

1.0 Scope

General

The environmental policy and environmental management system defined in this manual are designed to satisfy the requirements of BS EN ISO 14001:2004. The management system applies to all Biotage GB Limited operations.

2.0 Environmental policy

Paragraph 4.2 BS EN ISO 14001:2004

An environmental policy has been established and signed by the Managing Director. The policy is communicated to all personnel through the training procedure and is available via the company intranet.

Procedures and projects defining objectives and targets for environmental improvement support this policy.

3.0 Planning

Paragraph 4.3 BS EN ISO 14001:2004

3.1 Environmental aspects

Paragraph 4.3.1 BS EN ISO 14001:2004

Identification of the environmental aspects and subsequent environmental impacts of Biotage's business activities is described in procedure [EM 1](#) Aspects identification and significance assessment. The activity or process and scope of environmental aspect identification are documented.

Aspect significance is determined by scoring and ranking methodology defined in the procedure. A register of significant aspects is maintained. The register is revised on completion of new aspect identification and impact significance assessments determination or re-assessment.

3.0 Planning (continued)
Paragraph 4.3 BS EN ISO 14001:2004

3.2 Legal and other requirements
Paragraph 4.3.2 BS EN ISO 14001:2004

Identification, collation and filing of applicable legal requirements, international and national acts / guidelines and other requirements are described in procedure [EM 2](#) Register of regulations and compliance.

A register of documents will be maintained and reviewed at to ensure it is up to date.

3.3 Objectives, targets and programme(s)
Paragraph 4.3.3 BS EN ISO 14001:2004

Objectives and targets relating to identified environmental aspects and impacts will be set by the management team taking the following into account:

- i. environmental policy
- ii. legal requirements
- iii. register of significant aspects
- iv. operational and business requirements
- v. technological options - best practice
- vi. views and feedback from the public, company personnel and customers

Environmental projects detailing environmental aspects together with agreed objectives and targets will be completed, approved and issued to relevant personnel as per quality management procedure [QP3](#) Project management procedure.

4.0 Implementation and operation
Paragraph 4.4 BS EN ISO 14001:2004

4.1 Resource, roles, responsibility and authority
Paragraph 4.4.1 BS EN ISO 14001:2004

The Quality Manager is the appointed Management Representative responsible for ensuring that ISO 14001:2004 environmental management system requirements are established, implemented and maintained.

The Quality Manager is additionally responsible for:

- i. planning and coordinating internal quality audits of the environmental system.
- ii. supplier and customer liaison with respect to environmental related matters.
- iii. reporting overall performance of the environmental system to Senior Management.

The nominated deputy representative is the Chemical Production Manager.

The organisational chart in Appendix 1:

- i. the interrelation of personnel in all areas of activity.
- ii. management with the responsibility and authority to manage environmental projects including meeting objectives and targets and to ensure adherence to operating procedures.

4.0 Implementation and operation (continued)
Paragraph 4.4 BS EN ISO 14001:2004

4.2 Competence, training and awareness
Paragraph 4.4.2 BS EN ISO 14001:2004

Personnel training is identified and recorded as per quality management procedure [QP12](#) Training. Training records are maintained for all personnel and contain details of training requirements and actions taken to provide training e.g. attendance at training courses, conferences, seminars and additional information pertinent to their job function. Additional training will be given where identified.

It is the responsibility of departmental Management personnel to maintain training records.

4.3 Communication
Paragraph 4.4.3 BS EN ISO 14001:2004

4.3.1 Internal Communication

The Environmental Policy and Environmental Manual are communicated to personnel under quality management procedure [QP12](#) Training.

The environmental management system is reviewed at monthly meetings. The team may additionally review environmental concerns reported internally or externally, discuss potential environmental improvements or environmental performance. Corrective action may result in the creation of projects. Minutes of meetings are maintained.

Environmental information may be disseminated to company personnel via team briefs, Departmental Managers or by the Quality Manager.

4.0 Implementation and operation (continued)
Paragraph 4.4 BS EN ISO 14001:2004

4.3 Communication (continued)
Paragraph 4.4.3 BS EN ISO 14001:2004

4.3.2 External Communication

All external requests for details of significant environmental aspects and positive or negative feedback relating to its environmental operation will be documented via procedure [EM 4](#) Environmental feedback.

