PATENT COOPERATION TREATY

Common Quality Framework for
International Search and Preliminary Examination

Report Under Paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines

by: Nordic Patent Institute (NPI)

on: ***25January 2008***

Documents referred to in this report:
Quality Managing Manual of Nordic Patent Institute. Level 1 of the Manual is available on http://www.npi.int/About-us/Quality-Management/

[list any documents which appended to the report for information or publicly available documents which are referred to]

Each Authority must provide information with respect to its Quality Management System (QMS) arranged under the main headings as set forth in this template. The descriptions in this template below each main heading 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.

This template is to be used for a main report under paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines. Updating reports may thereafter usually be presented in abbreviated format using template T21-18.

INTRODUCTION (PARAGRAPHS 21.01–21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:

- *Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.*

NPI has established a Quality Management System (QMS) which is intended to operate according to ISO 9001 standards. It is the intention of NPI to apply for certification of its QMS under the ISO 9001 system. The system covers all services offered by NPI.

- *An organigram showing at least the organisational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.*

The organigram can be found in sections 1.1.3 to 1.1.5 of the Quality Manual: http://www.npi.int/About-us/Quality-Management/

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

(a) sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E);

(b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.

(a)

The NPI QMS generally consist of three components:

a. Quality standards for Search & Examination work

b. A quality management system including procedures, tools, manuals, training, competences, communication, procedures for measuring quality, etc.

c. A review mechanism for monitoring compliance with quality standards

Search and Preliminary examination of PCT applications will be carried out by staff of the Danish or Norwegian patent offices on behalf of NPI.

NPI has Order Agreements with the Danish Patent Office and the Norwegian Industrial Property Offices governing the work carried out on behalf of NPI in accordance with the PCT guidelines.

The NPI quality assurance system is based on the national quality systems in Denmark and in Norway, witch both are certified under the ISO 9001 system.

The Order Agreements between NPI and the Danish Patent Office and the Norwegian Industrial Property Offices specify exact requirements for the quality management system in the national patent offices of Denmark and Norway.

The national quality systems in both Norway and Denmark, and the NPI quality system, are described and maintained in electronic form.

Since Iceland will not perform any searches or examinations on behalf of NPI, the quality management system of NPI does not contain provisions concerning search and examination carried out by Iceland.

(b)

The quality standards and practices in the national quality systems and the embracing NPI quality system are harmonized with respect to any PCT work and are brought in full compliance with the standards and practices established by the PCT and applied by the EPO.

Resources - infrastructure (Paragraph 21.05)

Provide information about the infrastructure in place which ensures the following:

(a) Adequate quantity of search and examination (S&E) staff, including:

(i) means for matching the quantity of S&E staff to the inflow of work;

(ii) means for ensuring that recruited S&E staff have the necessary technical qualifications;

(iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.

(b) Adequate quantity and skills of administrative staff to support S&E.

(c) Provision of appropriate equipment and facilities to support S&E.

(d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.

(a)
(i)
The Danish Patent Office has approximately 90 examiners and the Norwegian Industrial Property Office has approximately 75 examiners. Most examiners of the two offices are employed on a full-time or almost full-time basis and are predominantly occupied with search and examination and related tasks such as training of examiners.
The examining divisions of both offices are roughly similar and comprise of a total of approximately 30 examiners in each of the divisions Electricity & Physics, Machinery, Biotechnology, and Organic Chemistry, a few less in Industrial Chemistry, and approximately 15 in each of the divisions Construction and Foodstuff & Healthcare.
The examiners are all experts in their own branch of technology and allocated to specific technical areas. A large number of examiners have many years of experience in the patent field. The density of examiner qualifications within the various technical disciplines obviously reflects the structure of national industry. However, in general, all technical areas are covered in each office, and together the two offices cover of all technical fields more than adequately.

(ii)means for ensuring that recruited S&E staff have the necessary technical qualifications;

(ii)
The examiners hold a university degree in technology or natural science and in some cases further postgraduate degrees such as DSc, PhD or equivalent.

(iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.

(iii)
In addition to their ability to understand Danish, Norwegian and Swedish, all examiners have an excellent knowledge of English and good skills of the German and French languages. The examiners work stations includes electronic dictionaries and translating software. Some examiners are also skilled in the Spanish, Russian, Turkish and Persian languages. Additional language training for examiners is provided if necessary.

(b) Adequate quantity and skills of administrative staff to support S&E.

(b)
The NPI has an adequate and qualified staff to support the search and examination process in both Denmark and Norway. Administrative staff is continuously receiving relevant training when needed.

(c) Provision of appropriate equipment and facilities to support S&E.

(c)

NPI has a modern IT infrastructure, and IT-tools used by the examiners and other staff of the national offices to support the search and examination process are of high and modern standard. This includes workflow based IT-case processing systems and access to the most comprehensive databases for search purposes.

(d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.

(d)

Searches are mainly conducted online by using the same databases and search systems as used by the EPO. The most important databases are EPODOS, WPI, PAJ and INSPEC accessed via the EPOQUE search tool. Other important document databases are accessed for instance via Dialog and STN. Examiners also use full text databases in various languages and other databases containing articles and other non-patent literature

The collection of patent documents and other publications in paper form is very comprehensive and is used whenever appropriate.

The NPI has full access to PCT-minimum as referred to in Rule 34.

(e) Provision of up-to-date work manuals. These must include explanations of:

All examiners have on line access to PCT Guidelines and PCT Regulations. Both the Danish Patent Office and the Norwegian Industrial Property Offices have extensive manuals for all parts of the patent process, including in particular guidelines with respect to search, examination and communication with applicants. Permanent working groups specifically dedicated to improvement of tools and procedures, quality control, and initiation of corrective action in response to feedback from the quality control have been established. Harmonization work between the two offices has been established in order to harmonize the tools and procedures in the offices. The objective is to ensure that search and examination of any application will lead to the same result irrespective of the office performing the task.

As a further step of harmonisation, the quality standards, practice, tools and (where appropriate) procedures will be harmonised with the procedures applied at the EPO.

Procedures and systems relating to timeliness of search and examination and for coping with fluctuations in workload are available.

(i) quality criteria and standards;

The NPI Quality Manual includes the quality criteria and standards.

(ii) descriptions of work procedures;

The work procedures are described in the NPI Quality Manual and Quality Systems of the NPOs.

(iii) instructions ensuring that the work procedures are adhered to.

The quality systems in both the Danish Patent Office and the Norwegian Industrial Property Offices includes procedures for ensuing that the work procedures are adhered to. This is done by regular review mechanisms including audits and quality control.

(f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and familiarity with work manuals.

New examiners are trained and supervised by a senior examiner for about 18 months. The senior examiner acts as personal tutor and is responsible for all decisions by the new examiner during the processing of an application. During the time of apprenticeship, the new examiner takes part in in-house training programmes that gives her or him a deep insight in the patent processing procedure including the various legal aspects of patent law and the capability of performing searches. The training programmes also give the new examiner an understanding of the patent system in a wider perspective such as the role of patents as an economical tool for enhancing innovation and as a strategic business tool for companies.

