CPVO
Community Plant Variety Office

# QAS Entrustment Procedure Manual

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# 1. Scope

The intention of this procedure manual is to provide an outline for operations of the **Quality Audit Service (QAS)** within the **Community Plant Variety Office (CPVO)**. It concerns assessments conducted by QAS and Entrustment decisions by the **Administrative Council (AC)** concerning **Examination Offices (EOs)** within or outside the European Union. It also refers to more detailed standard operating procedures for the individual processes.

The QAS Entrustment Procedure Manual is formally approved by the AC.

# 2. Related Documents

Council Regulation (EC) No 2100/94

Commission Regulation (EC) No 874/2009

ISO/IEC 17060:2022 *recommends good practices for all elements of conformity assessment, including objects of conformity assessment, specified requirements, activities, bodies, systems, schemes and results.*

ISO/IEC 17000:2020 *specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade.*

ISO/IEC 17011:2017 *specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies.* The document can be used also for peer evaluation process.

ISO/IEC 17012:2024 *specifies guidance on the use of remote auditing methods in auditing management systems. It is applicable to all organizations that plan and conduct all kinds of internal and external audits (i.e. first party, second party and third-party audits) of management systems. This document supports the general principles of auditing given in ISO 19011:2018 and provides further guidance on specific conditions, possibilities and limitations for implementing remote auditing methods. This document is meant to strengthen confidence in the use of remote auditing methods for auditing management systems amongst customers, regulators, accreditation bodies, certification bodies, scheme owners, industry, employees, consumers, suppliers and other interested parties. The use of remote auditing methods for auditing management systems is not intended to replace on-site audit methods. Instead, remote auditing methods are intended to serve as a tool to effectively and efficiently conduct the audit.*

ISO 19011:2018 *provides guidelines for auditing management systems, including quality management systems (ISO 9001) and environmental management systems (ISO 14001). It outlines the principles of auditing, managing audit programs, and conducting management system audits*.

ISO 9001:2015 ISO 9001 *is a globally recognized standard for quality management. It helps organizations of all sizes and sectors to improve their performance, meet customer expectations and demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system (QMS). Implementing ISO 9001 means your organization has put in place effective processes and trained staff to deliver flawless products or services time after time.*

NOTE: the information in italics about the content of the ISO documents is citation from ISO website.

## 3. Terms and definitions

For the purposes of this document, the following terms and definitions apply:

**Assessment/audit:** process undertaken by QAS to review the competence of an EO, based on Entrustment requirements and for a defined scope of entrustment of certain botanical taxa.

NOTE: Assessing the competence of an EO involves assessing the competence of the entire operations of the EO, including the competence of the personnel, the validity of the variety testing methodology for **distinctness, uniformity and stability (DUS)**, and the validity of the variety testing results.

**Audit Advisory Board (AAB)**: independent body made of five members: An external Chairperson, two senior CPVO representatives, and representatives from two breeders' organisations, which reviews complaints brought by EOs against decisions of QAS, and provides advice thereof to QAS and the AC.

**Caseholder**: expert within the CPVO Plant Variety Expertise Unit responsible for the management of **Community plant variety right (CPVR)** applications in a number of botanical taxa across one or more crop sectors.

**Complaint:** expression of dissatisfaction, other than objection, by any person or organisation, to the CPVO where a response is expected.

**Designation agreement**: contractual agreement between CPVO and an EO.

**Electronic Records and Documents Management System (ERDMS**): electronic system used by the CPVO to create, edit, review, share and store records and documents.

**Entrusted Examination Office (EO):** office entrusted by the AC to perform DUS variety tests on behalf of the CPVO.

NOTE: Whenever the word EO is used in the text, it applies to both entrusted EOs and EOs applying for entrustment, unless otherwise specified.

**Entrustment**: attestation by the AC related to an EO, conveying formal acceptance of its competence to carry out tasks related to DUS variety testing for a defined set of botanical taxa or types of varieties within a botanical taxon.

**Extending entrustment:** process of enlarging the scope of entrustment to other botanical taxa or types of varieties within a botanical taxon.

**Objection:** request by an EO for reconsideration of adverse decisions, actions or recommendations made by the QAS in the assessment process and related to its desired entrustment status.

NOTE: Adverse decisions include:

1) Recommendations

- not to accept an application for entrustment,
- to refuse to proceed with an assessment exercise,
- to change the entrustment scope,
- to deny, suspend or withdraw entrustment,
- corrective action requests of the QAS, and

2) Any other action by any member of the QAS that impedes the attainment of entrustment.

NOTE: Objections cannot be made against decisions of the AC.

**Preparatory meeting**: a virtual meeting involving ATL, TE(s) and Caseholder(s) organised shortly before an assessment exercise to discuss issues of last minute preparation to the assessment.

**QAS Assessment Team Leader (ATL):** responsible for the QAS, who is given the overall responsibility for specified assessment activities, including the creation and leading of QAS Teams in individual EO assessments.

**QAS Technical expert (TE):** person assigned by QAS to provide specific knowledge or expertise with respect to the scope of entrustment to be assessed.

**Reducing entrustment:** process of terminating entrustment for part of the scope of entrustment for one or more botanical taxa or types of varieties within a botanical taxon.

**Scope of entrustment:** list of botanical taxa or types of varieties within a botanical taxon for which an EO holds authorisation to carry out DUS variety testing work on behalf of the CPVO. The validated scope of entrustment and additional specifications on applicable cultivation types for each EO is published in the S2/S3 of the CPVO website.

**Surveillance:** assessment of specific elements related to an EO's scope of entrustment outside the regular reassessment schedule.

**Suspending entrustment:** process of temporarily making entrustment invalid, in full or for part of the scope of entrustment of the EO.

**Technically qualified body (TQB):** organisation performing all or part of the DUS variety testing activities under subcontracting arrangements with an entrusted EO, for one or more botanical taxa or types of varieties within a botanical taxon.

