

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

[ANNUAL](#) 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)

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

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

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings

The Intellectual Property Office of Singapore (IPOS) has implemented a quality management system for its patent search and examination functions that conforms to the ISO 9001 standards. The certification according to the ISO 9001:2008 standards ~~is expected to take place in September 2014~~ [has been attained on November, 03, 2014.](#)

1. LEADERSHIP AND POLICY

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

- (a) The quality policy established by top management.*
- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.*

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 improve our systems, practices and programs 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 and reliable, delivered in an efficient and pragmatic 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 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

Products and services are delivered efficiently when they are delivered in a timely manner. We are committed to delivering first office actions within 6 months and not allow any backlog to build up. We have been meeting this commitment.

IPOS has a monitoring system that reflects the pendency of all office actions in real-time. Reviews are conducted weekly to ensure that all office actions are issued within set time limits. 2 weeks before any case becomes due, individual emails will be sent to the examiners to alert them of time-limit conformity.

Pragmatic

IPOS expects the examiners to take a pragmatic and common-sense approach to deliver the products and services in the best way to the customers.

The quality policy and objectives are described in the S&E Unit QMS. The QMS document is stored and accessible on the Intranet.

The Quality Management Office (QMO) within the S&E Unit coordinates the works on development, implementation and maintenance of the QMS processes. The QMO is formally trained on ISO 9001 Documentation and Implementation and ISO 9001 Internal Auditor Training. Both courses equipped the QMO with the techniques and know-how to carry out an effective internal QMS audit for the organisation.

The QMO organisational structure is presented below.

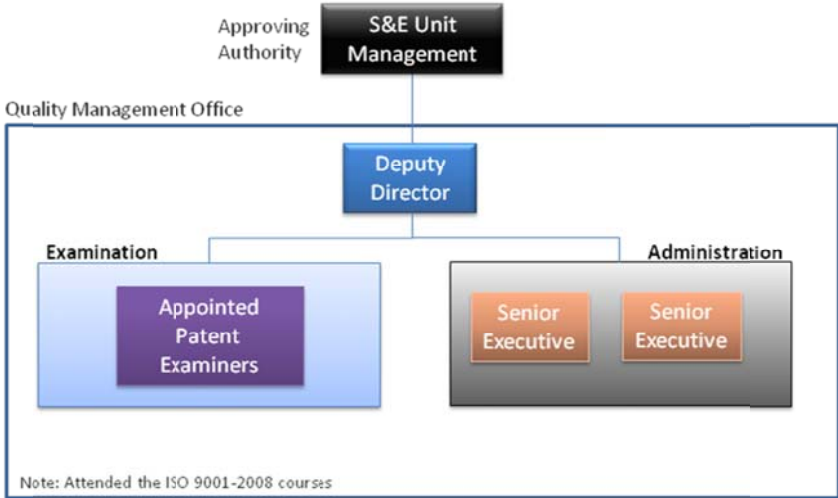


Figure 1: Organisational structure of the S&E Unit Quality Management Office

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

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	✓		
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	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 throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS is based on Chapter 21	✓		
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.17	✓		
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(a)	System in place for monitoring resources required to deal with demand	✓		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channeling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.19		Established communication with WIPO and designated and elected Offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	<u>✓</u>		✓*
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed	<u>✓</u>		✓*
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.22	(a)	Quality policy of the Authority and commitment to QMS	✓		
	(b)	Scope of QMS	✓		
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes	✓		
	(f)	a description of the interaction between the processes and the procedures of the QMS.	✓		
21.23	(a)	Records which documents are kept and where they are kept	✓		
	(b)	Records of results of management review	<u>✓</u>		✓*
	(c)	Records about training, skills and experience of staff			
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits	<u>✓</u>		✓*
	(i)	Records on actions taken re. non-conforming products	✓		
	(j)	Records on actions taken re. corrective actions	✓		
	(k)	Records on actions taken re. preventive actions	✓		
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(i) Recording of the databases consulted during search	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) Recording of keywords, combination of words and truncations during search	✓		
		(iii) Recording of the languages used during search	✓		
		(iv) Recording of classes and combinations thereof consulted during search	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes	✓		
21.26-21.28		Additional information on further inputs to its internal reviews	✓		
21.29		Initial report called for by paragraph 21.29	✓		

