

<u>Product Approval Work Instructions</u>	Work Instruction No.: PAD 12.19
<u>01/11/2025</u> (09--04-2026)	Work Instruction: Internal Audits

Change follow up

Revision	Date	Changes

1. General

1.1 Scope

- 1.1.1 This procedure specifies the method for carrying out internal audits and follow-up of the corrective actions taken consequently, in the Product Approval Directorate (PAD).

1.2 Objectives

- 1.2.1 To verify that Internal Audits are carried out efficiently and effectively and encompass activities of PAD in accordance with the requirements of ISO/IEC 17065 and ISO/IEC 17020/17025, PAD Procedures and with instructions applicable to PAD.

1.3 Applicability

- 1.3.1 The procedure applies to all personnel of PAD.

2. Applicable documents

2.1 Documents mentioned in this work instruction

- 2.1.1 ISO/IEC 17065- Conformity assessment—Requirements for bodies certifying products, processes and services
- 2.1.2 ISO/IEC 17020- Conformity assessment—Requirements for the operation of various types of bodies performing inspection
- 2.1.3 Work Instruction PAD 12.16 Personnel Competencies

3. Appendices and forms

- 3.1 None.



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<u>01/11/2025</u> (09--04-2026)	Work Instruction: Internal Audits

4. Definitions and terms

- 4.1 **Internal Auditor**- A senior auditor who was authorized for his position by the Head of the Product Approval Directorate and holds the competencies described in PAD 12.16

5. Details and instructions

- 5.1 Internal audits shall be carried out in accordance with the annual audit plan and applicable standards.

5.2 Planning internal audits

- 5.2.1 In the course of the last quarter of each year, the PAD Manager shall prepare a plan of internal audits in the PAD Directorate, covering the following year. The plan shall include, at the least, an annual review of implementation of all requirements defined in ISO/IEC 17065 and ISO/IEC 17020 and, at the least, a biannual review of all PAD procedures.
- 5.2.2 If necessary, the plan may be updated during the year, for instance, should additionally audits or additional activities be required, or if the subject of a certain audit has become irrelevant. The update will be approved and signed by the Head of PAD. Records of the decisions pertaining to the frequency of conducting audits shall be maintained by PAD.
- 5.2.3 Where an external auditor, either from the Institution or from other organizations is assigned to perform internal audits, his background and experience in performing internal or external audits or in implementation and maintenance of Quality Systems shall be reviewed. Evidence of such experience shall be documented and retained in personal files, by the Quality Manager.

5.3 Audit Performance

- 5.3.1 The PAD Internal Auditor shall be independent of the audited activities.
- 5.3.2 The auditor shall verify that the various PAD activities are carried out in accordance with the applicable procedures and standards
- 5.3.3 During the Audit the Auditor may present questions to PAD personnel in respect to the subjects audited, the auditor will check documents, and will conduct any other check required to ensure that the work is done according to the procedures.
- 5.3.4 All of the PAD employees shall cooperate with the auditor, answer his questions, provide him with all of the relevant information and documents and enable him to carry out his mission.



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<u>01/11/2025</u> (09--04-2026)	Work Instruction: Internal Audits

5.3.5 The Internal audit reports shall be submitted to the Quality Manager and the Head of PAD. The internal audit reports shall point out both positive and negative findings objectively. If corrective action is required, details of this action shall be outlined in the appropriate paragraph in the audit summary.

5.3.6 The audit findings shall be submitted to the Head of PAD, who shall direct the relevant findings to the person responsible for the audited activity.

5.4 Follow-up and Corrective Actions

5.4.1 The Quality Manager shall prepare a corrective action plan, in accordance with the audit reports and nonconformities found, including a root cause analysis, the name of the person in charge of each action's execution, a method for follow-up of the activities and a schedule.

5.4.2 The corrective action plan will be sent for approval to the internal auditor. Where necessary a follow-up audit will be performed for checking the corrective actions.

5.4.3 The Quality Manager shall follow up implementation and the effectiveness of the required corrective actions. (Within the framework of periodical or special audits).

5.4.4 Audit results shall be used as an input to PAD's Management Reviews.