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 in the Government Gazette.

2 Non-conformities

Article 3.
A situation that does not conform to the requirements is regarded as a non-conformity (also denoted 'NC'). 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.

3 Identification and reporting of non-conformities

Article 4.
1) Non-conformities are identified by RvA assessors and categorised by the RvA lead assessor.
2) Before non-conformities are identified, the RvA assessment team explains its findings and observations of assessments, and the potential non-conformities associated with them, to a representative of the CAB:
   a) The explanation is given, depending on the assessment situation, at a closing meeting, by telephone, or otherwise;
   b) The explanation by the RvA assessment team is given to the regular contact person of the CAB;
   c) If the regular contact person is not available, for example because an assessment is taking place at a location other than the main location or operational activities are being witnessed

elsewhere, the explanation by the RvA assessment team is given to the representative(s) present at the location concerned or witnessed person or persons.

Article 5.

1) The RvA reports identified non-conformities to the CAB using the RvA reporting system.
2) The reporting of non-conformities using the RvA reporting system must take place within 10 working days of the assessment at which the non-conformity is identified.
3) The RvA can depart from the fixed reporting deadline to report on multiple connected assessments at the same time:
   a) The RvA can decide independently to report at the same time on assessments performed no more than one month apart, for example if an office assessment and related witnessing closely follow each other.
   b) The RvA can decide in agreement with the CAB to combine reports of assessments performed no more than three months apart.

   The latest reporting deadline for combined reports is 10 working days after the last assessment, or the last assessment part, being reported has been performed.
4) A category A non-conformity will, notwithstanding the above, be reported as soon as possible.

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. The period for corrective action begins the day after the NC report is made available in the RvA reporting system. The RvA board lays down the reporting method for other forms of assessment not listed.

4 Dispute over interpretation regarding non-conformities

Article 7.

1) If the conformity assessment body and the assessment team have different opinions about the interpretation of accreditation requirements on identifying or resolving a non-conformity, a dispute over interpretation can be submitted by the conformity assessment body in respect of this non-conformity.
2) A dispute over interpretation in respect of a non-conformity will be submitted using the form RvA-F039, Dispute concerning an RvA Assessment, within ten days of the dispute arising.
3) No dispute over interpretation may be submitted to question an observation that has led to a non-conformity.
4) The handling of a dispute over interpretation may lead to maintenance, reformulation or withdrawal of the non-conformity in question.
5) In the dispute over interpretation the identification of the non-conformity will be reconsidered, together with one or more RvA leaders assessors who have not been involved in the identification. Before consultation with these (independent) lead assessors takes place, the leader assessor who has identified the non-conformity will him or herself be given the opportunity to withdraw or reformulate the non-conformity he or she has identified.
6) RvA lead assessors involved in the handling of the dispute over interpretation may involve experts or expert groups from inside or outside the RvA in their consideration.
7) The conformity assessment body is not required to take corrective action during the handling of the dispute. The non-conformity in respect of which a dispute over interpretation has been submitted, or a dispute over interpretation being handled, has no impact on the decision-making of the RvA in respect of the assessment in which the non-conformity has been identified.

5 Corrective Action

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.
1) The RvA will close a non-conformity when the CAB has shown it is rectified and it is taking appropriate action to eliminate the root cause of the quality problem. This means that the CAB can demonstrate that it:
   a) has carried out an analysis showing the root cause and the extent of the non-conformity;
   b) 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;
   c) 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;
   d) has taken action on the basis of the cause analysis aimed at eliminating the root cause.
2) The CAB will report on the action referred to in paragraph 1 of this Article in a Corrective Action Report (CAR) in the RvA registration system. The CAB is thereby delivering objective proof, on the basis of which the RvA assessor can confirm the execution of the action.
3) With regard to the taking of corrective action, as referred to in paragraph 1(d) of this Article, the CAB demonstrates the effectiveness of action taken by means of its own assessment. This is possible for example by a special internal audit aimed at the problems in question
4) If the effectiveness of the action cannot be demonstrated within the time applicable for(see Article 18) a RvA lead assessor will decide whether the action plan is sufficient in a particular case or that closure of the non-conformity continues to depend on action being taken and its effectiveness being demonstrated. To close a non-conformity on the basis of an action plan, the RvA assessor will decide whether there is sufficient confidence that the proposed action will be effective and whether the proposed implementation period is justified in the light of the nature of the quality problems identified..

