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WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

ORIGINAL: ENGLISH
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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Spanish Patent and Trademark Office (OEPM)

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

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

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

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

The most important changes that have taken place on OEPM Quality Management System, since the previous report are the following:

- ~~2024 users satisfaction surveys (USS)~~2025 European Patent Validation users satisfaction survey and Distinctive Signs user satisfaction survey.
- Preparation and monitoring of the Operative Plan for 2026.
- Implementation of the activities of the Operative Plan for 2026 of the Strategic Plan 2025-2027.
- Self-assessment process of the Common Assessment Framework (CAF) model and presentation of the candidature (30 junio 2026).
- OEPM continues working for updating the new electronic filing system for inventions, **OEPMSEI** (developed in cooperation with the European Patent Office – EPO), which will gradually replace the current system (e-OLF). This system (e-OLF) will be discontinued for filings with the OEPM during 2026.
- Implementation of the methodology for process risk analysis for Utility Models process and working on National Patent process.
  -
- Renewal of three Service Charters:
  - National Patent Service Charter
  - Industrial Design Service Charter
  - Distinctive Signal Service Charter
- Several documents have been updated and published on the intranet:
  - Stakeholders' needs and expectations
  - Supplier evaluation
  - Lists of external and internal documentation
  - Process charts

The OEPM has a Quality Management System certified according to ISO 9001:2015.

The scope of this System includes PCT procedure, Technological Watch procedures, Industrial Designs, National Trademarks and Commercial Names, National Patents, Utility Models, Supplementary Protection Certificates SPCs, Inscription of licensing and Transfer Agreements over national patents and utility models, Decisions on restoration of rights, Appeals and Validation of European Patents.

After a positive external audit run in June 2026, the ISO 9001:2015 Certification has been successfully followed up and a new process has been certified: Inscription of licesing and Transfer Agreements over industrial designs.

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Deleted: <#>Preparation of the Strategic Plan 2025-2027¶
Preparation of the Operative Plan 2025¶
Five protocols have been published on the intranet:¶
Protocol for conducting satisfaction surveys on the Technological Information (TI) service¶
Protocol for conducting satisfaction surveys on the SME support service.¶
Protocol for conducting satisfaction surveys on the Historical Archives service.¶
Protocol for conducting satisfaction surveys on the information service¶
Protocol for handling complaints, suggestions and compliments.¶

Deleted: <#>Renewal of five Service Charters, published on the OEPM website:¶
Search and International Preliminary Examination Authority Service Charter¶
Information and Customer Service Charter¶
Technological Information Service Charter¶
Utility Models Service Charter¶
Archiving Service Charter…

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1. LEADERSHIP AND POLICY

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

(a) The quality policy established by top management.

(b) The roles and names of those bodies and individuals responsible for the QMS, as specified by top management.

(c) An organizational chart showing all those bodies and individuals responsible for the QMS.

a) OEPM Quality policy is defined within the parameters established by ISO 9001:2015 standard.

The new Quality Policy was approved in October 2024 and is aligned with the Strategic Plan 2025-2027 of the OEPM.

The directives are the following:

1. To work efficiently, offering services with quality and legal certainty to our users and in accordance with the service commitments established by the OEPM, which must improve the deadlines and standards defined by the legal and regulatory requirements demanded by the regulations and legislation in force, where this is possible.
2. To promote awareness of sustainability and the appropriate use of public resources in daily management, so that the OEPM moves towards a more sustainable and environmentally friendly labour, energy, social and consumption model, aligned with the Sustainable Development Goals and that encourages flexibility and resilience across the organization to adapt to a changing world.
3. To promote the knowledge and appropriate use of the electronic tools made available to the public by the OEPM, as a means of facilitating the presentation of applications and speeding up the subsequent processing of these, incorporating innovative solutions and applications for the implementation of new technologies, always in accordance with the criteria of professionalism, closeness, ethics and transparency in management, in full respect for the personal data of citizens and interested parties.
4. To manage the processes by means of strategic and operational planning, control and permanent evaluation to guarantee the fulfilment of its objectives and commitments and to foresee and solve possible service incidents.
5. To develop a participatory management model that promotes the skills, of the highly qualified OEPM team, and enables their use for the benefit of the OEPM and the society, valuing and encouraging creativity, training and participation of all employees and involving them in the achievement of our objectives.

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6. To implement, with the participation of workers' representatives, a responsible, innovative, updated and evaluated training model that allows constant recycling and the increase of the capacities of the personnel at the service of the OEPM, through annual plans.

7. To provide systems to maintain effective and adequate communication with users, analyze their expectations, evaluate their satisfaction, and deal with their complaints to offer excellent service to obtain their full satisfaction, facilitating the use of our services.

8. Formulate an adequate relationship of collaboration and trust with our suppliers, contractors and other collaborators for the permanent improvement of services, especially promoting the application of social and environmental criteria foreseen in the corresponding legislation.

9. To develop a proactive international activity, promoting and participating in alliances with all the actors of Industrial Property, which promotes a climate of understanding and cooperation with strategic partners, based on respect for general international principles and with the aim of contributing to the values and guiding principles of Spain's foreign policy and foreign action.

