



## **National Accreditation Board for Testing and Calibration Laboratories (NABL)**

### **Procedure for Integrated Assessment of laboratories in Defence aviation sector & Additional Requirements of DGAQA**

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## AMENDMENT SHEET

| S. No. | Amendment No. | Page No. | Clause No. | Date of Amendment | Amendment | Reasons | Signature QA Team | Signature of Competent Authority |
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## **1. Procedure for Integrated Assessment of Testing Laboratories to obtain approval from DGAQA**

- 1.1. This document describes specific requirements of assessment that a testing laboratory, seeking approval from Directorate General of Aeronautical Quality assurance (DGAQA) has to meet, in parallel to the accreditation in accordance with of ISO/IEC 17025 by NABL. Firm holding AFQMS approval from DGAQA are not covered under the scope of this document (except their testing laboratory).
- 1.2. The application for integrated Accreditation/Approval scheme for the specific scope shall be taken into consideration only on the scrutiny by NABL and evaluation of competence and compliance through integrated assessment approach by NABL /DGAQA, grant of accreditation by NABL and parallel approval from DGAQA. This will be based on meeting all the requirements stipulated in the test methods / standards like MIL/ Defence publications /FTM/ ASTM/J SS etc. & other QMS requirements of DGAQA.
- 1.3. All other charges including the Annual recognition fee/ Membership fee/ Approval fee as applicable shall be payable to DGAQA and shall be in accordance with SOP for Approval of testing labs issued by DGAQA vide document No. 01/2019 issue No. 001, dated 19/06/2019 as amended from time to time.
- 1.4. Laboratory seeking approval from DGAQA with NABL accreditation through integrated assessment approach, shall apply to NABL Office in the prescribed application form (NABL 233) for all the parameters under product group as specified by DGAQA vide para No.3 of DGAQA approval SOP No. 01/2019 issue No. 001 dated 19/06/2019 along with a copy of its Quality manual/ Management System document, enclosures, and application fee, as prescribed from time to time.
- 1.5. On receipt of the application, laboratory Quality Manual/ Management System document along with the fee details and other requisite enclosures, NABL will scrutinize the same for its completeness as well as adequacy of facilities with regard to list of equipment and details of personnel to meet the basic requirements, with the applied scope of interest to NABL, DGAQA for accreditation/ approval. NABL shall intimate DGAQA whenever application of testing laboratory is received for NABL accreditation as well as DGAQA approval for the testing of products under the purview of DGAQA.
- 1.6. The application shall be signed by the Chief Executive Officer (CEO) of the Laboratory or any person duly authorized for this purpose. The authorization shall be supported with the Board resolution or a letter, as applicable under Companies Act /Rules. The name and designation of the person signing the application must be recorded legibly in a space apart for the purpose in the application form.
- 1.7. NABL shall process the application for pre-assessment (which is optional) only after adjudging the suitability of management system by adequacy audit. Lead assessor shall be deputed to

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ascertain compliance to the documented Management System, equipment, facilities/ infrastructure & the requirements of DGAQA. Pre-assessment report will be shared by NABL to DGAQA after the completion of pre-assessment is completed.