All examiners are kept updated with respect to amendments of the relevant legislation, and changes in practice and procedures. There are also regular training activities on improved search tools, etc.

Examiners will only be authorised to make decisions on their own after a thorough verification of their qualifications and skills.

An examiner who has been authorised to make decisions carries out search and examination of patent applications without detailed supervision. However, with respect to opposition procedures and

in certain other instances, decisions involving refusal of the granting of a patent must always be discussed with and approved by a senior examiner.

Examiners may be promoted through several standardised steps on a scale of qualifications. Before any promotion, the examiner's qualifications are tested against the required targets.

Examiners are invited to participate in seminars and courses in their respective technological fields in order to maintain and update their qualifications at a high level.

(g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

The NPI Quality Organization and the Management in the two patent offices continuously monitors the resources required to deal with any quality demand.

Administration - procedures (Paragraphs 21.06(a) and (b))

Provide information on those administrative procedures and control mechanisms which ensure the following:

(a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.

(b) Coping with fluctuations in demand and backlog management.

(a) The NPI quality organization receives on regular basis reports on results from the monitoring of all the relevant due dates handled of the national quality systems in Denmark and Norway.

(b) The Management in each office continuously monitors both the fluctuations in demand and possible backlogs to ensure there at any time are enough resources available.

Information mentioned in (a) and (b) can be extracted form an IT case handling system, and reports concerning this information are generated for management

Quality Assurance Procedures (Paragraph 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance with PCT/GL/ISPE are issued. In particular, provide information on:

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

(b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

(c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:

(i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards;

(ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

(a)

Both the Danish Patent Office and the Norwegian Industrial Property Offices have extensive manuals for all parts of the patent granting process, including in particular guidelines with respect to search, examination and communication with applicants as part of the QA-system certified after ISO 9001:2000. The guidelines are including the PCT guidelines.

The QA-system includes internal audits and reviews and reports to the NPI QA-head and the NPI quality managing group.

(b)

The NPI Quality managing group analyses and monitors the performance of the QA system and assesses its conformity with Chapter 21 and ISO 9001:2000.

(c)

(i)

Deficiencies of products are corrected when detected by quality checks according to the ISO-certified systems in the Danish Patent Office and the Norwegian Industrial Property Offices.

(ii)

To eliminate the causes of deficient S&E-work, the QA-groups in the Danish Patent Office and the Norwegian Industrial Property Offices will harmonize and update the patent manuals and implement the new procedures into training and information.

An internal system to encourage new ideas for improvement is part of the QA-system both in the Danish Patent Office and the Norwegian Industrial Property Offices.

(d)

Under the ISO-certified QA-system both in the Danish Patent Office and the Norwegian Industrial Property Offices, there are QA-groups that have as the main task to continuously improve the patent process, including all part of the PCT-process, in order to achieve products in compliance with regulations, standards and customers needs. Full harmonization between the Danish Patent Office and the Norwegian Industrial Property Offices in the PCT patent process is a task for the different QA-groups and the NPI QA-head.

In addition to this all staff can file suggestions for improvement of the quality management system ensuring a continuously improvement.

Customers satisfaction analyses and customer meetings are performed on a regular basis.

Feedback arrangements (Paragraph 21.08)

Give information on arrangements to:

(a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that:

(i) deficient S&E work is corrected;

(ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;

(ii) best practice is identified, disseminated and adopted.

(b) Accommodate prompt feedback from WIPO, designated and elected offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

(a)

(i)

The Director of NPI receives feedback.

Feedback is communicated to relevant people and necessary actions are taken.

(ii)

The quality management organization of NPI identifies the quality problem and the cause of inconsistency, based on reports from internal review or any kind of feedback. Corrective actions are communicated to all relevant staff.

(ii)

Teams of patent experts in the Danish Patent Office and the Norwegian Industrial Property Office discuss and conclude best practices. Best practice is implemented in training and by drawing up guidelines.

(iii)

Feedback from WIPO is handled by the NPI director or by the PCT units, according to which type off feedback is given.

The PCT units in the Danish Patent Office and the Norwegian Industrial Property Offices have good communication with the WIPO.

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09)

Give information on arrangements to:

(a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

(b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.

(c) Monitor and react to user needs and feedback, including:

(i) measuring user satisfaction and perception;

(ii) handling complaints;

(iii) correcting deficiencies identified by users;

(iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.

(v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;

(vi) ensuring needs and legitimate expectations of users are met.

(a)
The examiners and the supporting staff are available for applicants by e-mail and phone. Meetings are held at the request of applicant.

(b)
The PCT unit in the Danish Patent Office and the Norwegian Industrial Property Office provides detailed guidance for applicants.

The NPI web pages will continuously be improved for better information and guidance for customers.

(c)
Measuring user satisfaction and perception, handling of complaints, correcting deficiencies identified by the users, taking correcting actions, preventive acting and ensuring that needs and expectations of the users are all handled according to the ISO 9001:2000 system.

INTERNAL REVIEW (PARAGRAPHS 21.10–21.15)

Paragraph 21.10 specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Paragraphs 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Paragraph 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are as below.

Required Arrangements for Internal Review (Paragraph 21.10)

The Authority should show that arrangements are in place to ensure that:

(a) An internal review is carried out to determine:

(i) the extent to which a QMS complying with the model of Chapter 21 has been established;

(ii) the extent to which the Authority complies with the requirements of its QMS;

(iii) the extent to which the Authority complies with PCT/GL/ISPE.

(b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.

(c) The internal review takes place at least once a year.

The PCT/GL/ISPE in incorporated in the QA-system in both the Danish Patent Office and the Norwegian Industrial Property Office.

Internal reviews are a formalized part of ISO 9001 and hence the Danish Patent Office and the Norwegian Industrial property Office already have internal reviews at least twice a year.

In addition to the internal reviews, an independent external review will take place at least annually by an external certification company.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17

Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

Paragraph 21.11 states that 21.12 - 21.15 are "proposed as a guide to the basic components of an internal review mechanism and reporting system", and are thus optional. Authorities may respond to the following points to indicate the provisions they have in place for Internal Review.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

(a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point (a) under "Quality Assurance" above].

(b) Arrangements providing information on the effectiveness, and the extent of implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

(a) The QA- head in the Danish Patent Office and the Norwegian Industrial Property Office on regular basis report to the NPI QA-head on observed unconformities and makes proposals for improvements and best practice.

The internal and the external audit system report on the observed inconsistencies and unconformities. Proposals for improvement are reported.

(b) The QA-head in the Danish Patent Office and the Norwegian Industrial Property Office on regular basis report to the NPI QA-head on inconsistencies, unconformities and on the progress of improvements.

External audits will be organized in order to ensure the conformity on NPI QA-system with both Chapter 21 and ISO 9001:2000. The national quality systems in Denmark and in Norway are certified under the ISO 9001:2000.