10. To establish continuous improvement as a management priority, working towards a model of excellence, by measuring, analyzing and interpreting the results of processes, promoting and valuing people's ideas and proposals and the opportunities provided by technology for the continuous improvement of our performance and maintaining permanent communication with users, suppliers and collaborators as sources for detecting improvements in the service provided.

These principles serve as a frame for the establishment of specific objectives of quality that periodically are evaluated and reviewed by the Management Committee of the Organization.

The Quality Policy is reviewed annually, by Top Management, in the process of system review. It is available internally through our intranet and externally through our webpage. It is also communicated using different channels like corporate large TV monitors placed in the Office and it is displayed in meeting rooms and several places in our premises.

b) The QMS responsibilities at the OEPM are organized in different levels: first of all, top management is directly involved through the Quality Committee (which is the steering committee). Secondly, there are Quality Management Groups in the departments within the scope of the QMS. Apart from that, there is a Quality Manager in each department.

c) The roles responsible for the QMS are described at the Quality Manual.

The updated version of the Quality Manual is available at the OEPM intranet.

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 to the relevant staff at 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 aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according to paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to			
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			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 technical qualifications to search and examine in all technical fields	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff			
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to 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	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(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	✓		
	(iii)		Clear and concise guidance and information on the search and examination process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21		(a)	Established communication with the International Bureau	✓		
		(b)	Established communication with designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.25	(i)		Records of 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)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records 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	✓		
21.26	(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	✓		
	(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 limitation of search and its justification	✓		
	(vii)		Records about lack of clarity of the claims	✓		
	(viii)		Records about lack of unity	✓		
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews	✓		
21.31			Initial report called for by paragraph 21.31	✓		

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

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As indicated before, there is a Quality Committee of which the Director General is a member, and Quality Management Groups in the departments.

Therefore, the *Quality Management Group* at the Patent Department plays a central role in the Quality Management System. All the Heads of the Operative Units and Sections, both administrative and technical, the Director of the Patent Department and the Quality Manager of the Patent Department form it.

The main tasks of this group are:

- To ensure compliance with the Quality Policy.
- To analyse changes in the organizational context.
- To promote actions to achieve the Quality objectives and evaluate their effectiveness
- To track and to analyse the results of quality indicators and to take the necessary action as a result of this analysis.
- To support the implementation of the QMS and evaluate its effectiveness.
- To analyze non-conformity reports and initiate corrective actions when necessary.
- To determine the effectiveness of corrective actions.
- To analyze results of applicant satisfaction through surveys and claims and to take action when necessary.
- To analyze and decide actions needed to minimize risks.

The Director General chairs the *Quality Committee* of the OEPM. Directors of all the departments of the OEPM are also members of the *Quality Committee*: General Secretary, Patents, Industrial Designs and Technological Information, Trademarks, International Relationship Department and Information Technology (IT) Department. The main functions of the Committee are:

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1. To approve the executive Report prepared by the Quality Management Groups reported by the Director of each department.
2. To define the general strategy for Quality in the Office.
3. To provide coordination among the different departments.
4. To provide financial and human resources to the Quality activities.

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.

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Heads of units have regular meetings with the examiners and administrative staff to inform them about the evolution of their work, in those meetings the information about treaty and regulatory requirements, quality standards and quality system are disseminated.

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The Technical Advisor of the Patent Department sends regularly information to all the staff about all the important issues as the evolution of indicators, new procedures or whatever information is relevant for the work of the Patent Department staff.

When new staff joins OEPM they receive training with contents including the international framework of Quality, about the OEPM QMS and the importance of meeting treaty and regulatory requirements. These type of guidelines are also highlighted through the Quality Policy, which is displayed on TV monitors in different places in our premises.

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

(a) conducts management reviews and ensures the availability of appropriate resources;

(b) reviews quality objectives; and

(c) ensures that the quality objectives are communicated and understood by the relevant staff at the respective Authority.

See point 21.09.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

(a) at least once per year (cf. paragraph 21.27);

(b) in accordance with the minimum scope of such reviews as set out in Section 9, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

(c) in an objective and transparent way (cf. paragraph 21.27);

(d) using input including information according to paragraphs 21.29 (ii)-(vi);

(e) recording the results (cf. paragraph 21.30).

Following the suggestions of previous audits, and in accordance with the requirements of the UNE-EN ISO 9001:2015, to improve the efficiency of the Quality Management System and to perform a better analysis of the information, analyzing the data and Quality objectives of a complete calendar year, the 2025 QMS Management Review took place in February 2026. At the beginning of 2027, the Management Review for the period 2026 will takeplace, . All defined Quality objectives for 2025 were achieved and aligned with the OEPM Strategic Plan. Again, the objectives defined for 2026 are aligned with the results and activities of the 2026 Operational Plan.

