



Labour Standards Assurance Policy & Management System

(ISK/LSASV1_010616)

Version 1: 01-06-2016

Iskus Health Ltd

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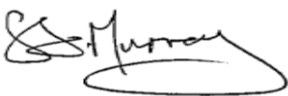
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As part of our Business Ethics Policy Iskus Health is committed to upholding an ethical labour policy in-line with it's legal and moral obligations. The standards are maintained within the Company and the Suppliers within the Companies supply chain.



Approved By: Stuart Murray, Commercial Director

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OVERVIEW

Iskus Health Group of companies (trading as Iskus Health Ltd & Iskus Health UK Ltd) are privately-owned companies. Our business is focused on the sales, marketing, clinical support and distribution of medical and surgical consumable products within the UK and Ireland.

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

Iskus Health 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 (ISK/BEPV1_010616_SJM).

Iskus Health, 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 ETI (ethical trading initiative) base code.

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

Iskus Health has formulated a 'Labour Standards Assurance System Policy' in accordance with its commitment to its Business Ethics Policy.

1. Policy

Iskus Health Labour Standards Policy is outlined within this Labour Standards Assurance Policy & Management System (LSAS). It applies to both the internal organisation, and its supply chain and is approved by the Iskus Health Board of Directors, Executive Management Team and specifically, by the Commercial Director, **Stuart Murray**.

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

Adequate & sufficient resources will be made available to the LSAS, and this manifests in both time and financial backing.

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

It was communicated to all employees during June 2016 and evidence retained. All suppliers were sent a copy of the policy in June 2016.

The policy is publicly available on request.

This Ethical Labour Standards Policy is reviewed annually and evidence of that review is contained in the minutes of the Iskus Health Board Meetings.

Iskus Health Ltd 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.

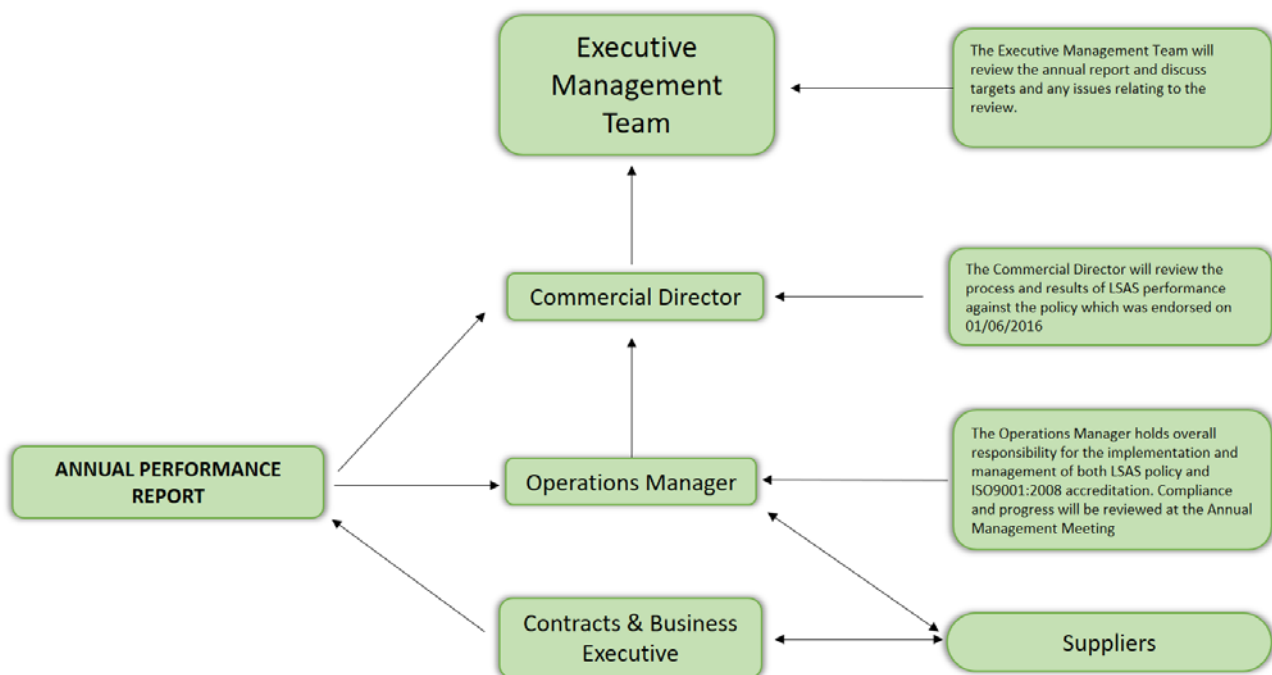
2. Management Representative

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

Business Quality Analyst	Administration & Daily management of LSAS
Commercial Contracts Executive	Supplier Interaction and Management
Operations Manager	Supplier management & approval.
Commercial Director (Stuart Murray)	Senior Management Approval

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

How Iskus Health works with LSAS – Labour Standards Assurance System



Typical duties include:

- Creating and publishing of Iskus Health 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 9001 Quality Management System that Iskus Health conform to
- To set objectives & targets for the overall improvement of the LSAS
- To communicate the LSAS issues throughout Iskus Health
- 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 Status Review

This procedure undertakes to identify how labour standards such as the NHS Labour Standards Assurance System and the Ethical Trading Initiative relate to Iskus Health 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

Labour Standards Status Reviews and Supplier Performance reviews are carried out as part of the Internal ISO9001 Audit process on an annual basis.