- 1.8. The assessment team shall be nominated by NABL for on-site witness assessment of the laboratory pertaining to verification for the methods of testing. The team so nominated shall conduct assessment; follow up assessments, if needed as well as surveillance of the laboratory.
- 1.9. The composition of assessment team would be selected from NABL empanelled assessors/ experts, representative depending upon the scope from DGAQA for testing laboratories; the team shall be independent and impartial conforming to requirements of Accreditation/ Approval.
- 1.10. The constitution of assessment team may be shared with the DGAQA before approval to avoid potential conflict of interest.
- 1.11. The duration of assessment shall be normally of 2 days depending upon the scope applied.
- 1.12. The assessment team will be based on the scope applied. The assessment team will cover compliance to ISO/IEC 17025, NABL Policies and relevant additional requirement of DGAQA.
- 1.13. The integrated assessment conducted shall cover areas of the relevance to the scope of Accreditation / Approval of the laboratory. Assessment shall include verification of test facilities, accommodation and environment, examination of documents and records, competence of laboratory personnel in conducting laboratory analysis/ testing, performance in witness tests, documentary evidence of participation in Proficiency testing programs for relevant analytes and matrices and compliance to its plan for participation in such program & any additional requirements as stipulated by DGAQA.
- 1.14. The assessment team shall recommend for Accreditation / Approval of the laboratory for the specific scope in case there is no major or minor NC. The Lead assessor and the corresponding technical assessor shall duly sign on the recommended scope with appropriate recommendation.
- 1.15. In case of any NC, the assessment team may recommend for Accreditation / Approval of the laboratory subject to closure of those said NCs. No NC shall be closed at the time of assessment.
- 1.16. During the assessment if any observation/NCs raised by DGAQA officer which is beyond the scope of this document viz AFQMS audit of the laboratory shall be intimated to NABL for necessary corrective action on application or accreditation status of the lab as applicable.
- 1.17. The laboratory shall take necessary corrective actions within the stipulated time period of not more than 30 days for the closure of NCs, brought out on record by the assessment team.

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The minor NC closure may not require on-site verification; however, closure of major NC may require on-site verification by assessment team.

- 1.18. The follow up visit, for full or partial assessment, may be carried out on request. Laboratory shall bear the applicable assessment charges and make arrangements of accommodation and travel for the assessment team. During the verification assessment, if the implementation of the corrective action is not found satisfactory, then the laboratory shall not be recommended for Accreditation / Approval and the laboratory shall have to apply afresh after taking satisfactory corrective action.
- 1.19. In case of Non-closure of the non-conformities within stipulated time period, action shall be taken as per NABL 216. Any additional action by DGAQA if required will be as per the Airworthiness governing document/DGAQA approved document/AQA directives.
- 1.20. On receipt of corrective action report, NABL shall review the actions taken along with the objective evidence that the actions taken are sufficient and effective and obtain comments of the team members regarding the closure of non-Conformities. If the actions taken by the laboratory are insufficient, further information shall be sought.
- 1.21. A representative from DGAQA will be the part of the accreditation committee or the assessment report will be shared for comments with DGAQA prior to decision making.
- 1.22. After approval from the CEO, NABL, Accreditation certificate with the scope of accreditation shall be issued by NABL. The Accreditation Certificate and scope of Approval shall be issued by NABL along with name & logo of DGAQA
- 1.23. The Accreditation / Approval granted shall be valid for a period of four years from the date of approval and it shall be renewable after four years at a time. Validity of the laboratory Accreditation / Approval shall be specified on the Approval/Accreditation certificate.
- 1.24. During the validity of approval, if the laboratory is found violating the terms and conditions of approval, its approval is liable to be suspended and may call for verification visits, for which the laboratory is liable to pay visit charges.
- 1.25. The accredited/ approved laboratory shall be subject to on-site surveillance once in a year jointly by NABL & DGAQA to verify the continued compliance, competency and the implementation of quality system established by the laboratory. The on-site surveillance assessment will be less comprehensive than reassessment.
- 1.26. Any Accredited/Approved laboratory automatically expires at the end of the period of its Accreditation / Approval. The Lab shall apply to NABL at least three months before the date of expiry of its Accreditation / Approval.
- 1.27. The approved laboratory can request NABL for extension of its scope of approval to cover additional product and parameter/ personnel responsible for authorizing the results. The Laboratory shall apply in the prescribed format by filling in the relevant information applicable for the extension of the scope along with supporting documents and application.

- 1.28. For qualification & experience requirements for personnel responsible for authorizing the results, please refer Appendix A of this document.
- 1.29. If approval by DGAQA is denied for a particular product group, the laboratory shall apply afresh for the complete set of parameters by submitting the applicable fee as defined in NABL 100A.
- 1.30. All the test reports issued by the laboratory for the scope under Integrated Assessment shall bear NABL symbol in line with NABL 133 'Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark' and DGAQA logo

*Note: In addition to the above-mentioned procedure & requirements, other NABL requirements as defined in relevant NABL documents such as NABL 131, 132, 133, 134, 142 & 216, shall also be applicable.*

