Management System and Standards for RBU UK and Ireland

Attachments:

Purpose

Purpose

The purpose of this document is to describe the structure of the SHEQ Management System and demonstrate how it:

- ensures control of all critical business processes
- achieves compliance with relevant legislative and elected management system requirements
- provides processes to facilitate continual improvement.

Overview

This document, together with ***Management Responsibility for RBU UK and Ireland***:

- fulfils the requirements for a Quality, Safety and Environmental Manual
- provides cross-references between LiMSS and the external management system standards that the system has been developed to satisfy.

Scope

Scope

This document applies to UK and Ireland.

Audience

This document is aimed at all Business and Operational managers responsible for SHEQ legal and/or accreditation/certification compliance and the Central and local SHEQ Managers/Advisors whom advise them.

Review period

The review period for this document is 5 years from the date of last issue.

Management System

General

BOC developed and Linde subsequently adopted an Integrated Management System and Standards (LiMSS) to ensure effective and efficient control of all business activities.

This system has been developed by process mapping the business activities, to identify interface and control points and by reviewing legislative and elected management system requirements.

Principles applicable to The Linde Group LiMSS are detailed in the global chapter ***Management System Overview***.

This document provides additional detail relevant to the UK and Ireland.

Business Processes

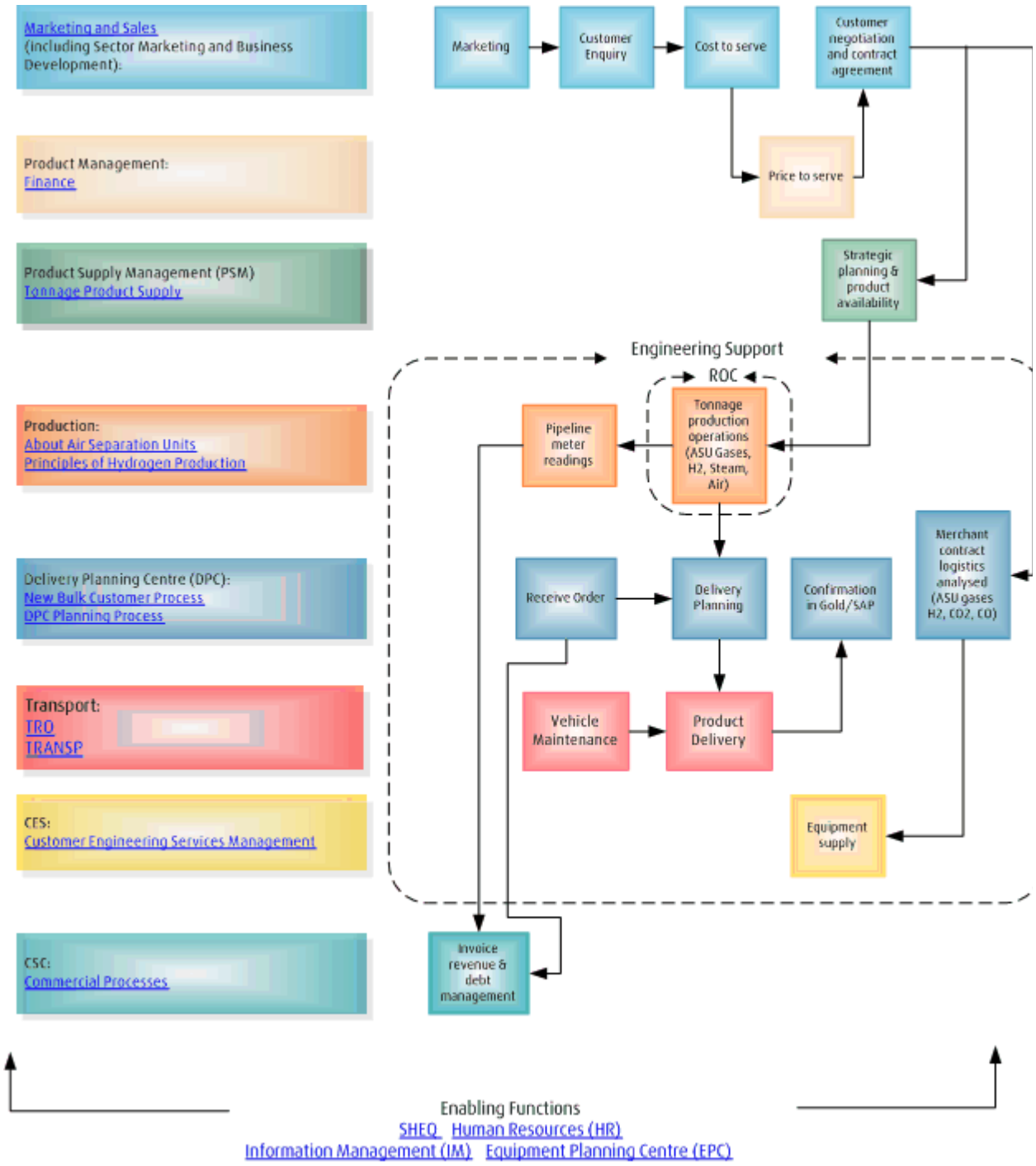
General

BOC UK & Ireland embraces a number of product and business processes.

