

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)

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

The INPI-Br is effectively performing the function of International Search and Preliminary Examination Authority since September 2009, and has been gradually increasing the implementation of procedures for international searches and examinations.

Since the beginning of the activities, it was aimed the establishment of foundations of the Quality Management System, defining policies and criteria for managing the workload, providing the necessary resources and performing verification of compliance of the procedures performed. All the media already in use by the framework of national phase examination in the Institute were made available for use in activities of international searches and examinations.

The INPI-Br, in order to increase the quality of its work and its production, increased its effective number of patent examiners to about 300, and it is expected to double this figure by 2014. It has also revised its organizational structure, increasing the number of patent examination divisions, from 6 to 20, and the creation of the General Coordination of Quality (CGQUA), directly linked to the Presidency of the Institute. The General Coordination of Quality (CGQUA) encompasses and extends the previously existing working groups in Quality Management.

The Quality Management System of the INPI-Br has as a normative reference the principles established by ISO 9001:2008, by the Quality Program of the Federal Government (PQGF) and the Excellence Model for Public Management (MEGP).

The INPI-Br decided to get the ISO 9001:2008 certification for all of its processes. Among the first processes for which certification is sought are those relating to the International Search and Examination under the PCT. For this purpose it is performing the contracting of a consulting firm in quality management.

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 organisational chart showing all those bodies and individuals responsible for the QMS.

21.04 (a) Quality Policy

The quality policy of the INPI-Br was defined, established and approved by the top management, and is present in the highest level document of the Institute, the Strategic Planning.

In this document, established and approved in August 2010, it is presented the vision of the Institution:

VISION: "The INPI-Br should become one of the Intellectual Property Offices of reference in the world, with regards to efficiency and quality of its various services."

Hence the seven guidelines established in the Strategic Planning, so that it can achieve a condition lined up with the INPI-Br Vision, the first one of these being "***Ensuring Quality and Efficiency in Examination and Registration I.P. Rights.***"

Seventy-three specific projects were established, aiming at consolidating the guidelines, which are guided by 18 strategic objectives, among which are included the deployment of a Quality Management throughout the entire INPI-Br, increased operational efficiency and updating the guidelines and the examination procedures.

The assumptions of Strategic Planning are available on the computerized system, in frames distributed into specific points of the Institute and through the awareness of the staff.

21.04 (b) Personnel Responsible for the Quality Management System

The INPI-Br is headed by a President, a Vice-President and five Directors, appointed in accordance with legislation. Appointments to positions in committee, roles and functions gratified commissioned members of the regimental structure of the INPI-Br are made in accordance with current legislation.

The powers and responsibilities of those responsible for the Quality Management System are described below:

■ Presidency

The Presidency, amongst other functions, shall:

- represent the INPI-Br in court or elsewhere;
- approve the budget programming;
- represent the Institute in national and international fora, to decide on the advisability of signing, ratification and denouncement of conventions, treaties, covenants and agreements on industrial property;
- decide on appeals and amending decisions primarily taken by the Directors of the INPI, in the form of (according to) legislation, and
- watch over for the development, legitimacy and internal and external credibility of the INPI-Br.

■ Vice Presidency

The Vice Presidency, amongst other functions, shall:

- assist the President of the INPI-Br in implementing policies of the Institute, coordinating and overseeing the Directorates and other units of the Institute;
- substitute the President in their absence, and
- perform other duties as may be delegated.

■ General Coordination of Quality

The General Coordination of Quality, amongst other functions, shall:

- plan, coordinate and implement the quality policy:
 - a) of the activities of patents, trademarks, contracts and other registers;
 - b) of the activities of regional and international partnerships, dissemination of the intellectual property, of education and research and of technological documentation, and
 - c) of the other activities of the INPI-Br;
- promote and coordinate the preparation and updating of standards and procedures of the INPI-Br;
- promote and coordinate certification of all activities of the INPI-BR according to the standards and rules established by the Presidency;
- ensure that procedures for the Quality Management System (QMS) are established, implemented and maintained according to the requirements of standards: ISO 9001:2008, Guidelines and Rules of the PCT and Chapter 21;
- develop, distribute, review and update the Quality Manual;
- develop the Quality Policy to be approved by the Top Management;

