

EHSS MANAGEMENT SYSTEM MANUAL

Version No. : 001	Supersedes : NA	Next Review : 04 Nov 2025
Effective Date : 04 Nov 2022	Date : NA	

EHSS MANAGEMENT SYSTEM MANUAL	
Document Ref. No. / Version No.	EHSS-MSM/V1
Dated	04 Nov 2022

REFERENCE:

This manual is prepared in accordance with the requirements of ISO 14001:2015 and ISO 45001:2018 Standards.

Syngene International Ltd
 Biocon Park, Plot No. 2,3,4 and 5
 Phase - 4, Bommasandra Jigani Link Road
 Bengaluru – 560099

Syngene International Ltd (Clinical Development)
 Plot No.29 (P1) and31 (P2), Electronic city
 Phase -II, Hosur Road, Bengaluru - 560100.

Syngene International Ltd, Unit - II
 113 – C2,
 Bommasandra Industrial Area
 Bengaluru - 560099



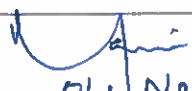
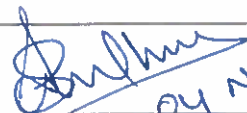

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2. DOCUMENT APPROVAL PAGE

DOCUMENT PREPARED BY		
NAME	DESIGNATION	SIGNATURE & DATE
Manivannan Arumugam	Manager -EHSS	 04 Nov 2022
DOCUMENT REVIEWED BY		
NAME	DESIGNATION	SIGNATURE & DATE
Dr. Sunil Kumar	Assistant General Manager - EHSS	 04 Nov 2022
DOCUMENT APPROVED BY		
NAME	DESIGNATION	SIGNATURE & DATE
Rajendra Patil	Head - EHSS	 04 NOV 2022



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3. AMMENDMENT SHEET

Existing V. No	New V. No	Changes made in new Version No.	Effective Date
NA	001	<ul style="list-style-type: none"> • New EHSS management system manual has been incorporated for Syngene International Ltd, Bangalore previously the EHSS System manual part of Biocon Group of Companies. 	04 Nov 2022



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5. FOREWORD

Syngene believes that responsible stewardship of environment and implementing a policy on health and safety is essential for business success.

The Environment, Health, Safety and Sustainability Manual sets out policy and commitments that gives power and action to this belief. It is a signpost to arrangements and procedures for Environmental, Health, Safety and Sustainability controls.

To provide structure and coordination for Environment Health, Safety and Sustainability Manual, Policy and actions, the International Standard for Environmental Management Systems, ISO 14001:2015 and Occupational Health and Safety Management System ISO 45001:2018 has been selected as the basis of management system.

The Environment, Health, Safety and Sustainability Manual and all documentation and data of Environment, Health, Safety and Sustainability Management System are confidential and should not be reproduced in whole or part by any means, transmitted, or translated into electronic document without written permission of the organization.

The EHSS Manual shall be uploaded in Syngconnect and will be made available to all employees in the organization.

The following is the background for Integration of ISO 14001:2015 and ISO 45001:2018

- ✓ ISO 14001 is an Environmental Management System (EMS) which provides a structure for measuring and improving an organization's environmental performance.
- ✓ ISO 45001 is an Occupational Health and Safety Management System (OHSMS) which enables an organization to provide safe and healthy workplace by preventing work-related injury and ill health, as well as by proactively improving its OH&S performance. It focuses to eliminate hazards and minimize OH&S risks (including system deficiencies), take advantage of OH&S opportunities, and address OH&S management system nonconformities associated with its activities.
- ✓ We have integrated both standards through PDCA cycle. Since both standards are designed on principle of continual improvement through a "Plan-Do-Check-Act" (PDCA) cycle hence it offers a great opportunity for an integrated approach to address EHSS issues.
- ✓ Integrated EHSS Management System (EHSSMS) shall be based on ISO 14001 and ISO 45001 which will support to optimize the resources and aid effectively to identify the key environmental and OHS risks so as to address them in a systematic way to achieve continual improvement in the overall EHSS performance.

**The PDCA model clauses has been explained in CORRESPONDENCE BETWEEN
ISO 14001:2015 AND ISO 45001:2018**

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6. SYNGENE PROFILE

Syngene International Ltd. is an integrated research, development and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical sectors.

Headquartered in India and listed on the Indian stock exchanges, Syngene's research, development and manufacturing operations are based at the original 90- acre campus in Bangalore, supported by two satellite campuses that house enabling functions and the clinical development facility. A new, state-of-the-art discovery research campus in Hyderabad, India, located in the government-sponsored biotech zone, currently accommodates 600 scientists with further phases of expansion planned. The large-scale active pharmaceutical ingredient (API) manufacturing site is located on a dedicated campus in Mangalore, India. US clients are supported by Syngene USA Inc., a US-based subsidiary.

Syngene's more than 5200 scientists offer both skills and the capacity to deliver great science, robust data management and IP security and quality manufacturing at speed to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen and Bristol-Myers Squibb as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA.

Syngene's world-class facilities have received ISO 9001:2008, ISO 14001:2004, and OHSAS 18001:2007 certifications and have been audited by the United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA), and major life sciences partners. Its animal health facilities are Good Laboratory Practice (GLP) certified by the Indian authorities and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accredited.

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7. CORRESPONDENCE BETWEEN ISO 14001:2015 AND ISO 45001:2018

ISO 45001:2018		PDCA	ISO 14001:2015	
SECTION / CLAUSE	ISO		SECTION / CLAUSE	ISO
1	Scope	PLAN	1	Scope
2	Normative References		2	Normative Reference
3	Terms and Definitions		3	Terms and Definitions
4	Context of the organization (title only)		4	Context of the organization (title only)
4.1	Understanding the organization and its context		4.1	Understanding the organization and its context
4.2	Understanding the needs and expectations of workers and other interested parties		4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the OH&S Management System		4.3	Determining the scope of the environmental management system
4.4	OH&S Management System		4.4	Environmental management system
5	Leadership and worker participation (title only)		5	Leadership (title only)
5.1	Leadership and commitment		5.1	Leadership and commitment
5.2	OH&S Policy		5.2	Environmental Policy
5.3	Organizational roles, responsibilities and authorities		5.3	Organizational roles, responsibilities and authorities
5.4	Consultation and participation of workers			
6	Planning (title only)		6	Planning (title only)
6.1	Action to address risks and opportunities (title only)		6.1	Action to address risks and opportunities (title only)
6.1.1	General		6.1.1	General
6.1.2	Hazard identification and assessment of risks and opportunities		6.1.2	Environmental Aspects
6.1.3	Determination of legal requirements and other requirements		6.1.3	Compliance Obligations
6.1.4	Planning Action		6.1.4	Planning Action

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6.2	OH&S objectives and planning to achieve them (title only)		6.2	Environmental Objectives and Planning to achieve them (title only)
6.2.1	OH&S objectives		6.2.1	Environmental objectives
6.2.2	Planning to achieve OH&S objectives		6.2.2	Planning actions to achieve environmental objectives

ISO 45001:2018		PDCA	ISO 14001:2015	
7	Support (title only)	DO	7	Support (title only)
7.1	Resources		7.1	Resources
7.2	Competence		7.2	Competence
7.3	Awareness		7.3	Awareness
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7.5.3	Control of documented information		7.5.3	Control of documented information
8	Operation (title only)		CHECK	8
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8.2	Emergency preparedness and response	8.2		Emergency preparedness and response
9	Performance Evaluation (title only)	9		Performance Evaluation (title only)
9.1	Monitoring, measurement, analysis and evaluation (title only)	9.1		Monitoring, measurement, analysis and evaluation (title only)
9.1.1	General	9.1.1		General
9.1.2	Evaluation of compliance	9.1.2		Evaluation of compliance
9.2	Internal Audit (title only)	9.2		Internal Audit (title only)
9.2.1	General	9.2.1		General
9.2.2	Internal audit program	9.2.2		Internal audit program

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9.3	Management Review	ACT	9.3	Management Review
10	Improvement (title only)		10	Improvement (title only)
10.1	General		10.1	General
10.2	Incident, nonconformity and corrective action		10.2	Nonconformity and corrective action
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8. SCOPE

(Clause 1 ISO 14001:2015, ISO 45001:2018)

Organisation has determined boundary and applicability of EHSS Management systems for Occupational Health & Safety and Environmental performance of its products and processes to customers and other interested parties.

We consider environmental aspects and high, very high risks OHS and other risks of all our activities, processes, products and services towards EHSS. We consider all internal and external issues relevant to organization and incorporate the interested parties' needs and expectations by considering following factors:

- The internal and external issues
- The compliance obligations, Legal requirements & Other Requirements applicable to our Premises
- The physical boundary of the facility and functions
- The various operations and activities, services functioning at the facility
- The products manufactured at this facility
- Needs and expectations of interested parties
- The outsourced processes
- The environmental aspects & Occupational Health & Safety & other risks of activities, products and services which can control or influence through life cycle perspective.

Syngene Vision

To be a world-class partner delivering innovative scientific solutions

Syngene Values

Integrity: To be ethical, honest and transparent in all we do.

Excellence: To commit ourselves to the highest levels of scientific and operational excellence.

Professionalism: To practice the highest degree of professionalism by fostering individual accountability, reliability, continuous improvement and customer focus.

Syngene Commitment

Syngene, aims to contribute to the evolution of scientific research using our skills, technology and experience to find solutions to the world's most complex challenges.

Clients: Deliver scientific innovation that meets our clients' requirements and, in turn, helps them to meet the needs of the people and patients they serve.

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The physical boundary of this facilities is as mentioned below:

Syngene International Ltd (Biocon Park),

Plot No. 2,3,4 and 5 Phase - 4,
Bommasandra Jigani Link Road
Bengaluru – 560099

Syngene International Ltd (Clinical Development)

Plot No.29 (P1) and31 (P2), Electronic city
Phase -II, Hosur Road, Bengaluru-560100.

Syngene International Ltd, Unit - II

113 – C2,
Bommasandra Industrial Area
Bengaluru – 560099

The scope of Environment, Health, Safety and Sustainability (EHSS) Management System at Syngene is as follows:

- **Syngene International Limited** - Contract research in drug discovery and contract-Manufacture of Biopharmaceuticals
- **Syngene International Limited - Unit – II** - Contract research in drug discovery
- **Syngene International Limited (Clinical Development)** - Contract research services in clinical drug development

Reference Clause:

- ISO 45001: 2018 Occupational health and safety management systems – Requirements – Scope
- ISO 14001: 2015 Environment Management systems – Requirements – Scope
- ISO 14040 Environmental Management- Life cycle assessment- Principles and framework
- ISO 14044:2006 Environmental Management- Life cycle assessment- Requirements and guidelines.

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9. NORMATIVE REFERENCE/REFERENCE PUBLICATIONS
(Clause 2 ISO 14001:2016, ISO 45001:2018)

The normative references are listed below:

- ISO 45001:2018 Occupational Health and Safety Management Systems –Requirements with guidance for use
- ISO 14001:2015 Environment Management System – Requirements with guidance for use
- ILO – OSH:2001 Guidelines on Occupational Safety and Health Management System (OSH – MS)
- ISO 14004: 2015 Environmental Management systems -General Guidelines on Implementation
- ISO 14010:1996 Guidelines for Environmental Auditing
- ISO 14011:1996 Guidelines for auditing of an EMS
- ISO 14044:2006: Environmental Management- Life cycle assessment- Requirements and guidelines
- ISO 14063 - Environmental Management - Environmental communication- Guidelines and examples

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10. TERMS AND DEFINITIONS (Clause 3 ISO 14001:2015, ISO 45001:2018)

10.1 TERMS

LIST OF ABBREVIATIONS:

HOD	Head Of the Department
LAN	Local Area Network
EHSS	Environment, Health, Safety and Sustainability
EHSSM	Environment, Health, Safety and Sustainability Manual
EHSSMSP	Environment, Health, Safety and Sustainability Management System Procedure
EHSSMS	Environment, Health, Safety and Sustainability Management System
MP	Management Program
CMD	Chairman and Managing Director
SDS	Safety Data Sheet
OCP	Operational Control Procedure
ISO	International Standards Organization
KSPCB	Karnataka State Pollution Control Board
CPCB	Central Pollution Control Board
MoEF	Ministry of Environment and Forest
IOP	Instrument Operating Procedure
EOP	Equipment Operating Procedure
SOP	Standard Operating Procedure
HIRA	Hazard Identification and Risk Assessment
cGMP	Current Good Manufacturing Practices
HR	Human Resources
CO	Compliance Obligation
EMS	Environment Management System
OHSMS	Occupational Health & Safety Management Systems

10.2 DEFINITIONS

10.2.1 Auditor: Person with Competence to conduct an Audit.

10.2.2 Continuous improvement (*Internally defined*): Recurring process of enhancing the environmental, occupational health, safety and sustainability management system in order to achieve improvements in overall environmental, health, safety and sustainability performance in line with organization's environment, occupational health, safety and sustainability policy.

10.2.3 Corrective Action: Action to eliminate the cause of a detected nonconformity (ISO 14001: 2015, 3.4.4).

10.2.4 Documented Information (*defined internally*): Information and supporting Medium in form of paper, Magnetic, electronic or optical computer disc, photograph or master sample, or a combination of thereof (ISO 14001:2015, 3.3.2).

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- 10.2.5 Environment:** Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation (ISO 14001:2015, 3.2.1).
- 10.2.6 Environmental aspect:** Element of an organization's activities, products or services that can interact with the environment (ISO 14001:2015, 3.2.2).
- 10.2.7 Environmental impact:** Any change to the environment whether adverse or beneficial, wholly or partially resulting from an organization's activities, products or services (ISO 14001:2015, 3.2.4).
- 10.2.8 Significant environmental aspect (*Internally defined*):** An environmental aspect that has or can have significant environmental impact.
- 10.2.9 Environment Management System:** Part of an organization's management system manage environmental aspects and fulfil compliance obligations and risk and opportunities (ISO 14001:2015, 3.1.2).
- 10.2.10 OH&S management system:** Part of an organization's management system used to develop and implement its OH&S policy and manage its OH&S (ISO 45001:2018, 3.13).
- 10.2.11 Environment, Health, Safety and Sustainability Management System (*Integrated definition*):** The part of overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining environmental, health, safety and sustainability policy. The EHSS management system also facilitates management of EHSS risks associated with business organization.
- 10.2.12 Environment, Health, Safety and Sustainability objective (*Integrated definition*):** Overall environmental, health, safety and sustainability goal arising from EHSS Policy, that an organization sets itself to achieve, and which is quantified where practicable.
- 10.2.13 Internal Audit (*Integrated definition*):** Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which Environment Management System Audit criteria are fulfilled.
- 10.2.14 First party Audit (*Internally defined*):** EHSS assessment (KAVACH standards, ISO 14001 and 45001 standards) of a location/sites that is conducted by management or employees of the location/site. Auditors are within the OU/EFs unit being audited. Lead auditors are to be chosen from CFT.
- 10.2.15 Second party Audit (*Internally defined*):** A comprehensive EHSS performance assessment of a location/site that is conducted by internal EHSS team utilising the experts within the team.
- 10.2.16 Third Party Audit (*Internally defined*):** An assessment of a location/site or process plant conducted by personnel who are external to SYNGENE; a regulatory inspection that is conducted by governmental agencies.
- 10.2.17 Environment Performance:** Measurable results of an organization's management of its – environmental aspects (ISO 14001:2015, 3.4.10).
- 10.2.18 Occupational Health and Safety Performance:** Performance related to effectiveness of prevention of injury and ill health to workers and provision of safe and healthy workplaces. (ISO 45001:2018, 3.28).
- 10.2.19 Environment, health, safety and sustainability performance (*Integrated definition*):** Measurable results of environmental, health, safety and sustainability management system.

