SUBJECT: Accreditation Program for Quality Management Systems (QMS)

APPLIES TO: ISO 9001 QMS ANAB-Accredited and Applicant Certification Bodies

PREFACE
This Accreditation Rule is to inform certification bodies (CBs) of ANAB requirements for accreditation to certify organizations for QMS conforming with ISO 9001.

ACCREDITATION RULE

1. Requirement Documents (current versions unless specified)
   1.1. ISO 9001, Quality management systems – Requirements
   1.2. ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems
   1.3. ISO/IEC 17021-3, Competence requirements for auditing and certification of quality management systems
   1.4. MA 5000, ANAB Management Systems Accreditation Manual, and applicable ANAB Accreditation Rules
   1.5. IAF MD 17, Witnessing Activities for the Accreditation of Management Systems Certification Bodies
   1.6. Other IAF Mandatory Documents as applicable

2. Application Process
   2.1. CBs can obtain applications for informational use at www.anab.org.
   2.2. The application process outlined at www.anab.org must be completed via ANAB’s Enterprise Quality Manager (EQM) database when the CB is ready to apply for QMS accreditation.
   2.3. The application fee includes the cost of one assessor day for the off-site documentation review.

3. Initial Assessments for Accreditation
   3.1. An ANAB accreditation assessor shall conduct a full documentation review.
   3.2. After the documents are found acceptable, ANAB shall conduct an office assessment and required witnessed audits.
      3.2.1. The office assessment shall be conducted on site or remotely (at ANAB’s discretion) and is conducted to ensure the CB’s certification process for QMS conforms with ISO/IEC 17021-1 and is effective.
      3.2.2. ANAB shall witness the CB conducting a two-stage audit process (stages 1 and 2).
         3.2.2.1. The ANAB assessment team shall have the same number of members as the CB audit team.

4. Surveillance Assessments
   4.1. ANAB shall conduct an annual office assessment and annually witness a CB team conducting a QMS audit.
      4.1.1. When possible, the office assessment shall be conducted concurrently with assessments for other ANAB accreditation programs for which the CB is accredited.
4.1.2. ANAB will select the witnessed audit in accordance with this Accreditation Rule, Accreditation Rule 18, MA 5000, and IAF MD 17.

4.1.2.1. ANAB shall evaluate the CB’s full system audit process during at least one annual witnessed audit (stages 1 and 2 certification audit or recertification).

4.1.2.2. When selecting additional audits to witness in the accreditation cycle, ANAB will consider the IAF MD 17 technical clusters (listed in Annex 1 below) for which the CB is accredited, the CB’s audit activity, and management system findings, and will include audit types such as surveillance, special, multi-site, scope expansion, transfer, integrated, ASRP, and/or ICT.

4.1.3. During the accreditation cycle, ANAB shall assess the competence of the CB during office assessments and witnessed audits for all QMS scopes for which the CB is accredited.

4.1.4. All QMS assessments shall be planned for and recorded on the ANAB assessment program (per MA 5000), including identification of the competence reviews by the scope of accreditation.

5. Reaccreditation Assessments

5.1. ANAB shall conduct a document review and an on-site full system office assessment at approximately six months prior to the expiration of accreditation.

5.2. ANAB may reduce the CB’s scope of accreditation if competence has not been confirmed during the accreditation cycle. ANAB will consider if the CB is in the first or second accreditation cycle per IAF MD 17 and as outlined below.

6. Scope of Accreditation

6.1. The scope of accreditation shall be for IAF scopes specified in IAF ID 1 and further defined in IAF MD 17, based on assessment of the CB in accordance with IAF MD 17. IAF scopes, technical clusters, and critical codes are listed in Annex 1 (following).

6.2. During the initial accreditation process, the CB shall identify all desired scopes in the application. To expand the scope after initial accreditation, the CB shall provide a completed scope extension application (via EQM) for each desired scope.

6.3. The application process for initial accreditation or extension of scope shall include review of evidence demonstrating an appropriate level of competence for each scope for which the CB applies.

