



EH&S Corporate Standard

**Environmental
Sustainability**

EHS03-S03-02

Environmental Sustainability

Corporate Standard

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1.0 Purpose

Patheon has made a Commitment to *demonstrate Leadership in Environmental Sustainability by minimizing our impact on the environment through the conservation of natural resources and by conducting our business in an environmentally responsible manner*. This document describes the key elements that must be incorporated into an environmental sustainability program to establish priority, execution and alignment with this commitment.

2.0 Scope

This document applies to all Patheon facilities.

3.0 Responsibilities

3.1 Executive Leadership Team

Demonstrate leadership and advocate priority for all of Patheon to align with Environmental Sustainability Vision, Mission and Goals.

3.2 Site Leadership

Provide sufficient resources and support implementation of the standard and program elements described below. Ensure participation in site environmental sustainability program by all employees.

3.3 Corporate EH&S

Provide sufficient resources, support and advocacy at the Executive Committee, Corporate and Site levels to execute a successful environmental sustainability program.

3.4 Sustainability Subject Matter Experts (SME)

Support Corporate EH&S by demonstrating a leadership position in their area of expertise to advance Patheon's Environmental Sustainability Commitment. Develop the global standard for Environmental Sustainability. Provide guidance and support to Global Executive Team, Corporate, and each site regarding design, implementation, or optimization of the environmental sustainability program.

3.5 Site EH&S

Establish new or review existing environmental sustainability programs and ensure consistency with the global standard. Assure appropriate training is conducted for all employees.

3.6 Supervisors

Ensure employees under their supervision are aware and receive training on environmental sustainability program requirements and procedures. Set expectation for all employees' participation.

3.7 Employees

Work in compliance with sustainability program requirements and procedures.

4.0 Key Elements

4.1 Risk Management

4.1.1 Environmental Sustainability Risk Assessment

When quoting, reviewing, or developing a new or modified product, process, facility or equipment the environmental sustainability impact should be assessed. Conduct a risk assessment to determine environmental sustainability impact using the Risk Assessment Tool from Corporate Standard EHS04-S09 (Risk Management) and Corporate Standard EHS04-S02 (EH&S Assessment for New Projects). Controls should be implemented based on the Risk Management Hierarchy:

- Elimination/Substitution
- Engineering Controls
- Awareness Means
- Procedural and Administrative Controls
- Personal Protective Equipment

Update the risk assessment as available information or assumptions (e.g. sold quantities) change.

4.1.2 Site Programs

All programs shall meet local regulatory requirements at a minimum and as required in Corporate Standard EHS03-S02 (Environmental Protection). Sites shall review existing programs and put actions in place to meet the requirements of all elements of this standard. Where programs are not yet in place, programs shall be initiated as per the required elements of this standard.

4.1.3 Monitoring and Measurement

Sites shall put appropriate metrics in place for each element of this standard to demonstrate compliance and improvements to the environmental sustainability.

4.2 Communication

4.2.1 Training

Employees who will be responsible for the implementation of any of the technical elements of the site environmental sustainability program shall be trained appropriately to carry out their functions in a safe and efficient manner, and according to applicable legislation and site/corporate policies, procedures, and standards.

4.2.2 Employee Awareness

All Employees shall be made aware of the current environmental sustainability programs in place at the site, ideally during on-boarding. As new programs are initiated or current programs revised, all employees shall be made aware of the changes that impact their job functions in order to maintain compliance to the program and to improve the overall environmental sustainability of the site.

4.3 Compliance

4.3.1 Documents & Records

Documents and records are to be maintained for each of the elements of this standard according to local legislative requirements. Sites shall maintain adequate records and documentation to demonstrate the level of compliance to this standard, and to monitor continuous improvement initiatives.

4.3.2 Auditing

As per the Auditing Program (*see Corporate Standard EHS04-S07: Auditing Program*) periodic audits must be conducted in order to evaluate compliance with site-specific procedures, corporate standards, and regulatory requirements.

5.0 Specific Requirements

5.1 Administrative Requirements

5.1.1 Programs

Documented programs outlining the required practices to support each of the elements of this standard shall be in place.

5.1.2 Corporate Reporting

As requested from Corporate EH&S, sites shall provide environmental sustainability metrics to comply with requested reporting, webpage posting or for client / public disclosure.