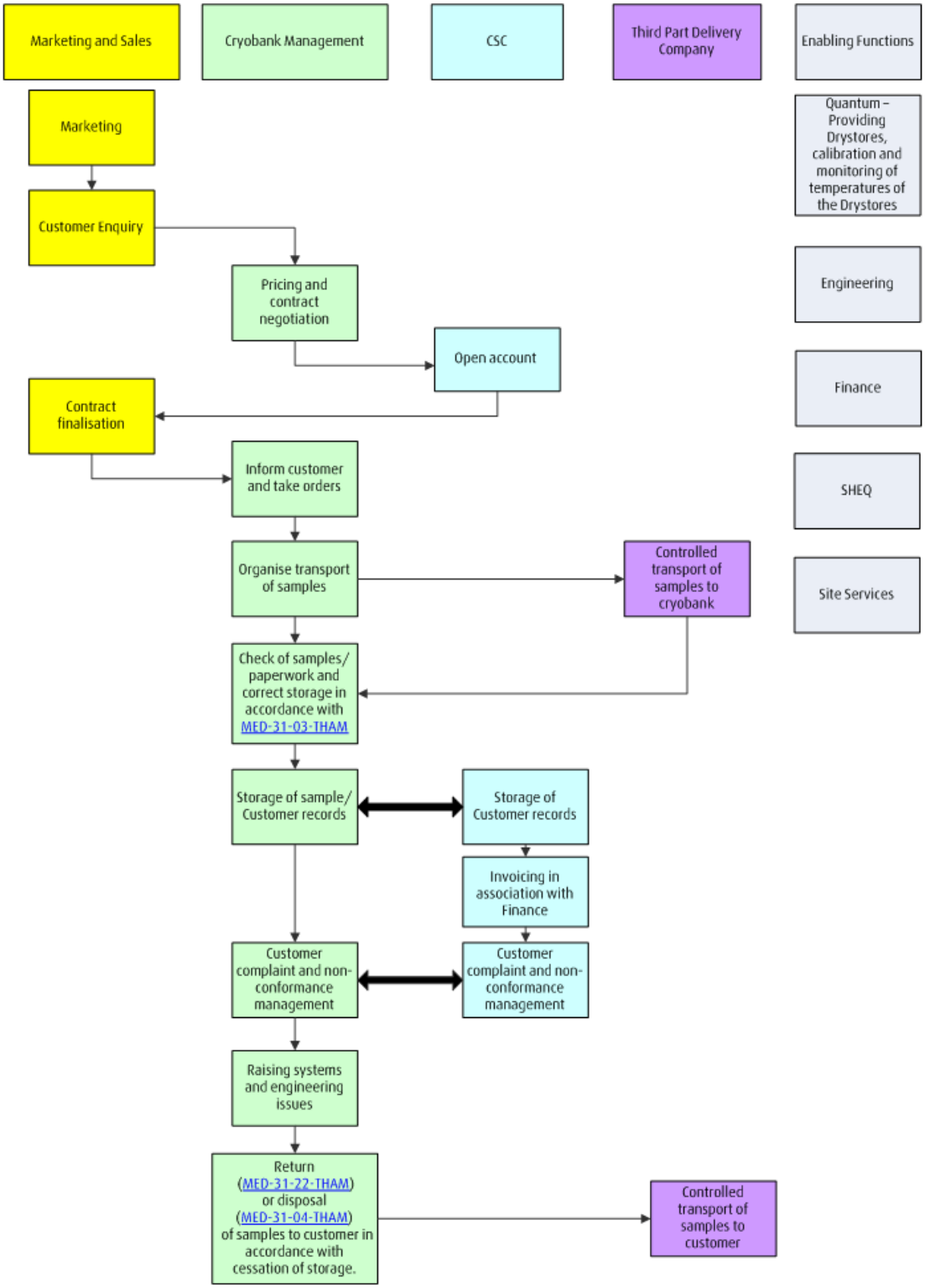
These processes, which could have an impact upon the SHEQ performance of the Company, have been documented as business flow diagrams that identify critical stages of the processes:

Filling and transportation of packaged goods

Tonnage and bulk business process



Cryobank process flowchart



Ireland (Belfast) process maps:

Ireland (Belfast) Critical Process Maps (see attachment)

Ireland (Dublin/Cork) process maps:

- ***CES Process Map (see attachment)***
- ***Cryospeed/Helispeed Process Map (see attachment)***
- ***CSC Dublin Critical Process Map***
- ***Homecare Process Map (see attachment)***
- ***HR Critical Process Maps (see attachment)***
- ***Legal Critical Process Maps (see attachment)***
- ***PG&P Process Map (see attachment)***
- ***Planning & Logistics Process Map (see attachment)***
- ***Retail Management Critical Process Maps (see attachment)***
- ***SHEQ Critical Process Maps (see attachment)***
- ***Sureserve Critical Process Map (see attachment)***
- ***Test Shop Process Map (see attachment)***
- ***TMM Critical Process Map (see attachment)***
- ***Onsites Process Map***
- ***Sureserve E-Call Handling Procedure***

Monitoring and Measurement of Processes

Measurement

Management System and Business processes contain specific measurement criteria relevant to the process outputs, with the key processes being detailed in the ***Business process flow diagrams***.

Monitoring

Management System and Business processes are monitored on a regular basis to ensure that they continue to operate effectively and achieve the desired process outputs.

This monitoring may include:

- Quality Control records.
- Routine management monitoring.
- Reporting of Key Performance Indicators.
- Management Reviews.

External benchmarking

Referring to the practices or performance of external organisations is undertaken in order to benchmark systems and processes. For example, by:

- involvement in structured forums (e.g. participation in industry associations)
- less formal or opportunistic means (review of public reports, interaction with major customers)
- reviewing trade or professional journals, professional networking etc.

External Management System Compliance

Compliance requirements

The LiMSS system has been developed to ensure compliance with legislative requirement and contracted or elected Management System requirements.

Legislative management system requirements

To:

- Satisfy the management system requirements of current Occupational Health and Safety Legislation, the UK Health & Safety Executive's guidance document, *HSG65 Successful Health and Safety Management,* has been chosen as the model against which BOC's UK & Ireland Integrated Management System complies with.
- Note the specific requirements for a management system to deal with Major Accident hazards is covered in ***Process Safety Management System***.
- Satisfy the management system requirements of current Environmental Legislation, the International Environmental Management System Standard *ISO 14001* has been chosen as the model against which BOC's UK & Ireland Integrated Management System complies with.
- Meet the management system requirements for medical gases manufacture and supply for patient use, the principles of Good Manufacturing Practice (GMP) specified in the *EC Directive 2003/94/EC Laying Down the Principles and Guidelines of Good Manufacturing Practice for Human Medicines (GMP)* have been incorporated into the Integrated Management System.
- Meet the management system requirements for the storage of human tissue and cell samples at the Cryobank as specified in the European Tissues and Cells directives 2004/23/EC, 2006/17/Ec and 2006/86/EC.

Non-legislative management systems requirements

In addition to legislative requirements, there are a number of management system models or standards that UK & Ireland RBU businesses have either chosen to adopt or have contractually agreed to operate. These are:

Model/Standard	Title
ISO 9001:2008	Quality Management System – Requirements.
ISO 13485:2012	Medical Devices -Quality Management System.
BS EN ISO/IEC 17020:2012	Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection.
ISO/IEC 17025:2005	General Requirements for Competence of Testing and Calibration Laboratories.
ISO Guide 34: 2009	General Requirements for the Competence of Reference Material Producers.

Management System Requirements LiMSS Cross References

Management system requirements/LiMSS cross references

For each external standard/guidance document there is a cross-reference table indicating which LiMSS Standard(s) satisfies the requirement of a specific clause/sub-clause of the external document.

The LiMSS reference is provided as a hyperlink to enable the document to be launched directly from the cross-reference table.