[End of report]

Quality Management Manual
Nordic Patent Institute

For the Following Processes:

- **Statutory work**
- **Contract work for foreign authorities and commercial enterprises**

Level 1 – Policy, Goals and Organisation

Version dated November 9, 2007

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PREFACE

The cooperation under Nordic Patent Institute (the Institute) shall contribute to stimulating Nordic companies, in particular small and medium-sized enterprises, to innovation and economic growth. This shall be achieved by maintaining and developing the national patent offices as competence centres for Industrial Property Rights in the individual countries, capable of offering customised services of a quality and efficiency which is competitive by international standards.

Another objective of the Institute is to contribute positively to the development of a coherent and efficient European patent system based on the European Patent Convention and on cooperation between the European Patent Office (EPO) and the national patent offices (NPOs), and to offer Nordic users the best possible platform for taking advantage of such European network cooperation.

Cooperation under the Nordic Patent Institute comprises the following services which supplement each other in a synergistic way:

- PCT applications (international search and preliminary examination) and related tasks such as International Type Searches (ITS). Consequently, the Institute acts as an International Authority (IA) under the PCT system (Patent Cooperation Treaty).
- Contract work, i.e. work subcontracted from external patent authorities, and commercial services based on contracts with private customers (large scale contracts as well as contracts on an ad hoc basis in individual cases).

In performing its tasks, the Nordic Patent Institute draws upon the specialist resources of the national patent offices of the contracting parties.

High and consistent quality is an indispensable precondition for the Institute in order to achieve its objectives. The contracting parties have therefore decided to establish a quality assurance (QA) system for the Institute with the following objectives:

1. The quality of the services offered by the Nordic Patent Institute shall be consistent irrespective of who has performed the task on behalf of the Institute.
2. The quality of the services offered by the Nordic Patent Institute shall meet the standards established under the European network cooperation and by the PCT Guidelines.
3. The quality of the services offered by the Nordic Patent Institute shall meet the specifications requested by customers and other interested parties including third parties (society).
4. The quality delivered by the Nordic Patent Institute shall be documented in a way which enhances the objective of attracting contract work on an international market.

The QA system for the Nordic Patent Institute covers the processing of PCT applications in the international phase, International Type Searches requested in national applications, and contract work. It shall be certified according to the ISO 9001 system.

The quality management for the Nordic Patent Institute comprises a policy on quality which applies to the entire Institute.

NN
Director of the Nordic Patent Institute

1. Level 1 – Policy, Goals and Organisation

1.1. ORGANISATION

1.1.1. Architecture of Nordic Patent Institute

The Nordic Patent Institute (the Institute) is an authority controlled jointly by the Norwegian, Danish and Icelandic patent offices. The Institute will collaborate with the national offices in order to carry out its tasks.

1.1.2. Work Structure

The Nordic Patent Institute shall act as PCT authority for the participating states (presently DK, NO, IS) and carry out contract work for foreign authorities and private customers.

The basic structure of the PCT work in the Institute will be explained in the following.

PCT-work will be carried out on behalf of the Institute by the Danish Patent and Trademark Office and the Norwegian Patent Office, who will act as suppliers. The Icelandic Patent Office does not have search and examination capacity and therefore does not carry out substantive PCT work.

Each national patent office (NPO) has a Receiving Office (RO) for receiving PCT-applications (Chapter I). RO is not part of the Nordic Patent Institute. Each RO carries out a preliminary formalities check and collects fees for the applications it receives. It forwards the dossier to the International Bureau of WIPO (IB) and also forwards certain documents (including the search copy of the application) to the international searching authority (ISA). The applicant can choose between the following international authorities: Nordic Patent Institute, EPO or the Swedish Patent Office (PRV).

An applicant can request an International Type Search as part of the procedure for a national patent application at an NPO. The NPO forwards the request to the PCT authority chosen by the applicant (Nordic Patent Institute, EPO or PRV).

An applicant can file a demand for a preliminary examination (Chapter II) directly with an international preliminary examining authority (IPEA).

Hence, the Nordic Patent Institute acts as both ISA and IPEA.

The Nordic Patent Institute has an Order Agreement with each NPO under which the national offices perform the tasks of the International Secretariat (ISEC). ISEC is responsible for further communication with the international Bureau (IB) of WIPO, with the applicant, all PCT formalities tasks and collection of later fees. The IB has overall responsibility for the administration of the PCT system. The IB checks that the formalities pertaining to the system are met, maintains the files, publishes applications and search

reports, etc. The activities of IB are based on communication with the various PCT authorities, in this case the Nordic Patent Institute, as well as with the Receiving Offices.

The Nordic Patent Institute has an Order Agreement with both the Norwegian Patent Office and the Danish Patent and Trademark Office governing the search and examination according to PCT guidelines.

Communication between the Nordic Patent Institute and the NPOs about these tasks is handled by ISEC. This includes all types of formalities as well as reallocation between NO and DK in case of mistakes. Reallocation between NO and DK in case of temporary under-capacity at one office is handled by departmental heads on an *ad hoc* basis. Each NPO updates on a regular basis a list of technical areas for which it on a long term has no capacity available for work for the Nordic Patent Institute. The Institute makes a consolidated list covering all NPOs and the Board of Nordic Patent Institute takes the necessary steps to ensure that there will always be capacity available for work for the Institute in at least one NPO.

Relations between Receiving Office, Nordic Patent Institute, NPOs and International Bureau

