

1 **Accreditation Specification RvA**

2 **Riskbased approach accreditation**

3 **Document code: ASR003-UK**

4 **Version 1.0, effective date: 15-09-2025**

5

CONCEPT 2.0

6

7 **Contents**

8 **Chapter 1. Scope of application3**

9 **Chapter 2. Definitions and abbreviations.....3**

10 *Article 1. Abbreviations 3*

11 *Article 2. Definitions 3*

12 **Chapter 3. Conditions multisite accreditation3**

13 *Article 3. Conditions multisite accreditation 3*

14 *Article 4. Additional condition cross-border multisite accreditation 4*

15 *Article 5. Responsibility for non-conformities 4*

16 *Article 6. Information contained in document EA-2/13 4*

17 **Chapter 4. Risk assessment4**

18 *Article 7. Evaluation of different types of risks 4*

19 *Article 8. Activities carried out under accreditation 5*

20 *Article 9. Past performance review 5*

21 *Article 10. Impartiality and independence 6*

22 *Article 11. Organisation and structure of the CAB 6*

23 *Article 12. Staff 6*

24 *Article 13. Locations where the CAB is established and/or carries out work 6*

25 **Chapter 5. Sample locations and witnessing7**

26 *Article 14. Sample of locations 7*

27 *Article 15. Sample of files and witnessing 7*

28 *Article 16. Sample for witnessing in several countries 7*

29 **Chapter 6. Changes compared to previous version8**

30 **Chapter 7. Transitional arrangements8**

31 **Chapter 8. References8**

32 **Annex 1. Essential business processes9**

Chapter 1. Scope of application

This Accreditation Specification RvA describes:

- the risk-based approach to the CAB's operations, sites, staff, operations and structure, and
- the conditions and procedure for multisite accreditation, an accreditation with more than one location on the annex to the accreditation declaration.

Chapter 2. Definitions and abbreviations

Article 1. Abbreviations

CAB: Conformity assessment body;
 NAB: National accreditation body

Article 2. Definitions

In addition to the definitions in EN-ISO/IEC 17000 and the RvA Policy Rule BR001, the following definitions apply:

1. *The same organisation*: Group of (legal) entities composed of a head office and locations connected to the registered legal entity on the basis of contractual or equivalent legal relationships, which operates under the same (commercial) name and the same logo;
2. *Final responsibility for the accredited conformity assessment activities*: Responsibility for the performance and outcome of accredited activities;;
3. *The same general management system*: Set of linked rules and procedures defined by *the same management* allowing this management to take *responsibility for the accredited activities*;
4. *The same management*: The same set of persons or organisational entities (of the same organisation taking overall responsibility for the accredited activities;
5. *Multisite accreditation*: Accreditation covering multiple locations of a CAB belonging to the same organisation.
6. *Virtual location*: online environment in which work is carried out or services provided, allowing individuals to carry out processes regardless of their physical location.

Chapter 3. Conditions multisite accreditation

Article 3. Conditions multisite accreditation

Accreditation to a CAB covering more than one location is only possible if all activities are under the final responsibility of one accredited legal entity.

The responsibility for the accredited conformity assessment activities should be demonstrated through contractual or other legal agreements between the accredited legal entity and the location(s). In

65 addition, internal arrangements should be available at the location(s) that specify the relationships in
66 terms of management and responsibility.

67 The accredited CAB must demonstrate that it has control over the activities at all sites, that they are
68 monitored and that the control and monitoring function correctly.

69 **Article 4. Additional condition cross-border multisite accreditation**

70 If locations are located in a country other than where the accredited legal entity is located, those foreign
71 establishment locations may also have a different legal entity. In that case the different legal entities
72 must be part of each other and part of the same organization.

73
74 The accreditation declaration and the annex to the accreditation declaration shall mention only the legal
75 entity that has ultimate responsibility for the accredited conformity assessment activities. All locations
76 operate under the same management and the same management system.

77
78 Local legal entities are not allowed to offer accredited activities under their own legal entity to the local
79 market, as the local legal entity is not covered by the RvA-accreditation.

