Dutch Accreditation Council (RvA)

Policy rule Non-conformities and Corrective actions

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RvA policy guidelines describe the RvA rules and the policy on specific subjects.
A current version of the policy guidelines can be obtained through the RvA website (www.rva.nl).

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1 Introduction

Article 1.

In an RvA assessment the RvA assessment team may decide that the requirements are not being met, in which case it will formulate a non-conformity and give the conformity assessment body (hereinafter CAB) the opportunity to take action before the RvA takes a decision on the accreditation in question. This policy document sets out the rules for categorising non-conformities, periods of time for resolving non-conformities and for measures and follow-up assessments. These rules apply to all types of assessments that the RvA carries out, except for the preliminary assessment.

Article 2.

This document comes into force on the date of publication of the notice in the Netherlands Government Gazette.

2 Non-conformities

Article 3.

A situation that does not conform to the requirements is regarded as a non-conformity. The RvA distinguishes three categories of non-conformity:

Category A: A situation that is regarded as not conforming to an accreditation requirement and that, according to the RvA assessment team, may lead, is leading or has led:
- to incorrect or unreliable (not demonstrably correct) conformity assessment results, or
- to the improper use of the RvA accreditation mark or in some other way an improper claim of RvA accreditation, or
- to a concrete threat to the health or safety of persons or to the environment.

Appendix 1 of this policy guideline contains examples to illustrate category A non-conformities for different types of conformity assessments.

Category B: A situation that is regarded as not conforming to an accreditation requirement but that, according to the RvA assessment team, is not leading, has not led or may not lead to one of the situations specified under the definition of Category A above.

Category (B): A non-conformity in respect of new accreditation requirements for which the transitional period laid down by the RvA has not yet ended. This means that the CAB meets the requirements applicable at the time of the assessment. Without prompt corrective action the new requirements will not be met at the time the transitional period ends.

Article 4.

The categorisation of a non-conformity is the responsibility of the RvA team leader.

Article 5.

Depending on the nature of the assessment, a non-conformity (denoted NC) is reported to the CAB as follows:

1. An assessment at the main office referred to in the scope of accreditation: the NC is reported in writing at the closing meeting, once it has been categorised by the team leader. The CAB representative is asked to confirm the correctness of the observation underlying the non-conformity by signing the summary of the report in which all the non-conformities found have been listed. The point at which the team leader reports the NC using the non-conformities form (NCF) is the formal reporting of the non-conformity.
2. An assessment at a CAB office other than the main office: the NC is reported by the RvA assessor in writing to the CAB representative at the office concerned. If the assessment at this other office is followed within a month by an assessment at the main office, the final reporting,

including categorisation, takes place at the closing meeting at the main office. In case of a potential category A non-conformity and in all other cases the responsible RvA team leader will report the NC to the main office in its final, categorised form by email as an NCF within ten working days of the discovery of the NC. The point at which the NCF is sent is the formal reporting of the non-conformity.

