Related Documents

TEM-080	Internal Audit Report Template
TEM-120	Vendor Audit Report Template
Form-385	Vendor Audit Questionnaire
Form-445	EHS Workplace Instruction Checklist
QMS-010	All Documents - Classification, Definition and Approval Matrix
EHS-010	Environmental, Health and Safety - Risk Management
QMS-015	Quality Documentation Management and Change Control
QMS-030	Preparation, Maintenance and Change Control of Master Documents
QMS-025	Quality Documentation - Control, Tracking and Distribution
QMS-035	Deviation Report System
QMS-105	House Keeping Audit Procedure
QMS-045	Vendor Selection and Evaluation

EHS Statement

Audits must be conducted with due concern for employee safety and environmental protection.

Table of Contents

Overview 2
Procedure 3
1. Internal Quality Audit 3
2. Vendor Audit 5
3. Environmental, Health and Safety (EHS) Audit 6
4. Environmental, Health and Safety (EHS) workplace Inspection 6
5. Housekeeping Audits 7
6. Regulatory inspection 8
7. Summary of Changes 9
End of Procedure 9

Overview

An audit is a systematic and independent review to verify compliance, suitability and/or data integrity.

Audits may assess: systems, processes, procedures, facilities, products, records and/or data for compliance with policies, standards, procedures, guidelines, regulations or regulatory submissions.

The Documentation Database:

The Documentation Database is used to facilitate creation, control, maintenance and tracking of Quality, External and Master file documents. These are also referred to as “Controlled Documents. The Documentation Database is divided into three (3) of areas of control:

Observations of a less serious or isolated nature that are not deemed Critical or Major, but require correction, or suggestions given on how to improve systems or procedures that may be compliant, but would benefit from improvement (e.g. Good Practice seen elsewhere).

These are to be considered as a **Deviation** and raised as a DR.

Standard Observation is the first text to be written in the "description" long text of the DR.

A response indicating responsibilities and timescales of corrective actions is required.

All tasks in the audit Deviation Report are to be reviewed and approved by QA/auditor. Any problems relating to agreement of corrective action are to be reported to the Quality Assurance Manager, EHS Manager or Production Manager for resolution.

A copy of the draft report is to be forwarded to QA for review. After the debrief meeting, and agreement is reached between the auditor and auditee, a signed copy is to be forwarded to QA.

The report is to be issued as per **SOP QMS-015** in the Quality Audit area in the Documentation Database as a **confidential** document to management of the audited area and Manufacturing Management Team.

(The content of internal audit reports are confidential and will not be shared with any external regulatory agency, unless approved by Quality Assurance Manager, however audit schedules/logs may be reviewed).

1.5.4. Audit Outcome Review

All Observations are to be raised as Deviation Report. Auditors are to record all audit **DRs** in a Tracking Spreadsheet, so tracking and trending of topics of **DR** can take place. The spreadsheet will be reviewed by QA department on a quarterly basis. Any significant observations or trends should be referred to QA Management and together with corrective actions will be considered, implemented and follow up.

1.5.5. Archiving of Documentation

Master copies of audit reports and related documentation are to be filed in a satellite file location for QA and retained as listed in the document Retention time section of SOP **QMS-010**. Soft copies of the report are to be stored in the document database by report number.

2. Vendor Audit

2.1. Schedule

An audit schedule is to be established commencing in the beginning of the year with a 12-36 month period. All audits are to be entered in the Documentation Database with the schedule date reflective of the schedule.

2.2. Preparation

The Vendor Questionnaire **(Form-385)** may be sent out to the vendor. This will become part of the preparation for the audit.

2.3. Performing the audit

The audit is to be lead by a qualified QA auditor with assistance from Technical, Manufacturing, Engineering, EHS or a relevant staff member, reflecting the audit needs. A maximum of two people should facilitate the audit.

2.4. Reporting

Vendor Audit reports, written using template **TEM-120** should be issued within 30 calendar days after the audit, indicating the audit team's observations and recommended status of the Vendor. The Vendor should be requested to provide a formal response to the audit report within 30 working days of its receipt.

The auditors should use the Housekeeping checklist for area audited. Non-conformances made during the inspection should be discussed with personnel at the time they are observed, so that observations are clearly understood by all involved. Non-conformances should be resolved as soon as possible, and are to be documented in the housekeeping checklist. Non-conformances are also captured using the Deviation Report system and are to be raised by the designated Housekeeping Auditor or Process Manager. DR number must be recorded on the Housekeeping Checklist.

6. Regulatory inspection

6.1. Schedule

Regulatory Agency inspections may be announced or unannounced. The Quality Assurance Manager is the primary contact for Regulatory Agency Inspections. Should the Quality Assurance Manager not be available on site, this responsibility will be defined in the letter of delegation issued prior to planned absences.