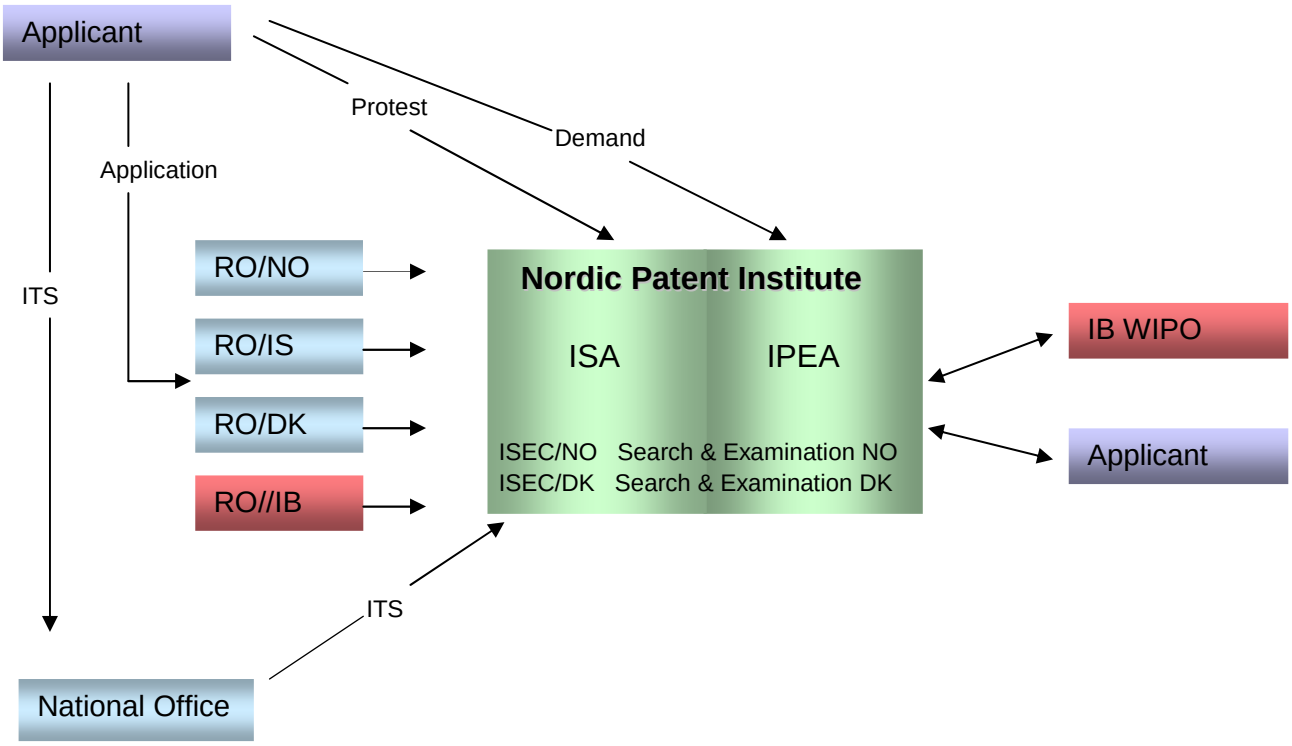


Figure 1 indicates the basic structure of the relations

The ROs receive applications (Chapter I) as described above and forward the application to the Nordic Patent Institute at the request of the applicant. At this stage the application is in an electronic form and is entered into the administrative system of Nordic Patent Institute. Demands for preliminary examinations (Chapter II) are filed directly at Nordic

Patent Institute and requests for International Type Searches are filed at the national office. The subsequent handling of the files is done by the corresponding ISEC in the NPO of the filing country. Applications from Iceland are distributed between NO and DK according to agreement.

ISEC communicates with IB as described above, and allocates the application to the patent division in the NPO for search and examination.

The patent division returns an international search report (ISR) and a written opinion (WO), an International Preliminary Report on Patentability (IPRP) or an International Type Search (ITS) to ISEC.

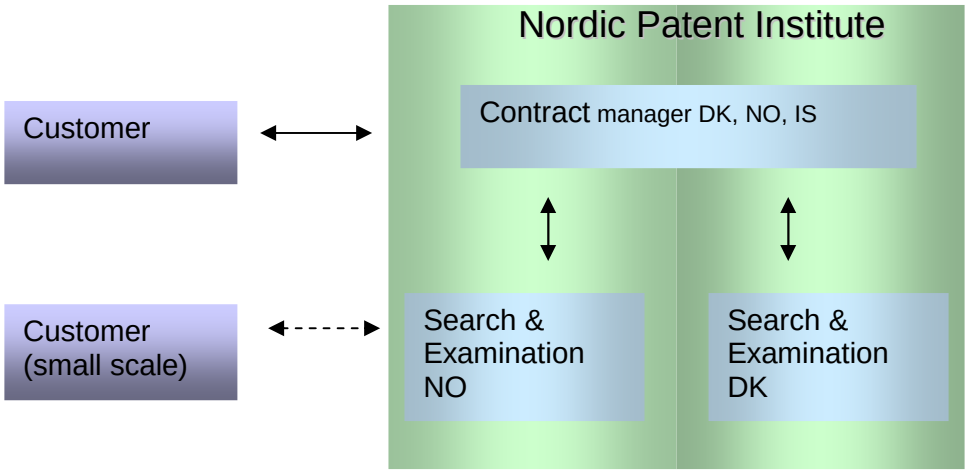
ISEC sends the report to the IB and the applicant.

The applicant can file a protest at the Nordic Patent Institute in relation to a decision on non-unity.

The basic structure of the contract work in the Nordic Patent Institute will be explained in the following.

Contract work will be carried out on behalf of the Institute by the Danish Patent and Trademark Office and by the Norwegian Patent Office. The general conditions for the contract work will be outlined in the Order Agreement between the Nordic Patent Institute and the NPOs.

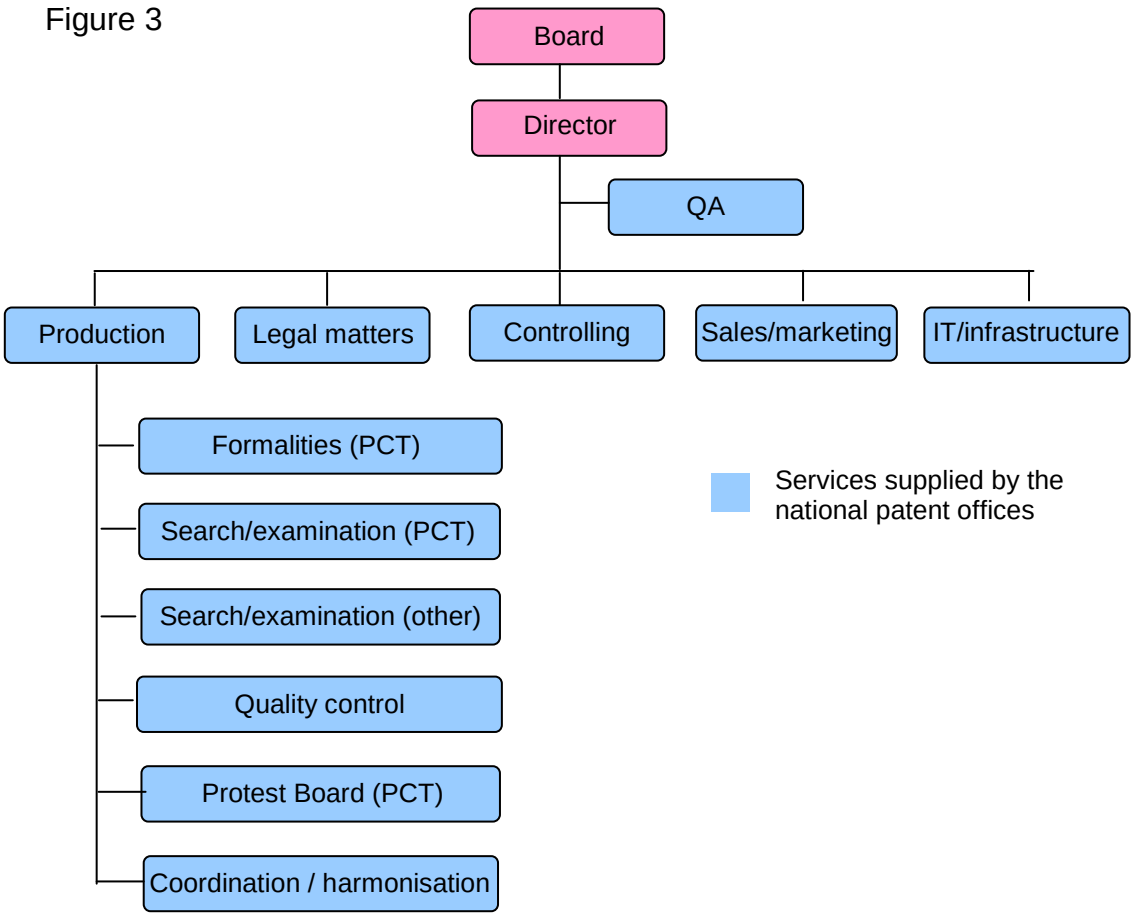
Each contract with external patent authorities and each large scale contract with private customers will be assigned to a contract manager who is responsible for the communication with the customer on issues such as quality, payment of bills, form of reporting, delays in delivery etc. All tasks under a contract will be sent to the office of the assigned contract manager and the secretariat of the managing office will check formalities and handle the distribution between the NPOs according to the principles set out in the individual contracts. Small scale commercial services will be handled according to written procedures by the individual examiner in collaboration with the Sales and Marketing departments.