5.2 Program Requirements:

5.2.1 General:

Patheon business processes and manufacturing practices should be designed to ensure the best possible use of all resources. In order to minimize the amount of waste generated, detailed review of processes and maintenance of equipment will ensure maximum efficiency. The following are general components that should be present:

- Consumption of every resource at Patheon facilities must be well managed.
- Build awareness concerning consumption at work and at home.
- Motivate employees to take steps to reduce their consumption (rewards / recognition).
- Seek out best practices and technology related to natural resource conservation.
- Periodic analysis of resource consumption to maintain focus on conservation.
- Report to management on consumption and results of efforts to conserve achieved.

5.2.2 Safety of Chemicals

Where possible, reduce risks by replacing highly hazardous chemical substances with less dangerous substances. Consider all types of hazards (e.g. reactivity, toxicity, mobility, persistence, potential for environmental damage, public acceptance, etc.) and the reliability of the assessment when comparing the substitute chemicals with the initial solution.

Develop processes to ensure safe and correct labeling, transport, storage, handling and disposal of all chemicals, with special emphasis on dangerous goods. Support / comply with national and international risk reduction programs for substances which constitute a threat. Patheon-specific programs for replacing such substances will be set up on a case-by-case basis.

Regularly search for possible synthesis and process improvements and evaluate new technologies. Consider the full life-cycle of these materials (including production, transport, use and disposal). Specifically control specially regulated materials:

- Narcotics and drugs that have the potential of illegal use,
- Environmentally hazardous substances.
- Recycle materials where reasonably possible.

5.2.2 Air Emissions Control

Take the necessary measures according to the following priority list:

- Avoid emitting pollutants to the atmosphere
- Reduce quantities of pollutants.
- Control the remaining pollutant emissions in order to meet all regulatory and corporate standards.
- Maintain a continuous improvement program for production processes (process development).
- Control unavoidable pollutants at the source whenever possible.
- Where applicable pre-treat the waste streams to avoid impairment of the functioning of end-of-pipe equipment and processes.
- Monitor emissions and the corresponding data in accordance with regulatory and corporate standards.

Ensure integrity of installations, thus avoiding contamination. Protect the air from undue contamination, in particular from toxic substances, volatile organic carbon (VOC) compounds, ozone-depleting compounds, greenhouse gases (in particular halogenated hydrocarbons - CFC, HCFC, PFC, HFC), carbon dioxide (CO₂), nitrogen oxides (NO_x), sulfur dioxide (SO₂), dust and particulate matter.

Limit physical effects on air (e.g. heat input or extraction, clouding, noise, light, disturbance of wildlife).

Ensure early detection of leaks. Develop and implement systems and processes to handle situations when leaks occur.

Where necessary, treat waste air in an exhaust air treatment system. Ensure air emission control in case of malfunctioning or outage of such systems. Ensure immediate detection of such situations.

5.2.3 Land/Soil/Waste Management:

Maintain adequate systems, installations and procedures to avoid accidental or insidious contamination of the soil. Avoid landfilling wherever possible.

Initiate a process that generates waste only after determining an acceptable method of re-using, recycling or disposing of the waste. Treat waste and residual materials using the following prioritization methodology (from most preferred to least preferred):

- Reduce the amount of waste generated by a process
- Reuse the waste generated in another process or consider selling these materials as raw materials or for energy recovery.
- Recycle the waste, as far as technically, ecologically (in terms of energy expenditure and generation of further waste) and economically feasible.
- Incinerate with energy recovery
- Incinerate without energy recovery
- Landfill

Collect and identify all waste and residual materials. Separate the materials to assist in their further use or in optimizing waste disposal. Avoid mixing of waste. Safely store and transport wastes according to their hazards

Document type, quality and quantity of all wastes and residual materials and the pathway of their disposal. Ensure safekeeping of this documentation for an unlimited period. Ensure compliance with all local regulatory and Patheon provisions regarding such documentation.

Re-use or recycle wastes and residual material whenever possible and sensible. Consider selling these materials as raw materials or for energy recovery. If not re-used or recycled internally, ensure that you select an outside partner who operates on an acceptable EH&S level. Verify this by audit.

Ensure proper transport of the waste materials, in full compliance with local regulations.

Do not landfill pharmaceutical and chemical wastes or any hazardous materials.

5.2.4 Water / Effluent:

Protect water bodies and groundwater from contamination from persistent and poorly degradable chemicals, halogenated compounds (in particular solvents), heavy metals, insoluble contaminants, unacceptable non-deactivated biological materials, particularly if they are genetically modified active pharmaceutical ingredients and process intermediates.

