AGSI Certification Pvt. Ltd.

208, Kartik Complex, New Link Road, Andheri (West), Mumbai 400 053

Department/ Function-wise
AUDIT CHECK-LIST (ISO 9001:2015)
For a Typical Manufacturing Company
(Guidance document)

(Note: Quality policy awareness, Quality objectives, Control of documented information, Communication, Continual improvement, Responsibility and authority, Competency may be audited at each of the following functions, as appropriate)

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Top Management:

Clauses applicable: 5.1, 5.1.2, 5.2, 5.3, 7.1.6, 9.3, 4.1, 4.2, 4.3. 4.4

Useful inputs:

- **Company website**
- **Company profile**
- **Organization scope**

Auditing:

- **What are the products? Who are the customers? What is the market scenario?**
- **What are turnover, sales or production figures during previous 3 years. Any increase or decrease; possible reasons**
- **What are the strengths and weaknesses (e.g. SWOT), relevant external and internal issues**
- **Who are the interested parties and what are their requirements?**
- **Any risks and opportunities identified based on outcome of SWOT analysis or interested parties' requirements?**
- **What actions are taken to address risks and opportunities?**
  Has the effectiveness of the actions taken to address risks and opportunities evaluated?
- **Is the quality policy established and communicated within the organization?**
- **Are the quality objectives (measurable) set at corporate level and at all relevant functions**
- **What are the continual improvement plans**
- **How is it ensured that the organization is safeguarded from loss of knowledge e.g. through staff turnover or failure to capture or share information**
- **Any other relevant issues**

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Marketing:

Clauses applicable: 5.1.2, 8.1.2, 8.2.1, 8.2.2, 8.2.3, 8.2.4, 9.1.2

Useful inputs:

- **Customer list**
- **Product list**
- **Company web-site**
- **Specifications**
- **Customer POs (Purchase orders)**
- **Customer feedback and complaints**
- **Customer communication – enquiries, letters, mails**

Auditing:

1. **Verify customer PO/s**

   - **Does the PO have all relevant details?**
     - customer name, address, P.O. number, Date, etc.
     - product characteristics or reference to drawings, specifications, brochures, ..
     - delivery requirements
     - post-delivery requirements, if any.

     - **If the customer has not provided a documented statement of their requirements, have the customer's requirements confirmed by the organization before acceptance?**

2. **Did the organization review the customer contract before committing to supply products to the customer?**

3. **Has the organization retained the documented information, as applicable, on:**
   - the results of review?
   - any new requirements for the products?

4. **Has the organization considered any applicable statutory and regulatory requirements for the product or those considered necessary by the organization?**
5. **Has the organization considered the requirements not stated by the customer, but necessary for the specified or intended use, when known?**
6. **Are the contracts or order requirements differ from those previously expressed? If yes, have these differences resolved?**
7. **Are there any post-delivery activities associated with the products? E.g. warranty provisions, contractual obligations such as maintenance services, and supplementary services like recycling or final disposal**
8. **If the requirements of products are changed,**
   - are the relevant documented information amended?
   - are relevant persons made aware of the changed requirements?
9. **If a nonconforming product is supplied to a customer, has the organization informed the customer?**
10. **Has the organization monitored and reviewed customers' perceptions (customer feedback) and customer complaints? Has the organization evaluated degree of customer satisfaction?**

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Purchasing:

Clauses applicable: 8.4

Useful inputs:

- **Approved suppliers' list**
- **Supplier evaluation/ re-evaluation criteria**
- **Supplier evaluation/ re-evaluation records**
- **List of items purchased**
- **Purchase orders**

Auditing:

Verify the criteria for evaluation/ re-evaluation of suppliers
Verify if the suppliers are evaluated/ re-evaluated as per the set criteria?
Verify if there is an approved supplier list prepared?

Verify the Purchase Order/s

1. **Does the Purchase Order have all the relevant details:**
    - **P.O. number, Date; Name, address, contact details of the supplier**
    - **Is the supplier is in the approved supplier list**
    - **Name, quantity, packaging and delivery requirements**
    - **Characteristics of the product requisitioned or reference to specifications/ drawings,**
    - **Are the Purchase Orders signed or authenticated by authorized personnel**
    - **Any product related statutory requirements**
2. **Verify if the product received:**
    - **Has been tested/ inspected and accepted by QC**
    - **If the acceptance is based on the "Test Certificate" received from the supplier, then was it reviewed/ approved by the authorized personnel**
      If the product received is non-conforming, what actions were taken? ***Back..***

<u>Outsourced Processes</u>:

Clauses applicable: 8.4.1, 8.4.2, 8.4.3

Useful inputs:

- **Process flowchart**

Auditing:

Are any of the processes or part a process, is provided by an external provider as a result of a decision by the organization?
If yes,

1. **Verify the controls exercised on these outsourced processes?**
    - **Through incoming goods inspection – check inspection reports**
    - **Surveillance of the outsourced service provider – check surveillance reports**
    - **Reviewing the test certificates or certificates of analysis – check certificates**
    - **Second party audits – check audit reports**
    - **Any other method – specify**