6.2. Planning

For Regulatory inspections, either announced or unannounced, the following should be identified and made available in a timely manner to facilitate the auditing process.

- An inspection team with specific roles such as runners, scribes and subject experts to be able to quickly respond to the needs of the auditor.
- An appropriate individual to assist the auditor in conducting the audit and be available at all times to the auditor to facilitate the timely gathering of information.
- A conference room or office available to the auditor for the purpose of reviewing notes, inspection of company documents and /or use of telephone to contact his/her office.
- The auditor should be made aware that the taking of photographs, use of tape recorders or other electronic equipment, the listening to, reading and signing of affidavits, the review of internal audit reports and the allowing of access to computer databases is **NOT ALLOWED** and requires consultation with the Quality Assurance Manager.

6.3. Audit Performance

Once the Regulatory Inspection has commenced, the following process should be followed:

- Senior management should be present at the opening and closing meeting of a regulatory inspection. It is suggested that the senior management give a brief introductory presentation to the Regulatory Authorities (with their agreement) covering the department, function or site being audited.
- Auditors should be accompanied at all times to meet the organization's EHS requirements and to facilitate the provision of documents, information and movement through the facility.
- Auditor's questions must be answered truthfully and honestly, in the most direct manner to ensure prompt provision of information and adherence to the audit schedule timeliness.
- Auditors must go through proper Induction Training Programs for areas audited should they request entrance into restricted areas of facility.
- Inspection team members should keep accurate detailed notes on issues, products, operations, documents reviewed and samples taken during the audit, to facilitate timely clarification and resolution of issues arising during the audit.
- Documents or copies of documents provided to the auditor should be stamped as "CONFIDENTIAL" to ensure company confidentiality and a duplicate copy of these documents must be included as part of the inspection file at QA Office to facilitate the timely resolution of any future queries from the Regulatory Agency relating to the audit, should they arise.
- Daily summary sessions (daily wrap-up meetings) with the auditors at the end of each day's activities should be requested for the purpose of clarifying any issues that may have been

Vendor Audit Questionnaire

(Ref. SOP QMS-045; QMS-080)

For "Yes" / "No" answers; Please tick the box for the one which applies, or select "N/A" (Not Applicable)			
Management Responsibility			
Is an organization chart available? If yes, please enclose a copy.	Yes	No	N/A
Are there any written job descriptions defining each individuals responsibilities	Yes	No	N/A
How many shifts of operation are there in the Production Area? How many shifts of operation are there in QC Laboratory?			
Approximately how many employees do you have? - Site total			
- QA/QC			
- Production			
To whom does the QA/QC Manager report?			
Does the company have a policy on EHS (Environmental, Health & Safety)?	Yes	No	N/A
Does the company have a policy on Quality?	Yes	No	N/A
Who is responsible for contacts with Sydco with regards to the following areas: Quality: Technical: Commercial:			
Are subcontractors (if used), used for significant steps or components in Preparation of Sydco's products? The term subcontractors includes both contracted operations within Production and the Laboratory	Yes	No	N/A
If "Yes", please list and explain:			

All information contained within this document will be treated as confidential between the Supplier and Buyer.

Vendor Audit Questionnaire

(Ref. SOP QMS-045; QMS-080)

Warehouse			
Are storage facilities/equipment/ rented or personnel contracted?	Yes	No	N/A
If "Yes", please provide details.			
Are receipt and release procedures documented?	Yes	No	N/A
Is the supply chain documented?	Yes	No	N/A
How is material status controlled? (i.e. Physical, system or labelling)			
How is rejected material controlled? (i.e. Physical, system or labelling)			
Is there an identified sampling area?	Yes	No	N/A
Are all containers identified?	Yes	No	N/A
Is a First-In-First-Out or First-Expiry-First-Out system in use? (Identify)	Yes	No	N/A
Are shelf life/expiration dates used?	Yes	No	N/A
Is Temperature (T°), controlled and documented?	Yes	No	N/A
Comments:			
Is Relative humidity (RH%), controlled and documented?	Yes	No	N/A
Comments:			

Production			
Is there more than one site or plant used for the manufacture of the specified material(s)?	Yes	No	N/A
If "Yes", please provide details.			
Is plant equipment labelled as to its status and contents?	Yes	No	N/A
Is Pipe work labelled?	Yes	No	N/A
Are critical processes validated?	Yes	No	N/A
Does process documentation include: Process instructions	Yes	No	N/A
Cleaning instructions	Yes	No	N/A
Cleaning records	Yes	No	N/A
Area clearance	Yes	No	N/A
Are cleaning processes validated?	Yes	No	N/A

All information contained within this document will be treated as confidential between the Supplier and Buyer.

