CPVO
Community Plant Variety Office

QAS Entrustment Procedure Manual

Andrew Mitchell 12/10/2015

Date and Signature Mr Andrew Mitchell, Chairperson of the Administrative Council

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1. Scope

The intention of this internal procedure manual is to provide an outline for operations of the Quality Audit Service (QAS) within the Community Plant Variety Office (CPVO). It specifies interactions of the QAS with other CPVO entities with respect to assessments conducted by QAS and to entrustment decisions by the Administrative Council (AC) concerning Examination Offices (EOs) in Member states. It also refers to more detailed standard operating procedures for the individual processes

The Entrustment Procedure Manual is to be approved by the Administrative Council.

2. Related Documents

Council regulation (EC) No 2100/94

Commission regulation (EC) No 874/2009

ISO/IEC Guide 60:2004 recommends good practices for all elements of conformity assessment, including normative documents, bodies, systems, schemes and results

ISO/IEC 17000:2004 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/PAS 17001:2005 contains principles and requirements for the element of impartiality as it relates to standards for conformity assessment

ISO/PAS 17002:2004 contains principles and requirements for the element of confidentiality as it relates to conformity assessment.

ISO/PAS 17003:2004 contains principles and requirements for the elements of complaints and appeals as they relate to conformity assessment.

ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies.

ISO 19011:2011 provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits. It provides guidance on the competence of management system auditors and introduces, in its latest version, the concept of remote auditing methods.

ISO 9001:2008 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

3. Terms and definitions

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

Assessment/audit: process undertaken to review the competence of an EO, based on quality requirements and/or other normative documents and for a defined scope of entrustment.

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 and the validity of the variety testing results.

Assessor: person assigned by the CPVO to perform, alone or as part of an assessment team, an assessment of an EO.

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.

Entrusted Examination Office: office entrusted by the AC to perform variety tests on behalf of the CPVO.

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

Entrustment: attestation by the AC related to an EO, conveying formal acceptance of its competence to carry out tasks related to variety testing.

Extending entrustment: process of enlarging the scope of entrustment.

Lead assessor: assessor who is given the overall responsibility for specified assessment activities.

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

a) Recommendations

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

b) 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

Reducing entrustment: process of terminating entrustment for part of the scope of entrustment.

Scope of entrustment: list of genera and/or species for which an EO holds authorisation to carry out variety testing work on behalf of the CPVO. The validated scope of entrustment and additional specifications, e.g. applicable cultivation types, for each EO is published in the public area of the CPVO website.

Surveillance: Assessment of specific elements related to an EO's (intended) 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.

Technical expert: person assigned by CPVO to provide specific knowledge or expertise with respect to the scope of entrustment to be assessed.

Technically qualified body: agency performing variety testing activities under subcontracting arrangements with an entrusted EO.

Withdrawing entrustment: process of terminating entrustment in full.

4. Entrustment Authority

4.1. Legal Responsibility

The CPVO, which is a decentralised Community 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: the CPVO is supervised by its Administrative Council (AC), comprising a representative of each Member State and a representative of the European Commission, and their alternates. The Administrative Council 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.

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 in order 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 is assisted by a Vice-President who ensures his replacement in case of impediment. The President has delegated some of his duties to the Vice-President.

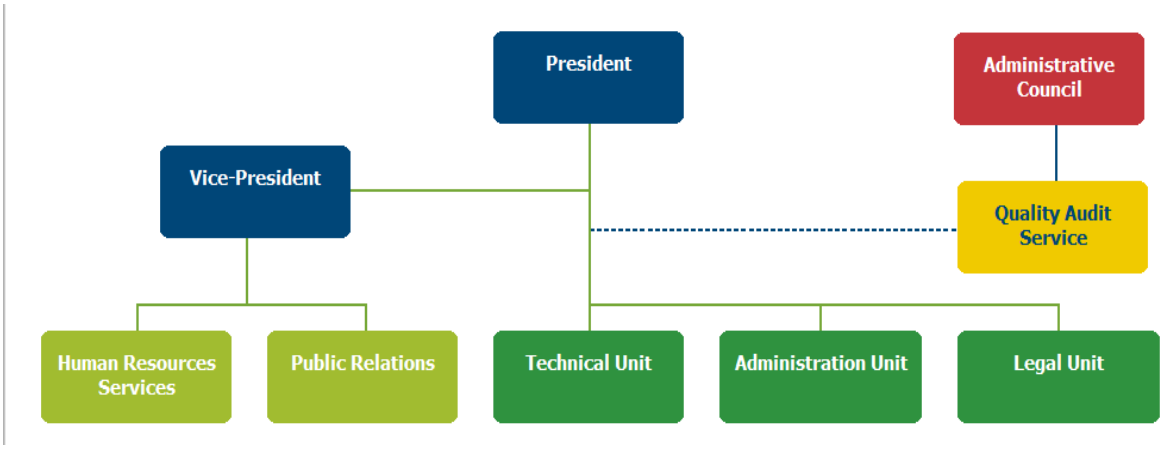
Internal organisation of the CPVO: The CPVO is organised internally into three units (Technical, Administration & Legal) and two support services (Human Resources & Public Relations). There is also a service responsible for the quality auditing of examination offices. This service is under the administrative responsibility of the President while being independent with regard to its audit operations.