HSG 65: Successful Health and Safety Management

HSG 65 Requirement	LiMSS Standard
Policy	***Linde Group SHEQ Policy***
	Major Accident Prevention Policy for RBU UK and Ireland
Organisation	
Control	***Management Responsibility for RBU UK and Ireland***
	LiMSS Organisation and Resource
	Golden Rules of Safety
	Approval/Design Authorities
	Landlord and Tenant Arrangements
Co-operation	***SHEQ Committees***
Communication	***Managing Legislative Compliance***
	About Internal and External Communication Processes
	Group Meetings
	DAB: Directives and Alerts.
Competence	***Training for RBU UK and Ireland Employees***
	About Competence Assessment
	Competence Assessment Process
	Competence Assessment Standard
Planning and Implementation	
	Engineering Management of Change (EMOC) for RBU, UK and Ireland
	Organisational Management of Change
	Establishing a Maintenance and Condition Monitoring Programme
	Incident Investigation and Reporting in RBU UK and Ireland
	Hazard Identification and Risk Assessment
	IMS-25: Site Emergency Plan
	About Safe Systems of Work
	Contractor Contro
Monitoring Performance	
	Management Responsibility for RBU UK and Ireland
	Planned Workplace Inspection
Audit and Review	
	About Auditing
	Management Review Process

ISO 9001:2008 Quality Management System - Requirements

ISO 9001 Clause		LiMSS Standard
4.0	**Quality Management System**	
4.1	General Requirements	***Management System Overview***. IMS-02-02-RUK: Management System and Standards (this chapter).
4.2	Documentation Requirements	
4.2.1	General	***Linde Group SHEQ Policy***. IMS-02-02-RUK: Management System and Standards (this chapter).
4.2.2	Quality Manual	IMS-02-02-RUK: Management System and Standards (this chapter).
4.2.3	Control of Documents	***Document and Data Control in UK and Ireland***
4.2.4	Control of Records	***Control of Management System Records***
5.0	**Management Responsibility**	
5.1	Management Commitment	***Management Responsibility for RBU UK and Ireland***
5.2	Customer Focus	***Customer Satisfaction Process***
5.3	Quality Policy	***Linde Group SHEQ Policy***
5.4	Planning	
5.4.1	Quality Objectives	***Management Responsibility for RBU UK and Ireland***
5.4.2	Quality Management System Planning	***Management Responsibility for RBU UK and Ireland***
5.5	Responsibility, Authority and Communication	
5.5.1	Responsibility and Authority	***Management Responsibility for RBU UK and Ireland***
5.5.2	Management Representative	***Management Responsibility for RBU UK and Ireland***
5.5.3	Internal Communication	***Group Meeting***. ***SHEQ Committees***.
5.6	Management Review	
5.6.1	General	***Procedure for Management Review***
5.6.2	Review Input	***Procedure for Management Review***
5.6.3	Review Output	***Procedure for Management Review***
6.0	**Resource Management**	
6.1	Provision of Resources	***Management Responsibility for RBU UK and Ireland***
6.2	Human Resources	
6.2.1	General	***Training in RBU UK and Ireland***
6.2.2	Competence, Awareness and Training	***Training in RBU UK and Ireland***
6.3	Infrastructure	***Management Responsibility for RBU UK and Ireland*** and relevant Business Process

ISO 9001 Clause		LiMSS Standard
6.4	Work Environment	***Management Responsibility for RBU UK and Ireland*** and relevant Business Process
7.0	**Product Realisation**	
7.1	Planning of Product Realisation	This is detailed in relevant ***Business Process flow charts*** and also within the relevant business in the Operations category of LiMSS.
7.2	Customer-Related Processes	
7.2.1	Determination of Requirements Related to the Products	***IMS-03-01-BOC: Contract Review***
7.2.2	Review of Requirements Related to the Product	***IMS-03-01-BOC: Contract Review***
7.2.3	Customer Communications	***Customer Complaints Procedure***. ***Product Recall***. ***CSC: CSC: Business Process***.
7.3	Design and Development	
7.3.1	Design and Development Planning	***About Product Development***. ***Product Development Process***.
7.3.2	Design and Development Inputs	***About Product Development***. ***Product Development Process***.
7.3.3	Design and Development Outputs	***About Product Development***. ***Product Development Process***.
7.3.4	Design and Development Review	***About Product Development***. ***Product Development Process***.
7.3.5	Design and Development Verification	***About Product Development***. ***Product Development Process***.
7.3.6	Design and Development Validation	***About Product Development***. ***Product Development Process***.
7.3.7	Control of Design and Development Changes	***About Product Development***. ***Product Development Process***.
7.4	Purchasing	
7.4.1	Purchasing Process	***Supplier Quality Evaluation and Assessment***
7.4.2	Purchasing Information	***IMS-06-02-GB: Requirements for Procurement***. ***IMS-06-07-GB: About Types of Contract***. ***IMS-06-08-GB: Technical Purchasing Requirements***.
7.4.3	Verification of Purchased Product	***Goods Receipt & Stores Operation***
7.5	Product and Service Provision	
7.5.1	Control of Production and Service Provision	See relevant ***OPS: Operations Processes***.

ISO 9001 Clause		LiMSS Standard
7.5.2	Validation of Processes for Production and Service Provision	***OPS: Operations Processes***
7.5.3	Identification and Traceability	***IMS-08: Identification and Traceability***
7.5.4	Customer Property	***Control of Customer Supplied Product and Property***. ***Personal Data Policy***.
7.5.5	Preservation of Product	See relevant ***OPS: Operations Processes***
7.6	Control of Monitoring and Measuring Equipment	***Inspection, Measuring and Test Equipment Calibration for UK and Ireland***
8.0	**Measurement, Analysis and Improvement**	
8.1	General	***Procedure for Management Review***. ***Planning and Resource Process for Continual Improvement***.
8.2	Monitoring and Measurement	
8.2.1	Feedback	***Customer Satisfaction Process***. ***Planning and Resource Process for Continual Improvement***. ***IMS-13: Control of Non-Conformance***
8.2.2	Internal Audit	***Auditing***
8.2.3	Monitoring and Measurement of Processes	***Management Responsibility***. ***Management Review Process***.
8.2.4	Monitoring and Measurement of Product	***IMS-10: Inspection and Testing***
8.3	Control of Non-conforming Product	***IMS-13: Control of Non-Conformance***
8.4	Analysis of Data	***Customer Satisfaction Process***. ***Planning and Resource Process for Continual Improvement***. ***Customer Complaints Procedure***. ***Corrective and Preventive Action***. ***Supplier Quality Evaluation and Assessment***.
8.5	Improvement	
8.5.1	Continual Improvement	***Planning and Resource Process for Continual Improvement***. ***Procedure for Management Review***.
8.5.2	Corrective Action	***Corrective and Preventive Action Process for Europ***.
8.5.3	Preventive Action	***Corrective and Preventive Action Process for Europe***.

