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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

*prepared by the **VISEGRAD PATENT INSTITUTE (VPI)***

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 Visegrad Patent Institute (VPI) is founded by the Industrial Property Office of the Czech Republic (IPO CZ), the Hungarian Intellectual Property Office (HIPO), the Patent Office of the Republic of Poland (PPO) and the Intellectual Property Office of the Slovak Republic (IPO SR). The VPI will start its operation on 1st of July 2016.

The VPI will establish a Quality Management System (QMS) which is intended to operate according to ISO 9001 standards. It is the intention of the VPI to apply for certification of its QMS under the ISO 9001 system. The system will cover all services offered by the VPI.

The system will cover all services offered and consist of three levels. Level 1 will describe the policy, goals and organization of the Institute, Level 2 will contain procedures for handling of the quality assurance system and Level 3 will contain the procedures for the daily operation of the VPI.

The national offices (NPOs) will participate in the VPI's operation. The NPOs have already well established quality management systems on 3 levels as it was mentioned and described earlier which also cover all patent related procedures. The NPOs' quality management systems are already ISO 9001 certified and periodically recertified by a certification authority.
The NPOs' national systems currently comply to a great extent with the provisions on quality management in the PCT International Search and Preliminary Examination Guidelines (PCT/GL/ISPE).

The VPI quality management system will also be based on the national quality management systems but they will have to be obviously extended to cover the full PCT procedure. The quality standards and practices at the NPOs will be harmonized with respect to any PCT work and will be brought in full compliance with the standards and practices established by the PCT. On the other hand the quality management system of the VPI will also cover all PCT workaround.
The PCT minimum requirements will be fully met relating to the VPI, with respect to competence and the number of examiners. In addition, the requirements for access to the PCT minimum documentation will also be met by the VPI.
Any possible gaps that might be identified will be rectified before the VPI will start its operation as a PCT authority.
Reference is made to document *PCT/CTC/28/3* regarding the appointment of the Visegrad Patent Institute as an International Searching and Preliminary Examining Authority under the PCT.

Search and preliminary examination of PCT applications will be carried out equally by the staff of the Czech, Hungarian, Polish and Slovak patent offices on behalf of the VPI.
The national quality management systems of NPOs **are certified under the ISO 9001 standards**.

The VPI's QMS generally will consist of three components:
a. Quality standards for Search & Examination work
b. A quality management system containing general rules including procedures, tools, manuals, training, competences, communication, procedures for measuring quality, etc.
c. A review mechanism for monitoring compliance with quality standards

The quality standards and practices in the national quality management systems and the embracing quality management system of the VPI will be harmonized with respect to any PCT work and will be brought in full compliance with the standards and practices established by the PCT.

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.

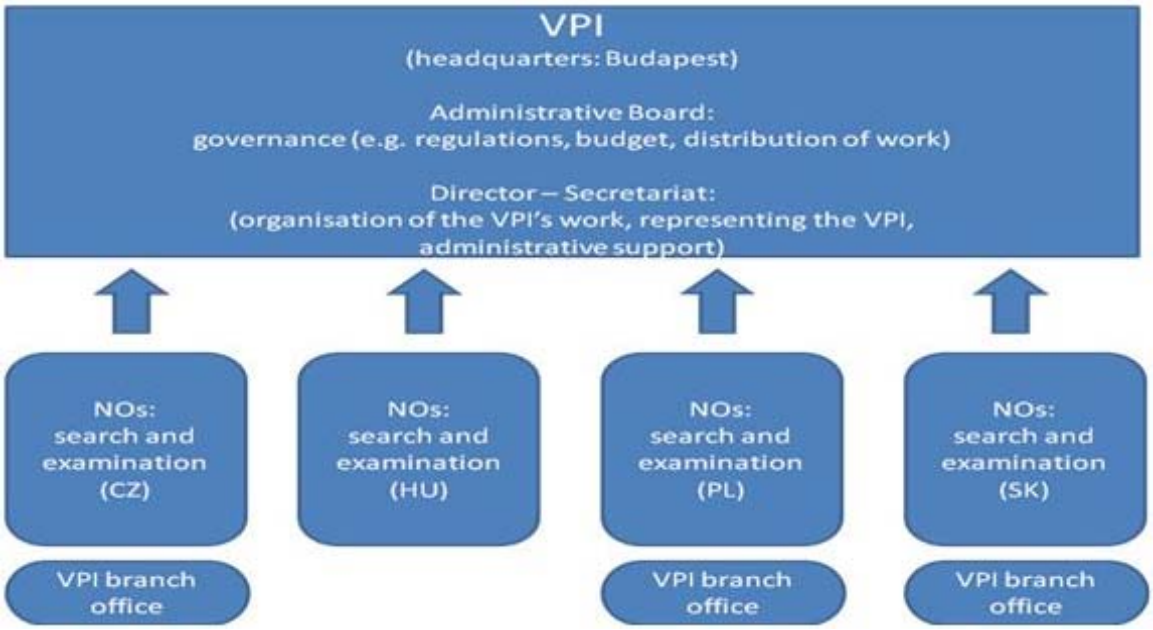
(b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.

