WORLD INTELLECTUAL PROPERTY ORGANIZATION

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

YEARLY 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 started its operation on 1st of July 2016.

The VPI establishes 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 in the year 2017. The system will cover all services offered by the VPI and will be connected to the national Quality Management systems.

The QMS will cover all services (management, support and core) offered and consists of three levels. Level 1 describes the policy, goals and organization of the Institute, Level 2 will contain procedures for handling of the quality assurance system, described by process cards and forms and Level 3 will contain the procedures for the daily operation of the VPI.

The national offices (NPOs) participating in the VPI's operation have already well established quality management systems in place also based on the 3 levels principle described above, covering all processes related to the PCT activities. The NPOs' quality management systems are ISO 9001 certified and periodically recertified by a certification authority. The national quality management systems of NPOs are currently certified under the ISO 9001:2008 standards. The NPOs will carry on recertification of their QMS to the ISO 9001:2015 in the year 2017. 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 is based on the national quality management systems which were extended to cover the full PCT procedure. The quality standards and practices at the NPOs were harmonized with respect to any PCT work and were brought in full compliance with the standards and practices established by the PCT. The QMS of the VPI and NPOs are connected by Service Level Agreements (SLAs) between each NPOs and the VPI to reach the required quality work level and timeliness.

The PCT minimum requirements are 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 are also met by the VPI via NPOs´ accesses to the most important patent and non-patent databases.

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 have been carried out by the staff of the Czech, Hungarian, Polish and Slovak patent offices on behalf of the VPI.

The VPI's QMS generally consists 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

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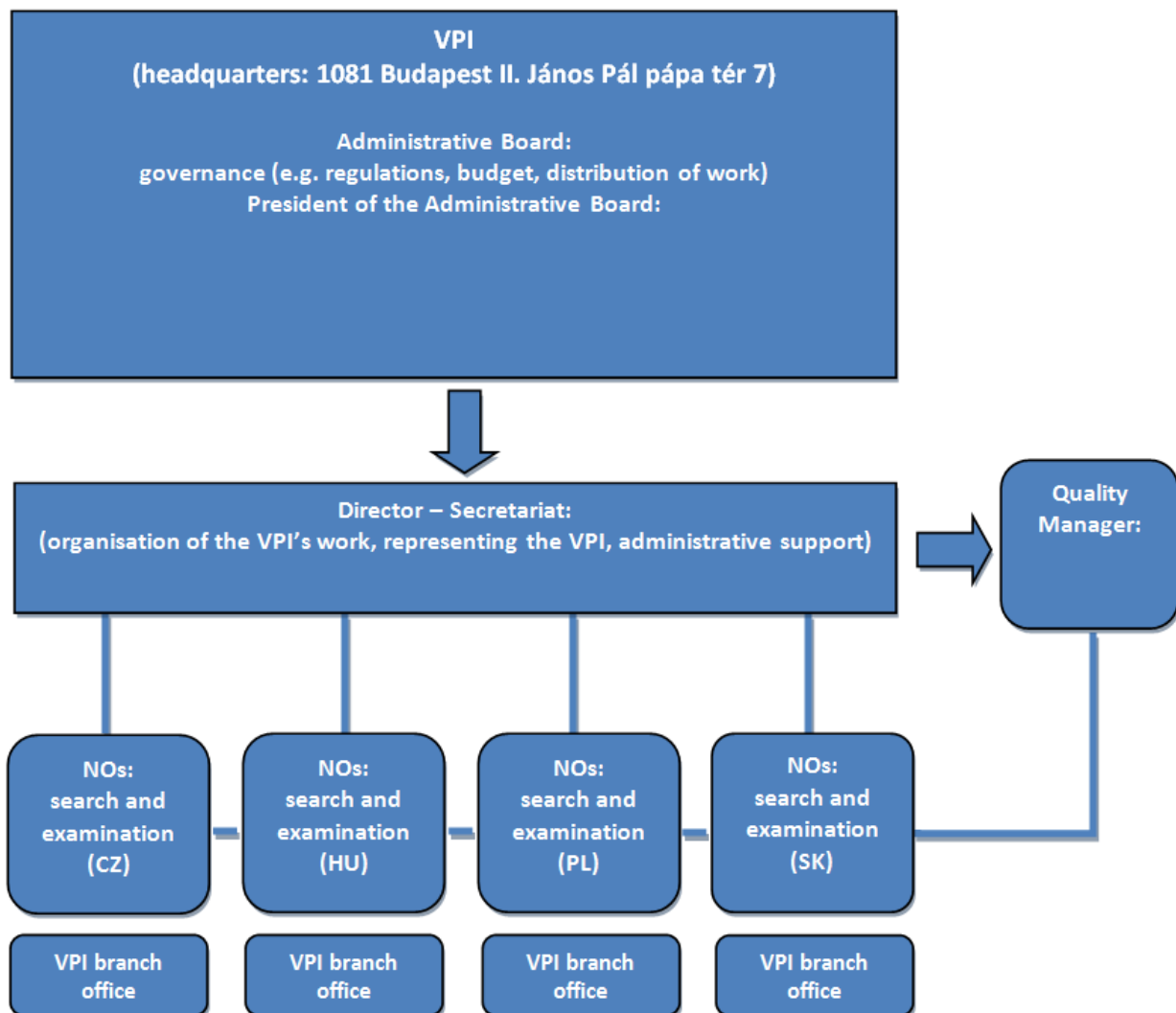
The VPI's Quality Management System (QMS) is based on the systems of the participating national offices and extended in order to fully cover the PCT procedures of the international phase as well as to comply with the PCT/GL/ISPE, and especially with Chapter 21 thereof.