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related to an organization's control of its environmental aspects, health, safety and sustainability risks based on its environmental, health, safety and sustainability policy, objectives and targets.

10.2.20 Environmental policy: Intentions and direction of an organization related to its environmental performance as formally expressed by top management (ISO 14001:2015, 3.1.3).

10.2.21 OH&S policy: Policy to prevent work-related injury and ill health to workers and to provide safe and healthy workplaces. (ISO 45001:2018, 3.15).

10.2.22 Environment, Health, Safety and Sustainability policy (*Integrated definition*): Statement by the organization of its intentions and principles in relation to its overall environmental, health, safety and sustainability performance which provides a framework for action and for the setting of its EHSS objectives and targets.

10.2.23 Compliance Obligation: Legal requirement that organisation has to comply with and another requirement that an organisation must or choose to comply with. (ISO 14001:2015, 3.2.9).

10.2.24 Interested party (*Integrated definition*): Individual or group concerned with or affected by the environmental, health, safety and sustainability performance of an organization.

10.2.25 Organization: Person or group of people that has its own functions with responsibilities, authority and relationship to achieve its objectives. (ISO 14001:2015, 3.1.4).

10.2.26 Prevention of pollution: Use of processes, practices, materials or products, services or energy to avoid, reduce or control creation, emission or discharge of any of pollutants or waste, in order to reduce environmental impacts. (ISO 14001:2015, 3.2.7).

10.2.27 Corrective Action: Action to eliminate the cause of a nonconformity or an incident and to prevent recurrence (ISO 45001:2018, 3.36).

10.2.28 Non-conformity (*Integrated definition*): Any deviation from work standards, practices, procedures, Legal requirements, Management System performance etc. that could either directly or indirectly lead to injury or ill health, property damage to the workplace environment or combination of these.

10.2.29 Hazard: Source with a potential to cause injury and ill health. (ISO 45001:2018, 3.1)

10.2.30 Injury and Ill Health: Adverse effect on physical, mental or cognitive condition of a person. (ISO 45001:2018,3.18).

10.2.31 Incident: Occurrence arising out of, or in the course of, work that could or does result in injury and ill health. (ISO 45001:2018, 3.35)

NOTE 1 An incident where injury and ill health occurs is sometimes referred to as an "incident".

NOTE 2 An incident where no injury and ill health occurs but has the potential to do so, may be referred to as a "near-miss", "near-hit" or "close call".

NOTE 3 Although there can be one or more nonconformities related to an incident, an incident can also occur where there is no nonconformity.

10.2.32 Risk: Effect of uncertainty. (ISO 45001:2018, 3.20).

10.2.33 Risk assessment: Process of evaluating the risk(s) arising from a hazard(s), considering the adequacy of any existing controls, and deciding whether the risk(s) is acceptable.

10.2.34 Life cycle: Consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal (ISO 14001: 2015, 3.3.3).

10.2.35 Outsource: Make an arrangement where an external organisation performs part of an organisation or Process (ISO 14001: 2015, 3.3.4)

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10.2.36 Risk and Opportunities: Effect of uncertainty (ISO 14001:2015, 3.2.10; ISO 45001:2018, 3.20), Potential adverse effects (threats) and Potential Beneficia.

10.2.37 Occupational health & safety risk: Combination of likelihood of occurrence of a work-related hazardous event (s) or exposure (s) and severity of injury and ill health that can be caused by the event (s) or exposure (s). (ISO 45001:2018, 3.21).

10.2.38 Occupational health & safety opportunity: Circumstance or set of circumstances that can lead to improvement of Occupational health & safety performance (ISO 45001:2018, 3.22).

10.2.39 Hazard Identification & Risk Assessment: Process that encompasses all activities involved in identifying hazards and evaluating risk at facilities, throughout their life cycle, to make certain that risks to employees, the public, or environment are consistently controlled within the organization's risk tolerance.

10.2.40 Workplace: Place under control of organization where a person needs to be or to go for work purposes. (ISO 45001:2018, 3.6).

10.2.41 Procedure: Specified way to carry out an activity or a process (ISO 45001:2018, 3.26).

10.2.42 Documented information: Information required to be controlled and maintained by an organization and the medium on which it is contained (ISO 45001:2018, 3.24).

10.2.43 Indicator: Measurable representation of the condition or status of operation, management or conditions (ISO 14001: 2015, 3.4.7).

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11. GENERAL REQUIREMENT

The Environment, Health, Safety and Sustainability Management System is an organizational framework that is continually monitored and periodically reviewed in response to the internal and external factors. The system is documented to consolidate the environment, health, safety and sustainability controls, assist communication and implementation, and to facilitate auditing and review.

Suppliers and contractors must have Environmental & OHS awareness and appropriate controls for their processes.

The Environment, Health, Safety and Sustainability Management System complies with ISO 14001:2015 and ISO 45001:2018. The core system is based on following principles:

Principle 1 Commitment and Policy

Top management and employees are committed to achievement of the policy.

Principle 2 Planning

A comprehensive plan of action supports the achievement of Environment, Health, Safety and Sustainability Policy.

Principle 3 Implementation

Top management provides the resources, including human and financial resources, for effective environmental management. The Environment, Health, Safety and Sustainability Management System include systematic controls and procedures for the application of the resources.

Principle 4 Measurement and Evaluation

Environment, Health, Safety and Sustainability Management System performance and effectiveness of controls are continuously monitored and evaluated. Corrective actions are taken appropriate to the magnitude of problems and level of environmental impact / health and safety risk encountered.

Principle 5 Review and Improvement

Environment, Health, Safety and Sustainability Management System is reviewed and continually improved as and when applicable with the aim of improving overall environment, health and safety performance.

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12. SALIENT FEATURES OF ENVIRONMENT, OCCUPATIONAL HEALTH, SAFETY & SUSTAINABILITY POLICY

12.1 ENVIRONMENT, OCCUPATIONAL HEALTH, SAFETY & SUSTAINABILITY POLICY







ENVIRONMENT, OCCUPATIONAL HEALTH, SAFETY & SUSTAINABILITY POLICY

The Biocon Group, an integrated Biopharmaceutical enterprise, is committed to high standards and continual improvement in the areas of Environment, Occupational Health, Safety and Sustainability (EHSS).

We shall strive to achieve this by:

- Complying with all applicable laws, regulations, legal requirements and other requirements in all countries in which the company operates
- Ensuring protection of environment and prevention of pollution at all levels of operations
- Providing safe and healthy working environment for our employees, contract workers, visitors and other stakeholders, by eliminating hazards and reducing occupational health and safety risks to prevent work-related injury and ill health
- Empowering employees and contract workers through training programs that are focused on operational safety, occupational health and environmental protection
- Ensuring a sustainable value chain by building a network of responsible business partners committed to environmental stewardship across the product life cycle starting from sourcing of raw materials to manufacturing and distribution of our products
- Adopting energy conservation, reduction of waste through recovery, recycle and reuse, mitigation of climate change risks and threats to biodiversity in all process operations thereby integrating sustainability in our business operations
- Providing the framework and resources for setting, renewing and achieving Environment, Health, Safety and Sustainability objectives & targets. Continually evaluating and improving Environment, Health, Safety and Sustainability performance through compliance, periodic audits and effective documentation
- Adopting best practices of Environment, Health, Safety and Sustainability through continual improvement of EHSS management system that pursues the latest developments in this area
- Using effective communication, consultation and participation of employees and contract workers to maintain highest standards of Environment, Health, Safety and Sustainability

The Biocon Group management is committed towards implementation of the EHSS policy. This policy is applicable to all businesses, employees and contract workers of all entities of the Biocon Group.



Kiran Mazumdar Shaw
Chairperson & Managing Director

Date: 21.08.2019
V.07

Emergency Contact No. 2000

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12.2 SALIENT FEATURES OF ENVIRONMENT, OCCUPATIONAL HEALTH, SAFETY & SUSTAINABILITY POLICY

(Clause 5.2 ISO 14001:2015, ISO 45001:2018)

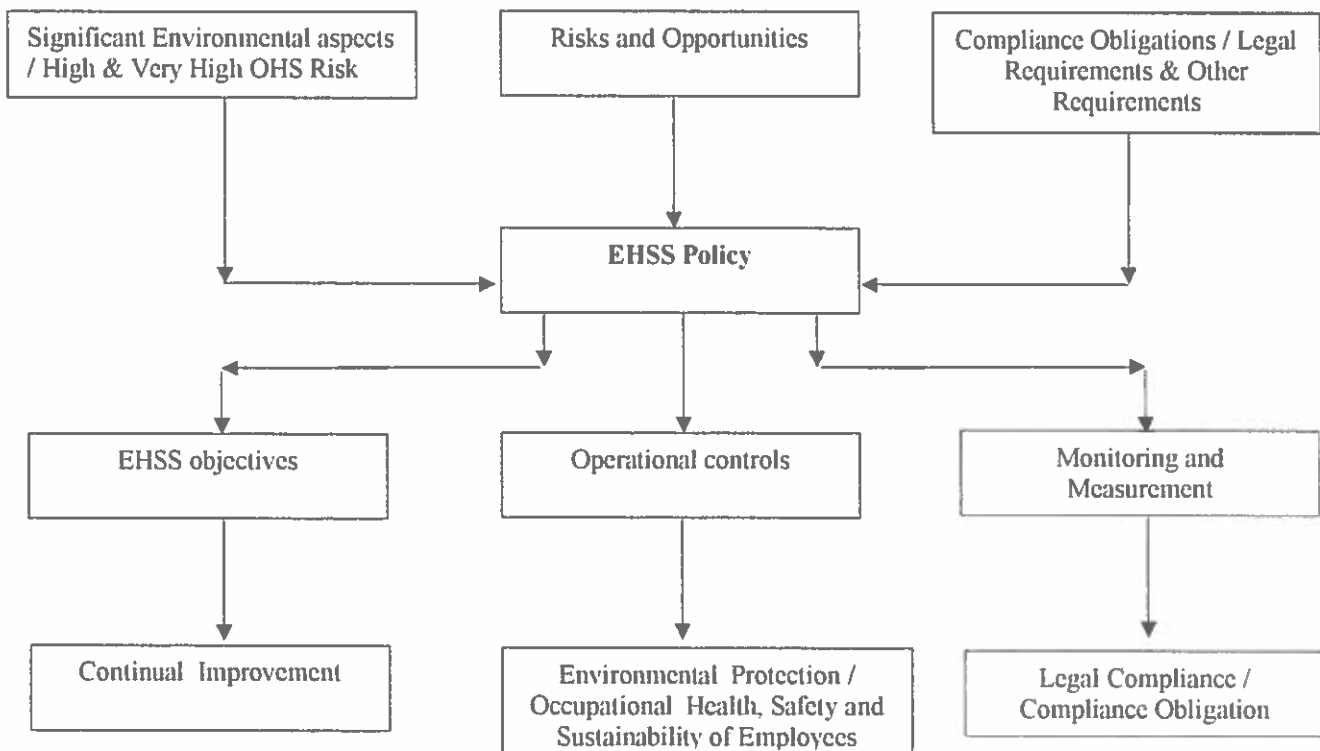
Syngene has developed an Environment Health Safety & Sustainability Policy that defines the top management’s commitment towards environmental protection, enhancement of the EHSS performance and prevention of injury and ill Health and to provide safe & healthy workplace to its employees.

Policy also focusses on Internal and External Issues, Legal requirements and other requirements / Compliance Obligations, Trainings, Energy Conservations, life cycle perspectives, Sustainable Development, Climate change protection of biodiversity ecosystems and its restoration.

Environment, Occupational Health, Safety & Sustainability Policy has been displayed and circulated to all the employees across the Company for their awareness. EHSS Policy is communicated to the interested parties by displaying it at the entrance areas (security gate) and by way of external communication to the suppliers and customers. EHSS Policy is published in company web site <https://www.syngeneintl.com> (URL [EHS Policy 2019-eng-kan.cdr \(syngeneintl.com\)](https://www.syngeneintl.com)) for communication to all concerned parties. Policy copy is circulated to all stakeholders, vendors, suppliers and interested parties and are expected to adhere and abide by the EHSS Policy.

The policy is reviewed and changes are made as and when required (for example: changes in the standards/ compliance obligation / Legal requirement and amendments if any).

Policy Deployment plan is as below:



Reference Clauses:

5.2 Environment Policy (ISO 14001: 2015)

4.2 Occupational Health and Safety Policy (ISO 45001: 2018)

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13. UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

(Clause 4.1 ISO 14001:2015, ISO 45001:2018)

Syngene located at Biocon park located in Jigani Link Road holds a major portion in 87 acres, Syngene Unit 2 located at Bommasandra is around 1.2 acres and Syngene Clinical Development located at Electronic city is around 0.7 acres.

Syngene International Limited (Syngene) is engaged in business of contract research & manufacturing in drug discovery while Syngene Clinical Development is in clinical development space which is located at Electronic city. The Unit 2 of Syngene is located in Bommasandra Industrial Area.

The Facility comprises of:

- Extraction
- Purification
- Milling and Drying
- Quality Analysis
- Packing
- Distribution
- Animal studies (Vivarium)
- Contract research (Syngene)
- Clinical trials (Clinical development)

Syngene has a strong scientific talent base and world-class manufacturing facilities, which produces biopharmaceuticals and biologics. Our manufacturing facilities are approved by international regulatory agencies. We possess state-of the-art manufacturing facilities required for API, Biosimilars, Branded formulation production and MAb research etc. Our manufacturing facilities are designed to comply with stringent cGMP standards and are supported by state-of-the-art process development and quality control laboratories and has an efficient service infrastructure.

Other functions of the organization are as following:

- Research and Development (Office, R&D Lab)
- Marketing
- Sales
- Quality Assurance
- Quality control
- Central Utilities (cooling towers, Air Compression System, Alternate Power Generators)
- Supply Chain Management (Supplier Development and Procurement)
- Distribution & Logistics
- Warehouse (Storage of RM, Products & consumables)
- Human Resources
- Environment, Health, Safety and Sustainability
- Security and Admin/Facility
- Projects
- Legal
- Finance
- IT

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- Corporate communication
- Commercial
- Regulatory
- Process Engineering
- Biocon Foundation (CSR Wing)

Context of the organization has been classified in the following ways:

- **Internal context:** Activities, products and services within our organization's control or influence that can affect our environmental and OH&S performance.
- **External context:** It includes anything related to political, economic, social, technological, Environmental and legal issues.
- **Environmental context:** All the environmental aspects that may be susceptible to damage organization's environmental performance.
- **OH&S context:** All OH&S hazards and risks that may be susceptible to damage organization's OH&S performance.

Reference Clauses:

4.1 Understanding the Organization and its context (ISO 14001:2015, ISO 45001:2018)

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14. UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES (Clause 4.2 ISO 14001:2015, ISO 45001:2018)

Syngene has addressed the needs and expectations of its internal interested parties. Employees are considered as internal interested parties.

Syngene has understood and addressed the needs and expectations of its external interested parties. The external interested parties considered are:

- Local Communities / Neighbours (residential areas, neighbouring Industries),
- Karnataka State Pollution Control Board
- Department of factories, boilers, industrial safety & health, Karnataka
- Lake Development Authority
- Karnataka State Fire Emergency Services
- Petroleum & Explosive Safety Organisation - PESO
- Key Business Partners
- Business councils, Confederation of Industries & Industry forums
- Customers (for B2B)
- End Consumers
- Contractors working at the site
- Shareholders
- Non-Profit Organisations/NGOs
- Visitors
- Suppliers
- Media forums/channels
- Auditors and Consultants

The following needs and expectations of the above mentioned interested parties have been considered:

(a) Local Communities / Neighbours: The neighbouring communities and industries expects that, there should not be any operations related to dust, high noise, foul smell, odour release of air pollutants, fire and smoke, toxic gas release, effluent discharge outside the premises and untreated disposal of hazardous waste outside the premises.

