Procedure for Factory Audit

Contents

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Approved By Technical Manager

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 REPL provide certifications.

3. Responsibility

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

4. Terms and Definitions

5. 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: REPL is responsible for selection of the auditors from the list of approved auditors (MGT/L65/05/04). The entire competency requirement (Competency and authorization) should be done for all auditors before putting them in to the list.

4.2.2 Audit Plan: Auditor prepares the detailed audit plan (QCI/F65/02/01) based on requirement of particular scheme with required number of man day calculated as per man day calculation sheet (QCI/F65/02/02). 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, auditor 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 (QCI/F65/02/02) 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 Man-days 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 Auditor Evaluation Form (MGT/L65/05/06).

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 are responsible for identifying any conflict of interest with the specified client and report to Technical Manager. Technical Manager shall review the same and take necessary decision which may include replacing the person with some other approved auditor 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 auditor 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 such 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.

6. References

- ISO 17065:2012(E) Clause No: 7.1
- Quality Manual Section: 7.0

7. Records

Sr. No	Document Description	Document Number
1.	Audit Plan	QCI/F65/02/01
2.	Man-days Calculation Table	QCI/F65/02/02
3.	Factory Audit Report	QCI/F65/02/03
4.	Factory Audit Log Report	QCI/F65/02/04