The VPI's quality standards and practices shall be consistent and harmonized with respect to all sorts of PCT work and the cooperation of the participating national offices shall be strengthened in order to further harmonize their patenting practices.
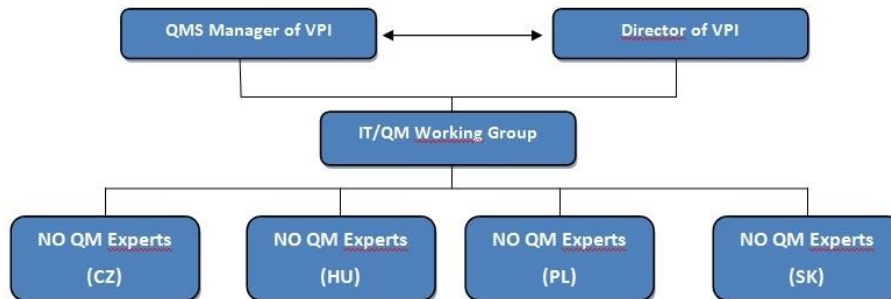
The Quality Management and IT Working Group (hereinafter referred to as "QM/IT WG") is responsible for two main areas, namely *quality systems* and *IT and communication infrastructure* at the Visegrad Patent Institute. This platform creates a key base for the representatives of national IP offices of the Czech Republic, Hungary, Republic of Poland and the Slovak Republic to communicate, evaluate and submit proposals of solutions and measures on all relevant issues concerning quality systems and IT/communication infrastructure to the Administrative Board. The QMS Manager of the VPI manages the quality management system with the assistance of the Secretariat of the VPI and the QM experts of other NPOs.

To achieve the VPI's strategic objectives, the VPI determined its organizational structure. In accordance with each part of the QMS, we have determined the responsibilities and authorities of each responsible person or body in the QMS.

ORGANIZATIONAL CHART OF THE VPI:

VPI
(headquarters: 1081 Budapest II. János Pál pápa tér 7)

Administrative Board:
governance (e.g. regulations, budget, distribution of work)
President of the Administrative Board:

Director – Secretariat:
(organisation of the VPI's work, representing the VPI, administrative support)

Quality Manager:

NOs:
search and examination (CZ)

NOs:
search and examination (HU)

NOs:
search and examination (PL)

NOs:
search and examination (SK)

VPI branch office

VPI branch office

VPI branch office

VPI branch office

The relationship between the Director of the VPI and the quality management is depicted as follows.