(c) An organizational chart showing all those bodies and individuals responsible for the QMS.

The VPI's quality policy will be clearly described in *Level 1* of the embracing VPI quality management system as described above. It is also defined in accordance with ISO 9001 standards.

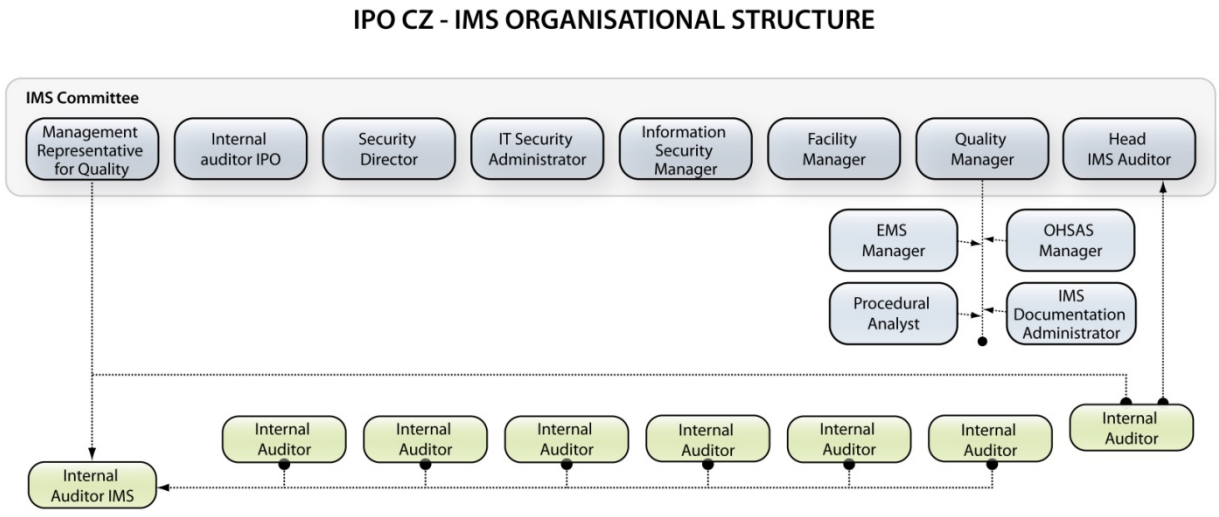
The VPI's Quality Management System (QMS) will be based on the systems of the participating national offices and extended in order to fully cover the PCT procedures of the international phase as well as to comply with the PCT/GL/ISPE, and especially with Chapter 21 thereof.

