PROCEDURES FOR DESIGNATION OF OIE REFERENCE LABORATORIES

1. Scope and background

In May 2011, the World Assembly of Delegates of the OIE (hereafter the Assembly) adopted new Terms of References (ToRs) and Internal Rules for OIE Reference Centres. The ToRs for Reference Laboratories had emphasised their role in developing and recommending test methods, storing and distributing reference reagents, providing advice, diagnostic support and training to OIE Member Countries, and their reporting obligations. From 2011, the ToRs added the recommendation that laboratories establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results, as well as organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results.

OIE Reference Laboratories are designated to pursue scientific and technical problems relating to a named disease or pathogen. The Expert for the OIE and its Member Countries with regard to these issues, should be a leading and active researcher helping the Reference Laboratory to provide scientific and technical assistance and expert advice on diagnosis and control of the disease or pathogen for which the Reference Laboratory is responsible. Reference Laboratories should also provide scientific and technical training for personnel from Member Countries, and coordinate scientific and technical studies in collaboration with other laboratories or organisations, including through OIE Laboratory Twinning.

The integrity and credibility of the OIE is intimately linked to the quality of the science to which it has access on disease control methods. The OIE depends very heavily on its designated Reference Laboratories and disease experts for scientific advice and support, both to the OIE Headquarters in developing standards, participating in *ad hoc* Groups and providing general advice, and to individual Member Countries.

The OIE has developed this document on the Procedures for designation of OIE Reference Laboratories to assist Member Countries, current OIE Reference Laboratories and experts, and applicant laboratories to better understand the applicable procedures.

2. Submission of an application

The OIE work programme cycle runs from May to May, of which the General Sessions of the Assembly are the start and end points. There are two Specialist Commissions responsible for evaluating OIE Reference Laboratory applications: Biological Standards Commission and Aquatic Animal Health Standards Commission for OIE Reference Laboratories for terrestrial and aquatic animal diseases, respectively. These Commissions meet twice in a cycle, with the first meeting usually held August/September and the second meeting in February/March; these dates can slightly vary each cycle based on the availability of the members of the relevant Commissions (cf. Figure 1).

Applications should be submitted 45 days before the date scheduled for the meetings of the relevant Commission. The 45-day period gives the OIE sufficient time to screen, translate into English when necessary, and process the dossiers for the Commission's evaluation. Deadlines must be strictly observed to allow a full evaluation of the dossiers by the members of the Commission prior to the meeting. Applications received after the deadline are examined at the next Commission meeting.

The applicant laboratory should submit the information using the guidelines for applicants for OIE Reference Laboratory status (cf. Appendix 1) published on the OIE website: http://www.oie.int/en/our-scientific-expertise/reference-laboratories/guidelines-for-applicants/. Applications must be limited to no more than 20 pages in A4 format, single-spaced using Times New Roman font size 10pt. Relevant appendices may be attached with clear cross-referencing to the core document. All documents must be prepared in one of the official languages of the OIE (English, French or Spanish).

While evaluating a submitted dossier, the Commission may have questions for the applicant laboratory. These questions will be sent by letter signed by the Director General of the OIE after the Commission meeting. The applicant laboratory should provide written answers by an appointed deadline or by the deadline prior to the next meeting of the Commission (45 days before the date scheduled for the next meeting of the relevant Commission).

3. Preliminary screening of application

On submission of the dossier, the OIE Headquarters (Science and New Technologies Department) acknowledges its receipt and confirms the meeting dates of the relevant Commission. If a gap in the information provided is identified, the OIE Headquarters may request the submission of an amended application or additional information before a set deadline.

4. Evaluation by the relevant OIE Specialist Commissions

As stated previously, the Biological Standards Commission and the Aquatics Animal Health Standards Commission conduct evaluations of OIE Reference Laboratory applications for terrestrial and aquatic animal diseases, respectively.

The Terms of Reference, Internal Rules, Qualification and election procedures of members of the Commissions are found in the OIE *Basic Texts*. The members of the Commissions are elected or re-elected every 3 years by the Assembly.

Commission members are requested to comply with the OIE requirements and procedures regarding confidentiality and the management of conflicts of interest. The President of the Commission and the OIE Secretariat ensure that any members with conflicting interests in relation to a particular dossier do not take part in the discussions and final decision-making.