The AC entrusts EOs to perform variety testing on behalf of the CPVO. The entrustment decision is taken with due consideration of findings and recommendations issued by QAS after a comprehensive assessment. It approves the rules governing the operation of QAS and the annual management review.

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

The Quality Audit Service performs assessments of EOs independently of the management of CPVO, which has a supervisory role in administrative and financial issues and in relation to human resources management (dashed line in the organisation chart).

4.3. Organisation Chart



5. Impartiality and Confidentiality

5.1. Impartiality in the assessment process

Subject to the availability of personnel, QAS has a policy of not sending the same technical expert to one EO in two subsequent on-site visits.

Assessors and experts are committed to highest professional standard and are under appropriate arrangements to avoid conflict of interest.

Assessment findings and resulting recommendations are the sole responsibility of QAS, particularly of the respective lead assessor.

The Audit Advisory Board is consulted if the EO concerned raises an objection. Confidentiality arrangements for members of the Board 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 a comprehensive set of requirements with a strong emphasis on internationally harmonised technical protocols.

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 Community Plant Variety right 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 technical examinations carried out by the EOs and the purchase of existing technical examination reports.

The CPVO runs a balanced budget.

The costs associated with the assessments (CPVO staff expenditure, travel costs for assessors and TEs and honorarium) are shared between the CPVO and the examination offices according to a scheme approved by the Administrative Council. It takes into account that EOs and other stakeholders provide a substantial contribution through the participation of technical experts in assessment missions, working groups and consultations. At regular intervals financing of the audit scheme will be reviewed with respect to adapt the cost sharing arrangements.

7. Entrustment /Auditing/EO assessment

QAS conducts assessments of EOs against requirements specified in *Entrustment Requirements for* CPVO *Examination Offices* and related documents such as technical protocols, designation agreements and other guidance documents.

'Entrustment requirements' were established in a strategic discussion process involving the CPVO and its AC, EOs and breeder organisations. Additional requirements pertaining to quality management principles as used in established international standards were incorporated.

The assessment process involves expertise from external sources through experts participating in on-site visits and through an Audit Advisory Board.

Initial and continuous training of assessors follows an established programme in accordance with the CPVO training policy. Qualification requirements and responding to training needs concerning TEs follows the qualification guidelines for TEs.