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## 2. Additional Requirements of Directorate General of Aeronautical Quality assurance (DGAQA)

- 2.1. This clause describes specific requirements of Directorate General of Aeronautical Quality assurance (DGAQA) which, a testing laboratory has to comply in conjunction with the requirements of ISO/IEC 17025.
- 2.2. The laboratories seeking approval shall have implemented and maintained laboratory management system in accordance with ISO/IEC 17025; 'General requirements for competence of testing and Calibration Laboratories' and adequate capability and competence for testing of aviation products as per the requirements of DGAQA. The approval for the scope of interest to DGAQA is granted, provided, it is adjudged for its capabilities and competency as per the requirements and notifications issued from time to time.
- 2.3. The application for approval shall be considered based on the testing requirement, which DGAQA is looking for. NABL/ DGAQA concerned reserves the right to reject an application for one or more of the following reasons:
- The Laboratory is seeking approval for the scope, which is not the need of DGAQA at that time.
  - The Laboratory does not have adequate facilities for the scope for approval and adequate audit fee, as applicable has not been submitted.
  - The laboratory is subcontracting any test under the scope for approval (except for unforeseen situation). Sub-contracting is permitted to another DGAQA approved laboratory with valid scope of approval only in case of failure of instrument. Subcontracting is not permitted from the laboratory, which is not approved by DGAQA.
  - Any other reason as deemed fit by NABL/ DGAQA, informing the reason.
  - The approved laboratory shall participate in the Proficiency Testing Programmes conducted by PT Providers accredited as per ISO/IEC 17043 by NABL.
- 2.4. The approved laboratory can request NABL for approval of additional personnel responsible for authorizing the results.
- 2.5. Based on the finding of the verification assessment, NABL along with DGAQA shall take appropriate action including suspension / withdrawal of accreditation/approval of the laboratory as per NABL 216 document.
- 2.6. The approved laboratory shall not make any change in the Quality Management System, which forms the basis for the grant of the approval and which prevents its compliance to the Scheme without prior approval of DGAQA.
- 2.7. Any change in key personnel in relation to quality assurance, key technical functions (including personnel responsible for authorizing the results) or senior management shall be duly intimated to NABL/DGAQA within a period of 15 days.
- 2.8. The approved laboratory shall inform NABL/DGAQA, immediately about the major changes/breakdown of equipment with reasons thereof etc. effecting testing of the relevant