In accordance with the criteria for designation as an OIE Reference Centre listed in the OIE *Basic Texts*, and Resolutions adopted at each General Session with regard to the designation of OIE Reference Laboratories for terrestrial and aquatic animal diseases, all applications are assessed using standardised principles that include: the institution's ability, capacity and readiness to provide services; the scientific and technical standing of the institution concerned at the national and international levels; the quality of its scientific and technical leadership including internationally recognised expertise; the institution's prospective stability in terms of personnel, activity and funding; and the technical and geographical relevance of the institution and its activities to the OIE's programme priorities.

When conducting an evaluation of an applicant OIE Reference Laboratory, the Commission may also take into account any other information available in the public domain that is considered as pertinent to the evaluation of the dossier.

In accordance with the *Basic Texts* of the OIE, all formal correspondence between the Commission and outside individuals or bodies shall be issued through the office of the Director General of the OIE. All correspondence between an applicant laboratory and the OIE Headquarters is duly documented by the OIE Headquarters.

5. Endorsement by the OIE Council

In accordance with Article 3 of Chapter 4 on the Internal Rules and relevant Resolutions previously adopted, all OIE Reference Laboratory applications are endorsed by the OIE Council before presented to the Assembly for approval.

6. Communication on the outcome of the evaluation with the applicant laboratory

After its meeting, the Commission produces a report that includes the outcomes of the evaluation of Reference Laboratory application. The identity of the applicant laboratory is published in the report along with the recommendation that it be accepted by the Assembly for adoption by resolution. Unsuccessful applicants are informed by letter from the Director General of the OIE. This letter is not released in the public domain and the identity of the laboratory is not revealed in the Commission report. In some cases, the Commission may have questions or require additional information before a final decision can be taken. This information should be submitted to the OIE by the appointed deadline for consideration by the Commission at its next meeting.

7. Designation of OIE Reference Laboratories by the Assembly

The Assembly, on the basis of the assessment by the relevant OIE Commission and the endorsement by the OIE Council, adopts by Resolution all new OIE Reference Laboratories. Official designation as an OIE Reference Laboratories comes into force only after adoption by Resolution of the Assembly.

Shortly after the General Session, the newly designated OIE Reference Laboratory will receive a letter from the Director General of the OIE. The OIE Headquarters also updates the list of Reference Experts and Laboratories on its website.

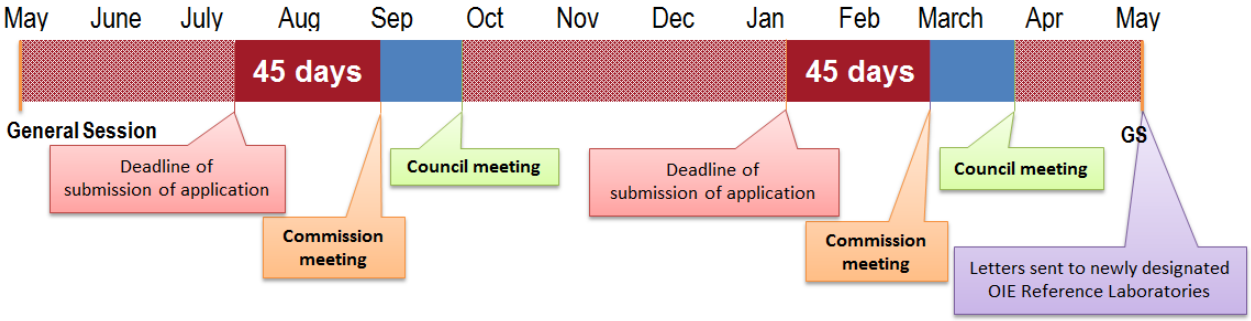

Figure 1. Timeline for applications for OIE Reference Centres

8. Change of the OIE Reference Laboratory expert

In accordance with Resolution No. 34 adopted at the 81st General Session in May 2013, the Assembly delegated to the Council the authority to approve, on its behalf, the replacement of OIE designated Experts at existing OIE Reference Laboratories, provided that the nominations submitted by the head of the Reference Laboratory through the OIE Delegate of the country of location have been examined and endorsed by the relevant OIE Specialist Commission.

If the expert decides to relinquish the title of OIE designated expert and if the laboratory wishes to maintain its OIE Reference Laboratory status, an official letter – detailing the situation and enclosing a nomination for a replacement expert, including a curriculum vitae together with documentation of his or her work related in the disease or pathogen – should be submitted to the OIE through the Delegate of the country. The nomination will be considered by the relevant OIE Specialist Commission at its next meeting, and the decision will be notified to the OIE Reference Laboratory. The official change of OIE Reference Laboratory expert will take place only after the approval of the Council.

