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CONTINUOUS EMISSION MONITORING SYSTEMS AUDIT CHECKLIST

Contract: \_\_\_\_\_ Date: \_\_\_\_\_  
 Site: \_\_\_\_\_ Auditor: \_\_\_\_\_

Operation	Yes	No	Comments
<b>General Check Points</b>			
1. Qualified personnel?			
2. QAPP or work plan on site? Revision # _____			
3. Spare parts and support equipment available?			
4. Instrumentation and apparatus maintained in good condition?			
5. Adequate facilities?			
6. Instrument certification and/or calibration documentation available?			
7. Sample (and/or) properly located to obtain representative sample?			
8. Instrument logbook and maintenance record properly maintained (up-to-date, entries dated and initialed)?			
<b>Calibration Procedures</b>			
1. Calibration frequency appropriate?			
2. Multipoint calibration/linearity check performed regularly?			
3. Zero point included in calibration?			
4. Calibration gases of acceptable quality, analyzed within last 12 months?			
5. Adequate supply of calibration gases?			
6. Calibration gas mixture appropriate and PPE being sampled?			Dis
7. Appropriate record keeping procedures used for calibration documentation?			

Process audit checklist. Manufacturing process audit checklist template excel. Checklist for manufacturing process audit.

Objective performance evaluations are done by measuring actual performance against the standard set by manufacturing SOPs. If management and workers don't follow the same standard, expectations become unclear and evaluations may be influenced by personal biases. Manufacturing SOP Compliance Template | Example 1: Scope: - Where is the SOP to be used? SOPs should be continuously reviewed and updated, preferably every 6-12 months or as necessary. A manufacturing SOP commonly uses a step-by-step format, which is straightforward and easy to follow. Tablet Compression SOP Checklist | Example 2: Scope: - Where is the SOP to be used? Step 5: Review and update where necessary After writing your SOP document, review and test it with other team members before sending it to stakeholders for approval. It clarifies details such as limitations or exceptions of the SOP, and the people who will be engaging with it or will be impacted. Use iAuditor on your phone or tablet and do walkthrough site inspections to ensure that workers are complying with manufacturing SOPs. Take notes and assign necessary actions to address noncompliance. Once it gets approved, it will then be implemented and shared across relevant employees. Step 1: Determine the goal Writing your manufacturing SOP begins with thinking of what you want to accomplish. When internal audit can spend more of their time and resources aligned to their organization's key objectives, internal auditor job satisfaction will increase because they'll be taking on more interesting projects. With iAuditor, the world's #1 mobile inspection app, you can also: generate on-site reports; take photos of equipment, appliances, and areas for evidence; indicate corrective measures and set priority and due date; and save reports online and keep them safe in the cloud. In addition to identifying and testing control activities, internal audit should seek to identify and test the other components of a well controlled process. Review COSO's 2013 Internal Control components, principles, and points of focus here. 4. Initial Document Request List Requesting and obtaining documentation on how the process works is an obvious next step in preparing for an audit. Low productivity Manufacturing SOPs are designed to improve efficiency. Manufacturing SOP Compliance Template | Example 1: Procedure: Step 1 - Wear PPE or sanitary clothing before entering the production floor Step 2 - Activate vents before turning on industrial machines Step 3 - Set oven to 200°C for initial roasting of coffee beans Step 4 - Set coffee freezing hall to -50°C Step 5 - Put on thermal clothing before entering coffee freezing hall Step 6 - Set low pressure vacuum at 60°C Step 7 - Check conformity to specs and for visual defects during assembly line production Step 8 - Perform final inspections before products are packed in boxes Tablet Compression SOP Checklist | Example 2: Procedure: Remove "Cleaned" label prior to operating tablet press Affix label "[Product Name] and [Batch Details]" to tablet press Issue the punch set suitable for the compression as per separate SOP Set the machine as per tablet parameters given in BMR Destroy tablets from first few rotations before starting the machine for the 1st batch Collect tablets generated per batch then pack and label Stop compression as material in the hopper reaches the lowest level Clean all outside containers and store them with labels that show batch details Remove punch sets and clean as per separate SOP Preview the full manufacturing standard operating procedure sample PDF report. If workers fail to comply with SOPs, they risk making errors that could compromise the quality and efficiency of their work. Step 2: Define the scope The scope defines the extent of your SOP document. Step 3: Choose a format There are various formats you can write an SOP document. Communication breakdown SOPs communicate process updates to workers. Do you want to create a flexible, risk-based audit program - but don't know where to start? Whether starting a new process or improving an existing one, determining the end game or the goal makes it easier to write the SOP document. Read our Internal Audit Planning Checklist to learn which audit steps and requirements you should keep in mind, and download our full guide to "Planning an Audit from Scratch" below! What can internal auditors do to prepare a more comprehensive scope for their internal audit projects? There is no official standard in writing an SOP document. Subjective performance evaluations SOPs clearly define worker tasks and responsibilities. Failure to comply with manufacturing SOPs may result in inconsistent quality outcomes and unsatisfied clients. This is most suitable for processes that require decision-making. Step 4: Write down the procedures Depending on the format you chose, start writing down the procedures of your SOPs focus. Once this research is completed, internal audit should meet with their business stakeholders to confirm their understanding of the process. 6. Preparing the Audit Program Once internal audit has confirmed their understanding of the process and risks within the process, they will be prepared to create an audit program. The Audit Committee and C-suite may become more engaged with internal audit's work in strategic areas. However, for internal audit to keep pace with the business's changing landscape and to ensure key processes and controls are also designed correctly, seeking out external expertise is increasingly becoming a best practice. At least one of the following should be used to evaluate the design of the process audited: Once you have leveraged internal and external resources to identify relevant risks, you will want to build an audit program that tests for these risks. 