80
81 Individual locations of the CAB may offer conformity assessment activities on the local market only on
82 behalf of the accredited CAB. The certificates, declarations and reports issued shall contain only the
83 name and address of the RvA-accredited legal entity, without reference to the name or logo of a local
84 CAB. The offers, contracts, certificates and reports that are issued must not create confusion about the
85 legal entity of the CAB that holds the RvA accreditation.

86 **Article 5. Responsibility for non-conformities**

- 87 1. A non-conformity at each location of a CAB accredited by the RvA is considered a non-conformity
88 for which the head office of the RvA-accredited CAB is responsible. The RvA decides on the next
89 steps and closing of such non-conformities.
- 90 2. This approach is also applicable to an assessment that is outsourced to a NAB as a cross border
91 accreditation assessment.

92 **Article 6. Information contained in document EA-2/13**

93 More information on the application of the concepts in the definitions and in the previous articles can be
94 found in the Appendix of document EA-2/13, available on the website [https://european-](https://european-accreditation.org/)
95 [accreditation.org/](https://european-accreditation.org/).

96 **Chapter 4. Risk assessment**

97 **Article 7. Evaluation of different types of risks**

98 The RvA considers the following risk factors on a specific CAB to the extent that they apply:

99 1. The activities carried out under accreditation, see Article 8;

100 2. The past performance review, see Article 9;

- 101 3. Impartiality and, where applicable, independence, see Article 10;
- 102 4. The organisation and structure of the CAB, see Article 11;
- 103 5. The staff and competence of the CAB, see Article 12;
- 104 6. The locations where the CAB is established and/or where the CAB carries out activities, see
- 105 Article 13.

106 **Article 8. Activities carried out under accreditation**

- 107 1. The complexity of the scope of accreditation → different competencies needed to cover the
- 108 scope of accreditation;
- 109 2. The use of outsourcing and externally procured services within the scope of accreditation;
- 110 3. The complexity and importance of external rules and requirements for a specific sector, e.g. the
- 111 diversity of requirements, regulations;
- 112 4. Is the sector concerned a critical sector according to NIS2 (Network Information Security)
- 113 regulations?;
- 114 5. The overall level of competence and compliance in the sector, based on number of deviations,
- 115 critical deviations, notifications, government oversight where applicable;
- 116 6. Frequency and volume of activities (number of test reports, certificates, etc.);
- 117 7. The market share of the CAB;
- 118 8. The use of a flexible scope;
- 119 9. A change in the number and/or type of customers and market share.

120 **Article 9. Past performance review**

- 121 1. The implementation and execution of the accreditation cycle assessment programme of the
- 122 CAB, including
- 123 a. The history number and nature of deviations
- 124 b. The history of additional assessments;
- 125 c. The history of suspensions and withdrawals;
- 126 2. The way in which non-conformities are handled;
- 127 3. The results of the internal audits and the management review;
- 128 4. The number and nature of reports;

- 129 5. Historical performance in external monitoring activities (government supervisor, scheme owner);
130 6. The historical performance in comparative studies (Proficiency testing and Interlaboratory
131 comparisons (ILC)).

132 **Article 10. Impartiality and independence**

- 133 1. Other activities that may affect or conflict with the conformity assessment activities (e.g.
134 consultancy, regulatory activities (both legislative and executive), involvement in the object to be
135 tested, etc);
136 2. The ownership;
137 3. The related organizations and the activities they carry out;

138 **Article 11. Organization and structure of the CAB**

- 139 1. The number and type of departments involved in the activities;
140 2. The number and type of locations;
141 3. The geographical distribution of establishments;
142 4. The management of departments and branches;
143 5. The outsourcing of activities that are part of or supportive of the conformity assessment
144 process;

145 **Article 12. Staff**

- 146 1. The competence and experience of the staff;
147 2. The inflow and outflow of staff (compared to other companies in the sector);
148 3. The capacity and ability to carry out the conformity assessment activities in a timely and
149 competent manner;
150 4. The ratio between new and experienced staff for specific positions;
151 5. The use of remote working (where individual employees work a large part of their working time
152 independently, not from a location of the CAB);

153 **Article 13. Locations where the CAB is established and/or carries out work**

- 154 1. The type of sites – the sites, the mobile sites, the temporary sites, the clusters of delivery points
155 at the medical laboratories;
156 2. The activities carried out by/in the different types of sites (see Annex 1);

Met opmerkingen [Mv1]: To be elaborated in the ASR101 for POCT etc.