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The agenda of the review meeting of the system is:

1. Follow-up actions from previous management reviews.
2. Changes in the organizational context and in needs of interested parties that might affect the System. Adequacy of the Quality Policy.
3. Efficiency of actions taken to address risks and opportunities
4. Non Conformities and Corrective actions
5. Customer feedback: Satisfaction Surveys and Complaints
6. Quality objectives evolution
7. Quality indicators evolution
8. Audits: Follow-up of the annual Plan, Audit Reports and deviation analysis
9. Training: follow up of the annual Plan and Evaluation of the effectiveness of the training actions taken
10. Monitoring of supplier evaluations
11. Quality Control results
12. Review of the infrastructure and work environment
13. Identification of necessary resources.
14. Improvement actions as a result of the meeting

In September, the Quality Committee (QC) holds a follow up meeting with the following agenda similar to the agenda of the review of the system:

1. Follow-up actions from previous management reviews.
2. Changes in the organizational context and in needs of interested parties that might affect the System.
3. Efficiency of actions taken to address risks and opportunities
4. Non Conformities and Corrective actions
5. Customer feedback: Satisfaction Surveys and Complaints
6. Quality objectives evolution
7. Quality indicators evolution
8. Audits: Follow-up of the annual Plan, Audit Reports and deviation analysis
9. Identification of necessary resources

The minutes of these meetings are published and accessible to all the Department staff through our OEPM intranet. These meeting minutes include all the information about quality objectives and their follow up, as well as indicators. This way we assure that all the staff involved in QMS has access to this information.

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To assure that the reports issued are compliant with the PCT Guidelines several controls are set up during the process of search and examination. First, Heads of Technical Sections do a quality review prior to the issue of all the Reports. This review is recorded in ALFA (the electronic workflow tool implemented by OEPM since November 2010). In case any non-compliance with the guidelines is detected, the Report is sent back to the examiner.
Another control is monthly done on a sample of issued reports by the head of technical sections and its results are feed backed at the moment to the examiner, when necessary, and commented on QMG meetings. In addition, this information is deeply analysed in the Internal Review meeting to identify improvement actions.

To determine the extent to which the QMS is based on Chapter 21, before the QMS was first implemented at OEPM, a study was done about the correspondence between Chapter 21 and ISO 9001. At that time, the Authority concluded that fulfilling all the requirements of the ISO standard assured the complete fulfilment of Chapter 21. With the new version of the standard ISO 9001:2015, the study was updated.

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

See points 21.09 and 21.13.

2. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

(i) (a) understand issues that affect its ability to achieve intended results of the QMS, and

(b) understand the needs and expectations of interested parties;

(ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;

(iii) plan and implement actions to address risks and opportunities;

(iv) check the effectiveness of the actions taken; and

(v) continuously update risks and opportunities.

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

In 2017, when OEPM adapted its quality system to the new requirements of ISO 9.001:2015 a study of context and interested parties needs and expectations was done. In addition, a Risks and Opportunities Management Manual was set. Finally, after analysing context and interested parties information, Risks and Opportunities were identified and evaluated. On December 2017, top management approved a Risks and Opportunities plan.

The context study, the identification of needs and expectations from interested parties and the risks and opportunities plan, are reviewed every year, to identify possible changes. Top management reviews the effectiveness of the actions taken to address Risks and Opportunities during Quality Committee meetings.

In 2018, OEPM started analysing risks and opportunities in operational processes in a more specific way. Finally, in 2019 an identification of risks and opportunities was done in the Appeals process. As a result of this analysis, 6 specific risks were identified and, for 5 of them, specific actions were determined. These actions are reviewed in the Appeals Unit Quality Group meetings.

In 2020, an identification of risks and opportunities was done in the five products produced by the Technological Information Unit: Patent Technological Reports, Custom technology surveillance reports, Retrospective searches, Technological surveillance bulletins, Technological Alerts. Different actions have been defined to reduce or eliminate the identified risks. These actions are reviewed in the Patent Department Quality Group meetings.

In 2021, an identification of risks and opportunities was done in the process of European patent validation in Spain. These actions are reviewed in the Patent Department Quality Group meetings.

In 2022, an identification of risks and opportunities was done in the granting process of Industrial Designs. These actions are reviewed in the Patent Department Quality Group meetings.

In 2023, an identification of risks and opportunities was done in the Technological Information Services process. These actions are reviewed in the Patent Department Quality Group meetings.

In 2024 an identification of risks and opportunities was done in the Supplementary Protection Certificate process. These actions are reviewed in the Patent Department Quality Group meetings.

In addition, during 2024 a revision of the risk and opportunities score, at high level was done by the Top Management and the Risk Working Group, created in 2023 to analyse and evaluate the success of the actions implemented to mitigate risks or take advance of the opportunities.

In 2025, an identification of risks and opportunities was done in the Utility Model process. These actions are reviewed in the Patent Department Quality Group meetings.

In 2026, the Quality Management Service and the Patent areas are working together in the identification of risks and opportunities in the National Patent process.

3. RESOURCES

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

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff:

sufficient to deal with the inflow of work; and

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

OEPM continuously holds a management control for every operative unit, which assures control over fluctuations in demand and possible job accumulation. This allows OEPM to adapt its financial and human resources accordingly.

Maintenance of the technical qualifications to search and examination in the required technical fields and of the qualifications of the Administrative staff is assured by our recruiting program and by our yearly training plan.

The process to become an examiner is based in competitive exams with more than 103 themes of industrial property including PCT, and an English exam. Therefore, technical qualifications, PCT knowledge and language skills are assured. Once the examiner joins OEPM, he goes through a period of practice with a tutor.

Most OEPM personnel, like patent examiners are civil servants and every year there is a proposal to hire new personnel for the Public Administration. Depending on the need and the expected demand, OEPM can propose hiring new staff.