- develop the Quality Objectives and their performance indicators;
- ensure that the deployment of the Quality Policy properly reflect the intentions of the organization;
- perform controls to check the implementation of quality policy, with the elaboration of detailed reports containing proposals for measures to redress the dysfunctions detected;
- implement a Quality Management System (QMS) that: support, monitor and improve quality;
- provide resources and support for the deployment of Quality;
- ensure that deadlines and objectives are met, by:
 - establishing priorities
 - allocating resources
 - allocating tasks;
- propose, coordinate and supervise surveys and satisfaction surveys among users of the INPI-Br and identify critical areas;
- promote standards and procedures and provide technical guidance to the units involved, and
- promote contact with other offices to exchange information, experiences and cooperation;
- attend meetings and forums of experts (eg. PCT);
- report to MIA on the activities of the Office as required by the guidelines of the PCT;
- support and manage the work of the Quality Internal Audit teams in the INPI-Br;
- plan and organize the program's Internal Audit of Quality Management System (QMS) to be approved by Top Management as well as record the detected nonconformists and corrective actions implemented;
- develop the Internal Audit program for the work of the international search and international examination under the PCT;
- promote critical analysis meetings of the Internal Audit program;
- analyze, critically, corrective and preventive actions;
- promote and coordinate actions to disseminate the results and improvements;
- propose and coordinate activities to verify and ensure the continuous improvement of products and services of the INPI-Br;
- structure and coordinate working groups, organized by subject matter of technical, administrative and general, to identify opportunities for quality improvement activities of the INPI-Br, and
- participate in studies and to carry out other activities that will be conferred to it by the Presidency.

■ **Quality Division of Patent Activities and Institutional Partnership and Technological Information**

The Quality Division of Patent Activities and Institutional Partnership and Technological Information, amongst other functions, shall:

- assist the General Coordination of Quality (CGQUA) to conduct the acts necessary for the performance of the Coordination Unit;
- supervise and monitor the implementation of quality activities in their

respective areas;

- propose measures to streamline the work and the adoption of continuous improvement;
- implement the Quality Policy;
- supply guidance to internal staff when drafting the procedures of the Quality Management System (QMS), verifying their adequacy;
- advise the internal units of the INPI-Br in developing its procedures and work instructions;
- develop, where necessary, procedures and work instructions;
- perform surveys and satisfaction surveys among users of the INPI-Br;
- perform internal audit;
- critically analyze corrective and preventive actions;
- discuss and analyze the causes of poor work and take preventive actions in the areas, including with regards to the work of PCT search and examination (both normal and examination under the PCT);
- prepare, monitor and supervise their performance indicators;
- make recommendations for best practices;
- consider the suggestions of best practices of the Quality Group and other areas, discuss and decide on them, taking into account all available information, as well as provide preparation and training of the procedure;
- coordinate working groups set up by the General Coordination of Quality (CGQUA);
- coordinate the PCT Quality Work Group;
- advise the internal units of the INPI-Br, in its areas of expertise to conduct its analysis of the quality of their services, and
- participate in studies and conduct other activities as may be conferred by the General Coordination of Quality.

■ **PCT Quality Work Group**

The PCT Quality Work Group, amongst other functions, shall:

- define and standardize procedures for the Quality Management System (QMS) under the PCT;
- define and standardize work instructions for the Quality Management System (QMS) under the PCT;
- resolve issues related to the work of ISA/IPEA;
- monitor questions in the examination and operations;
- establish policies for education and training within the PCT for examiners;
- prepare manuals for examination;
- review national rules under the PCT;
- manage the system of specialists of the PCT;
- build a system to critically analyze the quality of reports of the PCT;
- ensure that the working procedures of search and examination fulfills all requirements of the PCT;
- conduct reviews;
- analyze the results of reviews of feedback;
- plan the User Satisfaction Surveys for the PCT;
- collect samples at pre-determined, the search and examination reports and

make critical analysis for each survey group;

- make recommendations for best practices;
- consider the suggestions of best practices Quality Group and other areas, discuss and decide on them, taking into account all available information. To provide the procedure and preparation of training;
- help disseminate best practices of the patent office;
- discuss and analyze the causes of search and examination work of disabled and take preventive actions within the PCT;
- discuss deficiencies identified by the user and, if agreed, to take the necessary corrective actions, and
- participate in studies and conduct other activities as may be conferred by the Quality Division of Patent Activities and Institutional Partnerships and Technological Information.

■ **Ombudsman**

The Ombudsman shall:

- receive, analyze and provide appropriate treatment for complaints, compliments and suggestions from users;
- generate reports of indicative and qualitative analysis, identifying critical points and contributing to finding solutions.

■ **Directorate of Administration**

The Directorate of Administration shall:

- plan, coordinate, conduct, supervise, promote, monitor and evaluate the implementation of the activities of:
 - a) human resource administration and development;
 - b) acquisition of goods and services and general services;
 - c) federal accounting and financial management, and
 - d) architecture and engineering and the social and environmental responsibility.

■ **General Coordination of Human Resources**

The General Coordination of Human Resources shall:

- plan, coordinate, direct and supervise the implementation of activities related to personnel administration and human resource development of the INPI-Br, including training and capacity building.