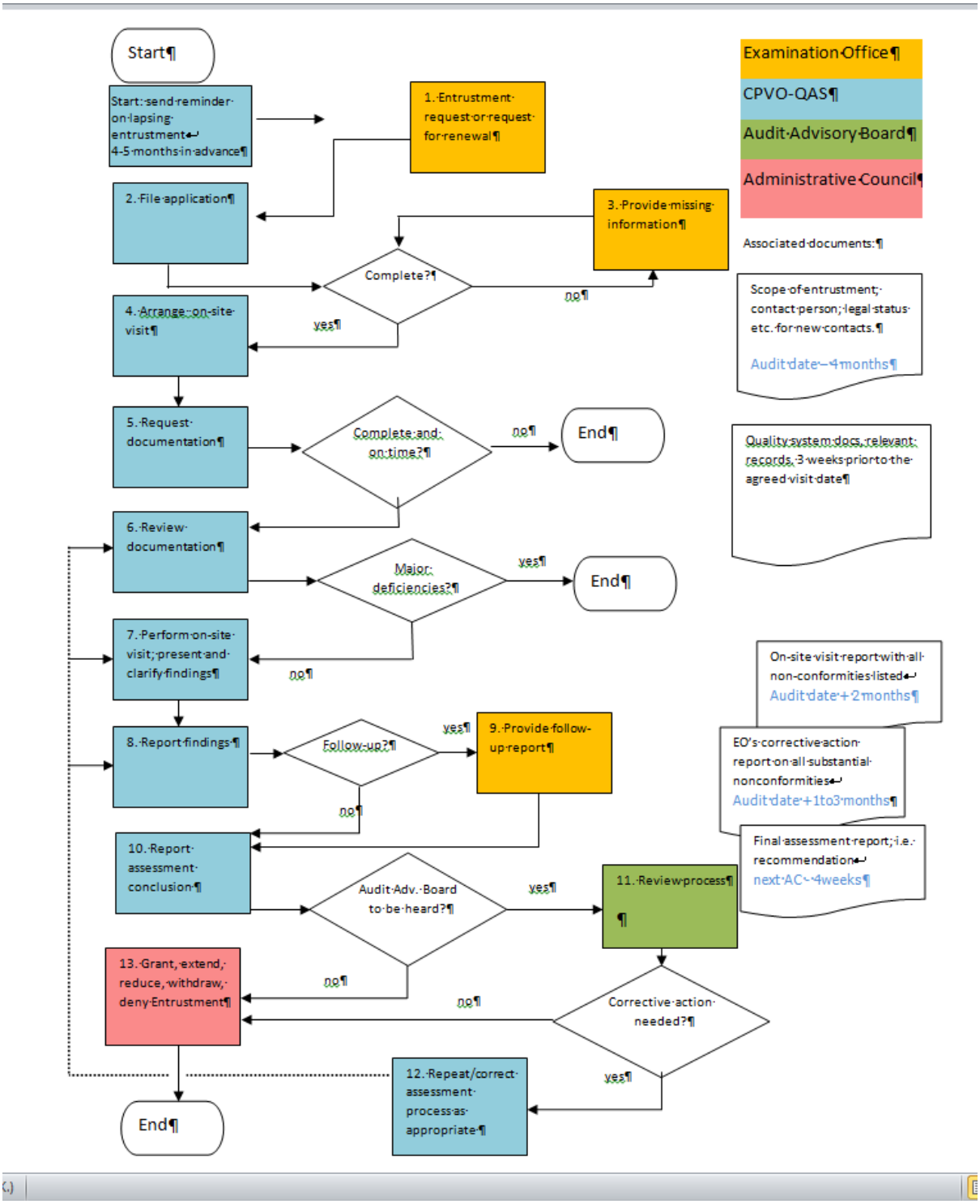
EOs with a certification or accreditation covering all or part of their activities will be able to use systems developed in order to demonstrate compliance with respective requirements. While an assessment by a QAS audit team will be conducted as in EOs without certified management system, the documentation 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*.

New species and new interspecific hybrids

For species without Community 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 species for which examination offices have expressed their interest. The extension will then be subject of an on-site assessment at the time of the next regular audit scheduled for the examination office in question.

7.1. **Process Flow Chart**



8. Management

8.1. Management system

QAS, through the Quality Audit Team Leader, reports directly to the AC in 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 technical experts 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 17011:2004** 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 Quality Audit Team Leader 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 to the AC are routed through the regular AC meetings and the annual Management Review.

8.2. Document control

Uncontrolled external documents are available through the library, the internet and other sources. It is each individual's responsibility to make sure that up to date versions of relevant 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 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 will be kept in the document management system of CPVO with defined access authorisations (Docman). 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 members of the QAS. Access to specific records to others 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. Access restrictions for members of the CPVO staff apply until an entrustment decision by the AC has been taken in respect of any given set of files. Requests for access to documents made by members of the CPVO staff in their personal capacity shall be assessed under paragraph 13.

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.

Database records have appropriate logs that keep track of amendments.

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. Internal audit recommendations and observations are addressed through the CPVO centralised internal audit follow-up procedure.

8.5. **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 enhance the system by being addressed.

8.6. **Internal audits**

Internal audits of QAS are carried out as integral part of the CPVO internal audit programme. Results of 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.

