

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by *INDIAN PATENT OFFICE*

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

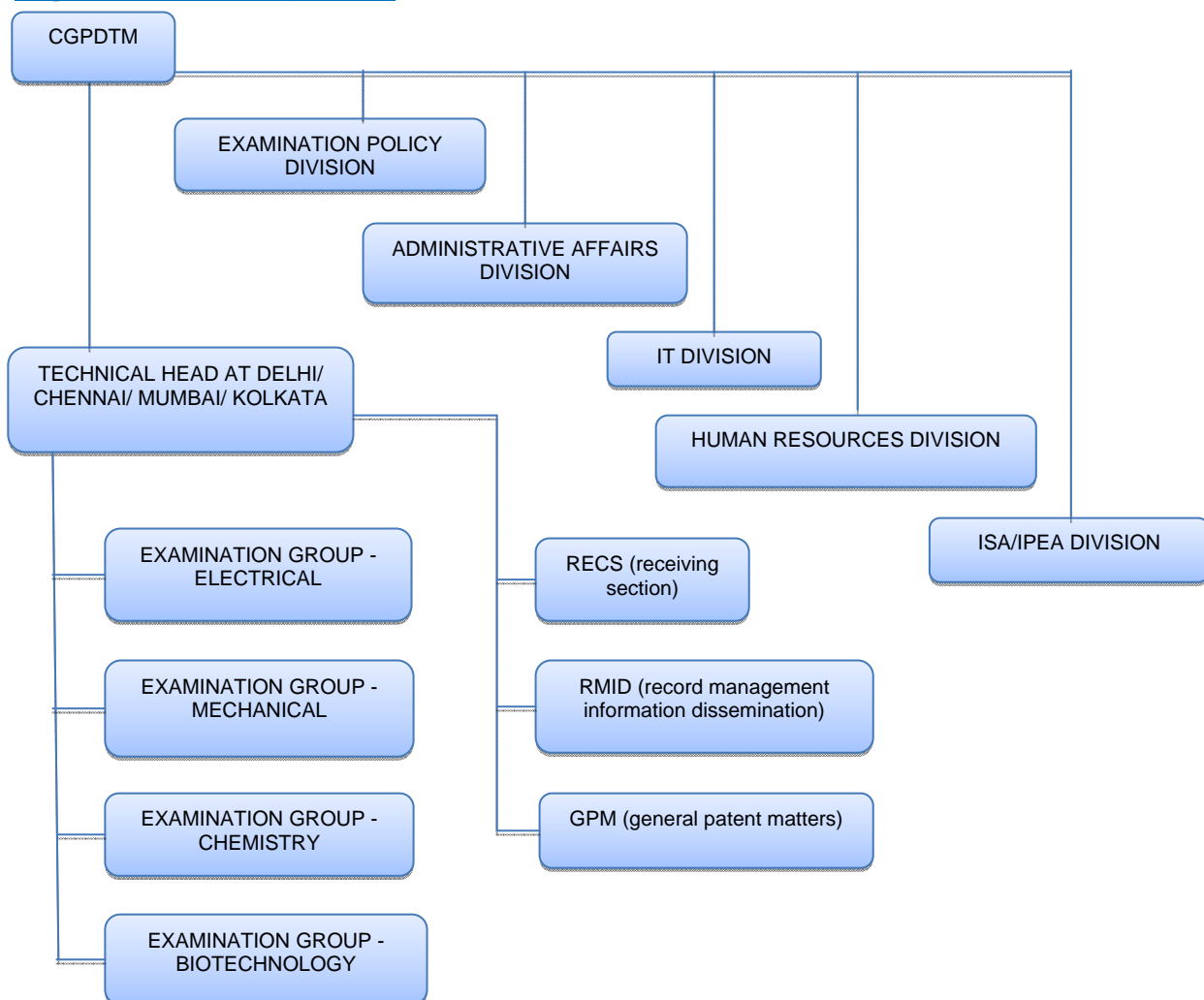
The Indian Patent Office (IPO) is part of the office of the Controller General of Patents, Designs and Trademarks (CGPDTM) under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India and is responsible for the grant of patents in India.

The Patents Act 1970 was amended to fulfill the obligations of international agreements and treaties to which India became a party. The Government of India invested on infrastructure, both physical and manpower during the past decade, establishing a strong intellectual property regime in the country.

The Indian Patent Office was recognized as an International Searching Authority and International Preliminary Examining Authority under the PCT and started functioning from 15th October 2013. IPO has access to a comprehensive collection of patent and non-patent literature that covers the PCT minimum documentation. Professionally qualified and skilled Examiners are assets of IPO.