~~*Requirement will be complied with by September 2014.~~

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 S&E Unit management reviews the internal audit reports of the QMO and the external audit reports. The QMO conducts the internal audit at least once every 6 months and submits its report consisting of its findings on the QMS and recommendations for corrective/preventive actions. The S&E Unit management will consider the report and adopt, modify or reject the recommendations.

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.*

On behalf of the S&E Unit management, the QMO communicates to the staff the importance of QMS. The communication is conducted via the monthly unit sharing sessions and meetings.

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

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

Please see paragraph 21.06 on management reviews.

Every year, the S&E Unit management will review the results of the current workplan and plan for the next workplan. 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 at the monthly 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 21.25-21.28:

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

The QMO carries out the internal review of the QMS at least once a year. The review results are recorded and reported to the S&E Unit management.

2. RESOURCES

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

21.11 Human resources:

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

As at September 2014, IPOS has 82 full-time patent examiners. All of them have at least a good class honours degree, with 95% having a PhD degree.

The examiners have at their disposal a comprehensive suite of search platforms (EPOQUENet, a commercial patent search platform and a specialised commercial patent search platform for Chemistry and Biotechnology searches), 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.

The number of personnel supporting the examination work is 9.

The S&E Unit management monitors and discusses the matching of human resources with the workload requirements, for both examination staff and administrative staff. The staff is 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. They can be activated should the review by the S&E Unit management determines the need for new hires.

21.12 Human resources:

- (a) Describe the infrastructure in place to ensure that:*

 - (i) appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
 - (ii) at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.*

- (b) Describe how instructions*

 - (i) to help staff understand and adhere to the quality criteria and standards; and;*
 - (ii) to follow work procedures accurately and consistently*

are documented, provided to staff, kept up-to-date and adapted where necessary.

IPOS provides modern IT hardware and up-to-date software for the examiners to carry out their work. Every examiner has a high-specification desktop and two 24-inch monitors. Stable and high-speed internet connection is also provided to allow efficient access to any web-based search platforms. The patent search system described in paragraph 21.11 is an electronic search system accessible in the office of IPOS. Patent application documents that are subject of the search and examination required are stored electronically in IPOS and accessible to the examiners only from their workstations.

All work processes are documented in a set of guidelines that are maintained and stored on the Intranet. For search and examination practices, the examiners are guided by the IPOS Examination Guidelines on Patent Applications that is available on the IPOS corporate website¹, as well as, the Intranet.

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

¹ "IPOS Examination Guidelines for Patent Applications (2014)" can be viewed at http://www.ipos.gov.sg/Portals/0/Patents/Examination%20Guidelines%20for%20Patent%20Applications%20at%20IPOS_Feb%202014.pdf

21.13 Training resources:

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

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

IPOS has a structured and competency-based training programme for its examiners. First, a 6-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 our training. 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, visit other IP Offices, or host Visiting Examiners from other IP Offices.

21.14 Oversight over resources:

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

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

Please see paragraph 21.15.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

One of our quality objectives is to issue reports in a timely manner. We have been delivering first office actions within 6 months. In 2014, we began a pilot to issue first office actions within 60 days for first filings and had been achieving good performance results on this pilot.

To ensure timely issue of search and examination reports, the S&E Unit monitors them based on the performance reports generated from a workflow management system. The 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 weekly by the management to ensure that all search and

examination reports are issued within set time limits. 2 weeks before any case becomes due, individual emails will be sent to the examiners to alert them of time-limit conformity.