8.7. **Review report to the Administrative Council**

Annually a report to the AC takes account of

a) results of audits;

b) results of peer evaluation where relevant;

c) participation in international activities, where relevant;

d) feedback from interested parties;

e) new areas of entrustment;

f) trends in nonconformities;

g) status of preventive and corrective actions;

h) follow-up actions from earlier management reviews;

i) fulfilment of objectives;

j) changes that could affect the management system;

k) objections;

l) analysis of complaints;

m) need for certification of the QAS under ISO 9001 or others.

8.8. **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 two posts within the audit service for operating the entrustment system, namely one lead assessor and one administrative assistant. Job descriptions specifying the requirements of the posts are held and regularly updated in the CPVO HR Service.

Technical experts involved in assessment missions are approved by the AC (List of Technical Experts in entrustment assessments) and assigned on a needs basis for individual on-site visits. The pool of TEs is approved for a term of three years, notwithstanding individual approvals for any remainder of the three 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.

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

Roles and responsibilities assessment team leader and technical expert:

ATL

- have overall responsibility for the assessment;
- organise trip and prepare assessment schedule;
- assign TE for specific assessments;
- interact and make arrangements with EO and associated technically qualified bodies;
- present assessment objective;
- prepare on-site record summary (at the time of assessment), specifying observations with reference to related assessment requirements;
- provide assessment findings and assessment conclusion;
- prepare assessment report;

- follow-up on corrective action reports supplied by EO.

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.

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

For internal 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 experts are recruited on a honorarium basis. Appointment criteria such as technical expertise, experience in conformity assessments and communication skills are specified in the TE guidelines.

The Audit Advisory Board 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 ESA (1) and provides advice to the AC in its final entrustment decision. The Audit Advisory Board is appointed by the AC for a period of three years. Its chair shall not be a member of the AC, employee of the CPVO or affiliated with breeders and should preferably have experience in conformity assessment or auditing. Individuals appointed as members will not have alternates or proxies. The Board 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 is 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 lead assessor continuously monitors the work of technical experts during the assessments and feeds the findings into the training programme. Upon appointment and later once every two years each lead assessor is peer monitored during an onsite visit, 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 technical experts and other external resource persons are kept in the CPVO Contact database and in PVR. Training records are with the CPVO training coordinator.

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

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

b) 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);

c) general information about the fees relating to the entrustment (Audit fees procedure)

d) a description of the rights and obligations of EOs (designation agreements, Entrustment Procedure Manual);

e) information on the entrusted EOs (CPVO intranet, CPVO website);

f) information on procedures for lodging and handling complaints and objections (Entrustment Procedure Manual);

g) information about the authority under which the entrustment programme operates (Entrustment Procedure Manual, CPVO intranet, Basic Regulation);

h) a description of its rights and duties (Entrustment Procedure Manual, CPVO intranet, Basic Regulation);

i) general information about the means by which it obtains financial support (annual report, CPVO intranet);

j) information about its activities and stated limitations under which it operates (Entrustment Procedure Manual);

k) 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 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;

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 examination work;

For subsequent assessments EOs are contacted by QAS 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:

1) any of above if changes occurred compared to the situation at the time of the most recent assessment;

2) a clear definition of the scope of entrustment requested;

3) a list of proposed technically qualified bodies with their respective scope of examination work;

EOs wishing to extend their scope of entrustment can submit a request any time. If such an extension request cannot be handled at a regular assessment, an extension audit will be organised.

Before arranging for an on-site visit, the EO may be requested to submit a copy (on paper or in electronic form) of its quality manual and relevant associated documents or excerpts, in English, as selected by the

assessment team. For EOs using subcontracting arrangements a request for relevant documents held by the cooperating technically qualified bodies will be made in due course.

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

10.3. **Audit fees**

Audit fees are levied in accordance with a procedure approved by the Administrative Council. The procedure defines the cost sharing level and the specifications required for being equitable and transparent. Its initial implementation shall be in conjunction with a cost calculation exercise in order to enable examination offices to make the necessary budgetary arrangements. Any subsequent changes are implemented at the beginning of a new audit cycles.

10.4. **Resource review**

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

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

10.5. **Subcontracting the assessment**

Assessments are carried out by QAS staff and appointed technical experts.