Limit physical effects on water bodies and groundwater (e.g. heat input, cooling, influence on the circulation). Where necessary wastewater must be treated in a suitable wastewater treatment plant (own plant or common plant with other companies or the public).

Ensure protection of water bodies and groundwater in the event of malfunctioning or outage of the wastewater treatment plant. Ensure detection is provided for these situations. Ensure integrity of plants and installations (and in particular wastewater systems) and thus avoid infiltration of contaminants into the soil. Ensure early detection of non-integrity.

Avoid excessive exploitation of water resources. Reduce water consumption. Consider possibilities to capture, re-use and recycle used water. Optimize the quantity of water used in all types of processes. Use technologies and equipment designed to consume less water.

5.2.5 Energy Management:

Energy Management programs must align with Patheon Energy Management Engineering Standard (ENG-SE6-EM1)

Manage energy production, distribution and consumption (energy management system) to minimize environmental impact. Measure and monitor all energy flows using metered technology and systematically look for energy conservation opportunities.

Reduce emissions from energy production, distribution and consumption by conceptual and engineering measures. Where possible, use low sulfur fuels with favorable carbon dioxide coefficients. Optimize combustion technology (e.g. to reduce NO_x emissions). Encourage or the use of co-generation and energy recovery technologies where appropriate.

Optimally design new buildings, machines and processes to minimize energy consumption and to use sustainable types and sources of energy. Optimize existing buildings, machines and processes regarding energy consumption.

Evaluate potential and feasibility (e.g. reasonable cost) of alternative energies while maintaining uninterrupted energy supply wherever this is of importance for the operation.

5.2.6 Buildings/Installations/Infrastructure:

Design buildings and installations using environmentally safe technologies (containment vs. relief, passive vs. active, etc.) as part of the User Requirement Specification. Perform risk analyses at multiple points in the design and planning process and implement the identified measures. Use appropriate materials, including recycled material where possible. Carefully select the energy sources and use best available energy technology where feasible.

Minimize land use and soil sealing through appropriate master planning of the Site and building design. Consider seepage of uncontaminated water. Build the necessary safety equipment (alarms, automatic shut-down, release installation).

Construct buildings and installations in a way that they can be operated and maintained in a safe manner, and not by primarily relying on worker behavior. Provide clear and comprehensive standard operating procedures and instruction manuals prior to use of new/modified facility or equipment.

Maintain and buildings and installations using a Preventive Maintenance Program. Provide the necessary heating, cooling and ventilation and optimizing for environmental protection. Reduce heating, cooling and ventilation to what is really necessary and use best available HVAC technology with special emphasis on heat recovery where feasible.

Fire safety and life safety should be inherent in the design. Build the necessary fire protection installations and escape routes. Install the necessary monitoring and communication systems. Organize appropriate emergency response.

5.2.7 Suppliers, Service providers, Outsourcing partners, Contractors:

When selecting suppliers, service providers, outsourcing partners or contractors, consider their EH&S performance and sustainability practices in addition to their quality, financial, technical or capacity capabilities.

The depth of the evaluations and the decision criteria depend on the nature of the proposed level of business with these partners:

- Inherent EH&S risks and problems in the supplies or services delivered
- Specificity for our type of business vs. general types of supplies or services, volume of the contract, exclusivity vs. commodity.
- Regularly evaluate existing suppliers, service providers, outsourcing partners and contractors regarding their EHS performance through questionnaires, and where necessary by means of audits.

Urge existing suppliers, vendors and contractors who do not meet our minimum environmental sustainability requirements to implement the CAPA's and to improve their performance and standards. Ensure a process is in place for contract termination and exit strategy (e.g. finding and qualifying an alternate supplier) as necessary for unresponsiveness or non-compliance with requirements. Contracts should contain corresponding environmental sustainability requirement compliance provisions (ie. EH&S agreement).

5.2.8 Logistics / Transportation:

Ensure safe and secure storage of environmentally hazardous materials with the necessary safety measures according to the inherent hazards associated with the materials. Separate non-compatible materials.

Construct warehouses for appropriate heating and cooling for materials stored. Ship materials in containers of good integrity as per regulatory specification to minimize EHS and material impact in the event of an incident.

Optimize transport of all materials, especially those classified as dangerous goods, for safety and ecology and consider selecting the most ecological transport means and routes. Avoid unnecessary transport and ensure full compliance with transport regulations.

Verify that only contract transport and warehousing service providers with a regulatory compliant EH&S level are utilized.

-END -



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