



Labour Standards Assurance Policy & Management System

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1. Overview

Osteotec Limited is a privately owned company based in the UK. The Company's principal activities are as an orthopaedic and maxillofacial manufacturer and distributor, with specialist expertise in products for the extremities.

The products we supply are used throughout the healthcare systems in the UK and in most major clinical acute departments such as Operating Theatres, Intensive Care, Emergency Departments and Acute Care departments.

Osteotec Limited believes that it is important to maintain high levels of ethical standards to preserve its reputation within the market place and this is detailed in our Business Ethics Policy.

Osteotec Limited expect our suppliers to maintain appropriate ethical standards and will take all reasonable steps to establish the ethics and/or employment standards of its suppliers in line with the Ethical Trading Initiative (ETI) base code.

Where it is feasible Osteotec Limited will only source products from suppliers who maintain appropriate ethical standards for the area in which they operate.

Osteotec Limited has formulated a 'Labour Standards Assurance System Policy' in accordance with its commitment of the Business Ethics Policy.

Policy

Osteotec Limited's Labour Standards Policy is outlined within this Labour Standards Assurance Policy & management System (LSAS). It applies to both the internal organization, and its supply chain and is approved by the Osteotec Limited's Board of Directors and Executive Management Team.

It commits to continual improvement and sets out 7 core minimum labour standards

Adequate & sufficient resources will be made available to the LSAS, including time and financial backing.

It is appropriate to Osteotec Limited, as its scope includes a wide range of disposable medical and surgical devices.

It is communicated to all employees by way of induction and training updates and evidence retained. All suppliers are sent a copy of the policy and will be updated annually.

The policy is publicly available via our website www.osteotec.co.uk

This Ethical Labour Standards Policy will be reviewed annually and evidence of that review is contained in the minutes of the Osteotec Limited's Board Meetings.

Osteotec Limited also requires its suppliers to comply with their national laws along with the principles held within the LSAS Specification and the base code of the Ethical Trading Initiative.

