

ORIGINAL: ENGLISH DATE: DECEMBER 1, 2025

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Intellectual Property Office of Singapore (IPOS)

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.

The Intellectual Property Office of Singapore (IPOS) has earlier implemented a quality management system (QMS) for its patent search and examination functions that conforms to the ISO 9001:2008 standard with effect from November 3, 2014. With effect from November 2015, the patent search and examination functions have come under IPOS International Pte Ltd ("IPOS International"), a wholly owned subsidiary of

IPOS. IPOS International has since transited to ISO 9001:2015 and the QMS maintains the certification as of 25 26 February 26 April, 20254.

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.

Our quality policy is to work together with our customers to provide high quality products and services which are delivered in an efficient and consistent manner. We are committed to continually improvinge our systems, practices and programmes in order to provide robust intellectual property rights that will foster a thriving and vibrant Singapore intellectual property environment.

Our quality objectives are to provide high quality search and examination products and services that are valid, reliable and delivered in an efficient manner.

Valid and Reliable

We regard a search to be valid when the search was conducted employing an appropriate search strategy and using a comprehensive set of authoritative sources of information. A search is considered reliable when it is sufficiently documented to permit a reproducible and consistent search result.

An examination is valid when the law is correctly interpreted and logically applied to arrive at a sound decision, and where that decision and its basis are clearly communicated to the customer. An examination is reliable when examiners use a consistent approach based on an open and transparent set of guidelines and where considerations for arriving at a decision have been documented to show that guidelines have indeed been followed during the examination.

Efficient - Commitment to Timely Actions

We are committed to delivering the reports within the time limits as set out in the Regulations under the PCT, and regularly review our processes to prevent late issuance of reports.

The Quality Management System (QMS) Group is a functional committee that works with the Practice and Performance (P&P) Division to oversees the QMS of Patent Search, Examination and Analytics Unit in IPOS International. The Its The QMS Group comprises members who in the QMS Group representatives from the examination Divisions who have undergonewere formally trained on formal training in the ISO 9001:2015 Internal Auditor Trainingcourse. The course training has equipped these members them with the necessary techniques and know howknowledge to carry out an effective internal QMS quality audits for the organisation. The internal quality audits determines if assess whether the QMS conforms to the ISO 9001:2015 standard and ensures the effectiveness of the procedures and processes. In addition, the QMS

Group P&P Division provides updates oin internal search and examination guidelines, processes as well as to conduct ad-hoc trainings when required (See Figure 3).

The organisational structure of <u>the Patent Search</u>, Examination and Analytics Unit in IPOS International is presented below.

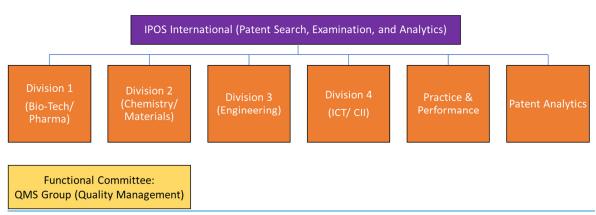


Figure 11114: Organisational structure of Patent Search, Examination and Analytics Unit in IPOS International.

21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines.

Alternatively, indicate where the Authority is not yet compliant with these requirements).

Chapter 21 requirement						of
				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	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to:	√		

Chapter 21 requirement				of e
		full	part	no
21.28- 21.30	Additional information on further inputs to its internal reviews	√		
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.

The IPOS International management reviews the internal quality audit reports of the QMS Group and the external audit reports. Internal quality audit is conducted annually to determine if the QMS conforms to the ISO9001:2015 standard. The standard comprises clauses relating to the effectiveness of the processes and products, as well as continual improvement. An audit report consisting of the audit findings on the QMS will be submitted to the IPOS International management. The management will consider the report and make any necessary changes to the QMS for continual improvement.

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 importance of QMS is communicated by IPOS International management to the staff at town_halls, and at division meetings. The town_hall and division meetings are conducted at least annually and quarterly respectively.

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.

Please see paragraph 21.06 on management reviews.