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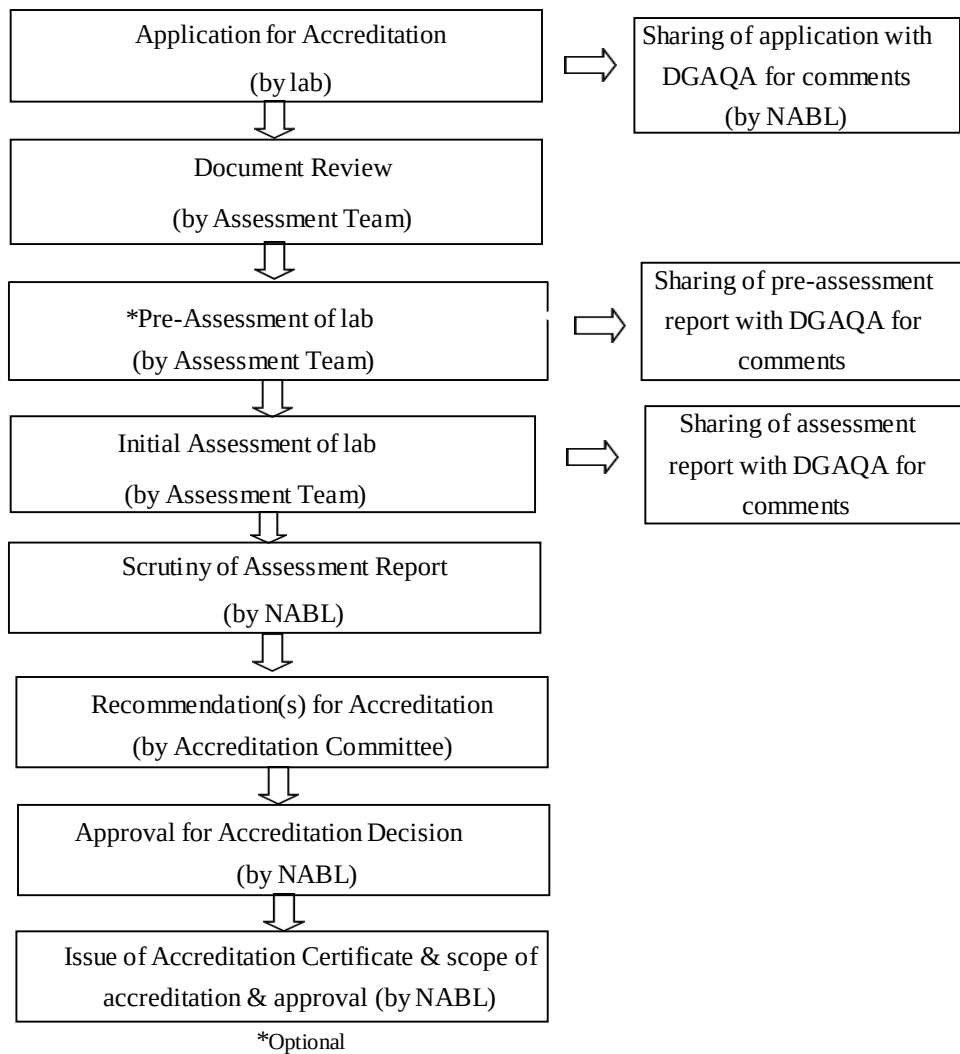
products/compliance to this scheme. The laboratory shall not accept any sample for testing, when there is breakdown of the equipment to be required for performing the test(s). The laboratory shall not accept any sample for testing, without prior approval of DGAQA, when there is major change in the Management System, which may affect performance of the testing.

- 2.9. Samples sent by DGAQA or manufacturer for the purpose of monitoring shall always be accompanied by a test request specifying the parameter, specification and purpose. Samples shall not be accepted by them if they are not accompanied by such test requests.
- 2.10. The laboratory is liable to maintain confidentiality of samples and information thereof.
- 2.11. The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by DGAQA.
- 2.12. The laboratory shall retain the remnants of the sample after testing for a minimum period of three months in stipulated storage conditions before they are disposed of or returned to the customer.
- 2.13. The laboratory shall maintain the record of observations, a copy of the test report and purchase documents for a minimum period of four years. Original data/records to establish audit trail/data integrity shall be maintained in the lab pertaining to each activity which affects the quality of test results.
- 2.14. The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of 7 days, excluding the time period for testing by the relevant specification.
- 2.15. The authorized signatory(ies) of the test report shall comply with the requirements of NABL/ DGAQA.
- 2.16. The approved laboratory shall participate in Proficiency Testing / Inter-Laboratory Test Comparison programmes organized by national and international bodies of repute for demonstrating technical competence of the laboratory personnel, at its own cost. The 2 years plan for participation in Proficiency testing programs pertaining to approved scope shall be submitted to DGAQA/NABL. The laboratory shall cover all the critical parameters in the relevant matrix within a period of 2 years. In case of, unsatisfactory result (Quantitative score  $Z > \pm 2$ ), the same shall be informed to DGAQA immediately with appropriate root cause analysis.
- 2.17. The approved laboratory shall permit access to DGAQA officer (s) / team (s) deputed for the purpose of any assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipment etc. for the purpose of verifying any details.
- 2.18. An approved testing laboratory shall not use its approval in such a manner as to bring DGAQA/ Government of India into disrepute/ dispute and shall not make any statement relevant to its approval, which DGAQA may consider to be misleading.