IPO has established a Quality Management System covering technical and administrative tasks of the office. Fully electronic processing system ensures speedy disposal and dissemination of information on real time basis. Steps have been initiated by IPO to make the QMS fully compliant with Chapter 21 of the Guidelines for Authorities under the PCT. A Quality Manual is being drafted for compliance by all members of IPO.

Organizational set up of IPO



1. LEADERSHIP AND POLICY

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

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

The Quality Management System for the Indian Patent Office is established by the Controller General. The unit of IPO that is responsible for the Quality Management System is the Quality Management Committee (QMC) of IPO which is headed by the CGPDTM. The QMC is composed of representatives of Examination Policy Division (EPD), Administrative Affairs Division (AAD), Human Resources Division (HRD), IT Division (ITD) and the ISA/IPEA Division.

The QMS is documented and contains the Quality policy in the form of Vision and Mission of IPO. It defines the roles of each Division responsible for QMS.

The Examination Policy Division (EPD) heads all the technical examination Groups of IPO at all India level and is responsible for establishing and updating guidelines for search and examination, ensuring capacity building and bringing in uniformity and consistency in practice followed by the Examiners and Controllers at all locations of IPO. It is also responsible for planning the disposal of applications to reduce backlog. The EPD monitors the review reports of quality of the four Examination Divisions at all locations of IPO.

The supporting divisions that manage the digitization and records are monitored and controlled by the Administrative Affairs Division (AAD). It monitors the implementation of the Document Management System in IPO. The AAD is also responsible for maintenance of IP records in the IPO. Separate wing is constituted to implement the Document Management System for International applications that includes receipt of applications, scanning, data entry and verification of data for international applications. The AAD trains the officers and staff posted at the supporting divisions.

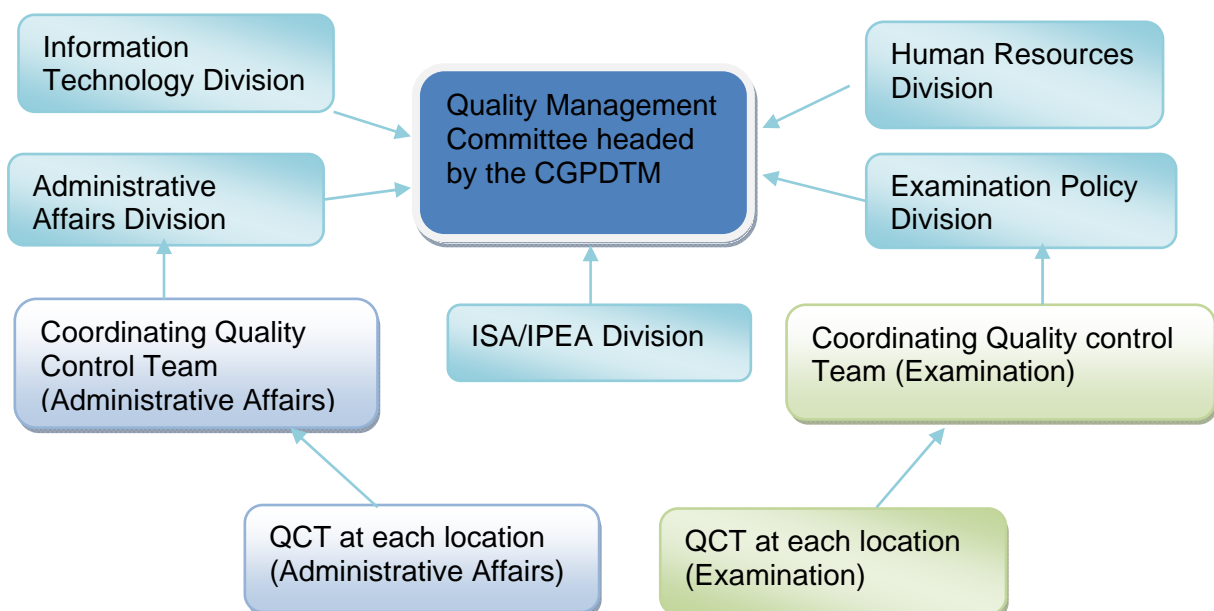
The (Human Resources Division) HRD maintains the records of qualification, experience and training of the staff of IPO.

The (IT Division) ITD is responsible for software development for the electronic processing of applications and also for management of the database. The ITD builds changes in the processing software to reduce errors while processing and to facilitate reforms. It ensures real time dissemination of information as well as transparency within the organization and to the public.

The ISA/IPEA Division addresses the requirements to function as ISA/IPEA. It ensures that the Guidelines for international search and examination are followed correctly and also imparts training to the staff entrusted with the tasks as ISA/IPEA. It manages the Formality Division of ISA/IPEA.