ORGANIZATIONAL CHART OF THE VPI:



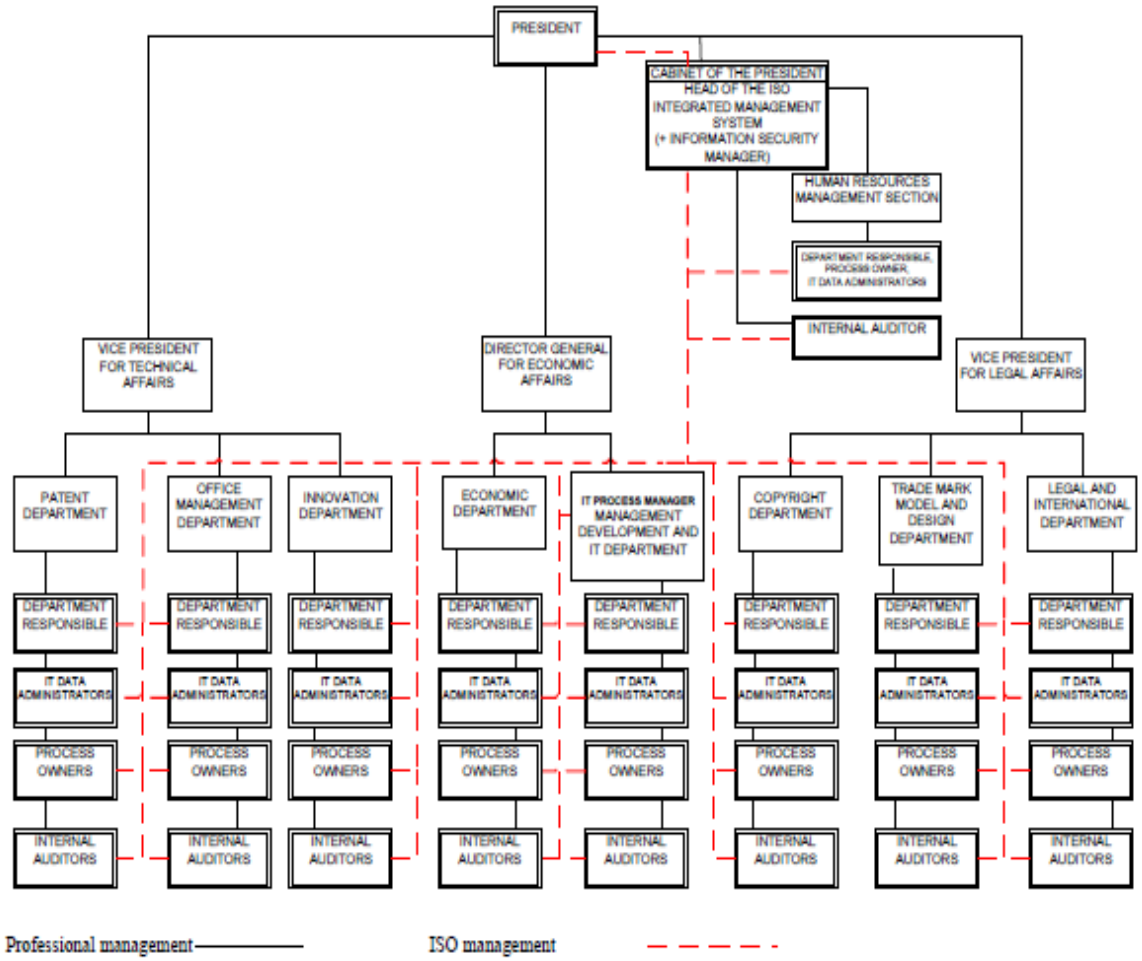
Furthermore the NPOs of the VPI (IPO CZ; HIPO; PPO; IPO SR) have the following organization of their quality management:

IPO CZ



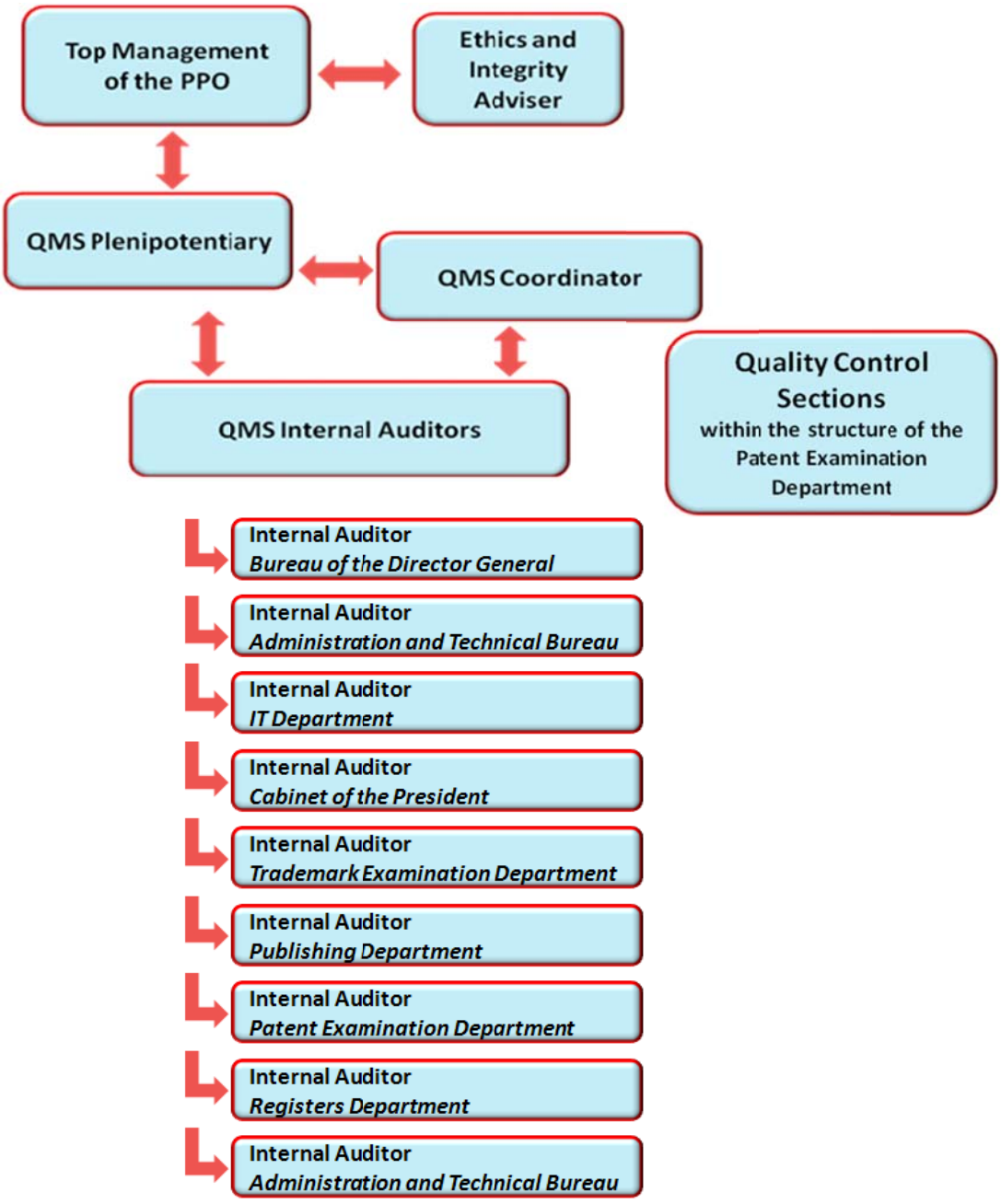
HIPO

ISO Integrated Management System organization chart of the
Hungarian Intellectual Property Office