Given the meeting schedules of the Specialist Commissions and the Council, the possibility exists that an OIE Reference Laboratory could temporarily have no designated expert. The OIE expects that, under normal circumstances, Reference Laboratories will always have an OIE designated expert in place and will plan ahead to take into account retirement or resignation.

9. De-listing of OIE Reference Laboratories

Upon the screening and analysis performed by the OIE Headquarters (cf. **Section 10.1.**), the relevant Commission reviews the reports and activities of the Reference Laboratories. Where there is insufficient evidence of OIE mandate-related activities, the Commission may recommend to the Council and to the Assembly the withdrawal of the Reference Laboratory designation.

In accordance with Article 9 of the Internal Rules, a Reference Laboratory may revoke the designation at any time. If an OIE Reference Laboratory decides to withdraw its designation as such, an official letter should be submitted to the OIE through the Delegate of the country.

Moreover, in accordance with Article 9 of the Internal Rules, the designation of a Reference Laboratory shall be withdrawn if the Reference Laboratory fails to comply with the provisions of the ToRs and the present Rules. In

such cases, the Director General of the OIE, after consulting the appropriate OIE Specialist Commission and OIE Council and notifying the Delegate of the country, proposes the withdrawal to the Assembly.

According to the February and September 2016 meeting reports of the Commissions, four critical points for consideration when evaluating a laboratory's performance were identified:

i) the lack of submission of an annual report;

ii) no progress or explanation provided on achievement of accreditation to ISO 17025 or equivalent quality management system, ideally with relevant tests included in the scope of the accreditation;

iii) a pattern revealing lack of diagnostic activity or production and supply of reference material related to the disease or pathogen;

iv) no response to requests from the OIE Headquarters for scientific expertise (e.g. inquiry of technical advice from OIE Member Countries, revision of the *Terrestrial manual* chapters, etc.).

Furthermore, the Director General has determined that the importance of transparency and confidentiality require a further critical performance criteria:

v) no response to requests from the OIE for administrative issues relating to transparency and confidentiality (e.g. not renewing the potential conflict of interests declaration or providing a confidentiality undertaking [(cf. Appendices 2 and 3)]).

*** Timeline for achievement of quality management system**

With reference to the recommendations made at the 3rd Global Conference of OIE Reference Centres in October 2014, OIE Reference Laboratories were given until the end of 2017 to achieve accreditation to ISO 17025 or an equivalent quality management system; the experts agreed to this deadline.

At the end of 2017, the OIE Headquarters and the relevant Commissions will review the status of the quality management system in operation in all OIE Reference Laboratories to ensure that accreditation is to the ISO 17025 standard.

For those laboratories that have not achieved such by the announced deadline, the OIE Reference Laboratory status will be suspended with the possibility to reinstate it within 2 years should they achieve accreditation in that time. Laboratories that have still not achieved accreditation 2 years after suspension would have to re-apply for OIE Reference Laboratory status once accreditation is achieved.

10. OIE Reference Laboratory Annual report

In accordance with Article 8 of the Internal Rules, the Reference Centre shall provide to the Director General a brief report of activities related to their ToRs at the end of each calendar year, according to the template established by the OIE Headquarters. A letter from the Director General of the OIE is sent to all designated experts of OIE Reference Laboratories for submission of the annual report.

Since December 2013, an on-line system for submitting annual reports the OIE Reference Laboratories has been in place.

The template of the annual report is structured around each ToR for OIE Reference Laboratories as adopted in May 2011. Questions are close-ended (yes/no answers) to generate more accurate and comparable information from the laboratories. Tables to allow for the collection of detailed information related to the activities carried out by the laboratories are also included. The on-line annual reporting system can be accessed via a dedicated link and a randomly generated username and password that are sent to all Experts of OIE Reference Laboratories in a letter signed by the Director General of the OIE during the last month of the reporting year. The deadline to submit the annual report of the OIE Reference Laboratory activities of each calendar year is usually by mid-January of the following year.

10.1. Review and analysis of the annual reports

The submitted annual reports are first screened and quantitatively analysed, based on the close-ended (yes/no) answers, by the OIE Headquarters. An overview of the analysis is presented to the relevant Commission at its February/March meeting.

OIE Reference Laboratories are expected to fulfil the ToRs adopted by the OIE World Assembly of Delegates as reflected in the annual report.