**Withdrawing entrustment:** process of terminating entrustment.

# 4. Bodies in relation to the Entrustment process

## 4.1. Legal Responsibility

The CPVO, which is a decentralised European Union agency, has its own legal status. It is self-financing, mainly on the basis of the various fees received.

## 4.2. Structure of the CPVO and the actors involved

**The Administrative Council (AC):** the CPVO is supervised by its AC, comprising a representative of each Member State and a representative of the European Commission, and their alternates. The AC advises the CPVO, formulates its general orientations and general guidelines, provides opinions, constitutes the budgetary authority of the CPVO, examines and controls both its activities and those of its President.

The AC entrusts EOs to perform variety testing on behalf of the CPVO. The entrustment decision on an EO is taken with due consideration of findings and recommendations issued by QAS after a comprehensive assessment exercise and resulting reports. The AC approves the Entrustment Requirements and the rules governing the operation of QAS. The AC is provided an annual review on the activities of QAS by the ATL, as well as a wider review at the end of each assessment cycle.

**CPVO management:** the management of the CPVO is ensured by its President, nominated by the Council of the European Union. The President takes all the necessary measures to produce the budget of the CPVO and to ensure its correct implementation in the framework of the powers conferred on him under the Community Regulations. He/She is assisted by a Vice-President who ensures his/her replacement in case of impediment. The President has delegated some of his/her duties to the Vice-President.

**Internal organisation of the CPVO:** The CPVO is organised internally into four units: Legal & Governance Affairs Unit, People & Resources Unit, **Plant Variety Expertise Unit (PVEU)**, Digital Transformation Unit. There is also the Quality Audit Service (QAS), responsible for the quality assessment of EOs. QAS performs assessments of EOs independently of the management of CPVO and reports directly to the AC regarding its assessment operations. The management of the CPVO has a supervisory role in the administrative and financial operation of QAS.

**Audit Advisor Board (AAB):** in case the EO raises an objection, the Final assessment conclusions by the assessment team are subject to review by the AAB. The AAB can further be involved in resolving complaints concerning the QAS and providing advice in the continuous development of the system.

## 4.3. Internal communication between QAS and the PVEU

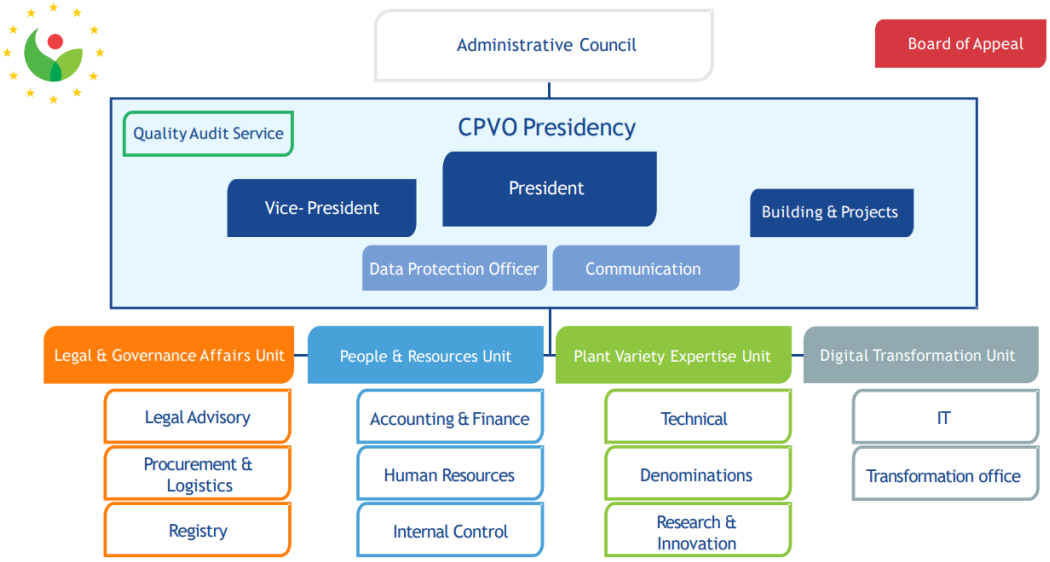
QAS acts independently within the CPVO whilst providing transparency in its activities. To ensure the best functioning of the CPVR system, QAS will provide a list at the beginning of the year of the EOs to be assessed and organise quarterly pre-briefing meetings between QAS and the PVEU, at which time QAS will address the following:

- the dates of forthcoming assessment exercises to EOs,
- the foreseen schedule of the assessment exercises to EO, including testing stations/TQBs to be assessed, crop sectors and botanical taxa being sampled,
- inform about the TE (s) assigned to each assessment exercise,
- highlight issues picked up by QAS during the analysis of information available on the EO which require further investigation,
- discuss with PVEU other issues which may require further investigation based on their daily workings with an EO,
- based upon the crop sector and botanical taxa being sampled, decide which Caseholder(s) should be present in the QAS Team virtual preparatory meeting shortly before the assessment to an EO,
- minutes shall be taken and stored in ERDMS of the quarterly QAS-PVEU meeting.

During the on-site assessment to an EO, the QAS Team may consult the relevant Caseholder(s) at a distance for clarification purposes on any issue which the QAS Team considers important.

Within three weeks after an assessment exercise to an EO, QAS shall organise a de-briefing meeting with the PVEU where it shall outline the main findings of the assessment exercise to the EO, including the nonconformities encountered and the observations made by QAS Team for improvements.

**CPVO Organisation Chart**




# 5. Impartiality and Confidentiality

## 5.1. Impartiality in the assessment process

Subject to the availability of TEs according to crop sectors, QAS has a policy of wherever possible not sending the same TE to the same EO in more than one in three subsequent assessment exercises.