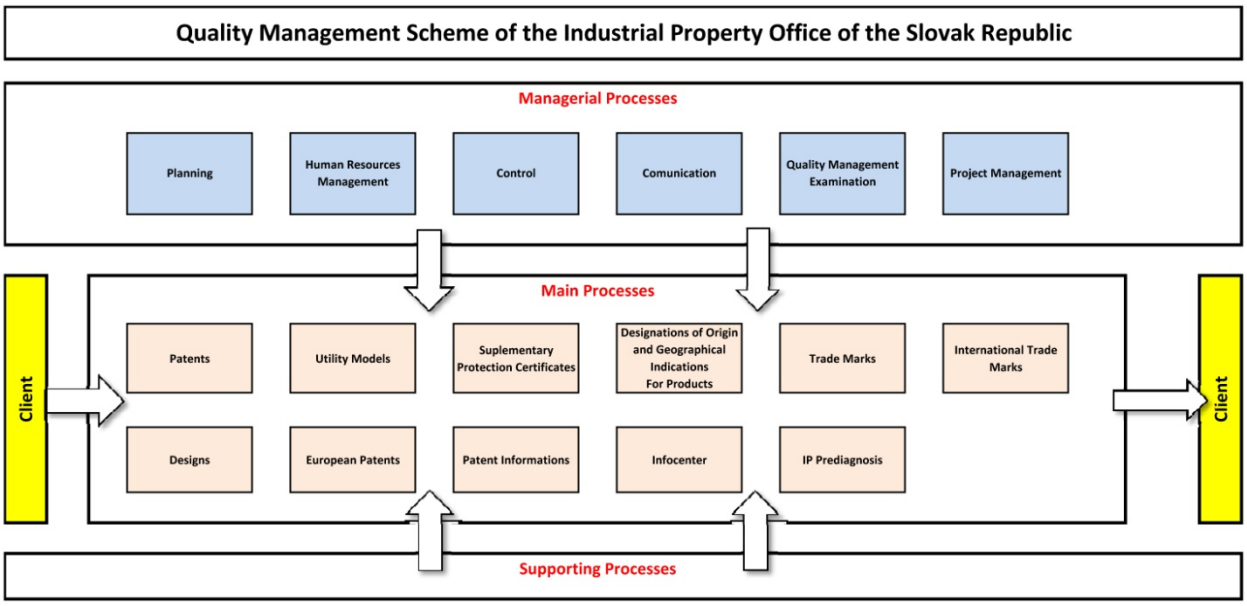


PPO

Roles within the Integrated Management System under the ISO QMS in the
Patent Office of the Republic of Poland



IPO SR



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.).

The VPI will start operating on the 1st of July 2016, therefore its QMS is in planning phase currently. Only partial compliance is indicated below in the relevant lines, since the VPI's QMS is not in place, yet.

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		✓	

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

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

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

In order to assess the QMS's effectiveness, the VPI will yearly develop and formulate measurable quality goals and delegate personal responsibilities.

There will be internal and external audits once a year. Moreover, the internal auditors will conduct random-like cross-checks regularly. The results of the internal audits will be discussed and analyzed according to the mechanisms laid down in the QMS.

The VPI will yearly develop and re-formulate measurable quality goals and indicate the persons responsible for ensuring their achievement, and approve the QMS internal auditing program.

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.

The Director of the VPI and the managements of NPOs concerning S&E work will communicate to the NPO's staff the importance of fulfillment of the QMS requirements, including requirements under the PCT, relating to the international search, supplementary international search, international-type search and international preliminary examination quality provision.

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.

The VPI will analyze and monitor the performance of the QMS and the quality objectives and will assess its conformity with Chapter 21 and ISO 9001 standards.

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).

Internal audits will be carried out once a year. The group of internal auditors will have responsibility for PCT processes to organize and perform the audits. For each audit, specific areas of activity, including S&E and compliance with the PCT Guidelines will be established. Follow-up, corrective and improving measures will be presented for the Director of the VPI and managements of the NPOs concerning S&E work, and the status for improving measures will be followed by the VPI. The effectiveness of corrective measures will also be periodically evaluated by the VPI.

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 VPI as an ISA/IPEA will have altogether 185 full-time and 10 to 12 part-time examiners at its disposal capable of searching and examining all technical fields. They all have the sufficient technical qualifications and the necessary experience to carry out high-quality search and examination in an efficient and timely manner. They are all master's degree or PhD holders who have undergone comprehensive, intensive and well-structured training programs and passed the relevant exams before their appointments as examiners. In addition, most of them have

largely benefited from the training programs organized by WIPO, EPO, USPTO, other International Authorities and national offices as well as by universities and other training institutions specialized in IP. Training of the VPI's examiners is also envisaged in the framework of the cooperation established with the JPO and the NPI, as described in Chapter 1.2 of Annex to document PCT/CTC/28/2. In order to constantly improve the skills and competencies of the VPI's examiners and keep their technical knowledge up-to-date, the Administrative Board of the VPI will establish a training framework for them ensuring appropriate planning and an efficient use of the various training opportunities. In addition, the VPI will organize examiner exchanges and regular meetings with a view to further enhance quality and consistency in search and examination practices.

