**ISO 9001:2015 internal audit checklist for manufacturing companies**

Notes:

* More questions can be added or modified in this checklist according to specific activities conducted by the company. Often, these additional questions are related to documentation of the manufacturing process.
* This checklist is to be used for auditing the manufacturing process; however, this list does not represent a full checklist that covers all requirements of ISO 9001:2015. Other kinds of processes, such as management processes or support processes, normally follow a more comprehensive internal audit checklist that includes specific questions for each clause of ISO 9001:2015. See useful resources at the end of this document for more information about a complete internal audit checklist.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **ISO 9001 Clause** | **Audit Question** | **Compliant (Yes/No)** | **Audit Evidence** |
| 1 | 6.1 | Has the company determined the risks associated with its manufacturing process? |  |  |
| 2 | 6.1 | Is there any evidence of the effectiveness of the actions taken to address the risks in the production process? |  |  |
| 3 | 6.1 | Does the company identify and implement opportunities in the production process? |  |  |
| 4 | 7.1 | If there is a maintenance procedure for production equipment and tools, has it been followed? |  |  |
| 5 | 7.1 | Are there any records for the maintenance of the production equipment and production tools? |  |  |
| 6 | 7.1 | Are gauge calibrations up to date? |  |  |
| 7 | 7.1 | Are the work environment and equipment appropriate for the job, safe, and clean? |  |  |
| 8 | 7.2 | Has the worker been appropriately trained on the job conducted? Are there records for this training? |  |  |
| 9 | 7.2 | Are suitable methods used to verify training effectiveness for the employees involved in the manufacturing process? |  |  |
| 10 | 7.5 | Is the necessary documentation available and suitable for its use in production? This includes work instructions, job orders, checklists, visual cards, etc. |  |  |
| 11 | 7.5 | Have workers received the most recent version of that documentation (work instructions, job orders, checklists, visual cards, etc.)? |  |  |
| 12 | 7.5 | Are there records of the production process for every shift? Were these records properly completed? |  |  |
| 13 | 8.1 | Are production samples inspected and provided to customers if requested? |  |  |
| 14 | 8.1 | Are customer requirements and quality specifications reviewed? |  |  |
| 15 | 8.5 | Does the company provide appropriate work instructions where needed that describe the working methods during the production process? |  |  |
| 16 | 8.5 | Are the working methods conducted during the production process as per working instructions provided by the company? |  |  |
| 17 | 8.5 | Is the raw material used in the process appropriately identified and traceable (if required)? |  |  |
| 18 | 8.5 | Are there records necessary to enable traceability of the product (if required)? |  |  |
| 19 | 8.7 | Does the company have a corrective action system used to carry out root cause analysis and perform timely and effective actions? |  |  |
| 20 | 8.7 | Are nonconforming materials or parts segregated (where applicable) and properly identified during the production process? |  |  |
| 21 | 8.7 | If there is any procedure for nonconforming material or parts, is it being followed? |  |  |
| 22 | 8.7 | Does the organization confirm compliance with requirements when nonconforming materials or parts are corrected? |  |  |
| 23 | 8.7 | Are there records of the nonconforming material or parts and the actions taken? |  |  |
| 24 | 8.7 | Is there a system to notify customers of nonconforming product that has already been shipped? |  |  |
| 25 | 9.1 | Has the company established the monitoring, measuring, and reporting of the manufacturing process? |  |  |
| 26 | 9.1 | If there are quality objectives defined for productivity and effectiveness, are these included in the business plan and monitored for improvement? |  |  |
| 27 | 10.1 | Is there a formal approach in the production process to pursue improvement? |  |  |
| 28 | 10.1, 10.3 | If negative trends are shown in the evaluation charts or data analysis, has the company conducted any action for the continual improvement of the process? |  |  |

**The use of turtle diagrams for auditing manufacturing processes**

A turtle diagram can be used by an internal auditor to better understand the inputs and outputs of the process and related activities that will be audited.

This turtle diagram helps to guide the auditor by making the characteristics of the manufacturing process more visual, including process owners, procedures followed, controls and mechanisms in place, competence and training of the employees, as well as interactions with other processes.

In the diagram, inputs are usually the resources, such as human resources, money, or raw material, invested in the production process to generate outputs, that is, finished goods. For example, in a manufacturing company of beer, inputs include the money needed to buy materials and equipment, raw material such as yeast, hops, water, and malt, production equipment, and labor hours.

Below, you can find a regular turtle diagram for a manufacturing process.

**MANUFACTURING PROCESS**

**Equipment & Facilities**

**Employees**

**Process Control**

**INPUTS**

**OUTPUTS**

**Procedures & Work Instructions**

**Support Processes**

**Key Performance Indicators**

**USEFUL RESOURCES**

*Figure 1: Turtle diagram for a manufacturing company*

The following materials will help you with the ISO 9001:2015 internal audit:

* A “full” checklist that covers all processes and requirements of ISO 9001:2015: [Internal Audit Checklist](https://advisera.com/9001academy/documentation/internal-audit-checklist/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=paid-documents-9001)
* Template for the [Procedure for Internal Audit](https://advisera.com/9001academy/documentation/procedure-internal-audit/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=paid-documents-9001)
* [ISO 9001:2015 Internal Audit Toolkit Documentation Toolkit](https://advisera.com/9001academy/iso-9001-2015-internal-audit-toolkit/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=paid-toolkit-9001) – set of documents for conducting an internal audit
* [How to perform an ISO 9001:2015 internal audit](https://advisera.com/9001academy/webinar/how-to-perform-an-iso-9001-2015-internal-audit-free-webinar/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=free-webinars-9001) - free webinar that explains how to conduct an internal audit
* [ISO 9001:2015 Internal Auditor Course](https://training.advisera.com/course/iso-90012015-internal-auditor-course/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=online-training-9001) – free online training that prepares you for conducting an internal audit

Articles:

* [Five main steps in ISO 9001 internal audit](https://advisera.com/9001academy/knowledgebase/five-main-steps-in-iso-9001-internal-audit/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=free-knowledgebase-9001)
* [Writing a good QMS internal audit report](https://advisera.com/9001academy/blog/2015/03/17/writing-a-good-qms-internal-audit-report/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=free-blog-9001)
* [ISO 9001 – How to prepare for an internal audit](https://advisera.com/9001academy/blog/2017/09/26/iso-9001-how-to-prepare-for-an-internal-audit/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=free-blog-9001)
* [ISO 9001 audit checklist](https://advisera.com/9001academy/knowledgebase/iso-9001-audit-checklist/?utm_source=iso-9001-internal-audit-checklist-for-manufacturing-companies&utm_medium=downloaded-content&utm_content=lang-en&utm_campaign=free-knowledgebase-9001)

**About the author**

*Iciar Gallo has more than 10 years of experience in business consulting, training, and auditing, including a number of management systems such as ISO 14001 and ISO 9001. She has worked for several international companies and prestigious universities, leading projects in Spain, Panama, Venezuela, England, and more recently in the USA. She has also worked as a teacher of several courses on environmental standards and at AENOR and Advisera. Iciar holds a MSc degree in Environmental Management and Control from the Technical University of Madrid and is certified as an auditor of ISO 9001 and ISO 14001.*