Any questions or concerns that may arise during the review of annual reports by the Commission can be referred to the concerned OIE Reference Laboratory through the office of the Director General of the OIE.

All annual reports of OIE Reference Laboratories are made available to all Member Countries on the OIE website (***http://www.oie.int/en/our-scientific-expertise/reference-laboratories/annual-reports/***) shortly after the February meeting of the Commissions.

10.2. Lack of submission of the annual report

After the meeting of the relevant Commissions, laboratories that have not submitted their annual reports will be sent a letter of reminder, with the Delegate of the host Member Country in copy, to submit the report by an extended and prescribed deadline. For the laboratories that have still not submitted an annual report by the end of March, a reminder will be addressed directly to the Delegate, with the expert in copy, giving a 2-week deadline to reply to the OIE with an explanation of the situation or circumstances that may have prevented the laboratory from fulfilling this ToR.

Further communication by letter or direct communication during the General Session may be considered, if needed, prior to the final recommendation to de-list the laboratory, which would be taken by the Commission at the September meeting. This procedure could also be applied to laboratories falling under one of the four other de-listing criteria (cf. **Section 9).**

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.../Appendices

Appendix 1.

GUIDELINES FOR APPLICANTS FOR OIE REFERENCE LABORATORY STATUS

OIE Reference Laboratories must provide evidence of scientific leadership and of the capability to fulfil the Terms of Reference: all applicants should preferably be the national reference laboratory; they should be able to receive samples from other countries for diagnostic testing; they should demonstrate the capability and willingness to organise rather than just participate in proficiency tests; they should be capable of providing confirmatory diagnostic services, reference materials, training, etc., internationally; and the designated expert should have a number of recent relevant publications in peer-reviewed journals.

Applications should be submitted 45 days before the date scheduled for the meetings of the relevant Specialist Commission (Biological Standards Commission [xx August–xx September 20xx; the next deadline is therefore **xx July 20xx**] and Aquatic Animal Health Standards Commission for OIE Reference Laboratories for terrestrial and aquatic animal diseases [xx to xx September 20xx and xx to xx February 20xx; the next deadlines are therefore **xx August 20xx** and **x January 20xx**], respectively)*. The 45-day period gives the OIE sufficient time to screen, translate into English when necessary, and process the dossiers for the Commission's evaluation. Deadlines must be strictly observed to allow a full evaluation of the dossiers by the members of the Commission prior to its meeting. Applications received after the deadline will be examined in the next meeting of the Commission.

Applications shall be submitted in accordance with Article 1 of the Internal Rules and should include the following information:

Administration and management

1. Name of expert (a curriculum vitae using this template).

2. Name and address of laboratory (telephone and e-mail address [fax numbers or Web site, if available]).

3. Name of the Head of laboratory (Responsible Official).

4. Demonstrate that legal and budgetary provisions are in place that provide assurance on the sustainability and functioning of the laboratory.

5. Provide documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system, ideally with relevant tests included in the scope of the accreditation.

Technical expertise and experience

6. Give details of experience in diagnostic testing for the disease according to the OIE Standards nationally and internationally (approximate number of tests performed annually for each technique).

7. Provide additional information on expertise in diagnostic techniques (agent characterisation techniques, molecular techniques, monoclonal antibody techniques, etc.), epidemiology and control of the disease.

8. Give details of experience in standardisation and validation of diagnostic tests.

9. Demonstrate reagent production capability (provide details of current stock of reagents for the disease).

10. Demonstrate capability for timely international shipment and receipt of samples in accordance with the requirements for postage and packaging of biological materials described in the OIE *Manual of Diagnostic Tests and vaccines for Terrestrial Animals*, and the OIE *Terrestrial Animal Health Code* or the OIE *Aquatic Animal Health Code*.

11. Provide a list of completed research and methods development projects on the disease.

12. Provide a list of inter-laboratory proficiency tests that the laboratory regularly organises and participates in.

13. Give details of training and consultation experience for the disease in the last 2 years (courses provided, number of people trained, examples of international consultation).

14. Provide a list of scientific meetings that the laboratory has organised and participated in.

15. Provide a list of reference documents (chapters for the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, OIE *Manual of Diagnostic Tests for Aquatic Animals*, disease cards, etc.) to which the laboratory contributed.

Collaborations, confidentiality and conflicts

16. Provide a list of collaboration agreements with other laboratories, centres or organisations.

17. Provide guarantees to ensure that staff respect the confidential nature of certain subjects, results or communications, and with regard to management of potential conflict of interests through completion of the required declarations.

