#### PATENT COOPERATION TREATY

Common Quality Framework for International Search and Preliminary Examination

# **Supplemental Report Under Paragraph 21.18 of the PCT International Search and Preliminary Examination Guidelines**

by: Canadian Intellectual Property Office (CIPO)

on: *January 8, 2010* 

Date of main report and any supplemental reports to which this is a supplement:

January 4, 2007

January 23, 2008

February 9, 2009

## Documents referred to in this report:

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

As a result of our most recent internal review under PCT/GL/ISPE paragraphs 21.10-21.15, this Authority has made modifications to its Quality Management System (QMS) as discussed below.

The modifications are given with reference to the sections of the revised template for responses to PCT/GL/ISPE Paragraph 21.17, to which the changes relate.

The Authority should describe any changes made to its QMS making reference to the specific sections of the earlier report using template T21-17, and / or making reference to any supplemental report(s) established in the meantime using template T21-18.

If no changes have been made to its QMS since the last report, the Authority should indicate such.

## **Quality Management System (Paragraphs 21.03-21.09)**

## Resources (21.05)

(d) Possession of, or access to, at least the minimum documentation referred to in Rule 34, properly arranged for search and examination purposes, on paper, in microform or stored on electronic media

In addition to its existing patent and non-patent literature databases, CIPO entered into an agreement with the European Patent Office in 2009 to provide EPOQUE access to the entire examination corps.

Moreover, the Canadian internal patent database was completely remodeled to include an enhanced GUI interface with added functionalities. CIPO's non-patent literature collections are continually augmented, and include comprehensive coverage from reputed journals, publications and databases, such as the American Chemical Society, Knovel and Scopus.

(e) Comprehensive and up-to-date work manuals to help staff understand and adhere to the quality criteria and standards and follow work procedures accurately and consistently

All of CIPO's work manuals are assigned an owner and follow CIPO's procedure for control of documents for updates. In addition, a master list of all internal and external documents provides information on names of authors/owners, document location and dependencies, as well as expected revision dates. Authors and owners are responsible for regularly updating and disseminating information to appropriate staff members.

All documents under the document control procedure are posted on the intranet.

The entire ISA/IPEA training manual has been revised. A section on annotated forms was added to provide examiners with information and concrete examples on how to complete the various ISA/IPEA forms.

(f) An effective training and development program for all staff involved in the search and examination process to ensure they acquire and maintain the necessary experience and skills and are fully aware of the importance of complying with the quality criteria and standards

An enhanced Continuous Training Program was effected to institute a point system for all training completed by examiners during a fiscal year. Examiners are required to meet a minimum point score per year, specifically in areas related to intellectual property and science and technology. The training point system allows examiners and supervisors to track training completed and determine future training needs.

All training matter is handled by the Program Manager - Patent Examination Training.

## **Quality Assurance (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 analyzing 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 authorize 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

## Procedure for Corrective and Preventive Action

The Procedure for Corrective and Preventive Action has been completed and successfully implemented. This procedure is linked to the procedure for Cross-Unit Nonconformity, which allows any staff member to raise issues at any time within a process for correction to appropriate authorities. All issues and corrections are recorded for later review by the International Issues Working Group (IIWG), which evaluates the seriousness of issues and requests for corrective actions as required. Only issues or potential issues which are deemed serious enter the Procedure for Corrective and Preventive Action. Senior management is responsible for assigning resources to address corrective action requests and arranging follow-ups to ensure measures taken were appropriate and effective.

The Corrective and Preventive Action Procedure may also be called upon to resolve issues arising from customer complaints, employees' feedback, data analysis on Quality Control (QC) and Quality Assurance (QA) and Internal Audit.

## Internal Audit

CIPO's Internal Audit program is headed by the Program Manager – Quality, and delivered by 18 professionally-trained internal auditors, representing all departments within the Canadian Patent Office.

The audit program includes an audit schedule for all processes of the Patent Office and provisions for impromptu audits at management request. Audits are performed annually for all processes within the Quality Management System for ISA/IPEA and on the Quality Management System itself to ensure compliance to requirements and effectiveness.

Internal auditors undertake intensive ISO quality audit training provided by a certified consulting firm. In addition, several auditors were further trained as lead auditors in order to conduct quality system audits.

An external auditor was hired to carry out the audit of the ISA/IPEA Quality Management System for compliance to ISO 9001:2008. Issues raised by the external auditor are currently being addressed.

## Internal Review (21.10)

In addition to establishing a quality assurance system for checking and ensuring compliance with the requirements set out in its QMS, 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 and the extent to which it is complying with the QMS requirements and these Search and Examination Guidelines. The reviews should be objective and transparent so as to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year.

A comprehensive management review of the QMS was conducted, whereby the following were explored at length:

- Statistical analysis of Quality Control and Quality Assurance results
- Internal and external feedback from employees and clients
- Internal audit results
- External audit results
- Previous corrective actions

Management is committed to continuously improving the Quality Management System and has taken appropriate measures to ensure its effectiveness and compliance to ISO 9001:2008.

[End of report]