■ **General Coordination of Resources and Administrative Processes of Nullity**

The General Coordination of Resources and Administrative Processes of Nullity, amongst other functions, shall:

- examine and provide technical support for President of the INPI-Br's decision on the appeals and administrative nullity proceedings, brought in the form of industrial property legislation, issuing an opinion on the technical issues raised;
- guide and coordinate the systematization, organization and updating of administrative decisions relating to industrial and intellectual property, seeking to

consolidate a matter of administrative law (jurisprudence on the subject), and

- propose improved guidelines and procedures for the examination of appeals and administrative nullity proceedings, brought in accordance with (according to) current legislation of industrial and intellectual property.

■ **Directorate of Patents**

The Directorate of Patents shall:

- analyze and decide upon the privileges of patent applications filed in the national phase according to the guidelines of industrial and technological policy adopted by the Federal Government of Brazil;
- participate in activities coordinated between the INPI-Br and other agencies, companies and entities in view of increasing the participation of Brazilians in the systems of intellectual property protection;
- technically evaluate proposals for new cooperative actions, agreements and treaties relating to patents;
- coordinate, supervise, monitor and promote the implementation of cooperative actions, international agreements and treaties concerning patents;
- propose improved practices and develop operating standards for review and granting of patents, and
- coordinate, supervise, monitor and promote the implementation of standards relating to the International Search Authority and Preliminary Examination Authority under the Patent Cooperation Treaty - PCT.

■ **General Coordinations of Patents and their subordinate Examining Divisions**

The General Coordinations of Patents and their subordinate Examining Divisions, amongst other functions, shall:

- propose improved guidelines and procedures in order to harmonize criteria for the examination of patent applications;
- coordinate studies for the improvement of routines and develop international standards for the examination and granting of patents;
- update the registration information and location of patent applications in the system of the Directorate, in their respective fields of work;
- promote the publications of the acts and dispatches issued in accordance with the powers conferred;
- support the elaboration of studies and other technical information on industrial property legislation, including treaties, agreements and other international counterparts (instruments) on this matter;
- participate in studies and undertake other activities that are assigned to it;
- conduct searches and technical examinations and decide upon the privileges of patent applications filed in the national phase, and
- perform the duties of Search and Technical Examination as International Search Authority and International Preliminary Examining Authority under the Patent Cooperation Treaty - PCT.

■ **General Coordination of the Patent Cooperation Treaty (PCT)**

The General Coordination of the Patent Cooperation Treaty (PCT) shall:

- propose improved guidelines and procedures in order to harmonize criteria for the activities of preparing the International Search Report, Written Opinion and of the International Examination Preliminary Report;
- coordinate the participation of the Patent Directorate in activities held by INPI-Br and other agencies, companies and entities in regard to the Patent Cooperation Treaty;
- consolidate and disseminate statistical data on activities related to the INPI-Br concerning the Patent Cooperation Treaty;
- coordinate the training of researchers in Industrial Property for the activities related to the role of the INPI-Br as International Search and Preliminary Examination Authority in the Patent Cooperation Treaty;
- support the elaboration of studies and providing information on the Patent Cooperation Treaty, including treaties, agreements and other international instruments on this subject, and in relation to proposals for national and international acts, with the participation in groups, committees or events;
- propose standards and internal guidelines to the President of the INPI-Br related to the Directorate of Patents for application and enforcement of existing legislation related to the Patent Cooperation Treaty;
- provide technical information to the President of the INPI-Br and their representatives related to consultations on the Patent Cooperation Treaty, and the Brazilian government in any discussion fora on the Treaty;
- participate in studies for the improvement of routines for the adoption of international standards for the preparation of the International Search Report, Written Opinion and of the International Examination Preliminary Report;
- promote the publications of the acts and dispatches issued in accordance with the powers granted under the Patent Cooperation Treaty;
- update the information and location of international patent applications in the Directorate of Patent System, in its respective fields of work;
- provide technical inputs in support of the General Coordination of Appeals and Administrative Processes of Nullity, for the decision of the President of INPI-Br, regarding the appeals within its jurisdiction;
- establish administrative procedures for referral of gatherings held in foreign currency to the International Bureau of World Intellectual Property Organization and the competent International Searching Authorities, and
- participate in studies and to undertake other activities that are assigned to it by the Patent Directorate.

■ **Receiving Division of the Patent Cooperation Treaty (PCT)**

The Receiving Division of the Patent Cooperation Treaty (PCT) shall:

- carry out activities related to the Receiving Office of international patent applications filed in Brazil under the Patent Cooperation Treaty;
- perform a formal preliminary examination of international patent applications for the purpose of determining the number of International Application filed, as well as the establishment of the international filing date;
- formulate the requirements for settlement of international patent applications

filed;

- reject the filing of international patent application when it does not meet the minimum requirements, in accordance with the Regulations under the Patent Cooperation Treaty;
- promote the withdrawal of the International Patent Application by non-payment of fees established by the Patent Cooperation Treaty or by failure to present the corrections requested;
- declare the Priority claimed in International Patent Application null if it exceeds the deadline set by the Paris Convention;
- provide the transmittal of international patent applications for the International Search Authority chosen declared in the form presented with the request for the international application at INPI-Br;
- update the information and location of international patent applications in the Patent Directorate System, in its respective field of work;
- technically and procedurally orienting users of the Patent Cooperation Treaty in the activities undertaken as Receiving Office;
- orient the Regional Divisions and Offices of the INPI-Br regarding the receipt of the International Patent Application;
- prepare spreadsheets to request delivery of fees received in foreign currency at the International Bureau of World Intellectual Property Organization and the competent International Searching Authorities, and
- participate in studies and perform other activities assigned by the General Coordination of the Patent Cooperation Treaty.