The goals of IPO in terms of our quality policy is reflected in Vision and Mission of IPO available on IPO website www.ipindiaservices.gov.in

Organizational set up for QMS



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]

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)	determine the extent to which the QMS is based on Chapter 21	✓	✗	
		determine the extent to which S&E complies with PCT Guidelines	✓	✗	
	(c)	an objective and transparent way	✓	✗	
	(d)	using input incl. information according paragraph 21.24	✓	✗	
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
	(i)	Infrastructure in place to ensure that a quantity of staff			
	(a)	sufficient to deal with the inflow of work	✓		
	(b)	which maintains tech. qualifications to S&E in all technical fields	✓		
	(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)	Infrastructure to provide a quantity of skilled administrative staff		✗	
	(a)	at a level to support the technically qualified staff	✓	✗	

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

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(iii)	Clear and concise guidance on the S&E process for the user		✓	
	(iv)	Indication where and how the Authority makes its quality objectives publicly available		✓	
21.16		Established communication with WIPO and designated and elected Offices	✓		
21.17		QMS of Authority clearly described (e.g. Quality Manual)		✓	
21.18	(a)	Documents making up the Quality Manual have been prepared and distributed		✓	
	(b)	Media available to support the Quality Manual			✓
	(c)	Document control measures are taken			✓
21.19	(i)	Quality policy of the Authority and commitment to QMS	✓		
	(ii)	Scope of QMS		✓	
	(iii)	Organizational structure and responsibilities		✓	
	(iv)	the documented processes are carried out in the Authority		✓	
	(v)	Resources available to carry out processes and implementing the procedures		✓	
	(vi)	a description of the interaction between the processes and the procedures of the QMS.		✓	
21.20	(i)	Records which documents are kept and where they are kept		✓	
	(ii)	Records of results of management review	✓		
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes		✓	
	(v)	Results of reviews of requirements relating to products		✓	
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record of QMS audits	✓		
	(ix)	Records on actions taken re. non-conforming products	✓	✗	
	(x)	Records on actions taken re. corrective actions	✓	✗	
	(xi)	Records on actions taken re. preventive actions	✓	✗	
	(xii)	Records referring to search process documentation		✓	
21.21	(i)	Recording of the databases consulted during search	✓		
	(ii)	Recording of keywords, combination of words and truncations during search		✓	
	(iii)	Recording of the languages used during search	✓		

Chapter 21 requirement			Extent of compliance			
			full	part	no	
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted		✓	
	(vi)		Records about other information relevant to the search		✓	
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.22			Report on its own internal review processes	✓	✗	
21.23-21.25			Additional information on further inputs to its internal reviews		✓	
21.26			Initial report called for by paragraph 21.26	✓		

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

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

Organisational set up of QMS shown in report for paragraph 21.04

The **first step** of the review is to determine the extent of achievement of quality objectives .This review is done every month by the Coordinating QC Teams.

The **second step** of review is done by a Committee composed of Group Leaders and Supervisory Controllers of each Examination Group, In-charge ISA, In-charge IPEA and In-Charge Quality Management and Development. This review is done every quarter and is utilized to remedy any shortfall in the implementation and achievement of quality objectives.

The **third step** of review is to review the quality objectives and the QMS itself wherein the organizational setup for QMS, the QMS document, the mechanisms for implementation/review etc., are considered. This is done in the Annual meeting of the Quality Management Committee (QMC).

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.*

Effective communication to staff regarding the importance of quality is done through circulars, meetings, guidelines etc. Copies of PCT Guidelines for Authorities are provided to all concerned officials and the need to abide by quality is stressed during meetings and trainings.

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

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

The Examination Groups are headed by Group Leaders who manage the output of each Group and report to the Technical Head at each location. Review meetings are held in each Group every month. Meetings chaired by the Technical Head with all Group Leaders and members of the Examination Groups are held in every quarter. RECS (Receiving Section), RMID (Record Management Information Dissemination) and GPM (General Patent Matters) also report to the Technical Head at each location. Review meetings are held annually by CGPDTM with the Technical Heads and Group Leaders as well as officers in charge of RECS, RMID and GPM at all locations.

The quality objectives and review mechanisms are documented and made available internally. Quality aspects are inbuilt in the electronic processing software for processing of applications. Auditing and reporting facilities are also built in the software.

The quality objectives themselves are reviewed keeping in mind continual improvement or to remedy any shortfall. This review is done during quarterly meetings of the QMC.