- 2.19. A laboratory may relinquish approval by giving three months notice in writing to both NABL and DGAQA. It shall however complete testing of all samples pending with it or return the samples pending along with the test requests.
- 2.20. NABL/DGAQA may, at its discretion, cancel or suspend approval, reduce its scope or direct re assessment due to change in personnel/ equipment, breakdown of equipment, and/ or if a complaint or any other information is received which indicates that the technical competence and integrity / confidentiality of the laboratory is not satisfactory.
- 2.21. An approved testing laboratory may make a public claim regarding its approval. However, such claim shall be strictly based on the scope of its approval. It shall discontinue claiming DGAQA approval and withdraw all promotional and advertising materials upon expiry / suspension or cancellation of its approval. Further, the approved laboratory shall not issue any test report under the purview of DGAQA.
- 2.22. The approved laboratory shall not handle any sample of the client for laboratory testing when the laboratory fails to demonstrate satisfactorily that its direct/indirect trade association has no consequence/ bearing on its test result
- 2.23. The approval of laboratories may also be suspended / cancelled any time during the approval period for any kind and or the reasons given below:
- i. If DGAQA feels that no useful purpose is being served by the continuation of the approval of the laboratory.
  - ii. If the laboratory is found violating the terms and conditions of the approval; and
  - iii. If the laboratory is unable to maintain the criteria for approval.
- 2.24. The Laboratory may apply afresh after three months from the date of cancellation / withdrawal / non-renewal of approval.
- 2.25. The laboratory shall return the pending sample (s) in appropriate conditions to the customer for onward transmission to another laboratory and undertake to retain records as per requirements stated above on cancellation/ withdrawal / non-renewal/ expiry of approval
- 2.26. Approval under the Scheme shall be accorded to a laboratory for single premise only where actual testing is carried out. If the laboratory carries out testing activities in more than one premise, separate approval for each premise will have to be obtained with a clear demarcation of scope of approval.
- 2.27. No testing charges shall be applicable for the samples submitted by DGAQA, of verification due to complaints, if any.
- 2.28. For qualification & experience requirements for personnel responsible for authorizing the results, please refer Appendix A of this document.
- 2.29. It is mandatory for an approved laboratory to apply for renewal at least three months before the expiry of the approval.

- 2.30. To avoid the possibility of approval of a testing laboratory for a particular discipline for which it might have been rejected for approval by any other authority, it will be incumbent on the part of testing laboratory to furnish all information regarding previous assessment results. Failing to do which (For such serious acts of omission and commission), the testing laboratory will not be considered for approval for a period of three years.
- 2.31. Compendium of Approved Test Laboratories updated on quarterly basis shall be made available on DGAQA website.
- 2.32. The name of the testing laboratory will be removed from the Compendium of Approved testing laboratories by DGAQA if a testing laboratory no longer has the required competence.
- 2.33. Effect of Removal from the List: Whenever a lab is removed from the list of approved testing laboratory its approval stands cancelled. Such removal must be communicated to all the QA agencies and concerned stakeholders.
- 3. The applicable disciplines of testing laboratory under this scheme are as follows:**
- i. Chemical
  - ii. Mechanical (including Metallurgical)
  - iii. Electrical
  - iv. Electronics
  - v. Non-destructive testing

#### 4. Process of accreditation / Approval:



**Flow Diagram of Accreditation/Approval Process**

**Qualification & Experience Requirements for personnel responsible to authorize results**

| S. No | Minimum Qualifications                                                                                                                             | Minimum Years of Relevant hands-on Experience |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 1.    | Bachelor degree in Engg / Technology or Post Graduate in Science in the same field of testing / calibration                                        | Two Years' experience                         |
| 2.    | Bachelor degree in Engg / Technology or Post Graduate in Science in the Similar* field of testing / calibration                                    | Three Years' experience                       |
| 3.    | Diploma in Engg. / Technology or Graduate in Science in the same field of testing / calibration                                                    | Three Years' experience                       |
| 4.    | Diploma in Engg. / Technology or Graduate in Science in the Similar* field of testing / calibration                                                | Five Years' experience                        |
| 5.    | ITI / Equivalent                                                                                                                                   | Ten Years' experience.                        |
| 6.    | Irrespective of the qualifications and experience, personnel accepted by the regulator, shall be considered eligible for those testing activities. |                                               |

Note -

(a) *\*Similar field may be considered when that particular subject is covered in the said qualification.*

