

ORIGINAL: ENGLISH DATE: SEPTEMBER 30, 2025

# **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

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

#### **INTRODUCTION (PARAGRAPHS 21.01 - 21.03)**

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

#### INTRODUCTION

The Visegrad Patent Institute (VPI) is founded by the Governments of the four Visegrad Countries, the Czech Republic, Hungary, the Republic of Poland and the Slovak Republic. The tasks of the VPI, as an International Searching and Preliminary Examining Authority under the PCT, are carried out by the participating National Offices (NOs): 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 Industrial Property Office of the Slovak Republic (IPO SR). The VPI started its operation on July 1, 2016.

Reference is made to document *PCT/CTC/28/3* regarding the appointment of the VPI as an International Searching and Preliminary Examining Authority under the PCT.

The PCT minimum requirements are fully met by the VPI, with respect to competence and the number of examiners. Search and preliminary examination of PCT applications are carried out by the staff of IPO CZ, HIPO, PPO and IPO SR on behalf of the VPI. The requirements for access to the PCT minimum documentation are also met by the VPI via NOs´ accesses to all required patent and non-patent databases.

The VPI established a Quality Management System (QMS) in accordance with the ISO 9001 standard in 2016, and it has been in continuous operation ever since. The normative reference for the QMS is ISO 9001. In 2017, the VPI successfully applied for certification of its QMS under the ISO 9001:2015 system. The QMS certification has been renewed twice for three-year terms. The last renewal took place in Q2 of 2023. The certification of the VPI's new services – the Global Patent Search Services and the international-type search under the PCT– took place in July 2024.

To eliminate overlaps in the QMS documentation, former Quality Manual and process cards have been replaced by the Quality Management Strategy on June 1, 2017. The Quality Management Strategy includes the following Annexes:

Annex 1: Process map;

Annex 2: Quality Policy;

Annex 3: Risk Management Strategy;

Annex 4: Quality Objectives;

Annex 5: Control of Service Process.

The Quality Management Strategy was last updated on April 26, 2024; however, the Quality Objectives contained in Annex 4 are updated yearly.

The QMS covers the VPI's procedures, including all PCT procedures and the Global Patent Search Services (GPSS), which were introduced on October 1, 2023.

The QMS covers all services (management, support and core business) of the VPI and consists of three levels.

Level 1 describes the policy, goals and organization of the Institute,

Level 2 contains procedures for handling of the quality assurance system, and

Level 3 contains the procedures for the daily operation of the VPI.

The QMS of the VPI is connected to the national quality management systems of the NOs participating in the VPI's operation. All NOs have well-established quality management systems in place also based on the 3 levels principle described above, covering all processes related to PCT activities. The NOs' quality management systems are ISO 9001 certified and periodically recertified by a certification authority. The NOs carry out internal and external audits annually and recertification of their QMS to the ISO 9001:2015 every three years. The VPI's and NOs' national systems comply with the provisions of quality management in the PCT International Search and Preliminary Examination Guidelines (PCT/GL/ISPE).

The VPI's QMS is based on the national quality management systems which were extended to cover the full PCT procedure. The quality standards and practices at the NOs 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 NOs are connected by Service Level Agreements (SLAs) between each NOs and the VPI to reach the required quality work level and timeliness.

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.

#### **SUMMARY OF CHANGES IN 2025**

The VPI's QMS undergoes internal and external audits every year. After a preparatory internal audit in May, successful external audit of the QMS took place on July 4, 2025.

Quality Objectives contained in Annex 4 of the Quality Management Strategy are updated yearly by the decision of the Administrative Board (AB) of the VPI. Quality Objectives were met in 2025 as well.

Customer feedback is considered as key element in respect of the continuous development and quality assurance of the VPI's work. The customer feedback process of the VPI was updated in 2024 which included a complete re-write of the survey questions as well as migrating the survey to a Google platform. An invitation to fill in the customers survey is sent to the applicant upon the completion of the international search by the competent NO. The invitation includes a clickable direct link to the customer feedback survey in the relevant national language, or English in case of Serbian applicants, and also a QR code for ease of handling in case the document is sent in paper form. Furthermore, the same link and QR code are included in the form PCT/ISA/213 to increase the response rate. Finally, the link is also made available on the VPI website "Contact us" page. In 2025, a small modification, namely the sending of a reminder in respect of the invitation to fill in survey, was introduced in the customer feedback process to increase response rate, which has proven a very successful initiative and multiplied the responses received from customers.

On October 1, 2025, the VPI expanded the scope of services offered under the GPSS. In addition to the Novelty Search and Novelty Search with Preliminary Patentability Report services, the Validity Search Service was included. This service provides information related to the validity of a granted patent.

