate.

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

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 isolated cases of difficulties.

More detailed work instructions are being reviewed and, where applicable, new work instructions are being developed in order to ensure greater consistency and adherence to procedures.

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 courses and training for examiners, including language, searching procedures, examination procedures and quality, among others. The need, frequency and content of these training programs are reviewed annually in line with internal procedures for evaluation.

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, etc.

The examiners are aware of the importance of compliance with criteria and quality standards.

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 General Coordination of Information Technology is responsible for maintaining and monitoring the SISCAP system.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.11 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 (Registration System of Production).

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.

The SISCAP system provides the automatic recognition of data. After registering the international application in SISCAP, the examiner may obtain the necessary forms with the data concerning the applicant, filing date and priority date automatically filled in.

The issuance of the reports is monitored and controlled by those responsible for managing ISA / IPEA activities, the PCT General Coordinator and the head of technical division of the PCT.

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

4. QUALITY ASSURANCE

21.12 The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality standard 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 4 steps of verification at ISA stages:

1. Self-checking by examiner: when conducting the formal examination, the formality examiner fill out checklists for each international application covering the steps at the ISA and IPEA stages.

2. Verification of substantive examination: the head of the technical division verifies 100% of the reports that mainly cover issues related to patentability requirements before issuing the ISR and the WOISA.

3. ISA formality examination checking: The head of PCT international division performs a formality checking on all PCT forms (100% sampling) to be sent to the applicant and IB, inspecting the integrity and consistency of the details in the forms.

4. Periodic audit of a random sample of cases: Approximately 5% of international applications where the INPI-Br is designated as ISA are verified by a second examiner using a compliance checklist. The audit findings and recommendations are recorded in the system for corrections and training.

The results of the audit, according to step 4, are computed for performance measurement and quality assurance. The indicator shall be monitored on a monthly basis.

5. COMMUNICATION

Inter-Authority communication:

21.13 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 21.13)

21.14 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.*

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Communication and guidance to users:

21.15 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.*
- (iv) An indication of 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 between examiners and applicants or their respective representatives:

- ✓ telephone,
- ✓ personal interview,
- ✓ mail, fax, e-mail
- ✓ Ombudsman.
- ✓ "Contact Us" system (web system available at INPI webpage: www.inpi.gov.br where anyone can open a case and make a complain, request information, etc.)

Applicants and/or Legal Representatives may also apply for an interview or meeting with the Patent Examiner, as long as it is requested with sufficient 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 about satisfaction and perception regarding INPI-Br services.

(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 (www.inpi.gov.br) 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 <http://www.inpi.gov.br/arquivos-videos/tratado-de-cooperacao-em-materia-de-patentes> 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.

- (iv) The quality objectives are available on INPI Website www.inpi.gov.br

21.16 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 General Coordination and the PCT National Division. These departments 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, and its response monitored by the Coordinator.

6. DOCUMENTATION

21.17 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

21.18 The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

- (a) the documents making up a Quality Manual that have been prepared and distributed;*
- (b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*
- (c) document control measures taken e.g. version numbering, access to latest version.*

(a) INPI-Br has developed a variety of documentation to support the QMS. These include a quality policy and objectives, the Quality Manual, Process Management Manual, Guidelines for Search and Examination at the Patent Directorate, Search and Examination procedures, and other documents necessary for planning, reporting, operating and controlling processes.

The documentation is available on INPI-Br intranet, SISCAP system (where examiners can easily access the procedures and manual) and provide staff with a central source of information on how INPI-Br manage its processes in order to assure quality of service.

(b) INPI-Br Quality Policy and Manual are available on intranet and internet site.

(c) The Process Management Manual provides to all staff on the correct procedures for process mapping and document control, including proper version numbering, access to latest version, etc.

21.19 Indicate whether the documents making up the Quality Manual 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 in INPI-Br covers the criteria under 21.19 (i) to (vi).

(i)-(ii) the quality policy document includes a clear statement of commitment to the QMS from top management, the scope of the QMS, including details of and justification for the exclusions.

(iii) the organizational structure and the responsibilities of each of its departments is described by a Brazilian Specific law (President act – Decree nº 8.854) and is available on INPI-Br website (www.inpi.gov.br)

(iv) The documented processes carried out in INPI-Br such as search, examination, publication and support process are the same as for the national granting procedure and they are available on intranet so that all staff and examiners are able to see.

(v-vi) The Quality General-Coordinator together with the PCT General-Coordination and Patent Quality Group organize all process implementation for the Quality Management System. For this reason, it is certain that interaction between the process and the procedures of the QMS is ensured.

21.20 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 7.*

(i) Control of Documents is managed within INPI-Br in accordance with the Document Control guideline and procedure outlined in the Quality Manual.

(ii) The Top Management meet at least once a month to follow and review the organization objectives, quality goals and the annual Plan of Action accomplishment. The main decision and corrective actions decided by the Management are spread-out towards 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 analyzes and audits and reports on quality activities.

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

(viii) The results of QM Audits are stored under the responsibility of the CQUAL.

(ix-xi) all action taken to correct and prevent non-conformity are stored in SISCAP and also passed out internally to the head of the examination units.

(xii) Guidelines for Search and Examination at the Patent Directorate are uploaded on SISCAP system and is also available on INPI-Br Intranet.

7. SEARCH PROCESS DOCUMENTATION

21.21 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).

8. INTERNAL REVIEW

21.22 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.

21.23-21.25 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.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

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