Every year, the IPOS International management, in consultation with IPOS, will review the results of the current work plan and plan for the work next year. A review of the required resources and quality objectives is undertaken as part of the process. Any new quality objectives are communicated to the staff by way of circulation of minutes of management meetings as well as at the quarterly unit sharing sessions or meetings.

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).

<u>The QMS</u> Group carries out the internal review of the QMS at least once a year. The review results are recorded and reported to the IPOS International management.

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 IPOS International management, in consultation with IPOS, conducts SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis to evaluate the organisation during the annual planning process, taking into consideration the organisational context (including the external and internal issues that affect its ability to achieve the intended results of its QMS). For example, the internal positive and negative attributes of search and examination processes in relation to theirite external environment and resources are identified and evaluated on their potential impactsimpact on the QMS and the conformity of products and services during this annual planning process. Please see paragraph 21.13 on the elaborated arrangements for establishing risk-based practices.

In addition, all staff will be informed of the necessity, purpose, outcome and/or advantages of implementing the practices to address risks and opportunities. The communication is conducted via the quarterly unit sharing sessions and meetings.

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).

The IPOS International management determines the external and internal issues that affect its ability to achieve the intended results of its QMS to help establish the organisational context during the annual planning and review sessions. Some examples of external issues that have been identified include updates to PCT Legislation and being up to date on relevant databases to support operations.

In addition, the needs and expectations of interested parties including key stakeholders are considered an essential input to this planning process. For example, where WIPO is the interested party, the corresponding needs have been identified as issuing quality and timely reports as a competent International Searching Authority and International Preliminary Examining Authority (ISA/IPEA). The information concerning the needs and expectations of interested parties <u>isare</u> regularly determined, monitored and reviewed by responsible personnel such as by collating and reviewing feedback from <u>the</u> annual customer satisfaction survey and other mechanisms (e.g. Figure 3).

As a basis <u>foref</u> planning and execution of the QMS, a standard risk assessment procedure is carried out at least once each year to identify the risks occurring at each stage of the search and examination process, together with potential impacts and corresponding risk controls to be implemented. Similarly, opportunities are identified for each stage of the search and examination process with corresponding action plans to be implemented.

Annual reviews are carried out to evaluate the effectiveness of actions taken to mitigate the risks and take advantage of the opportunities. Continual update of relevant risks and opportunities are identified such as through an internal feedback process and an external feedback process (see Figure 3).

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.

IPOS has gazetted more than 100 full-time patent examiners with a majority having PhD qualifications. The patent examiners reside in IPOS International.

The examiners have at their disposal a comprehensive suite of search platforms including commercial patent and non-patent literature search platforms and also their respective plugs in and standalone databases. Together, it provides the examiners access to the minimum documentation referred to in Rule 34 of the PCT Regulations and more.

There are 7–6 administrative staff supporting the international application's work.

The IPOS International management monitors and discusses the matching of human resources with the workload requirements, for both examiners and administrative staff. The examiners are supported by a policy of regular review of workload and re-distribution of workload, where necessary.

In addition, a systematic recruitment process with clear requirements for candidates and a systematic training programme for them are in place. The sey can be activated should the review by the IPOS International management determines the need for new hires.

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.

IPOS International provides modern IT hardware and up-to-date software for the examiners to carry out their work. Every examiner is provided with a high-specification laptop for accessing web-based search platforms and an in-house workflow management system capable of encrypting unpublished applications, which examiners can access via <u>a</u> secured VPN when working from home. Additionally, as an extra security precaution, all examiners are required to sign an undertaking form, affirming their commitment to adhering to strict rules governing the safe handling of documents.

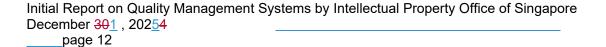
All work processes are documented in a set of guidelines that are maintained and stored on the company cloud drive. For search and examination practices, the examiners are guided by the IPOS Examination Guidelines on Patent Applications that is updated and available on the IPOS corporate website¹, as well as IPOS Procedural and Examination Guidelines for International applications filed under PCT which are also updated and available on the company cloud drive. The examiners also have online access to other resources like the PCT International Search and Preliminary Examination Guidelines and the PCT Regulations.

