FACTORY AUDIT

FOR PRODUCT CERTIFICATION

(ISO / IEC 17065:2012)

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1. PURPOSE

The purpose of this procedure is to describe a procedure for factory audit planning, conducting the factory audit at client premises, preparation of reports and submitting the reports.

2. SCOPE

This procedure is applicable to plan and execute factory audit, to applicable scheme, for which Verger Group certifications.

3. TERMS AND DEFINITIONS

All applicable as defined in clause 3 of Quality manual (QM-01).

4. PROCEDURE

4.1 GENERAL

The purposes of the factory audits are to provide reasonable assurance that the Client's product conforms to the requirements of scheme applied, as stated in the Certification Contract, and to verify that the control has been implemented.

The factory may inter alia cover:

a) Capability, capacity, experience, and organization structure of the manufacturer.
b) The qualification and experience of the production and QA/QC personnel.
c) Manufacturing facilities.
d) The system of checking raw materials.
e) Quality control operations during manufacture and on the finished products.
f) Packing, identification and labelling.
g) Storage facilities
h) Record keeping and traceability.

4.2 PRE-AUDITING PROCESS

4.2.1 Selection of subcontractor: Audit and Inspection Supervisor/ Coordinator is responsible for selection of the subcontractor from the list of approved outsourced service providers VG-F-43. All the accreditation certificates of sub-contractor need to be verified.

4.2.2 Audit Plan: Audit and Inspection Supervisor/ Coordinator prepares the detailed audit plan (Reference No: VG-F-49) based on requirement of particular scheme with required number of man day calculated as per man day calculation sheet (Reference No: VG-F-50 as describe in table no – 01). The plan addresses the on-site off-site activities to be performed A complete set of updated documents pertaining to evaluation like client profile, test reports, quality documents and prior factory audit report with previous comments if any as applicable are provided to auditing team.

On receiving the plan from the Audit and Inspection Supervisor/ Coordinator, auditor personnel discuss the logistics and plan with client in case of onsite visit. Qualification record of the auditor for the required scope sector as per sub-contractor unit needs to be verified. Audit and Inspection Supervisor/ Coordinator prepares the specific activity plan and intimates the client normally 3 days to one week before the planned date and the same is agreed upon prior to the activity.

4.2.3 Man-days Calculation: A man-day calculation sheet (Reference No: VG-F-50) will be provided to auditor. The same will be reviewed and approved by auditor to conduct factory audit as per audit plan.
Calculation is prepared to cover the requirement of factory assessment of quality assurance for production processes as per SASO technical regulations and IAF MD 5 is considered for the same.

Table No – 01 (Man Day Calculation)

Sr. No	Description	Quantity	Weightage	Effective Man Day
1	Number of employees	(A)	0.5	(A)X Weightage
2	Number Operations - Production processes	(B)	0.2	(B)X Weightage
3	Number of sites	(C)	0.2	(C)X Weightage
4	Products under scope	(D)	0.1	(D)X Weightage
TOTAL MANDAYS CALCULATED				(N)

4.2.4 Auditor Evaluation: Based on plan, the evaluation activities are assigned to personnel by nominating with same plan. The outsourced activities shall be carried out by approved subcontractor through personnel nominated for communication and overseeing the activities. Nominated auditor will be evaluated by CB and recorded on VG-F-53 Auditor Evaluation Form.

Unless required for technical reasons and logistics, care shall be taken to ensure that same auditor does not visit the client more than three consecutive visits. This shall ensure “no bias”. The auditor/subcontractors are responsible for identifying any conflict of interest with the specified client and report to Audit and Inspection Supervisor/ Coordinator. Audit and Inspection Supervisor/ Technical Manager shall review the same and take necessary decision which may include replacing the person with some other approved evaluator by CB.

4.3 AUDITING PROCESS

The audit shall be resulted in to reporting the compliance and non-compliances and where one or more nonconformities have arisen. The client shall submit the evidence of corrective actions taken within given time frame based on scheme requirements. Failure to satisfactory closure shall result in complete re-evaluation or suspension or withdrawal of certificate.

In case of any changes required by the client the same is captured as part of the Incident

Report and necessary actions taken and the audit plan developed by Audit and Inspection Supervisor is amended accordingly. In case of any changes in the activity plan during the execution, the same is captured as part of the evaluation report/ documents.

Upon completion of each activity, the outcome is kept in records in VG-F-46 as reports, evidence, certificates etc. Specific activities shall be completed as per overall audit plan, and it shall be ensured that the products are evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

Non-conformances are raised after proper investigation against a product specification found non-compliant. The observations are issued identifying areas of improvement only. The caution will be observed in recording the observations so that the issues pertaining to non-conformance are not reflected as observations and vice versa. The recording of observations will be strictly confined to areas of improvement only. All records shall be properly documented prior to submitting for review.