ISO 13485:2012 Medical Device - Quality Management System – Requirements

ISO 13845 Clause		LiMSS Standard
4.0	**Quality Management System**	
4.1	General	***Management System Overview***. IMS-02-02-RUK: Management System and Standards (this chapter).
4.2	Documentation Requirements	
4.2.1	General	***Linde Group SHEQ Policy***. IMS-02-02-RUK: Management System and Standards (this chapter).
4.2.2	Quality Manual	IMS-02-02-RUK: Management System and Standards (this chapter).
4.2.3	Control of Documents	***Document and Data Control in UK and Ireland***
4.2.4	Control of Records	***Control of Management System Records***
5.0	**Management Responsibility**	
5.1	Management Commitment	***Management Responsibility for RBU UK and Ireland***
5.2	Customer Focus	***Customer Satisfaction Process***
5.3	Quality Policy	***Linde Group SHEQ Policy***
5.4	Planning	
5.4.1	Quality Objectives	***Management Responsibility for RBU UK and Ireland***
5.4.2	Quality Management System Planning	***Management Responsibility for RBU UK and Ireland***
5.5	Responsibility, Authority and Communication	
5.5.1	Responsibility and Authority	***Management Responsibility for RBU UK and Ireland***
5.5.2	Management Representative	***Management Responsibility for RBU UK and Ireland***. ***Procedure for Management Review***.
5.5.3	Internal Communication	***Management System Overview***. ***Group Meetings***. ***SHEQ Committees***.
5.6	Management Review	
5.6.1	General	***Procedure for Management Review***
5.6.2	Review Input	***Procedure for Management Review***
5.6.3	Review Output	***Procedure for Management Review***
6.0	**Resource Management**	
6.1	Provision of Resources	***Management Responsibility for RBU UK and Ireland***.
6.2	Human Resources	

ISO 13845 Clause		LiMSS Standard
6.2.1	General	***Training in RBU UK and Ireland***
6.2.2	Competence, Awareness and Training	***Training in RBU UK and Ireland***
6.3	Infrastructure	***Management Responsibility for RBU UK and Ireland***. ***Establishing a Maintenance and Condition Monitoring Programme***.
6.4	Work Environment	***Management Responsibility for RBU UK and Ireland***. ***Training in RBU UK and Ireland***. ***MED-06-01-BOC: About Premises and Equipment***.
7.0	**Product Realisation**	
7.1	Planning of Product Realisation	***Tonnage & Bulk Business Process Flowchart*.** ***OPS: Relevant Operations category of LiMSS***. ***About Risk Assessmen***. ***Design Validation***.
7.2	Customer-Related Processes	
7.2.1	Determination of Requirements Related to the Products	***IMS-03-01-BOC: Contract Review***
7.2.2	Review of Requirements Related to the Product	***IMS-03-01-BOC: Contract Review***
7.2.3	Customer Communications	***IMS-03-01-BOC: Contract Review***. ***Customer Complaints Procedure***. ***Product Recall***. ***Medical Device Vigilance Reporting for United Kingdom and Ireland***. ***Review of Marketing Related to Healthcare Products and Services***. ***CSC: CSC: Business Process***.
7.3	Design and Development	
7.3.1	Design and Development Planning	***About Product Developmen***. ***Product Development Process***. ***MED-32: Medical Devices***.
7.3.2	Design and Development Inputs	***About Product Development***. ***Product Development Proces***. ***MED-32: Medical Devices***
7.3.3	Design and Development Outputs	***About Product Development***. ***Product Development Process***. ***MED-32: Medical Devices***

ISO 13845 Clause		LiMSS Standard
7.3.4	Design and Development Review	***About Product Development***. ***Product Development Process***. ***MED-32: Medical Devices***
7.3.5	Design and Development Verification	***About Product Development***. ***Product Development Process***. ***MED-32: Medical Devices***
7.3.6	Design and Development Validation	***About Product Development***. ***Product Development Process***. ***MED-32: Medical Devices***
7.3.7	Control of Design and Development Changes	***About Product Development***. ***Product Development Process***. ***MED-32: Medical Devices***
7.4	Purchasing	
7.4.1	Purchasing Process	***Materials and Service Management***
7.4.2	Purchasing Information	***IMS-06-02-GB: Requirements for Procurement***. ***IMS-06-07-GB: About Types of Contract***. ***IMS-06-08-GB: Technical Purchasing Requirements***.
7.4.3	Verification of Purchased Product	***Inspection and Testing Overview***
7.5	Product and Service Provision	
7.5.1	Control of Production and Service Provision	***Tonnage & Bulk Business Process Flowchart***
7.5.2	Validation of Processes for Production and Service Provision	***MED-13: Validation***
7.5.3	Identification and Traceability	***IMS-08: Identification and Traceability***
7.5.4	Customer Property	***Control of Customer Supplied Product and Property***. ***Personal Data Policy***.
7.5.5	Preservation of Product	***Tonnage & Bulk Business Process Flowchart***
7.6	Control of Monitoring and Measuring Equipment	***Inspection, Measuring and Test Equipment Calibration***.

8.0	**Measurement, Analysis and Improvement**	
8.1	General	***Procedure for Management Review***. ***Planning and Resource Process for Continual Improvement***.
8.2	Monitoring and Measurement	
8.2.1	Feedback	***Customer Satisfaction Process***. ***Planning and Resource Process for Continual Improvement***. ***IMS-13: Control of Non-Conformance***
8.2.2	Internal Audit	***Auditing***
8.2.3	Monitoring and Measurement of Processes	***Management Responsibility for RBU UK and Ireland***. ***Management Review Proces***.
8.2.4	Monitoring and Measurement of Product	***IMS-10: Inspection and Testing***
8.3	Control of Non-conforming Product	***IMS-13: Control of Non-Conformance***
8.4	Analysis of Data	***Customer Satisfaction Process***. ***Planning and Resource Process for Continual Improvement***. ***Customer Complaints Procedure***. ***Corrective and Preventive Action***. ***Supplier Quality Evaluation and Assessment***.
8.5	Improvement	
8.5.1	General	***Planning and Resource Process for Continual Improvement***. ***Procedure for Management Review***. ***IMS-13: Control of Non-Conformance***. ***Medical Device Vigilance Reporting for United Kingdom and Ireland***.
8.5.2	Corrective Action	***Corrective and Preventive Action Process for Europe***.
8.5.3	Preventive Action	***Corrective and Preventive Action Process for Europe***.