The ATL and TEs are committed to highest professional standard and are under appropriate arrangements to avoid conflict of interest. This includes preventing the use of a TE for the assessment of an EO for which they currently or have previously worked. Confidentiality arrangements for TEs have to be in place.

Assessment findings and resulting recommendations are the sole responsibility of QAS, particularly of the ATL.

The AAB is consulted if the EO concerned raises an objection. Confidentiality arrangements for members of the AAB are in place.

## 5.2. Impartiality in the entrustment decision

Entrustment decisions by the AC are based on the recommendation resulting from the assessment process. Evaluation of EOs' competence is performed against the Entrustment Requirements.

In order to further avoid conflicts of interest, TEs cannot be Members or Alternate Members of the AC, and in the voting process at the AC for the entrustment of an EO, the Member State in which the EO is based is required to abstain from that particular vote.

# 6. Liability and financing

CPVO is entirely self-financing.

The CPVO receives revenue from fees for actions it performs under the Basic Regulation. These fees cover the various stages through which an application for CPVR must go and are detailed and available/published.

The amount of the various fees is set in Commission Regulation (EC) n°1238/95 and is based on experience, sound financial considerations and cost effectiveness.

The expenditure of the CPVO consists, apart from staff and general running costs, of operational expenditure, i.e.: expenditure on DUS technical examinations carried out by the EOs for the CPVO and the purchase by the CPVO of existing national DUS technical examination reports (take overs).

The CPVO runs a balanced budget.

The costs associated with the assessments of EOs (CPVO staff expenditure, travel and subsistence costs for the ATL and the TE(s), as well as the honorarium for the TE(s)) are borne solely by the CPVO. QAS makes use of an annual budget line dedicated to audit expenditure in the CPVO accounts. Before any TE is formally appointed for an assessment exercise, the ATL is required to make a formal financial commitment to ensure that assessments are carried out within budget.

# 7. Entrustment /Auditing/EO assessment

## 7.1. Entrustment Requirements for CPVO EOs

The Entrustment Requirements shall be reviewed on a regular basis. QAS conducts assessments of EOs against requirements specified in the latest adopted version of the *Entrustment Requirements for CPVO Examination Offices* and related documents such as CPVO technical protocols, UPOV test guidelines, national protocols, CPVO Designation Agreements and other guidance documents.

## 7.2. Frequency of assessment exercises to EOs

Each assessment cycle lasts four years, during which time QAS has to undertake a regular assessment for each entrusted EO at least once. Under exceptional circumstances, the AC may decide to prolong the assessment cycle.

## 7.3. Assessment process

The assessment process involves expertise from external sources through TEs participating in assessments, and if necessary, through the AAB.

EOs with a certification or accreditation covering all or part of their activities will be able to use systems developed in order to demonstrate compliance with respective requirements. While an assessment by a QAS assessment team will be conducted as in EOs without certified management system, the documentation submitted to CPVO in English may be limited to technical documents and records and appropriate evidence that the certification addresses the corresponding organisational aspects of *Entrustment Requirements for CPVO Examination Offices*. Auditing activities initiated under such schemes will be recognized as equivalent to internal audits required by CPVO to the extent they include activities covered by *Entrustment Requirements for CPVO Examination Offices*.

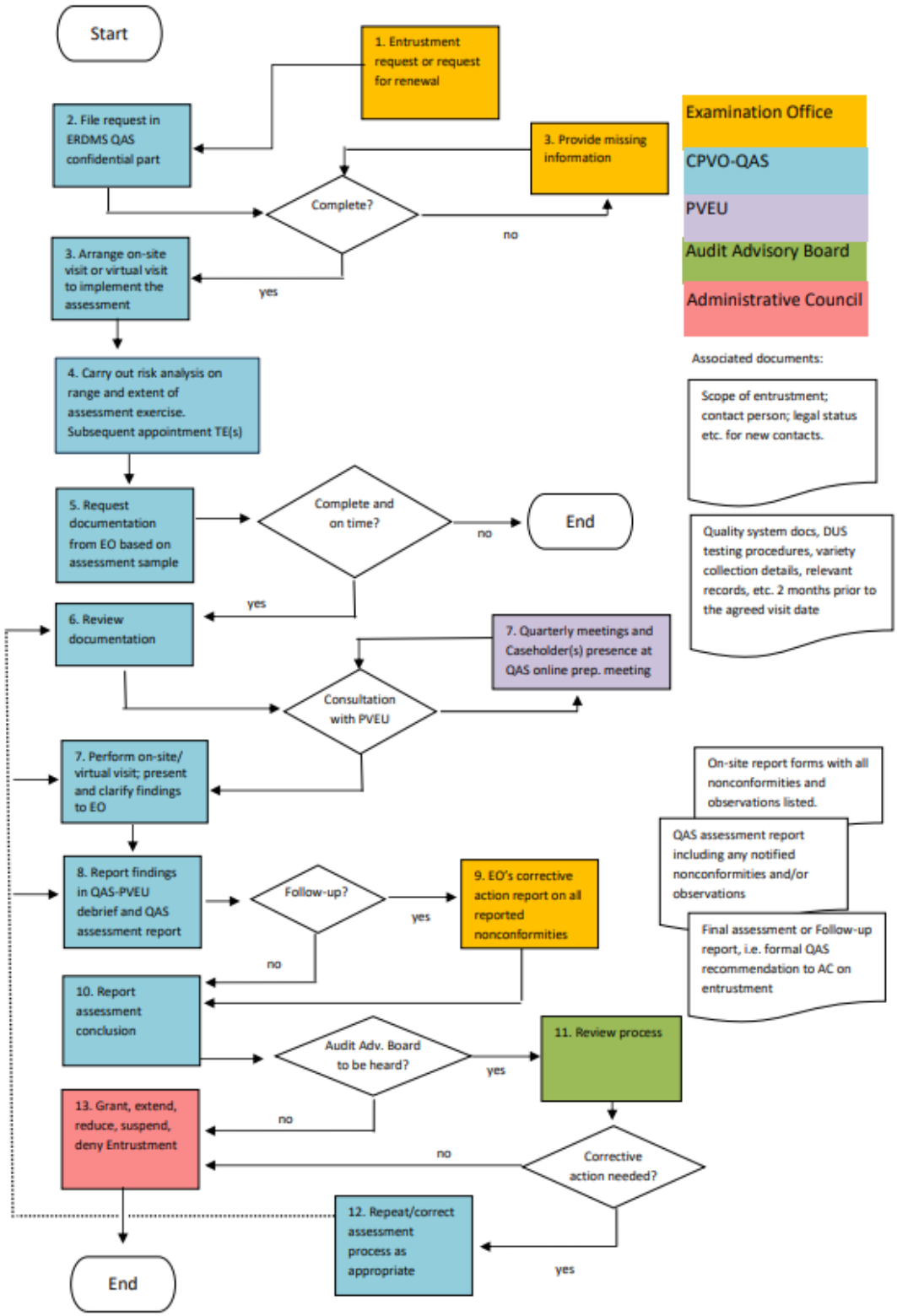
Whereas each assessment exercise to an EO normally requires a physical on-site visit by QAS, circumstances may dictate that this is not possible or desirable. In such circumstances, a remote assessment exercise can be carried out to replicate an on-site visit in the most appropriate manner. QAS and the EO in question will consult and decide together whether an on-site visit can go ahead, and if not, to revert to a remote assessment on the same dates as had been foreseen for the on-site visit. Remote assessments and desktop assessments can also be utilised for extension of entrustment or surveillance assessments EOs where a limited number of botanical taxa are concerned.