In 2025, seven new patent examiners, one expert in IT and five new Law graduates have joined OEPM.

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The technical staff working at the OEPM comprises 123 Patent Examiners, 6 heads of patent and utility model divisions and 9 heads of technical sections. All of them are civil servants who have

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the required technical qualifications (MS Engineering, Architecture, Science, Physics, Chemistry...- degree) to search and examine in the different technical fields and mastery of languages to level needed to be able to read and understand technical texts, especially patent documents.

The competencies required for the examiners are the following:

A. Linguistic skills

They should possess, apart from Spanish, a knowledge of English (mandatory).

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B. Patent law skills

B.1 An in-depth knowledge of the most important Articles and Rules of the PCT Treaty, the Search and Examination Guidelines, the relevant sections of other Treaty's Guidelines and Administrative Instructions. International treaties such as the Paris Convention, European Patent Convention, the TRIPS agreement and Patent Law Treaty should also be familiar to all examiners. Over and above that, field relevant treaties should be seen as essential.

B.2 Apart from the above, there is a large body of knowledge and information that it is considered to be useful to an examiner in his/her work, such as the equivalent to the PCT Guidelines and Administrative Instructions in the EPC, in as far as they differ from the PCT. Likewise, Knowledge on the significance of the TRIPS agreement and the general political environment in which it operates are as useful as understanding the basics of Intellectual Property.

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C. Technical & analytical skills

A University level degree in a technical subject is a pre-requisite for examiners. Beyond that, there are essential skills, which are not necessarily created or enhanced through that basic requirement. An examiner should be able to focus on technical & procedural essentials. S/he needs to be able to complete a competent claims analysis, synthesize legal & technical issues in applications and deal with clarity issues to required level particularly with regard to "complex" applications.

S/he needs to be able to plan & perform a search, optimize strategy, perform documentary analysis and determine their primary & secondary technical relevance. S/he needs decisiveness and the ability to set appropriate priorities.

Thorough familiarity with search tools (Ansera based Search, WPI, NPL, etc.) and knowledge of

WIPO standards are equally useful in enhancing an examiners work above the average.

D. Classification skills

An in depth understanding of classification systems in general (IPC, CPC, F(I)-terms, etc.) and their basic philosophies is indispensable. Skill and knowledge on their application to classify technical documents is as important as an awareness of their usefulness as search tools.

E. IT skills & operation of electronic tools

All examiners need to be competent in the usage of their Office's electronic internal and external communication systems. In depth knowledge of the modern IT systems implemented in the OEPM, such as the ALFA patent processing system, are also a requirement for examiners.

F. Search strategy & search execution skills

For every examiner to be able to perform a quality search, search skills are of great importance. This means primarily an understanding of the philosophy and the working of the search engines made available to the examiner. In depth knowledge of the composition and content of databases and their relevance to particular fields is equally essential. Furthermore, devising focused strategies, knowledge of which are the most appropriate databases to be searched and sufficient knowledge of the technical field concerned to be able to take an informed decision on the extent of the search are all part of the basic skills of a competent examiner.

G. Drafting skills

All examiners need the ability to write structured and comprehensible opinions and to formulate substantiated arguments in writing.

Recruitment and Training programs in the Spanish Patent and Trademark Office

Next, is a summary of the Recruitment process and Training programs for new examiners and ongoing training activities for existing examiners, including typical times spent on training.

RECRUITMENT

Due to the special features of the Spanish Law concerning contracting people for working as civil servants, the recruitment process to become a Patent Examiner is extremely stringent. Only those

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with a Technical Degree and deep knowledge of English and national and international laws can attend the competitive exams where the candidates must proof their skills, sometimes orally. After this, the patent examiner must show his/her adaptation to the job in a practice period after which he/she is evaluated again.

The number of examiners requested and the specialization is determined to ensure that the differences in the demand in the technological fields throughout time do not alter significantly the quality in terms of timeliness and completeness.

Similarly, the administrative staff follows a very exigent process to become a civil servant with clear requirements with respect to education received, languages, use of computers and previous experience.

A.- Recruitment of examiners

Recruitment of Examiners is an open competition for a limited number of posts, consisting of four exams:

First exam: It consists of doing a writing test in which a questionnaire of 100 questions on the entire agenda, divided in three groups:

Group I. General part (Spanish Public Administration)

Group II. Regulations on Industrial Property (National and European and International Regulations)

Group III. Technical Topics

Second exam: Languages. It consists of two tests:

a) Compulsory test with two parts:

English -> Spanish translations

English speaking test

If the candidate has a B2 level certification or higher, it will not be necessary to pass the exam.

Third exam: It consists of orally presenting in public session three topics from the Group I and Group II of the agenda for a maximum time of one hour.

Fourth exam: It consists of a writing resolution of a practical case for a maximum period of four hours. (These exercises consists of: A legal practical case, the classification according to the IPC of two patent applications and a substantive examination where the candidate is provided with the relevant prior art regarding a patent application).

The participants that pass the four exams are nominated "Examiner in practice", under training, remaining in this status for at least a period of 2 months.

Patent Examiners in practice receive initially at OEPM a one month and a half intensive training course about Industrial Property topics, national and PCT procedures, search, examination and databases.