3. COSO'S 2013 Internal Control - Integrated Framework While used extensively for Sarbanes-Oxley (SOX) compliance purposes, internal auditors can also leverage COSO's 2013 Internal Control - Integrated Framework to create a more comprehensive audit program. Audit Program and Planning Review Audit programs, especially those for processes that have never been audited before, should have multiple levels of review and buy-in before being finalized and allowing fieldwork to begin. How to Write a Manufacturing SOP Complying with regulations and producing consistent outputs don't have to be an arduous journey. And where can internal auditors find the subject matter expertise needed to create an audit program "from scratch"? The following questions should be answered and approved before fieldwork begins: Why was the audit project approved to be on the internal audit plan? How does the process support the organization in achieving its goals and objectives? What enterprise risk(s) does the audit address? Was this process audited in the past, and if so, what were the results of the previous audit(s)? Have there been significant changes in the process recently or since the previous audit? The following requests should be made before the start of audit planning in order to gain an understanding of the process, relevant applications, and key reports: All policies, procedure documents, and organization charts Key reports used to manage the effectiveness, efficiency, and process success Access to key applications used in the process Description and listing of master data for the processes being audited, including all data fields and attributes After gaining an understanding of the process to be audited through the initial document request, you should request access to master data for the processes being audited to analyze for trends and to aid in making detailed sampling selections. 5. Preparing for a Planning Meeting with Business Stakeholders Before meeting with business stakeholders, internal audit should hold an internal meeting in order to confirm the high-level understanding of the objectives of the process or department and the key steps to the process. Audit Board's "Planning an Audit: A How-To Guide" details how to build an effective internal audit plan from the ground up through best practices, resources, and insights, rather than relying on template audit programs. One of the guide's highlights is a comprehensive checklist of audit steps and considerations to keep in mind as you plan any audit project. Noncompliance with manufacturing SOPs could result in the following consequences: Lack of quality control Manufacturing SOPs help produce high-quality products consistently. Lab Personnel and Tablet Press Operators - Are there any specific limitations or exceptions to this SOP? Chemical Manufacturing Lab - Who is the SOP for? Preparing a well-written manufacturing SOP document can guide employees to perform routine tasks in the best and safest way possible. Noncompliance makes it difficult to achieve maximum productivity since operational time frames will vary for each worker. Perhaps most importantly, recommendations made by internal audit will have a more dramatic impact to enable positive change in their organizations. The following steps should be performed to prepare for a planning meeting with business stakeholders: Outline key process steps by narrative, flowchart, or both, highlighting information inflows, outflows, and internal control components Validate draft narratives and flowcharts with subject matter experts (if any) Create an initial pre-planning questionnaire to facilitate a pre-planning meeting with key audit customers Preparing the questionnaire after performing the initial research sets a positive tone for the audit, and illustrates that internal audit is informed and prepared. An audit program should detail the following information: Process Objectives Process Risks Controls Mitigating Process Risks Control Attributes, including: Is the control preventing or detecting a risk event? Control frequency (e.g. daily, weekly, monthly, quarterly, etc.) Does the control mitigate a fraud risk? Is the control manually performed, performed by an application, or both? An initial assessment of the risk event (e.g. high, medium, or low) Testing Procedures for Controls to be Tested During the Audit, including: Inquiry, or asking how the control is performed Observation, or physically seeing the control be performed Inspection, or reviewing documentation evidencing the control was performed Re-performance, or independently performing the control to validate outcomes 7. Increased risk of accidents Safe work practices are often integrated into manufacturing SOPs. Noncompliance may put workers at a higher risk of work-related accidents or injuries. Mobile App for Conducting Manufacturing SOP Inspections Perform hassle-free SOP compliance checks using a digital checklist. Performing an audit based on internal company information is helpful to assess the operating effectiveness of the process's controls. This article features the following: Consequences of Noncompliance With Manufacturing SOPs A good manufacturing SOP is designed to streamline the production process while minimizing the risk of errors. Lastly, the flowchart format where processes are illustrated. A good principle to follow when writing is the 5 C's: clear, concise, correct, courteous, and complete. Initial Audit Planning All internal audit projects should begin with the team clearly understanding why the project was put on the audit plan. The following individuals should review and approve the initial audit program and internal audit planning procedures before the start of fieldwork: Internal Audit Manager or Senior Manager Chief Audit Executive Subject Matter Expert Management's Main Point of Contact for the Audit (i.e. Audit Customer) Internal auditors who can create and document audit programs from scratch - and do not rely on template audit programs - will be more capable and equipped to perform audits over areas not routinely audited. Use the checklist below to get started planning an audit, and download our full "Planning an Audit: A How-To Guide" for tips to help you create a flexible, risk-based audit program. Internal Audit Planning Checklist 1. You can choose to use one or combine them, so long as it's appropriate and can be easily understood by your audience. To give you an idea, we've written down the following examples: Manufacturing SOP Compliance Template | Example 1: Purpose: The purpose of this SOP is to ensure that the correct steps are taken to roast, freeze-dry, and process coffee beans to produce instant coffee. Tablet Compression SOP Checklist | Example 2: Purpose: The purpose of this SOP is to ensure that the correct steps are taken when using the tablet press to perform tablet compression. Doing so will help eliminate the guesswork from the procedure and ensure that each step performed is consistent. There's also the hierarchical format which is similar to the prior, the only difference is that it provides more detailed and specific instruction for each step. However, it doesn't stop there. However, some steps can help in writing an effective SOP. This only applies to the production of pharmaceutical tablets.

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