3. On-site assessment activity: the term on-site assessment activity means an assessment of the performance of the conformity assessment activity that takes place away from the CAB office or laboratory environment. Examples include shadow assessments, witnessing of audits, inspections or examinations or of sampling. The following rules apply to observations that, according to the RvA assessor for the activities, may have to be regarded as not conforming to the accreditation requirements:
   - The observation is put down in writing by the RvA assessor immediately after the on-site assessment activity has ended and is reported in the course of the feedback to the witnessed person/persons. At this point this observation is not yet an NC.
   - The CAB representative at the witnessing is asked to confirm the correctness of the observation underlying the non-conformity in writing. If this is not possible at the location, the RvA assessor will send the observation to the witnessed person(s) no later than the next day with the request to confirm the observation.
   - If the team leader of the on-site assessment is of the opinion that the observation must be rated as an NC, depending on the context of the on-site assessment activity, the subsequent reporting will take place as follows:
     - if the on-site assessment activity has been planned as an independent assessment activity, the RvA team leader will formulate the observation as an NC and categorise and report it to the management of the CAB by means of a NCF within ten working days, at a closing meeting or in some other appropriate way (for example, by telephone, followed by sending the NCF by e-mail);
     - if the on-site assessment activity is part of a more comprehensive assessment and a closing meeting at the main office or a branch is planned within a month of this on-site assessment activity, the reporting of the NC will take place in the form of an NCF by the team leader in the course of this closing meeting.
   - The occasion of the closing meeting or the sending of the NCF by the team leader is the formal reporting of the non-conformity.
   - The agreements on reporting the on-site assessment activities, including the reporting of non-conformities, are laid down in the programme for a series of assessments for a CAB. Departure from the above rules is possible in consultation with the CAB on the understanding that a non-conformity discovered by the RvA is always reported formally to the CAB within three months.
   - An observation that according to the RvA assessor gives reason for formulating a category A non-conformity will, contrary to the foregoing periods of time, be reported as an NC to the CAB as soon as possible.
4. Document assessment (not being a preliminary assessment): the non-conformity is included in the report of the assessment as an NCF. The report is sent to the CAB by the RvA team leader according to the period of time specified in the document assessment plan. The point at which the report is sent to the CAB is the formal moment of reporting the NC.

Article 6.

In this document the moment of the formal reporting of a non-conformity is important for setting the period of time for corrective action. From now on in this document this moment is called NC report. The period for corrective action begins following submission of the NC report; this usually happens at the closing meeting of an assessment in the form of a completed NCF. The RvA Director operations lays down the reporting method for other forms of assessment not listed.

3 Corrective Actions

Article 7.

The period for corrective actions and the consequences for the accreditation process if the non-conformities are not remedied on time are described in the following articles for the different types of assessment. The period starts at the moment of the NC report referred to in Article 6. The RvA Director operations lays down the periods of time for each assessment that cannot be regarded as one of the types covered in chapters 4 to 6.

Article 8.

The RvA applies the quality management principle that the corrective action must eliminate the root cause of a non-conformity so that repetition is prevented. This requires an analysis of the root cause and an analysis of the extent of a quality problem underlying an NC. The term extent means that the CAB analyses where else in the organisation or the system the quality problem identified by the RvA assessment team occurs. If applicable, the period within which the problem has manifested itself will also be determined. The analyses of cause and extent will also have to demonstrate the impact of the quality problems on work done previously and set out clearly the need and possibility of repairing work done previously.

Article 9.

The RvA will close a non-conformity when the CAB has shown that the measures are appropriate. The term appropriate means that the CAB:

1. has carried out an analysis showing the root cause and the extent of the non-conformity;
2. where necessary, has immediately ceased activities as long as results may have to be regarded as incorrect or unreliable as a consequence of the quality problems found;
3. has taken action on the basis of the extent analysis by which results delivered (reports, certificates, etc) that do not meet the requirements have been rectified or revoked and where necessary persons concerned have been informed about the consequences of the problems found;
4. has taken measures on the basis of the cause analysis aimed at eliminating the root cause;
5. has determined the effectiveness of such measures by means of their own assessment (for example by a special internal audit aimed at the problems in question);
6. has provided objective proof that the RvA assessor can use as a basis for confirming the performance of the above measures.

Article 10.

To make an efficient assessment of the response of the body possible, the RvA expects that the result of the actions referred to in Article 9, the Corrective Action Report (CAR), will be included in the NCF used for the NC, in an editable file format (so not pdf, jpeg or similar).

Article 11.

If the effectiveness of the action cannot be demonstrated within the time applicable for the non-conformity, the RvA assessor can nonetheless regard the action as appropriate. This is conditional upon the RvA assessor having the confidence that the action will be effective and the longer implementation period is justified in the light of the nature of the quality problems found. In this case the effectiveness will be (further) verified by means of a supplementary assessment or at the next regular assessment.

