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: QA Engineer 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: QA Engineer 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 QA Engineer, 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. Auditor 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 Rev 01) 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 F-16 Evaluator 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 QA Engineer. QA Engineer/ Technical Director 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 QA Engineer 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.

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-16 Evaluator 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