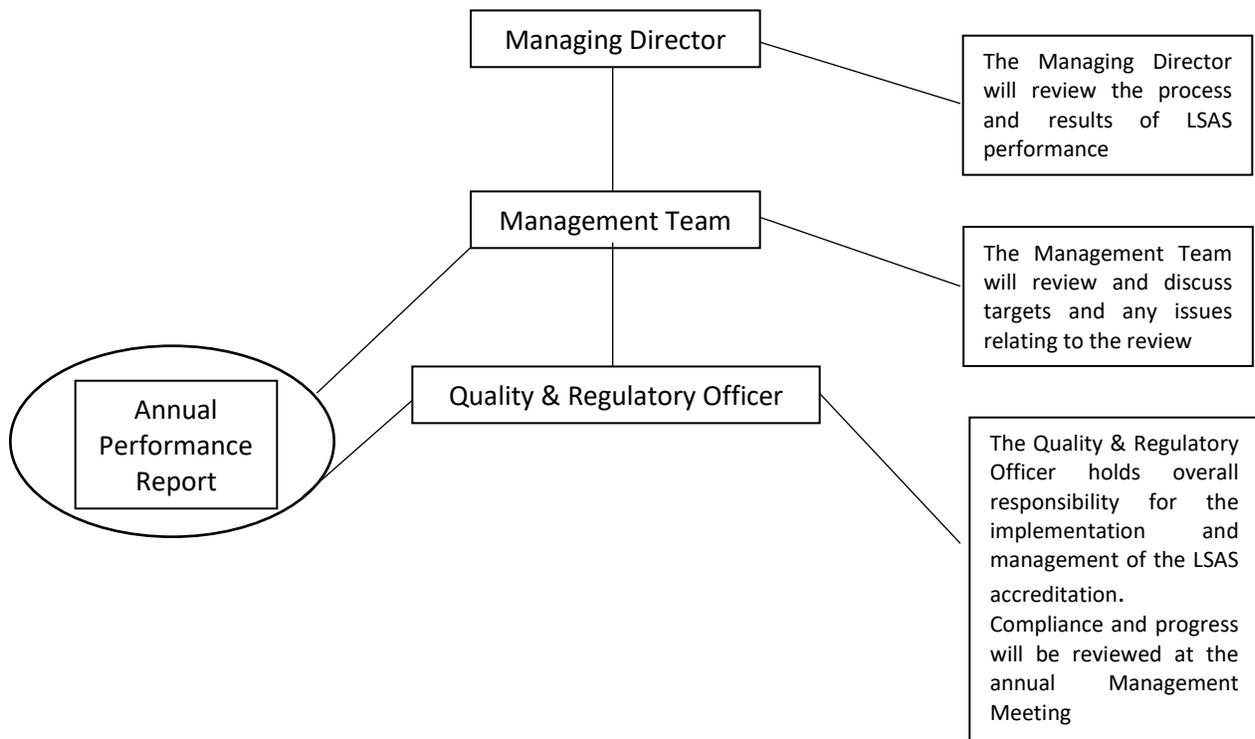
2. Management Representative

The Management Representatives for this Labour Standards Assurance Policy & Management System (LSAS) is a shared responsibility within the following roles:

- | | |
|------------------------------|---|
| Quality & Regulatory Officer | Administration & Daily Management of LSAS and Supplier Interaction and Management |
| Managing Director | Senior Management Approval |

These positions have full responsibility & authority for its establishment, implementation, management and ongoing continual improvement.

How Osteotec Limited works with LSAS – Labour Standards Assurance System



Typical duties include:

- Creating and publishing of Osteotec Limited Ethical Labour Standards Policy
- Approving all other relevant and related LSAS policies and procedures
- Carrying out a periodic review of the LSAS, typically on an annual basis
- To encourage suppliers and other parties key to the business, to comply with the principles of the Ethical Trading Initiative and/or NHS Labour Standards Assurance System
- Completing risk assessments to determine the level of risks related to each supplier
- Ensuring that any corrective action requests raised against a particular supplier, are addressed in a timely manner
- Allowing the administrative staff sufficient time to progress LSAS issues if required
- Documenting and taking action relating to any concerns about labour abuses
- To comply with UK employment law
- To align these tasks and duties wherever possible to the ISO 13485 Quality Management System that Osteotec Limited conform to
- To set objectives & targets for the overall improvement of the LSAS
- To communicate the LSAS issues throughout Osteotec Limited
- To carry out training with the administration staff who may be involved in the LSAS and if applicable other parties
- To comply with the NHS Supply Chain Framework Agreements (relevant to specific frameworks and products)

3. Labour Standards Review

This procedure undertakes to identify how labour standards such as the NHS Labour Standards Assurance System and the Ethical Trading Initiative relate to Osteotec Limited and its supply chain.

Labour Standards are then assessed to ascertain which standards apply to either the company or our supply chain (suppliers & contractors).

Labour Standard	Country	Status
NHS LSAS Specification	UK	Compliant
NHS Supply Chain Code of Conduct	UK	Compliant
Equality Act 2010	UK	Compliant
Public Interest & Disclosure Act 1998	UK	Compliant
Bribery Act 2010	UK	Compliant
Health & Safety at Work Act 1974	UK	Compliant
Employment Act 2008	UK	Compliant
Ethical Trading Initiative 2014	UK	Compliant
Sancroft Country Profile	China	
International Labour Organisation Conventions	China	
UN Universal Declaration of Human Rights 1948	Worldwide	
UN Global Compact Principles	Worldwide	
General Data Protection Regulation (GDPR) and Data Protection Act 2015	UK & EU	

Labour Standards Status Reviews and Supplier Performance reviews are carried out as part of the LSAS internal audit process on an annual basis. All results are recorded in the Supplier Management Tracker.

THESE MINIMUM LABOUR STANDARDS ARE DETAILED BELOW:

1. Child Labour

The Company does not engage in or support the use of child labour, defined as labour that:

- Is mentally, physically, socially or morally dangerous and harmful to children.
- Interferes with their schooling by:
 - Depriving them of the opportunity to attend school.
 - Obliging them to leave school prematurely.
 - Requiring them to attempt to combine school attendance with excessively long and heavy work.
 - If young workers are engaged for the purpose of work experience then appropriate checks will be carried out to ensure they are not exposed to any harmful conditions and working day is limited to 8 hours.

2. Forced & Compulsory Labour

Osteotec Limited shall not engage in or support the use of forced or compulsory labour, or bonded or involuntary prison labour. Employees are free to leave upon reasonable notice.

4. Legal & Other Requirements

This procedure has been established to help ensure applicable/relevant legislative and/or voluntary obligations pertinent to employment, welfare, human rights, ethical procurement, equality, discrimination etc. are either available or accessible to staff, and to maintain Osteotec Limited awareness of those labour standards requirements.