The VPI's examiners have, in addition to their ability to use their own languages (Czech, Hungarian, Polish, Slovak), excellent knowledge of English, and most of them also have a good knowledge of German and/or French. Other languages understood and used by them include Croatian, Italian, Japanese, Russian, Spanish and Swedish. These inherent flexibilities will significantly facilitate an optimal distribution of the VPI's workload, for which the Director and the Secretariat of the VPI will be responsible.

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.

The VPI will have in place appropriate equipment and facilities based on the current infrastructure of the participating offices. An IT system (hardware and software) will be available for the VPI by the time of starting its operation, which will support the search and examination process and facilitate the cooperation, the distribution of work and office management in the most efficient way. This IT system will also have to be in conformity with IT security requirements. Best practices for using IT resources are currently available at the participating offices of the VPI.

The communication tool between the VPI, the Receiving Offices and the International Bureau will be the ePCT system operated by WIPO.

Each participating office of the VPI has a wide range of accessible patent information and scientific literature, search platforms and links available to the examiners. Since the V4 countries are Contracting States of the EPC, the participating offices of the VPI have access to EPOQUENET and several commercial search platforms:

(a) The EPOQUENET search tool grants access to all patent databases in conformity with the PCT search minimum documentation and to most of the non-patent literature (NPL) databases as well as to the databases of other commercial hosts (e.g. WPI).

(b) With the help of the STN Express software, the STN International Databases can be searched, and access to further patent databases, non-patent literature and business databases from Thomson Reuters is available via Thomson Innovation. STN is used predominantly for structure searches (e.g. CAP and CAS registry) in the field of chemistry and pharmaceuticals, and for nucleotide or amino acid sequence searches (CAS Registry, USGENE®, PCTGen and DGene) in the field of biotechnology.

(c) Further non-patent literature databases, such as MEDLINE, ELSEVIER, EMBASE, IEEE and PUBCHEM can be searched via EPOQUENET or STN as well as directly via online web searches.

(d) The patent and utility model documentation of more than 80 countries and authorities starting from 1920 is also accessible and searchable through CD/DVD media in all the participating offices of the VPI.

(e) The participating offices of the VPI also have access to national patent and utility model information originating from various other IP offices via online national databases.

(f) In addition to the electronic sources of databases mentioned above, in the libraries of the participating offices of the VPI, one can find official bulletins and journals from all over the world and books in various fields of technology, science, law and linguistics. A large number of expert magazines and periodicals are also available.

(g) Each participating office of the VPI has access to all the classification system databases. The examiners use classification systems for their daily searches. The IPC and the new CPC systems are also well-known to the VPI's examiners.

The participating offices of the VPI continuously review their access to patent and NPL databases, and improve the search procedure by introducing new databases and information sources. This contributes to maintaining a high standard for the search procedure.

The above-mentioned search platforms provide each examiner with access to, at least, the minimum documentation referred to in PCT Rule 34.

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.

The examiners of the VPI's branch offices will participate in training courses and seminars related to patent search, including those on the efficient use of patent and NPL databases. The management of the NPOs is also responsible for raising their staff's awareness of complying with the quality criteria and standards relating to the Authority's work.

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.

The VPI's management will continuously monitor and discuss the demand for resources to ensure the quantity of staff sufficient to deal with the inflow of work. Furthermore the management of the NPOs will assure control over workload changes and qualified personnel at all time.

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.

The administrative workload will be managed by the Director and the Secretariat of the VPI, and it will be distributed among the participating offices following a work-sharing model developed by the Technical Experts' Working Group. The VPI will have in place appropriate, effective and harmonized control mechanisms in order to ensure the timely issuance of search and examination reports in accordance with the applicable quality standards. The participating offices will be responsible for monitoring compliance with the harmonized standards and reporting thereon. Statistical performance reports will be prepared at regular intervals. Standardized tables have already been drafted to this end.

