## D12e Submission of information ahead of assessment activities

*1 General*

1.1 The following is ISAC’ requirements on submission of information ahead of assessment activities that accredited CABs must comply with.

1.2 According to **ACR-0001** 3.13, the CAB shall submit the documents that ISAC requests within the following timeframes:

a) Initial assessment, at least 8 weeks prior to on-site assessment.

b) Surveillance, at least 4 weeks prior to the on-site assessment.

c) Reassessment, at least 4 weeks prior to the on-site assessment.

d) Applications for extension to scope of accreditation, at least 8 weeks prior to the on-site assessment.

1.3 According to **ACR-0001** 3.14, CABs shall, at the request of ISAC, submit a summary of planned conformity assessment activities.

*2. Inspection Bodies*

Inspection Bodies shall submit the following documents:

a) Its Quality Manual and/or an access to the CABs management system.

b) Documentation describing the management system and a list of amendments.

c) A master list of documents, identifying the documents which have been updated since the last assessment activity.

d) All new and/or revised management system documentation, including revised procedures and forms, introduced or updated since the last on-site assessment or assessment activity.

e) A schedule of internal audits, identifying planned and completed audits since the last assessment activity.

f) Minutes of the last management review meeting.

g) The latest version of the organisation chart including the names of key personnel, highlighting any changes.

h) Details of changes to legislation, if any, that have had an impact on the scope of accreditation.

i) The most recent documented analysis of the inspection body’s risks to its impartiality and independence status, including those risks that arise from:

i) the inspection body’s activities;

ii) from its relationships;

iii) from the relationships of its personnel.

j) A documented procedure on how the CAB handles conflicts of interest.

k) Details of all locations where conformity assessment activities are performed, including:

i) what is inspected;

ii) number of inspections performed last year and by whom;

iii) number of inspections performed current year, so far, and by whom;

iv) any changes from the last assessment.

l) An updated list of authorised inspectors who perform inspections within the scope of accreditation, showing:

i) which inspections each inspector is competent to perform;

ii) who are new inspectors and when were they authorised;

iii) who are authorised to perform maintenance on equipment and carry out in-house calibrations.

m) A list detailing all instruments calibrated in-house, including:

i) descriptions of in-house calibration procedures;

ii) information about equipment (calibration reports) for which in-house calibration has started since the last assessment.

n) Any other information which the inspection body deems necessary.

o) ISAC can ask for further documents and records as necessary, such as information on inspection methods for inspections to be witnessed during the next on-site assessment.

*Inspection Bodies – Witnessing inspection activities*

p) A copy of an inspection plan, where applicable.

q) Information about the conformity assessment activity to be witnessed, including directions on how to get there and information about a contact person on-site.

r) Records showing that the competence of all personnel involved in the activity has been assessed and demonstrated;

s) Detailed information about the expected duration of the planned conformity assessment activity (provide calculations if applicable).

t) A copy of the inspection procedures and any other working documents used by the inspector.

*3. Testing Laboratories*

Testing Laboratories shall submit the following documents:a) Its Quality Manual and/or an access to the CAB’s management system

b) Documentation describing the management system and a list of amendments

c) A master list of documents, identifying the documents which have been updated since the last assessment activity.

d) All new and/or revised management system documentation, including revised procedures and forms, introduced or updated since the last on-site assessment or assessment activity.

e) A schedule of internal audits, identifying planned and completed audits since the last assessment activity.

f) Minutes of the last management review meeting.

g) The latest version of the organisation chart including the names of key personnel, highlighting any changes.

h) Details of changes to legislation, if any, that have had an impact on the scope of accreditation

i) The most recent documented analysis of the CAB’s risks to its impartiality, including those risks that arise from:

i) the CAB’s activities;

ii) from its relationships;

iii) from the relationships of its personnel.

j) A documented procedure on how the CAB handles conflicts of interest.

k) Documentation on changes of accredited testing methods since the last assessment, if any. Information about the reason for the changes of the method must be delivered along with a confirmation that the new method has been verified and still serves its intended purpose. A copy of the new method shall be submitted.

l) An updated list of authorised personnel who perform tests within the scope of accreditation, showing:

i) which tests each testing personnel is competent to perform;

ii) who are new testing personnel and when were they authorised;

iii) who are authorised to perform maintenance on equipment and carry out in-house calibrations.

m) A list detailing all instruments calibrated in-house, including:

i) descriptions of in-house calibration procedures;

ii) information about equipment (calibration reports) for which in-house calibration has started since the last assessment.

n) Information about the number of tests performed under accreditation:

i) number of tests performed under accreditation last year,

ii) number of tests performed under accreditation the current year, so far.

o) Any other information which the laboratory deems necessary.

p) ISAC can ask for further documents and records as necessary, such as information on testing methods and procedures for tests to be witnessed during the next on-site assessment.

*4. Certification bodies*

Certification Bodies shall submit the following documents:a) Its Quality Manual and/or an access to the CABs management system.

b) Documentation describing the management system and a list of amendments.

c) A master list of documents, identifying the documents which have been updated since the last assessment activity.

d) All new and/or revised management system documentation, including revised procedures and forms, introduced or updated since the last on-site assessment or assessment activity.

e) A schedule of internal audits, identifying planned and completed audits since the last assessment activity.

f) Minutes of the last management review meeting.

g) The latest version of the organisation chart including the names of key personnel, highlighting any changes.

h) Details of changes to legislation, if any, that have had an impact on the scope of accreditation

i) The most recent documented analysis of the CAB’s risks to itsimpartiality, including those risks that arise from:

i) the CAB’s activities;

ii) from its relationships;

iii) from the relationships of its personnel.

j) A documented procedure on how the CAB handles conflicts of interest.

k) An updated list of authorised auditors who perform certifications within the scope of accreditation, showing:

i) which certifications each auditor is competent to perform;

ii) who are new auditors and when were they authorised.

l) Any other information which the certification body deems necessary.

m) ISAC can ask for further documents and records as necessary, such as information on audit procedures for certification to be witnessed.

*Certification Bodies – Witnessing certification activities*

n) A copy of an audit plan, where applicable.

o) Information about the conformity assessment activity to be witnessed, including directions on how to get there and information about a contact person on-site.

p) Records showing that the competence of all personnel involved in the activity has been assessed and demonstrated;

q) Detailed information about the expected duration of the planned conformity assessment activity (provide calculations if applicable).

r) A copy of the audit procedure and any other working documents used by the auditor.

*5. Notified Bodies*

Notified Bodies are CABs and as such must submit information for relevant conformity assessment activities, however, they must also additionally provide the following information:

a) Confirmation of participation in the work of a Notified Bodies group in the appropriate technical field within Europe.

b) A list of approved subcontractors, if applicable.

c) The Notified Body identification number.

d) A list over all personnel authorised as competent in the conformity assessment activities.

e) A summary of all issued/suspended/withdrawn certificates since the last accreditation assessment.

f) A summary of the communications with the relevant Notifying Authoritiy.