Environmental feedback will be investigated under procedure [EM 4](#) Environmental feedback. The assigned investigation Manager may meet with the Management team to decide what information is to be released and by what method.

4.4 Documentation
Paragraph 4.4.4 BS EN ISO 14001:2004

The Environmental Manual, procedures and forms are controlled and issued under procedure [EM 3](#) Control of records, storage and retention.

4.5 Control of documents
Paragraph 4.4.5 BS EN ISO 14001:2004

Environmental management documentation is controlled under procedure [EM 3](#) Control of records, storage and retention.

4.6 Operational control
Paragraph 4.4.6 BS EN ISO 14001:2004

The need for environmental control is documented in work instructions, made available to personnel via the company intranet. Work instructions form part of personnel training.

4.0 Implementation and operation (continued)
Paragraph 4.4 BS EN ISO 14001:2004

4.7 Emergency preparedness and response
Paragraph 4.4.7 BS EN ISO 14001:2004

The plan to respond to identified accident and emergency incidents is defined in procedure [EM 5](#) Emergency preparedness and response.

The procedure includes personnel charged with the responsibility for dealing with emergency situations, what actions are to be immediately implemented. Accidents or incidents involving flammable or hazardous chemicals are reported to the Quality Manager.

Accident and emergency plans will be reviewed annually or following any incident and amended as appropriate.

5.0 Checking
Paragraph 4.5 BS EN ISO 14001:2004

5.1 Monitoring and measurement
Paragraph 4.5.1 BS EN ISO 14001:2004

The environmental permit issued by Natural Resources Wales specifies seven spot samples of emissions to air, frequency is annual.

Air monitoring results and measurement of other waste streams will be reviewed and reported under environmental procedure [EM 7](#) Evaluation of compliance with regulatory requirements. Monitoring results are reported to Natural Resources Wales in January of each year.

5.0 Checking (continued)
Paragraph 4.5 BS EN ISO 14001:2004

5.2 Evaluation of compliance
Paragraph 4.5.2 BS EN ISO 14001:2004

The management team will review compliance with applicable regulations and permits annually as per procedure [EM 2](#) Register of regulations and compliance. Minutes of the review will be maintained.

Any identified nonconformities are recorded on a Nonconformity Summary report with corrective or preventive action record on a CAP (corrective action plan) form.

5.3 Nonconformity, corrective action and preventive action
Paragraph 4.5.3 BS EN ISO 14001:2004

Nonconformities, investigation and suggested corrective and preventive action is established in procedures [EM 4](#) Environmental feedback, [EM 5](#) Emergency preparedness and response and [EM 6](#) Environmental internal audits

Nonconformities requiring extensive corrective and preventive action will be managed and controlled under ISO 9001:2008 quality management system procedure [QP3](#) Project management.

5.4 Control of records
Paragraph 4.5.4 BS EN ISO 14001:2004

Procedures and work instructions will typically contain documentation sections, specifying type of documents to be completed and filed. Procedure [EM 3](#) Control of records, storage and retrieval specifies the records to be maintained, record type, location and retention period. Records are periodically reviewed during internal environmental audits.

5.0 Checking (continued)
Paragraph 4.5 BS EN ISO 14001:2004

5.5 Internal audit
Paragraph 4.5.5 BS EN ISO 14001:2004

Environmental audits are performed as per procedure [EM 6](#) Internal environmental audits. Activities and operations are monitored according to an audit schedule. Audits are performed under the authority of the Quality Manager. Observed nonconformities are reported and agreed with the departmental Manager. Suitable corrective/preventive actions and timeframe are recorded.

To ensure that actions have been implemented, a follow-up audit may be performed using original audit reports. The results of internal audits are reviewed by the management team.

6.0 Management review
Paragraph 4.6 BS EN ISO 14001:2004

The effectiveness of the environmental management system will be reviewed annually by the management team under environmental procedure [EM7](#) Evaluation of compliance with regulatory requirements.

Minutes of review meetings are recorded and suitably maintained.



ISO 14001:2004 ENVIRONMENTAL MANAGEMENT MANUAL

Appendix 1

Environmental Management System Organisational Chart