Syngene ensures that operational noise is below permissible limit as per state pollution control board norms, disposal of hazardous waste, effluent discharge, air pollutants released is within the limit of pollution control norms. Local community programmes shall be planned in co-ordination with our CSR team.

(b) KSPCB: Compliance Obligations stated through consent for operation (CFO) issued by the Karnataka State Pollution Control Board (KSPCB) for operation of the organisation with special conditions related to manufacturing capacity, consumption of water, generation and release of wastewater, generation and release of air pollutants, usage of fuel, generation and disposal of biomedical, hazardous and non-hazardous waste, plantation of trees, etc.

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(c) Department of Factories, Boilers, Industrial Safety & Health, Karnataka: To protect the interest of the workmen, minimum basic amenities, prevent accidents, occupational diseases that are likely to occur in the course of employment, ensuring conducive safe workplace.

(d) Business councils, Confederation of Industries & Industry forums: Syngene is an active member of the Confederation of Industries and various industry forums. We ensure that during any policy reforms or changes by the Govt. of India, we provide our inputs through these forums.

(e) Customers (For B2B): Syngene supply chain team focuses on use of 'green solvents' that are non-petrochemical based, such as ethanol, for majority of our business units, thereby reducing the dependency on non-renewable forms of energy. Deployment of professional and regulatory compliant logistics providers helps in consolidating solvents deliveries which further helps in achieving reduction in fuel cost per unit of solvent consumed at Syngene. This overall helps in the safe delivery of our products to our customers. To meet the customer's needs we conduct various customer expectations survey. The feedback from the customers will be considered and necessary actions will be taken up.

(f) End Consumer: Usage and disposal of Biopharmaceuticals by the end consumer is communicated through the approved product & patient leaflet which is provided along with the product. The Safety datasheet is also provided along with the product which enables the consumer to understand the storage and disposal of the products.

(g) Contractors working at the site: Our organisation ensures safe working environment for the contract workmen who are working inside our premises. The needs and expectations of the contractors shall be surveyed, and the necessary actions shall be taken.

(h) Non-profit Organisations/NGOs: Our organisation engages with various Non-Profit Organisations/NGOs on CSR activities and campaigns for raising the awareness on environmental stewardship to neighbours, residents and nearby industries

(i) Suppliers: Syngene ensures to comply with all applicable laws and regulations protecting the environment and OH&S, continuously improve the resource efficiency, and not adversely affect the local community. Syngene shall ensure a safe and healthy workplace for all its suppliers and vendors.

(j) Media: Syngene will maintain a transparent and accurate disclosure of environmental and OH&S issues (if any) to all the stakeholders and will also ensure corporate responsible citizenship & stewardship.

(k) Society: Syngene ensures that the operational noise is within the standard requirement and disposal of hazardous waste, effluent discharge, air pollutants release is within the limit of pollution control norms without impacting the society and environment. Syngene will ensure safe development and manufacture of products and services. Continual improvement has been shared through Annual report as well as Annual General Body meeting annually.

(l) Visitors: Syngene maintain their workplace in a healthy and safe manner. Syngene also provide appropriate PPEs to the visitors during their visits to the Factory.

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(m) Pandemic Response- covers workers and other interested parties.

The needs and expectations of workers and other interested parties has been considered. Syngene considers all the needs and expectations of workers which will have direct needs, concerns, and expectations with regard to pandemics, also stakeholders such as patients, clients, suppliers, public, and even health authorities and regulators. Additionally, with pandemics, it will be necessary to consider families, particularly those with vulnerable dependents who may be at increased risk of becoming infected or may require extended care if they become ill.

Reference Clauses:

4.2 Understanding the needs and expectations of interested parties (ISO 14001:2015).

4.2 Understanding the needs and expectations of workers and other interested parties (ISO 45001:2018)

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15. ENVIRONMENTAL MANAGEMENT SYSTEM (EMS) & OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM (OHSMS) REQUIREMENTS

Syngene has established an Environmental Management System and an Occupational Health, Safety and Sustainability Management System for management of significant environmental aspects, hazards, risks and opportunities to meet compliance obligations, legal requirements and other requirements for enhancing our environmental & safety performance. The EHSS Management System is established in accordance with requirements of ISO 14001: 2015 standard & ISO 45001:2018 standard.

The EHSS requirements of the organisation are detailed in the Manual:

- Scope of EHSS has been defined by the Top Management.
- Environmental, Sustainability, OH&S Policy as comprehensive EHSS Policy (Environment Health Safety & Sustainability) has been framed and communicated to all the relevant personnel, stakeholders and Interested parties.
- Syngene continually monitor and periodically review and respond to changing external and internal issues.
- Environmental aspect-impact study and Hazard Identification & Risk Assessment has been carried out for all activities, products and service that it can control and those that it can influence.
- Environmental, sustainability, OH&S Objectives have been set for all relevant functions. Resources have been provided as required.
- Top Management takes a leading role in improving environmental and OH&S performance of the organisation.
- Organizational Roles, Responsibilities and Authorities have been defined across the organisation at all levels.
- Competence and awareness related trainings has been imparted to all concerned and is a part of continuous process.
- Communication is made through e-mails within the organisation. Adequate EMS and OH&S documentation has been developed. Appropriate Operational controls have been established to manage significant aspects, hazards & risks, compliance obligations and risk and opportunity. Controlling or influencing the products and services are designed, manufactured, distributed, used and disposed considering the life cycle perspective.
- Monitoring, measurement and evaluation systems has been established. EMS & OH&S implementation is being checked through internal audits. Top Management reviews EMS & OH&S implementation periodically and actions are taken for the gaps identified leading to continual improvement of EMS and OH&S MS. These actions form the Objective, Targets and Management Programmes.
- The Environmental Management system & OH&S Management System is executed through PDCA model

Reference Clauses:

4.4 Environment Management System (ISO 14001:2015)

4.4 OH&S Management System (ISO 45001:2018)

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16. LEADERSHIP AND COMMITMENT (Clause 5.1 ISO 14001:2015, ISO 45001:2018)

Leadership and Commitment

Top Management demonstrates leadership and commitment with respect to the EMS and OHSMS by:

- a) Accountability for effectiveness of Environment Management System and Occupational Health & Safety Management System.
- b) Establishing Environmental and Occupational Health & Safety Policy and Objectives to ensure that they are in line with the strategic direction and context of the Organisation.
- c) Providing adequate resources in the form of latest technology, financial resources, adequate infrastructure and competent manpower for the implementation, maintenance and continual improvement of EMS and OHSMS.
- d) Ensuring that the EMS and OHSMS achieves the intended outcomes such as prevention of pollution, eliminating hazards, reducing risks, protection of environment, providing safe workplace and improving overall Organisation's performance while meeting the compliance obligations.
- e) Supporting the EMS Leader, OHSMS Leader or EHSS Leader, EHSS Committee and HODs for EHSS implementation and maintenance and to demonstrate their leadership as it applies to their areas of responsibility.
- f) Ensuring the integration of EMS and OHSMS requirements into Organization's business processes and strategy.
- g) Promoting continual improvement of environmental management through environmental objectives, green belt development, climate change mitigation, biodiversity, water and energy conservation.
- h) Promoting continual improvement of OHSMS through Safety objectives, workplace safety initiatives, safety trainings, reporting of EHSS events, technological advancements and positive safety culture.
- i) Inculcating and encouraging positive safety culture through various employee engagement initiatives and programs for eg. Observing and celebrating EHSS important days like safety day, environment day etc., Recognizing and rewarding employees for their safety awareness and initiatives, encouraging employees to report unsafe acts/conditions and near-miss and incidents.
- j) Establishing and implementing process for consultation and participation of workers in all EHSS matters. The same is also included in EHSS policy.
- k) Syngene Top management also ensures that roles, responsibilities and authorities are assigned. In relation to pandemics, there may be specific roles, responsibilities and authorities. This may be additional authority provided to line managers to let employees work from home during an incident; liaison with health authorities; or even a specific 'COVID-19' management team bringing together necessary expertise in occupational health, business continuity, communications, operations etc. The risk and opportunities associated with pandemic has been addressed all level of operations.

Reference Clauses:

5.1 Leadership and Commitment (ISO 14001: 2015, ISO 45001: 2018)

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17. RISKS AND OPPORTUNITIES

(Clause 6.1 ISO 14001:2015, ISO 45001:2018)

Syngene has established processes to address risks and opportunities associated with environmental aspects, hazard identification, risk mitigation and risks & opportunities assessments, compliance obligations / Legal requirements, other requirements and other issues identified in the context of the organization, in view of interested parties and the potential emergency situations related to all activities, products and services in order to:

- prevent, or reduce, undesired effects, including the potential for external environmental conditions to affect the Organisation
- give assurance that the EMS and OHSMS can achieve its intended outcomes
- achieve continual improvement in EMS and OHSMS

Potential emergency situations, including those that can have a significant OH&S and environmental impacts have been determined. These have been addressed in On-Site Emergency Plan.

Documented information related to risks and opportunities details the methodology of evaluation of Risk and Opportunity. It shall also detail the risk mitigation and action plan. Risk and Opportunities Register shall be maintained at site.

Function-wise risks and opportunities will be documented in the “Register of Risks and Opportunities”. All the environmental aspects, hazards and risks associated with “opportunities” will be prioritized for improvements through Objectives & Management Programs.

COVID-19 will pose a number of health and safety risks, as well as risks to OH&SMS. Additional risks may arise such as delayed or limited response from emergency services where an incident unrelated to the pandemic arises. Increased handwashing will increase the likelihood of dermatitis. There will also be opportunities such as introducing home working and reducing seasonal flu sickness rates as workers follow improved hygiene routines. Ref: Covid sanitization protocol, Covid Policy

Reference Clauses:

6.1 Actions to address risk and Opportunities (ISO 14001:2015, ISO 45001:2018) Risk and Opportunities Register

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18. ENVIRONMENTAL ASPECTS/ HAZARD IDENTIFICATION, RISK ASSESSMENT AND DETERMINING CONTROL

(Clause 6.1.2 ISO 14001:2015, ISO 45001:2018)

Syngene has established a procedure on Aspect – Impact assessment through risk based approach to identify the environmental aspects of its activities, products and services within defined scope of EHSS management system that it can control and those that it can influence taking into account planned / new developments, new or modified activities, products and services, abnormal conditions, potential environmental emergency situations in order to determine those aspects which have or can have significant impacts on the environment considering life cycle perspective.

Syngene has also established a procedure on hazard Identification and Risk assessment and determining Controls to identify hazards, assess risk – determine and implement necessary control measures. This is inclusive of routine and non-routine activities; activities of all personnel having access to the workplace (including subcontractors and visitors); facilities at the workplace, whether provided by the organization or others and service providers.

These procedures are established which explains criteria and methodology for determination of significant environmental aspects, which will have significant environmental impacts. These aspects, inclusive of those arising from works carried out by contractors / sub-contractors are documented in "Aspect – Impact Register". The significant environmental aspects are extracted from these Registers and listed separately in "List of Significant Environmental Aspects".

These procedures are established which explains criteria and methodology for determination of high & very high risks, which will have impact on Occupational Health and Safety. These hazards & Risks inclusive of those arising from works carried out by contractors / sub-contractors are documented in "HIRA Register". The High Risks are extracted from these Registers and listed separately in "List of High and Very High Risk".

The aspect - impact; hazard - risk analysis register is available at relevant departments. The information shall be kept updated as and when required. The Register is reviewed once in six months or whenever there is any change in product, process or equipment. The significant aspects and unacceptable hazards are taken into account in establishing, implementing and maintaining the EHSS Control procedures, Objectives, targets, management Programmes and as an EHSS management system performance indicator.

Reference Clauses:

6.1.2 Environmental aspects (ISO 14001: 2015)

6.1.2 Hazard Identification and assessment of risks and opportunities (ISO 45001:2018)

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19. LEGAL REQUIREMENTS AND OTHER REQUIREMENT / COMPLIANCE OBLIGATION

(Clause 6.1.3 ISO 45001:2018, Clause 6.1.3 ISO 14001:2015)

Legislation and regulations that apply to actual or potential environmental impacts, occupational health and safety hazards and risks of the organization have been identified. It includes internal, national, regional and local laws that are relevant to the organization in which the Company operates.

A Procedure / Documented information has been established for determination of compliance obligations and Legal requirements & other requirements related to the environmental aspects, hazards and risks of our activities, products and services. The Procedure also details the process of having access to these compliance obligations. It explains how these compliance obligations apply to our activities. These compliance obligations have been considered while establishing, implementing, maintaining and continually improving EHSS. Applicable legal requirements and other requirements / Compliance Obligations, compliance obligation register are reviewed once in six months and need basis (any changes in the statutory requirement/ new amendments etc) and communicated to relevant departments. Information is communicated to relevant interested parties and internally to provide an awareness of legal obligations.

Compliance Management system Tool has been developed to monitor the Legal compliance periodically and it comprises of act / rule, requirement, frequency, license / consent no., Inspections, validity, date of renewal, responsibility for relevant act / rule that Syngene's all sites comply. The act / rule has been evaluated and the same is indicated in the legal register.

Other requirements comprise of cGMP requirements (in relevant areas) and non-regulatory guidelines. Collaborator or customer requirements pertaining to EHSS issues will be addressed and same will be communicated. This is addressed by concerned department liaising with Quality Assurance and EHSS departments. Below is the list of other requirements pertaining to Syngene operations and activities:

- a) cGMP requirements laid down by Quality Assurance Team (Current Good Manufacturing Practices)
- b) GLP (Good Laboratory Practices) requirements laid by Quality Assurance Team
- c) Code of Conduct policy requirements laid down by Syngene
- d) ISMS requirements (Information Security management System)
- e) MOU requirements with Lake Development Authority of Karnataka, District Magistrate and Panchayat
- f) ISPE Guidelines
- g) PSCI requirements laid down by our B2B customers (Pharmaceutical Supply Chain Initiative)
- h) MOU on Emergency support and services with the neighbouring industries (Mutual Aid Agreement)
- i) Membership requirements and Tax Returns with ELTIA (Electronic City Industrial Township Authority)

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- j) Membership requirements with CII GreeCo Forum, FICCI, TERI, Bommasandra Industry Association and National Safety Council
- k) Site insurance related Safety requirements laid down by Marsh Consultancy Services
- l) Highway median irrigation related requirements by National Highway Authority of India
- m) AAALAC International - Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) requirements for Vivarium.
- n) CAP – The College of American Pathology (CAP) requirements for Clinical Laboratories.

Applicable legal and other requirements are considered for any new or modified activities, products and services; this is done by concerned department liaising with Quality Assurance and EHSS departments.

Any changes and new amendment will be routed to Risk Manager, and he / she shall carryout changes in Compliance Management system Tool and accordingly update legal requirements and other requirements / Compliance Obligation in Compliance Management system Tool and Liasoning with relevant authorities as indicated below:

- KSPCB, CPCB & MoEF: EHSS department, Legal Department
- Factories inspector: Legal, HR & Administration department and EHSS
- Labour department: HR Department
- Boiler Inspectorate, Electrical inspectorate, Chief controller of Explosives: Utilities and Maintenance department
- Food Safety and Standards Authority of India (FSSAI): Administration Department
- Other requirements: Concerned department liaising with Quality Assurance, Strategic Sourcing, Commercial and Admin department and EHSS department

The respective department head is responsible for compliance to above-mentioned requirements. EHSS leader is responsible to monitor compliance pertaining to legal requirements. All Compliance obligation will result into Risk and Opportunity.