The examiners have at their disposal a comprehensive suite of search platforms, including commercial patent and non-patent literature search platforms, and their respective plug-ins and standalone databases. Together, thiese provides access to the minimum documentation referred to in Rule 34 of the PCT Regulations, and more.

The examiners also have online access to other resources like the PCT International Search and Preliminary Examination Guidelines and the PCT Regulations.

Additionally, as an International Searching Authority under the PCT, IPOS meets the PCT Minimum Documentation requirements effective in force from January 1, 2026. From that date, IPOS's newly published patent documents from January 1, 2026-will be made available in text--searchable format in an SFTP repository. —This repository also allows provides access to access to any requesting ISAs upon

¹ "Examination Guidelines for Patent Applications at IPOS (2023)" can be viewed at https://www.ipos.gov.sg/docs/default-source/resources-library/patents/guidelines-and-useful-information/examination-guidelines-for-patent-applications.pdf



request to establish a connection to our SFTP server for the purpose of international search by establishing a connection to our SFTP server. Backfiles (patent collections from 1991-2025) will be available on request. An Authority fFile hasis also been created for our text--searchable patent collection data belonging to that forms part of the PCT Minimum Documentation. This file which will be updated following after our monthly national application, and publication, and publication and will include records which will be backdated to 1991.

Training resources:

(vi) Describe the training and development infrastructure and programme 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.

IPOS has a structured and competency-based training programme for the examiners. First, a 4-month formal training and followed by up to 12 months of on-the-job training. On-the-job training is supervised by senior examiners, who can tailor the training according to the assessment of the examiner based on a set of defined competencies.

Continuing development of the examiners is another aspect of the training. In addition to in-house training pertaining to search and examination, there are regular symposiums held in-house for knowledge sharing by internal or external speakers, the examiners attend IP or technical conferences locally or overseas, attend workshops conducted locally or by overseas IP Offices, participate in examiner exchanges with IP Offices, study visits to other IP Offices, and host visiting Examiners from other IP Offices. The training and workshops are conducted virtually and in-person.

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.

Please see paragraph 21.16.

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.

One of our quality objectives is to issue reports in a timely manner. Since <u>becoming</u> operational as an ISA/IPEA, IPOS has delivered the reports within the time limits as set out in the Regulations under the PCT, and regularly reviews our processes to prevent late issuance of reports. IPOS has maintained a good

timeliness record, i.e. issuance of ISR within the prescribed timelines as set out in the Regulations under the PCT.

To ensure timely issuance of search and examination reports, the IPOS management monitors them based on the performance reports generated from the in-house workflow management system. The in-house workflow management system tracks each step of the workflow and provides the latest action and timeliness status of each case, real-time. Performance reports are reviewed monthly by the management to ensure that all search and examination reports are issued within set time limits.

		<u>(b)</u>	Due In T	Due Date T	Assigned D T	Lock T	Task Status	Product T	Process Name T	Task Identifier	Application No.	IPC T
V			25	09/02/2021	27/11/2020		In Progress		PCT Chn 1 Request	76818	PCT/SG2020/050601	
v	ú	•	73	29/03/2021	05/01/2021		In Progress		PCT Chp 1 Request	78790	PCT/SG2020/050720	

Figure 2: A screenshot of the in-house workflow management system.

The wWorkload of examiners is monitored at least monthly. Preventive and corrective measures would be taken should any deviation be observed or anticipated.

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 QMS has two quality assurance measures for applications filed under the PCT: an internal feedback process and an external feedback process.

In the internal feedback process, the products international search report ("ISR"), written opinion ("WO-ISA") or international preliminary examination report ("IPER") may be subject to Quality Check (QC) or Quality Assurance (QA).