Article 10.
[Deleted per 13-01-2021. Content incorporated in Article 9.]

Article 11.
[Deleted per 13-01-2022. Content incorporated in Article 9.]

6 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 9. 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.

7 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 10 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 9;
   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 the actions referred to in Article 9 paragraph 1).
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 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 9) on the basis of the CAR that the CAB will provide within six weeks 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, 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 9, on the basis of the CAR referred to in Article 9 paragraph 2), that the CAB will provide to the RvA within six weeks 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 non-conformities cannot be closed, 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.

8 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 6.

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 7 for these non-conformities.

9 Follow-up assessment

Article 20.
The nature and extent of a follow-up assessment depend on the nature, extent and number of non-conformities identified in an assessment. 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 in the reporting of an NC and will, if possible, make an appointment for this at the closing meeting of the assessment. The RvA office will confirm this appointment.
3. On the basis of the CAR provided by the CAB the RvA may decide that an additional follow-up assessment is necessary for one or more non-conformities.
4. If the non-conformities cannot all be closed in these follow-up assessments, on the basis of the CAR provided by the CAB, the RvA may decide to perform a third follow-up assessment this third follow-up assessment can take place within the periods of time given in chapters 6 and 7.
5. The third follow-up assessment will be performed on the basis of a CAR corrected or supplemented by the CAB and will usually be performed 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.

10 Changes compared with previous version

Article 22.
Compared to version 3 of 13 November 2018, the following significant changes have been implemented:

- Article 4, 5 and 6, regarding identification and reporting of non-conformities have been adapted and have been incorporated in new Chapter 3. The content of the articles has been simplified and is adapted to match the use of the digital reporting system of the RvA.
- Article 7 has been renewed and contains new content. Former content is still incorporated in this policy rule by other articles (i.a. Article 6). The renewed article concerns Disputes over interpretation regarding non-conformities (new Chapter 4) and the content is not new. The dispute settlement rules have been moved from Policy Rule BR002 to Policy Rule BR004 to make a better match between the content of the article and the Policy Rule within it is incorporated. The dispute settlement rules have been rewritten for better clarity.
- Article 9, 10 and 11, regarding non-conformities have been merged, restructured and adapted to the new way of working following the implementation of the new digital report system of the RvA.
- The content of article 14 and 15 has been adjusted. The standard period for providing a corrective-action-report has been limited from 3 months to 6 weeks. As a counter measure, CAB's have explicitly been given the opportunity to work with an action plan (see new article 9 sub 4) and an extra (third) opportunity to take appropriate corrective action (see new article 20).
- Article 20, regarding follow-up assessments has been adjusted to better match the new way of working following the implementation of the new digital report system of the RvA. An opportunity for a third follow-up assessment and chance to take appropriate corrective action has been implemented.

Appendix 1: Examples of category A non-conformities

1. Laboratories
   a. The laboratory has reported erroneous results.
   b. In the absence of adequate quality controls it is not demonstrable that results are correct.
   c. The laboratory cannot demonstrate that the application of the method used gives correct results.
   d. 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.
   e. 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.

2. Inspection bodies
   a. The body cannot demonstrate that the inspector is competent.
   b. 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).
   c. During an inspection essential observations are missed or observations are rated incorrect causing the results of the inspection to be unreliable.
   d. 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.
   e. The use of incorrect inspection methods or the incorrect use of the prescribed methods leads to unreliable inspection results.
   f. 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.

3. Certification bodies
   a. The body cannot demonstrate that the auditor is competent.
   b. 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).
   c. Inconsistencies are observed in audits or decisions, et cetera.
   d. The body has wrongly provided a certificate; there were still some non-conformities not yet closed.
   e. 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.
   f. 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.
   g. 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.

4. Validation/verification bodies
   a. The body cannot demonstrate that the validation/verification staff are competent.
   b. During a validation/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.
   c. During a validation/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.
   d. 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 validation/verification were.
   e. 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.