■ **Technical Division of the Patent Cooperation Treaty (PCT)**

The Technical Division of the Patent Cooperation Treaty (PCT) shall:

- assist the General Coordination of the Patent Cooperation Treaty in conducting actions of coordination needed to the work of the entity;
- cooperate with the activities coordinated between the INPI-Br and other offices on the Patent Cooperation Treaty;
- operationalize the process of handling internal and external international patent applications that have chosen Brazil as an International Search Authority:
 - (i) update the information and location of international patent applications in the Patent Directorate System, in its respective field of work;
 - (ii) forward the applications to the appropriate Technical Division, observing the administrative acts on the matter, in the case of internal movement;
 - (iii) transmit the applications to the International Bureau of World Intellectual Property Organization and for applicants in case of external displacement;
- advise the Technical Divisions in the preparation of reports relating to: International Search, Written Opinion and of the International Examination Preliminary;
- monitor and supervise the performance of activities for the preparation of Reports of the: International Search, Written Opinion and International Preliminary Examination;
- operationalize the process of handling internal and external international patent applications that have chosen Brazil as an International Preliminary Examining Authority:

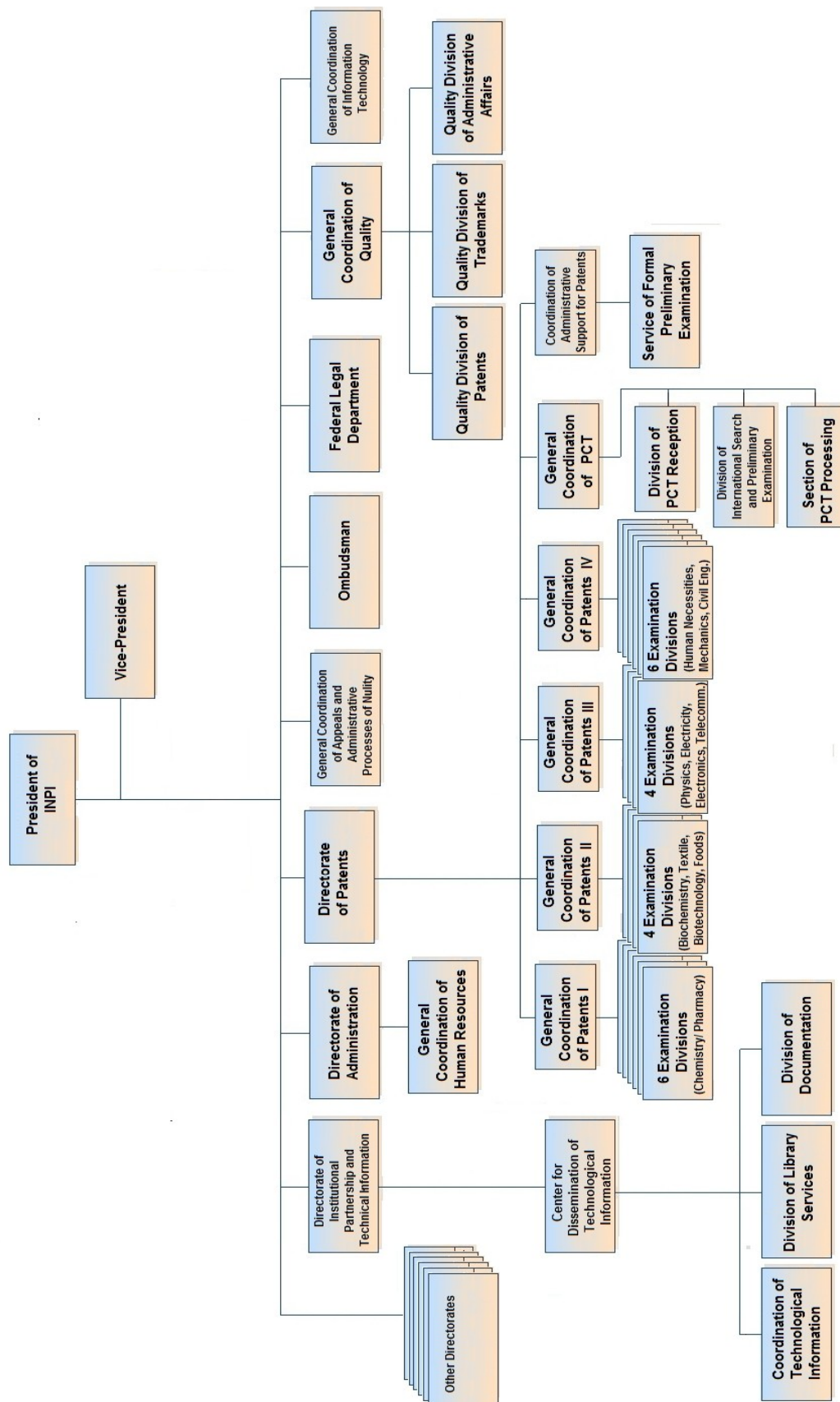
- (a) perform the formal preliminary examination related to the requirements for the International Preliminary Examination;
- (b) issuing requests for compliance to the International Preliminary Examination Requirements;
- (c) provide notifications relating to the activity as an International Preliminary Examination Authority;
- (d) update the information and location of international patent applications in the Patent Directorate System, in its respective fields of work;
- (e) forward the applications to the appropriate Technical Division, observing the administrative acts on the matter, in the case of internal displacement;
- (f) transmit the applications to the International Bureau of World Intellectual Property Organization and for applicants in case of external displacement;
 - retrieve and reconcile statistical data on activities of the INPI-Br related to the Patent Cooperation Treaty as International Authority;
 - keep updated and under its care the control of the files of the requests for International Search and Preliminary Examination;
 - technically and procedurally orient users of the Patent Cooperation Treaty in the activities undertaken as International Authority;
 - promote the secret processing of international applications of Brazilian origin Search and International Preliminary Examination interest of national defense;
 - prepare spreadsheets to request delivery of fees received in foreign currency at the International Bureau of World Intellectual Property Organization, and
 - participate in studies and perform other activities assigned by the General Coordination of the Patent Cooperation Treaty.