Nordic Patent Institute
Contract manager DK, NO, IS
Customer
Customer (small scale)
Search & Examination NO
Search & Examination DK

1.1.3. Organisation

The Nordic Patent Institute is organised as indicated in figure 3 below.

Figure 3



The Nordic Patent Institute is managed by a Director who is appointed by the Board. The Board is composed of the directors of the participating NPOs. The Director is responsible for the management of the Institute. The various functions will be supplied by one or more of the NPOs according to individual Order Agreements.

The production unit comprises the patent units of the Norwegian and Danish Offices, which are each under the responsibility of a Director of Patents. The patent units are sub-divided into a number of sections related to specific technical areas or industrial branches, e.g. biochemistry, computers and communication, and managed by a Head of Section. Each section consists of a number of technical examiners with a scientific background. The patent unit in each NPO (of sufficient size) also comprise a formalities section, which deals with administrative matters including formalities and thus functions as Receiving Office and International Secretariat. Each patent unit has an internal quality control unit

responsible for monitoring the work performed. The patent units of the NPOs are also responsible for coordination; this includes harmonization of practise and distribution of tasks both internally and between the patent units.

The Protest Board is a decentralised board in the production unit, which specifically deals with protests against a decision taken by the Institute ruling lack of unity when the claims contain more than one independent invention. The Protest Board consists of technical examiners from the Danish and Norwegian office and is headed by a protest manager who is appointed for one year at a time.

The production is supported by a number of support functions comprising the controlling unit (including economy), sales and marketing, legal matters, IT and quality assurance.

The Director of Patents at each NPO is responsible for personnel management and performance of the patent unit, and the Heads of sections have a similar responsibility at the section level.

1.1.4. Relation to the Quality Management Systems of the NPOs

Most functions of the Nordic Patent Institute will be supplied by NPOs under an Order Agreement.

Each NPO carrying out the PCT-work and contract work has an ISO-9001 certified quality management system. The NPO quality management systems cover all necessary procedures for carrying out the substantial work and the procedures for continuous improvements.

The Order Agreements with the NPOs specifying exact requirements for the quality management systems of the NPOs are found as annexes to the General Framework Agreement between the participating offices and the Nordic Patent Institute.

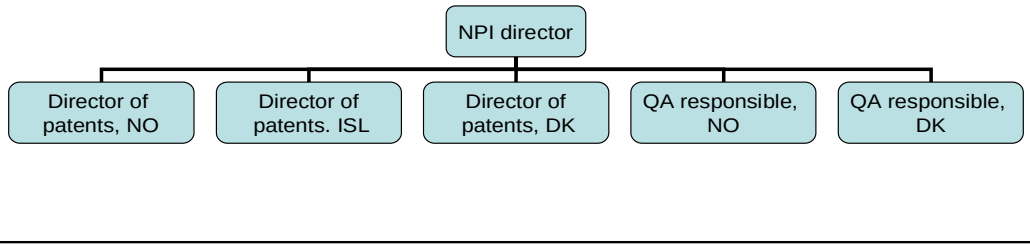
1.1.5. Quality Management Organisation

In parallel to its formal organisation, the Nordic Patent Institute has a quality management organisation consisting of appointed members of the participating office's quality organisation as well as the directors of patent. The primary executing participants could be one or more people involved in quality control, education or the quality managers themselves. The quality management organisation has the following responsibilities:

- revise the QMS with special reference to Order Agreements
- follow up on the goals in the QMS
- make recommendations for new goals
- monitor the quality of the deliveries
- handle suggestions for improvements and corrections of the QMS
- prepare the ISO – certification of Nordic Patent Institute

The quality management organisation is shown in figure 4.

Figure 4. Quality management organisation



1.2. QUALITY POLICY OF NORDIC PATENT INSTITUTE

1.2.1. Mission Statement

The Nordic Patent Institute shall supply international patenting and information services in close cooperation with the participating national patent offices in order to stimulate industrial innovation in the contracting states.

The Institute shall, in particular

- Support an efficient and high-quality, centrally controlled patent granting procedure for Europe within the framework of the European Patent Convention.

- Provide the basis for maintaining highly competitive IPR competence centres in the Nordic countries and for offering Nordic users a professional and customised interface to the patent system via their national patent offices.

- Exploit the synergy of cooperation on contract work for other parties, PCT applications and patent information services.

- Address the needs of small and medium sized enterprises in the Nordic countries.

1.2.2. Vision

The Nordic Patent Institute aims at offering products based on professionalism, competencies and services of such quality that it becomes

- the preferred PCT authority for applicants of the participating parties
- an attractive business partner for contract work

1.2.3. Policy

The Quality Policy of the Nordic Patent Institute is the joint, overall declaration of the Board and the director of the Institute on how the Institute shall manage its tasks in a quality context.

The overall Quality Policy constitutes the framework for detailed instructions on working and quality control procedures and, additionally, provides guidance to employees and suppliers regarding their daily work. The Quality Policy should encourage the Institute to deliver products of a high and uniform quality.

The Quality Policy is expressed in three headings “Customers”, “Suppliers” and “Leadership”, and states the values, methods and procedures chosen by the Board and the director of Institute.

Customers

We will develop and deliver quality work by observing the following criteria

- deliver correct and comprehensive information
- deliver consistent, well-founded and valid opinions by the agreed deadline
- treat all applicants and customers in a constructive, open-minded and helpful manner
- adjust our services to meet the needs of customers

Suppliers

We will on the supplier level continuously develop and improve our performance in respect of

- sharing of knowledge and mutual resources
- taking responsibility for reaching the goals
- observing the Quality Policy and procedures

Leadership

We will

- ensure that objectives and goals are clear to suppliers and will be continuously adjusted according to customer demands
- follow up on detected errors and deficiencies through education and adjustment of procedures

1.3. QUALITY MANAGEMENT SYSTEM

1.3.1. Purpose

The purpose of the Quality Management System (QMS) is to

- Ensure a uniform quality of products irrespective of the National Office (NPO) performing the work.
- Ensure that the Nordic Patent Institute delivers work of a high quality, which provides customers a solid basis for further decisions.