New species and new interspecific hybrids

For botanical taxa without CPVR applications to date and that are not yet covered in an existing scope of entrustment, CPVO may initiate a call for expression of interest once an application for CPVR is received (new species procedure).

The result of the new species procedure will be a recommendation by CPVO to the AC in order to extend entrustment concerning the botanical taxon for which the EO has expressed its interest. The extension will then be subject of an assessment by QAS at the time of the next regular assessment scheduled for the EO in question.

## 7.4. **Process Flow Chart**



# 8. Management

## 8.1. Management system

QAS, through the ATL, reports directly to the AC on all activities related to the assessment of EOs. Quality is the responsibility of all QAS personnel. All individuals involved in work of QAS are committed to providing high quality assessment services through the continuous improvement of QAS' management system. This commitment is reflected in the following objectives for quality:

- to communicate frequently with stakeholders to determine their needs and requirements with respect to entrustment,
- to develop assessment programmes, using balanced input from TEs and interested parties,
- to meet the highest professional standards for integrity, impartiality, and ethical conduct,
- to manage resources in a manner that maximizes delivered value to EOs,
- to achieve cost effectiveness.

The management system is modelled on the requirements of ISO/IEC 17011:2017 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies. Documented procedures and policies are available in all areas postulated by this standard:

- effective involvement of interested parties,
- subcontracting based on contractual agreements,
- possible extension of activities and making use of external expertise,
- document control,
- record control incl. retention aspects,
- nonconformities and corrective action,
- preventive action,
- internal audits and checklist,
- reviews by ac,
- complaints,
- selection and appointment of people involved in entrustment process, where necessary, training requirements and training plan,
- monitoring the assessment process,
- sampling of representative scope elements/test sites,
- objections,
- surveillance activities (visits and others) and their frequency,
- suspension, withdrawal and reduction of scope of entrustment.

The position of the ATL includes the responsibility and authority to ensure that procedures needed for the management system are established, adhered to and that performance of the system is monitored. Reports on the annual activities of QAS are routed through the regular AC meetings and CPVO Management Reviews.

## 8.2. Document control

Uncontrolled external documents are available through the CPVO website and other sources. It is each individual's responsibility to make sure that up-to-date versions of relevant QAS-related publications are consulted.

CPVO internal documents are available on the CPVO intranet. These documents are under the control of different units and are updated according to the procedures implemented in those units.

Internal documents relevant to the entrustment process are issued with distinct document control features such as the approval, a version number and the date of issuance. Version control, access restrictions and archiving is achieved through the SharePoint and ERDMS document management

system. For specific documents access to other stakeholders or the general public is provided through the extranet.

Reviews of controlled documents ideally involve the functions that participated in drafting the original document.

## 8.3. **Records**

Assessment records and associated files linked to individual EO assessment exercises are kept in the document management system of CPVO with defined access authorisations (QAS sensitive area of ERDMS). Electronic files are kept for an undetermined period, hard copies for a minimum of six years in a locked filing cabinet. Unrestricted access is granted to QAS personnel within the CPVO. Access to others to specific records or individual assessment exercises, is limited to situations where this is needed in order to fulfil a function defined in this manual or in one of the regulations governing the operations of the CPVO.

Where operating procedures refer to a specific form, this will be used. All forms have provisions for unambiguous identification of records. In all other cases records are identified by a series of entries that will include but not be limited to:

- section/ subject,
- date,
- person(s) taking the record.

Corrections to paper records are made by invalidating the relevant entry without rendering it illegible and by authorising the correction with date and initials.

## 8.4. **Nonconformities and corrective actions**

Nonconformities are addressed in a timely and systematic manner through the corrective action and complaint procedure. The approach is extended to complaints and to observations indicating the potential for improvements. Records are kept on the related form. Preventive actions

Preventive measures are implemented through the *Corrective action and complaint procedure* which allows for a risk assessment approach by following up on observations that do not qualify as nonconformities but carry the potential to improve the DUS testing system by being addressed. Any such observations will be reported by QAS to the CPVO Management and the PVEU on a regular basis through the QAS de-briefing meetings within three weeks after the assessment of an EO.