The QMS Manager reports directly to the Director in matters regarding the quality of the services and the QMS. The management review is held yearly by the AB. It is scheduled to incorporate the results and the follow-up matters of the following year's activity plan. The agenda for the meeting includes the following issues but is not limited to:

1.   Status of follow-up actions from previous management review.
2.   Evaluation of quality policy, quality objectives and risk management
3.   Non-Conformities, Corrective and Preventive actions
4.   Quality Control measurements
5.   Personal, resources, competence and employee's satisfaction measurements
6.   Customer satisfaction survey and complaints
7.   Reports from internal audits
8.   Reports from external audits
9.   Any other matters

In order to assess the effectiveness of the QMS, the VPI yearly develops and formulates measurable goals and delegates personal responsibilities. There are internal and external audits once a year. The results of the internal audits are to be discussed and analyzed according to the mechanisms laid down in the QMS. The VPI yearly develops and re-formulates measurable quality goals and indicates the persons responsible for ensuring their achievement and approve the QMS internal auditing program.

VPI Quality management scheme
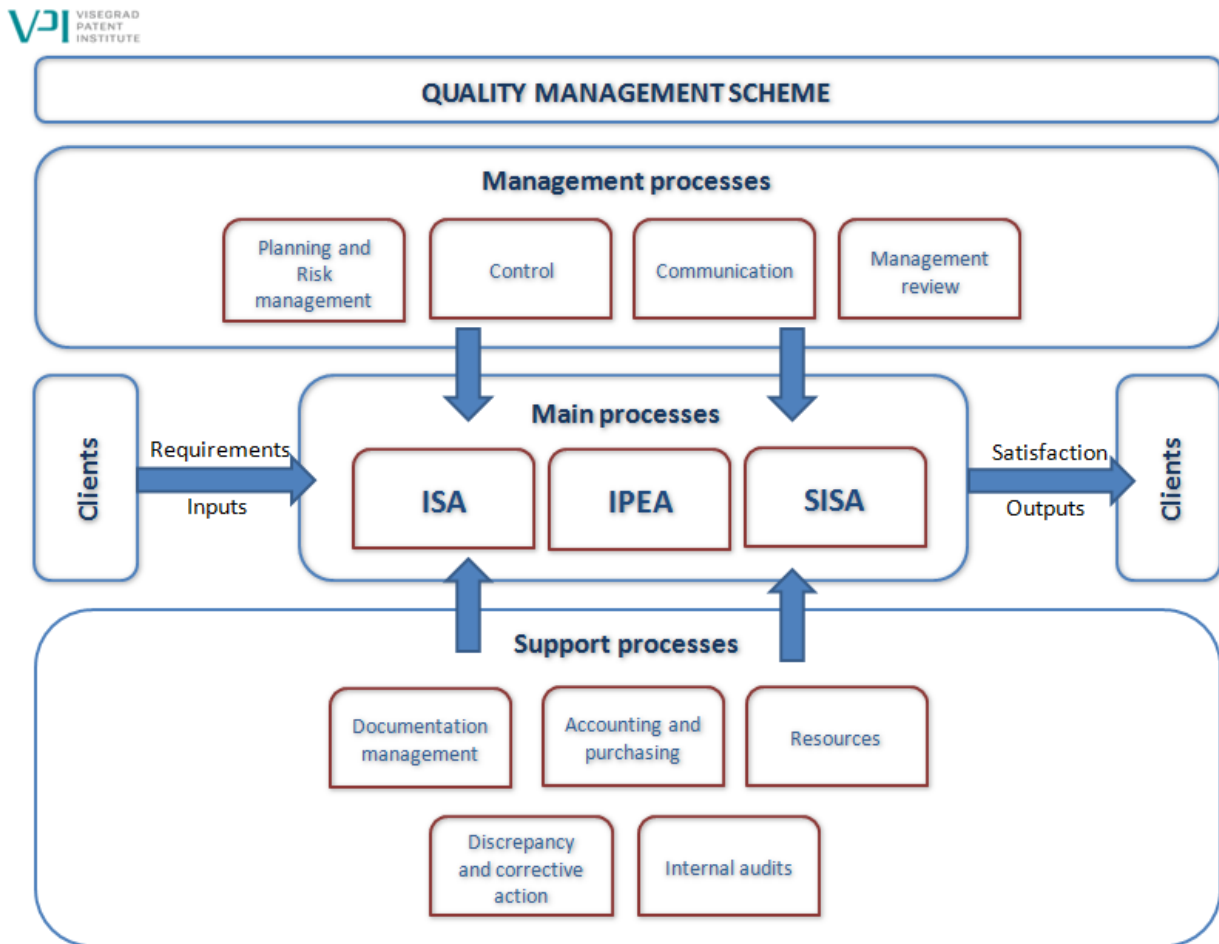
The VPI started operating on the 1st of July 2016, therefore its QMS is in developing phase currently. Only partial compliance is indicated below in the relevant lines, since the first internal audit and management review will be performed in 2017.