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After the one month and a half initial training course, Patent Examiners under formation become Junior OEPM Patent Examiners. When a Spanish Patent Examiner begins his/her work at OEPM, he/she has a Senior Examiner as a Tutor that helps and gives him/her training on the job. When the training on the job is over (6 months), the Tutor acts as a Patent Assistant for the new Patent Examiner (2-3 years more) until he/she becomes a senior patent examiner.

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B. - Recruitment of administrative staff:

B1) Selection within the framework of the Spanish General Administration of the State

The (OEPM) is an Autonomous Institution assigned to the Ministry of Industry, and Tourism. Therefore, like such organization, within the General Administration of the State, the access to the public function is determined by the national laws, which establish three forms of access, depending on the status of applicants within the public function, all of them based on the open competition of the job applicants. Consequently, all the civil employees of the OEPM and, in particular, the assigned ones to this Administrative Unit, have acceded to the Administration through some of those mechanisms. The selection process is made through different exercises that intend to determine the knowledge degree that the candidate has of the programme and/or the practical exercises that the selective process is made up. When finishing it and before acceding to the condition of civil employee, the candidate must pass a period of practices.

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B2) Selection within the framework of the Spanish Patent and Trademark Office (OEPM)

The candidates that comply with general conditions and particular requirements may apply for the post. Particular requirements are described, as an example, in the next table:

Description of the Job	Courses required	Specific Merits

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○ Formal examination and procedure of PCT international applications ○ Control, registry and verification of PCT applications	○ Related to Industrial Property, National administrative procedure and PCT ○ Office computerization. Knowledge of data bases	○ Experience in administrative procedures ○ Knowledge of administrative procedures, special in Industrial Property and PCT ○ English and/or French Knowledge

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.

OEPM IT department is in charge of maintaining and monitoring the IT software and hardware. According to the specific procedure established for Maintenance of the equipment, this department plans and records all reviews done in order to fulfil the requirements established on ISO 9001:2015.

There is a Unit dedicated to the corrective and preventive maintenance of all the equipment. They work with service level agreements, assuring that the examiners have always the equipment needed for the search and examination processes.

New applications are identified and updated in a permanent way. There is a continuous communication between PCT responsible people and IT dpt. to maintain updated all PCT support software.

OEPM has been implementing a voluntary Teleworking Programme for several years. At present, the Teleworking Programme has been extended to include the whole Office. All patent examiners and administrative staff are permitted to work from home three days a week.

OEPM has guaranteed that our examiners can have access to the PCT minimum documentation as defined in Rule 34 PCT in electronic media.

Access to Spanish documentation, not completely present at EPO databases, is assured by using our database called INVENES, which includes all the digitised Spanish documentation. Regarding the documentation written in Spanish from 18 Latin-American countries, OEPM has created the database LATIPAT in co-operation with National Offices of Latin-America, WIPO and the EPO.

New databases are identified and evaluated by the Head of the Documentation Area in collaboration with the Heads of Technical Areas.

PCT Search and Examination Guidelines are electronically accessible. PCT service charters are also accessible, so that staff understand and adhere to the commitments. On the other hand, PCT workflows are designed in our computer tools to ensure that time limits are known and are compiled with.
In addition, in order to contribute to the harmonization between examiners, a full set of electronic standard clauses have been developed.

All the examiners have been provided with detailed information on PCT procedures through the set of different procedures included in the documentation of the quality management system. The updated version of these documents is available to all the examiners at OEPM intranet.

All the relevant documentation for QMS is controlled according to the requirements of ISO 9001:2015.

From decades, there has been a sustained effort to improve the documentation in the OEPM. Starting from the traditional formats (paper, microfiche and microfilm) and as technology was evolving very quickly; we were incorporating documents in other formats, CDs, DVDs. In this way, the OEPM already ensured, in the early 1990s, the requirement to have access to the PCT minimum documentation. Currently, online databases are playing the key factor for accessing the documentation easier and quicker. The electronic tools for the examiners and administrative staff, both for accessing the search documentation and for automation of the granting procedure are continuously improved. This improvement means a continuous update of the computer infrastructure. As described below the OEPM has access to the most modern and complete databases, which allow us to obtain the most relevant information of patents and non-patent literature. Consequently, the OEPM has full access to all documentation as defined in Rule 34

PCT.

Search systems:

Main databases used currently by the OEPM (among others):

- ABS/AbSearch, incorporating access to Derwent World Patent Index (DWPI) (provider: Clarivate Analytics); BIOSIS (provider: Clarivate Analytics); COMPENDEX (provider Elsevier); EMBASE (provider Elsevier); SCIENCE DIRECT (provider Elsevier); INSPEC (provider IET); IEEE (provider: Institution of Electrical and Electronics Engineers); XPAID (provider: European Patent Office). As of 01/01/2025 patent examiners have also access to Springer-Nature and IOP publishing.
- STN International databases, through the STN express platform. We use them mainly in the chemical, pharmaceutical, food and biotechnology fields (most used databases are, among others: Chemical Abstracts, Registry, FSTA, DGENE and so on)
- The OEPM is also using free databases for genetic sequences searching provided by EBI.

Databases for Spanish language collections:

- INVENES: Spanish documentation, not completely present at EPO databases, is assured by using this free public access database which includes the digitized Spanish documentation from 1826.
- LATIPAT: Documentation written in Spanish from Latin-American countries. Many efforts with all Latin-American countries are carried out, in order to assure the exchange of documentation: more than 2.500.000 documents from 18 countries.