## 8.5. **Internal audits**

Internal audits of QAS are carried out as integral part of the CPVO internal audit programme. Results of the QAS related observations and audit findings will be presented to the members of the AC in a summary report, where relevant with details on the corrective action initiated. Internal audits may be carried out by the contracted internal audit supplier of the Office or by CPVO staff appointed for that purpose.

## 8.6. **Review report to the AC**

Annually a report by QAS to the AC takes account of:

- results of audits,
- results of peer evaluation where relevant,
- participation in international activities, where relevant,

- feedback from interested parties,
- new areas of entrustment,
- trends in nonconformities,
- status of preventive and corrective actions,
- follow-up actions from earlier management reviews,
- fulfilment of objectives,
- changes that could affect the management system,
- objections,
- analysis of complaints,
- need for certification of the QAS under ISO 9001 or others.

At the end of each 4-year assessment cycle, QAS will also provide to the AC a review of the completed cycle and proposals (if any) for improvement to the following cycle.

### 8.7. **Complaints**

Complaints may relate to any aspect of the work of QAS or entrustment of EOs. Complaints are addressed through the corrective action and complaint procedure. Irrespective of the origin, complaints are recorded, reviewed and receipt is confirmed to the complainant. In case further action is needed in order to deal with the complaint, parties concerned are provided with feedback at appropriate stages.

## 9. Human resources

### 9.1. **Personnel associated with the QAS**

The CPVO has one full-time post within the Quality Audit Service for operating the entrustment system, namely the ATL. To ensure QAS continuity of service, the ATL shall have a permanent substitute within the CPVO. The ATL and the substitute ATL shall meet regularly to ensure the assessment schedule in the ongoing four-year assessment cycle and to provide mutual advice. Job descriptions specifying the requirements of the posts are held and regularly updated in the CPVO HR Service. Initial and continuous training of the ATL and his/her substitute follows an established programme in accordance with the CPVO training policy.

TEs involved in assessment are approved by the AC (List of TEs in entrustment assessments) and assigned on a need's basis for individual assessments by the ATL. TEs can be renewed an indefinite number of times. At the end of each assessment cycle a call for tender is made by the CPVO to renew the pool of TEs. The eligibility criteria to become a TE are the following:

- be a national of a Member State of the European Union,
- have proven experience of having worked in DUS testing for a period of at least five continuous years and have proven knowledge of this,
- if the applicant no longer works in DUS testing or has retired, his/her last experience in this area shall be no more than three years before the closing date outlined in the call for tender for receipt of applications to become a TE,
- have a satisfactory level of English at least to the B2 level. Proof of such level may be required,
- have been subject of a QAS assessment exercise themselves and is aware of its procedures.

A selection board of the ATL, the substitute ATL and the Head of the PVEU shall review the candidatures for TEs based on the criteria above and propose a list of eligible candidates to the AC for approval.

The pool of TEs is approved for a term of four years corresponding to the assessment cycle, notwithstanding individual approvals for any remainder of the four-year period. In case the number of experts available for audits drops significantly (more than 15 %) a simplified call for expression of interest shall be launched.

QAS shall provide specific training to first-time TEs on auditing techniques at the start of each 4-year assessment cycle. Such training may also be provided to reappointed TEs upon request, and after evaluation of the request by the ATL. In case of changes to QAS procedures and/or the Entrustment Requirements, information session on these will be provided to all TEs.

Scope and limits of duties related to the ATL and the TE involved are specified in the job descriptions and terms of reference.

Roles and responsibilities ATL and TE:

ATL

- has overall responsibility for the assessment,
- launches formal notification of the assessment exercise to the EO,
- assigns one or more TEs according to crop sector for specific assessment exercises and makes corresponding budgetary commitment,
- interact and make arrangements with EO and associated TQBs via the TLO,
- organises trip and prepares assessment schedule,
- requests detailed documentation on DUS testing process and quality manuals from EO and distributes this to the TE(s),
- organises a virtual bilateral meeting with the TE(s) one week before the assessment to review the documentation received from the EO, and to highlight any aspects which need to be analysed further
- presents assessment objectives,
- evaluates EO's organisational and structural arrangements in accordance with assessment criteria and schedule,
- prepares record summary (at the time of assessment), specifying nonconformities and observations with reference to related assessment requirements,
- provides assessment findings and assessment conclusion,
- prepares assessment report,
- follow-up report(s) on corrective action reports supplied by EO,
- preparation and presentation of QAS recommendation on entrustment to the AC.

TE

- evaluate EO's technical arrangements in accordance with assessment criteria and schedule,
- verify implementation aspects for relevant technical protocols,
- advise ATL in technical and related fields (including aspects on intercultural communication if required),
- participate in the follow-up on assessment findings, including the associated reports.

## 9.2. **Personnel involved in the entrustment process**

For CPVO QAS personnel involved in the entrustment process, all regulations and arrangements of the CPVO and governing EU regulations apply, namely staff regulations and associated rules.

External TEs are recruited on an honorarium basis. Appointment criteria such as technical expertise, experience in conformity assessments and communication skills are specified in the TE guidelines. TEs shall have their expenses reimbursed based upon the applicable rules of the CPVO and be paid

an honorarium for their services based upon the duration and complexity of the assessment exercise as outlined in a decision of the CPVO.

The AAB is an independent body involved in the entrustment process in case of doubts as to the integrity of an assessment. It is composed of a Chair and four members representing CPVO (2, outside QAS), CIOPORA (1) and Euroseeds (1) and provides advice to the AC in its final entrustment decision. The AAB is appointed by the AC for a period of four years. Its Chair shall be a member of the AC whose Member State does not possess an entrusted EO, or potential entrusted EO, within the same assessment cycle; he/she should preferably have experience in conformity assessment or auditing. Individuals appointed as members will not have alternates or proxies. The AAB convenes well in advance of AC meetings in order to fulfil its advisory role at the occasion of AC entrustment decisions. In addition, it may consult by correspondence or be called for an extraordinary meeting.