The VPI actively participated in the Harmonisation Files Exercise (HFE) Project organized by the European Patent Office (EPO) in 2025 with 20 files. The VPI has the intention to continue its active participation in the coming years. The VPI allocates necessary resources to this task every year and treats the HFE Project as one of its priorities. The project's main benefits are the benchmarking and quality assurance of the VPI's search work.

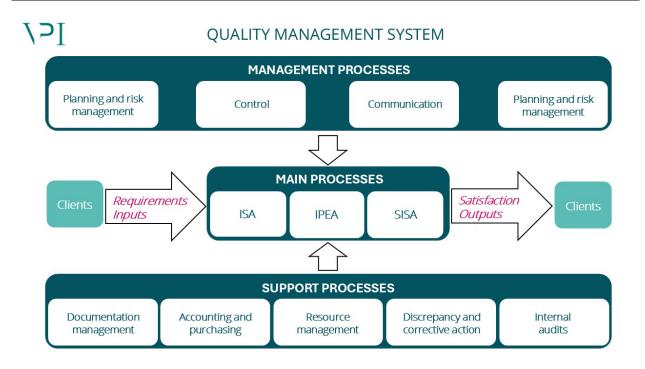
It should be noted that the HFE project between the European ISAs and the EPO is a reliable tool for long-term monitoring and quality assurance of the PCT Authorities' search activity. The continuation of the HFE project is ensured because it is an activity that implements the cooperation foreseen in the Protocol on Centralisation of the European Patent Convention regarding the harmonization of the search activities of the European PCT Authorities. The HFE project's results are assessed yearly at the Permanent Committee on the Harmonisation of Search Activities' formal meeting. Additionally, the VPI analyzes the HFE project results internally at IT/QM Working Group meetings.

## 1. LEADERSHIP AND POLICY

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

- (a) The quality policy established by top management.
- (b) The roles and names of those bodies and individuals responsible for the QMS, as specified by top management.
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.
- (a) The VPI's quality policy reflects on and supports the implementation of the VPI's task that is to provide high-quality search and examination products to consistently meet users' requirements and increase their satisfaction. Quality standards and consistent, harmonized practices are used to achieve this goal in respect of all PCT work.

The VPI's Quality Management System (QMS) is implemented in all processes of the VPI.



The VPI's operation is based on the cooperation of the participating national IP offices (NOs), therefore, the VPI's own QMS is also based on the QMSs of the NOs that are also extended in order to fully cover the PCT procedures of the international phase as well as to comply with the PCT/GL/ISPE, with special regards to Chapter 21 thereof.

This important feature is also reflected in the VPI's quality policy. Special emphasis is put on making ongoing efforts to further harmonize the patenting practices of NOs, as VPI's Branch Offices' (BOs).

The VPI's quality policy established by the top management, as clearly described in Level 1 of the overall VPI QMS above, is also defined in accordance with ISO 9001 standards.

The quality policy established by the top management of the VPI is an integral part of the VPI's Quality Management Strategy and provides guidance in all activities of the VPI.

The VPI's quality policy is contained in document QS/M2 annexed to the Quality Management Strategy of the VPI. It was last updated on April 26, 2024. The document is publicly available on the VPI website as well: <a href="https://vpi.int/en/wp-content/uploads/2025/05/QS\_M2\_Quality-Policy\_V3.pdf">https://vpi.int/en/wp-content/uploads/2025/05/QS\_M2\_Quality-Policy\_V3.pdf</a>.

(b) The Director of the VPI has an overall responsibility for the QMS. The Director and the Quality Manager of the VPI (QM) manage the QMS with the assistance of the Secretariat of the VPI and the quality experts of NOs as BOs.

The QM reports directly to the Director in matters related to the quality of the services and the QMS.

The IT/Quality Management Working Group (hereafter referred to as the 'IT/QM WG') is responsible for two main areas: QMS and IT infrastructure at the VPI. This platform enables representatives of the NOs to communicate, evaluate and discuss proposals for solutions and measures relating to all relevant issues concerning the quality management system and IT infrastructure. The IT/QM WG also serves as a preparatory body for the VPI's Administrative Board (AB). Documents regarding IT and QMS can first be submitted to the IT/QM WG before being presented to the AB. Detailed discussion within the IT/QM WG facilitates discussion at AB level and supports informed decision-making.