2. **Verify if the organization communicated to the external provider the requirements and controls it needs for externally provided processes, services or products (e.g. through purchase order)**
3. **Verify if purchasing information provides details related to any methods, processes, and equipment that should be used e.g. certain welding techniques, or use of specific calibrated equipment, packaging, labelling, etc.**

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Design and Development:

Clauses applicable: 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6

Useful inputs:

- **Process flowchart**
- **Specifications**
- **Statutory & regulatory requirements for the product**
- **Customer purchase orders (POs)**
- **Organization Chart**

Auditing:

1. **Has the organization claimed and justified that Clause 8.3 (fully or partly) not applicable?**
   If yes, verify:

   i. **Does the organization do any design work?**
   ii. **Is the organization responsible for defining the characteristics of the product?**
   iii. **Does the organization strictly work from the designs given by their customers?**
   Example: A machine shop only takes the drawings and CAD programming files from customers, and uses these to machine the parts on the CNC machines? In doing so, the customer is in charge of the design and design changes, and for the machine shop these requirements are not applicable.
   iv. **If an organization claims that D&D is not applicable merely because the product is made as per product statutory requirements e.g. I.S. Standard,**
   verify if all the product characteristics are defined in the product standard.
   v. **If an organization claims that the D&D is not applicable, since it has a long established and well validated product design, such that they are adequate for the subsequent production,**
   verify if it still needs to ensure that any design changes are managed in accordance with clause 8.3.6, then D&D would be partially applicable.

2. <u>Design & development planning (Clause 8.3.2)</u>

Verify if the organization determined the stages and controls for D&D.

Has the organization considered:

- **Nature, duration and complexity of D&D activities?**
- **Required process stages (including D&D reviews)?**
- **Required D&D verification and validation activities?**
- **Responsibilities and authorities involved in the D&D process?**
- **Internal and external resource needs?**
- **Need to control interfaces between persons involved in D&D process?**
- **Need for involvement of customers and users?**
- **Requirement for subsequent provision for products?**
- **Level of control expected for D&D process by customers and other relevant interested parties?**
- **Has the documented information needed to demonstrate that D&D requirements have been met?**

3. <u>Design & development inputs (Clause 8.3.3)</u>

Verify if the organization has retained documented information (records) on D&D inputs.

Has the organization considered:

- **Functional and performance requirements**
- **Information derived from previous similar D&D activities**
- **Statutory and regulatory requirements**
- **Standards or codes of practice that the organization has committed to implement**
- **Potential consequences of failure due to nature of products or services**

Are the inputs adequate for D&D purposes, complete and unambiguous

Are conflicting D&D inputs, if any, resolved?

4. **Design & development controls (Clause 8.3.4)**

   Verify if the organization has retained documented information (records) on D&D controls.

   Verify if these controls ensure:
   - **The results to be achieved are defined?**
   - **Review are conducted to evaluate the ability of the results of D&D to meet the requirements**
   - **Verification activities are conducted to ensure that D&D outputs meet the input requirements**
   - **Validation activities are conducted to ensure that resulting products and services meet the requirements for the specified application or intended use**
   - **Any necessary actions are taken on problems determined during the reviews, or verification and validation activities**

5. **Design & development outputs (Clause 8.3.5)**

   Verify if the organization has retained documented information (records) on D&D outputs.

   Verify if these outputs ensure that:
   - **Input requirements are met**
   - **Are adequate for subsequent processes for provision of products and services**
   - **Monitoring and measuring requirements, as appropriate, and acceptance criteria are included or referenced**
   - **Characteristics of the products and services that are essential for their intended purpose and their safe and proper provision**

6. **Design & development changes (Clause 8.3.6)**

   Verify if the organization has retained documented information (records) on D&D changes.

   Verify if these include:
   - **D&D changes**
   - **The results of reviews**
   - **The authorization of the changes**
   - **The actions taken to prevent adverse impacts**

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Production:

Clauses applicable: 8.5.1, 8.5.2, 8.5.3, 8.5.4, 8.5.6, 8.7

Useful inputs:

- **Process flow charts**
- **Machinery list**
- **Monitoring and measurement equipment list**
- **Calibration records**
- **Production plans (say, monthly)**
- **Production schedules (say, daily)**
- **Production records**
- **Preventive maintenance records**
- **Machinery downtime records**
- **Work instructions (WIs); Standard Operating Conditions (SOCs) ; Daily logs**

Auditing:

1. **Verify compliance – Production plan/ schedule: planned vs. actual**
2. **Verify compliance – Preventive maintenance: planned vs. actual**
3. **Verify down time records**
4. **Verify Monitoring/ measurement equipment list and calibration records**
5. **Verify WIs, SOCs and daily logs**
6. **Witness production activities. Verify the operating conditions: Standard vs. actual**
7. **Interview the production personnel – supervisors/ operators**
8. **Verify the competence requirements as applicable, e.g. welder qualification**
9. **Observe general housekeeping, work culture, use of PPEs (Safety goggles, gloves, shoes, helmets, ear-plugs, etc.)**
10. **Verify how the nonconforming products are controlled?**
    Are records maintained on a) details of nonconformity, b) actions taken , c) concessions obtained.
    Who is authorized to decide on the action in respect of nonconformity? Verify evidence.