The AC is responsible for Entrustment of EOs. Its establishment and composition are governed by Council Regulation EC 2100/94 and related Commission Regulations.

### 9.3. **Monitoring**

The entrustment process is monitored by always involving a number of people at all stages and by implementing a separation of duties concept as a form of internal control. The ATL continuously monitors the work of TEs during the assessments and feeds the findings into the training programme. Upon appointment and no later once every four years, the ATL is peer monitored during an onsite visit by an external auditor or the CPVO internal auditor, unless there is sufficient documentary evidence that the performance is up to the requirements. Reviews of assessment reports and feedback from EOs are taken into account continuously, through the corrective action and complaint procedure or the objection procedure.

### 9.4. **Personnel records**

Records for CPVO employees are kept with the HR Service. Relevant personnel data for TEs and other external resource persons are kept in the CPVO Contact database and in PVR. Training records are with the CPVO training coordinator.

QAS is bound by the same personal data protection measures as the rest of the CPVO entities, namely Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.)

## 10. Entrustment process

### 10.1. **Entrustment criteria and information**

Criteria used in assessing the competence of EOs are documented in the *Entrustment Requirements for CPVO Examination Offices* issued under the authority of the AC.

Via the CPVO annual reports and documents available on the CPVO website, regular updates of information in relation to the activities of the QAS are provided:

- detailed information about its assessment and entrustment processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing entrustment (Entrustment Procedure Manual),

- a document or reference documents containing the requirements for entrustment, including technical requirements specific to each field of entrustment, where applicable (technical protocols and Entrustment Requirements),
- a description of the rights and obligations of EOs,
- information on the entrusted EOs (CPVO intranet, CPVO website),
- information on procedures for lodging and handling complaints and objections (Entrustment Procedure Manual),
- information about the authority under which the entrustment programme operates (Entrustment Procedure Manual, CPVO intranet, Basic Regulation),
- a description of its rights and duties (Entrustment Procedure Manual, CPVO intranet, Basic Regulation),
- general information about the means by which it obtains financial support (Single Programming Document, CPVO intranet),
- information about its activities and stated limitations under which it operates (Entrustment Procedure Manual),
- information about the related bodies (Entrustment Procedure Manual).

## 10.2. **Application for entrustment**

EOs filing an application for entrustment are requested to provide information in respect of:

1) general features of the EO, including legal entity, name, addresses, legal status and human and technical resources,

2) general information concerning its activities, its relationship in a larger corporate or government entity if any, and addresses of all its physical location(s) to be covered by the scope of entrustment,

3) a clear definition of the scope of entrustment requested (botanical taxa),

4) specifications on any existing certification/accreditation including the areas of work relevant to the variety testing work covered by such existing attestation,

5) information as indicated in 1)-4) for each technically qualified body intended to be carrying out all or part of the DUS examination work for any given botanical taxa.

Before the initial assessment, a preliminary evaluation may be conducted if this is the expressed wish of both, the CPVO and the EO; for example, in the pursuit of improving the assessment procedure. Wherever possible, this preliminary evaluation shall be done by virtual means. The main scope of any such preliminary assessment will be the confirmation of the EOs conformance with the requirements and identification of likely nonconformities. Under no circumstances will consultancy be provided.

## 10.3. **Renewal of entrustment**

For subsequent assessments EOs are contacted by QAS every four years to establish whether they intend to maintain their entrustment. A positive response by the EO leads to an extension of the validity of the current entrustment for the period until a new recommendation by QAS is submitted to the members of the AC. Routinely information requests to the EOs include:

- any of above if changes occurred compared to the situation at the time of the most recent assessment,
- a clear definition of the scope of entrustment requested,
- a list of proposed technically qualified bodies with their respective scope of examination work.

Before arranging for an assessment, the EO may be requested to submit a copy of its quality manual and relevant associated documents or excerpts (wherever possible in English) as selected by the assessment team. For EOs using subcontracting arrangements a request for relevant documents held by the cooperating TQBs will be made in due course.

The information supplied will be reviewed for adequacy and assessment arrangements made as appropriate.

## 10.4. **Resource review**

QAS regularly reviews its ability to carry out the assessment of the applicant EO, in terms of its own policy, its competence and the availability of suitable TEs.

The review also includes the ability of QAS to carry out the initial assessment in a timely manner.

## 10.5. **Preparation for assessment**

After agreement between QAS and the EO on the dates for the assessment, QAS shall carry out a risk analysis of that EO to determine the range and extent of the assessment exercise. This shall determine in particular the DUS testing sites to be assessed and the sample of botanical taxa to be evaluated. Amongst the criteria that QAS shall consider are:

- volume of DUS testing work performed by the EO for the CPVO,
- number and relative importance of botanical taxa for which the EO is entrusted and last time in which the botanical taxa were assessed by QAS,
- the last time when the DUS testing sites for that EO were visited,
- changes in the scope of entrustment of the EO, either in the form of botanical taxa or use of TQBs,
- findings from previous QAS assessment reports,
- areas of concern highlighted during the QAS-PVEU quarterly meetings,
- information provided in Caseholders' monitoring mission reports.

For each assessment exercise an assessment team is appointed, consisting of the ATL and TE(s) qualified for the sample of botanical taxa as determined above Where the nature of the EO's scope and the number of crop sectors during the assessment exercise so requires, more than one TE may be appointed. The selection of the assessment team is a function of the required qualifications – including language knowledge and availability. It takes into account the provisions for impartiality and avoiding conflicts of interest. The team composition is communicated to the respective EO at least two months before the assessment. Provided the EO is able to substantiate any objection as to the composition of the assessment team, this will be taken into account and to the extent practically feasible.