Effective communication to staff regarding the importance of quality is done through circulars, meetings, guidelines etc.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));
to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));*
- (c) in an objective and transparent way (cf. paragraph 21.22);*
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.25).*

The QMS is reviewed wherein the organizational setup for QMS, the QMS document, the mechanisms for implementation/review etc., are considered. This is done in the Annual meeting of the QMC.

2. RESOURCES

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

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work;

which maintains the technical qualifications to search and examine in the required technical fields; and

which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

The Examiners are qualified and possess different subject specialization. The work of Search and Examination are done by the subject experts depending on the technical content of the applications processed by IPO. The Examiners are given technical training in emerging fields through lectures. All Examiners are proficient in English language.

Training is imparted to staff to support the Examination Divisions in making available prints of documents and also to manage inflow and outflow of documents.

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.

A core Committee on IT composed of Examiners and Assistant Controllers from IPOs of all four locations as well as the IT Division makes assessment about the requirements for hardware and software at all locations. The Committee decides the software as well as the specifications of hardware to be procured and used at all locations of IPO so that uniformity in standards is maintained.

IPO has access to PCT minimum documentation. IPATS, a search tool to conduct search on Patent and non-Patent literature comprehensive to cover the minimum documentation is being

developed by IPO. Search Process Documentation is also a feature of IPATS, the in-house search system of IPO. It includes the details like the databases consulted (patent and non-patent literature); the keywords, combinations of words and truncations used; the language(s) in which the search was carried out; the classes and class combinations searched, at least according to the IPC or equivalent; and a listing of all search statements used in the databases consulted.

Instructions to eliminate errors and to maintain quality are built into the in house processing software for ISA/IPEA operations.

Effective communication to staff regarding the importance of quality and to follow procedures accurately and consistently is done through circulars, meetings, guidelines etc.

Training resources:

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

acquire and maintain the necessary experience and skills; and

are fully aware of the importance of complying with the quality criteria and standards.

The Examiners are given initial training of 3 months duration immediately after induction as Examiners. This is followed by on the job training for eight months under the supervision of a senior Examiner. Refresher training is given during the last one month of the first year. Training programs are conducted at the Rajiv Gandhi National Institute for Intellectual Property and Management located at Nagpur, India.

Training is imparted to staff to support the Examination Divisions in making available prints of documents and also to manage inflow and outflow of documents.

The Controllers are given judicial training to help them perform their quasi-judicial functions effectively.

Trainings are also imparted to Examiners and Controllers by experts from other patent offices functioning as ISA/IPEA and from the WIPO. Special training for Examiners is also conducted in respect of International Patent Classification.

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

The work in the Examination Groups is continuously monitored by the Group Leaders who report the changes in demand to the Technical Head. Quality assessment is also done by the Group Leaders. The work of Examiner is supervised by Controller for correctness and quality. Digitization reports are generated for the quantum of inflow and outflow from the Receipt Section to analyze the timely digitization of documents. These reports are reviewed by the Controller in charge of the Receipt Section at each of the locations of IPO and the manpower is adjusted to cope up with the demand. The Review report and the changes are reported to the Technical Head at each location.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

When an international application is allotted for international search/ preliminary examination, the Examiner is also provided with a time limit sheet which guides the Examiner regarding the time limits to be followed for issue of invitations and notifications as well as the ISR/WO/IPER. Please see report on paragraph 21.14

4. QUALITY ASSURANCE

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

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

As per the work flow decided for ISA/IPEA, the ISR/WO/IPER or the declaration that no ISR will be established is supervised for correctness and quality by a Supervisory Controller and again by the Group Leader before issue by Examiner, in respect of all PCT international applications. Since September 2015, there has been a change in the quality assurance process in ISA/IPEA. The reports prepared by the Examiner are checked for correctness and quality by a supervisory Controller in each of the four Technical Examination Groups. The Examiners generate the reports after approval by the Supervisory Controller of the Group. A central Quality Cell has been constituted in September 2015 to conduct post generation quality checks on all the reports before issuing them to the applicants and the IB. In case of non-conforming products, the Quality Cell intimates the Examiner and Controller and the remedial actions are taken before issuing the reports. The Quality Cell also has the responsibility to sensitize the Examiners for corrective/preventive steps. The records relating to non-conforming products, corrective and preventive actions are maintained for future reference.

-Quality Teams composed of Examiners are constituted for each of the Examination Groups at all locations of IPO. There are 4 Examination Groups namely, Chemical, Bio-technology, Mechanical and Electrical Groups at each of the locations. Thus there are QT-C, QT-B, QT-M and QT-E at IPOs at Delhi, Chennai, Mumbai and Kolkata. These Quality Teams randomly select patent applications at the beginning of a month which are examined by the Examiners of the Group and conduct search and examination independently for quality audit. The feedback is given to the Examiner who examined the case.