Job Type	Application No	Applicant	Internal Due Date	Latest Date to Establish Rpt	Folder location	Status	Assigned To	Admin-Examiner	QC Buddy	BuddyQC	QC Examiner	QC
Assigned To: (50)												
Request for S&E		GABA INTERNATIONAL HOLDING AG	2/09/2014	18/02/2016		1.Assigned		In Progress				
Request for S&E		GABA INTERNATIONAL HOLDING AG	2/09/2014	18/02/2016		1.Assigned		In Progress				
Request for S&E		KEIO UNIVERSITY, DAIICHI SANKYO COMPANY, LIMITED	25/08/2014	28/10/2015		1.Assigned		In Progress				
Request for S&E		1) PREGLEM SA	28/07/2014	30/09/2015		1.Assigned		In Progress				
Request for S&E		1) PRESIDENT AND FELLOWS OF HARVARD COLLEGE 2) CHILDRENS MEDICAL CENTER CORPORATION	28/07/2014	1/01/2016		1.Assigned		In Progress				
Response to WO		IVAX PHARMACEUTICALS IRELAND/TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC	6/07/2014	12/07/2015		1.Assigned		In Progress				
Request for S&E		1) THE JOHNS HOPKINS UNIVERSITY	5/07/2014	6/10/2015		1.Assigned		In Progress				
Request for S&E		1) BIOGEN IDEC MA INC. 2) THE FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH	29/06/2014	7/09/2015		1.Assigned		In Progress				
Request for S&E		UNIVERSITI PUTRA MALAYSIA	29/06/2014	29/08/2015		1.Assigned		In Progress				
Response to WO		SANGAM BIOSCIENCES, INC.	23/06/2014	18/08/2015		1.Assigned		In Progress				
Request for S&E		1) CHUGAI SEIYAKU KABUSHIKI KAISHA	13/07/2014	28/09/2015		2.QC Completed		In Progress		Completed		Completed
Response to WO		IMMUNOVATIVE THERAPIES, LTD.	9/06/2014	13/01/2015		2.QC Completed		In Progress		Completed		Completed
Response to WO		INDENA S.P.A.	9/06/2014	24/02/2015		2.QC Completed		In Progress		Completed		Completed
Response to WO		CALIFORNIA INSTITUTE OF TECHNOLOGY	26/05/2014	28/12/2014		2.QC Completed		In Progress		Completed		Completed
Request for S&E		DJAMGOZ, MUSTAFA, BILGIN, ALI	8/05/2014	13/07/2015		2.QC Completed		In Progress		Completed		Completed

Figure 2: A screenshot of the workflow management system

Every week, the S&E Unit management reviews the workload of the examiners. Preventive and corrective measures would be taken should any deviation be observed or anticipated. Specific measures taken include assigning a complex case to two examiners to work on collaboratively, and more targeted coaching or mentoring by the senior examiners.

4. QUALITY ASSURANCE

21.16 The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:

- (a) An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:
 - (i) for compliance with these Search and Examination Guidelines;
 - (ii) for channeling feedback to staff.
- (b) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.
- (c) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

The S&E Unit QMS system has 2 quality assurance measures: (1) an internal feedback process and (ii) an external feedback process.

In the internal feedback process, there is a triple-check process for corrective actions for each search report ("SR"), written opinion ("WO") or examination report ("ER"). Without the approval of the senior examiners, the products cannot be sent to the applicants. The triple-check process is as follows:

- a. A quality check performed by the examiner himself/herself – 100% of the search strategy and the decisions made by the examiner. The examiner will send his/her SR/WO/ER to the appointed buddy examiner for quality check.
- b. A quality check performed by the buddy examiner (buddy QC) – 100% of the decisions made by the examiner. The buddy examiner will check the logic of the arguments and the formalities, before sending the files back to the examiner with his/her comments. The Examiner amends the SR/WO/ER based on the comments, and sends it to the senior examiner for final quality check.
- c. A quality check performed by the senior examiner – 100% (to be reduced progressively to 5%-10% at steady state). The senior examiner will send the SR/WO/ER back to the examiner if there are queries, and this process is iterative. Otherwise the senior examiner will approve the release of the SR/WO/ER and submit a copy of the Quality Check form to the QMO.