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	✓		

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

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	✓		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.11	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog		✓	
21.12	(i)		Internal quality assurance system for self assessment		✓	
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff		✓	
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.14		(a)	Contact person helping identify best practice between Authorities		✓	
		(b)	Contact person fostering continual improvement		✓	
		(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation		✓	
21.15	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met		✓	
	(iii)		Clear and concise guidance on the S&E process for the user	✓		
	(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		✓	

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.19	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		the documented processes are carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		a description of the interaction between the processes and the procedures of the QMS.	✓		
21.20	(i)		Records which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Evidence of conformity of processes		✓	
	(v)		Results of reviews of requirements relating to products		✓	
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Record of data allowing individual work to be tracked	✓		
	(viii)		Record of QMS audits		✓	
	(ix)		Records on actions taken re. non-conforming products		✓	
	(x)		Records on actions taken re. corrective actions		✓	
	(xi)		Records on actions taken re. preventive actions		✓	
	(xii)		Records referring to search process documentation		✓	
21.21	(i)		Recording of the databases consulted during search	✓		
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(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		✓	

Chapter 21 requirement			Extent of compliance		
			full	part	no
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 ensure the QMS's effectiveness, the VPI yearly develops and formulates 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 have communicated 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.

This communication is established at the different managerial levels of each NO. The importance of the requirements is communicated also on the level of the different working groups of the VPI. The VPI and its contracting states use several ways for communication, such as harmonization of the PCT guidelines in the TE WG, regular meeting of the head of sections at every branch office's patent department, in the report of the Quality Manager to the AB and internal audit report done yearly by the internal audit group

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 is analyzing and monitoring the performance of the QMS and the quality objectives and will assess its conformity with Chapter 21 and ISO 9001 standards.

Management reviews will be performed and quality objectives are set by the Administrative Board annually.

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 at least once a year (starting in year 2017 and continuing the audits conducted at Branch Offices in 2016). The chief auditor is responsible to organize and conduct internal audits for the QMS and PCT processes. For each audit, specific areas of activity, including S&E and compliance with the PCT Guidelines is established. Follow-up, corrective and improving measures will be presented to 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.

Search and preliminary examination of PCT applications are carried out by the staff of the Czech, Hungarian, Polish and Slovak industrial property offices on behalf of the VPI.

Important aspects of quality are the competence and number of full-time examiners as well as access to the PCT minimum documentation. The VPI meets the PCT minimum requirements with respect to the number of examiners, their competence, skills and capability to search in the required technical fields, and their command of languages. VPI gives priority to the training of examiners in order to maintain their high level of knowledge, competences and motivation.

The VPI has the infrastructure and resources to continually support the search and examination process while also accommodating the changes in workload and meeting the QMS requirements. The VPI meets the PCT minimum requirements with respect to human and material resources under Chapter 21 of the PCT Guidelines.

The VPI as an ISA/IPEA has altogether about 200 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 for 2017 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, training courses will be organized. In addition, the VPI organizes examiner exchanges and 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 mother tongues (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 are significantly facilitating an optimal distribution of the VPI's workload, for which the Director and the Secretariat of the VPI are 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 has in place appropriate equipment and facilities based on the current infrastructure of the participating offices. An IT system (hardware and software) are available for the VPI, 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, has 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 is 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.

With the new STN platform the following databases are accessible:
 CAplus, MARPAT, BIOSIS, CABA, FSTA, COMPENDEX, INSPEC, and ReaxysFile.
STN is used also 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 main classification system databases. The examiners use IPC classification for classification purposes and IPC as well as CPC classification for search purposes. 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 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.

In order to continuously monitor and discuss the demand for resources to ensure the quantity of staff sufficient to deal with the inflow of work, the Director and the Secretariat of the VPI circulates between the NPO's data updated every three months, concerning the latest skills of the examiners. Furthermore, the management of the NPOs assures 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.