■ **Processing Section of the Patent Cooperation Treaty (PCT)**

The Processing Section of the Patent Cooperation Treaty (PCT) shall:

- perform a formal preliminary examination of international patent applications for purposes of entry into the national stage of the Patent Cooperation Treaty;
- formulate requests to comply the international patent applications with the requirements of entry into national stage under the Patent Cooperation Treaty;
- promote the withdrawal of international patent applications that do not meet the legal provisions concerning the entry into the national stage;
- arrange for the publication of the entry into the national phase of international applications filed under the Patent Cooperation Treaty;
- update the registration information and location of international patent applications in the Patent Directorate System, in their respective field of work;
- technically and procedurally orient users of the Patent Cooperation Treaty in the activities related to entry into the national phase;
- keep updated and under its care the control of the files of the International patent applications entering in the national phase and awaiting request for examination as the Brazilian legislation;
- provide notifications and publications related to the competence of the unit, and
- participate in studies and perform other activities assigned by the General Coordination of the Patent Cooperation Treaty.

21.04 (c) Organizational Chart



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)	Organisational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS		✓	
	(b)	Control of the continual improvement process		✓	
21.07	(a)	Communication of management about this standard to staff	✓		
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to		✓	
	(b)	(i) determine the extent to which the QMS is based on Chapter 21		✓	
		(ii) determine the extent to which S&E complies with PCT Guidelines		✓	
	(c)	an objective and transparent way		✓	
	(d)	using input incl. information according paragraph 21.17		✓	
	(e)	recording the results		✓	
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards		✓	
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.		✓	
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(a)	System in place for monitoring resources required to deal with demand	✓		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channelling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users ✓	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.19		Established comm. with WIPO and desig. + elected offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed	✓		
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.22	(a)	Quality policy of the Authority and commitment to QMS	✓		
	(b)	Scope of QMS	✓		
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes	✓		
	(f)	a description of the interaction between the processes and the procedures of the QMS.	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.23	(a)	Records which documents are kept and where they are kept	✓		
	(b)	Records of results of management review	✓		
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits	✓		
	(i)	Records on actions taken re. non-conforming products	✓		
	(j)	Records on actions taken re. corrective actions	✓		
	(k)	Records on actions taken re. preventive actions	✓		
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(i) Recording of the databases consulted during search		✓	
		(ii) Recording of keywords, combination of words and truncations during search		✓	
		(iii) Recording of the languages used during search		✓	
		(iv) Recording of classes and combinations thereof consulted during search	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes		✓	
21.26-21.28		Additional information on further inputs to its internal reviews		✓	
21.29		Initial report called for by paragraph 21.19	✓		

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

21.06 (a) and (b)

Due to the increasing activities of the INPI-Br, the organizational chart was restructured, including the establishment of the General Coordination of Quality (CGQUA), linked directly to the President of the INPI-Br.