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Quality Control:

Clauses applicable: 8.5

Useful inputs:

- **Specifications/ acceptance criteria**
- **Quality plan for testing**
- **Sampling methods**
- **Incoming materials tested**
- **In-process materials tested**
- **Finished products tested**
- **Test methods; Testing/ inspection equipment**
- **ASTM, IS Standards, if applicable**

Auditing:

1. **What tests/ inspections carried out for incoming materials?**
2. **What tests/ inspections carried out for in-process materials?**
3. **What tests/ inspections carried out for finished products?**
4. **Are the test procedures documented?**
5. **Are the acceptance criteria documented?**
6. **Are copies of any applicable Standards like ASTM, IS or MSDS available?**
7. **What are the testing/ inspection equipment available?**
8. **Verify if these testing/ inspection equipment calibrated? Verify the records of calibration.**
9. **Verify if any specific qualifications or approvals required for those performing the tests/ inspection?**
10. **Verify if any specific licenses are mandatory for installation and operation of any of the testing equipment?**
11. **Verify if any specific environmental conditions (eg. temperature, humidity, proper lighting) required for any of the tests/ inspections carried out?**
12. **Witness some of the tests/ inspections in process.**

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Human Resources:

Clauses applicable: 7.1.2, 7.2

Useful inputs:

- **Competence criteria requirement**
- **Individual Education, Training and Experience records**
- **Training needs identified**
- **Trainings conducted**
- **Organization chart**
- **Responsibilities and authorities**

Auditing:

1. **Verify the organization chart**
2. **Are the organizational roles, responsibilities and authorities assigned, communicated and understood within the organization**
3. **Verify the competence criteria requirement**
4. **Verify the individual records of qualification, experience and trainings**
5. **Verify Competence criteria vis-à-vis actual competence of the person(s) doing work under organization's control**
6. **Verify the training needs identification records**
7. **Verify the trainings given and evaluation records**
8. **Verify the actions taken, where applicable, to acquire necessary competence; Verify the effectiveness of the actions taken**
9. **Verify if the evidence of competence is retained as documented information**

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Stores:

Clauses applicable: 8.5.2, 8.5.3, 8.5.4, 8.7.1

Useful inputs:

- **Stock register**
- **Indent copies**
- **Issue slips**
- **MSDS (Material Safety Data Sheet)**

Auditing:

1. **Is the stock register maintained?**
2. **Are all the materials stored uniquely identified?**
3. **Verify if the procedure for:**
   - **Handling**
   - **Contamination control**
   - **Packaging**
   - **Storage**
   - **Transmission or transportation, and**
   - **Protection**

   ensure preservation of the material to the extent necessary to maintain conformity to the requirements
4. **Are the weighing scales calibrated? Records available?**
5. **Is the status of the material stored identified to know, if it is:**
   - **To be tested**
   - **Tested and o.k**
   - **Nonconforming or Rejected**

   Are the areas segregated to ensure the above material will not get mixed-up?

Is the 'shelf-life', where applicable, of the various material known and ensured that the materials will not be issued after the expiry.

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Despatch:

Clauses applicable: 8.6, 8.7

Useful inputs:

- **Delivery challans**
- **Product test records/Test certificates**

Auditing:

1. **Verify the approved list of the person/s authorized to release the products.**
2. **Verify the approved document identifying the authority for deciding the action in respect of the nonconformity.**
3. **Verify the evidence that the products released conform to the acceptance criteria.**
   - Verify the dispatch documents, test records / test certificates.
4. **Verify if any of the nonconforming products are dispatched? If yes, check:**
   a. **If there is authorization to release this product under concession.**
   b. **If the customer is informed.**
5. **Verify if there are any special packaging requirements particularly in case of exports.**

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Internal audits and management reviews:

Clauses applicable: 9.2, 9.3

Useful inputs:

- **Internal audit plans, schedules, audit reports, non-compliances (NCs), Corrective actions records**
- **List of trained internal auditors and evidence of their training/ competence**
- **Management review agenda, circulars, attendance sheets and minutes of the meeting**

Auditing:

1. **Verify the internal audit plan**
   Verify if the internal audits carried out as per the plan.
2. **Verify the internal audit schedule**
   Verify if all the department/ functions, including the top management, were audited
3. **Verify who did the internal audit. Verify their competence/ training records**
4. **Verify the internal audit reports, NCs and observations, if any. Verify if the corrective actions were taken, where required, and effectiveness verified.**
5. **Verify if the management reviews were held at the planned frequency**
6. **Verify the circulars sent to participants in advance. Verify the agenda points. verify whether the agenda points covered all the requirements as per Clause 9.3.2 a) to f)**
7. **Verify the minutes of the management review meetings. Verify if the top management personnel were present for the meeting.**
8. **Verify if the management review outputs included decisions and actions related to:**
   a) opportunities for improvement
   b) any need for changes to the quality management system
   c) resource needs

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