4 Initial assessments

Article 12.

The RvA will make a decision about the accreditation within six months of the application, in accordance with section 5 of the National Accreditation Body Appointment Act. If the applicant has to take corrective actions, this period can be extended once by six months. The RvA will need part of these latter six months to plan, carry out and report on the follow-up assessment described in chapter 7. If it has not been established within the periods of time laid down that the requirements are met, the RvA can take a negative decision.

Article 13.

In the event of a category (B) non-conformity in an initial assessment, this non-conformity will not prevent the granting of the accreditation against the accreditation requirements applying at that time if the reporting shows that these requirements are met. The verification of the action for the category (B) non-conformities will in this case have to take place within the periods of time given in the transitional arrangement concerned.

5 Surveillance assessments, extraordinary assessments and reassessments

Article 14.

In case of a category A non-conformity the procedure is as follows:

1. The RvA will immediately suspend the accreditation of the CAB unless the RvA has, within a period, not exceeding 20 working days, determined by the RvA team leader on the basis of the nature of the non-conformity, received the following from the CAB:
   a. an adequate analysis of causes and extent as referred to in Article 8;
   b. confirmation of the immediate cessation of the activities as long as results may have to be regarded as incorrect or unreliable as a consequence of the quality problems found;
   c. an action plan for carrying out actions 3 to 6 as referred to in Article 9.
2. The RvA will assess and report whether the measures and the action plan give the confidence that the action may be regarded as appropriate (see Article 9) within ten working days of receipt of the above.
3. Once the RvA has accepted the analysis and the action plan, it will carry out the follow-up assessment (according to the rules set out in chapter 7) on the basis of the CAR that the CAB will provide within three months of the NC report to the RvA.
4. The RvA assessment team will draw up a final report and advice on the assessment within not more than five months of the NC report.
5. If the conclusion of the RvA assessment team is that the measures are not appropriate (as explained in Article 9), the team will recommend the initiation of the suspension procedure.

Article 15.

In case of a category B non-conformity the procedure is as follows:

1. The RvA will carry out a follow-up assessment, as described in chapter 7, on the basis of the CAR referred to in Article 10, that the CAB will provide to the RvA within three months of the NC report.
2. The RvA assessment team will draw up a final report and advice on the assessment within not more than five months of the NC report.
3. If the conclusion of the RvA assessment team is that the measures are not appropriate (as explained in Article 9), the team will recommend the initiation of the suspension procedure.

Article 16.

In case of a category (B) non-conformity the procedure for assessing the action, including the period of time for submitting the action, is included in the transitional arrangement concerned.

6 Extension of scope

Article 17.

The procedure in the case of non-conformities found in an assessment pertaining to an application for extension of a scope is the same as the initial assessment procedure set out in chapter 4.

Article 18.

A decision to extend the scope may be deferred if the CAB has a non-conformity outstanding from a surveillance assessment, reassessment or extraordinary assessment that is relevant to the new area, or in the event that the CAB's accreditation is suspended at that time. If this deferral leads to a decision on the extension not being taken within the period of six or twelve months from the extension application, a negative decision may be taken.

Article 19.

In the event that non-conformities are found in an extension assessment that, according to the RvA assessment team, are structural non-conformities, relevant to activities previously carried out under accreditation, the RvA applies the periods of time set out in chapter 5 for these non-conformities.

7 Follow-up assessment

Article 20.