Its operation is through coordination of activities of critical analysis, conducted by “ad hoc” working groups formed in all areas of the INPI-Br.

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

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.*

21.07 (a) and (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 Quality Management System (QMS). Moreover, this communication is also done through e-mail, intranet and internet. The administration also includes training in their communication materials of the Quality Management System (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.*

21.08 (a) and (b)

The Top Management administration promotes annually, together with its Strategic Plan, or when appropriate on the basis of circumstantial facts, the Critical Analysis of Quality Management System (QMS). The analysis aims to ensure the continuing suitability and effectiveness of the Quality Management System (QMS). In this analysis, the needs to changes in the system are assessed, including those relating to the Quality Policy and Quality Objectives, as well as the need for resources and user satisfaction.

The results of the Critical Analysis are released to all levels of the Institute, which should be aware of them, using the means provided for in items 21.04 (a) and 21.07.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:

- (a) at least once per year (cf. paragraph 21.25);
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
 - (i) to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));
 - (ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));
- (c) in an objective and transparent way (cf. paragraph 21.25);
- (d) using input including information according to paragraphs 21.27 (b)-(f);
- (e) recording the results (cf. paragraph 21.28).

21.09 (a) to (e)

Given the decision to obtain ISO 9001:2008, the INPI-Br is hiring a consultant in order to revise and extend their rules and procedures. Therefore, the Internal Critical Analysis of the Quality Management System (QMS) is undergoing restructuring.

2. Resources

21.10 Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

- (a) Provide information about the infrastructure in place to ensure that a quantity of staff:
 - (i) sufficient to deal with the inflow of work;
 - (ii) which maintains the technical qualifications to search and examine in the required technical fields; and
 - (iii) which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translatedis maintained and adapted to changes in workload.
- (b) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
 - (i) at a level to support the technically qualified staff and facilitate the search and examination process;
 - (ii) for the documentation of records.

21.10 Infrastructure adequate to accommodate changes

Although the operational capability of the INPI-Br, at the time it received the title of ISEA, 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 such as those below:

- hiring new examiners and administrative staff;
- 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.

21.11 Human Resources

■ Examiners

- The INPI-Br has expanded its human capacity to manage examination procedures in a quicker and more reliable fashion. Previously to the condition of ISEA, the number of patent examiners at INPI-Br disposal quadrupled by the year 2005, amounting to ~300 patent examiners, ensuring that pre-requisite for the granting of the ISEA.
- 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. It is underway the preparing of a bid for a professional audit for certification of quality standard ISO 9001:2008, which includes new training for staff in specific matters of Quality.
- 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. For this, additional courses in English and Spanish languages are held for interested examiners, in basic, intermediate, advanced and superior levels, totaling up to two years of additional training in languages.

■ Administrative Staff

- The INPI-Br created and appointed staff in the administrative areas and adapted sectors to meet the demands of the workload. Regarding technical support, it is available a physical infrastructure, technological and human support for the examiners and search capabilities. To this end, it settled areas distributed among the divisions of the examination, provided with qualified personnel and material infrastructure specifically to work in technical support.
- The administrative staff were 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.

21.12 Material resources:

- (a) Describe the infrastructure in place to ensure that*
 - (i) appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
 - (ii) at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.*
- (b) Describe how instructions*
 - (i) to help staff understand and adhere to the quality criteria and standards, and*
 - (ii) to follow work procedures accurately and consistently*
are documented, provided to staff, kept up-to-date and adapted when necessary.

21.12 Material Resources:

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, creation of new stalls with dividers, 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.
- The minimum documentation, referenced in Rule 34 is available, accessible and kept ready for search and examination purposes. All documentation is on paper and also registered with the software developed by the INPI-Br. The basis of non-patent literature search was expanded with the expansion of access to the Portal CAPES and DIALOG databases. (CAPES database collects non-patent literature).

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.

Examiners that have been trained in the procedures of the PCT in a more extensive work, shall where appropriate 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.

The procedures specifically related to the Quality Management System (QMS) are in preparation, and will be discussed with the team of consultants in quality management, which is in the contracting phase.

21.13 Training resources:

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

- (i) acquire and maintain the necessary experience and skills; and*
- (ii) are fully aware of the importance of complying with the quality criteria and standards.*

21.13 Training Resources

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.

Through training courses for examiners maintained by the institute, it is sought to maintain the necessary skills and broaden the experience for examination.

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

21.14 Oversight over resources:

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

- (a) to deal with demand; and*
- (b) comply with the quality standards for search and examination*

21.14 Monitoring resources

Requests for international search and international preliminary examination under the PCT are recorded and controlled through an Internal Electronic System (SINPI). Each new request is identified and updated constantly. The system informs automatically the deadline for submission of reports (as shown in paragraph 21.15 (a)), ensuring the proper demand for services.