6.4. A competent accreditation assessor or technical reviewer will review the application and documentation, including the CB’s competencies and processes for the specific scope, and prepare a written response on the CB’s conformance.

6.5. After ANAB confirms competence for each scope identified in the CB’s application, ANAB will determine the witnessing needed for the scopes, considering the CB’s clients and technical clusters per Annex 1 and as defined in Table 1 (below):

Table 1.

<table>
<thead>
<tr>
<th>Requested Scope</th>
<th>Cluster (per Annex 1)</th>
<th>Witnessing Requirements (per IAF MD 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope is a critical code</td>
<td>Cluster with no other critical codes</td>
<td>Scope is witnessed</td>
</tr>
<tr>
<td></td>
<td>Cluster with other critical codes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>At least one critical code has been witnessed</td>
<td>No witnessing required</td>
</tr>
<tr>
<td></td>
<td>No critical code has been witnessed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After a witnessed audit in a critical code has been</td>
<td>Witnessing required</td>
</tr>
<tr>
<td></td>
<td>successfully completed, additional critical and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>non-critical codes in the cluster may be granted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>following successful application review for evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>of competence</td>
<td></td>
</tr>
</tbody>
</table>
Scope is not a critical code

<table>
<thead>
<tr>
<th>CB scope of accreditation includes no codes from the cluster</th>
<th>Witnessing in a critical or non-critical code in same cluster required</th>
<th>After a successful witnessed audit in a critical or non-critical code, the non-critical code can be granted following successful application review for evidence of competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>CB scope of accreditation includes codes from the cluster</td>
<td>Witnessed audit in a critical code or non-critical code previously completed</td>
<td>Non-critical code can be granted without a witnessed audit following successful application review for evidence of competence</td>
</tr>
<tr>
<td>After a witnessed audit has been successfully completed for a non-critical code, additional non-critical codes in the same cluster may be granted following successful application review for evidence of competence</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.5.1. If the CB applies for any scopes for which it does not have clients and witnessing is required prior to granting the scope in accordance with this Accreditation Rule and IAF MD 17, ANAB can accept the application but will not grant accreditation until successful witnessing is completed.

6.6. Maintaining Accreditation and Assessing IAF Technical Clusters

6.6.1. Initial (First) Accreditation Cycle

6.6.1.1. During the initial QMS accreditation cycle, ANAB conducts one witnessed audit in each QMS technical cluster for which the CB is accredited. The witnessed audits may or may not be in critical codes (see section 4 above). This is in addition to the initial accreditation or scope extension witnessed audits.

6.6.1.2. This approach continues until ANAB determines the CB has demonstrated sufficient experience and performance.

6.6.1.3. For CBs accredited by ANAB for other standards seeking to add QMS, the QMS accreditation cycle may expire on the same date as the cycle for standards for which the CB is already accredited; upon initial QMS accreditation, the required witnessed audits will be determined and outlined in the assessment program.

6.6.2. Subsequent Accreditation Cycles

6.6.2.1. In subsequent accreditation cycles after the initial accreditation cycle, required QMS witnessed audits are completed over two accreditation cycles (i.e., up to a 10-year period). Witnessed audits may or may not be for the critical codes (see section 4 above).

6.6.2.2. This approach continues unless the CB’s EATL and/or ANAB management recommend requiring all witnessed audits in one accreditation cycle (i.e., up to a five-year period) because of poor performance and/or significant concerns about competence.

6.6.3. ANAB will consider witnessed audits of other IAF MLA management systems signatory ABs and witnessed audits conducted for subordinate standards (e.g., AS9100, TL 9000) to fulfill the witnessed audits required per Annex 1; both will be considered by ANAB and the CB when developing and maintaining the assessment program.

7. End User Expected Outcomes for Accredited Certification to ISO 9001

7.2. The CB shall have processes to continually communicate and consistently reinforce expected outcomes with auditors, certification personnel, customers, and other stakeholders.

8. Requirements for Transition to ISO 9001:2015


8.1.1. IAF resolution 2017-13 requires that as of 2018/03/15, all initial, surveillance, and recertification audits shall be to ISO 9001:2015.