The products and services delivered by processes covered by the QMS of the Institute depend on deliveries from a number of supporting processes. The specifications as to substance and quality of the deliverables from these processes will be covered via Order Agreements. The Institute has specific Order Agreements with each NPO specifying the obligations of the NPO in order to ensure that all work supplied by the individual NPOs meets the objectives and goals set by the Institute. It is mandatory for each NPO to have a certified Quality Management System.

Level 2 of the QMS describes the general conditions for handling documents in the QMS. Level 3 contains a number of procedures describing the different processes in the Nordic Patent Institute, including how to interact with the national offices according to the Order Agreements

Order Agreements with NPOs are as a minimum required for the following areas:

- IT administrative system (uPDate)
- Internal Services including archiving
- Handling of complaints
- Infrastructure in general (furniture, logistics, communication lines etc)
- General controlling (budgeting, monitoring of production and finances, etc)
- Legal support
- Delivery of PCT-work and contract work (e.g. amounts, deadlines, quality and price)
- Production data
- Marketing / general communication / sales
- Participation in the quality management of the Institute including internal audits

Development (ISO ref. 7.3) and construction (ISO ref. 7.3) are excluded from the QMS. Processing of intellectual property rights is solely regulated through legislation and hence no development at the level of the Institute is present. Monitoring and measuring equipment (ISO ref. 7.6) are also excluded from this QMS.

1.3.2. Primary Legislative and Administrative Basis

The basis for establishing the Nordic Patent Institute is the *Agreement on the Establishing of the Nordic Patent Institute* between Denmark, Iceland and Norway which was signed on behalf of its governments by the directors of the Danish, Icelandic and Norwegian patent offices on July 5, 2006 and approved, together with certain additional documents, on (date). The additional documents comprise the Protocol on Privileges and Immunities, the Regulations and the Rules of Procedure for the Board.
The primary legislative basis for the work performed by the Nordic Patent Institute is therefore the Agreement Establishing the Nordic Patent Institute and the said additional documents. This covers PCT work as well as contract work.
Furthermore, the legislative basis for Institute in its capacity as International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty is the Agreement between the Nordic Patent Institute and WIPO. The work must fulfil the requirements of the Patent Cooperation Treaty, the regulations under PCT and the guidelines attached thereto.

Finally, the legal basis for the Nordic Patent Institute to act as ISA and IPEA under the European Patent Convention (EPC) is governed by the Protocol on Centralisation under EPC. Further details are set out in a special Agreement between EPO and the Nordic Patent Institute.

Contract work for external patent authorities will be performed according to the patent legislation specified in the contract with the authority, usually the legislation of the country which the patent authority represents. The specific contracts also contain further specification for the work such as a description of the relevant patent practice, which the Institute is required to follow. The standards based upon the requirements found in PCT, the regulations and the guidelines will be applied. Patent practice established under the framework of the European Patent Organisation will be applied, if relevant.

Contract work (commercial services) for private customers will be made according to the specific agreement between the Institute and the customer in question.

1.4. QUALITY OBJECTIVE

1.4.1. 1-Year Action Plan

The quality in the processing of PCT applications and ITS in 2008 is improved by

- Establishing a QMS which fulfils the PCT guidelines, part VII, Chapter 21, which ensures that the
    - Necessary procedures are present
    - Necessary resources are present
    - Necessary communication and feedback channels are present
    - Necessary competences allocated to specific technical areas are present
    - Necessary coordination between the suppliers is present
    - Necessary Order Agreements between the Institute and the NPOs are present.

- Publishing quality related information (results) of relevance for customers

- Measuring customer satisfaction with delivered products

The quality in each search and examination is improved and measured by

- establishing benchmarking systems between the NPOs
- evaluating spot checks

1.4.2. 3-year action plan

The quality in the processing of PCT applications and ITS in 2008 - 10 is improved by

- Ensuring that the 1-year action plan objectives as a minimum are maintained
- Improving the search and examination procedures

1.5. QUALITY GOALS

The suppliers (the participating NPOs) are obliged to follow the PCT-regulations. Additional specific goals are defined below.

1.5.1. Timeliness

The following goals for timeliness apply to PCT-work:

- ITS-report issued within 5 month from the date of filing of the national application

- ISR and WO issued within 15 months from the priority date of the international application
- Declaration of Non-Establishment of ISR (and WO) issued within 15 months from the priority date of the international application
- IPRP issued within 27 months from the priority date

(Other time limits may apply under certain circumstances (PCT/GL/ISPE/p's 3.13-14 and 18.11-12))

The following goal applies to contract-work:

- Agreed deadlines for contract work shall be met in at least 98% of all cases.

1.5.2. Quality

Quality in PCT-work and contract-work is monitored and improved with the aim of ensuring that spot checks will show that

- Maximum 5% of all samples in a calendar year are marked as unsatisfactory
- All contractual agreements as to specific quality criteria and requirements are met

Quality (harmonisation) of the PCT-work is improved by

- Benchmarking search and examination results between NPOs

1.5.3. Customers

Product quality and customer satisfaction is improved by

- Carrying out a customer satisfaction analysis at least every second year
- Conducting regular (at least annual) meetings with customers for contract work
- Striving to establish and understand customers needs and expectations

1.6 ABSTRACT OF THE QUALITY MANAGEMENT SYSTEM

The QMS consists of a number of procedures in order to ensure that work is performed at a uniform and consistently high quality level. The efficiency of the QMS is dependent on the procedures being up-to-date and the system being continuously improved in a systematic way. Therefore procedures for maintenance and improvement are part of the system.

External and internal audits are conducted regularly to ensure that the QMS functions properly. Audits are conducted with checklists and auditors prepare a written report of their observations.

Both auditors and employees can make suggestions for improvement or point out deficiencies which require changes in processes. Suggestions are submitted to the quality management organisation of the Nordic Patent Institute.

The efficiency of the QMS is continuously measured by regular meetings in the quality management organisation. The task of this organisation is to follow up on the daily running of the QMS, e.g. the NPOs' compliance with Order Agreements with the Institute, with audits, customer feedback and performance.

The quality management organisation consists of the director of the Nordic Patent Institute and appointed quality members and directors of patents from each NPO. The quality management organisation meets at least twice a year in order to evaluate the QMS, e.g. with regards to the NPOs' compliance with Order Agreements with the Institute, quality policy, objectives, goals and resources.

The Director is responsible for presenting an annual evaluation of the QMS to the Board.