(i) Ensuring timely issuance of search and examination reports
The VPI secretariat and each national office are responsible of establishing a register wherein all the data and relevant information is collected. As a part of this register the relevant time data are also recorded and monitored continuously. Every two weeks a list, prepared by the Secretariat, of outstanding files containing time limits is forwarded to the point of contacts of the particular VPI/NPO. The list also contains those applications in which the time limit is very close. In these cases, we provide the opportunity to every VPI/NPO to reassign the application to another examiner of another VPI/NPO to be able to prepare the report to be issued in time.

The working method within the VPI will have the benefit that the applications can be immediately handled by the competent VPI/NPOs or NPO sections *without loss of time.* As certain documents filed by the applicants immediately reach the competent office/section, the method is cost effective, making maximal use of the NPOs' individual infrastructure and manpower, while reducing the risk of becoming accidentally publicly available during transferring them between the participating offices. The decentralized work sharing, however, requires that each VPI/NPOs provide reports to the VPI Secretariat on their administrative, technical and financial activities within the VPI on a regular basis.

As a main rule, the VPI/NPOs' corresponding patent sections shall prepare the ISR/WO-ISA, international-type search, supplementary search and IPER, respectively, in English as working language. In case the language of the international application is the official language of one of the Contracting States (ie. Czech, Hungarian, Polish or Slovak), the VPI provides the possibility of consultation(s) between the VPI and the applicant (or its representative) in that particular language.
Unless otherwise indicated, during preparing ISR/WO, international-type search, supplementary search and IPER, the VPI/NPOs' patent sections shall communicate with the applicant on behalf of the VPI.

(ii) Work sharing within the VPI to ensure demand and backlog management
The tasks within the individual NPOs are delegated to the appropriate departments considering the particular process to be carried out. This means that the tasks of the Receiving Office are handled by the department of the NPO, which is responsible for this type of procedure, while substantive search and examination is done by the patent sections.

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 quality objective is to issue high-quality search and examination reports in a timely manner. The search and examination processes are described in detail in a comprehensive documentation containing process flowcharts and explanation texts belonging to them also specifying quality indicators. The VPI will have in place an internal quality assurance system for monitoring the fulfillment of the set indicators and compliance with the PCT/GL/ISPE.

Harmonized quality assurance measures have been put in place building upon the current best practices of the participating offices. Guide for search and examination are available for internal users, the Quality Manual is available for both, internal and external users via the website of the VPI. Self-assessment will be done by using checklist forms. It is the intention to apply harmonized procedures for verifying and accepting the search and examination reports and prepare periodic statistical reports. Based on the results of these reports, deficiencies and non-conformities with the VPI's QMS will be identified and the necessary actions will be taken. Annual internal audits will be performed. The harmonized tools and procedures will enable that search and examination of any application will lead to the same result irrespective of the participating office performing the task.

(i) Internal quality assurance system for self-assessment

The quality assurance system can be summarized in the following picture:
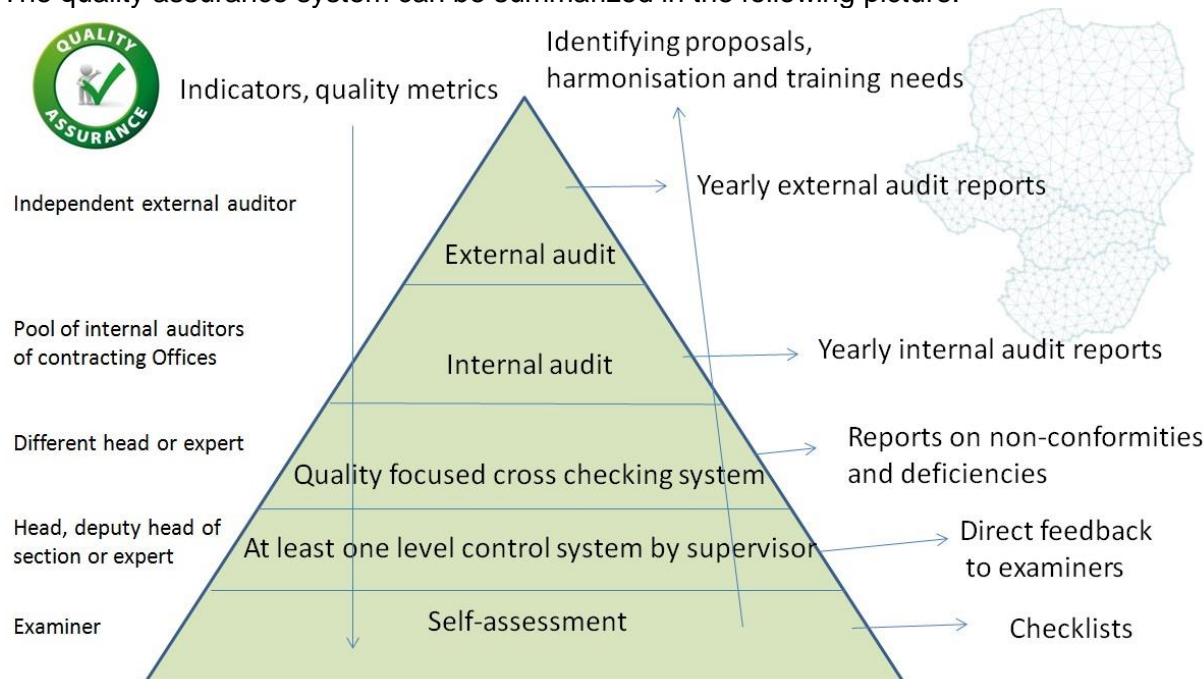
This quality assurance system provides 5 levels of quality control.