10.6. **Preparation for assessment**

Before the initial assessment, a preliminary visit may be conducted if this is the expressed wish of both, the CPVO and the EO; for example in order to provide training to future assessors or in the pursuit of improving the assessment procedure. The main scope of any such preliminary visit will be the confirmation of the EOs conformance with the requirements and identification of nonconformities. Under no circumstances will consultancy be provided. Audit fee arrangements as for surveillance assessments apply.

For each assessment an assessment team is appointed, consisting of a lead assessor and a technical expert for the EO's specified scope. Where the nature of the EO's scope so requires, more than one technical expert may be appointed. Lead assessors are employees of the CPVO; TEs are selected in accordance with the qualification guidelines. 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 in due course of arranging the visit. 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 on-site assessment will be carried out by an assessment team as described above (ATL and TE) 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 on-site 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 test locations and for those with subcontracting arrangements on-site visits shall preferably cover all sites within two consecutive assessment visits.

10.7. **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 on-site visit(s)

10.8. **On-site 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 team cannot conclude on a specific observation the issue will be recorded as pending. The assessment team will organise a timely follow-up and present it to experts for clarification. 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, where appropriate, further details can be put on record. The EO's comments, explanations and clarifications are taken into account (step 7 in process flow chart). A copy of the record of all observed non-conformities 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.

Within six weeks after the on-site visit, an assessment report will be issued and sent to the EO. The assessment report provides a comprehensive summary of the assessment and lists the nonconformities with a reference to the respective requirement. It also includes an assessment conclusion and a deadline for reporting corrective action measures and for providing evidence of their effectiveness.

Review of corrective action

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

10.9. **Recommendation for entrustment decision**

Once the final deadline is reached or the corrective action reports are evaluated, the audit team summarises the activities carried out in the follow-up process and adopts a recommendation 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:

a) unique identification of the EO and associated technically qualified bodies;

b) date(s) of the on-site assessment;

c) name(s) of the assessor(s) and/or experts involved in the assessment;

d) unique identification of all premises assessed;

e) proposed scope of entrustment that was assessed – extension/reduction of scope;

f) the assessment report;

g) 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;

h) information on the resolution of all nonconformities;

i) any further information that may assist in determining fulfilment of requirements and the competence of the EO;

j) a recommendation as to granting, reducing or extending entrustment for the proposed scope, as appropriate.

10.10. Suspending, withdrawing, reducing or extending entrustment

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

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.

Withdrawing of the entrustment as a whole for a given EO terminates any variety testing work on behalf of the CPVO.

Reduction of the scope of entrustment in response to noncompliance that cannot be remedied or simply to take testing demand into account implies that a specified part of the testing work or a specific test site is no longer covered by the entrustment.

Extending the scope of entrustment in order to cover additional species and or involve additional technically qualified bodies under the responsibility of an EO typically requires the assessment of the ability to cope with the new scope elements. Preferably this will be done during a regular assessment, but it may in principle be initiated any time and lead to assessment activities commensurate to the complexity of the additional testing work and its related arrangements.

Based on a recommendation to suspend, withdraw reduce or extend, the AC takes a decision as provided for in section 10.11.

10.11. Decision-making and granting entrustment

The AC takes a formal entrustment decision on the basis of the recommendation and after having reviewed the opinion of the Audit Advisory Board in cases where it has been necessary to consult it (step 13 in process flow chart). The AC decision should not be taken earlier 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 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 (docman).

Validity of entrustment is for three years based on the date of the on-site visit at the main site. In case an application for re-entrustment is filed towards the end of that period, validity it 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, i.e. the recommendation, was issued. The Audit Advisory Board 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 Audit Advisory Board is informed in due course.

Stage 1

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

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 36 months ± 4 months based on the on-site visit of the main site. Additional surveillance visits may be organised in exceptional cases such as for scope extensions, additional subcontracting arrangements or substantial changes in the EO's setup.

13. Records on EOs

Assessment related records are kept in confidence at the QAS until a respective entrustment decision in respect of any given set of files by the AC has been taken. After a decision on the entrustment has been taken by the AC, requests for access to documents made by third parties shall be assessed according to the rules of Article 4 of Regulation (EC) No 1049/2001 and to the implementing rules thereof adopted by the AC. 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 Community plant variety rights 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.

15. Abbreviations

AAB Audit Advisory Board

AC Administrative Council

ATL Assessment Team Leader

CPVO Community Plant Variety Office

EO Examination Office

TE Technical Expert

QAS Quality Audit Service