It is also an Osteotec Limited requirement for our company to comply with all UK employment laws and, to influence our suppliers wherever practicable, that they too need to conform to employment legislation as a requisite to supply Osteotec Limited with goods and/or services.

It is the responsibility of the Quality & Regulatory Officer to periodically review these requirements, to confirm our ongoing compliance. In addition, future/proposed changes in legislation will also be identified during that review, and records retained. It is also the responsibility of the Quality & Regulatory Officer that those identified requirements (listed below) are kept up to date.

The sources used to identify and review applicable legislation typically are as follows:

- Advisory, Conciliation and Arbitration Service HSE (Health & Safety Executive)
- UK Government Employing People Business & Human Rights Resource Centre Ethical Trading Initiative
- International Labour Organisation
- United Nations Global Compact Office of the High Commissioner Business for Social Responsibility
- British Medical Association
- Social Accountability International Global Reporting Initiative Sancroft International
- National Health Service National Archives
- External HR Consultant

Web Site Sources:

Advisory, Conciliation and Arbitration Service	www.acas.org.uk
UK Government Employing People	www.gov.uk
Ethical Trading Initiative	www.ethicaltrade.org
United Nations Global Compact	www.unglobalcompact.org
Business for Social Responsibility	www.bsr.org
Social Accountability International	www.sa-intl.org
Sancroft International	www.sancroft.com
National Archives	www.legislation.gov.uk
HSE (Health & Safety Executive)	www.hse.gov.uk
Business & Human Rights Resource	www.business-humanrights.org
International Labour Organisation	www.ilo.org
Office of the High Commissioner	www.ohchr.org
British Medical Association	www.bma.org.uk
Global Reporting Initiative	www.globalreporting.org
National Health Service UK	www.nhs.uk
Information Commissioner’s Office	https://ico.org.uk/

This procedure also identifies information on relevant employment and human rights legislation and other requirements as they apply to our direct operations, suppliers and other parties in the supply chain.

Those identified include:

Typical obligations	Osteotec Limited Documents	Document Reference
ETI Base Code / Modern Slavery Act 2015	Supply Chain Management Policy	OST-MDOC45
Labour Standards Assurance System/ International Bill of Human Rights/ ILO	Ethical Policy	OST-MDOC04
Health & Safety at Work Act 1974	Health & Safety Policy	OST-MDOC16
Bribery Act 2010	Anti-Bribery Policy	OST-MDOC03
Environmental Protection Act 1990	Environmental Policy	OST-MDOC13
Equality Act 2010 (as amended 2012)	Equal Opportunity/Bullying & Harassment Policy	OST-MDOC14 & OST-MDOC15
ILO Convention/China	Supplier Evaluation Questionnaire	2000F09
General Data Protection Regulation (GDPR) and Data Protection Act 2015	Osteotec Limited Employee Handbook	OST-MDOC28
NHS Supply Chain	NHS Supplier Code of Conduct	N/A

Up to date versions of each requirement can be accessed from the various applicable web sites listed above

The relevant control document for our suppliers is the "Osteotec Ltd Supplier Evaluation Questionnaire" which requires the supplier to confirm that they comply with their national laws.

All documentation associated with the Legal & Other Requirements of our LSAS policy is filed in the LSAS Section - Legal & Other Requirements Documentation.

These examples are not intended to be exhaustive; however, they do provide an excellent foundation to help ensure that throughout our supply chain, labour abuses are not acceptable. These examples are indeed available to our staff to help them understand, and if relevant to their role, how they might apply to them. Besides, other documents and records may also be in place to support compliance, for example, employees Contract of Employment; Employment Handbook, NHS Country Profile

5. Objectives, Targets & Programmes

Osteotec Limited has established several objectives and targets which are outlined within our LSAS Business Ethics Policy.

These objectives shall be maintained by a monitoring programme to ensure they are implemented effectively. The ongoing monitoring shall form part of the company's internal audit programme which is listed on the Internal Audit Plan.

These LSAS objectives, which have been agreed with the Managing Director, when practicable have a plan of action in place to demonstrate how these targets may be achieved.