The General Coordination of Information Technology is responsible for maintaining and monitoring the internal electronic system.

3. Management of administrative workload

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

- (a) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and
- (b) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

21.15 (a) Mechanisms for effective control over the issue of timely reporting of search and international preliminary examination

Requests for international search and international preliminary examination are monitored by two internal electronic systems: SINPI (Integrated System of Industrial Property) and SISCAP (Registration System of Production) working interconnected.

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

The screenshot displays the 'Cadastro PCT ISAI/PEA' interface. At the top, a blue header contains the title. Below it, a yellow banner displays a warning: 'Faltam 8 meses e 11 dias para completar 16 meses a partir de 10/02/2010'. The main area shows a search box for 'Pedido Internacional:' with the value 'BR/2010/000311'. Below this are three tabs for 'Dados PCT (1)', 'Dados PCT (2)', and 'Dados PCT (3)'. A toolbar with icons for search, refresh, print, and other functions is visible. At the bottom, there are input fields for '1. Dt Dep. Internacional:' (22/09/2010), 'Nome Organismo Receptor:' (RO/BR), and 'Idioma:' (port.).

Furthermore, by moving the page request in the SINPI, one can view and control the amount of time that any application was in each sector where it has passed, and the person responsible.

Movimentação PCT ISA/IPEA

Pedido Internacional: Faltam 8 meses e 11 dias para completar 16 meses a partir de 10/02/2010
 BR/2010/000311

Setor Usuário:

Setor Destino:

Técnico:

Observação:

Setor Destino	Dt. Localização	Técnico	Movimentador	Observação
DIQUIM II	28/09/2010 08:59:36		leogomes	
ISA/IPEA	27/09/2010 17:07:11		mariahpf	
DIBIOTEC	27/09/2010 10:24:48		leogomes	
ISA/IPEA	23/09/2010 10:16:13		marciat	
RO	23/09/2010 10:16:03		marciat	

The SISCAP provides the automatic recognition of data from the PDF file generated by SINPI, so 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 general coordinator of the PCT and the head of technical division of the PCT.

21.15 (b) Mechanisms of adequate control regarding fluctuations in demand and managing backlog

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

This monitoring is done for each technology area, showing not only the deadline for completion of the activity requested, but also the type of requester. To avoid rework with respect to procedural irregularities in the completion of forms a document has been issued, "Tips for Filling", which seeks to remedy the more common problems identified.

4. Quality assurance

- 21.16 *The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:*
- (a) *An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:*
 - (i) *for compliance with these Search and Examination Guidelines;*
 - (ii) *for channelling feedback to staff.*
 - (b) *A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*
 - (c) *A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

21.16 (a) to (c)

The Technical Division of the PCT performs a formal examination of search reports and written opinions on all international applications. Based on the verification of the most common errors in completion, a document was prepared and it is handed in conjunction with the international application, when it is delivered to the examiner with the instructions on how to correctly fill the forms.

The SISCAP system used by the examiner to generate and record the forms also allows that the information from documents of the prior art and their families are obtained in a consistent and uniform way, since it uses an automated system to capture the database from the Epodoc database.

5. Communication

- 21.17 *Inter-Authority communication:*
- Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:*
- (a) *helping identify and disseminate best practice among Authorities;*
 - (b) *fostering continual improvement; and*
 - (c) *providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

21.17 Inter-Authority Communication

The Top Management of the INPI-Br has appointed Mr. Luiz Otavio Beaklini, General Coordinator of the Quality, as the Management Representative, to which was granted authority to the full implementation of the Quality Management System (QMS), as required by ISO 9001:2008, PCT Guidelines and Rules, and Chapter 21, leaving him the responsibility of reporting to the top management regarding the Quality Management System (QMS) performance, identifying and disseminating best practice between Authorities, promoting continuous improvement and maintaining the channel of communication with other Authorities. He can be contacted via the e-mail address: lobeak@inpi.gov.br.

21.18 Communication and guidance to users:

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

- (a) An appropriate system for
 - (i) handling complaints and making corrections;*
 - (ii) taking corrective and/or preventative action where appropriate; and*
 - (iii) offering feedback to users.**
- (b) A procedure for:
 - (i) monitoring user satisfaction and perception; and*
 - (ii) for ensuring their legitimate needs and expectations are met.**
- (c) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.*
- (d) An indication of where and how the Authority makes its quality objectives publicly available for the users.*

21.18 Communication and guidance to users

There are several communication channels available for a direct contact between examiners and applicants or their respective representatives, through telephone, personal interview, mail, fax, e-mail and/or Ombudsman.

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

In addition, 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 is being developed by INPI-Br a User's Guideline to explain how to file patent applications through the PCT System.

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.

INPI-Br created a modern electronic system, called "e-marcas", that made the Institute capable to receive and to speed up the internal application's flow. A link to "e-marcas" is available to INPI-Br website users. A similar system is being developed to the patent area in order to facilitate patent application filing.