Reference Clauses:

- 6.1.3 Compliance Obligations (ISO 14001:2015)
- 6.1.3 Determination of legal requirements and other requirements (ISO 45001:2018)

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20. PLANNING ACTION

(Clause 6.1.4 ISO 45001:2018, ISO 14001:2015)

Actions are planned to address:

- Significant environmental aspects
- Legal requirements and other requirements, Compliance obligations
- High & Very High OH&S Risks
- Risks and opportunities
- Preparedness and Response to emergency situations

These actions are planned through:

- Operational Controls
- Environment and Occupational Health & Safety Objectives and Management Programmes
- On-Site Emergency Plan
- Environmental Monitoring and measurement
- Hazard identification and Risk assessment on Risk based Opportunity
- Aspect - Impact Assessment and Risk based Opportunity Register
- Pandemic Response

While planning the actions, consideration is given to the technological options, financial, operational and business requirements. All the planning actions are by and large based on the Planning forecaste document prepared by EHSS Leader. It shall ensure that these actions are integrated into various EMS, OHSMS and business processes. Effectiveness of the actions is evaluated through the following:

- Monitoring, measurement, analysis and evaluation of environmental performance
- Evaluation of fulfilment of compliance obligations
- Internal audit of the EHSS management system
- Management Review

Reference Clauses:

6.1.4 Planning Action (ISO 14001:2015, ISO 45001:2018)

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21. OBJECTIVES AND TARGETS AND EHSS MANAGEMENT PROGRAMME(S) (Clause 6.2 ISO 14001:2015, ISO 45001:2018)

Environment, Health, Safety & Sustainability objectives and targets has been established in relevant functions and levels in the organization. These shall be measurable where practicable, and is consistent with EHSS Policy, including a commitment to prevention of pollution, prevention to injury and ill health; to compliance with applicable legal requirement / Compliance Obligation and other requirements to which organization subscribes, and its significant aspects and OH&S hazards & Risks. It is compatible with significant aspects and impacts, health and safety hazards and risks, EHSS Policy, technological options, its financial, operational and overall business objectives and views of interested parties. Implementation of these is co-ordinated through management programs that define responsibility and timeframes for completion.

While identifying EHSS objectives and targets, consideration shall be given to:

- EHSS Policy
- Significant Environment aspects and Risk and opportunity
- Climate change
- Life cycle perspective
- Health and Safety Hazards and Risks and opportunities
- Legal Requirement / Compliance Obligation and Other requirements
- Views of interested parties including the workers and inputs after the workers consultations
- Prevention of pollution
- Natural resources conservation
- Optimum use of raw material
- Emergency Preparedness and Response
- Technological options and the financial, operational and business requirements
- Results of environmental reviews
- Non-Conformity, Actions & Corrective action
- Management Review

Environment, Health, Safety & Sustainability Management Program has been established to manage the implementation, monitoring and accomplishment of EHSS objectives and targets. Management Programmes will consist of the following: All Risk and Opportunity routed through EHSS Management programme and effectiveness will be measured through Monitoring, Measurement and analysis.

- Performance indicator for the Objectives
- Listing of detailed activities
- Listing of Resources required for each activity
- Responsibility for each activity
- Target time frame for each activity
- Status of monitoring of the performance indicator

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- Results of evaluation of the performance indicator
- Conclusion towards achievement of the Objective

Management programmes shall be integrated in day-to-day activity of each Function. It includes:

- The designated responsibility and authority for achievement of objectives and targets at relevant functions and levels of organisation.
- And the means and timeframe by which they are to be achieved.

The progress of Environment, Health, Safety & Sustainability Management Program is reviewed by department heads / relevant EHSS Core team members; it is also reviewed during Management Review meeting. Any deviations shall be identified along with reasons attributed and appropriate corrective actions shall be planned.

Reference Clauses:

6.2.1 Environmental Objectives (ISO 14001:2015)

6.2.1 OH&S Objectives (ISO 45001:2018)

6.1 Actions to address risk and Opportunities (ISO 14001:2015)

6.1 Actions to address risk and Opportunities (ISO 45001:2018)

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22. RESOURCE, ROLES, RESPONSIBILITY AND AUTHORITY (Clause 7.1 ISO 14001:2015, ISO 45001:2018; Clause 5.3 ISO 14001:2015, ISO 45001:2018)

Adequate resources will be provided in form of financial resource, competent human resource, Communication, Equipment, latest appropriate technology and adequate infrastructural support for establishment, implementation, maintenance and continual improvement of EHSS. The top management reviews requirements of resources during each management review.

The Management has defined, documented and communicated responsibilities and authorities of key personnel in order to facilitate effective EHSS Management System.

Organisation Chart has been enclosed as part of Annexure 1 of this Manual. This Chart indicates the reporting structure of the top, middle and lower management.

The CEO of Syngene entities is authorized to activate /close the pandemic response plan.

The Management has given a responsibility of implementation of ISO 14001: 2015 and ISO 45001: 2018 to Head – EHSS and he shall also be designated as EHSS Leader. Responsibilities and authorities of key personnel have been defined below:

Management System responsibilities (EMS & OHSMS)	Person Responsible
Establish overall direction	Chief Operating Officer (COO), Managing Director (MD)
Develop Environment, Health, Safety & Sustainability Policy	Chief Operating Officer (COO), Managing Director (MD), EHSS Leader
Identification of Environmental & Safety objectives and processes	EHSS Leader, All department Head's
Consider environmental aspects, Hazards and risks during design processes and consideration through Life cycle perspective	R&D, Production
Preparation of AIM and HIRA register	All departments in coordination with EHSS
Monitor overall EMS performance	EHSS Leader, Environmental Manager
Monitor overall OHSMS performance	EHSS Leader, Line Manager & Safety Manager
Adherence and fulfilment of compliance Obligation and Legal Requirements & Other Requirements	EHSS Leader, All department Head's
Review of EHSS Management Programme(s)	Concerned HOD, EHSS Core team and EHSS Leader
Definition of Roles, Responsibilities and Authorities of departmental personnel	Concerned HOD
Provision of adequate Resources	Concerned HOD

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Organisation of Induction training, Environmental, Health, Safety & Sustainability Management System Awareness Training	HR, EHSS
Identification of training needs; defining the competence requirement (if required) and imparting training for relevant department procedures	Concerned HOD

Management System responsibilities (EMS and OHSMS)	Person Responsible
Maintaining Risk and Opportunity Register	Concerned HOD
Internal communication pertaining to EMS and OHSMS	EHSS Leader
External communication pertaining to EMS and OHSMS	EHSS Leader, Factory Manager, HR, Corporate Communication, Legal
Promote continual improvement	Concerned HOD
Identification of customers' expectations	Strategic Sourcing, Business Development Team
Identification of requirements for suppliers and criteria for procurement	Strategic Sourcing
Maintaining accounting processes	Finance
Conform to EMS and OHSMS requirements	All persons working under the organization's control
Review operation of EMS and OHSMS	Top Management
Management Review	Top Management, EHSS Leader
Information Security Management System	IT, Concerned HOD, HR
Management System Internal audit	EHSS Leader
Approval of All EMS and OHSMS Documents	Head EHSS / EHSS Leader
Energy conservation	Utility/Energy Manager
Statutory requirements (Factories act 1948 and KFR 1969)	Factory Manager and Occupier
Analysis of Occupational illness	Occupational Health advisor and Factory Medical Officer

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Document Control <ul style="list-style-type: none"> • EHSS Manual • Operational Control Procedures, SOP, IOP, EOP and other related procedures • Work Instructions, formats • Documents of external origin 	EHSS Leader QA, IT Concerned HOD Concerned HOD Concerned HOD
Complaints from internal and external interested parties: receipt, evaluation and resolution	Head EHSS, EHSS Leader, Legal, Factory Manager
EHSS related Documentation and Records	HODs / EHSS Leader
Develop, review and update Emergency Preparedness and Response procedures	Head - EHSS in consultation with Factory Manager, concerned HOD / EHSS Core team
MOU between the Nearest industries for rendering the Emergency support services	Head EHSS/Legal
Non-conformance, Investigating and Corrective action	Head – EHSS, Concerned /Factory Manager
Pandemic Response Team- Committee	Head of EHSS, HR, IT, Risk and compliance, Admin, clinical Development Head etc
Pandemic Response Coordinator	Management staff and other department heads from time to time

22.1 ROLES AND RESPONSIBILITIES

At Syngene, safety is at the heart of everything we do personally and professionally. Syngene has placed safety at par with business performance with shared responsibility and accountability, including following safety guidelines, procedures and SOPs, in letter and spirit.

Mandatory expectation for all roles as per Syngene safety guidelines

- Overall adherence to safe practices and procedures of oneself and the teams aligned
- Contributing to development of procedures, practices and systems that ensures safe operations and compliance to company’s integrity & quality standards
- Driving a corporate culture that promotes environment, health, safety and sustainability (EHSS) mindset and operational discipline at the workplace at all times.
- Ensuring safety of self, teams and lab/plant by adhering to safety protocols and following environment, health, safety and sustainability (EHSS) requirements at all times in the workplace.
- Ensure all assigned mandatory trainings related to data integrity, health, and safety measures are completed on time by all members of the team including self
- Compliance to Syngene’s quality standards at all times
- Hold self and their teams accountable for the achievement of safety goals
- Govern and Review safety metrics from time to time

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22.1.1 TOP MANAGEMENT (MANAGEMENT COMMITTEE: CHAIRMAN AND MANAGING DIRECTOR, EXECUTIVE DIRECTORS, BOARD OF DIRECTORS, OU HEADS, EHSS LEADER & FACTORY MANAGER)

- Establishment and Review of EHSS Policy and Communication of Policy to relevant Interested Parties
- Ensuring the Policy commitments are complied
- Review of objective and Target
- Review of EHSS performance Indicators
- Review of Incident statistics
- Review of complaints received by the Interested Parties
- Ensuring appropriate resource allocation to enable the effective operation, implementation, maintenance and continual improvement of the EHSS
- Defining the responsibilities and authorities of all employees
- Check effective implementation of ISO 14001: 2015 and ISO 45001: 2018 by conducting management reviews

22.1.2 EHSS LEADER:

Roles: Establish, Implement, maintain and continually improve EHSS Management System

Responsibilities:

- To ensure effective implementation of EHSS Management Standards i.e., ISO 14001 and ISO 45001 in the organization
- To ensure effective implementation of KAVACH standards across the organisation.
- To review and approve EHSS Manual related to EHSS Management Standards
- To review legal Requirement and other requirements and Compliance Obligation of the organization pertaining to EHSS Management System
- To review the Aspect Impact and Hazard Identification and Risk Assessment register
- To Identify Risk and Opportunities for all significant aspects
- To set up Objectives and Targets for the betterment of EHSS Performance
- To review and approve the status of the EHSS Management Programmes
- To impart EHSS Management System awareness to all personnel in the organization
- To review the observations from the Emergency Preparedness and Response and take necessary actions
- Coordinating internal EHSS audits to ensure the EHSS has been properly implemented and maintained;
- To review the observed non-conformities pertaining to EHSS Management System related and the effectiveness of the Corrective action taken for the non-conformities
- To schedule Management Review meetings
- To communicate the overall EHSS Management System performance to the Top Management
- To implement the decisions taken in the Management review

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Authority

- Approving the EHSS Manual, Environmental System Procedures; Compliance Obligations Register and On-Site Emergency Plan
- Approving the Environmental Objectives
- To review high risk & very high risks and significant aspects from HIRA/AIM registers
- To approve the budget for the EHSS Objectives and targets
- To review and sign the EHSS Internal Audit Reports
- To review Monitoring and Measurement details of EHSS
- Final closure of Internal Audit and Operational NCs

22.1.3 SENIOR VICE PRESIDENT/ VICE PRESIDENT:

Roles and Responsibilities:

- To ensure Implementation of EHSS Management System
- To ensure effective implementation of KAVACH standards
- Monitoring of EHSS performance Indicators
- Monitoring of Incident statistics & trends
- Monitoring of complaints received from the Interested Parties

Authority:

- To review Monitoring and Measurement details of EHSS
- To approve the budget for the EHSS Objectives and targets

22.1.4 Factory Manager

Roles and Responsibilities:

- Responsible to maintain all the statutory compliances and correspondence and communication to Dept. of Factories and Boilers.
- Responsible for submission of returns, accident reports etc.
- He is jointly responsible with the occupier in implementing the applicable provisions of the Act

Authority:

- Factory Manager shall have an authority to stop any production/maintenance related activity, if he feels that the method applied / condition for the same is unsafe / not as per the rules and regulations of the applicable statute or as per standard operating procedures.

22.1.5 GENERAL MANAGER/ASSOCIATE VICE PRESIDENT

Roles and Responsibilities:

- To ensure effective implementation of EHSS Management System
- Participate in Management Review Meeting
- To review and act for complaints received from the External parties
- To review and approve budget for objectives and target
- To propose new initiatives to improve the EHSS performance

Authority:

- To review and approval of EHSS Capex

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22.1.6 ASSISTANT GENERAL MANAGER/ SENIOR MANAGER/ SENIOR DIRECTOR Roles and Responsibilities:

- To monitor effective implementation of EHSS Management System
- Participate in Management Review Meeting
- To monitor and act for complaints received from the External parties
- To propose budget for objectives and target
- To participate in review of objectives and Target
- To recommend new initiatives to improve the EHSS performance

22.1.7 DEPARTMENT HEAD (MANAGER/ASSOCIATE MANGER/DEPUTY MANAGER)

Roles and Responsibilities:

- To enhance participation of employees for better implementation of EHSS management systems
- To ensure established procedures and policies of company pertaining to EHSS being followed by subordinates
- Participation in aspect-impact analysis and hazard-risk analysis study
- To prepare management programs pertaining to respective Objectives and targets taken
- Ensure respective legal and other requirements are compiled at every time
- Assessment of training needs of department
- Ensuring the safety norms defined are adhered by department personal
- Participation in safety committee meetings
- Participation in incident investigations
- Ensuring effectiveness of operational control procedures pertaining to significant aspects and high risk and very high risks
- Participation in internal audits related to EHSS management systems
- To ensure all the audit findings are closed within stipulated time
- Ensuring Annual Health Check-up for sub-ordinates
- Participation in emergency preparedness and response drills
- Ensure the adherence to Work Permit System
- Participation in Management review meetings
- To suggest best available technology to improve performance of EHSS for continual improvement
- Liaising with external bodies/entities

Authority:

- To delegate roles and responsibilities in department
- To review and sign the EHSS Violations raised
- To give clearance for those works coming under purview of Work Permit System

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22.1.8 ASSISTANT MANAGER/ SENIOR EXECUTIVES

Roles and Responsibilities:

- To follow established procedures and policies of company pertaining to EHSS
- To adhere to safety norms defined
- To understand implications of not following defined procedures with respect to EHSS and to ensure continual improvement of system
- Participation in Safety Committee meetings
- Participation in EHSS trainings
- To ensure proper maintenance of Emergency safety equipment
- To ensure effectiveness of the action taken or proposed to be taken to prevent personal injuries
- Participation in incident investigation
- To implement, maintain and continually improve Work Permit System
- To co-ordinate in Conducting Emergency Preparedness and Response Mock Drills
- Participation in Internal and External EHSS audits
- To ensure proper disposal of waste and Pest control activities
- To participate in HAZOP study and Risk assessment

Authority:

- To give clearance for those works coming under Work Permit System
- To raise safety violation and comply with safety violation procedure
- To sign gate passes for scrap material
- To check and review Safety Audit requirements
- To give clearance for specific Work Permits
- To cancel work permit

22.1.9 EXECUTIVE/JUNIOR EXECUTIVE/TECHNICIAN

Roles and Responsibilities:

- To follow established procedures and policies of company pertaining to EHSS
- To adhere to safety norms defined
- To understand implications of not following defined procedures with respect to EHSS
- To participate in Safety Committee meetings, Environmental day celebrations, Safety Day celebrations etc.,
- Attend EHSS Trainings and EHSS Induction training programs
- To ensure proper maintenance of Emergency safety Equipment
- To coordinate in investigating cases of industrial diseases contacted and dangerous occurrence
- Adhere to Work Permit System
- Participation in Emergency Preparedness and Response Drills

Authority:

- Empower to stop activities which have potential impact on occupational health, safety and environment

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22.1.10 Legal Department

Roles and Responsibilities:

- To follow established procedures and policies of company pertaining to EHSS
- To adhere to safety norms defined
- To participate in Safety Committee meetings, Environmental day celebrations, Safety Day celebrations etc.,
- Coordination to EHSS to all legal and legislation requirement

Authority:

- Empower to stop activities which have potential impact on occupational health, safety and environment
- Participation in annual health check-up
- Report unsafe conditions/acts, near miss and incident(s) to EHSS department
- To ensure proper segregation of waste

22.1.11 EHSS CORE TEAM

Roles and Responsibilities:

- Ensuring effective implementation of EHSS Management System in the organization.
- Propagating EHSS Management System awareness to all personnel.
- To follow established procedures and policies of company pertaining to EHSS and report on performance to EHSS Leader.
- To ensure that all activities, products and services are listed and related aspects and impacts, hazard and risks are identified.
- To guide personnel during aspect-impact and hazard identification and to identify significant aspects and high risk & very high risks.
- To co-ordinate between EHSS Head, EHSS Leader and respective Department Heads and ensure identification of aspect-impact, hazard identification and risk assessment is periodically reviewed.
- To co-ordinate with Department Head to prepare EHSS management programme (s).
- To co-ordinate status of EHSS Management programme with EHSS Leader.
- To monitor effectiveness of operational control procedure.
- To Identify Potential Emergency situations & ensure preparedness.
- To Ensure Inspection of Emergency safety equipment monthly in co-ordination with EHSS department.
- To Coordinate Emergency Mock Drill and Initiate Corrective actions for the findings.
- To co-ordinate workplace monitoring.
- To monitor usage of first aid medicines.
- To monitor waste segregation and proper disposal.
- To ensure effective usage of PPEs.
- To monitor effectiveness of corrective action(s) proposed for non-conformities.
- To coordinate with internal audits and Incident Investigation.
- To follow up and close observations of Internal Audit.