SASO Factory Audit Remote Procedure

1. Pre-Audit Preparation

1. **Define Audit Scope and Objectives**
    - Establish the scope (product category, manufacturing processes, and compliance requirements).
    - Identify the objectives, such as SASO compliance, quality assurance, and supply chain verification.
2. **Technology Setup**
    - Use secure video conferencing tools (e.g., Zoom, Microsoft Teams, or proprietary platforms with encryption).
    - Ensure internet reliability on both sides.
    - Identify virtual tour tools
3. **Document Collection**
    - Request documentation from the factory in advance:
        - ISO certifications, quality management system (QMS) records.
        - Bill of materials (BOM), production workflow diagrams.
        - Equipment calibration records, inspection logs.
        - Employee training records and safety compliance reports.
4. **Time Zone and Scheduling**
    - Coordinate with the factory to align schedules, considering time zones.
    - Reserve sufficient time for contingency if technical issues arise.
5. **Assign Responsibilities**
    - Nominate a factory representative as the primary point of contact.
    - Assign specific roles for the audit, such as camera operator and Q&A liaison.

2. Remote Audit Execution

1. **Opening Meeting**
    - Introduce all participants and clarify roles.
    - Confirm the objectives, scope, and schedule of the remote audit.
    - Discuss confidentiality and data protection measures.
2. **Virtual Facility Tour**
    - Conduct a live video walkthrough of:
        - Raw material storage and handling.
        - Production lines, assembly areas, and testing zones.
        - Packaging and labeling sections.
        - Final product storage and shipment areas.
    - Ensure the auditor/technical expert directs the camera operator and requests close-ups as necessary.
3. **Document Verification**
    - Share digital documents via a secure platform.
    - Verify quality control procedures, inspection reports, and compliance records in real-time.
    - Cross-check documents against live footage (e.g., matching production logs to observed operations).
4. **Interviews and Observations**
    - Conduct virtual interviews with key personnel, such as:
        - Quality control managers.
        - Line supervisors.
        - Maintenance engineers.
    - Observe employee practices and adherence to SOPs during live sessions.
5. **Testing and Sampling (if applicable)**
    - Supervise testing of products remotely using live video or recorded sessions.
    - Arrange for third-party sample collection and testing at an accredited lab.

3. Post-Audit Activities

1. **Closing Meeting**

- Summarize findings, including strengths, non-conformities, and areas for improvement.
- Discuss corrective actions and deadlines for implementation.
- Allow time for factory representatives to address concerns.
- Draft a comprehensive report with:
    - Observations and evidence (screenshots, video snippets).
    - Document reviews and interview outcomes.
    - Corrective actions and compliance recommendations.

- Include a risk analysis of remote auditing limitations and mitigation actions.
- Schedule a follow-up remote or onsite audit if required.
- Request evidence of corrective actions through photos, videos, or updated documents.

2. **Audit Report Preparation**
3. **Follow-Up Plan**

Risks and Mitigation Strategies

Risk	Potential Impact	Mitigation Strategy
Technical Issues (e.g., internet)	Disruption in audit process	Test connections in advance; have backup tools.
Data Manipulation	Misrepresentation of compliance	Request real-time footage, timestamps, and metadata verification.
Limited Observational Scope	Missed non-conformities	Use multiple cameras and request diverse angles.
Language Barriers	Miscommunication during interviews or tours	Arrange for interpreters or bilingual representatives.
Resistance from Factory Staff	Incomplete cooperation	Clearly communicate the purpose and importance of the audit.
Confidentiality Breaches	Data leaks	Use secure platforms and NDAs.

5. REFERENCES

- ISO/ IEC 17065:2012
- Quality manual VG-QM-01

6. RECORDS

6.1 VG-F-46 Factory Audit Report
6.2 VG-F-53 Auditor Evaluation Form
6.3 VG-F-49 Audit Plan
6.4 VG-F-50 Man-days calculation table

CHANGE HISTORY

ISSUE	CHAPTER	PAGE	CHANGE INTRODUCTION	REV NO.	EFFECTIVE DATE
01	/	/	First version	00	20/11/2020
01	/	/	Reformatted the whole document and amended the document control no. as per procedure.	01	04/02/2021
01	/	ALL	The evaluation term was replaced with audit to give more clarity	02	05/06/2021
01	4.2	3	Pre-audit process steps added	03	13/09/2021
01	4.3	4	Auditing process added	03	13/09/2021
01	6	5	Forms number added	03	13/09/2021
01	4.2	4	Man-Day calculation sheet is added with references	04	27/09/2021
01	4.2	3	Accreditation certificates	05	16/10/2021
01	4.2	4	Qualification record of auditor	05	16/10/2021
01	/	/	Reformatted document as Verger Group	06	21/07/2022
01	4.2.4	4	Due to amended in auditor's evaluation agreement	07	07/06/2023
01	/	/	Made required changes and added criteria for remote audit part	08	17/12/2024