No-Patent Literature. Magazine articles:

- OEPM retrieves most articles from the full text databases, for example, Elsevier and full articles from Science direct
- Other sources for providing articles come from agreements with Spanish Universities Libraries. Also the Official Research Council in Spain, which has one of the most comprehensive network of libraries, specialized in almost every field of technology provides the OEPM with copies of the NPL articles upon demand.
- British Library: In very specific cases, the British Library also provides the NPL upon demand.
- TKDL (Traditional Knowledge Digital Library; provider: Indian Council of Scientific and

Industrial). We use it to get information about knowledge of India traditional medicine.

The OEPM access to patent documentation and non-patent literature exceeds by far the minimum documentation required by Rule 34.

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 standards of training of all staff across the OEPM are very high since training is a core quality value. The OEPM assigns one full-time position to designing training courses for its Departments, according to their different needs. These people, with the participation of all parties involved establish annual training plans. Both, the training plan and the different seminars, courses, etc. receive an evaluation, which helps to design future plans.

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Continuous training is provided to Spanish Patent Examiners. On an annual basis, the OEPM offers courses of a general nature as well as specialized courses, including training in basic computer tools, general administrative procedures, Industrial Property, and updates on amendments to PCT procedures. A program called *Individual Tailored Training* is scheduled for next year, enabling patent examiners to obtain funding for courses designed to enhance their technical expertise.

Deleted: There is a continuous training for Spanish Patent Examiners. The OEPM every year organizes courses of general character or specifically related to certain matters, i.e. courses on basic tools of computers, courses to emphasize general administrative procedure or Industrial Property and courses to update any change in PCT Procedures.¶

In particular, for the staff involved in Search and Examination training covers the main topics involved in the required competencies for examiners described above , i.e.:

- Language Training Courses
- Patent Law Seminars (PCT Procedure Revision, PCT new Guidelines, etc.)
- Technical and Analytical Skills (Technical courses on specific fields, work visits, Exchange Programme Examiners)
- PC Skills and operation of electronic tools (ABS – Ansera Based Search, specific Databases, etc.)
- Classification Systems Seminars (IPC, CPC, F-terms)
- Search and Examination Skills (Courses on Novelty, Inventive step, Complex Applications, Non Unity, etc.)

These courses are conducted by the head of divisions and experienced Senior Examiners. EPO

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experts have taught Senior Patent Examiners on these topics. OEPM also participates very actively in the training courses organized by the European Patent Academy. Patent examiners tend to rate these courses very highly .

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Every year, the training program is evaluated and updated accordingly to this evaluation.

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.

OEPM continuously holds a management control over every operative unit which assures control over fluctuations in demand and possible job accumulation. This allows OEPM to establish recruitment plans.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

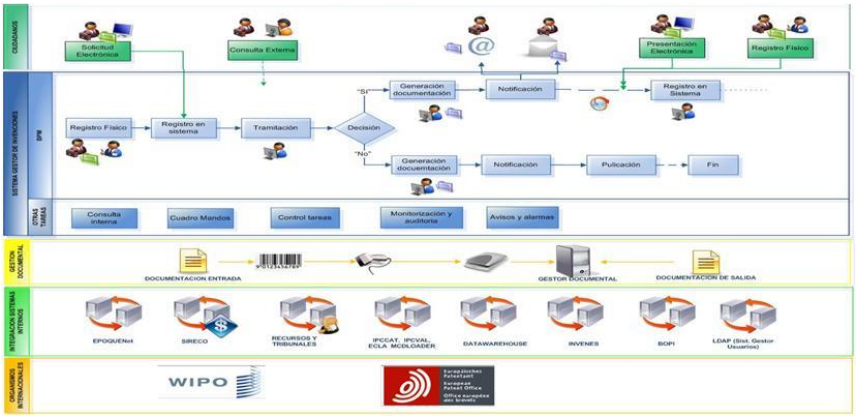
21.16 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:

(i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and

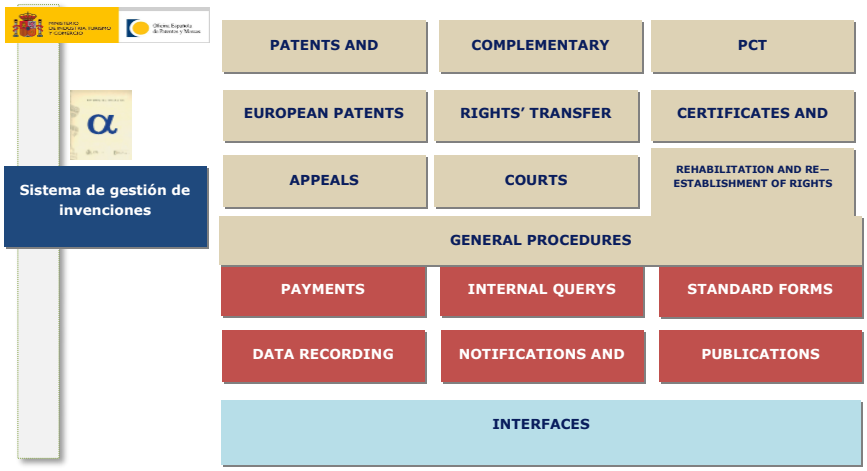
(ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