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Authority:

- Empower to stop activities which have potential impact on occupational health, safety and environment

Reference Clauses:

7.1 Resources (ISO 14001: 2015, ISO 45001:2018)

5.3 Organizational Roles, Responsibilities and Authority (ISO 14001: 2015, ISO 45001: 2018)

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23. COMPETENCE, TRAINING AND AWARENESS

(Clause No. 7.2, 7.3 ISO 14001:2015, ISO 45001:2018)

The company has provided adequate resources in the form of financial resources, competent human resource, latest appropriate technology and adequate infrastructural support for establishment, implementation, maintenance and continual improvement of our EMS. The Management Committee reviews the requirements of resources during each management review.

We shall determine competence of employees and contractors working within scope of EHSS management system in the areas / processes which can cause significant environmental and OH&S impact and / or which can impact compliance obligations of organization, based on appropriate education, training or experience (Refer Manpower Requisition Form).

Wherever, there are gaps found in competence of relevant personnel, appropriate actions shall be taken in form of:

- Provision of fresh or re-fresher trainings (Internal as well as External)
- Swapping of jobs with other competent personnel or through Internal Job Posting
- Hiring or contracting alternative competent personnel
- Evaluation of effectiveness of trainings through demonstrations, participation in emergency preparedness and response drills

Any personnel (employed or on contract) performing tasks for department or on its behalf need to be aware of relevance and importance of their activities and how they contribute to achievement of EHSS objectives and policy. This is done by way of imparting awareness training to all personnel. To ensure and to cover specific training in relevant department, training needs have been mapped accordingly in consultation with department heads.

Procedures are available to ensure that employees and contract personnel at each relevant function and levels are aware of:

- The importance of conformance with EHSS Policy and procedures and with requirements of EHSS management system
- The significant environmental impacts, actual or potential, of their work activities and environmental benefits of improved personnel performance; health and safety consequences, actual or potential, of their work activities and the health and safety benefits of improved personal performance
- All workers are empowered to stop work at any point of time whenever they consider that work situations pose imminent and danger to their life and health. The Safety coordinator along with Line Manager will inspect and ensure that the risks are managed through hierarchy of controls by providing appropriate control measures.
- Their roles and responsibilities in achieving conformance with EHSS Policy and procedures and with requirements of the EHSS management system, including emergency preparedness and response requirements.

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- The potential consequences of deviation from specified operating procedures.
- Their contribution to effectiveness of EHSS management System Standards, including the benefits of enhanced EHSS performance.
- The implications of not conforming to the EHSS management system requirements, including not fulfilling the compliance obligations.
- The necessary resources, competency, awareness, and communication will be required in relation to pandemic has been provided. Addition Facilities has been provided, which includes
 - This may mean additional alcohol-based hand sanitisers,
 - Licences for remote access to computer systems, repatriation mechanisms, access to additional health expertise, emotional and psychological support, etc. Resources, in particular people, should be carefully reviewed.
 - Critical workers should be identified, and implications of their absence assessed. This may include top management, safety critical workers or key contractors. Consideration of emergencies during holidays, shut down or other times when there may be reduced resourcing should also be considered. This should take account of any travel restrictions.
 - Workers who use public transport may not be able to attend work if travel restrictions are in place.
 - Where remote working is required, access to computer systems is prone to outside attacks and threats, especially with regard to fraudulent COVID-19 scams.
 - Syngene has reviewed information security awareness program and ensure necessary resources to provide regular updates / training to everyone working remotely.
 - Provision of additional food counter to maintain social distance
 - Frequent pandemic related communication to all employees through corporate communication.

To ensure accountability and responsibility and for effectiveness in training - identification of training needs; defining the competence requirement (if required) and imparting training for relevant department procedures is responsibility of department head. Training records can be accessed in relevant departments.

Organising new employee Induction training by HR department is a centralized activity. General EHSS related training and awareness is imparted by EHSS department. It is responsibility of Department Head and EHSS core team in the relevant department to ensure that personnel are trained in areas identified in their respective departments and records are maintained by them. EHSS department will provide the training (if required with external intervention) and the records are maintained by them. Planning and organising EHSS Training Programs for all employees as per EHSS SOP: SOP-EHSS-EHSS-0051 and EHSS Employee Training SOP-EHSS-EHSS-0013. Technical Induction Training and Annual Periodic training shall be conducted as per EHSS procedure through LMS (Learning Management System).

Records of competence determination process shall be maintained by concerned Process Owner and a copy will be forwarded to Human Resource department.

Reference Clauses:

7.2 Competence (ISO 14001: 2015), ISO 45001: 2018)

7.3 Awareness (ISO 14001: 2015, ISO 45001: 2018)

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24. COMMUNICATION

(Clause 7.4 ISO 14001:2015, ISO 45001:2018)

To ensure and facilitate effective implementation and maintenance of EHSS system, Communication, Participation and Consultation is essential and encouraged at Syngene A Procedure has been established, implemented and maintained which describes process of internal and external communication relevant to EHSS. This Procedure details information related to what information to be communication, when to communicate, with whom it should be communicated and how it will be communicated. Consideration has been given in process to compliance obligations and reliability of information during internal and external communication.

All internal / external communication relevant to EHSS matters shall be responded as necessary by concerned personnel as defined in Procedure and / or compliance obligations. Records of all types of communication relevant to EHSS shall be retained by concerned personnel as defined in Procedure.

Internal Communication:

Communication internally is through mails, telephones, notice board, training programme, meetings, etc. Internal communications are established between all functions and levels to ensure:

- Understanding of EHSS Policy and objectives
- Feedback of operational experience and performance to management
- Results of audits and reviews
- Environment aspects - impacts and health and safety issues
- All Promotion activates and campaign pertaining to Occupational Health and safety

As a part of proactive internal communication, following EHSS information shall be communicated to Employees and related interested parties such as

- Environmental Health, safety and Sustainability Policy
- Potential Hazards and High & Very high risks
- Environmental Aspects - Impact, Risks and Opportunities
- Compliance Obligations/ Legal requirement
- Environmental Health and Safety Objectives and Action Plans
- Responsibilities and Authorities related to EHSS
- EHSS Training related data
- Operational Control Procedures (SOPs, Guidelines)
- Emergency Preparedness and Response Procedures
- Environmental Health and Safety performance
- Internal Audit Results and Incidents and their Corrective actions
- Outcome of management review
- Environment Day/Safety Day/Fire Services Week/Road Safety Week/Chemical Disaster Prevention Day Celebration

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- Any Changes with respect to Standards, other statutory requirements
- Pandemic response communication
- Internal communication will depend upon suggestions or concerns raised by employees. Records of such communication will be retained.

Modes of Internal Communication

What	To Whom	By Who	Mode	Frequency	Records
Organization Scope	All employees	EHSS Leader	E-mails	As and when required-	Through ISO certification
EHSS Policy	All employees	EHSS Leader	Display Boards Pocket cards	Every time when policy is made or revised	Policy cards Display boards
Potential Hazards and High & Very high risks	HODs	EHSS Leader	Documentation	As and when changes in HIRA	HIRA Register
Significant Environmental aspects, Risk and opportunities	HODs	EHSS Leader	Documented information	As and when changes in AIM	AIM Register
Compliance Obligation / Legal and Other requirement	HODs	EHSS Leader	Trainings / E-mails	As per training Planner	Training Record
Objectives and Targets and performance of EHSS MPs	HODs	EHSS Leader	MRM / Documented Information	As and when the MPs are considered	MRM and Objectives and Target Records
Training	All Employees	EHSS Dept.	Training	As per Training planer	Training Records
EPR	All the Employees	EHSS Leader	Training / Document / E-Mails	As per Training Planner	Training Records
SOPs / OCPs	All Employees	EHSS Leader	Documents	As when the changes made	SOP and OCP Documents
EHSS Audit Results	HODs	EHSS Leader	Audit Report	As scheduled for Internal/ External Audits	Internal and External Audit Reports
Management Review Meeting Minutes	HODs	EHSS Leader	E-Mail	Once in 6 Month as scheduled	MRM record
Incidents and its Investigation	HODs	EHSS Leader	E-Mail / Incident Investigation Reports	As and when there is an Incident	Incident Investigation Reports
Safety committee & canteen Managing committee	HODs	EHSS Leader	E-Mail	Once in 3 months	Attendance & MOM report
POSH committee	Selected committee member	POSH chairman	E-Mail, Company correspondence	Once in 6 months	Attendance & MOM report

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Work permit	All employees	Safety Officer	Documents	As when the changes made	Records of individual Permit
Two-way communication	Between employees & Sr. Management	Employees	Electronic Mail	Not defined	IOM records'
Pandemic related communication	All employees	Corporate communication	E-mails	As and when required-	Nil

External Communication:

External communication systems provide public access to EHSS Policy statement and ensure efficient and constructive response to inquiries and complaints from interested parties. Decisions are recorded for all external communications related to significant environmental aspects, hazard identification, risk assessment and control. Communication channels and methods are built into all procedures to ensure transfer of information and data. Records are maintained for same.

EHSS Leader maintain records of communication. The respective department head (for department listed in table) is responsible for requirements and maintaining records

Modes of External Communication

What	To Whom	By Who	Mode	Frequency	Records
Policy	Customers	EHSS Leader/ Marketing	Letters	Original issue and when revised	Files
	Suppliers	Strategic sourcing	Letters Terms and Conditions. Supplier evaluation form	Every new contract or during change of policy	Files
	Public in the neighbourhood	EHSS Leader	Board in front of the factory	As and when change in the Policy	Display Board
Scope	Public, share Holder and stakeholders	Corporate communication	Published in Syngene Web site	As and when Required	Display on website
Reports as per regulatory requirements	To PCB / Boiler / Factory Inspectors	EHSS Leader, Factory Manager	Reports and Letters	As Specified	File Copies
	To shareholders	Files / Accounts	Annual reports	Once in a year	Annual report
Responding to concerns from interested parties	To public Neighbourhood	EHSS Leader	Publication Media advertising Meetings	Not specified	Copies in file
	Received by organization from any	EHSS Leader Corporate communication	Phone calls Complaint box in front of	-	Compliance Report.

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	interested parties		company Any other Mode		
Pandemic Response	Public, Customers, Suppliers	Corporate Communications	Published in Syngene website	As and when required.	Display on website.

EHSS Core team has been constituted with cross-functional employees of different designation levels. They are involved right from stage of identification of aspects, impacts; hazards and associated risks and managing risks. They also review implementation of recommendations for improving EHSS performances. Various units are inspected, and actual conditions are monitored.

The decisions to improve EHSS taken by team during these inspections are documented and circulated to concerned department head for implementation. EHSS Core team meets at least once a year or as and when required – this includes training for EHSS Core team wherein implementation, trouble shooting, exchange of ideas and other relevant EHSS matters are discussed, and notes exchanged. Any pending issues are communicated to EHSS Leader. If necessary, contractors, subcontractors and relevant external interested parties will be consulted about pertinent EHSS matters to ensure the betterment of company’s overall EHSS performance.

Syngene receives external communication whenever change in new standards, amendments etc from

- Enviro trends Subscription
- Certifying Bodies
- NGOs/Non-Profit Organisations
- Drug controller
- EHSS professional groups
- Through company internal audit groups
- Company Auditing Bodies

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25. CONSULTATION & PARTICIPATION

(Clause 5.4 ISO 45001:2018)

Organisation has set up a process of consultation and participation of workers at various levels which includes:

- Safety Committee meeting (Every Quarter)
- Canteen Committee meeting (Every Quarter)
- Toolbox Talk Meetings (Every Week)
- Contractor Safety Trainings (Every Week)
- Reporting of EHSS events like Unsafe acts/conditions, Near-Miss and accidents
- Great Place to Work initiatives (GPTW)
- Leaders GEMBA walk (Once in a week)
- Risk Assessment activities (HIRA/AIM/PRA/FMEA/JSA etc.)
- Incident investigation and evaluation (Event driven)
- Safety Campaigns and various other employee engagement activities
- Medical surveillance activities (Half yearly and yearly)
- Reward and Recognition programs (Quarterly)
- CSR activities specific to Environment and Safety (Event driven)

External consultation takes place where there are any changes that can impact or affect OH&S & EMS performance. The following are consultancy agencies normally engaged by Syngene.