The nature and extent of a follow-up assessment depend on the nature, extent and number of non-conformities. The following policy applies:

1. As far as possible a follow-up assessment is carried out on the basis of the documented CAR, unless the assessment team is of the opinion that the effectiveness of the action must be verified in some other way, such as a follow-up assessment at the offices of the CAB and/or a follow-up assessment in the form of an on-site assessment activity.
2. The assessment team will give the CAB an indication of the nature and extent of the follow-up assessment on the reporting of an NC and will, if possible, make an appointment for this at the closing meeting of the assessment. The RvA bureau will confirm this indication and these appointments.
3. In the event that not all non-conformities can be closed in the follow-up assessment, on the basis of the CAR provided by the CAB (according to the provisions laid down in Article 9 and Article 11), the RvA may decide to carry out a second follow-up assessment if:
   a. the RvA team leader has the confidence that the CAB is able to take further action by which the non-conformity can be closed, and
   b. this second follow-up assessment can take place within the periods of time given in chapters 4 and 5.
4. The second follow-up assessment will be carried out on the basis of a CAR corrected or supplemented by the CAB and will as a rule be carried out at the offices of the CAB.

Article 21.

In the case of a follow-up assessment at the offices of the CAB or in the form of witnessing, the results will be reported to the CAB verbally. In all other cases the results will be reported by the team leader by telephone or by e-mail within five working days of the conclusion of the follow-up assessment.

8 Changes compared with previous version

Article 22.

The following significant changes have been made in this version compared with version 2 of January 2015:

- Article 5 contains a more extensive explanation of the way in which non-conformities are reported after a witness assessment.
- In Article 14 it is clarified that in case of a category A non-conformity activities must be stopped **as long as** the results have to be regarded as possibly incorrect or unreliable as a result of the quality problems established.

Appendix 1: Examples of category A non-conformities

a. Laboratories
   - The laboratory has reported erroneous results.
   - In the absence of adequate quality controls it is not demonstrable that results are correct.
   - The laboratory cannot demonstrate that the application of the method used gives correct results.
   - The accreditation mark (or other communication) is used in a way that suggests that the body is accredited for an activity where this is not the case.
   - In one or more files so many of the records required are lacking that it is no longer possible to see that tests have been carried out correctly.

b. Inspection bodies
   - The body cannot demonstrate that the inspector is competent.
   - The team's observations raise doubts about the independence of the body (for example, in the case of demonstrable mixing of inspection and conflicting activities such as design, production, etc, or demonstrable dependence on a design organisation).
   - During an inspection essential observations are missed or observations are rated incorrect causing the results of the inspection to be unreliable.
   - The accreditation mark (or some other communication) is used in a way that suggests that the body is accredited for an activity where this is not the case.
   - The use of incorrect inspection methods or the incorrect use of the prescribed methods leads to unreliable inspection results.
   - in one or more files so many of the records required are lacking that it is no longer possible to see that a reliable inspection has been carried out at this client or these clients.

c. Certification bodies
   - The body cannot demonstrate that the auditor is competent.
   - The team's observations raise doubts about the impartiality or independence of the body (for example, in the case of demonstrable mixing of certification and consultancy or demonstrable dependence on a consultancy organisation).
   - Inconsistencies are observed in audits or decisions, et cetera.
   - The body has wrongly provided a certificate; there were still some non-conformities not yet closed.
   - During an audit essential observations (systemic, that is relating to key points of the standard, such as the hazard analysis in the case of FSMS or the inventory of customer requirements in the case of a QMS) are missed or observations are rated incorrectly, in such a way that the CAB has made or would make an incorrect decision.
   - In one or more files so many of the records required are lacking that it is no longer possible to see that a reliable certification decision has been made at this client or these clients.
   - The accreditation mark (or other communication) is used in a way that suggests that the body is accredited for an activity where this is not the case.

d. Verification bodies
   - The body cannot demonstrate that the verifier is competent.
   - During the verification essential observations are missed (for example, material non-conformities in declaration, material non-conformities between described situation and reality, such as missing emission sources) or observations are rated incorrectly, in such a way that the body has made or would make an incorrect decision.
   - During the verification the risk analysis of the body turns out to be based on erroneous information (on possibly material matters) without this being noticed or reported by the verifier.
   - The records at the body are so brief that it is actually no longer possible to see what has been verified and what the results of the verification were.
   - The accreditation mark (or other communication) is used in a way that suggests that the body is accredited for an activity where this is not the case.