SageTech Medical Equipment Ltd
Quality Management System

RA-021 - Environmental Risk Assessment for Permitted Activities

APPROVALS

Title	Name	Signature	Date
Regulatory Compliance Lead	S Finlay	Su Finlay	29-Jan-2025
2nd Approver (if applicable)	N/A	N/A	N/A

FORMAL TRAINING REQUIREMENT

Formal Training Requirement:	N/A

This Environmental Risk Assessment assesses the potential risk to the environment and to human health that may be associated with the proposed permitted operations at the facility. The document identifies the risks and what mitigation will be implemented to manage and minimise any potential negative effects.

This ERA uses the following steps for identifying and assessing the risks from the proposed permitted operations:

Step 1 Identify and consider risks for your site and the sources of the risks.
Step 2 Identify the receptors at risk from your site.
Step 3 Identify the possible pathways from the sources of the risks to the receptors.
Step 4 Assess risks relevant to your specific activity and check they are acceptable and can be screened out.
Step 5 State what you will do to control the risks if they are too high.

Step 1.
The risks considered as part of the risk identification process, and if the risks were applicable to the permitted facility, are shown below:

Discharges: Any discharge to ground or surface water.
Not applicable as the process does not discharge anything to ground or surface waters.

Accidents: The potential for accidents.
Applicable.

Odours: The potential for odours.
Not applicable, SageTech's process does not generate odours.

Noise and vibration: The potential for noise and vibration.
Applicable.

Emissions: The potential for uncontrolled or unintended emissions, such as dust, litter, pollutants, and pests.
Applicable.

Visible emissions: The potential for visible emissions, such as smoke or plumes.
Not applicable. SageTech's process does not generate smoke or plumes.

Bioaerosols: The potential for the release of bioaerosols, such as from shredding, screening, or turning.
Applicable.

Radiation: The potential for an exposure to radiation.
Not applicable. Radiation exposure is not applicable to SageTech's process.

Hazardous substances: storage, use, and disposal.
Applicable.

Step 2
The identified receptors at potential risk at the permitted facility are:

Employees and visitors
Residential areas
Businesses
Schools or other public buildings/facilities
Environment
Sensitive receptors (see appendix 1 STME-EP-005 Magic map for site)

Step 3 Identify the possible pathways from the sources of the risks to the receptors

Source of risk (hazard)	Possible pathways	Step 4 Acceptability of risk and mitigation potential	Step 5 Mitigation deployed to reduce risk to acceptable
Accidents	Accidents are possible and represent a risk mainly to employees, but also visitors, and the environment.	It is possible to mitigate the risk for accidents to occur.	SageTech have procedures that minimise risk of accidents for all processes. SageTech also have procedures for risk management and reporting, including near-miss events.
Noise and vibration	The level of noise generated through SageTech's process will not exceed 87 dB, which is identified by the HSE as the maximum permitted noise exposure. Noise levels below this could still represent a potential risk to employees. SageTech's process does not generate excessive vibration.	It is not acceptable for employees or other receptors to be persistently exposed to high or nuisance levels of noise. Mitigation is possible and must be deployed to reduce noise levels to an acceptable level.	Design and construction controls to minimise noise generation. Regular monitoring of sound levels during processing activities. Provision of appropriate PPE to reduce exposure if necessary. The process is performed inside a closed building. The closest neighbour, another business shares the development premises with SageTech, and they are not exposed

			to unacceptable or nuisance noise levels. There is an outside college facility within 25 meters of SageTech premises, there are no residential premises within 500 metres. Neither of these premises are exposed to unacceptable or nuisance noise levels.
Emissions	Dust is present at SageTech's facility. Employees are most at risk through exposure to any dust present. * cause a nuisance through noise or odours	Dust exposure can represent an unacceptable risk to employees and visitors and may additionally be a fire hazard. It is possible to mitigate dust exposure. Nuisance due to odour is not considered significant as the process outlets are filtered with activated carbon. The risk to the countryside or places of special interest and risks to water, air, soil, plants or animals is considered negligible.	Dust is controlled through processing batch procedures to prevent buildup of dust that may represent a risk to employees or visitors and reduce the potential fire risk.
Bioaerosols	There is a potential risk from bioaerosol generation through SageTech's process as the waste material originates from a medical facility. Bioaerosols could be of bacterial, fungal, or viral origin. Employees are most at risk of exposure.	It is not acceptable for employees to be exposed to bioaerosols that may be generated through the handling of waste materials originating from a medical facility. Mitigation is possible and must be used to reduce the potential of this risk.	SageTech has procedures for the safe handling of waste materials on site to minimise the potential for generation of bioaerosols and to reduce the risk of exposure to employees through system design, (closed systems) and appropriate PPE.

Hazardous substances	The waste material that SageTech process (anaesthetics – sevoflurane, isoflurane, desflurane) are classified as hazardous because they bear the hazard statement code H361 – substance suspected of damaging fertility or the unborn child. Therefore, employees or visitors could potentially be at risk through exposure to the waste material.	Exposure to waste material or substances that is classified as hazardous above the pre-determined safe levels is not acceptable. Mitigation is possible and must be taken to reduce the risk of exposure to employees and visitors to hazardous substances.	SageTech has procedures for the safe handling of waste materials on site to reduce the risk of exposure to employees through system design, (closed systems) and appropriate PPE. Employees screening takes place to prevent exposure to hazardous substances when pregnant. In the UK, there is a published safe exposure limit of 50ppm over 8 hours for Isoflurane. No published exposure limits for other volatile anaesthetics are published in the UK. Other nations have set limits that range from 5-10ppm over an 8-hour period, with short term exposure limits ranging from 2ppm to 20ppm. SageTech will adopt the most conservative limits and monitor for adherence.
Fire	The pathways for fire hazards, those at risk, and the mitigation identified is detailed in the separate document STME-QMS-8-1-0 Fire Prevention Plan		

The sensitive receptor site in attachment STME-EP-005 Magic map illustrates that there is no identifiable risk from SageTech's permitted facility to sensitive receptors.

This environmental risk assessment concludes that deploying the risk management and mitigation measures described reduces the potential risk to the receptors identified to an acceptable level. No further measures are envisaged at this time. Risk identification and assessment is an ongoing process for which SageTech has procedures to control.

DOCUMENT HISTORY SECTION

DOCUMENT AUTHOR AND REVIEWER

Role	Name	Job Title
Authored by	S. Wileman	Head of Research
Reviewed by	S Finlay	Regulatory Compliance Lead

DOCUMENT HISTORY

Reason for Change	Change Request ID	Version Number	Issue Date
New document	936	1.0	25 Oct 2024
Revised to add reference to external parties.	975	2.0	18 Dec 2024
Amendment of admin error. Doc ID and title updated to replace the letter for the version	1010	3.0	29-Jan-2025

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MAGIC

Magic Map