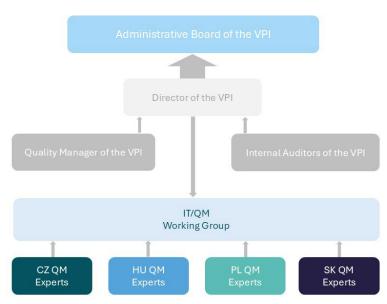
In order to assess the effectiveness of the QMS, the VPI develops and formulates measurable goals and defines personal responsibilities on a yearly basis. The quality goals are discussed in

the IT/QM WG and adopted by the AB yearly. To ensure the goals are achieved, the QMS is audited.

Internal and external audits are held once a year. The results of the internal audits are discussed and analyzed according to the mechanisms laid down in the QMS, and are on the agenda of IT/QM WG and AB meetings. The internal audits are performed by internal auditors appointed by the AB. The list of internal auditors was last renewed by decision AB/D 7/24 of the AB. The IT/QM WG is responsible for keeping the list of internal auditors up-to-date. If necessary, the IT/QM WG requests the AB's decision.

The relationship between the responsible persons and bodies is depicted as follows:

# RELATIONSHIPS BETWEEN PEOPLE RESPONSIBLE FOR QMS



The VPI defined its organizational structure in order to achieve the VPI's strategic objectives. In accordance with each part of the QMS, the responsibility of each person or body in charge of the QMS is clearly determined.

(c)

# Headquarters: Budapest, H-1081 II. János Pál pápa square 7. ATIVE BOARD (AB) The chairperson of the AB and norm-setting body of the VPI and regulations, budget Director, Quality Manager, Internal Auditors)

SECRETARIAT

Managed by the Director

organisation and distribution of the work
Representation

provision of administrative support

Czech Branch
Office
Search and
examination

Slovak Branch
Office
Search and
examination

Vesarch and
examination

Vesarch and
examination

Vesarch and
examination

Quality
Vesarch operation
Vesarch and
examination

Slovak Branch
Office
Vesarch and
examination

Slovak Branch
Office
Vesarch and
examination

Vesarch and
examination

ORGANIZATIONAL CHART OF THE VPI

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

# [Sample table, to be amended as necessary]

'				Extent of compliance		
			COII	ірпапс	e	
			full	part	no	
21.04	(a)	Quality policy available	✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓			
	(b)	Identified roles and names for QMS responsibility	✓			
	(c)	Organizational chart available	✓			
21.05		Established compatibility of QMS with Chapter 21	✓			
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓			
	(b)	Control of the continual improvement process	✓			
21.07	(a)	Communication of management about this standard to staff	✓			
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓			
21.08	(a)	Management reviews take place	✓			
	(b)	Quality objectives are reviewed	✓			
	(c)	Communication of quality objectives to the relevant staff at the Authority	<b>✓</b>			
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓			

Chapte	e21 re	quire	ment			
				full	part	no
		(b)	determine the extent to which the QMS is aligned with Chapter 21	<b>√</b>		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	<b>√</b>		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according to paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains technical qualifications to search and examine in all technical fields	<b>√</b>		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	<b>√</b>		
		(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>✓</b>		

Chapte	e21 re	quire	ment	Extent of compliance		e
				full	part	no
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	<b>√</b>		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	<b>√</b>		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	<b>√</b>		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	<b>√</b>		
21.17	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	<b>√</b>		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	<b>√</b>		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	<b>√</b>		
21.20	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	<b>√</b>		
	(iii)		Clear and concise guidance and information on the search and examination process for the user	<b>√</b>		
			Indication where and how the Authority makes its quality objectives publicly available	<b>√</b>		
21.21		(a)	Established communication with the International Bureau	<b>√</b>		
		(b)	Established communication with designated and elected Offices	<b>√</b>		
21.22			QMS of Authority clearly described and documented	<b>√</b>		

Chapte	e21 red	quire	ment	Extent of compliance		
				full	part	no
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	<b>√</b>		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	<b>√</b>		
	(v)		Resources available to carry out processes and implementing the procedures	<b>√</b>		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	<b>√</b>		
21.25	(i)		Records of which documents are kept and where they are kept	<b>√</b>		
	(ii)		Records of results of management review	<b>√</b>		
	(iii)		Records about training, skills and experience of staff	<b>√</b>		
	(iv)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	<b>√</b>		
	(v)		Records of results of reviews of requirements relating to products	<b>√</b>		
	(vi)		Records of the S&E process carried out on each application	<b>√</b>		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	<b>√</b>		
	(xi)		Records on actions taken re. preventive actions	<b>√</b>		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	<b>√</b>		
	(ii)		Recording of keywords, combination of words and truncations during search	<b>√</b>		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		

			Exte	е	
			full	part	no
	(v)	Recording of a listing of all search statements used in databases consulted	<b>√</b>		
	(vi)	Records about limitation of search and its justification	✓		
	(vii)	Records about lack of clarity of the claims	✓		
	(viii)	Records about lack of unity	✓		
21.27		Report on its own internal review processes	✓		
21.28- 21.30		Additional information on further inputs to its internal reviews	<b>√</b>		
21.31		Initial report called for by paragraph 21.31	✓		

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

- (a) the effectiveness of the QMS; and
- (b) that the process of continual improvement progresses.