No	Objective	Action Plan & Update.
POLICY	The labour standards and policy requirements Osteotec Limited is committed to, both internally and throughout its supply chain	To launch our LSAS policy within the organisation and make available on request
LEGAL AND OTHER REQUIREMENTS	The procedure(s) the organisation has in place to: Identify information on relevant employment and human rights legislation and other requirements as they apply to its direct operations, contractors, sub-contractors, suppliers and parties in the supply chain. Communicate this information to staff with responsibility for labour standards assurance	To establish a way of identifying the legal requirements in areas of the supply chain which are known to be of elevated risk and also a way of maintaining a current understanding of relevant employment
OPERATIONAL CONTROL	The processes, procedures and systems the organisation has in place to manage labour standards through its direct operations (including both mitigating the risk of non-compliance and driving improvement). This will include how the organisation manages its critical control points	To document a process for critical control Points, supplier approval and site visits for those suppliers purchasing/manufacturing from high risk countries. And begin to implement them into the business processes.
PERFORMANCE MONITORING AND MEASUREMENT	The procedures the organisation has in place to collect appropriate information in order to monitor and measure performance in relation to: <ul style="list-style-type: none"> • Its stated objectives and targets • Compliance with relevant legislation and any other requirements that it subscribes to 	To develop a system that allows us to regularly monitor our compliance to our objectives, targets and relevant legislation. A system that will allow us to identify critical dates and flag action points relating to supplier performance.

	<ul style="list-style-type: none"> • Conformance to planned arrangements for labour standards assurance 	
CORRECTIVE ACTION	The procedures the organisation has established in order to manage actual and potential non-conformities to its own labour standards assurance systems, including corrective and preventative action.	To demonstrate the procedures we have established, and are using, to manage both actual and potential non-conformities to our labour standards assurance systems, including corrective and preventative action and also document action plans to mitigate and manage any risks that may arise. This would build further on the incorporation of risk assessments into the new

These objectives shall also be reviewed at the both a Quality Management Review Meeting & Annual Board Meeting

6. Roles & Responsibilities

This procedure should read in conjunction with the company's Quality Management System Manual.

Responsibilities:

The Quality & Regulatory Officer to ensure the availability of adequate resources to establish, maintain and continually improve the LSAS.

- Overall responsibility to ensure objectives are met.
- To liaise with suppliers to gather required empirical evidence.
- To carry out internal audits, report on the findings and generally advise the Managing Director.

The LSAS programme shall communicate across the Company which includes issuing LSAS related policies.

Besides, the relevant policies shall also be sent out to all suppliers.

Roles and responsibilities reviewed at the annual Management Review Meeting.

7. Competence, Training & Awareness

This procedure should be read in-conjunction with our Quality Management System Procedure Administration of Staff Training.

Training records are recorded for LSAS and in the LSAS Training File

Initial training and awareness has been conducted throughout the organisation to raise awareness of the required labour standards.

Business Ethics and LSAS is addressed at our annual company meeting:

- Business Ethics Policy
- Initial LSAS awareness
- LSAS Company policies
- Ethical Trading Initiative Base Code
- LSAS Specification
- Objectives & targets

Acknowledgement of this information will be recorded to confirm employee compliance with the policy.

Additional training to gain greater competence will be arranged on a case by case basis dependent on how the staff member can have an influence on labour standards.

Training Plans for each year will be documented in the 'LSAS Training Schedule' which are reviewed at each LSAS Management Meeting.

All Staff who are directly involved in the Management of LSAS will be reviewed annually in their respective Performance Reviews and any additional training and development steps identified to ensure compliance and development of the LSAS is maintained. Once training is completed by LSAS Responsible people, it is recorded and signed off by the Managing Director.

8. Communications

This Communications Procedure has been established to ensure effective & appropriate communication is in place for internal communication; receiving & responding to correspondence from interested parties relating to labour standards, protecting information from whistle blowers, and the external communication carried out by Osteotec Limited in relation to the practices and performance of our labour standards.

Interested parties could include legislators, regulators, customers, suppliers, enforcement agencies, Certification Bodies; Notified Bodies, Competent Authorities, Local Authorities, Trade Unions, Lobbying Groups, Department of Employment, etc.

Key communication issues shall be reviewed at the Management Review meeting, along with information from Whistle Blowers.

We shall receive and respond to allegations, complaints or other alerts about labour standards issues as part of our whistle blowing procedures.

Whistle blowing can be reported directly to the Managing Director

As Osteotec Limited is a small business, there have been no formal internal communication channels set up such as employee satisfaction surveys and staff forums. However, all staff are encouraged to discuss labour standards issues between themselves and with the Management Team.