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.

The VPI's primary quality objective is to issue high-quality search and examination reports in a timely manner. The relevant search and examination processes have been identified and described in detail in the draft Quality Manual, which also serves as guidelines for search and examination. It will be made available to internal users as well as to external ones via the website of the VPI.

Specifying performance (P), time (T) and quality (Q) indicators is in progress. Self-assessment will be carried out by using checklist forms (a number of such forms have already been prepared). The latter are intended to be applied in harmonized procedures for verifying and accepting search and examination reports. Annual internal audits will be performed. These harmonized tools and procedures will ensure that search and examination of any application will lead to the same result irrespective of the participating office performing the task.

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.

The main lines of communication will be determined by the Director and the Secretariat working at the VPI's headquarters. Therefore the Director of the VPI will be the designated contact for this purpose on behalf of the Visegrad Patent Institute.

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.

Measuring user satisfaction and perception, handling of complaints, correcting deficiencies identified by the users, taking corrective and preventive measures and ensuring that needs and expectations of the users will be handled according to the ISO 9001 system.
Furthermore, the VPI will provide comprehensive information and guidance to the users in English through the VPI's website and the websites of the participating NPOs in their native languages.

Customer satisfaction survey forms will be available both **electronically** (on the website of the VPI) and **physically** at all NPO. The users will get feedback both on the web site of the VPI or personally during face-to-face discussions at NPOs.

The description of search and examination processes will be available in the Quality Manual, which will be accessible at the future website of the VPI.
The quality objectives of the VPI will also be available at the website of the VPI.

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 from WIPO is handled by the Director of the VPI. The Director of the VPI will also participate in the relevant WIPO meetings. Effective communication will be carried out with the designated and elected offices preferably electronically.

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.

The VPI's QMS will be clearly described at different levels so that all processes, products and services can be monitored, controlled and checked for conformity. The relevant documents will form part of the VPI's Quality Manual. The VPI will maintain records required by paragraph 21.23 of the PCT/GL/ISPE. International search and examination processes as well as

processes of contractual international work to be performed by the VPI have been identified, and draft process flowcharts have already been developed. P, T and Q indicators have also been identified. Checklists have already been drafted, which will be filled in by the participating offices upon completion of the product. These documents and the relevant procedural, technical and other aspects are currently under deliberation in the Technical Experts' Working Group and the IT and Quality Management Working Group, taking also account of the fact that the ISO 9001 systems of the participating national offices already provide a solid basis in that regard.
The documents will be available for the staff by the means of internal publication and on the NPO's intranet, respectively.

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 Quality Manual will include all the mandatory elements and meet all the PCT requirements.

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.

The VPI and the NPOs will maintain all the needed records of the above mentioned types of documents according to the relevant PCT rules.

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.

Examiners will make a record of their search processes and store them for the purposes of review and documentation. At its first meeting, the Technical Experts' Working Group decided that such documentation should be used internally solely for the purposes of quality assurance. The Working Group also approved that checklists would be used and search strategies would be recorded. All the information relevant to the search process will be duly documented in full accordance with paragraph 21.24 of the PCT/GL/ISPE. With regard to the classes searched, the IPC classes will be indicated automatically, and CPC classes (where applicable), which help to refine the search in the relevant databases, will also be recorded.

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.

A review mechanism will be put in place for monitoring compliance with quality standards, under which objective and transparent reviews will be carried out. A joint internal review team within

the VPI will also be established consisting of quality management experts of the participating offices. Audits will be carried out on a regular basis through the use of checklists, and auditors will have to prepare written reports containing their observations. Besides internal audits, external reviews will take place at regular intervals. It is envisaged that internal and external audits will be undertaken once a year with the aim of assessing the conformity of the VPI's QMS with the applicable standards. It is intended that the first internal audit will be carried out 6 months after the VPI becomes operational, at the latest. In parallel with this, an independent external auditor will be selected for future external audits and ISO certification.

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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