The application will be processed by the OIE in accordance with Articles 2, 3 and 4 of the Internal Rules.

A short summary of activities of relevance to the status of OIE Reference Laboratory (no more than one page) should be included.

Applications comprising the information requested in all the above-mentioned points must be no longer than 15–20 pages in A4 format, single-spaced using Times New Roman font size 10 pt. The application must be prepared in one of the official languages of the OIE (English, French or Spanish).

* The deadline for submission of date scheduled for the meetings of the relevant Commission

Appendix 2.

World Organisation for Animal Health (OIE)
Confidentiality Undertaking

For OIE Reference Centres

<Name of the Designated OIE Reference Centre>

On behalf of the above institution, the undersigned accepts and agrees to respect the legitimate confidentiality of such information as may be obtained from the OIE or on behalf the OIE in the framework of its activities as OIE Reference Centre as defined by the applicable terms of reference, the disclosure of which would undermine the interests of the OIE or of its Member Countries or the privacy and the integrity of individuals associated with the OIE. This Undertaking is valid for the institution and its staff.

In particular, the undersigned accepts to respect the legitimate confidentiality of information the disclosure of which would undermine the protection of commercial interests of a natural or legal person, including intellectual property, legal proceedings and advice, and the purpose of inspections, investigations and audits. That commitment is made in compliance with the mandate and obligations adopted by the Assembly.

The undersigned accepts that there is a life-long duty of confidentiality in regard to the protection of legitimate confidentiality as described above, and that this obligation does not cease after the termination of a working or other relationship with the OIE, except in the case that the information legally enters the public domain or is disclosed by the Director General when there is an overriding public interest in such a disclosure.

Date: _____ Signature_____

Name:

Institution:

Address:

Telephone:

Email:

Notes:

All Members of Specialist Commissions, members of OIE Working Groups and ad hoc Groups, OIE Experts and specialists participating at the invitation of the Director General in meetings and in expert missions are required to complete an Undertaking to protect legitimate confidentiality. Heads of institutions that are OIE Reference Centres are required to complete a similar Undertaking covering the institution and its staff.

At the specific level dealing with intellectual property, the Standard Operating Procedures for OIE Validation and Certification of Diagnostic Assays will continue to be used and will be adapted to other situations requiring the protection of intellectual property as appropriate. The completion of a generic undertaking to respect legitimate confidentiality does not annul the requirement to complete a specific undertaking in regard to the protection of intellectual property.

Failure to complete an Undertaking in respect of legitimate confidentiality may result in the person concerned no longer being considered as an OIE Expert or as a member of a Working Group or ad hoc Group, or revocation of designation in the case of an OIE Reference Centre; alternatively, it may be decided to restrict the access of the person or institution concerned to any information available from the OIE. Such decisions shall be managed by the Director General in consultation as appropriate with the Delegate of the Member Country concerned, the executive head of the International Organisation with which the expert is associated, or the Council of the OIE. In the case of a Member of a Specialist Commission the Director General will consult the President of the Specialist Commission concerned (or one or both of its Vice Presidents if the matter concerns the President) the President of the Assembly and the Delegate on the action to be taken.

Any dispute relating to the interpretation or application of this Undertaking shall, unless amicably settled, be subject, at the request of either party, to one conciliator. Should the parties fail to reach agreement on the name of a sole conciliator, each party shall appoint one conciliator. The conciliation shall be carried out in accordance with the Conciliation Rules of the United Nations Commission on International Trade Law, as at present in force. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law as at present in force. The parties shall accept the arbitral award as final.

Appendix 3.

DECLARATION OF INTEREST FOR OIE REFERENCE CENTRES

To be completed by the Head of the Reference Centre on behalf of the Centre itself and for Staff of the Institution involved in matters related to the work of the OIE

Annual Declaration of Interests with Commercial Entities

Part A: Institution

Type of interest, and basic descriptive details.	Name of the commercial entity	Amount of income or value of interest	Current interest (or year ceased)

Part B: Staff of the Institution working on OIE matters

Name and position	Type of interest, <u>and</u> basic descriptive details.	Name of the commercial entity	Current interest (or year ceased)

Date: _____ Signature_____

Name:

Institution:

Address:

Telephone:

Email:

Note:

Part B of the above report is required only for Staff of the Reference Centre whose work relates to the work of the OIE in the capacity of the Institution as a designated OIE Reference Centre.