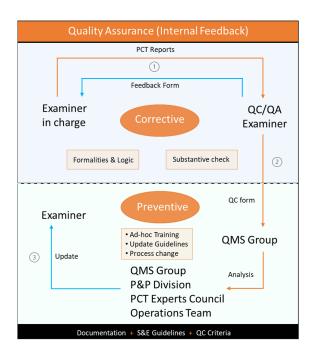
It is mandatory for the examiner to document search strategy, search results, a short excerpt from the relevant prior art and considerations during examination in an internal document. The internal document

will serve to facilitate the QC/QA process (see the Figure 3 below), which is mandatory for all the reports established under the PCT.

<u>The QMS</u> Group collates and analyses the QC/QA <u>forms</u>, <u>forms and</u> identifies the issues that need to be addressed in a report to the management team. Upon the management <u>team</u>'s endorsement, <u>the QMS</u> Group, <u>P&P Division</u>, PCT Experts Council or Operations Team will <u>follow upfollow up</u> thereafter. To close the loop, the examiners will be updated on the actions to be carried out.

In the external feedback process, any feedback or complaint from the applicant/attorneycustomer will be referred to the P&P Division and the QMS Group QMS Group. In turn, the P&P Division and the QMS Group will collate and analyse the feedback and complaints, identify the issues that need to be addressed, and recommend appropriate action. The Customer Service section or the Registry of IPOS will be informed of the outcomes. The applicant/attorneycustomer will be updated on the outcomes so as to close the loop. In the event that there is a need for our examiners to communicate directly with the applicant/attorneycustomer, a meeting with an appropriate agenda will be convened.

The process diagrams to illustrate the internal feedback process and the external feedback process are as shown.



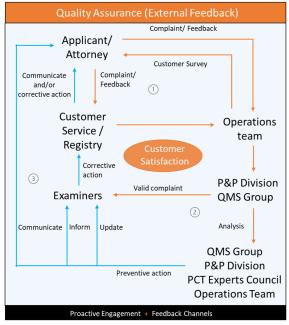


Figure 222223: Diagrammatic representation of the quality assurance internal feedback and external feedback processes.

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.

For communication with other Authorities, Sharmaine Wu (<u>Sharmaine Wu@ipos.gov.sg</u>), Director of the Registries of Patents, Designs and Plant Varieties, has been appointed as the designated contact for this purpose on behalf of IPOS.

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.

(i) System for handling complaints and making corrections IPOS has established procedures to seek customer feedback and vice versa. Public opinions are sought before any amendment to the patent law and examination guidelines are published. A Public Consults on the proposed legislative amendments wereas conducted in 2021 and October 2025.

IPOS conducts a biennial survey with its users to solicit feedback on search and examination work products and on possible improvements to the patent system in Singapore. The survey helps to provide an indication of the satisfaction levels of users of the patent system. In addition, a PCT User Survey will bewas conducted scheduled in 2024 and the results are being analysed.

<u>Based Upon on analysis of customer feedback or complaints the information analysis received from the applicants, attorneys and public, IPOS management will take actions to address any shortcomings and will continue to improve on the procedures and processes wherever applicable (see paragraph 21.17).</u>

The applicant/attorney customer has the possibility avenue to communicate on the written opinion with the examiner face-to-face. There is an internal procedure to set upset up this meeting which requires less than five working days to arrange. An appropriate agenda is a must for such a meeting.

(ii) Procedure for monitoring user satisfaction and ensuring needs are met Based on the information analysis received from the applicants, atterneys and public, IPOS management will take actions to address any shortcomings and will continue to improve on the procedures and processes wherever applicable (see paragraph 21.17).

IPOS has established procedures to seek customer feedback and engage with stakeholders for on stakeholders' engagement. Public opinions are sought before any amendments to the patent law and examination guidelines are published. Public We conduct public consultations on the proposed legislative amendments are conducted regularly, with the most recent in 2021 and October 2025. Public opinions We seek public feedback on are sought before any amendments to the patent law and the patent examination quidelines are published.

IPOS conducts a biennial survey with its userscustomers to solicit gather feedback on search and examination work products and on possible improvements to the patent system in Singapore. The survey results helps to provide an indication of the satisfaction levels of users of the patent system. For example, recent user surveys were conducted in 2022 and 2024.

