Scope and Purpose: this document describes the philosophy, process and method of review of the initial and recertification application for approval of a laboratory as ECVCP training laboratory. Approval by the Laboratory Standards Committee (briefly called LSC throughout the document) is required for the primary laboratory in which training of candidates for the European College of Veterinary Clinical Pathology examination occurs. The primary laboratory is the one linked to the training programme for the candidate (the training programme is approved by the Education Committee). Documentation of the approach to application evaluation helps providing standardisation of the evaluation process, as well as a basis for training new members of the committee in the processes, methods and steps that should occur. Periodic recertification is needed every five years.

Ambit: this SOP is intended for all LSC members who are involved in the evaluation of the initial or recertification application of a laboratory for approval as an ECVCP training laboratory. It furthermore furnishes information to all interested ECVCP members.

Changes: can be suggested by any LSC member and have to be approved by the LSC committee/Chair and the ECVCP Board.

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1. Application for Training Laboratory Approval

A copy of the Initial and Recertification Application form is provided in Appendix 1 ("LSC Appendix 1 Initial + Recertification Application Form" in its current version). The part about the recertification application is not applicable for laboratories applying the first time as ECVCP training laboratory.

2. Initial and Recertification Application Evaluation Form

A copy of the Initial and Recertification Application Evaluation Form is provided in Appendix 2 (LSC Appendix 2 Initial + Recertification Application Evaluation Form" in its current version). The Evaluation Form includes the standard format for a letter of response that will be prepared by the Chair of the LSC when the evaluations of the reviewers are combined (see pertinent section below).

3. Persons Conducting Evaluations

The LSC includes members who have years of experience with laboratory quality systems, their planning, implementation and monitoring. Members of the LSC with less experience (new diplomates in most cases) should be assigned to evaluate applications with a more experienced member of the committee and should discuss by email or telephone with the experienced member any questions they may have about the suitability of the application or its parts and the philosophy or historical bases for making judgments regarding the application. Such a pairing of the evaluators/reviewers of the application should be continued until less experienced evaluators have reviewed a minimum of 3 applications.

Consultation with the Chair of the LSC, the other assigned evaluator and/or other members of the committee is desirable should there be any question or doubt as to the completeness or suitability of the information provided in the application.

4. Procedure

4.1. ECVCP Administrative Assistant

    4.1.1. The application has to be sent by email to the ECVCP Administrative Assistant who will forward a copy of the application to the Chair of the LSC. The Administrative Assistant also has to contact the ECVCP Treasurer to assure that the laboratory registration has been paid.

    4.1.2. The ECVCP Administrative Assistant will acknowledge the receipt of the application by email to the contact person noted on the application form.

4.2. ECVCP LSC Reviewers

The Chair of the LSC will select two members of the LSC to evaluate the application.

4.2.1. The Chair of the LSC will approach members until reviewers have been identified to complete the review within the agreed time frame. For most applications, it is anticipated that the application will be reviewed within 30 days of receipt.

4.2.2. Upon receiving confirmation of the availability of the evaluator, the Chair of the LSC will forward by email all documents pertaining to the application (completed application form and any addenda) to the reviewer.

4.3. Evaluation of the Application

Once the reviewer is in possession of the application, he/she will use the *Initial + Recertification Application Evaluation Form* to complete his/her evaluation of the application according to the following guidelines:

4.3.1. The *Initial and Recertification Application Evaluation Form* has the following sections

1. General Information
2. Recertification Application
3. Personnel
4. List of Equipment
5. List of tests
6. List of SOPs
7. Haematology
8. Biochemistry
9. Endocrinology
10. Haemostasis
11. Cytology

corresponding to the sections in the Application Form, with columns labelled for each section noted above: 'Included in the Application', 'Major Comments', 'Minor Comments' and 'Conclusions'.

4.3.2. If the indicated subparts of each section are included in the application, this is noted and indicated to be '*Complete*' in the column labelled '*Included in the Application*'. If the content of each section is not considered adequate or is not included, this is noted and a designation of '*Incomplete*' entered in the column labelled '*Included in the Application'*. Notation of what is missing or inadequate is included in the 'Major Comments'. The evaluator may make comments in the 'Major Comments' or 'Minor Comments' columns at their discretion.