Name/ Agency	Need of Consultation
OHC consultation	Occupational Medical Officer, Paramedical staffs
Vijayashree Hospital	Referral Hospital for medical and emergency services
Kavery Hospital	Referral Hospital for medical and emergency services
Indian Red cross society, St. Johns Ambulance	First aid training
EHSS Consultants	Inspection, Audit, training and expert opinion
Envirotrend	Legal amendments or any changes in legal and other requirements
National Safety Council	Various OHS trainings and campaigns
Subject Matter Expertise	For water audit, energy audit, fire suppression systems etc
Karnataka Industrial Association	Any amendment in legal requirements and other requirements
Certification Agencies (TUV Nord/BSI)	For any inputs on EHSS-MS, ISMS and BCMS implementation

Reference Clauses:

7.4.1 General (ISO 14001: 2015, ISO 45001: 2018)

7.4.2 Internal Communication (ISO 14001: 2015, ISO 45001: 2018)

7.4.3 External Communication (ISO 14001: 2015, ISO 45001: 2018)

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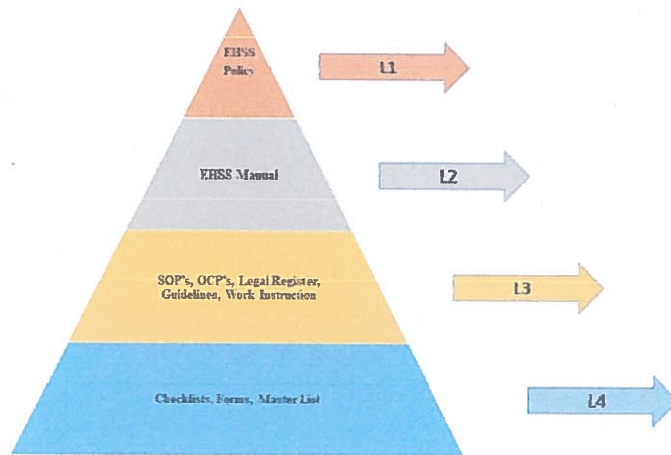
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26. ENVIRONMENT HEALTH, SAFETY AND SAFETY DOCUMENTED INFORMATION & CONTROL OF DOCUMENTED INFORMATION
(Clause 7.5, 7.5.2, 7.5.3 ISO 14001:2015, ISO 45001:2018)

The levels of documentation in our EHSS – MS is as below:



The EHSS Management System documentation and documented information includes:

- The scope of the environment and Occupational Health & Safety Management systems
- EHSS Manual
- Documented statements of EHSS Policy.
- Identified Risk and opportunities
- Environmental aspects, and its impact, significant environmental aspects
- EHSS Objectives and Targets
- Legal Register / Compliance Management System
- Relevant documented procedures required by ISO 14001:2015 and ISO 45001:2018 and these procedures are established, documented, implemented and maintained.
- Procedure related to operational control process to meet EHSS-MS requirements
- Identified Potential Emergency situations
- Documents required by the organization to ensure effective planning, operation and control of its processes
- Records required by ISO 14001:2015 (as documented information as evidence) and ISO 45001:2018 which includes
- Competency matrix
- Internal and external communication records
- Monitoring, measurement, analysis and performance evaluation results
- Compliance evaluation results
- Internal Audit results
- Minutes of Management review
- Results of Actions and Corrective action in case of non-conformity

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- External Documents

To ensure accountability and responsibility and its effectiveness in implementing the EHSS Management system, documents related to the departments are prepared, reviewed and updated by the authorized personnel in the respective departments as per QA procedure. The EHSS manual is approved by the EHSS Leader.

Note:

- EHSS Manual shall be coded as EHSS-XXX/VN
XXX: Manual type such as MSM (Management system Manual)
VN: version number
- EHSS Manual Shall be reviewed at least once in three years or changes in the standard and documents or as and when applicable.

Documents and the documented information's required by the Environment, Health, Safety and Sustainability Management System are controlled.

A documented information / procedure has been established to define controls needed as given below:

- Approval of documents for adequacy prior to use
- Review and update as necessary and approve documents
- Changes and the current revision status of documents are identified
- Relevant versions of applicable documents are available at points of use
- Documents are legible and readily identifiable
- Documents of external origin are identified, and their distribution controlled
- To prevent unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
- Archival documents and data retained for legal or for knowledge preservation purpose are suitably identified

Apart from this, external documents like Supplier Equipment Manuals, Supplier Technical literature and other requirements / protocols, safety data sheets / chemical safety data sheets; permits, licences issued by Government authorities / regulatory authorities / certifying authorities; Procedures and Product Specifications received from Customers as well as National and International Standards come under the purview of document and data control.

Well established procedures exist to control all documents and data related to requirements of ISO 14001:2015 and ISO 45001:2018 including operational control procedures and other relevant procedures available in departments.

The EHSS Management System documentation encompasses five levels as described below.

The document structure is as given below:

- EHSS Policy
- EHSS Manual is the apex document - the EHSS Management System of the company is defined in this EHSS Manual
- Mandatory documents (procedures) required by ISO 14001:2015 and ISO 45001:2018 addressing relevant clauses; documents (procedures) required by the relevant department

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(process) to address the activities in the department (these procedures are department specific).

- Work instructions, checklists
- Documented Information

EHSS Manual:

- The EHSS Manual is available on the Syngconnect (Intranet) to all the personnel in the Organisation. All employees of organisation have Read Only Access for this Manual. The updated and current version is uploaded and made available every year.
- The EHSS Manual is a compilation of different sections pertaining to ISO 14001:2015 and ISO 45001:2018 std.
- The EHSS Manual is structured as shown in contents of this Manual. Different chapters are arranged under different sections. The Sections are numbered serially along with ISO standard clauses.
- Second page of Hard Copy carries signature of person who has Prepared, Checked and Approved the Manual. Soft copy of Manual also contains same except signature of authorized personnel. Each section of manual carries version Number and Effective date.
- Control of document is maintained as Hard Copy as per QA procedure by the EHSS dept.; EHSS Manual is also available in SyngConnect and it is controlled by way of access control - wherein everyone has read access and administrator from EHSS shall have Read & Edit access. The administrator is by default EHSS Leader and his delegate.
- The edit access is restricted to EHSS Leader and delegate user who is authorized by EHSS Leader.
- The EHSS Manual amendments (revisions / changes) are made only by EHSS Leader who has edit, create and amend access to EHSS Manual. Amendments shall be listed in amendment sheet of Manual and revisions are recorded and dated as per QA procedure. The amended copy shall be issued to EHSS Leader, which is made available to Auditor when required.
- To safeguard EHSS Manual from accidental erasures and data corruption, the IT department takes backups once a month. The information security is in line with the ISMS requirements.
- Annexures, supporting documents of EHSS Manual can be Read, Edited or Created by initiating Change Control as per Annexure 6

Creating, Updating and Control of Documented Information is governed by the protocols below:

- Documents shall be reviewed, revised as necessary and approved for adequacy by authorized personnel;
- Documents of external origin determined by the Syngene to be necessary for planning and operation of EHSS are identified and their distribution controlled;
- Obsolete documents shall be promptly removed from all points of issue and use, or are otherwise assured against unintended use; and

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- Any obsolete documents retained for legal and / or knowledge preservation purposes shall be suitably identified.

Documents, work instructions, checklists:

- Documents required by this international standard as well as that of department (inclusive of work instructions and checklists) are prepared as per 'Document preparation and control in EDMS and Manual' (SOP-EHSS-EHSS-0027)
- These procedures address approval of documents for adequacy prior to use, review and update as necessary and re-approve documents, changes and current revision status of documents are identified, relevant versions of applicable documents are available at points of use, documents are legible and readily identifiable, documents of external origin are identified, and their distribution controlled, to prevent unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

CONTROL OF DOCUMENTED INFORMATION

Procedure for identification, maintenance and disposition of EHSS documented information is available. Training records, internal audit records and reviews come under its preview.

Following are covered in record management:

- Record legibility, identification and traceability to the activities involved.
- Storage and maintenance to ensure easy retrievability and to protect against damage, deterioration or loss; retention time have been established and recorded

Documented information are maintained as appropriate to system and to organization and to demonstrate conformance to ISO 14001:2015 and ISO 45001:2018 standards.

With reference to this EHSS Manual, the details of the documented information maintained are listed in Annexure 4: External Origin Documents, Records, and its Retention Period

Responsibilities:

- EHSS Leader
- Head - EHSS
- Department Heads

Cross Reference:

- Procedure for control of records
- Master list of records in all the departments

Documented Information:

Documented information maintained in all the departments (Measurement and monitoring documented information, Audit documented information and other relevant documented information)

Annexure 4: External Origin Documents, Records, and its Retention Period

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Reference Clause:

7.5 Documented Information (ISO 14001: 2015, ISO 45001: 2018)

7.5.1 General – Documented Information (ISO 14001: 2015, ISO 45001: 2018)

7.5.2 Creating and Updating (ISO 14001: 2015, ISO 45001: 2018)

7.5.3 Control of documented information (ISO 14001 :2015, ISO 45001: 2018)

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27. MANAGEMENT OF CHANGE

(Clause 8.1.3 ISO 45001:2018)

Management of Change is applicable to new and existing documents, procedures, equipment/instruments, workplace/facilities and surrounding, working conditions, workforce comprising of workers & contractors utilities, molecules, engineering batches, pre-validation batches which are manufactured at production and all changes in process steps, Batch manufacturing records, packaging, specifications, material management, vendor management, product labelling and contractors which has any impact on Quality systems, product quality, GMP requirements and EHSS Management system.

The Management of Change process shall be followed in order to manage variations in operational risks (OHSMS risks, hazards, significant aspects and impacts) resulting from deviations/significant change, which are not addressed by any of the existing SOPs and documented information.

In general, all changes whether temporary or permanent which have potential to impact quality of a material/product, quality systems and EHSS Management system is controlled as per Management of change process (also called as Change Control) in order to:

- a) Safeguard quality, safety and efficacy of the products
- b) Ensure compliance with the legal requirements and other requirements
- c) Ensure that any technological advancements or change with respect to information about hazards, OHS risks and signification environmental aspects and their impact is communicated to all stakeholders involved
- d) Provide traceability of changes made throughout life cycle of the material, product, equipment, process and facility
- e) Ensure that associated environmental aspects, its impacts and OHS risks associated with the implementation of changes are evaluated and controlled

There are two categories of changes at Syngene viz. temporary change and Permanent Change.

- a) Temporary Change – are changes for a specified duration where changes are approved prior to change being temporarily implemented with the intention of returning the system to its previous state. Temporary changes are only for a specified period. The evaluation of impact on QMS, EMS & OHSMS shall be the same as for any permanent change conditions. For e.g., Temporary modifications in the processing area/facility/utility/equipment/instrument, Process modification as part of any trials or investigation recommendation, change in packaging procedures, Work permit extension for critical activities etc.
- b) Permanent Change – are the changes made permanently where changes are approved prior to implementation. For e.g., Change in facility design/layout, change in manufacturing location, changes in equipment and its accessories, changes in process for any new product introduction or any associated activities, changes in materials and vendors, changes in product testing, changes in the documentation.

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The impact evaluation will be done by conducting applicable Risk assessment exercises such HIRA, AIM, JHA, PSM studies, WHRA studies, Product stability tests, powder testing etc. These impact evaluations are conducted by a Cross Functional Team comprising of Production, Utility, EHSS, Projects, R&D, Quality, SCM/Procurement, Regulatory and Process Engineering Teams. The cross functional team is selected based on the CFT matrix by QA team

After impact assessment change control is approved by site QA- Head/designee or Corporate QA Head/designee. Post approval, execution of changes shall be done by implementing all necessary requirements/recommendations. Our organization reviews consequences of changes, actions and corrective actions as necessary. All such change translates into risk and opportunities.

Reference Clause:

- 8.1.3 Management of Change (ISO 45001: 2018)
- ICH Q7 Guidelines
- 21 CFR 211 cGMP for finished pharmaceuticals

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28. OPERATIONAL PLANNING & CONTROL (Clause 8.1 ISO 14001:2015, ISO 45001:2018)

Operations and activities that have a significant environmental aspect, its associated environmental impacts, OHS hazards and High & very high OHS risk to the personnel shall be identified by the concerned Department Head / EHSS Core team.

Operational Controls shall be determined by following the hierarchy of controls mentioned below:

- Elimination: Elimination of the environmental aspects / OHS Hazards
- Substitution: Substituting the Occupational Hazards with low OHS risk / Environmental aspect with a low impact one
- Engineering Controls: Installation of appropriate Engineering Controls as required / Compliance Obligations
- Administrative Controls: Procedural Controls - OCPs, Signages, Guidelines, Instructions, SDS, Supervision, Visual display and close Monitoring and Measurement.
- Personal Protective Equipment.

Operational Control is combination of Engineering Controls as well as Administrative Controls or at minimum Administrative Controls / PPEs which shall be available for each operation having a significant environmental impact / High OHS risk & Very high OHS risk. Operational Control Procedures shall be prepared to control significant environmental aspects, occupational health and safety risks identified after prioritization by concerned Department Head / EHSS Core team.

All planned changes in activities, products or services shall be controlled through appropriate operational controls as mentioned above in line with identified significant environmental aspect, its impact and high & very high OHS Risks. For unplanned or un-intended changes, appropriate actions shall be taken to mitigate adverse environmental and OHS impact of such changes. We shall also ensure that all outsourced activities are either controlled or influenced to meet EHSS MS requirements.

Operational control procedure can be a separate document or in addition to it, control criteria might be reflected in an SOP / IOP / EOP or any other related document. Where applicable, existing work instructions can be updated to include operation control and operational criteria (e.g. limits of acceptance, values of operating range). Department Heads shall ensure effective implementation of these procedures (OCP /SOP/IOP/EOP) pertaining to their department.

The necessary guidelines related to identified significant environmental aspects/ health and safety hazards of products and services shall be communicated (where required) to the suppliers and contractors via a booklet, or instructions or work permit in consultation with relevant personnel, Top Management and Corporate Communications Department.

We take into account the life cycle perspective to all our products and services starting from design level itself i.e., Research and Development to final product development, manufacturing and its distribution to customers. The Life Cycle assessment manual lays down the procedure to carry out

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the Life cycle perspective of each product and documented information is maintained.

Procedure to access the OCP effectiveness would be

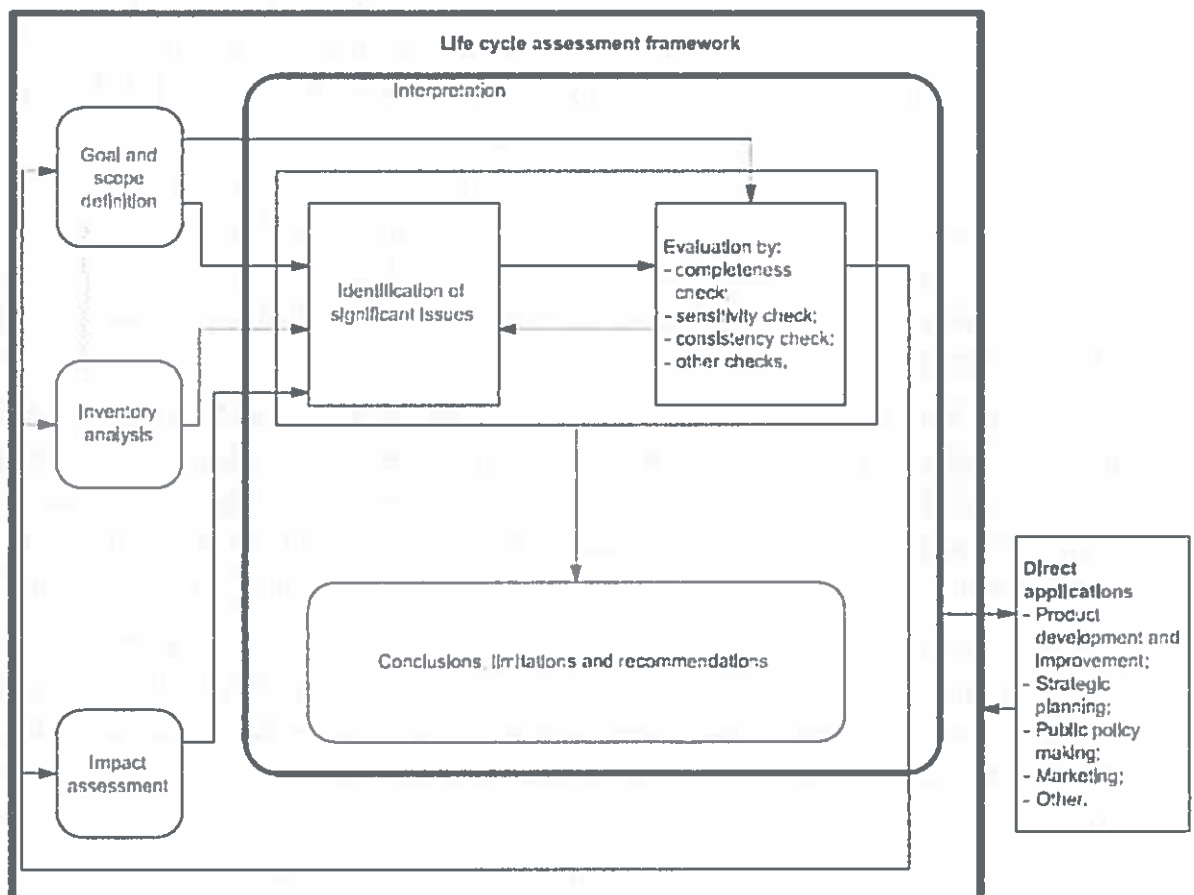
- Number of Near Miss captured with respect to identified significant activity
- Number of Incident in the span of six-month time
- Awareness training with respect to identified OCP to concern department
- Compliance of identified task in the OCP
- Reduction of Risk and Opportunities

All planned changes in activities, products or services shall be controlled through appropriate operational controls as mentioned above in line with identified significant environmental aspect / high risk & very high risk. For un-planned or un-intended changes, appropriate actions shall be taken to mitigate the adverse environmental impact of such changes.