In order to ensure the effectiveness of the QMS, the VPI develops and re-formulates measurable quality goals on a yearly basis based on the proposal of the Director. The document on Quality Goals, discussed in the IT/QM WG and adopted by the AB, indicates the persons responsible for ensuring the fulfilment of quality goals.

Internal and external audits are held once a year. The VPI approves the QMS internal audit program yearly. The results of the internal audits are discussed and analyzed in the IT/QM WG and presented to the AB, in accordance with the mechanisms laid down in the QMS.

Moreover, regular internal random cross-checks are performed between the NOs regarding the search and examination work products twice a year. The results of the cross-checks are shared among the NOs, evaluated at the IT/QM WG meetings twice a year, and the processes are corrected if needed.

Continuous improvement of VPI's QMS is ensured by the Director and the AB of the VPI based on the information related to the operation of QMS, gained during internal and external audits of the QMS and cross-checks. Improvement can be based on the suggestions made by the managements of the NOs and the quality manager of the VPI as well.

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- (a) those of this standard; and
- (b) complying with the Authority's QMS.
- (a) The Director of the VPI and the managements of the NOs clearly communicate the importance of fulfilling the QMS requirements of S&E work to the staff of the NOs, including the requirements under the PCT, related to the international search, international-type search, supplementary international search, and international preliminary examination quality provision. This communication is established at the various managerial levels of each NO at trainings, meetings, and individual feedback. The importance of the requirements is communicated also on the level of the IT/QM WG meetings of the VPI.

(b) The VPI and its contracting states use several ways of communication, such as harmonization of the common practice of the VPI NOs with the PCT Guidelines in the TE WG, regular meeting of the head of sections at the patent departments of every NO as BO, in the report of the Quality Manager to the AB and in the internal audit report carried out by the internal audit group on an annual basis.

Documents related to the VPI's QMS, such as Quality Management Strategy, and its Annexes, such as the yearly reviewed "Quality Objectives", setting the VPI's quality goals are published internally on the VPI's server.

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

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

The VPI constantly analyzes and monitors the performance of the QMS and the quality objectives, and assesses its conformity with Chapter 21 and ISO 9001 standards. Management reviews are performed and quality objectives are set on an annual basis.

- (a) The management review is held yearly and led by the Director. The results and the followup matters are incorporated into the activity plan for the following year. The agenda for the meeting includes but is not limited to the following issues:
- 1) state of the actions required by the previous management audit,
- 2) potential changes of the internal and external factors that may affect the quality management system,
- 3) information related to the performance and efficiency of the management system, including the tendencies of:
- client satisfaction and feedback from the most important stakeholders,
- fulfillment level of goals,
- performance of the processes and adequacy of services,
- shortcomings and corrective actions,
- results of monitoring and measurements,
- results of internal and external audits.
- performance of external service providers;
- 4) adequacy of resources;
- 5) steps carried out in relation to threats and opportunities;
- 6) potential developments.
- (b) Quality objectives defining quality goals are reviewed on a yearly basis. The quality goals are presented by the Director first to the IT/QM WG for discussion, and are adopted by the AB.
- (c) The VPI ensures communication through its internal communication channels, such as the publication of relevant documents on the VPI's internal server, and email communications to the persons responsible for the fulfillment of the quality objectives at NO level. At NO level, persons responsible for quality objectives communicate with staff members on the occasion of trainings, meetings, and individual feedbacks.

The Secretariat monitors the quality objectives, such as meeting of the deadlines, every two weeks. During these checks, the Director communicates any important information about the quality objectives directly to the relevant staff members, should further action be necessary to ensure full compliance.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

- (a) at least once per year (cf. paragraph 21.27);
- (b) in accordance with the minimum scope of such reviews as set out in Section 9, namely: to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i)); to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));
- (c) in an objective and transparent way (cf. paragraph 21.27);
- (d) using input including information according to paragraphs 21.29 (ii)-(vi);
- (e) recording the results (cf. paragraph 21.30).

Internal audits are carried out once a year in accordance with the minimum scope of such reviews as set out in Section 9.

Internal auditors are responsible for organizing and conducting internal audits of the QMS and PCT processes. Specific areas of activity are identified for each audit, including S&E and compliance with the PCT guidelines.

