



EUROPEAN COLLEGE OF VETERINARY CLINICAL PATHOLOGY

Document type: Standard Operating Procedure

Department or Committee: Laboratory Standards Committee

Document Number: ECVCP- Laboratory Standards Committee 2.0	Revision number 0
Title: Evaluation of Initial Application	

Changes made in this revision:

Date	Section	Description of change

Approved or Reviewed by	Date
Stefanie Klenner	5 th of March 2013



1. Purpose

This document describes the philosophy, process and method of review of the initial application for approval of a laboratory as ECVCP training laboratory. Approval by the Laboratory Standards Committee 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 that which is linked to the Training Programme for the candidate (the training programme is approved by the Education Committee).

2. Principle

Documentation of the approach to application evaluation helps providing standardization 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.

3. Application for Training Laboratory Approval – Initial Application

A copy of the Initial Application form (Excel Spreadsheet) is provided in Appendix 1.

4. Initial Application Evaluation Form

A copy of the Initial Application Evaluation Form is provided in Appendix 2. The Evaluation Form includes the standard format for a letter of response that will be prepared by the Chair of the Laboratory Standards Committee when the evaluations of the reviewers are combined (see pertinent section below).

5. Persons conducting evaluations

The Laboratory Standards Committee includes members who have years of experience with laboratory quality systems, their planning, implementation and monitoring. Members of the Laboratory Standards Committee 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 judgements 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 Laboratory Standards Committee, 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.

6. Procedure

.1 ECVCP Secretariat

1. The application will be sent to the ECVCP Secretariat, who will forward a copy of the application to the Chair of the Laboratory Standards Committee. The Secretariat will also ensure that the appropriate fee for laboratory registration has been submitted to the ECVCP Treasurer.
2. The ECVCP Secretariat will acknowledge the receipt of the application by email to the contact person noted on the application form.

6.2 ECVCP LSC Reviewers

The Chair of the Laboratory Standards Committee will select a minimum of two members of the Laboratory Standards Committee to evaluate the application.

1. The Chair of the Laboratory Standards Committee will approach members until reviewers have been identified to complete the review within the agreed upon time frame. For most initial applications, it is anticipated that the application will be reviewed within 30 days of receipt.
2. Upon receiving confirmation of the availability of the evaluator, the Chair of the Laboratory Standards Committee will forward by email all documents pertaining to the application (completed application form and any addenda) to the reviewer.

6.3 Evaluation of the Application

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



.1 The *Initial Application Evaluation Form* has the following sections

1. General Information
2. List of Parameters
3. Haematology
4. Biochemistry
5. Endocrinology
6. Haemostasis
7. 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'.

- .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.
- .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 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.

Guidance: it is required that an ECVCP diplomate is associated with the submitting laboratory.

Section 2: List of Parameters

A complete list of parameters 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 is used.



Section 3-6: Haematology, Biochemistry, Endocrinology and Haemostasis:

This should include the instruments, reference intervals, information about the internal QC procedures present at the moment (frequency of QC, QC rule used, additional information if needed), 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. Detailed information about QC (Bias, TEa, etc) is only required in the recertification application post 2014.

Section 6: 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.

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 reviewer may ask the contact person of the lab for further information if needed.

5. *Final evaluation of the review*

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

When the Chair of the Laboratory Standards Committee is satisfied with the report and letter, it should be emailed to the Secretariat for archiving, to the President of the ECVCP, the Laboratory Standards Committee Archivist and to the Contact Person indicated in the application. The Secretariat will have responsibility for communicating to the Education and Credentials Committee and to the Webmaster those laboratories that have received approval and the date of approval.



6. Archive

The Laboratory Standards Archivist should ensure that the Evaluation Log is updated with the information about and status of the First Recertification Application Post 2014.