ALFA is the electronic workflow tool implemented by OEPM since November 2010:

- It is a Business Process Manager. It works with Patent applications according to a defined Process model.
- It is a tool that allows the end users to interact with applications management
- It is integrated with external systems and organisms
- ALFA registers and keeps a record of all application data and how such applications are being processed
- Includes an alert system to control timely issue of the reports



ALFA includes many functional subsystems:



The system has interfaces with:

- Content Management System
- eOLF/OEPMSEI (electronic filing system)
- Official Gazette (BOPI)
- IPCCAT (IPC preclassifier)
- LDAP (user database)
- SPEP (Publication Service)
- Payment System
- ABS Search (Importing data from cited documents)

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In addition, Heads of Technical Units have Dataware reports that help them to control the backlog and the timely issue of the reports assigned to the examiners.

5. QUALITY ASSURANCE

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

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.

(iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

OEPM reviews a representative sample of Search Reports and 100% of International preliminary examinations issued by the office each month.

This review is registered through a checklist which helps to assure that search reports and written opinions meet the expected levels of clarity, consistency and reliability. It also includes formal aspects.

The sample of Search Reports is chosen taking into account the number of applications in each Technical Unit. The verification through the checklist is registered in a specific application called: “Application for Quality Management”.The results are analyzed in the Quality Management Group of the Patent Department, where improvement actions will be approved when necessary. It is a key tool of the QMS as a source of information for improvement actions, for example, to identify training needs. These results are also feed backed at the moment to the examiner, when necessary.

ALFA has also had an impact in the quality assurance systems, especially in quality control, since the tool includes a record of the quality review done by Heads of Technical Sections prior to the issue of all the Reports.

This sort of review was already done in the past, but thanks to the tool, we can record comments done during this evaluation and extract this information afterwards.

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Process indicators are set and reviewed at the quality group meetings in order to verify the conformity of the process and to approve improvement actions of the processes when necessary. In addition, non-conformities and corrective actions are studied at the Quality Management Group of the Patent Department.

All the information (indicators, checklist results, non-conformities, corrective actions, information related to user´s satisfaction etc.) is documented in the meeting minutes of Quality management groups and published in the intranet.

Their implementation is followed up and their effectiveness is verified at the QMG meetings.
The OEPM continues with its participation in the Harmonization Files Project with the EPO.

6. COMMUNICATION

Inter-Authority communication:

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

(Note: This point is informative. No response is required by the template to paragraph 21.18)

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

(a) helping identify and disseminate best practice among Authorities;

(b) fostering continual improvement; and

(c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The Quality manager of the Patent Department, Jaime Galán Mas is the designated contact persons for this Authority.

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Communication and guidance to users:

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

(i) An appropriate system for

handling complaints and making corrections;

taking corrective and/or preventative action where appropriate; and

offering feedback to users.

(ii) A procedure for:

monitoring user satisfaction and perception; and

for ensuring their legitimate needs and expectations are met.

(iii) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.

Indicate where and how the Authority makes its quality objectives publicly available for the users.

Complaints, Suggestions and Compliments received by OEPM are handled according to the Complaints Management Procedure included in the certified QMS.

The handling of Complaints/ suggestions is a process that consists of three tasks: 1. Registry: 2. Treatment, 3. Communication and closure: The Customer Service Unit registers the complaint/ suggestion in task 1 and sends it to the Quality Manager of the department involved in the complaint. After analyzing and investigating the cause and possible solution of the complaint (task 2), the department Quality Manager sends this information back to the Customer Service Unit, which is in charge of answering the user and closing the complaint in task 3. This process is managed entirely with an electronic workflow in a computer application (Platform JIRA) where all the information regarding a complaint/ suggestion is registered (Centralised registry).

During 2024 signature with an electronic certificate, to file a complaint o suggestion was implemented.

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Feedback information extracted from complaints and suggestions is analyzed by the Quality Management Group of each department, and Quality Committee in order to decide corrective actions if necessary. There is a Service Charter with a commitment of responding 100% of complaints and suggestions within 18 working days.

Annually at OEPM, we carry out several studies to get feedback from users and information about their satisfaction. All these **user satisfaction studies** are carried out in the framework of our ISO 9001:2015 certified Quality Management System (QMS) and their targets are users of services provided by OEPM: applicants, patent attorneys and representatives. Also partners collaborating in Technological Information products.

In the past, we have used different ways to gather users feedback:

- Surveys
- Focus Groups, sessions with users in which, with the help of an independent moderator, they express their opinions and suggestions about the different aspects of the service provided by OEPM.
- Meetings with clients, associations etc. There is a form used to gather information about their opinions and satisfaction.
- Number of visits of webpages, reports. In the case of Technological Surveillance Bulletins and Technological Alerts.

Surveys are launched for each IP right every three years. The reasons for this **3-year planning** is to not to disturb users with too many requests to participate in these surveys and the fact that Improvements and changes in the service will be perceived better from one survey to the next one. Nevertheless, for some services like, for example, information services where users are new and different, surveys are done every year.

The results of these satisfaction studies are used as inputs to the Review meetings of the Quality Management Group in each department and of the Quality Committee, in order to take improvement actions.