Customer feedback is monitored by the Secretariat on a monthly bases, and reported during each internal audit. Customer feedback is considered when developing further user-friendly solutions.

Follow-up, corrective, and improvement measures concerning S&E work are presented to the VPI Director and the NOs' management. The IT/QM Working Group (WG) periodically evaluates the effectiveness of corrective measures. The results and findings of internal audits are recorded in checklists and reports, which are then discussed at IT/QM WG meetings. The final report is also presented to the AB.

For full transparency, the IT/QM WG establishes action points for improvement measures, and follows up on their implementation status. The "execution of action points" is an integral part of the minutes of IT/QM WG meetings. This document provides information on the completion of measures contained in the action points.

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

The top management of the VPI promotes practices that ensure risks and opportunities affecting its QMS and the conformity of international searches and examinations are addressed. More information can be found in the response under paragraph 21.13.

#### 2. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

- (i) (a) understand issues that affect its ability to achieve intended results of the QMS, and
  - (b) understand the needs and expectations of interested parties;
- (ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;
- (iii) plan and implement actions to address risks and opportunities;
- (iv) check the effectiveness of the actions taken; and
- (v) continuously update risks and opportunities.

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

Staff members and the management of the VPI consider risks and opportunities at the beginning of the planning process. Prevention is part of strategic planning for the VPI. Combining process- and risk-based approaches ensure the operation of the QMS in conformity with the requirements of the standard ISO 9001.

All relevant staff members of the VPI assess and manage risks and opportunities during the implementation of processes, that may:

- improve the effectiveness of the QMS and the achievement of the goals;
- prevent or reduce unwanted effects;
- increase desirable effects;
- support continuous improvement.

The risk-based practices and methodology of the VPI, considering the basic components guided by paragraph 21.13. of the PCT/GL/ISPE, are based on the Quality Management Strategy of VPI, and Annex QS/M3 on the Risk Management Strategy of the VPI.

Risk Management Strategy of the VPI contains the steps for the assessment of risks and opportunities. In line with the Risk Management Strategy, in order to understand the needs and expectations of interested parties, the VPI determines the requirements of the interested parties for every milestone of every identified process. For every milestone of every identified process, the VPI also determines the risks preventing the fulfilment of the requirements of the interested parties.

The VPI also established the measure of the risk, based on

- the likelihood of the occurrence;
- the severity of consequences.

The action taken to handle the risk is determined on the basis of the measured potential of the risk. Value is also defined above which action and check of the effectiveness of the action is imperative.

The Risk Management Strategy contains the regularly updated assessment table of identified risks and determine the action to be taken to handle the risks. The current risk assessment table is reviewed at least once a year. For more information on quality and risk management mechanisms, please refer to the information provided under 21.17.

#### 3. RESOURCES

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

#### Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work; and which maintains the technical qualifications to search and examine in the required technical fields;

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

Search and preliminary examination of PCT applications are carried out by the staff of the IPO CZ, HIPO, PPO and IPO SR 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, competence 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 153 patent 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 all hold master's degree or PhD and have undergone comprehensive, intensive and well-structured IP 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. In order to constantly improve the skills and competencies of the VPI examiners and to keep their technical knowledge up-to-date, internal training courses are organized. In addition, the VPI organizes examiner exchange of views and meetings in order to further enhance quality and consistency in search and examination practices.

In addition to their mother tongues (Czech, Hungarian, Polish, Slovak), the VPI examiners have 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 Italian, Japanese, Russian, Spanish and Swedish. These inherent flexibilities significantly facilitate 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.

(iii) The VPI has appropriate equipment and facilities based on the current infrastructure of the participating offices in place. An IT system (hardware and software) is available for the VPI, which supports the search and examination process and facilitates the cooperation, the distribution of work and office management in the most efficient way. This IT system is 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 is the ePCT system operated by WIPO.

- (iv) Each NO has a wide range of accessible patent information, scientific literature, search platforms and links available to examiners. Since the V4 countries are Contracting States of the EPC, the VPI BOs have access to EPOQUENET and the ANSERA-based search tool (AbS), which is replacing EPOQUENET, and several commercial search platforms.
- The EPOQUENET search tool or AbS grant 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 (eg. WPI etc.).
- With the help of the STN platform, 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.
- Via the STN platform the following databases are accessible: CAplus, MARPAT, BIOSIS, EMBASE, CABA, FSTA, COMPENDEX, INSPEC, WPI and ReaxysFile. STN is used also for structure searches (eg. CAPLUS, CAS Registry and MARPAT) in the field of chemistry and pharmaceuticals, and for nucleotide or amino acid sequence searches (CAS Registry, USGENE, PATGENE, GENESEQ and GENBANK) in the field of biotechnology.
- Further non-patent literature databases, such as MEDLINE, ELSEVIER, EMBASE, IEEE and PUBCHEM can be searched via STN and/or directly via online web searches.
- Further patent literature databases (eg. Origin) can be searched directly via online web searches.
- The patent and utility model documentation of more than 80 countries and authorities starting from 1920 is also accessible and searchable in all the participating offices of the VPI.
- 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.
- In addition to the electronic sources of databases mentioned above, the libraries of the participating offices of the VPI have 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.
- Each participating office of the VPI has access to main classification system databases. Examiners use IPC for classification purposes and IPC as well as CPC 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. In order to keep up with the latest developments of search tools, all participating offices of the VPI take part in the project of the EPO in respect of the AbS. The year 2025 was still a transition year, with BOs switching from EPOQUENET to AbS. 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.