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

Iskus Health 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 Iskus Health awareness of those labour standards requirements.

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

It is the responsibility of the Management Representative 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 Analyst 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
- Voltege HR Consultants

Web Site Sources:

www.acas.org.uk

www.hse.gov.uk

www.gov.uk

www.business-humanrights.org

www.ethicaltrade.org

www.ilo.org

www.unglobalcompact.org

www.ohchr.org

www.bsr.org

www.bma.org.uk

www.sa-intl.org

www.globalreporting.org

www.sancroft.com

www.nhs.uk

www.legislation.gov.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:

1. ETI Base Code (& overseas)
2. Labour Standards Assurance System
3. Health & Safety at Work Act 1974
4. Bribery Act 2010
5. Environmental Protection Act 1990
6. Equality Act 2010 (as amended 2012)
7. Employment Promotion Act 1999 Germany
8. The French Labour Code 2009 France
9. The Labour Code 2006 (as amended 2012) Czech
10. NHS Supply Chain - Supplier Code of Conduct
11. BMA Ethical Procurement for General Practitioners
12. FCPA The Foreign Corrupt Practices Act of 1977

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

Note 1: Our examples are not intended to be exhaustive; however they do provide a good foundation to help ensure that throughout our supply chain, labour abuses are not perpetrated. All of these examples are indeed available to our staff to help them understand, and if relevant to their role, how they might apply to them.

Note 2: Up to date versions of each requirement can be accessed from the various applicable web sites listed above.

Note 3: In addition, other documents & records may also be in place to support compliance, for example employees Contract of Employment; NHS Country Profiles etc.

Note 4: There is a wide variety of other regulations within the employment sector, which will be addressed if an incident (labour abuse) occurs within our supply chain and any corrective actions put in place if appropriate.

5. Objectives, Targets & Programmes

Iskus Health 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 Commercial 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 Iskus Health is committed to, both internally and throughout its supply chain.	To launch our LSAS policy within the organisation and make available on request. Complete.
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 legislation. Complete: RSS feeds and Internet sites
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. Complete: Emergency & Critical Issue Response
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: Its stated objectives and targets Compliance with relevant legislation and any other requirements that it subscribes to Conformance to planned arrangements for labour standards assurance	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. Complete: Measurement, Analysis & Improvement Objective Compliance LSAS Annual Review Data

<p>CORRECTIVE ACTION</p>	<p>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.</p>	<p>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</p> <p>Complete: Emergency & Critical Issue Response</p>
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These objectives shall also be reviewed at the both a Quality Management Review Meeting & Annual Board Meeting.

6. Roles & Responsibilities

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

Commercial Director: Stuart Murray

To ensure the availability of adequate resources to establish, maintain and continually improve the LSAS. This shall include the appointment of LRQA as an external verifier.
Report to the Board of Directors of LSAS Compliance

Operations Manager: Barbara Gregg

Supplier Management through the LSAS guidelines
Oversight in Commercial Directors absence

Commercial Contracts Executive: Philip Wallnutt

Supplier Management through the LSAS guidelines
To liaise with suppliers to gather required empirical evidence

Business & Quality Analyst: Joanne Rakowska

Overall responsibility to ensure objectives are met
To carry out internal audits, report on the findings & generally advise the CD

The LSAS programme shall be communicated internally which includes issuing LSAS related policies.

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

Roles and responsibilities are 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.

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 was recorded to confirm employee compliance with the policy.

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

Plans for training (needs assessment) shall be recorded in the minutes of the Management Review.

All Staff (as detailed in section 6) 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.

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 Iskus Health 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 Commercial Director on stuart.murray@iskushealth.com

As Iskus Health 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 is 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 ref ISK/LSASv1_010616 has been established.

As an integral part of managing these activities Iskus Health 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 Standards	Operational Control
1	Appointing New Supplier	Supplier does not have in place adequate labour standards	Risk Assessment
2	Identifying non-conformance & agreeing	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 365 share-point file management system under Business Ethics File

All document changes / updates are controlled 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 9, 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

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 New Supplier Creation and Approval process Ordering and Receiving of goods.

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 Operations Manager 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 (section 14).

12. Emergency & Critical Issue Response

Iskus Health 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, Iskus Health will put in place a basic plan for each matter. These plans could also be created as a result of a status review (section 3) 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 Section 12 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 organisations 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 Commercial 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 (section 5); compliance with legislation & other requirements (section 4); and conformance to planned arrangements (section 3).

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 Commercial 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

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 section 11 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

The Management Representative shall review the Iskus Health Labour Standards Assurance Policy Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

As part of a Business Ethics review held twice per year at Iskus Health Board Meetings

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:

- Ethical 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 Iskus Health Outcomes
- Confirmation that the Commercial Director has approved all LSAS related Policies
- Confirmation that future plans for the LSAS have also been approved by the Commercial 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.