SOP Process of Initial + Recertification Application for Laboratories from Laboratory Standards Committee		European College of Veterinary Clinical Pathology
Document #: 2.2.	Version: 6	
Pages: 8	File short name: SOP Application for LSC	

1. Title:
   SOP Process of Initial and Recertification Application for Laboratories from Laboratory Standards Committee (LSC).

2. Section:
   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.

3. Scope:
   This document describes the philosophy, process and method of review of the initial and recertification applications for approval of a laboratory as ECVCP training laboratory. Approval by the LSC is required for the primary laboratory in which training of candidates for the ECVCP Examination occurs. The primary laboratory is the one linked to the training programme for the candidate (the training programme is approved by the Education & Credentials Committee). Documentation of the approach to application evaluation helps provide 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.

4. Equipment list:
   This Document, PC.

5. Procedure Instructions
   a. **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 section about the recertification application is not applicable for laboratories applying the first time as an ECVCP training laboratory.

Created	Date: 18th October 2024	By: Kathleen Freeman
Revised	Date: 26th August 2025	By: Stefanie Klenner
Checked/Released	Date: September 2025/April 2026	By: Executive Board and CC/Erika Furman
Approved	Date: 07. May 2026	By: EB, CC, DCP (Erika Furman)
Revised	Date:	By:

b. **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 most 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 section 6 below).

c. **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 or online meeting 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.

d. **Procedure**

i. ECVCP Administrator. The application must be sent by email to the ECVCP Administrator (secretariat@ecvcp.org) who will forward a copy of the application to the Chair of the LSC. The Administrator must contact the ECVCP Treasurer to assure that the laboratory registration has been paid. The ECVCP Administrator will acknowledge the receipt of the application by email to the contact person noted on the application form.

ii. ECVCP LSC Reviewers. The Chair of the LSC will select two members of the LSC to evaluate the application. 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 14 days of receipt.

iii. 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 reviewers.

e. **Evaluation of the Application**

Once the reviewer is in possession of the application, they will use the *Initial + Recertification Application Evaluation Form* to complete their evaluation of the application according to the following guidelines.

i.

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

ii.

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.

iii.

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'*.

iv.

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

v.

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 laboratory for which approval is sought, description of the purpose of the laboratory and a Quality Plan.

In addition, a proof of payment of the ECVCP Lab initial/ recertification application needs to be added to the files. The applicant shall therefore contact the ECVCP treasurer via *the current treasurer's email address* and ask for an invoice. After receiving the invoice, the payment shall be performed and a proof of payment added to the application.

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Guidance for ISO 17025 Certified Laboratories:
ISO 17025 certified labs already adhere to very high-quality standards. We want to facilitate their ECVCP LSC applications. Therefore, these laboratories do not need to fill out the sections: Personnel, List of Equipment, List of Tests and List of SOPs but can refer to the respective page in their ISO Quality Management Handbook, which should be attached to their application.
Guidance Quality Plan: The Quality Plan can be succinct and shall outline the framework and philosophy of which the laboratory 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 the status of the laboratory.

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 / organisation chart.
Guidance for ISO 17025 certified laboratories: Please see Guidance in Section 1.

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 for ISO 17025 certified laboratories: Please see Guidance in Section 1.

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 laboratory.

Section 5: List of tests

A complete list of tests available in the laboratory must be provided. It shall further be notated if the analysis is performed in-house or referred ('send out' tests) and the instrument and method used.

Guidance for ISO 17025 certified laboratories: Please see Guidance in Section 1.

Section 6: List of SOPs

A complete list of all SOPs present in the laboratory, including SOP-ID as well as title of the SOP shall be provided. If the title of the SOP is not in English, a translation in English must be provided. One example SOP of each core area for which the laboratory applies as a training laboratory shall be attached (SOP translated in English).

Guidance for ISO 17025 certified laboratories: Please see Guidance in Section 1.

Section 7-10: Haematology, Biochemistry, Endocrinology and Haemostasis:

This should include the instrument information, internal QC procedures [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/quality assurance programs.

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_a are the ones published in the latest ASVCP guidelines or those chosen by internal expert opinion by the organization.

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, turnaround-time, accuracy of report release.

6. Interpretation-approval, communication process:

   a. 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 laboratory for further information, if needed.

   b. Final evaluation of the review

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

When the Chair of the LSC is satisfied with the report and letter, it should be emailed to the ECVCP Secretary for final formatting and archiving. For laboratories which gain initial full approval as ECVCP training laboratory, a certificate will be prepared by the Chair of the LSC and sent to the ECVCP Secretary. The Secretary is responsible for emailing the final letter, and in the case of initial full approval, the certificate to the

contact person of the laboratory, with the Chair of the LSC and the Chair of the Education & Credentials Committee in copy.

c. Communication

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

7. Quality management information - Archive
   a. Relevant Documentation on QM processes of the ECVCP.
   b. The Laboratory Standards Archivist (if not nominated, the chair) should ensure that the Evaluation Log is updated with the information (sent in applications, comments on application from reviewers, final letter of approval/ decline, final formatted letter from the ECVCP Administrator, Certificate) and status of the application.

8. Terms and conditions:

After approval all applicable documents are archived and stored in the Evaluation Log. Evaluation log corresponds to:

   i. Timeline in LSC Google table
   ii. Folder for each lab in Google documents archive

9. References:
   Applicable College documents

Appendix 1
Appendix 2