This LSAS Policy will be published on the company's external web site as evidence of our labour standards programme.

9. Documentation & Records

The objective of these processes and procedures is to drive continual improvement throughout both the company and our supply chain.

To demonstrate compliance with the NHS LSAS Specification, this Labour Standards Assurance Manual has been established.

As an integral part of managing these activities Osteotec Limited shall wherever practicable, mitigate the risks of non-compliance.

Our documentation is also used to manage its Critical Control Points (CCP) that could have an impact (positively or negatively) on labour standards. Typically these could include:

N	Critical Control	Impact on Labour	Operational Control
1	Appointing New Supplier	Supplier does not have in place adequate labour standards	Risk Assessment
2	Identifying non-conformance & agreeing corrective action	Potentially improving labour standards	Record on Supplier log
3	Carrying out Supplier Performance Review	Identified gaps in the suppliers documentation which may pose additional risks to labour standards	Supplier Workplace Assessment
4	The company being subject to external verification	Lack of adequate resources to maintain the LSAS	Independent LSAS Certification Body Report of Findings

Policies and forms shall be recorded on the Shared Drive; SBSVR; Shared; LSAS, or where relating to QMS shall be available in SBSVR; Shared; Quality Documents; Current quality documents.

All document changes / updates are controlled by our QMS system for change control.

10. Operational Control

This operational control process shall also consider the method in which we manage our critical control points.

Within our documentation & records section, critical control points (CCP) have been identified and the associated risks have been listed. These CCP include:

- Appointing New Supplier
- Identifying non-conformance & agreeing corrective actions
- Carrying out Supplier Performance Review
- The company being subject to external verification

All audit results from LSAS Supplier Questionnaires are recorded in the Supplier Management Tracker. In addition to the above, other critical control points may be identified during our Labour Standards Status Review process.

Periodically critical control points shall be verified in the management review meeting by the senior manager.

11. Supply Chain Management

This procedure should be read in-conjunction with our Quality Assurance Procedures Manual; Purchasing and Supplier Surveillance process.

Those parties that are involved in the supply chain are generally included on the Approved Suppliers List

Information has been collected relating to our supplier's labour standards performance utilising our Supplier LSAS Risk Assessment Questionnaire Form. Key suppliers have been identified from the Approved Suppliers List and transferred to the Supplier Management Tracker.

Any issues identified as part of the risk assessments or audits will be recorded in the corrective action to highlight the fact that we need to respond to the information gathered.

Data received from the supply chain is then risk assessed to determine a suppliers' continued suitability.

If necessary, any issues would be highlighted by the Quality & Regulatory Officer at the management review meetings with a decision reached on further action.

When applicable other information shall be sent to members of the supply chain such as the ETI Base Code and our Bribery & Corruption Policy etc.

The country of origin of each supplier has been recorded on the Supplier Management Tracker.

Periodically we reserve the right to request additional evidence of labour standards compliance. Examples could include obtaining a copy of their workers contract of employment template from suppliers manufacturing in high risk areas.

During the verification of supplier performance, if any non-conformances are identified, the corrective action process should be followed.

12. Emergency & Critical Issue Response

Osteotec Limited shall identify and document responses to significant labour standards issues & risks.

The procedure adopted shall be appropriate to the issue and also reflect the current risks. This shall be achieved by evaluating any action taken during a periodic review.

Typical significant risks & issues include:

- Migrant workers -ostracized and discriminated against
- Dormitories - sub-standard lodgings provided to workers with poor safety and hygiene
- Failure of minimum wage payment - being paid a lower wage than nationals
- Double book keeping - factory workers working long hours is hidden data in separate books
- Unpaid internships - potential for forced labour
- Controlled trade unions - little freedom of collective bargaining
- Corruption - employees paid to "turn a blind eye" to unsafe practices
- Deterioration in the environment - water pollution amongst others
- Breach in labour laws & standards - non-compliance with LSAS

Dependent on the criticality or significance of the issue, Osteotec Limited will put in place a basic plan for each matter. These plans could also be created as a result of a status review, where a supplier is declared to be manufacturing in a high risk area.