At the first level the self-assessment of the examiner is done by using product related checklists. The self-assessment under consideration of the checklist guarantees a permanent reminding of the key criteria.

At the second level at least one level control system by a supervisor or another expert is implemented in every NPO. The supervisor or expert inspects the quality of the search strategy and the clearness of the report. This level of control system can be varied between the NPOs. All NPOs follow their own control system used for national patent granting procedures. The main criterion is that at least one type of direct control is needed for every office. The result of this check shall be a direct discussion of the content of the product with the examiner who prepared the product. If a systemic error can be recognized throughout this control system a corrective action shall be initiated.

At the third level of quality control system, the heads/directors of the NPOs patent departments shall prepare a quality- focused cross-checking by choosing some finished products randomly (5-10%) and periodically (on a yearly basis). As a result of this measurement a report on non-conformities and deficiencies is prepared. The reports shall be sent to the Quality Manager of the VPI from every NPO. The results of these reports shall be discussed at the QM/IT WG of the VPI, where the experts of the VPI/NPOs suggest corrective actions to the Quality Manager.

At the fourth level internal audit review procedures are conducted by planned and unplanned manners. As a result, a yearly internal audit report is prepared.

At the fifth level an independent external audit company is requested to audit the VPI's procedure. The yearly external audit report is discussed at the QM/IT WG and at the AB of the VPI.

(ii) A system of measurement and collection of data and reporting
We monitor, and if necessary measure, the performance of the processes assisted by executives' checks and by internal audits, to ensure the compliance and effectiveness. The actions, methods

related to the performance of our activities, and to the receipt of services purchased, the manner of monitoring the effectiveness of the processes are included in the process descriptions.
The results of monitoring are recorded. These records identify the employees responsible for the performance, and prove that the services, processes meet the requirements.

The management of the VPI has established the information, statistical reports and parameters to be regularly prepared on the operation; they shall cover the activities, processes, services, satisfaction, the integrated management system, the nonconformities and complaints, if any.

The data shall be analyzed and assessed by the management. If undesirable trends are detected, corrective and/or preventive actions shall be taken.
If we detect nonconformities concerning the quality or we are given a warning by the counsels, we shall endeavor to detect the reasons of nonconformities, shall take the necessary arrangements/corrections and then shall take corrective actions in order to prevent the recurrence of nonconformities.
When taking actions related to nonconformities, our basic objective – in addition to the correction and corrective actions – is to prevent the recurrence of nonconformities. Therefore, based on the data obtained from the analyses, we shall continually monitor and control our services and processes and, if needed, shall implement the methods of preventive actions in the documents describing the process concerned.

We shall make decisions on taking preventive actions with the involvement of the head directly managing the activity concerned. We shall also keep records on preventive actions and shall assess the preventive actions performed in the management reviews.

One of the key characteristics of our QMS is the continual improvement which shall be demonstrated in service, process and system level. The information required to take decisions for the improvement is gained by processing and analyzing the data arising in the operation, by examining the objectives and by monitoring the changes in external and internal circumstances.

Timely issue of search and preliminary examination reports or any other products is supported by a systemic monitoring system operated by the VPI/NPOs and as a further control by the VPI Secretariat as well. The quality standard of the reports consistent with our Guide is guaranteed by our Quality Assurance System mentioned above.