EOs with an implemented quality management system and associated certification or accreditation will be requested to submit documentary evidence in order to demonstrate to what extent the implemented arrangements cover the intended scope of entrustment. The assessment will be set up in a way to avoid duplication of effort, particularly with respect to providing translated versions of detailed procedures and work instructions. The assessment will be carried out by an assessment team as described above (ATL, TE(s) to take advantage of the internal control resulting from segregation of duties.

The task of the assessment team is to review the documents collected, conduct the assessment, follow up on and evaluate any corrective action reports that might be requested and to provide a final recommendation to the AC with respect to the application of the EO.

For EOs with several DUS test locations and for those with subcontracting arrangements, assessments by QAS shall wherever possible cover all sites within two consecutive assessment cycles.

## 10.6. **Document and record review**

The assessment team reviews all relevant documents and records supplied by the EO and the selected subcontractors to evaluate its system, as documented, for conformity with the relevant requirements (step 6 in process flow chart).

The evaluation of the documents leads to either:
- stopping the procedure due to nonconformities that cannot be remedied within a period of four weeks,
- requesting further documents / explanations, or
- making arrangements for the assessment exercise.

## 10.7. **On-site or remote assessment**

Opening meeting:

Purpose, scope and schedule are confirmed.

Conduct the assessment and collect audit evidence by observing, interviewing staff, reviewing records. Relevant evidence is recorded in the assessment checklist.

Evaluation of evidence:

Evidence is evaluated against the requirements and resulting audit findings are recorded.

In case the assessment team cannot conclude on a specific observation at the time of the visit, the issue will be recorded as pending. The assessment team will organise a timely follow-up and a final decision will be communicated to the EO within six weeks after the visit.

Closing meeting:

Observed non-conformities are presented to the EO and are placed on record in detail via the "Audit Observation Form: Nonconformity". The EO's comments, explanations and clarifications are taken into account, and a deadline is agreed upon for corrective action to be undertaken by the EO sufficiently in advance of the recommendation to the AC (step 7 in process flow chart).

Observations by the assessment team which are not in contravention of the Entrustment Requirements (and therefore not considered to be non-conformities), but which are nonetheless proposals for the improvement of an EOs DUS testing practices, are presented to the EO and are placed on record in detail via the "Audit Observation Form: Observation". The EO's comments, explanations and clarifications are taken into account, and a deadline may be agreed upon for action to be undertaken by the EO.

A copy of the record of all observed non-conformities and observations is made available to the EO. The aim is to provide a sufficient basis for follow-up activities and corrective action reports by the EO. An assessment conclusion is provided orally.

After the assessment, an assessment report will be drafted by the ATL in consultation with the TE(s). The assessment report provides a comprehensive summary of the assessment and lists the nonconformities and observations with a reference to the respective chapter in the Entrustment requirements. It also includes an assessment conclusion and the agreed deadline for reporting corrective action measures and for providing evidence of their effectiveness. The final version of the assessment report shall be signed off by the ATL and countersigned by the TE, and it shall be sent to the EO within one month after the on-site visit.

Review of corrective action:

Corrective action reports and submitted documents from the EO on nonconformities are reviewed by the assessment team. Further clarification and additional documents may be requested as necessary. The initial deadline for nonconformities shall not be extended for more than two months.

QAS shall report on all the observations noted during an assessment exercise to the PVEU in the debriefing meeting. The PVEU and CPVO management will review the observations and may take up the matter further in bilateral discussions with the relevant EO(s).

## 10.8. **Recommendation for entrustment decision**

Once the final deadline is reached on the nonconformities, the corrective action reports of the EO are evaluated by the assessment team. Within two weeks, the assessment team summarises the corrective action activities carried out by the EO and adopts a follow-up/recommendation report addressed to the entrustment decision body, the AC (step 10 in process flow chart). One copy of the recommendation report is sent to the EO for information, containing the following information:

- unique identification of the EO and associated technically qualified bodies,
- date(s) of the on-site assessment,
- name(s) of the ATL and TE(s) involved in the assessment,
- unique identification of all premises assessed,
- proposed scope of entrustment that was assessed – extension/reduction of scope,
- the assessment report,
- a statement on the adequacy of the internal organization and procedures adopted by the EO to give confidence in its competence, as determined through its fulfilment of the requirements for entrustment,
- information on the resolution of all nonconformities,
- any further information that may assist in determining fulfilment of requirements and the competence of the EO,
- a recommendation as to granting, reducing or extending entrustment for the proposed scope, as appropriate.

## 10.9. **Suspending, withdrawing, reducing or extending entrustment, and "new species" entrustment**

Changes to the current scope of entrustment may be initiated by the EO or through findings that transpire from QAS assessment or monitoring activities. They include:

i. Temporary reduction of the scope of entrustment or temporary discontinuation of testing work due to events that impact on the EO's ability to conduct its work or part thereof in compliance with the requirements, i.e. suspension. Suspension decisions by the AC typically involve a defined duration and a timeframe for re-assessment of the situation.

ii. Withdrawal by the EO of all its entrustment, or part of the entrustment for defined botanical taxa. This terminates any future DUS variety testing work on behalf of the CPVO, although in conformity with the Designation Agreement, the EO is obliged to conclude any ongoing technical examinations which are subject of the withdrawal.

iii. Reduction of the scope of entrustment in response to a nonconformity that cannot be remedied.

iv. Extending the scope of entrustment in order to cover additional botanical taxa and/or involve additional technically qualified bodies under the responsibility of an EO. This typically requires the assessment of the ability to cope with the new scope elements. EOs wishing to extend their scope of entrustment can submit a request to QAS at any time through the

TLO website; QAS will subsequently notify the PVEU and other entrusted EOs for that botanical taxon that a request for an extension of entrustment has been received from another EO. An extension request shall preferably be handled by QAS during a regular assessment exercise to an EO, but in pressing cases an extension assessment will be organised by QAS at an appropriate time during the assessment cycle.

v. When the CPVO launches a "new species" procedure, entrustment for botanical taxa is granted to an EO by a separate AC written procedure. Botanical taxa entrusted to an EO since the last regular assessment exercise will, wherever possible, form part of the assessment sample of botanical taxa to be reviewed by QAS at the next assessment exercise to that EO.