In 2026 the following User Satisfaction Surveys (USS) will be launched at the end of the year(all of the OEPM insourced surveys):

- USS on the SME (small and medium enterprises) Support Service
- USS on Patent “Examiner on call” service
- USS on Trademarks “Examiner on call” service
- USS on Patent Technological Reports
- USS on Retrospective Searches
- USS on Technological surveillance bulletins
- USS on Information Service
- USS on Historical Archive

As mentioned in the first section of this report, European Patent Validation User Satisfaction Survey was conducted in June 2025 and Distinctive Signs User Satisfaction Survey was conducted in March 2026.

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OEPM assures concise and comprehensive **guidance and information to users** (particularly unrepresented applicants) on the S&E process using the OEPM website. Through that page, users can also find information on Quality as:

- Quality Policy of OEPM
- Service Charters
- Scope of the QMS system
- Results of User Satisfaction Surveys
- Channels to get in contact with OEPM, including how to file suggestions, comments and complaints

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A specific site is established in the OEPM web dealing with PCT and the activities of the Office as International Authority. A complete and clear information and help is given to the applicant in this site (general PCT, applicant forms, fees, patent databases, PCT publications and online filing).

In April 2018, our PCT Quality Service charter as International Search and examination Authority was renewed. Follow up data, regarding the fulfilment of the commitments included in our service charters, is monthly published in our Quality website.

Also since 2013 a special service for face to face information has been established. It is called “On call Examiner”. Patent examiners give this service, in assigned turns. They give direct assistance to applicants, which come to our office searching for information regarding technical issues. They provide this service also by telephone and by e-mail.

There is another specific information service at OEPM: “SME support service”. This service gives guidance and information to entrepreneurs and small and medium enterprises.

Another way to communicate with users used by OEPM is INFO PI, an electronic publication containing relevant and up-to-date information from both OEPM and the Industrial Property Sector in general.

Finally, OEPM has also a presence in Social media (X, , blog, YouTube, Instagram, LinkedIn) as a more informal way of reaching the public and adding a direct and quick communication with our users.

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21.21 Communication with WIPO and designated and elected Offices:

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

Communication with WIPO and designated and elected offices is done through the PCT Service of the OEPM. This service belongs to the Patent Department of the office. PCT Service addresses all feedback given by WIPO or designated and elected offices to the Department management and to the Quality Management Group.

Communication with the International Bureau of WIPO is mainly provided via PCT-EDI, e-PCT, by e-mail and telephone.

7. DOCUMENTATION

21.22 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a) the documents making up the reference that have been prepared and distributed;

(b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and

(c) document control measures taken e.g. version numbering, access to latest version.

21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

(i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;

(ii) the scope of the QMS, including details of and justification for any exclusions;

(iii) the organizational structure of the Authority and the responsibilities of each of its departments;

(iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;

(v) the resources available for carrying out the processes and implementing the procedures; and

(vi) a description of the interaction between the processes and the procedures of the QMS.

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

- *(i) a definition of which documents are kept and where they are kept;*
- *(ii) results of management review;*
- *(iii) training, skills and experience of personnel;*
- *(iv) evidence of conformity of processes, resulting products and services in terms of quality standards;*
- *(v) results of reviews of requirements relating to products;*
- *(vi) the search and examination processes carried out on each application;*
- *(vii) data allowing individual work to be tracked and traced;*
- *(viii) records of QMS audits;*
- *(ix) actions taken re. non-conforming products, e.g. examples of corrections;*
- *(x) actions taken re. corrective action;*
- *(xi) actions taken re. preventative action; and*
- *(xii) search process documentation as set out in Section 8.*

There is a Quality Manual at OEPM with the description of all the relevant features of the QMS, including the interactions of the processes, the scope of the QMS and the organizational structure.

The Quality Manual together with process cards and relevant documentation of the QMS are available to all our staff through the OEPM intranet, where the access to the latest version is assured. This documentation is created and updated according to ISO 9001:2015 requirements.

Also, most part of QMS records are registered and managed on an application called: “Application for Quality Management”. The management of the records, which are not included in this application, is done according to our Quality Manual, compliant with ISO 9001:2015 requirements. As we have described in the above sections, guidelines and working instructions for all the staff are electronically accessible.

8. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

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

(i) the databases consulted (patent and non patent literature);

(ii) the keywords, combinations of words and truncations used;

(iii) the language(s) in which the search was carried out;

(iv) the classes and class combinations searched, at least according to the IPC or equivalent;

(v) a listing of all search statements used in the databases consulted.

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

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

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

(vi) limitation of search and its justification

(vii) lack of clarity of the claims; and

(viii) lack of unity.

During the process of filling out the information regarding the International Search Report and the Written Opinion, ALFA includes a screen for recording search strategy and other related information.

The record includes:

- Databases consulted (patent and non-patent)
- Keywords and combination
- Language in which the search was carried out
- Classes and class combination searched
- List of search statements used. This application can import data from AbSearch in order to compile the search statements used by the examiner during the search.
- Possible comments regarding the search done by the examiners

As said before, some of this search process documentation is automatically retrieved from AbSearch and the examiners can complete some other information.

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9. INTERNAL REVIEW

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

21.28-21.30 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting.

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