(b) *Qualification with specialized field like food, pharma, civil etc. shall be considered eligible for groups falling under more than one discipline of testing / calibration;*

(c) *In each case, merely requisite qualifications and experience is not sufficient to become the personnel responsible to authorize results; the technical competence shall be verified by NABL assessment team before recommending as personnel responsible to authorize results.*

**Assessment Checklist for additional requirements of DGAQA as per NABL 234***(To be filled by Associate Technical Expert)*

|                         |  |
|-------------------------|--|
| Name of the laboratory: |  |
| Name of the ATE:        |  |
| Date of the assessment: |  |

| Sl. | NABL 234,<br>Cl. No. | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Compliance/<br>Non-<br>compliance<br>(C/NC) | Remark<br>(Statement of<br>Compliance/<br>Non-compliance) |
|-----|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------------------------------------------|
| 1   | 2.7                  | Any change in key personnel in relation to quality assurance, key technical functions (including personnel responsible for authorizing the results) or senior management shall be duly intimated to NABL/DGAQA within a period of 15 days.                                                                                                                                                                                                                                                                                                         |                                             |                                                           |
| 2   | 2.8                  | The approved laboratory shall inform NABL/DGAQA, immediately about the major changes/breakdown of equipment with reasons thereof etc. effecting testing of the relevant products/compliance to this scheme. The laboratory shall not accept any sample for testing, when there is breakdown of the equipment to be required for performing the test(s). The laboratory shall not accept any sample for testing, without prior approval of DGAQA, when there is major change in the Management System, which may affect performance of the testing. |                                             |                                                           |
| 3   | 2.9                  | Samples sent by DGAQA or manufacturer for the purpose of monitoring shall always be accompanied by a test request specifying the parameter, specification and purpose. Samples shall be not be accepted by them if they are not accompanied by such test requests.                                                                                                                                                                                                                                                                                 |                                             |                                                           |
| 4   | 2.11                 | The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by DGAQA.                                                                                                                                                                                                                                                                                                                                                                                                                       |                                             |                                                           |

|   |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |  |
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| 5 | 2.12 | The laboratory shall retain the remnants of the sample after testing for a minimum period of three months in stipulated storage conditions before they are disposed of or returned to the customer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |  |
| 6 | 2.13 | The laboratory shall maintain the record of observations, a copy of the test report and purchase documents for a minimum period of four years. Original data/records to establish audit trail/data integrity shall be maintained in the lab pertaining to each activity which affects the quality of test results.                                                                                                                                                                                                                                                                                                                                                                                   |  |  |
| 7 | 2.14 | The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of 7 days, excluding the time period for testing by the relevant specification.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |  |
| 8 | 2.15 | The authorized signatory(ies) of the test report shall comply with the requirements of NABL/ DGAQA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |  |
| 9 | 2.16 | <p>The laboratory shall participate in Proficiency Testing / Inter-Laboratory Test Comparison programs organized by national and international bodies of repute for demonstrating technical competence of the laboratory personnel, at its own cost.</p> <p>The 2 years plan for participation in Proficiency testing programs pertaining to approved scope shall be submitted to DGAQA/NABL.</p> <p>The laboratory shall cover all the critical parameters in the relevant matrix within a period of 2 years. In case of, unsatisfactory result (Quantitative score <math>Z &gt; \pm 2</math>) is scored, the same shall be informed to DGAQA immediately with appropriate root cause analysis.</p> |  |  |

|    |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |  |
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| 10 | 2.21 | <p>An approved testing laboratory may make a public claim regarding its approval. However, such claim shall be strictly based on the scope of its approval. It shall discontinue claiming DGAQA approval and withdraw all promotional and advertising materials upon expiry / suspension or cancellation of its approval. Further, the approved laboratory shall not issue any test report under the purview of DGAQA.</p> <p>(Assessment team to verify if any instance of expiry/suspension or cancellation of DGAQA approval previously &amp; claim of DGAQA approval and issue of test report under the purview of DGAQA during that period).</p> |  |  |
|----|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|

|                                                 |
|-------------------------------------------------|
| Other Observation(s) during assessment (If Any) |
|                                                 |

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