(iii) Clear guidance and information to users

IPOS has published on its website information on the filing process for a Singapore or PCT patent application, the search and examination procedures in the form of Examination Guidelines for Patent Applications at IPOS². IPOS has established links oin its website to guide and introduce users to the information, regulations and guidelines concerning the process of obtaining the rights to inventions in Singapore and also and under the PCT with reference to the WIPO website. IPOS' website regularly announces IP courses and programmes available, so that the users/public can register and attend these activities whenever available.

² Information on these can be viewed at <u>www.ipos.gov.sg</u>.

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.

The Director of the Registries of Patents, Designs and Plant Varieties at IPOS is responsible for managing the communication with WIPO and designated and elected offices on quality matters.

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.

The process approach was adopted when developing and implementing the QMS, and it is applicable to the following:

- a. receiving requests and carrying out search and examination work;
- documentation and processing operations which include updating and operability assurance of the patent information file and availability of the reference and search tools;
- c. providing the examiners and the patent information system to process the files;
- d. managementing of oppositions and feedback concerning the issuance of the opinions and reports; and
- e. measuring, analysing and improving the overall search and examination processes.

The Quality Manual sets out the requirements and contains—its descriptions of the following core processes for the national and international applications. Specific to the international application, the Quality Manual covers the following aspects:

- a) PCT Chapter I request
- b) PCT Chapter II demand
- c) PCT Supplementary international search request

The Quality Manual is available in soft copy and is accessible on the company cloud drive.

- 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 Manual consists of the following content:

- quality policy;
- b. quality objectives;
- c. quality manual revisions;
- d. QMS scope, documented processes and justifications for exclusions;
- e. schedules and resources for implementing and carrying out processes;
- f. organisational chart, with described roles and responsibilities; and
- g. records required (see paragraph 21.25).
- 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.

According to the ISO 9001:2015 standard, IPOS International creates and maintains the following documents:

- a. control of document and records references
- b. quality manual;
- c. records on procedures for quality provision and risk assessments;

- d. records on management review and results;
- e. records on personnel training, conference and seminars attended;
- f. records on staff qualification, experience and performance monitoring;
- g. records on quality control of the product;
- h. records on conformity of the search and examination processes, including audit findings;
- records on corrective and preventive actions related to non-conforming products and processes, and follow up procedures to ensure service conformity in the event that planned results are not achieved;
- j. records on the results of search and examination for each patent application; and
- k. data summary of the search and examination quality and applicant_customer_feedback and follow-up actions.

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.

The examiners make a record of their search process and store itthem in the company cloud drive for internal review and documentation.

The search record documents the following:

- a. a description of the point of invention/technical problem to be solved;
- b. the search strategy adopted by the examiner, comprising:
 - classification of the subject matter to be searched e.g. IPC (for searches in patent databases);
 - ii. the databases consulted (patent, non-patent literature or Internet); and

iii. the keywords and synonyms describing the subject matter to be searched;

- c. the search statements used and results returned (i.e. search history);
- d. a list of the documents considered to be relevant and corresponding comments on their relevance;
- e. any search limitations resulting from claims that lack clarity or support to the extent that no meaningful search can be carried out;
- f. any indications regarding unity of invention; and
- g. the reasons for ending the search.

The search record documents the search procedure performed by the examiner, so that others can understand how the relevant documents are derived. This will include documents that are directly relevant to the claims, as well as documents which the examiner anticipates might become relevant later in the patent prosecution process.

WIPO Standard ST.14 is followed for identification and categorisation of any document cited.

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.

The internal quality audits are carried out regularly. The audits are to ensure that the QMS conforms to the ISO 9001:2015 standard. The internal quality audit <u>iwas</u> conducted in a way that all documents under audit <u>arewere</u> only accessed securely <u>oin</u> office premises, by auditees or auditors.

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.

IPOS supports the reporting arrangements on the QMS by the ISA/IPEA as required under Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.

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