The drawbacks noticed during quality audit are followed up to remedy them. Reports and suggestions for improvement are submitted by the Quality Teams of each Group to the Group Leader of the Group and a consolidated Report with recommendations is sent by the Group Leader to the Technical Head. Copies of this consolidated report are sent also to Group Leaders of the same Group and the Technical Heads at other three locations. This aids in establishing uniformity among Examiners working at different locations.

5. COMMUNICATION

Inter-Authority communication:

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

(Note: This point is informative. No response is required by the template to paragraph 21.13)

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

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

Name of designated quality contact person: Ms. Rekha.V

Job title: Assistant Controller of Patents and Designs

Contact details: Boudhik Sampada Bhawan, Sector 14, Dwarka, New Delhi-110078, India

Email: rekha.ipo@nic.in, Contact +911125301227

Communication and guidance to users:

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

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

The Technical Head at each location is the contact person for stakeholders for handling complaints and making corrections.

A separate Public Facilitation Centre for ISA/IPEA operations is functioning in IPO for assisting the stakeholders. The stakeholders can lodge complaints/grievances to the officer in charge of the Public Facilitation Centre of ISA/IPEA.

CGPDTM holds Stakeholder meetings in every quarter at all locations to have face to face interaction with stakeholders and to take suggestions.

The goals of IPO in terms of our quality policy are reflected in Vision and Mission of IPO available on [IPO website www.ipindiaservices.gov.in](http://www.ipindiaservices.gov.in) ISA/IPEA link provided on the home page of www.ipindia.nic.in

21.16 Communication with WIPO and designated and elected Offices:

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

The Head of ISA/IPEA Division of IPO is responsible for communication with WIPO and Designated/ Elected offices. WIPO circulars and feedback are promptly addressed.

6. DOCUMENTATION

21.17 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

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

For the purposes of this report indicate:

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

A Quality Manual is under documentation in the office. Currently, effective communication to staff regarding the importance of quality is done through circulars, meetings, guidelines etc. The quality objectives and review mechanisms are documented and made available internally. Quality aspects are inbuilt in the electronic processing software for processing of applications. Auditing and reporting facilities are also built in the software. Quality Teams and quality audit reports are communicated to all concerned.

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

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

The Quality Manual that includes all details is under documentation by the office. Quality policy, scope of QMS, organizational structure, and instructions to maintain quality in all processes are communicated to all concerned through circulars, office orders and meetings.

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

- (i) a definition of which documents are kept and where they are kept;
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 7.

The documents kept and where they are kept are documented and kept in the office of CGPDTM. The results of management review are also kept in the records of the office of CGPDTM.

Training, skills and experience of personnel is maintained in the Human Resources Division of the office of CGPDTM.

Evidence of conformity of processes, resulting products and services in terms of quality standards are recorded in the quality review reports of different works. Results of reviews of requirements relating to products are also maintained. This is maintained in the Quality Management Division of office of CGPDTM.

All details regarding search and examination processes carried out on each application as well as data allowing individual work to be tracked and traced are stored automatically as per the electronic processing software for ISA/IPEA operations.

Records of QMS audits, corrections, preventive action etc. are maintained in the Quality Management Division of office of CGPDTM.

7. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

- (a) which of the following are included in this record:
 - (i) the databases consulted (patent and non patent literature);
 - (ii) the keywords, combinations of words and truncations used;
 - (iii) the language(s) in which the search was carried out;
 - (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
 - (v) a listing of all search statements used in the databases consulted.
- (b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.
(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)
- (c) which special cases are documented and whether records are kept denoting any:
 - (vi) limitation of search and its justification
 - (vii) lack of clarity of the claims; and
 - (viii) lack of unity.

The details like databases consulted and search strategy are to be provided for each application by the Examiner as per the workflow of the electronic processing software.

Search Process Documentation is also a feature of IPATS, the in-house search system being developed. It includes the details like the databases consulted (patent and non-patent literature); the keywords, combinations of words and truncations used; the language(s) in which the search was carried out; the classes and class combinations searched, at least according to the IPC or equivalent; and a listing of all search statements used in the databases consulted.

Limitation of search and its justification; lack of clarity of the claims; and lack of unity are stored in the in-house electronic processing software for ISA/IPEA operations.

8. INTERNAL REVIEW

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

21.23-21.25 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

Quality Management Committee conducts annual review meeting chaired by CGPDTM to review the compliance and adequacy of the QMS.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

This is the report called for by paragraph 21.29 for the year ~~2014~~ [2015](#).

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