ISO 14001:2004 Environmental Quality Management Systems - Requirements

ISO 14001 Clause		LiMSS Standard
4.0	**Environmental Management System Requirements**	
4.1	General Requirements	***About Environmental Management Systems***. ***IMS-21: Environmental Assessment***.
4.2	Environmental Policy	***Linde Group SHEQ Policy***.
4.3	Planning	

ISO 14001 Clause		LiMSS Standard
4.3.1	Environmental Aspects	***About Environmental Impact Assessment***. ***Environmental Aspect/Impact Reviews***.
4.3.2	Legal and Other Requirements	***Managing Legislative Compliance***. ***Environmental Legislative Compliance***.
4.3.3	Objectives, Targets and Programmes	***SHEQ Continual Improvement***
4.4	Implementation and Operation	
4.4.1	Resources, Roles, Responsibility and Authority	***Management Responsibility for RBU UK and Ireland***. ***IMS-01-05: Organisational Charts and Functional Responsibilities***.
4.4.2	Competence, Training and Awareness	***About Training***. ***Competency Profiles***. ***Training in RBU UK and Ireland***. ***About Competence Assessment***. ***Competence Assessment Process***. ***Competence Assessment Standards***.
4.4.3	Communication	***Group Meetings***
4.4.4	Documentation	***About Environmental Management Systems***
4.4.5	Control of Documents	***About Document and Data Control in UK and Ireland*** ***Control of Management System Records***.
4.4.6	Operational Control	***About Chemical Storage & Spills***. ***Environmental Noise***. ***Energy Conservation***. ***Environmental Remediation***. ***Waste Administration***. ***Waste Electrical and Electronic Equipment (WEEE)***. ***Waste Storage, Drainage and Incidents***. ***IMS-32: Contractor Management***
4.4.7	Emergency Preparedness and Response	***About Chemical Storage & Spills***. ***IMS-25-01-BOC: Policy on Emergency Preparedness and Response***. ***IMS-25: Site Emergency Plan*** ***Testing of Site Emergency Plans and Procedures***.
4.5	Checking	

ISO 14001 Clause		LiMSS Standard
4.5.1	Monitoring and Measurement	***Maintenance, Inspection & Condition Monitoring***. ***Environmental Monitoring***. ***Environmental Risk Control Strategies and Good Operating Practice***. ***Inspection, Measuring and Test Equipment Calibration***.
4.5.2	Evaluation of Compliance	***Corrective and Preventive Action***. ***Corrective and Preventive Action Process for RBU UK and Ireland***. ***Incident Management***
4.5.3	Non-conformity, Corrective and Preventive Action	***Corrective and Preventive Action Process for RBU UK and Ireland***
4.5.4	Control of Records	***Control of Management System Records***
4.5.5	Internal Audit	***About Auditing*** ***Audit Schedule and Approved Auditors in RBU UK and Ireland***.
4.6	Management Review	***Procedure for Management Review***

BS EN ISO/IEC 17020:2012 Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection

BS EN ISO/IEC 17020 Clause		LiMSS Standard
1.0	**Scope**	
2.0	**Normative References**	
3.0	**Terms and Definitions**	
4.0	**General Requirements**	
4.1	Impartiality and Independence	
4.1.1		***Test Shop Approval and Regulatory Issues***
4.1.2		***Test Shop Approval and Regulatory Issues*** ***The Linde Group Values and Policies***
4.1.3		***Test Shop Approval and Regulatory Issues***
4.1.4		***Test Shop Approval and Regulatory Issues***
4.1.5		***Test Shop Approval and Regulatory Issues***
4.1.6		***Test Shop Approval and Regulatory Issues***.
4.1.6a		N/A
4.1.6b		***Test Shop Approval and Regulatory Issues***
4.1.6c		N/A
4.2	Confidentiality	

BS EN ISO/IEC 17020 Clause		LiMSS Standard
4.2.1		***Test Shop Approval and Regulatory Issues***
4.2.2		***Test Shop Approval and Regulatory Issues***
4.2.3		***Test Shop Approval and Regulatory Issues***
5.0	**Structural Requirements**	
5.1	Administrative Requirements	
5.1.1		***IMS-01-05: Organisational Charts and Functional Responsibilities*** (site specific) ***Test Shop Approval and Regulatory Issues***
5.1.2		***IMS-01-05: Organisational Charts and Functional Responsibilities*** (site specific)
5.1.3		***CMT: CMT- Container Maintenance Business Process***
5.1.4		***Test Shop Approval and Regulatory Issues***
5.1.5		***Test Shop Approval and Regulatory Issues***
5.2	Organisation and Management	
5.2.1		***Test Shop Approval and Regulatory Issues***
5.2.2		***Test Shop Management*** ***Organisational Management of Change*** ***Training for RBU UK and Ireland Employees***
5.2.3		***Test Shop Approval and Regulatory Issues*** ***Test Shop Management*** ***IMS-01-05: Organisational Charts and Functional Responsibilities*** (site specific)
5.2.4		***Test Shop Approval and Regulatory Issues***.
5.2.5		***Test Shop Approval and Regulatory Issues*** ***Approval/Design Authorities and Teams of Experts (ToEs) for RBU UK and Ireland***
5.2.6		***Test Shop Approval and Regulatory Issues***
5.2.7		***Test Shop Approval and Regulatory Issues*** ***Test Shop Management***
6.0	**Resource requirements**	
6.1	Personnel	
6.1.1		***Training for RBU UK and Ireland Employees*** ***Competence Assessment Standards*** ***Test Shop Approval and Regulatory Issues***
6.1.2		***IMS-01-05: Organisational Charts and Functional Responsibilities*** (site specific) ***Training for RBU UK and Ireland Employees***

BS EN ISO/IEC 17020 Clause		LiMSS Standard
6.1.3		***Training for RBU UK and Ireland Employees***
6.1.4		***Test Shop Approval and Regulatory Issues***
6.1.5		***About Hiring and Placement*** ***Training for RBU UK and Ireland Employees*** ***Conducting Leadsafe Behavioural SHEQ Observations***
6.1.6		***Training for RBU UK and Ireland Employees***
6.1.7		***Training for RBU UK and Ireland Employees*** ***About Competence Assessment***
6.1.8		***Management Responsibilities for RBU UK and Ireland*** ***Test Shop Approval and Regulatory Issues***
6.1.9		***Test Shop Approval and Regulatory Issues***
6.1.10		***Training for RBU UK and Ireland Employees*** ***Management Responsibilities for RBU UK and Ireland*** ***Test Shop Approval and Regulatory Issues***
6.1.11		***Test Shop Approval and Regulatory Issues***
6.1.12		***Test Shop Approval and Regulatory Issues***
6.1.13		***Test Shop Approval and Regulatory Issues***
6.2	Facilities and Equipment	
6.2.1		***IMS-04: Design, Project and Change Control*** ***Test Shop Approval and Regulatory Issues*** ***Test Shop Activity Planning***
6.2.2		***Test Shop Approval and Regulatory Issues***
6.2.3		***Maintenance, Inspection and Condition Monitoring***
6.2.4		***Test Shop Approval and Regulatory Issues***
6.2.5		***Maintenance, Inspection and Condition Monitoring***
6.2.6		***IMS-11: Control of Measuring and Monitoring Devices***
6.2.7		***IMS-11: Control of Measuring and Monitoring Devices***
6.2.8		***IMS-11: Control of Measuring and Monitoring Devices***
6.2.9		***IMS-11: Control of Measuring and Monitoring Devices***
6.2.10		***IMS-11: Control of Measuring and Monitoring Devices***