Based on a recommendation to suspend, withdraw reduce or extend, the AC takes a decision as provided for in section 10.10.

### 10.10. **Decision-making and granting entrustment**

The AC takes a formal entrustment decision on the basis of the recommendation from QAS and after having reviewed the opinion of the AAB in cases where it has been necessary to consult it (step 13 in process flow chart). The AC decision should not normally be taken less than four weeks after the recommendation of the QAS has been given to the EO concerned. The EO may waive the mentioned deadlines. Entrustment decisions enter into force on the date of the AC decision. A designation agreement between the EO and CPVO must be entered into in all cases entrustment is granted.

Entrustment decisions are notified to the EOs concerned and an Entrustment Certificate is issued. Records on the scope of entrustment, validity and technically qualified bodies agreed to be covered are retained in the document management system of the CPVO (ERDMS).

Validity of entrustment is for four years based on the date of the on-site visit at the main site of the EO. In case an application for re-entrustment is filed towards the end of that period, validity is automatically extended for the duration of the reassessment until the following entrustment decision by the AC for the respective EO is taken, subject to a valid designation agreement covering the extension period.

## 11. Objections

Objections by the relevant EO concerning the assessment or the recommendation issued by the assessment team may be filed at any time during the process until up to four weeks after the final assessment report, or where pertinent the follow-up report (i.e. the QAS recommendation) was issued. The AAB established in order to deal with such issues will be involved in accordance with the objection procedure and advise on appropriate measures.

Only EOs can raise an objection against an entrustment related decision within the four weeks after the assessment team's recommendation for granting, withdrawing, reducing or enlarging the scope of entrustment (final assessment report). The AAB is informed in due course.

<u>Stage 1</u>

The first steps of recording and providing feedback to the objector follow the corrective action and complaint procedure. The chair of the AAB establishes a preliminary timeframe which is communicated to parties involved:

- deadline for decision whether an objection is admissible,
- kind and format of additional information required,

- submission deadline for additional information,
- communication channels.

Stage 2

The AAB investigates the matter and solicits information and clarification as required. Statements and explanations provided will be circulated to the parties involved at the discretion of the AAB.

Stage 3

A recommendation resulting from the deliberations of the AAB issued by the chairperson will be forwarded to the AC that will take a decision regarding the action to be taken.

Stage 4

Following the AC's decision the QAS will be implementing the conclusion in cooperation with any other function as required. The objector will be duly informed.

# 12. Reassessment and surveillance

## 12.1. **Reassessment process**

Reassessment is similar to an initial assessment as described before, except that experience gained during previous assessments shall be taken into account. The interval between subsequent assessments at one EO should be 48 months ± 4 months based on the on-site visit of the main site. Additional reassessment visits may be organised in exceptional cases such as for scope extensions, additional subcontracting arrangements or substantial changes in the EO's setup.

## 12.2. **Surveillance assessment**

A surveillance assessment is launched by QAS after having been formally notified by the PVEU and the President of the CPVO of either (i) an important deficiency in the DUS testing procedures of an EO, or (ii) the non-respect of an EO of its obligations under the designation agreement. After the formal notification of the problem to QAS, the ATL shall contact the TLO of the pertinent EO to make them aware of the problem and shall liaise with the EO to organise an onsite surveillance assessment as soon as is practicably possible. The surveillance assessment will usually be conducted solely by the ATL, although in duly substantiated cases the ATL may be accompanied by a TE if a particular technical expertise is required.

The onsite surveillance assessment to an EO shall follow the same process as a regular assessment exercise, except that it shall limit itself to the problem highlighted to QAS by the CPVO. At the end of the onsite surveillance assessment, the ATL shall present its conclusions to the EO, including reports on any nonconformities or observations found by QAS in relation to the problem highlighted by the CPVO and the timeframes to remedy these. Within two weeks of the onsite surveillance assessment, the ATL shall issue a surveillance assessment report to the attention of the Presidency of the CPVO and to the Head of the PVEU, with a copy to the TLO of the EO.

In the case of severe nonconformities arising from the surveillance assessment, which would put into peril the continuation of DUS testing at the EO for certain botanical taxa, the ATL shall immediately inform the Presidency and the Head of the PVEU of the findings and issue an opinion on whether to suspend the entrustment of the EO for the botanical taxa in question. The decision on suspension of entrustment is taken by the AC.

# 13. Records on EOs

Assessment related records are kept in confidence at the QAS and stored electronically in the QAS sensitive area of ERDMS. Contractual arrangements with respect to the scope of entrustment and contact details for EO staff involved in communications are kept in the PVR database. Some of this information is available to a broader public on the restricted access area of the CPVO website. The scope of entrustment for entrusted EOs is published on the CPVO web site.

# 14. Responsibilities of the CPVO and the EO

## 14.1. **Obligations of the EO**

EOs are required to comply with the requirements linked to entrustment through the contractual agreement entered into with the CPVO.

## 14.2. **Obligations of the CPVO**

Relevant information in respect of the entrustment process, the current status of entrusted bodies and their scope of entrustment is accessible through the CPVO web site and may be requested by the public in accordance with the CPVO's information policy.

Changes to contractual arrangements and to the set of requirements governing entrustment undergo a system of consultation, review and approval as it was the case since the inception of the CPVRs system.

## 14.3. **Reference to entrustment and use of symbols**

There are currently no provisions for a symbol or mark to be used by entrusted EOs to emphasize their status on technical documents or promotional material. Reference to the status in an unambiguous statement on such documents shall be made at the discretion of the EOs. The logo of the CPVO shall not be reproduced by any EO.