4.3.3. If the subpart of the section is indicated to be 'Complete', the notation of '*Fulfilled'* is given in the column labelled '*Conclusions'*. If the subpart is indicated to be '*Incomplete'*, the notation of '*Not Fulfilled'* is given in the column labelled '*Conclusions'*.

4.3.4. If section 2 *Recertification Application* is not applicable in the application (i.e. if this is an initial application), the column labeled '*Conclusions'* is marked with '*not applicable'*.

4.3.5. The following are notes for guidance in evaluation of each section and subpart:

Section 1: General Information:
This includes date, name and address of the laboratory, contact details of contact person and diplomate in charge of the training program, job description of the diplomate, indicated sections of the lab where approval shall be gained for, description of the purpose of the lab and a Quality Plan.

Guidance: The Quality Plan can be quite short and shall outline the framework and philosophy of which the lab bases its quality system. Further guidance on how to write a Quality Plan can be found on the ECVCP website.

Section 2: Recertification Application
This section is only applicable for laboratories requiring recertification every 5 years after approval of their initial application. Recertifying laboratories shall provide a tabulated change log for changes applicable to sections 3-11. The applicant for the recertification application shall also fill out sections 3-11 to document actual status of the lab.

Section 3: Personnel
A list of full-time-equivalent personnel of the laboratory including function and full time equivalent shall be provided in a table as well as a workflow / organization charte.

Section 4: List of Equipment
A complete list of the equipment present shall be provided. Furthermore information about the laboratory information and management system (LIMS) shall be included as a short description.

Guidance: information about the LIMS shall include a short description as well as information about the i.e. backup solution and interface to other software programs used in the lab.

Section 5: List of tests
A complete list of tests available in the lab shall be provided. It shall further be notated if the analysis is performed in-house or referred and which instrument and method are used.

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Section 6: List of SOPs
A complete list of all SOPs present in the lab including SOP-ID as well as Name of the SOP shall be provided. If name of the SOP is not in English, translation in English has to be provided. One SOP of each core area for which the laboratory applies as a training laboratory shall be attached (SOP translated in English).

Section 7-10: Haematology, Biochemistry, Endocrinology and Haemostasis:
This should include the instruments information about the internal QC procedures present at the moment (frequency of QC, QC rule used, total allowable error (TE_a) chosen, source of TEa, calculated total observed error, additional information if needed), and external quality control.

Guidance: The instrumentation should be in accordance with a modern laboratory and should be suitable for modern laboratory testing. A minimum of two QCMs should be used for haematology and biochemistry. Recommended TE_{as} are the ones published in the latest ASVCP guidelines.

Section 11: Cytology:
Each of the items in the pre-analytical, analytical and post-analytical sections in the left hand column should contain information about QA/QC.

Guidance: The information should be in sufficient detail to determine if appropriate QA/QC for cytology is performed. For each section a few sentences are considered enough. An SOP may also cover these points and can be attached. Points to consider are for example but not exclusively: samples of insufficient quality, inadequate staining, adequate turnaround-time, accuracy of report release.

4.4. Combination of Comments of the Reviewer

One of the reviewers should be assigned responsibility by the Committee Chair for combining the comments of the two reviewers and preparing the letter to the applicant. The Committee Chair may ask the contact person of the lab for further information if needed.

4.5. Final evaluation of the review

The Chair of the LSC should review all comments and designations of the evaluators to ensure clarity in communication.

When the Chair of the LSC is satisfied with the report and letter, it should be emailed to the ECVCP Administrative Assistant for final formatting, and archiving. For laboratories which gained initial full approval as ECVCP training laboratory, a certificate will further be prepared by the Chair of the LSC and send to the Administrative Assistant. The Administrative Assistant is further in charge of emailing the final letter, and in case of initial full approval the certificate to the contact person of the lab with the Chair and Co-Chair of the LSC in copy.

The Administrative Assistant will have responsibility for communicating to the Education and Credentials Committee and to the Executive Board those laboratories that have received approval and the date of approval.

5. Archive

The Laboratory Standards Archivist (if not nominated, the chair) should ensure that the Evaluation Log is updated with the information (send in applications, comments on application from reviewers, final letter of approval/ decline, final formatted letter from ECVCP Administrative Assistant) about and status of the application.

The Evaluation Log corresponds to:
   • Timeline in LSC google table
   • Folder for each lab in archive