(iii) A system for verifying the effectiveness of actions taken to correct S&E work

In most cases the second level of quality assurance system provides immediate action for correcting the S&E work. The Quality Manager is responsible for monitoring and verifying the effectiveness of actions taken to correct S&E work if a systematic error has been identified.

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 are determined by the Director and the Secretariat working at the VPI's headquarters. Therefore, the Director of the VPI is the designated contact for this purpose on behalf of the Visegrad Patent Institute. All communication structure is described in the process card – Communication.

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 is handled according to the process cards related to the QMS based on ISO 9001 system.

Furthermore, the VPI provide comprehensive information and guidance to the users in English and all national languages of the VPI through the VPI's website and also through the websites of the participating NPOs in their native languages.

Customer satisfaction survey forms are distributed to the customers electronically or physically. Another basic user satisfaction survey will be run on the website of the VPI. The feedbacks are

processed by the Secretariat of the VPI and prepare as a part of the yearly Management review. Some part of feedback will be publicly available on the web site of the VPI.

Basic description of search and examination processes are available in the Quality Manual, which will be accessible at the website of the VPI, with links to comprehensive information about the processes.

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 also participates in the relevant WIPO meetings. Effective communication is 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 is clearly described at different levels so that all processes, products and services can be monitored, controlled and checked for conformity. The relevant documents are part of the VPI's Quality Manual. The VPI maintain all records required by paragraph 21.23 of the PCT/GL/ISPE. International search and examination processes as well as processes of contractual international work performed by the VPI have been identified, and all process flowcharts have already been developed. P, T and Q indicators have also been identified. Checklists have already been finalized, which are filled in by the participating offices upon completion of the product. These documents and the relevant procedural, technical and other aspects are mainly ready to use or used already. The Technical Experts' Working Group and the IT and Quality Management Working Group, are responsible for reviewing all this documents. Documentation management process card describe all work related to the document control including numbering and versioning.

The documents are 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 includes all the mandatory elements and meets all 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 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.

VPI keeps records of all information relevant to the searches performed by it. Records concerning performed searches, in line with paragraph 21.24 of the PCT/GL/ISPE, include information about the databases consulted, the keywords, combination of words and truncations used, languages in which the search was carried out as well as classes and class combinations searched (IPC classes and, if used, also CPC classes are recorded). In respect of every search performed VPI records also all search statements used in all databases consulted (special internal form has been prepared for this purpose). However, for the time being VPI does not make information concerning the search strategies public, it is kept just for internal purposes.

VPI documents also any limitations of performed searches. If the search is limited to certain claims, these fact is stated in VPI´s internal check list together with justification of such a limitation (internal check list is part of every application processed by VPI). If applicable, check list contains also information on lack of clarity of claims and/or lack of unity.

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 is put in place for monitoring compliance with quality standards, under which objective and transparent reviews will be carried out. Internal Audit reviews procedures and operations closely, confirming that they are being followed correctly and that they support the VPI's goals and objectives. After examining processes and procedures, the Internal Audit reports its findings and works closely with the audited fields to provide accurate and pertinent recommendations that help the VPI to adhere more closely to its objectives.

Internal Audit supports Management by staying fully educated about the intricacies of, implementation strategies for, and compliance with current regulations and legislation. Internal Audit is responsible for explaining and detailing the impact that non-compliance would have on the VPI, for informing the Management about signs of major non-compliance, and for identifying areas that do not conform to policies and guidelines.

Internal Audit evaluates the efficiency and effectiveness of current controls and determines if those controls can truly mitigate the risks that can threaten the VPI. Effective internal control is a built-in component to the management process and keeps the VPI on course toward its objectives and mission. Internal control promotes effective and efficient operations, reduces the risk of asset loss, and both heightens the reliability of financial reporting and strengthens compliance with laws and regulations.

The internal audits ensure:

(i) control of timeliness, effectiveness and compliance with documented procedures with regard to the quality system requirements,

(ii) control of compliance with the proposed corrective actions based on previous internal audits and, if necessary, propose new measures,

(iii) verifying the effectiveness of the process and by necessity of setting new targets and indicators,

(iv) verifying the accuracy defined process controls and their performance,

(v) verifying the accuracy of process orientation with respect to the Quality Policy.

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 9months 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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