The QMO collates and analyses the Quality Check forms, identifies the issues that need to be addressed in a report to the S&E Unit management. Upon the management's endorsement, the Examination Standards Office, the Training Cadre or the Operations Team will follow-up 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/Attorney will be referred to the Quality Management Office. In turn, the QMO will collate and analyse the feedback and complaints, identify the issues that need to be addressed, and recommend appropriate action. Upon the management's endorsement, the Examination Standards Office, the Training Cadre or the Operations Team will follow-up thereafter. The Examiners will be updated on the actions to be done or carried out. The Customer Service or the Registry will be informed on the outcomes. The Applicant/Attorney will be updated on the outcomes so as to close the loop. In the event that there is a need for our Examiner to communicate directly with the Applicant/Attorney, a meeting with an appropriate agenda will be convened. A process diagram to illustrate the internal feedback process and one for the external feedback process are in Figure 3.

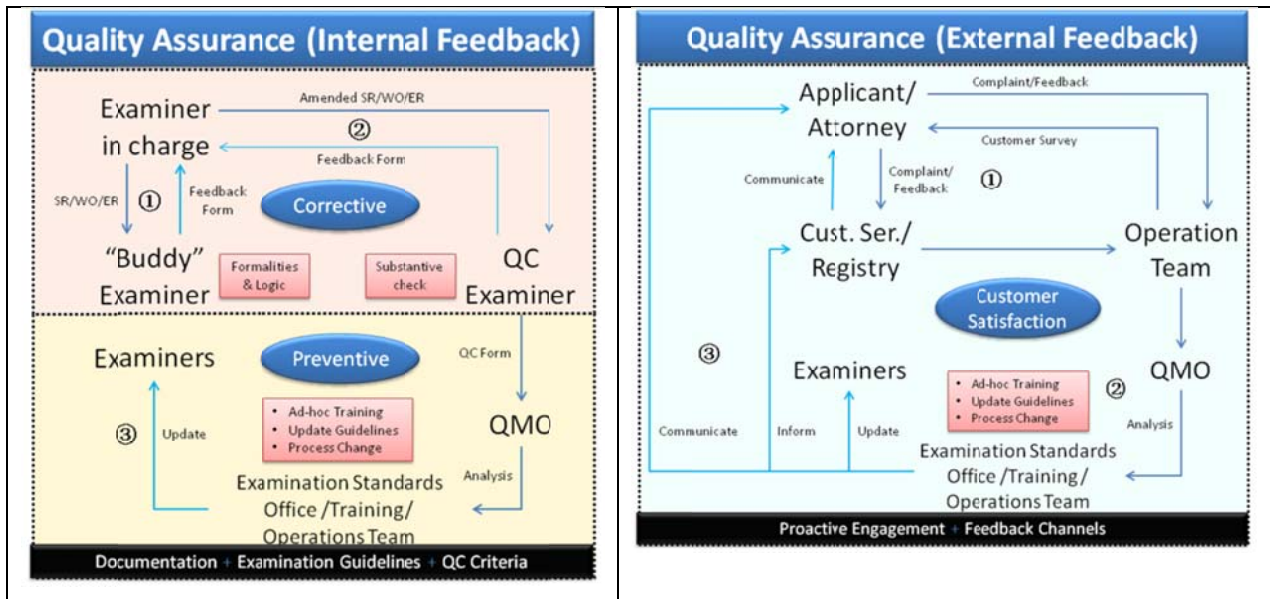


Figure 3: Diagrammatic representation of the quality assurance internal feedback and external feedback processes

5. COMMUNICATION

21.17 Inter-Authority communication:

Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- (a) helping identify and disseminate best practice among Authorities;
- (b) fostering continual improvement; and
- (c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

Mr. Dexter Teo (dexter_teo@ipos.gov.sg), Deputy Director of the S&E Unit, who is in-charge of the operations of the unit, is the designated contact for this purpose.