Vendor Audit Questionnaire

(Ref. SOP QMS-045; QMS-080)

Investigation of rejected material	Yes	No	N/A
Product complaints	Yes	No	N/A
Handling out of specification results	Yes	No	N/A
Are manual calculations checked by a second person?	Yes	No	N/A
Are data transcriptions checked by a second person?	Yes	No	N/A
Is all raw-data retained?	Yes	No	N/A
Are all standards traceable to their preparation and the reagents used?	Yes	No	N/A
Are analytical methods validated?	Yes	No	N/A
Do you perform stability testing on materials and/or products?	Yes	No	N/A
If so, what shelf life / retest dates are available for the referenced product(s)?			
Do you perform annual product reviews or campaign reviews on products?	Yes	No	N/A

Material Release

Is the decision to release/reject product made by a person or function independent from production?	Yes	No	N/A
Is the final status recorded?	Yes	No	N/A
Are certificates issued for each batch?	Yes	No	N/A
Are certificates signed by QA/QC?	Yes	No	N/A
If not, who signs certificates?			
Is shelf life or retest dates or expiry date provided on the “C of A “ OR “C of C’s”	Yes	No	N/A
Is there a documented recall procedure?	Yes	No	N/A

Transport

Is a list of approved hauliers in use?	Yes	No	N/A
Is temperature controlled transports used?	Yes	No	N/A
If “Yes”, are temperature records reviewed and retained?	Yes	No	N/A
If bulk tankers are used, is a cleaning certificate required?	Yes	No	N/A
If bulk tankers are used, are they dedicated?	Yes	No	N/A
If not, what other substances could be transported in the tankers?			

All information contained within this document will be treated as confidential between the Supplier and Buyer.

EHS Workplace Inspection Checklist

(Ref. SOP QMS-080)

Inspected by:	Date of inspection	Date of Report	Report #	Pages
Area Manager:				
Area Inspected:				

General

This EHS Workplace Inspection was conducted by:

Scope of the Inspection:

Write what is covered and what's not.

Inspection Observations:

(Write the inspection observations and recommendations here)

Summary / Inspectors' Comments

Your comments and suggestions regarding improvements to the above areas or the inspection process would also be much appreciated.

Inspector (s) **EHS Manager**

All information contained within this document will be treated as confidential between the Supplier and Buyer.

EHS Workplace Inspection Checklist

(Ref. SOP QMS-080)

Are all hot machine surfaces guarded & identified through signage?		
Other Comments		

ERGONOMIC AND MANUAL HANDLING

Item	Code	Comments
Are controls easily accessible?		
Is adequate lifting equipment available if required and staff trained in correct use?		
Are no static / awkward positions required or maintained for prolonged periods?		
Have seating / displays / ergonomics been designed to accommodate different demographics and minimise stress / error?		
Are there repetitive body movements required?		
Is there no repetitive reaching / pushing / pulling / bending / twisting / reaching over or arm raising required?		
There is no excessive vibration / friction?		
Do working positions appear comfortable?		
Other Comments		

LIGHTING HAZARDS

Item	Code	Comments
Is there adequate illumination for tasks?		
Is there direct or reflected glare?		
Are light fittings clean and in good condition?		
All light switches working correctly and positioned appropriately?		
Are there energy saving practices / equipment in place?		
Other Comments		

HAZARDOUS SUBSTANCES

Item	Code	Comments
Do employees know where to access MSDS?		
Do employees know how to dispose of used chemicals and containers?		
Are there sharps / appropriate disposal containers readily available?		
Are all containers clearly labelled?		
Is storage suitable for different chemical types?		
Are chemicals of incompatible classes stored separately?		
Are cabinets located more than 3 metres from ignition sources?		

EHS Workplace Inspection Checklist

(Ref. SOP QMS-080)

For each hazard, think about:

How likely is it to hurt someone or harm the environment?

How severely could it hurt someone or harm the environment?

LIKELIHOOD	kill or disable / major irrevesible environmental harm or pollution	several days off work / significant environmental incident	first aid / excess resource use or minor pollution
very likely could happen regularly ▼	1	2	3
likely could happen occasionally	2	3	4
unlikely Could happen, but only rarely	3	4	5
very unlikely Could happen, but probably never	4	5	6

The numbers show how important it is to do
1 do something immediately
6 do something when possible.

HAZARD IDENTIFIED	LIKELIHOOD Very likely Likely Unlikely Very Unlikely	SEVERITY Kill or disable Several days off First aid	Risk Level 1 - 6	Risk Controls

All information contained within this document will be treated as confidential between the Supplier and Buyer.