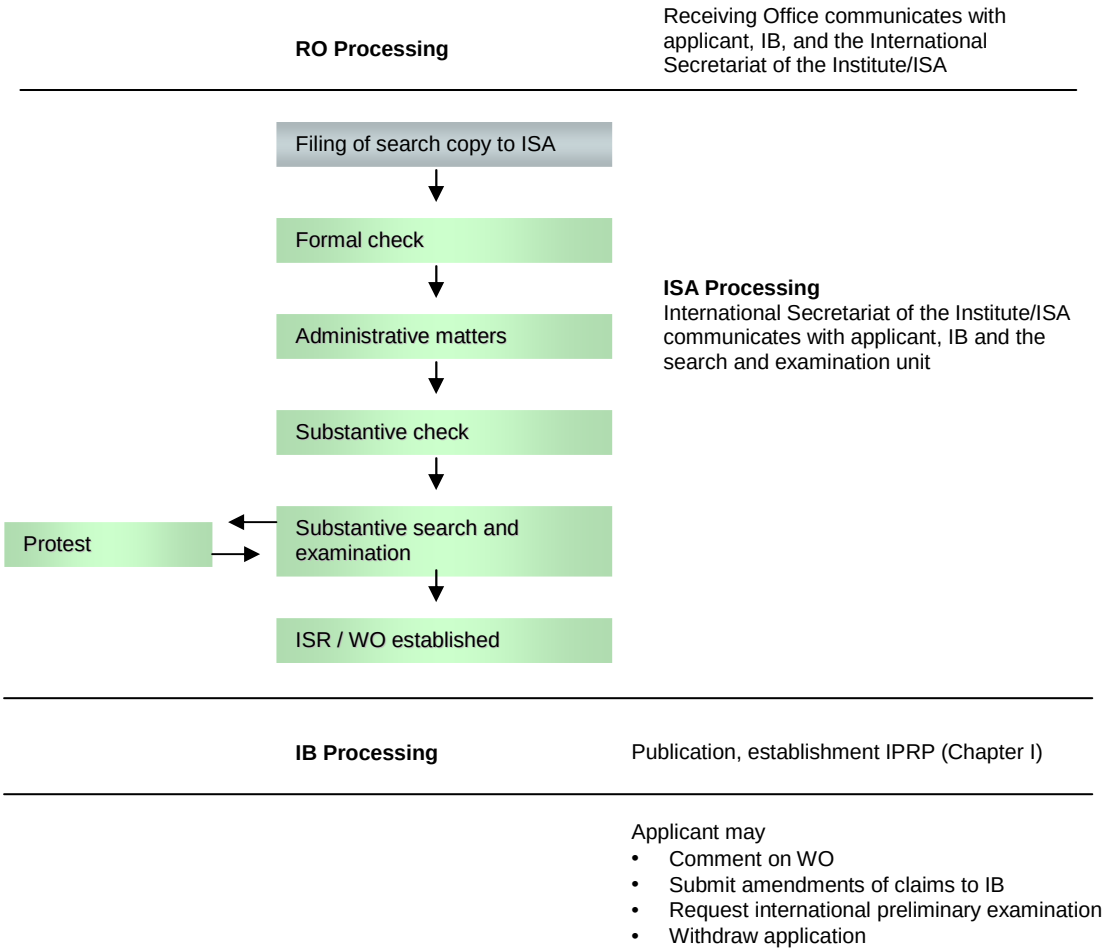
1.7 NPI PROCESSES

1.7.1. General Structure

Workflows for PCT work and International Type Searches as well as for contract work will be described in the following.

1.7.2. PCT Workflow, Chapter I

Figure 5 shows a simplified workflow for establishing an ISR (International Search Report) and a WO (Written Opinion) in accordance with Chapter I of the PCT.



1. Norwegian, Danish and Icelandic applicants (and residents), wishing to use the Nordic Patent Institute as an ISA, may file PCT applications at the RO of their local NPO together with a request that the application is processed by the Institute according to the Treaty. RO provides the international filing date and forwards the record copy to the International Bureau and the search copy to the Institute either in electronic form or in paper form. Prior to forwarding the search copy, RO collects RO handling fee, the

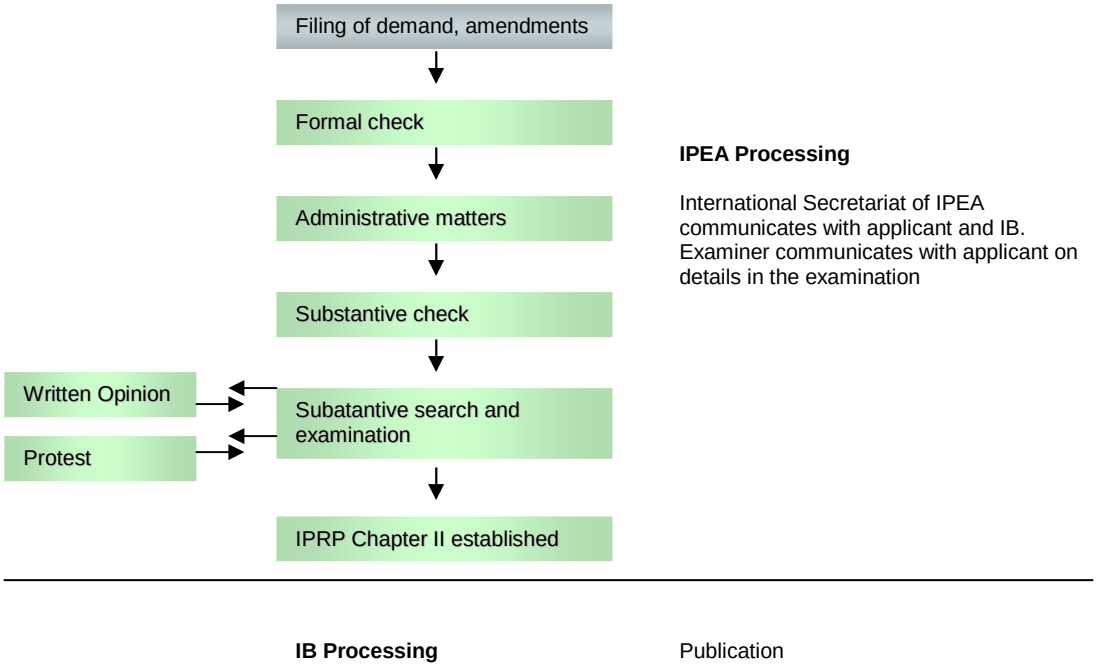
search fee, and the international filing fee and checks that the application is in one of the accepted languages. The collected fees are forwarded to the relevant NPO, the Institute and the IB, respectively.
2. When the application is received by ISA/(Nordic Patent Institute), all relevant data is entered into the administrative system (uPDate) and a receipt is forwarded to the applicant
3. Administrative matters - The application is classified according to IPC (International Patent Classification System) and allocated the relevant NPO section
4. The substantive check comprises a check in order to determine whether the application meets the requirements of unity of invention and if some of the subject matters should be excluded from search. Furthermore it is assessed to which extent results of any earlier search can be used in the international search report and consequently entitles the applicant to a partial refund. At this stage it is also determined if the applicant should be invited to provide a listing of sequence data.
5. The international search is carried out in order to establish relevant prior art. Some subject matters may not be searched if the search authority is not obliged to do so or for instance if the claims or drawings fail to comply with requirements. This includes claims relating to independent inventions if the applicant has not paid the additional search fees. The result of the international search is presented in a search report. Alternatively, a declaration is made stating that the search was not performed or would not be meaningful.
6. Based on the search result a written opinion is established. This includes an assessment of the novelty, inventive step, industrial applicability and compliance with the Treaty and Regulations.
7. The search report and the written opinion is forwarded to the International Bureau and the applicant
8. International publication of application, search report (if available) and amendments (if any) is performed by the International Bureau
9. The applicant may file a demand for International Preliminary Examination Chapter II with the International Preliminary Examination Authority (optional).
10. An International Preliminary Report on Patentability (IPRP Chapter I) is established by the International Bureau (if no demand filed). The report is based on the written opinion of the International Searching Authority (WO/ISA).
11. Applicant may file informal comments on written opinion (WO/ISA) to the International Bureau (optional).
12. The International Bureau publishes the International Preliminary Report on Patentability (IPRP Chapter I) incl. comments on WO/ISA if received. The report and comments (if any) may be forwarded to designated offices (DO) on request.
13. National / regional phase entry (if no demand for International Preliminary Examination Chapter II filed)