21.18 Communication and guidance to users:

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

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

Annually, IPOS sends our patent examiners to attend the international conferences and events and also to visit foreign patent offices to improve communication and understand the latest development in IP, especially in the area of patents.

IPOS's corporate website regularly announces its IP courses and programmes available, so that the users/public can register and attend these activities whenever available.

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.

IPOS conducts annual customer satisfaction survey with its customers to solicit feedback and improvement to the patent system in Singapore, and the survey also helps to determine the demands and satisfaction level of the patent applicants and attorneys.

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

Based on the information analysis received from the applicants, attorneys and public, the management of IPOS and the S&E Unit take actions to address any shortcomings and will continue to improve on the procedures and processes wherever applicable.

IPOS has published on its website information on the filing process for a Singapore patent application, the search and examination procedures in the form of Examination Guidelines for Patent Applications at

IPOS, and about its quality management system². IPOS has established links in 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 under PCT with reference to the WIPO website.

² Information on these can be viewed at www.ipos.gov.sg.

21.19 Communication with WIPO and designated and elected Offices:

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

The Deputy Director of the S&E Unit who oversees the operations of the unit will handle the communication with WIPO and designated and elected offices. In particular, all quality matters and communication to customers (including WIPO and other Authorities) are managed by him.

6. DOCUMENTATION

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

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

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

For the purposes of this report indicate:

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

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

- a. Receiving requests and carrying out S&E work;
- b. 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. managing of oppositions and feedback concerning the issuance of the opinions and reports;
and
- e. measuring, analysing and improving the overall S&E processes.

The QMS document sets out the requirements to the S&E Unit QMS and contains its description to the following core processes:

- a. the Search Request;
- b. the Examination Request;
- c. the Supplementary Examination Request;
- d. the Response to the Written Opinion Process; and
- e. the Non-Conformity (NC) Process.

The QMS document is available both on paper and Intranet.

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

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

The S&E Unit QMS document consists of the following chapters:

- a. quality policy;
- b. quality objectives;
- c. quality manual;
- d. QMS documented processes;
- e. schedules;
- f. organisational chart; and
- g. record.

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

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

According to the ISO 9001:2008 standards, the S&E Unit creates and maintains the following documents:

- a. quality manual;
- b. records on procedures for quality provision;
- c. records on management review and results;
- d. records on personnel training, conference and seminars attended;
- e. records on staff qualification and experience;
- f. records on quality control of the product;
- g. records on conformity of the S&E processes;
- h. records on the results of S&E for each patent application; and
- i. summary of the S&E quality and follow-up actions.

7. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

(a) which of the following are included in this record:

- (i) the databases consulted (patent and non patent literature);*
- (ii) the keywords, combinations of words and truncations used;*
- (iii) the language(s) in which the search was carried out;*
- (iv) the classes and class combinations searched, at least according to the IPC or equivalent;*
- (v) a listing of all search statements used in the databases consulted.*

(b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.

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

(c) which special cases are documented and whether records are kept denoting any:

- (i) limitation of search and its justification*
- (ii) lack of clarity of the claims; and*
- (iii) lack of unity.*

The examiners make a record of their search process and store them in the corporate 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:
 - i. classification of the subject matter to be searched e.g. IPC (for searches in EPOQUENet and other 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.

8. INTERNAL REVIEW

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

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

The S&E Unit's internal QMS audits will be carried out twice a year. External audit is scheduled once every 2-3 years. The audit is to ensure that the QMS conforms to the ISO 9001:2008 standards.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.29 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.29, and supplementary annual reports in accordance with paragraph 21.30. At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

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

[End of document]