(v) The documents on quality criteria, standards, and work procedures are contained in the QMS documentation and the Guide on Search and Examination in the VPI. Documents are kept up-to-date and new versions adopted at the IT/QM and TE WGs meetings. All documents are available to VPI staff on the internal server.

#### 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.

New colleagues participate in theoretical and practical training courses. Developing a basic understanding of industrial property rights and acquiring detailed knowledge of patent law are important elements of this training. More experienced colleagues are also available to provide coaching at the NOs.

The examiners of VPI's BOs, as staff members of the NOs, participate in-house and external training courses and seminars related to patent search, including those on the efficient use of patent and NPL databases.

The management of the NOs is also responsible for raising their staff's awareness of complying with the quality criteria and standards relating to the VPI'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.

To ensure there are sufficient staff to deal with the inflow of work, the Director and the Secretariat of the VPI regularly update and circulate data on the latest skills of the examiners to the NOs. Furthermore, the NOs' Management assures control over workload changes and qualified personnel at all times.

#### 4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

- 21.16 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:
  - (i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and
  - (ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.
- (i) The VPI Secretariat and each national office are responsible for establishing a register wherein all relevant data and information are collected. As a part of this register, the relevant deadlines are also recorded and monitored continuously. A list of outstanding files containing the deadlines is prepared by the Secretariat bi-weekly and forwarded to the point of contacts of the particular VPI BO. All previous lists of deadlines of the given year are stored in one file to enable tracking the progress. The list also displays the one-week shorter internal deadline of

the VPI applicable as from June 1, 2021 and a one-month shorter internal deadline for applications where the PCT deadline is 9 months as from January 1, 2023. Applications with less than a week deadline are marked. This list makes it possible to flag applications with approaching deadline and provides an opportunity to the NOs or the VPI to reassign the application to another examiner if needed in order to prepare the report in time.

The working method within the VPI has the benefit that the applications can be immediately handled by the competent NOs or NO sections without delay. Documents filed by the applicants immediately reach the competent office/section, which has a two-fold benefit. It is cost effective and makes maximum use of the given infrastructure and manpower of NOs and it also ensures maximum security of applications. However, the decentralized work sharing requires each NO to 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 corresponding patent sections of NOs prepare the ISR/WO-ISA and WO-IPEA/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 the preparation of ISR/WO-ISA and WO-IPEA/IPER, the patent sections of the NOs communicate with the applicant on behalf of the VPI.

(ii) Work sharing protocols within the VPI ensures demand and backlog management. The tasks within the individual NOs 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 departments of the NO which is responsible for this type of procedure, while substantive search and examination is done by the patent sections.

## 5. QUALITY ASSURANCE

21.17 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality as part of a post-issue review process:

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

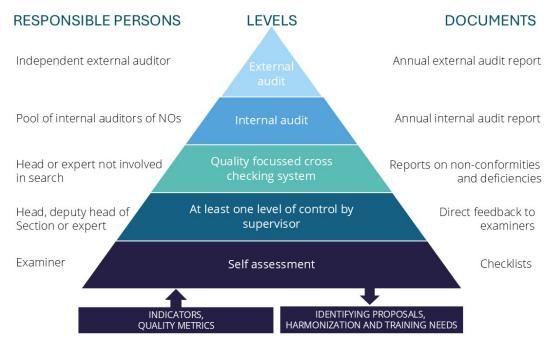
- (ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.
- (iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

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 also specifying quality indicators. The VPI has an internal quality assurance system for monitoring the fulfillment of the set indicators and compliance with the PCT/GL/ISPE in place.