BS EN ISO/IEC 17020 Clause		LiMSS Standard
6.2.11		***IMS-06: Supply Management***
6.2.12		***Goods Receipt and Stores Operation***
6.2.13		***Software Controlled Instrumentation Systems*** ***Establishing a Maintenance and Condition Monitoring Programme***
6.2.14		***Establishing a Maintenance and Condition Monitoring Programme*** ***Inspection, Measuring and Test Equipment Calibration for RBU UK and Ireland***
6.2.15		***Establishing a Maintenance and Condition Monitoring Programme*** ***Inspection, Measuring and Test Equipment Calibration for RBU UK and Ireland***
6.3	Subcontracting	***Test Shop Approval and Regulatory Issues***
7.0	**Process Requirements**	
7.1	Inspection Methods and Procedures	
7.1.1		***CMT: CMT- Container Maintenance Business Process*** ***Test Shop Approval and Regulatory Issues***
7.1.2		***CMT: CMT- Container Maintenance Business Process***
7.1.3		***CMT: CMT- Container Maintenance Business Process***
7.1.4		***CMT: CMT- Container Maintenance Business Process*** ***LIMSS*** ***Document and Data Control in UK and Ireland***
7.1.5		***CMT: CMT- Container Maintenance Business Process***
7.1.6		***Test Shop Approval and Regulatory Issues***
7.1.7		***CMT: CMT- Container Maintenance Business Process***
7.1.8		***Document and Data Control in UK and Ireland***
7.1.9		***CMT: CMT- Container Maintenance Business Process***
7.2	Handling Inspection Items and Samples	
7.2.1		***CMT: CMT- Container Maintenance Business Process***
7.2.2		***CMT: CMT- Container Maintenance Business Process***
7.2.3		***CMT: CMT- Container Maintenance Business Process***
7.2.4		***CMT: CMT- Container Maintenance Business Process***
7.3	Inspection Records	
7.3.1		***Control of Management System Records*** ***About Test Shop Data Collection***
7.3.2		***CMT: CMT- Container Maintenance Business Process***

BS EN ISO/IEC 17020 Clause		LiMSS Standard
7.4	Inspection Reports and Inspection Certificates	
7.4.1		***About Test Shops***
7.4.2		***About Test Shops***
7.4.3		***About Test Shops***
7.4.4		N/A
7.4.5		***About Test Shops***
7.5	Complaints and Appeals	
7.5.1		***Customer Complaints Procedure for UK and Ireland*** ***Corrective and Preventative Actions Process for Europe***
7.5.2		N/A
7.5.3		***Customer Complaints Procedure for UK and Ireland***
7.5.4		N/A
7.5.5		N/A
7.6	Complaints and Appeals Process	
7.6.1		***Customer Complaints Procedure for UK and Ireland*** ***Corrective and Preventative Actions Process for Europe***
7.6.2		N/A
7.6.3		***Customer Complaints Procedure for UK and Ireland***
7.6.4		***Customer Complaints Procedure for UK and Ireland***
7.6.5		***Customer Complaints Procedure for UK and Ireland***
8.0	**Management System Requirements**	
8.1	Options	
8.1.1		Note under multilateral agreement M261 Option B is not available for carriage of Dangerous Goods activities
8.1.2		N/A
8.1.3		ISO 9001:2008 certificate ***IMS: Management System***
8.2		
8.2	Management System Documentation	
8.2.1		IMS-02-02-RUK: Management System for UK and Ireland RBU (this chapter)
8.2.2		***Management Responsibility for RBU UK and Ireland***
8.2.3		***Management Responsibility for RBU UK and Ireland***
8.2.4		IMS-02-02-RUK: Management System for UK and Ireland RBU (this chapter)

BS EN ISO/IEC 17020 Clause		LiMSS Standard
8.2.5		IMS-02-02-RUK: Management System for UK and Ireland RBU (this chapter)
8.3	Control of Documents	
8.3.1		***Document and Data Control in UK and Ireland***
8.3.2		***Document and Data Control in UK and Ireland***
8.4	Control of Records	
8.4.1		***Control of Management System Records***
8.4.2		***Control of Management System Records***
8.5	Management Review	
8.5.1	General	
8.5.1.1		***Procedure for Management Review***
8.5.1.2.		***Procedure for Management Review***
8.5.1.3		***Procedure for Management Review***
8.5.2	Review Inputs	***Procedure for Management Review***
8.5.3	Review Outputs	***Procedure for Management Review***
8.6	Internal Audits	
8.6.1		***About Auditing***
8.6.2		***About Auditing***
8.6.3		***About Auditing***
8.6.4		***About Auditing***
8.6.5		***About Auditing***
8.7	Corrective Action	
8.7.1		***Corrective and Preventive Action for Europe***
8.7.2		***Corrective and Preventive Action for Europe***
8.7.3		***Corrective and Preventive Action for Europe***
8.7.4		***Corrective and Preventive Action for Europe***
8.8	Preventative Action	
8.8.1		***Corrective and Preventive Action for Europe***
8.8.2		***Corrective and Preventive Action for Europe***
8.8.3		***Corrective and Preventive Action for Europe***
Annex A (normative)	**Independence Requirements for Inspection Bodies**	
A.1	Requirements for Inspection Bodies (Type A)	
A.2	Requirements for Inspection Bodies (Type B)	
a)		***Test Shop Approval and Regulatory Issues***

BS EN ISO/IEC 17020 Clause		LiMSS Standard
b)		***Test Shop Approval and Regulatory Issues*** ***IMS-01-05: Organisational Charts and Functional Responsibilities*** (site specific)
c)		***Test Shop Approval and Regulatory Issues***
A.3	Requirements for Inspection Bodies (Type C)	
Annex A (informative)	**Optional Elements of Inspection Reports and Certificates**	

BS EN ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories and ISO Guide 34: 2009 General Requirements for the Competence of Reference Material Producers

ISO/IEC 17025

The management requirements of ISO/IEC 17025 are cross referenced in the table below.

This supplements ***ISO/IEC 17025 and ISO Guide 34 Quality Manual*** which is the definitive Quality Manual for BOC's accredited testing facilities and activities.