Life Cycle Assessment:

The Life Cycle Assessment concept is considered and applied for all Consecutive and interlinked stages of a product (or service) system, from raw material acquisition or generation from natural resources to final disposal.

LCA Reporting Framework is as below:



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The concept of life cycle assessment to all our products and all components going into product and Outsourced activities. Below mentioned environmental impacts may be considered for LCA:

- Climate change potential: quantification of emitted greenhouse effect gases (Carbon-dioxide, Methane.)
- Natural resources depletion: quantity of consumed raw materials.
- Ozone layer depletion potential: Quantification of polluting gases that provokes ozone layer depletion)
- Acidification potential: quantification of acid potential and its impact of acid rains for example.
- Air emissions from Process / Utilities leading to Air Pollution.
- Wastewater generated from Process / Utilities leading to Water Pollution / Land contamination.
- Hazardous Waste generated from Process / Utilities leading to Land contamination / Water Pollution.
- Impact on procurement and supply chain has been assessed.

Reference Clauses:

- 8.1 Operational Planning and Control (ISO 14001: 2015, ISO 45001: 2018)

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29. EMERGENCY PREPAREDNESS AND RESPONSE

(Clause 8.2 ISO 14001:2015, ISO 45001:2018)

Documented Information / Procedure is available to identify potential Emergency situations and responses to such emergency situations to prevent and mitigate the environmental impacts, OHS risks that may be associated with them.

Emergencies Identified are:

- Fire and Explosion
- Chemical Emergency (Bulk chemical release to environment)
- Electrical Emergency
- Medical Emergencies (Food Poisonings, Endemic infections etc.)
- Emergency scenario in any of the Neighbouring Industries
- Mass vomiting
- Failure of Pollution control equipment at site
- Road transport accidents at public place during the transportation of Biohazards/ Hazardous Waste
- Overflows of effluents from tanks
- Toxic gas release to environment
- Civil unrest riots/Mob attack
- Natural disasters like earthquakes and flooding
- IT related Emergency (Server down/Data loss)
- Pandemic response and preparedness

The emergency preparedness and response procedures is reviewed as and when required and in particular after occurrence of incidents or emergency situations. These are periodically tested whenever practical.

The procedure for Environmental Aspects and HIRA provides information on aspects and impacts, OHS risks and incidents that are significant under accident and emergency conditions. This information is used to focus on priority activities requiring emergency plans.

Emergency planning defines response to accidents and emergencies and measures to prevent or mitigate environmental impact and ensure personnel safety. The plan applies to all operations and all workers/employees and contractors, who are trained in emergency response procedures including periodic EPR mock drills. EHSS Dept. organize periodic trainings to all employees and Emergency responders on Firefighting and First aid through various internal and external agencies like “When It Strikes”, Usha Armour, Indian Red Cross Society, St. John Ambulance etc.

Biocon group has developed an Audio-Visual Safety training module for all the visitors and contractors wherein the necessary information on general safety and emergency procedures are covered. The visitors and contractors are issued the pass only when they complete this training module and sign up the self-declaration column. In addition, Syngene’s safety team also conducts weekly safety and emergency management training for all contractors.

Emergency plans are tested and evaluated by simulated events when possible and reviewed during scheduled internal audit and in an instance if any accident or emergency involving actual or potential environmental impact or personnel health and safety.

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The On-site Emergency Plan (OEP) addresses following:

- Description of expected responses to actual emergency situations.
- Periodical testing of planned response actions through EPR mock drills. EPR Mock drills shall be conducted at planned intervals in premises for each type of potential EHSS emergency. The planning and periodicity of mock drills is explained in On-Site Emergency Plan. Records of EPR mock drills shall be maintained.
- The On-site Emergency Plan (OEP) will be reviewed for any likely changes, after occurrence of an actual environmental emergency or after conduct of any mock drill. Changes, if necessary, will be made in OEP and communicated to all concerned.
- In case of emergency, for swift response unique emergency number for Syngene Site ERT (4001) and for the Group level emergency (2000) shall be used which is connected to top management personnel. They shall respond to emergency as per Emergency preparedness and response procedure.

Reference Clause:

- 8.2 Emergency Preparedness and Response (ISO 14001: 2015, ISO 45001: 2018)

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30. MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION OF EHSS PERFORMANCE

(Clause 9.1 ISO 14001:2015, ISO 45001:2018)

Syngene has developed a documented information for Monitoring, Measurement, Analysis and Evaluation of EHSS Performance. Key characteristics of activities, products and services that relate to significant environmental aspects, OHS risks are monitored and measured (wherever applicable). In particular, performance data is collected and reviewed to confirm legal compliance and monitor achievement of EHSS Policy, objectives and targets. To ensure valid data, all devices used in environmental monitoring and measuring are calibrated and maintained to ensure adequate accuracy of measurement. Monitoring and measurement results are reported to top management by EHSS Leader and used in review of management program(s) to check progress towards achievement of objectives and targets.

The procedure addresses the following:

- The EHSS parameters which is to be monitored and measured.
- The methods of monitoring, measurement, analysis and evaluation, and to ensure valid results.
- The criteria against which EHSS performance will be evaluated along with appropriate indicators.
- The frequency of monitoring and measurement.
- The frequency of analysis and evaluation of monitoring and measurement.

Measurement and monitoring of EHSS Performance indicators includes:

- Compliance Obligation / Legal requirement and other requirement status in terms of stack emission quality, ambient air quality, ambient noise quality and process effluent quality.
- Generation and Disposal of Hazardous waste.
- Monitoring of operational criteria.
- Monitoring progress / status of EHSS objectives.
- Nonconformity, Actions and Corrective actions.
- Periodic Health Checks for personnel involved in critical activities / monitoring health trends for people carrying out critical activities.
- Water consumption details
- Water Quality
- Wastewater generation, treatment & reuse details
- Hazardous waste generation and disposal details
- Environmental monitoring (AAQM, stack, soil monitoring etc.)
- Calibration of Industrial Hygiene Instrument, ETP equipment and instruments
- Workplace monitoring
- Work permit system
- EHSS Consequence Management, Actions and Corrective Actions
- EHSS trainings
- Incident statistics
- Energy Consumption
- Environment Performance communication to internal and external
- Fuel and energy Consumption

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EHSS management programme progress reports shall be established for each objective and target and are set and updated once in month. Effectiveness of operational controls shall be monitored once in six months. All incidents shall be recorded, and investigation shall be done in order to monitor the under lying root causes. Calibration requirements associated with EHSS measurement, and the equipment manufacturer shall determine test equipment. Instrumentation department is responsible for the preparation of in-house calibration schedule and its compliance. Equipment's related to EHSS performance monitoring which needs external calibration shall be monitored by EHSS department and the respective records shall be maintained.

In the event of change in compliance obligation / Legislation, the environment monitoring frequency shall be changed accordingly. The Monitoring and Measurement Plan, Analysis and Evaluation of the parameters with respect to Air, Water, Soil, Safety and Management System requirements shall be maintained in Excel sheet as a soft copy for easy tracking. The trend analysis of evaluation parameters shall be maintained quarterly. Concerned EHSS site in charge shall be responsible for updating of Monitoring and Measurement Plan and its analysis.

The Monitoring and Measurement Plan, Analysis and Performance Evaluation of parameters with respect to Lagging and Leading Indicators for e.g., Work permit System, Monitoring of Operational Controls, EHSS Trainings, Non-conformity, Actions and Corrective Actions, Review of Incident Statistics (Includes Accidents, Unsafe acts/conditions, Near-Miss), Workplace monitoring, PPE availability & adequacy. All Compliance obligations, Legal requirements and other requirements are fulfilled completely. In case of any ambiguity with respect to different legal and other requirements for any geographical location or site, we will follow most stringent norms. We shall always attain 'Beyond Compliance' for any EHSS requirements.

For all identified activities, we perform a through Risk Assessment process. All the identified opportunities translate into the Objectives and Targets for concerned function. Concerned EHSS team shall follow up progress of those objectives and targets and same shall be discussed in safety committee meetings in presence of Operations Head and EHSS Head.

For progress on Objectives and Targets and Effectiveness of Operational controls, we follow PLAN-DO-CHECK-ACT cycle with consultation and participation from workers. For any key decisions pertaining to infrastructure, resource requirements, new technology etc. shall be routed through Top management.

Pandemic response monitoring which considers of three pillars'

Pillar 1: Organization -level coordination, planning, and monitoring

Pillar 2: Risk communication and employee engagement

Pillar 3: Surveillance, rapid response teams and case investigation

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Pillar 1: Organization - level coordination, planning, and monitoring

- ✓ Availability of a trigger for activation and de-activation of a pandemic emergency response (and mechanism for updating)
- ✓ Use of reviews (e.g., through in-action reviews) to strengthen pandemic response
- ✓ Recommended isolation of confirmed and probable COVID-19 cases Quarantine for contacts of cases Quarantine of individuals arriving from countries considered high risk Stay-at-home orders or recommendations Recommended 1m physical distance between individuals in public spaces
- ✓ Interventions in place to restrict use of public transport
- ✓ Interventions in place on closing workplaces
- ✓ Recommendation to use face masks

Pillar 2: Risk communication

- ✓ COVID-19 risk communication plan in place
- ✓ Mechanisms in place to identify and segment specific populations/at risk groups in order to target them with culturally appropriate messages using relevant channels and community networks/influencers
- ✓ Mechanisms in place to provide practical and logistical support to people living in socially vulnerable settings

Pillar 3: Surveillance, rapid response teams and case investigation

- ✓ Surveillance systems in place for comprehensive monitoring of COVID-19 epidemiology
- ✓ Proportion of affected long-term care facilities reporting weekly surveillance data
- ✓ Availability of mobile app(s) to complement manual contact tracing and proportion of population that has downloaded them
- ✓ Proportion of cases where contact tracing is initiated (interview with case by public health authorities) within 24 hours of diagnosis

Reference Clause:

9.1 Monitoring, Measurement, Analysis and performance Evaluation (ISO 14001: 2015, ISO 45001: 2018)

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**31. PROCUREMENT AND OUTSOURCED ACTIVITIES
(Clause 8.1.4 ISO 45001:2018)**

Organisation has defined a procedure for the procurement of all raw materials, equipment, machineries, packing material and process consumables for the operational activities. Syngene has also established processes for the selection of suppliers and contractors for any procurement and outsourced activities. Health and safety evaluation is one of the criteria for selection. Suppliers and Contractors are informed about health and safety specifications and guidelines to be followed by them through EHSS Directive for suppliers and contractors, Purchase Orders, Work Orders, Control Procedures, awareness trainings, SDS, Toolbox talks etc. Performance evaluation of Suppliers and Contractors is carried out periodically by EHSS team to keep a check on their health and safety performance.

Before placing the order, a CFT (Cross Functional Team) assess requirements for any related environmental aspects, its impact and OH&S risks in order to make it at an acceptable level.

The process flow for procurement stage is as below:

- Equipment is delivered according to specification and tested to ensure it works as intended- Through URS
- Installation function as designed- Through DQ (Design Qualification)
- Material is received as per specification –IQ (Installation Qualification) & PQ (Performance Qualification)
- Training on safe work methods about equipment

Outsourced activities and Contractors

Organisation has identified its all outsourced activities as below:

- Treatment and disposal of Hazardous & Non-Hazardous waste
- Employee transportation
- Occupational Health Centre
- Physical Security services
- Project works involving construction & civil fabrication works

Syngene has clearly defined agreement and Terms & Conditions involving Health & Safety criteria for all outsourced activities. All the contractors and suppliers are provided a copy of EHSS policy and the EHSS directive through email communication and in person meetings. A self-declaration and sign off is received by the authorized signatories confirming their acceptance of all the EHSS requirements.

Controls are established for Contractors and workers involved in outsourced activities after identifying hazards and risks prevalent in their activities. Contractors are informed about hazards which their workers might face while carrying out their activities inside factory. Adequate awareness training is imparted to the Contractor’s workforce before inducting them into their work activity. They are also made aware of impact of their activities on organisation and other interested parties or workers at workplace.

Permit to work system for all non-routine activities with high risks has been established such as:

- Working at height
- Working in confined space

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- Working on fragile roof surface
- Electrical work
- Hot work (welding, brazing, etc.)
- Excavation work

Reference Clause:

8.1.4 Procurement (ISO 45001: 2018)

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32. EVALUATION OF COMPLIANCE (Clause 9.1.2 ISO 14001:2015, ISO 45001:2018)

Documented Information / Procedure is available for periodic evaluation of compliance with applicable Compliance Obligation /Legal and Other requirements. The procedure will address the following.

- Responsibility for evaluating compliance obligations / Legal requirements and other requirements.
- Frequency of evaluation.
- Method of evaluation.

The relevant act / rule has been evaluated and the same is indicated in Legal Register / Compliance Management System. An Action Plan will be developed based on Compliance status.

The EHSS Leader review compliance status with Chairman and Managing Director in Management Review meeting. Compliance Obligations / Legal requirements and other requirements related to EHSS are identified as given in SOP: Management of EHSS legal requirement and other Requirements and evaluation of compliance under ISO 14001 and 45001 SOP-EHSS-EHSS-0057.

All applicable Compliance Obligation / Legal requirements and other requirements are integrated in "Enterprise Risk Management". Compliance Management System tool and tool shall be updated as and when any amendment in applicable act or rule.

The Compliance Management tool is designed to track all applicable Legal requirements and other requirements / Compliance Obligations of organization and compliance status shall be updated by authorized responsible user for respective aspect.

The details updated in compliance management system tool shall be verified by Risk Management Team.

Evaluation of compliance to applicable Compliance Obligations / Legal requirements and other requirements shall be verified once in a Month via Compliance Management System tool. Compliance to EHSS legislations with status shall be evaluated as per SOP: SOP-EHSS-EHSS-0057 once in a Month and Checklist shall be amended as and when there is any change pertaining to applicable Compliance Obligation / Legal requirement and other requirement in consultation with Legal and Risk Team.

Reference Clause:

9.1.2 Evaluation of Compliance (ISO 14001: 2015, ISO 45001: 2018)

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**33. INCIDENT, NON-CONFORMITY AND CORRECTIVE ACTION
(Clause 10.2 ISO 14001:2015, ISO 45001:2018)**

Non-conformities shall be issued in the following circumstances:

- Deviation from EHSS Policy requirements
- Non-fulfilment of a requirement specified in the standard (can be identified during document review)
- Non-fulfilment of a requirement specified in EHSS Management System (can be identified during internal EHSS audit)
- Non-fulfilment of compliance obligations / Legal Requirements & Other requirements
- Non-fulfilment of operational control procedures (can be identified during day-to-day operations)
- Deviation from monitoring and measurement of key EHSS performance characteristics

In case of any non-conforming situation as mentioned above, first the non-conformity shall be reported in standard form given in SOP. Non-conformity shall be controlled by taking immediate actions for mitigation. Next step is to investigate and find root cause for non-conforming situation. Root cause determination shall be carried out through why-why analysis methodology. Corrective action shall be devised once root cause is determined to ensure that non-conformity does not re-occur. The planned corrective action shall be implemented, and the effectiveness shall be evaluated accordingly.