Within the Center of Divulcation, Documentation and Technological Information, a Section of Searches makes use of an evaluation handed out to our clients, as an important instrument of services improvement. Each received evaluation is treated individually and, in case of dissatisfaction, the problem is identified and fixed. Along with that, a further contact with the client

is established by either e-mail or telephone for any necessary clarification.

21.19 Communication with WIPO and designated and elected Offices:

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

21.19 Communication with WIPO and Designated and Elected Offices

The INPI-Br has direct communication with WIPO and designated and elected offices through e-mail, mail and fax, which are sent by the Chiefs of the Receiving Division of the Patent Cooperation Treaty and the Technical Division of the Patent Cooperation Treaty. The feedback given by WIPO and the offices are evaluated and treated by the Coordinator-General of the Patent Cooperation Treaty and, if necessary, it is redirected to a specific sector, and its response monitored by the Coordinator.

6. Documentation

21.20 Explanatory note: *The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).*

(Note: This point is informative. No response is required by the template to paragraph 21.20)

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

For the purposes of this report indicate:

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

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

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (b) the scope of the QMS, including details of and justification for any exclusions;*
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (d) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;*
- (e) the resources available for carrying out the processes and implementing the procedures; and*
- (f) a description of the interaction between the processes and the procedures of the QMS.*

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

- (a) a definition of which documents are kept and where they are kept;
- (b) results of management review;
- (c) training, skills and experience of personnel;
- (d) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (e) results of reviews of requirements relating to products;
- (f) the search and examination processes carried out on each application;
- (g) data allowing individual work to be tracked and traced;
- (h) records of QMS audits;
- (i) actions taken re. non-conforming products, e.g. examples of corrections;
- (j) actions taken re. corrective action;
- (k) actions taken re. preventative action; and
- (l) search process documentation as set out in Section 7.

21.20 to 21.23 Documentation

As a result of the decision of obtaining certification of ISO 9001:2008, all documents are being developed, according to the requirements of this standard. Among them there is a procedure for document and records control.

The scope of the Quality Management System (QMS) of INPI-Br is "Processing of International Patent Applications, under the Patent Cooperation Treaty – PCT", with the following exclusions:

- 7.3 - Design and development.
- 7.5.2 - Validation of production/service provision processes
- 7.6 - Control of monitoring and measuring equipment

The Quality Manual that is being developed includes the organizational structure of the Institute, and the responsibilities of each department, as shown in items 21.04 (b) and 21.04 (c).

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 sector.

All documents in the file search and examination of each application are kept in the Processing Section of the Patent Cooperation Treaty.

The traceability of the application is made through the SINPI, as shown in item 21.15.

As explained in section 21.16, with the detection of non-conformity, there is a retraining of the examiner.

All documents that are being developed will be available on the intranet of the INPI-Br.

7. Search process documentation

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

The Authority should indicate

- (a) which of the following are included in this record:
 - (i) the databases consulted (patent and non patent literature);
 - (ii) the keywords, combinations of words and truncations used;
 - (iii) the language(s) in which the search was carried out;
 - (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
 - (v) a listing of all search statements used in the databases consulted.
- (b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.
(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)
- (c) which special cases are documented and whether records are kept denoting any:
 - (i) limitation of search and its justification
 - (ii) lack of clarity of the claims; and
 - (iii) lack of unity.

21.24 Search process documentation

The record of the searches carried out for the conduction of international examinations are made on an individual basis by the examiners, with exception of the mentioning of fields of search in the IPC and of the consulted databases, when filling the corresponding fields of form ISA210.

The patent literature documents found are informed in the Follow up Internal Database (SISCAP) program.

The documents of non-patent literature are cited and stored in the Follow up Internal Database (SISCAP) program and a hard copy is made available to the applicant.

Further methods are being evaluated for the record of greater detail on the search strategies, such as languages in which the search was carried through, keywords used and boolean expressions, etc..., in order to compose a search strategy record form for examiners' use.

8. Internal review

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

21.26-21.28 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes

21.25 to 21.28 Internal Review and Continuous Improvement

Given the decision to obtain ISO 9001:2008 certification and hiring consultants, the internal review is undergoing restructuring. However, top management promotes every year, when its Strategic Plan, or when appropriate on the basis of circumstantial facts, the Critical Analysis of Quality Management System (QMS). The analysis aims to ensure the continuing suitability and effectiveness of the Quality Management System (QMS). This analysis needs are assessed for change in the system, including those relating to the Quality Policy and Quality Objectives, as well as the need for resources and customer satisfaction.

The General Coordination of Quality (CGQUA), has its operations through the coordination of activities of critical analysis, conducted by working groups formed “ad hoc” from all areas of INPI-Br.

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

9. Arrangements for Authorities to Report to the MIA

21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.

[End of document]