ISO/IEC 17025 Clause		LiMSS Standard
4.0	**Management Requirements**	
4.1	Organisation and Responsibilities	***The Linde Group Values and Policies***. ***Management Responsibility for RBU UK and Ireland***.
4.2	Management System	IMS-02-02-RUK: Management System for UK and Ireland RBU (this chapter)
4.3	Document Control	***Document and Data Control in UK and Ireland***
4.4	Review of Requests, Tenders and Contracts	***IMS-03-01-BOC: Contract Review***
4.5	Subcontracting of Tests and/or Calibration Work	No ISO 17025 scope work subcontracted.
4.6	Purchasing Services and Supplies	***IMS-06-02-GB: Requirements for Procurement***. ***Supplier Quality, Evaluation and Assessment***. ***IMS-06-07-GB: About Types of Contract***. ***IMS-06-08-GB: Technical Purchasing Requirements***. ***Goods Receipt & Stores Operation***.
4.7	Service to the Customer	No ISO 17025 scope work subcontracted.
4.8	Complaints	***Corrective and Preventive Action***. ***Corrective and Preventive Action for Europe***.
4.9	Control of Non-conforming Testing and/or Calibration Work	***Non Conformance***

ISO/IEC 17025 Clause		LiMSS Standard
4.10	Improvement	***Corrective and Preventive Action***. ***Corrective and Preventive Action for Europe***.
4.11	Corrective Action	***Corrective and Preventive Action***
4.12	Preventive Action	***Corrective and Preventive Action for Europe***
4.13	Control of Records	***Control of Management System Records***
4.14	Internal Audits	***About Auditing***
4.15	Management Review	***Procedure for Management Review***

Directive 2003/94/EC Laying Down the Principles and Guidelines of Good Manufacturing Practice for Human Medicines (GMP)

Directive 2003/94/EC Requirements		LiMSS Standard
1.0	**Quality Management**	IMS-02-02-RUK: Management System for RBU UK and Ireland (this chapter).
2.0	**Personnel**	***The Linde Group Values and Policies***
3.0	**Premises and Equipment**	
4.0	**Documentation**	***Document and Data Control in UK and Ireland*** ***Control of Management System Records***.
5.0	**Production**	***MED: Refer to Medical Business Process***
6.0	**Quality Control**	***MED: Refer to Medical Business Process***
7.0	**Contract Manufacture and Analysis**	No scope work subcontracted
8.0	**Complaints and Product Recall**	***Customer Complaints Procedure***. ***Corrective and Preventive Action***. ***Corrective and Preventive Action for Europe***.
9.0	**Self-Inspection**	***Management Responsibility for RBU UK and Ireland***. ***About Auditing***.

European Tissues and Cells directives 2004/23/EC, 2006/17/EC and 2006/86/EC

Directive 2004/23/EC Requirements	LiMSS Standard
Quality Management	IMS-02-02-RUK: Management System for RBU UK and Ireland (this chapter)
Organisation and Responsibilities	***The Linde Group Values and Policies*** ***Management Responsibility for RBU UK and Ireland***
Personnel	***Training for RBU UK and Ireland Employees***

Directive 2004/23/EC Requirements	LiMSS Standard
Equipment and Materials, Facilities and Premises	***Drystore Operation and Alert*** ***Oxygen Monitors*** ***Safe Handling and Use of Dryshippers*** ***Heating and Ventilation***.
Documentation	***Document and Data Control*** ***Documents and Records***
Storage and Release of Products Including Consent and Disposal	***Sample Handling*** ***Sample Disposal*** ***Creating a Customer Account and Order*** ***Sample Release and Return***
Complaints, Non-conformances and Product Recall	***Non-conformance*** ***Complaints Procedure*** ***Customer Complaints Procedure for UK and Ireland*** ***Recall*** ***Complaints and Non-conformances*** ***Recall of Samples***
Quality Review and Self-Inspection	***About Auditing*** ***Internal Auditing***
Serious Adverse Events	***Adverse Events and Reactions***

Accreditation and Certification Logos

Use of accreditation and certification logos

The use of logos issued by accreditation and certification bodies **must** be strictly controlled and there are rules as to which, where, when and what size can be used.

For further information, see:

- ***LRQA Quality and Environmental Management System Approvals (see attachment)***.
- ***Lloyd's Register Quality Assurance System Approval with UKAS QMS Mark (see attachment)***.
- ***Lloyd's Register Quality Assurance System Approval with UKAS EMS Mark (see attachment)***.
- ***UKAS Accreditation Approval***.
- ***NSAI Guidelines (see attachment)***.
- ***INAB Regulations***.

Document Information

About this Document

Version	Date	Author	Quality Reviewer	Approver
2.16	Jun 18	L Ramphele Technical Writer	B Loade SHEQ Manager Ireland	P Wesson Quality Assurance Manager
2.15	Aug 17	JR Ngobeni Technical Writer	C Delaney Sales Development Manager	P Wesson Quality Assurance Manager
2.14	Apr 17	JR Ngobeni Technical Writer	M Emsden Senior Project Manager	S Hourihan Homecare Business Manager
2.13	Feb 17	L Armstrong Technical Administrator	M Emsden Senior Project Manager	C Delaney BOC Sureserve
2.12	Sept 15	L Smith/P Crossman Technical Writers	S Hourihan Homecare Business Manager N Dunne Homecare Team Manager - Ireland S Trodd Office Manager P Hughes TMM Quality Manager P Laffan Dublin ASU Plant Manager	S Hourihan Homecare Business Manager P Hughes TMM Quality Manager B Loade SHEQ Manager Ireland
2.11	Sep 15	P Crossman/JA Shale Technical Writers	B Loade SHEQ Manager Ireland	I Reynor Sureserve & CES Manager
2.10	Aug 15	P Crossman Technical Writer	I O'Connor Technical Manager	I O'Connor Technical Manager

Previous Revisions

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2.9	Apr 15	M Emsden Technical Writer	B Loade SHEQ Manager Ireland	B Loade SHEQ Manager Ireland
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2.0	Mar 13	JA Shale TMSSS	P Wesson Quality Assurance Manager	P Wesson Quality Assurance Manager
1.11	Jan 10	P Govind TMSSS	J Cleary Operations Safety Manager	IMS RUK ToE
1.10	Dec 09	P Govind TMSSS	J Cleary Operations Safety Manager	IMS RUK ToE