Actions to be taken shall be in accordance with significance of the environmental impact and the high & very high risk of non-conforming situation. Actions required for similar type of situations in other areas also shall be implemented and verified for effectiveness. Any changes required to EHSS management system, if necessary, shall be carried out.

Records of non-conformities, immediate actions, mitigation and corrective actions shall be retained by concerned process Heads.

For the purpose of reporting and investigation, incidents have been classified as follows:

- Unsafe act and unsafe condition
- Near miss
- Accidents (Accident categories are as given in table below)
- Environmental Incidents & Emergencies

Criteria for Reporting Near miss are

- Deviation from operating standards beyond a defined safe range
- Failure of Safety Integrity Levels fixed to any equipment or materials
- Leakage or spillage of hazardous chemicals/materials
- Falls and trips without causing an injury

When there is any incident inside a work site, it should be immediately reported to the shift in-charge.

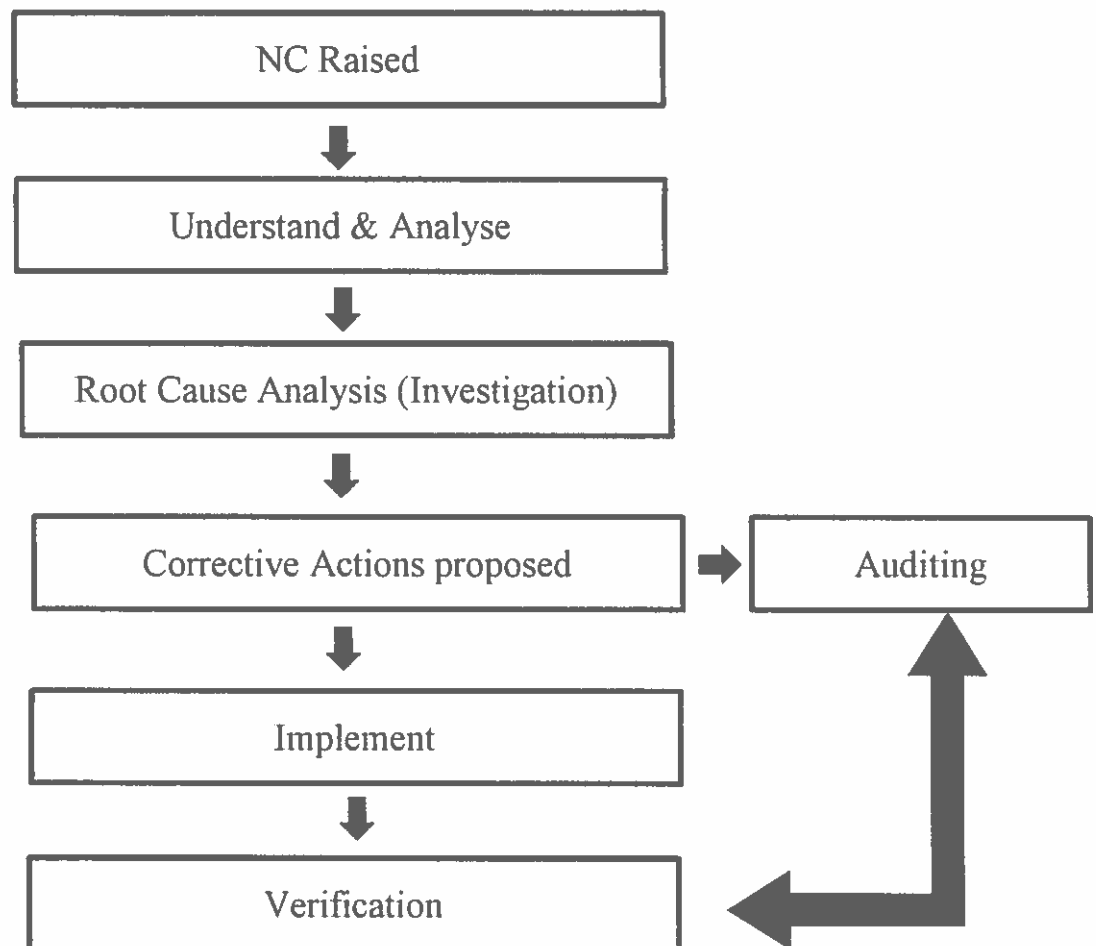
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The shift in-charge shall go to the incident spot and after examining shall inform the department head, unit head and EHSS department about incident in Incident Report. Incident report shall be issued by the concern user department.

The prime purpose of an incident investigation is to establish both immediate and underlying causes of incident to identify actions to prevent any incident that may result from hazard and to correct problem and to prevent reoccurrence. The investigating team consisting of Cross functional department which includes production, maintenance, EHSS, concerned shift in-charge and area employee shall investigate incident. The necessary Corrective action shall be ensured.

Procedure for closing the non-Conformity can be explained as below:



Reference Clause:

- 10.2 Non-conformity and Corrective action (ISO 14001: 2015)
- 10.2 Incident, nonconformity and corrective action (ISO 45001: 2018)

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34. ENVIRONMENT, HEALTH, SAFETY AND SUSTAINABILITY MANAGEMENT SYSTEM AUDIT
(Clause 9.2.2 ISO 14001:2015, ISO 45001:2018)

Audits are an important and comprehensive independent check on implementation and maintenance of Environment, Health, Safety and Sustainability Management System. They are carried out by trained Lead Auditors and Internal Auditors.

Audit checks focus on main issues:

- Conformation to planned arrangements for EHSS management including requirements for EHSS specifications.
- Efficient functioning of management system.
- Achievement of the EHSS Policy and objectives and targets.
- Review of the results of previous audits.
- Provide information on results of audits to management.

The internal audit schedule is based on importance of activity concerned and results of previous audits. Consideration for audit frequency would be:

- Always higher for activities involving significant environmental aspects and OHS risks
- High for activities showing non-conformance, until non-conformance is resolved.

The results of audits are communicated to respective HODs to confirm areas of conformance and to facilitate corrective actions in areas of non-conformance. The EHSS Leader summarizes audit results for Management for consideration at Management Review.

Syngene has established Documented Information for EHSS Internal Audit which covers following:

- Audit criteria
- Audit scope
- Audit frequency
- Audit methods
- Responsibilities for conducting audits
- Audit planning requirements
- Audit reporting requirements

Syngene shall define audit criteria and scope for each audit. Conducting audits and selection of auditors shall be carried out in such a manner that objectivity and impartiality of audit process is maintained. Results of internal audits are in form of Critical, Major and Minor nonconformity and it shall be summarised for each audit and presented to management committee during management review. Details of above process are explained in Document Information and relevant documented information of Internal audit process shall be retained by EHSS Leader. Actions and Corrective actions are taken to address identified non-conformity.

This eventually helps in continually improving EHSS performance. The timely actions and corrective actions are planned which are appropriate to magnitude of problems and

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commensurate with environmental impact encountered. Concerned department head communicates incidental non-conformity(ies) to EHSS – Head in order to assess environmental impacts, OHS risks and other risks, reoccurrence of similar incidents if non-conformities exist.

Actions and Corrective actions for any EHSS nonconformity (ies) shall be through any / all of following:

- Training
- Changes in the documents
- Changes in the technology
- Any other method

The documented information/records of Actions and Corrective Actions and affecting documents along with change details are maintained. The report is submitted to the concerned department head and EHSS Leader which includes the findings and recommendations for corrective actions, and shall ensure its timely implementation through the concerned department heads. The systematic follow-up and effectiveness of action taken shall be ensured during internal audits. All Actions and Corrective Actions shall be reviewed during the EHSS management review meetings.

On the basis of the non-conformity (ies) observed and, environmental impacts and health hazards encountered, the concerned Department Head takes action to mitigate the impact. It is the responsibility of the Head of the Department, EHSS Core team members and EHSS personnel to monitor and review the effectiveness of the implemented Actions and Corrective Actions on a regular basis depending on the severity. EHSS department representative shall review the effectiveness of Actions and Corrective Actions once in a month (if any). During this process, if Actions and Corrective Actions identifies any new impact or change in the identified impact on the environment and/or occupational health and safety hazards or the need for new and changed controls, the procedure shall require that the proposed actions shall be taken through impact and risk assessment prior to implementation.

Any Actions and Corrective Actions taken to eliminate the cause of actual and potential non-conformity (ies) shall be appropriate to the magnitude of problem and consider the severity or degree of impact on the environment and health and safety risk. If any nonconformity observed EHSS Consequence Management shall be issued (Ref: Procedure for EHSS Consequence Management). Customer audit, regulatory audit, statutory inspection conformities shall be discussed to top management and Actions and Corrective Actions shall be proposed accordingly. All the nonconformity shall be discussed in management review meeting.

Reference Clause:

9.2.2 Internal Audit Programme (ISO 14001 : 2015, ISO 45001 : 2018)

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**35. MANAGEMENT REVIEW
(Clause 9.3 ISO 14001:2015, ISO 45001:2018)**

Management review is conducted to review ISO 14001 : 2015 and ISO 45001 : 2018 system effectiveness. Regular management reviews ensure that EHSS management system is suitable, adequate, and effective. This allows top management to assess effectiveness of EHSS management system based on EHSS Policy and EHSS objectives, and to define opportunities for improvement and need for changes.

At Syngene, Management Reviews are held to ensure that Internal Audits are analysed and reviewed; management review is conducted once in six months after completion of each Internal Audit. EHSS Leader shall schedule meeting with top Management which includes Managing Director, Operation Unit Heads, Chief Operating Officer, Vice president and General Managers. The meeting shall be chaired by Chairperson and Managing Director where EHSS Leader presents updates and status of EHSS performance Indicators through power point presentation.

Agenda for management review includes:

- Status of actions from previous management reviews
- Extent to which EHSS Policy and objectives are met
- Changes in external and internal issues relevant to EHSS-MS including needs and expectations of interested parties, legal requirements and other requirements
- Results of Internal audits, Aspect – Impact; Hazard identification and risk assessment
- Risk & opportunities
- Results of participation and Consultation
- Environment, Health, Safety and Sustainability Management Programme (s)
- Legal compliance / Compliance Obligation
- Communication from External Interested Parties including Complaints
- Suitability, adequacy and effectiveness of the EHSS Policy
- Emergency Preparedness and Response
- Status of Incident Investigation, Corrective actions
- Changes that could affect Environment, Health, Safety and Sustainability Management Systems
- Monitoring and Measurement of EHSS Performance
- Recommendations for improvement
- Follow-up actions from previous management reviews

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The outputs of management review shall include decisions of management committee and action plans for following points:

- Status and Action Plan for previous Management Review
- EHSS Performance which includes Monitoring and Measurement, Results of audits and evaluations and fulfilment of compliance obligations
- EHSS Policy and Objective
- Communication from external interested parties
- Decision requirement for internal and external issues
- Significant environmental aspects, OHS risks and its Risk and Opportunity
- Continual improvement pertaining to EHSS
- Resource and its adequacy
- Adequate and effective implementation and Maintenance of EHSS Management System.
- How EHSS can be integrated with other business processes
- Need for any changes

An additional Management Review may be held at any time if special circumstances arise. For example, major restructuring of operations or management responsibilities, new processes that introduce significant new environmental issues or OHS risks or major external concerns arising and potentially affecting interested parties or legal obligations.

EHSS Leader maintains minutes of management reviews in the form of review records compiled and is responsible for coordinating all actions aimed at addressing issues discussed in meeting. EHSS Leader shall be responsible for communicating the outputs of Management reviews to workers.

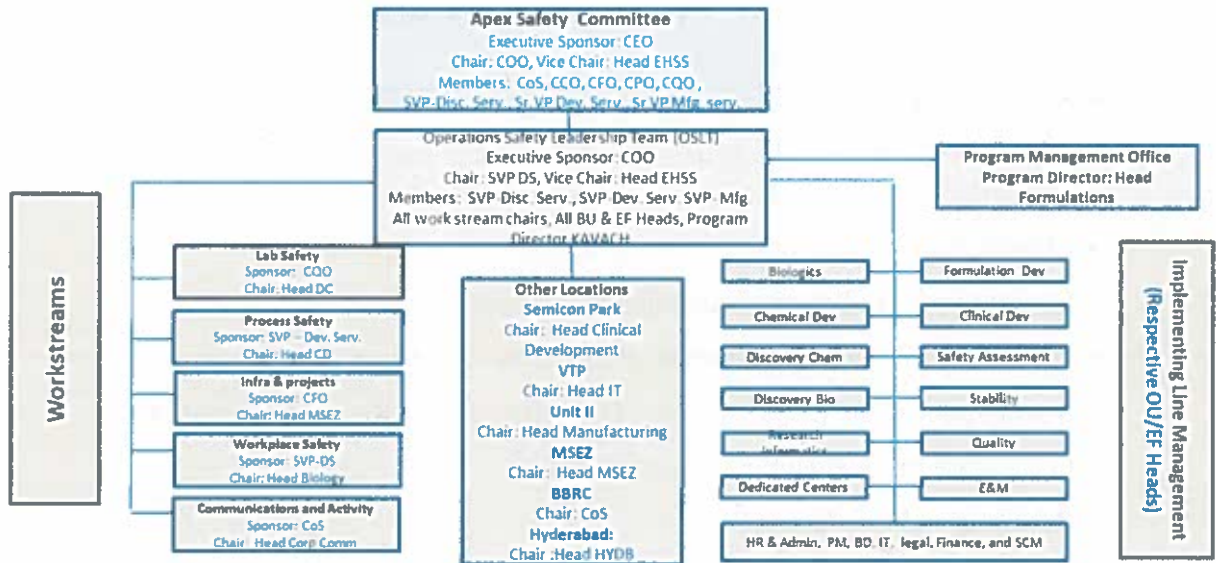
Syngene has a robust safety governance through 3 tiers of management review meetings. Below diagram shows the different tiers of Syngene Safety Council.

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Reference Clause:

- 9.3 Management Review (ISO 14001: 2015, ISO 45001: 2018)

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36. CONTINUAL IMPROVEMENT

Continual improvement in EHSS performance shall be achieved by various functions of Syngene in order to meet requirements of ISO 14001:2015 and ISO 45001: 2018 Standard and EHSS management system.

Continual improvement helps in:

- Enhancing the EHSS performance
- Promotes a positive EHSS culture in the organisation through various dept related management programs on EHSS
- Promotes communication, participation and consultation of workers in various EHSS related implementations

36.1 EHSS Audit

Syngene has established, implemented and maintained a procedure (SOP-EHSS-EHSS-0025) to ensure the internal audits of EHSS management system are conducted at planned intervals to conform its own requirements for its EHSS management system including the EHSS policy, EHSS objectives and the requirements of the documents retained.

Audit program

Syngene has established, implemented and maintained the internal audit program including the frequency, methods, responsibilities, consultation, planning requirements and reporting of internal audits. Taken into the consideration the EHSS importance of the processes involved, concerned changes affecting the organization and the results of previous audits.

Determined internal audit EHSS management system.

- a. Defined the audit criteria and scope for each audit.
- b. Selected auditors and conducted audits to ensure objectivity and impartiality of the audit process.
- c. Ensured that the results of the audits are reported to relevant management
- d. Taken action to address non-conformities and continually improved its EHSS performance.
- e. Retained documented information as evidenced of the implementation of the audit program and the audit result.

Reference Clause:

- 10.3 Continual Improvement (ISO 14001: 2015, ISO 45001: 2018)

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37. LIST OF ANNEXURE

Annexure 1: Organizational Chart

Annexure 2: Process Flow Chart

Annexure 3: Documented Information / Procedures Applicable for ISO 14001: 2015 and ISO 45001: 2018

Annexure 4: External Origin Documents, Records, and its Retention Period

Annexure 5: Internal and External Issues

Annexure 6: Change control for Change control for ISO 14001: 2015 and ISO 45001:2018

End of document