8.2. CB ISO 9001:2015 Activity with Clients

8.2.1. The expiration date of ISO 9001:2008 certifications issued during the transition period shall correspond to the end of the three-year transition period.

8.2.2. If the CB conducted transition audits to the FDIS, the CB must confirm any differences between the FDIS and the published standard with its clients (if applicable) prior to the CB issuing or reissuing ANAB-accredited certificates to ISO 9001:2015.

8.3. Verification of Effective Implementation

8.3.1. ANAB will verify continued implementation of the revised system at the CB’s normally scheduled office assessments and at an ISO 9001:2015 witnessed audit during the transition period.

8.3.1.1. All witnessed audits in 2018 and beyond shall be conducted to ISO 9001:2015.

8.3.1.2. If ISO 9001:2008 certificates remain in the marketplace after 2018/09/15, ANAB will issue an NCR or suspend the CB’s accreditation.
### Annex 1. QMS Technical Clusters and Codes (Scopes) Per IAF MD 17*

<table>
<thead>
<tr>
<th>Technical Cluster</th>
<th>IAF Code</th>
<th>Description of Economic Sector/Activity</th>
<th>Critical Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td>1</td>
<td>Agriculture, forestry and fishing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Food products, beverages and tobacco</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>Hotels and restaurants</td>
<td></td>
</tr>
<tr>
<td>Mechanical</td>
<td>17</td>
<td>Basic metals and fabricated metal products</td>
<td>22 or 20</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>Machinery and equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Electrical and optical equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>Shipbuilding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Other transport equipment</td>
<td></td>
</tr>
<tr>
<td>Paper</td>
<td>7a</td>
<td>Limited to “Paper products”</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Publishing companies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Printing companies</td>
<td></td>
</tr>
<tr>
<td>Minerals</td>
<td>2</td>
<td>Mining and quarrying</td>
<td>2 or 15</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Non-metallic mineral products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>Concrete, cement, lime, plaster, etc.</td>
<td></td>
</tr>
<tr>
<td>Construction</td>
<td>28</td>
<td>Construction</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>34</td>
<td>Engineering services</td>
<td></td>
</tr>
<tr>
<td>Goods production</td>
<td>4</td>
<td>Textiles and textile products</td>
<td>5 or 14</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Leather and leather products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Wood and wood products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>Rubber and plastic products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>Manufacturing not elsewhere classified</td>
<td></td>
</tr>
<tr>
<td>Chemicals</td>
<td>7b</td>
<td>Limited to “Pulp and paper manufacturing”</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Manufacture of coke and refined petroleum products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>Chemicals, chemical products and fibres</td>
<td></td>
</tr>
<tr>
<td>Supply</td>
<td>25</td>
<td>Electricity supply</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>Gas supply</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>Water supply</td>
<td></td>
</tr>
<tr>
<td>Transport and</td>
<td>24</td>
<td>Recycling</td>
<td>24</td>
</tr>
<tr>
<td>Waste Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>31</td>
<td>Transport, storage and communication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>39</td>
<td>Other social services</td>
<td></td>
</tr>
<tr>
<td>Services</td>
<td>29</td>
<td>Wholesale and retail trade; Repair of motor vehicles, motorcycles and</td>
<td>37 or 33</td>
</tr>
<tr>
<td></td>
<td></td>
<td>personal and household goods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>Financial intermediation; real estate; renting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>Information technology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>Other services</td>
<td></td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>Education</td>
<td></td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>Public administration</td>
<td></td>
</tr>
<tr>
<td>Nuclear</td>
<td>11</td>
<td>Nuclear fuel</td>
<td>11</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>13</td>
<td>Pharmaceuticals</td>
<td>13</td>
</tr>
<tr>
<td>Aerospace</td>
<td>21</td>
<td>Aerospace</td>
<td>21</td>
</tr>
<tr>
<td>Health</td>
<td>38</td>
<td>Health and social work</td>
<td>38</td>
</tr>
</tbody>
</table>

*For IAF code 7, “a” and “b” added to identify IAF codes split between critical codes.