A number of methods to manage escalations could be adopted in the plan including:

1. Any risk identified shall be assessed using Supplier Management Tracker, following this Section of LSAS Emergency and Critical Issue Response.
2. Ascertain whether the breach is major or minor (view ETI base code corrective action for clarification) Raise a non-conformance on Supplier Management Tracker and discuss corrective actions with the supplier. All agreements should be documented and copy sent to the supplier and logged against their account.
3. Commence seeking alternative supplier if the existing approved supplier does not implement corrective action in a timely manner.
4. Inform the suppliers/contractors ISO 9001 Certification Body or its ISO 13485 Notified Body to carry out an unannounced visit relating to the organisation's responsibilities of senior management.
5. Notify the relevant national enforcement office to intervene.
6. Delist the supplier/contractor from our Approved List of Suppliers.

Note: If an existing supplier is at risk of being delisted, the office administrators shall be informed to check with the Managing Director prior to placing any additional orders with that supplier.

13. Performance Monitoring & Measurement

Data shall be gathered to monitor and measure our stated objectives & targets; compliance with legislation & other requirements and conformance to planned arrangements.

The following data shall be subject to review:

- Number of prosecutions
- Number of employee tribunals
- Number of enforcement notices
- Number of non-conformances
- Number of whistle blowers reports
- Number of document changes
- Number of issues documented within the supply chain
- Number of supplier assurance questionnaires returned
- Number of objectives and targets achieved
- Number of conformances
- Number of requests for information relating our labour standards performance
- Number of risk assessments carried out & their results
- Number of labour standards abuses including near misses
- Number of observations for improvement documented during internal & external audits

Internal Audits are carried out annually and the outcome is reviewed as part of the LSAS element of the management review meeting. The Managing Director reports on LSAS performance as part of his Business Ethics update to the Board of Directors.

It is our policy to ensure continual improvement and to demonstrate this any observations for improvement will be recorded on the Supplier Management Tracker

14. Corrective Actions (CAPA)

Any correctives actions taken shall be recorded on our Supplier Management Tracker.

Any issues noted relating to our suppliers or other parties will generally be addressed in the Section above relating to Supply Chain Management. In those situations, corrective actions shall be recorded on the Supplier Management Tracker

As with our Quality Management System, once a corrective and/or preventive action has been agreed, time scales and responsibilities shall be defined.

Major Non-Conformance: Action - Immediate to One Month (dependent on criticality)

Minor Non-Conformance: Action - No more than Three Months

Observations for Improvement: Action - Dependent on issue, all outcomes will be recorded

The company shall wherever practicable identify the root cause of any issues of non-conformities raised

15. Management Review

LSAS Management Team will meet quarterly to review our compliance against our policy and assess any areas for development and improvement ensuring its continuing suitability, adequacy and effectiveness. Minutes of LSAS meetings are filed in the LSAS folder on the Shared Drive; SBSVR; Shared; LSAS.

Minutes of the previous management review meeting shall be reviewed and confirmed as accurate prior to the commencement of the current meeting. Any outstanding issues shall be addressed as required.

The meeting reviews the following topics:

- Labour Standards Policy & the Procurement & Supply Chain Policy
- Confirm that the duties of the Management Representative have been accomplished
- Review the status of our Labour Standards
- Check Legal & Other Requirements remain current; also review future legislation
- Monitoring Objectives & Targets; confirm effective programmes in place
- Review employee's roles & responsibilities; verify adequate resources are available
- Check Training, Competence & Awareness of LSAS; ensure initial training has been effective
- Evaluate Internal & External Communication; including whistle blowers process
- Assess the Documents & Records Procedure; confirm compliance with LSAS requirements
- Review Operational Control; and Critical Control Points
- Assess the Management of our Supply Chain; check Supplier Assurance Questionnaire is in place
- Review Emergency & Critical Issue Response; check labour issues & risks assessments
- Monitor & Measure our LSAS Performance; check compliance with legislation
- Consider Corrective Action; and Preventive Action if applicable
- Review Internal Audit Reports (if applicable); consider other internal checks on system
- Finally confirm continued suitability, adequacy & effectiveness of the LSAS for Osteotec Limited Outcomes
- Confirmation that the Managing Director has approved all LSAS related Policies
- Confirmation that future plans for the LSAS have also been approved by the Managing Director
- Creation of Meeting Minutes for the current LSAS Management Review Meeting
- List Action Points discussed at the meeting (if any) in the Improvement Log
- Confirm Continual Improvement of the LSAS is in place.

The Managing Director will also report on LSAS as part of a wider Business Ethics review held twice per year at Osteotec Limited Board Meetings.