Harmonized quality assurance measures have been implemented, building upon the current best practices of the participating offices. A comprehensive guide for search and examination (Guide on Search and Examination in the VPI) is available for internal users. Self-assessment is conducted using checklist forms. Harmonized procedures are applied for verifying and accepting the search and examination reports and for preparing periodic statistical reports. Following a thorough review of these reports, any identified deficiencies and non-conformities with the VPI QMS are addressed in a timely and effective manner. The internal audit is

performed on an annual basis. The harmonized tools and procedures ensure that any application is searched and examined in the same way, no matter which BO performs 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 by the checklist guarantees a permanent reminder of the key criteria.

At the second level, at least a one level control is carried out by an NO supervisor or another expert. The supervisor or expert inspects the quality of the search strategy and the clarity of the report. The control at this level of the quality assurance system can vary between the NOs as each NO follows its 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 is a direct discussion of the content of the product with the examiner who prepared the product. If a systemic error is recognized throughout this control system, a corrective action is initiated.

At the third level of quality control system, the heads/directors of the NOs' patent departments prepare a quality-focused cross-checking by randomly (5-10%) and periodically (on a half-year basis) selecting some finished products. As a result of this measurement, a report on non-conformities and deficiencies is prepared. The reports are sent to the Quality Manager of the VPI from every NO. The results of these reports are discussed at the IT/QM WG of the VPI, where the experts of the NOs suggest corrective actions to the Quality Manager (QM). If the non-conformities and/or deficiencies originate from incorrect interpretation of the guidelines or legislation, the question is discussed by the Technical Experts' Working Group, where the common practice to be followed by the VPI/NOs is agreed on.

At the fourth level, internal audit review procedures are conducted via planned manners. As a result, a yearly internal audit report is prepared and presented to the IT/QM WG and the AB. At the fifth level, an independent external audit company is hired to audit the VPI's procedure. The yearly external audit is conducted in line with an audit plan; however, applications that are checked are selected randomly. The report is discussed at the IT/QM WG and submitted to the AB of the VPI.

(ii) A system of measurement and collection of data and reporting

The performance of the processes is monitored, and, if necessary, measured assisted by executives' checks and by internal audits, to ensure the compliance and effectiveness. The actions, the methods related to measuring the performance of the activities, and to the services purchased, are included in the process descriptions as well as the manner of monitoring the effectiveness of the processes. The results of monitoring are recorded. These records identify the employees and their scope of responsibility, and provide proof that the services and processes meet the requirements.

The management of the VPI has established the list of required information, statistical reports and parameters that are to be regularly compiled regarding the operation of the VPI. These cover the activities, processes, services, satisfaction, the integrated management system, the non-conformities and complaints, if any.

The data are analyzed and assessed by the management. If undesirable trends are detected, corrective and/or preventive actions are taken.

If non-conformities concerning the quality are detected or a warning is given by the counsels, the management endeavor to detect the reasons of non-conformities, take the necessary arrangements/corrections and then take corrective actions in order to prevent the recurrence of non-conformities without delay.

The main consideration when taking actions related to non-conformities in addition to the correction and corrective actions is to prevent the recurrence of non-conformities. Therefore, based on the data obtained from the analyses, the services and processes of the VPI are continually monitored and controlled, and, if needed, preventive methods indicated in the documents describing the process are implemented.

Preventive actions are taken involving the manager in charge of the activity concerned. Preventive actions are recorded and their results are assessed in the management reviews. One of the key characteristics of the VPI QMS is the continuous improvement which is demonstrated on service, process and system level. Potential corrective decisions are based on processing and analyzing the data of the operation of the VPI by examining the objectives and monitoring the changes in external and internal circumstances.

Timely issuance of search and preliminary examination reports or any other products is supported by a systemic monitoring system operated by the VPI Secretariat and NOs simultaneously. The quality standard of the reports consistent with the PCT Guidelines and our internal guide is guaranteed by the 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 triggers immediate corrective action for 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 was identified.

#### 6. COMMUNICATION

Inter-Authority communication:

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

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

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

The main lines of communication are determined by the Director and the Secretariat of the VPI. Therefore, the Director of the VPI is the designated contact on behalf of the VPI in this respect. The designated quality contact person:

Name: Ms Johanna Stadler Job title: Director of the VPI

Contact details: director@vpi.int, +36 20 386 3557.

Communication and guidance to users:

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

(i) An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and

offering feedback to users.

(ii) A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

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

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

Measuring user satisfaction and perception, handling of complaints, correcting deficiencies identified by the users, taking corrective and preventive measures and ensuring needs and expectations of the users are handled according to the Quality Management Strategy related to the QMS based on ISO 9001 system.

The VPI provides comprehensive information and guidance to the users in English and all official languages of the VPI through the VPI's website, and also through the websites of the participating NOs in their native languages.