- 157 3. The use of virtual locations;
- 158 4. The level of control and monitoring by the main sit;
- 159 5. The geographical distribution of the locations with differences in language, culture, regulations;
- 160 6. The geographical distribution of performance of conformity assessment activities, with
- 161 differences in language, culture, regulations, transport times and conditions, and risks.

162 Chapter 5. Sample locations and witnessing

163 Article 14. Sample of locations

164 Samples of locations from which the CAB undertakes activities under accreditation are taken depending

165 on, amongst others:

- 166 1. The nature and extent of the activities at those locations;
- 167 2. The extent to which these activities are supervised from the main site of the CAB;
- 168 3. Scope and results of internal audits carried out by the main site;
- 169 4. Whether the relevant foreign location as a separate legal entity has its own accreditation;
- 170 5. Notifications about the CAB;
- 171 6. Relationships of a location with other organizations (for example, with an consultancy
- 172 organization).

173 Article 15. Sample of files and witnessing

174 The sample for the number and type of files (personnel files and files of conformity assessment

175 activities) and the assessment of the implementation of the activities depends on, amongst others;

- 176 1. The nature and scope of the activities;
- 177 2. The competence and experience of staff, including inflow staff;
- 178 3. The areas of competence in product groups, clusters, operations, etc;
- 179 4. The notifications on the CAB.

180 Article 16. Sample for assessment in countries without a CAB location

181 Where a CAB carries out conformity assessment activities in one or more countries other than where

182 the accredited CAB's is located, samples for file review and witnessing are taken in those countries.

183 This is depending on, amongst others

- 184 1. The nature and the extent of the activities in those countries;
- 185 2. The local legislations and regulations that influence the activities in those countries;
- 186 3. Notifications about the CAB.
- 187

188 **Chapter 6. Changes compared to previous version**

189 This is the second version of this document.

190 Some textual changes compared to the previous version.

191 Added to this document are:

- 192 - Chapter 4, giving an overview of the risk based factors, that are considered when an
- 193 accreditation cycle assessment programme is established for a CAB;
- 194 - Article 15, giving an overview of the risk based factors for the sample of files and witnessing;
- 195 - Annex 1 gives an overview of the essential business processes;
- 196 - In the references the documents EA-2/19 and IAF MD4 are added.

197 **Chapter 7. Transitional arrangements**

198 This document shall enter into force on 15 September 2025. A transitional arrangement is not
199 applicable.

200 **Chapter 8. References**

201	BR001	RvA Policy Rule Accreditations
202	EN-ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
203	EA-2/13 M: 2019	EA Cross Border Accreditation Policy and Procedure for Cross Border
204		Cooperation between EA Members
205	EA-2/19 INF: 2022	List of risks for accreditation processes and operation of national accreditation
206		bodies
207	IAF MD4: 2025	IAF Mandatory document for the use of information and communication
208		technology (ICT) for conformity assessment purposes
209		

210 **Annex 1. Essential business processes**

211 The following processes are essential for the conformity assessment activities:

- 212 1. Policy development;
- 213 2. The development of methods, processes and/or procedures;
- 214 3. The initial evaluation of competence of personnel involved in conformity assessment activities,
215 from acceptance of an application to decision-making;
- 216 4. Supervision of on-going monitoring of personnel involved in conformity assessment activities,
217 from acceptance of an application to decision-making;
- 218 5. The application acceptance and review process;
- 219 6. The selection of personnel carrying out the conformity assessment activity;
- 220 7. The management of the conformity assessment activity;
- 221 8. The performance of the conformity assessment activity;
- 222 9. Monitoring of staff performance;
- 223 10. Issuance of the final result of the conformity assessment activity;
- 224 11. The complaint handling.

225