1.7.3. PCT Workflow, Chapter II

Applicants may request an IPRP (Chapter II) despite the fact that the Chapter I procedure already comprises a Written Opinion. Such request may for instance be relevant if the applicant in response to the Chapter I report finds it necessary to amend the claims

substantially and would like to have a positive IPRP before entering the national or regional phase.

Figure 6 shows a simplified workflow for this procedure.

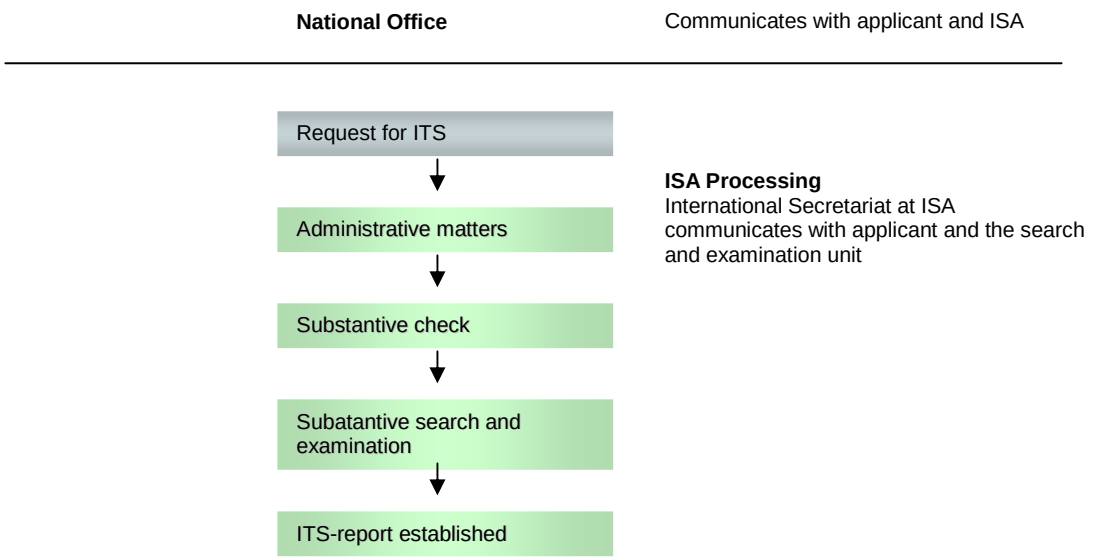


1. Applicant files a demand for International Preliminary Examination Chapter II with the elected International Preliminary Examination Authority (IPEA), i.e. with the International secretariat (ISEC) of the Nordic Patent Institute.
2. Applicant may file amendments and/or arguments
3. ISEC performs the formalities procedure including check of documents and forms as well as payment of fees and compliance with time limits. ISEC submits a copy of the demand to International Bureau and notifies the applicant of the receipt of the demand.
4. The International Bureau ensures that IPEA receives a copy of the written opinion from ISA (in the case where IPEA is different from ISA) and any amendments or additional information filed.
5. ISEC allocates the relevant NPO section. This will be the same as the section that acted for the Chapter I procedure, unless specific reasons indicate a need for allocating another.
6. The International Preliminary Examination Authority examines the international application, taking into account any amendments and arguments. IPEA may establish further written opinions and invite comments
7. An International Preliminary Report on Patentability (IPRP Chapter II) is established, typically based on the written opinion established by ISA and the subsequent amendments and comments received from the applicant. The applicant is entitled to at least one written opinion.
8. The International Preliminary Report on Patentability (IPRP Chapter II) is forwarded to the International Bureau and the applicant
9. National / regional phase entry

1.7.4 Workflow for ITS

National patent laws provide applicants the possibility of requesting an International Type Search (ITS) by an International Authority as a basis for the processing of a national patent application.

Figure 7 shows a simplified workflow for establishing an ITS.



1. The applicant requests an international-type search (ITS) with an NPO.

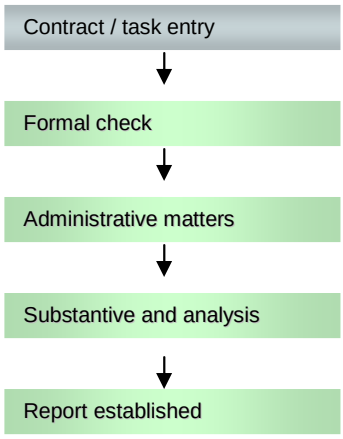
2. NPO checks formalities such as payment of ITS fee and timeliness of the request and payment. It also forwards the request and fee to ISA/(Nordic Patent Institute).

3. ISEC formally allocates a department to carry out the ITS. This will normally be the department responsible for the national application.

4. ISA/(Nordic Patent Institute) performs the ITS and forwards the report to ISEC for further processing.
   International-type searches are by definition similar to PCT international searches and similar considerations apply.

1.7.5 Workflow for Contract Work

Figure 8 shows a simplified workflow for large scale contract work.



Nordic Patent Institute Processing

Contract manager communicates on general issues with the customer and the patent unit

The customer communicates with the examiner on specific issues

1. All tasks must be sent to the appointed contract manager who checks for contractual formalities.

2. The contract manager allocates a unit in accordance with agreements specified in the contract.

3. The examiner consults, if necessary and if in accordance with each contract, the customer for clarification of the task.

In the case of small size commercial services on an ad hoc basis, a dialog is established directly between the customer and the examiner carrying out the task in order to agree on the purpose and scope of the task.

NOMENCLATURE and DEFINITIONS

DK – Country Code for Denmark
DO – Designated office
EPO – European Patent Office
IA – International Authority
IB – International Bureau of WIPO
Institute – Nordic Patent Institute
IPEA – International Preliminary Examination Authority
IPRP -- International Preliminary Report on Patentability (Chapter I or II)
IS – Country Code for Iceland
ISEC – International Secretariat in Nordic Patent Institute
ISA – International Search Authority
ISR – International Search Report
ITS – International Type Search
NO – Country Code for Norway
NPO – National Patent Office
PCT – Patent Cooperation Treaty
PRV – Swedish Patent Office
QA – Quality Assurance
QMS – Quality Management System
RO – Receiving Office
WIPO – World Intellectual Property Organisation
WO – Written opinion
XN – Country code for NPI