The renewal of the VPI website took place in 2022. The website is user-friendly and adaptive in its functionality, so that it caters to the browsing habits of users. Several new types of content have been developed on the website under "Knowledge Hub" including a Q&A, case studies, brochures and annual report with the purpose to increase the awareness of users on the PCT system and the work of the VPI. In 2023, the website was updated to give full information on the newly introduced services. In the first quarter of 2024, the information on "Fees and Refunds" on the VPI website was renewed. The restructuring of the website was initiated on the basis of customer feedback from the user survey conducted by the Secretariat of the VPI in 2023. In their responses, VPI users suggested further simplification of the means of submitting requests for refund of search fees. To meet the user need, a new "Fees and Refunds" page was launched, and an online form for filing a request for refund of search fees was added in all five of the VPI's official languages.

Customer satisfaction survey forms are available electronically after completing the search, as well as on the new VPI website. A QR code and a link to the survey are included in form PCT/ISA/213, and the Secretariat issues a reminder to increase the response rate. Event evaluation forms are made available electronically following an event.

#### 21.21 Communication with WIPO and designated and elected Offices:

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

Communication 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 electronically.

#### 7. DOCUMENTATION

21.22 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

- (a) the documents making up the reference that have been prepared and distributed;
- (b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and
- (c) document control measures taken e.g. version numbering, access to latest version.
- (a) The VPI's QMS is clearly defined at various 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 documentation, the Quality Management Strategy and its Annexes (Annex 1: Process Map, Annex 2: Quality Policy; Annex 3: Risk Management Strategy, Annex 4: Quality Objectives, Annex 5: Control of Service Process with flow charts). The VPI maintains all records required by paragraph 21.25 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 descriptions and flowcharts are in place. P. T. and O. indicators have also been identified. Checklists for search and examination
- performed by the VPI have been identified, and all process descriptions and flowcharts are in place. P, T and Q indicators have also been identified. Checklists for search and examination are filled in by the participating office's examiners upon the completion of the product. The Technical Experts' Working Group and the IT/QM WG are responsible for reviewing these documents.
- (b) The documents are available to the staff by means of internal publication (internal server) and on the NOs' intranet, respectively.
- (c) Document control measures, such as version numbering and dates, are taken for all the documents. To ensure access to the latest version, outdated versions are removed. Outdated earlier versions can be accessed only in archive folders.
- 21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:
  - (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
  - (ii) the scope of the QMS, including details of and justification for any exclusions;
  - (iii) the organizational structure of the Authority and the responsibilities of each of its departments;
  - (iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;
  - (v) the resources available for carrying out the processes and implementing the procedures; and
  - (vi) a description of the interaction between the processes and the procedures of the QMS.

The Quality Management Strategy includes all the mandatory elements and meets all PCT requirements.

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

- (i) a definition of which documents are kept and where they are kept;
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 8.

The VPI and the NOs maintain all the required records of the above-mentioned types of documents (i)-(xii) in accordance with the relevant PCT rules.

#### 8. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

- (a) which of the following are included in this record:
  - (i) the databases consulted (patent and non patent literature);
  - (ii) the keywords, combinations of words and truncations used;
  - (iii) the language(s) in which the search was carried out;
  - (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
  - (v) a listing of all search statements used in the databases consulted.
- (b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

- (c) which special cases are documented and whether records are kept denoting any:
  - (vi) limitation of search and its justification
  - (vii) lack of clarity of the claims; and
  - (viii) lack of unity.

VPI keeps records of all information relevant to the searches performed in the form of search strategy records concerning performed searches, in line with paragraph 21.26 of the PCT/GL/ISPE, including 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

(including searched chemical structures and SEQ IDs) 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 and quality purposes.

Documents on any limitations of performed searches are also kept. If the search is limited to certain claims, this 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.

#### 9. INTERNAL REVIEW

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

21.28-21.30 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

A review mechanism is put in place for monitoring compliance with quality standards, under which objective and transparent reviews are 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 the 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.

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

The 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 in the management process and keeps the VPI on course toward its objectives and mission. The 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 of defined process controls and their performance,
- (v) verifying the accuracy of process orientation with respect to the Quality Policy. Besides internal audits, external audits take place once a year to assess the conformity of the VPI's QMS with the applicable standards.

#### 10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting.

In view of the ongoing process of extending the appointments of the International Searching and Preliminary Examining Authorities, the Visegrad Patent Institute seizes this opportunity to present a fully updated, clear and transparent report. Considering the high number of changes, we decided to submit a clean document instead of highlighting each change, as this is more convenient for the readers. For information on quality-related developments at the Visegrad Patent Institute in 2025, please refer to the "Summary of Changes in 2025" under the "Introduction" heading.

[End of document]