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1.9	Jul 09	M Emsden TMSSS	J Cleary Safety Competency Manager	IMS RUK ToE
1.8	Sep 08	R Gunn TMS	J Cleary Safety Competency Manager	J Cleary Safety Competency Manager
1.7	Apr 08	R Newell TMS	J Cleary Safety Competency Manager	J Cleary Safety Competency Manager
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1.4	Nov 04	J Tingle	IMS UK ToE D Hayward – Leader GK Stebbings A Clapham J Tingle M Woods H Sullivan P Henrys P Wesson C Jubb	IMS UK ToE D Hayward – Leader GK Stebbings A Clapham J Tingle M Woods H Sullivan P Henrys P Wesson C Jubb
1.3	Apr 04	D Hayward	D Hayward	IMS UK TOE D Hayward – Leader GK Stebbing A Clapham J Tingle M Woods H Sullivan P Henrys P Wesson C Jubb
1.2	Apr 04	D Hayward	D Hayward	IMS UK ToE D Hayward – Leader GK Stebbing A Clapham J Tingle M Woods H Sullivan P Henrys P Wesson C Jubb

Version	Date	Author	Quality Reviewer	Approver
1.1	Oct 02	D Hayward	D Hayward	IMS UK ToE D Hayward – Leader GK Stebbings A Clapham J Tingle M Woods H Sullivan P Henrys P Wesson C Jubb
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Change History

Version	Description of Change
2.16	Document updated to the latest LiMSS standard. Homecare Critical Process Maps attachment updated. PG&P Production Critical Process Maps attachment updated. Tonnage Critical Process Maps renamed to Onsites Process Maps, attachment updated. Planning & Logistics Process Map attachment updated. CSC Dublin Critical Process Map attachment updated. Sureserve Critical Process Maps attachment updated.
2.15	Sureserve Emergency Process Maps updated • Emergency Handling Procedure • Order and Delivery
2.14	Homecare Critical Process Maps attachment updated Business Impact: None.
2.13	Document reviewed. No updates to document required. Attachment updates (See: Change History – Attachments) in accordance with current standards and procedures. Business Impact: None.
2.12	Homecare Critical Process Maps revised with new HOMECP6. TMM Critical Process Maps revised - TCP1, 2 and 3 updated, TCP4 and 5 added. Tonnage Critical Process Maps revised. No changes to the content of this document. Business Impact: None.
2.11	Sureserve Critical Process Maps amended. • Ecall Handling Procedure changed from SCP 6 to SCP 2 • New SCP 5 and SCP 6 added. CSC Dublin Critical Process Maps amended. Retail Management Critical Process Maps amended. No changes to the content of this document. Business Impact: None
2.10	Sureserve Critical Process Maps amended. No changes to the content of this document. Business Impact: None

Previous History

Version	Description of Change
2.9	CES Dublin Critical Process Map amended. No changes to the Chapter. Business Impact Statement: None.

Version	Description of Change
2.8	***European Tissues and Cells directives 2004/23/EC, 2006/17/EC and 2006/86/EC (page 24)*** LiMMS cross reference table added. Business Impact: None.
2.7	PG&P Process Map updated. Business Impact: None.
2.6	Tonnage Process Map updated. The PGCP10 Rev 05 has been updated to Machine Logs (BGI-T-099 & BGI-T-101). Completed ASU log sheet BGI-061 (once every two weeks to be included) has been updated to Completed Machine Logs BGI-T-099 & BGI-T-101 (once every 2 weeks). **Business Impact:** None. PGCP5 Rev 03 April 2007 needed to be reviewed as part of the 5 year review but no updates were required.
2.5	The following process maps have been added: • HR Critical Process Map • Legal Critical Process Map • Retail Management Critical Process Maps • SHEQ Critical Process Map Business Impact Statement: No impact
2.4	***BS EN ISO/IEC 17020:2012 Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection (page 17)*** – clause 8 updated Numerous document scopes changed throughout the document from BOC to GROUP to reflect changes made in LiMSS. **Business Impact Statement:** No new requirements, ISO 17020 cross reference table populated to reflect existing protocols to fulfil requirements of ISO 17020 Clause 8.
2.3	Updated to reflect the requirements of BS EN ISO/IEC 17020 2012. Business Impact Statement: No impact.
2.2	Sureserve Critical Process Map amended. No changes to the Chapter. Business Impact Statement: No impact.
2.1	All Process Maps updated. Homecare Process Map added. Business Impact Statement: No impact.

Version	Description of Change
2.0	Following flowcharts updated: • Filling and Transportation of Packaged Goods. • Tonnage & Bulk Business Process. 'Cryobank Process Flowchart' included. Following information amended: • ***Monitoring and Measurement of Processes (page 6)***. • ***External Management System Compliance (page 7)***. • ***Accreditation and Certification Logos (page 25)*** and relevant launchables. Update of ***HSG 65: Successful Health and Safety Management (page 8)***. Inclusion of: • ***TMM Critical Process Map (see attachment)***. • ***ISO 13485:2012 Medical Device - Quality Management System – Requirements (page 12)***. • Amendment of ***Management System (page 2)*** information. • Minor textual amendments. • Link tables updated throughout chapter. • TQs amended. Chapter updated to current template and standards.
1.11	IMSS Overview Presentation added to references of the Learning and Assessment Guide (LAG).
1.10	Changes to BS EN ISO 9001:2008 items 7.5.4 and 7.6.
1.9	References to Quality Management System – Requirements updated to BS EN ISO 9001:2008.
1.8	Minor text amendments and 'IMSS' changed to 'LiMSS'.
1.7	Changed scope from 'EUR' to 'RUK' No content change to chapter.
1.6	ISO 14001: 2004 and ISO 17025: 2005 requirements updated in accordance with legislation.
1.5	Chapter reviewed and updated in accordance with legislative requirements. Inclusion of BGI process flowcharts.
1.4	Removed section on Responsible Care. Repaired broken links.
1.3	Repair of broken links.
1.2	Corrections to hyperlinks in ISO 9001 cross reference table.
1.1	Changed 4 graphic links in 02-02-03.gif.
1.0	Initial issue.

Change History - Attachments

CES Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**

1.2	Apr 15	B Loade	Minor changes to process targets and measures.

Cryospeed/Helispeed Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**
1.1	Sep 13	B Loade	Updated.

CSC Dublin Critical Process Map			
Version	**Date**	**Approved**	**Description**
1.3	Jul 18	D Browne	Updated.
1.2	Sep 15	I Reynor	Updated.

Homecare Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**
1.3	Jun 18	N Dunne	Attachment updated
1.2	Apr 17	B Loade	Attachment updated
1.1	Sept 15	S Hourihan	Revised with new HOMECP6.

HR Critical Process Maps (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Aug 14	B Loade	Initial issue.

Ireland (Belfast) Critical Process Maps (see attachment)			
Version	**Date**	**Approved**	**Description**
1.1	Sep 13	B Loade	Updated.

Legal Critical Process Maps (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Aug 14	B Loade	Initial issue.

Lloyd's Register Quality Assurance System Approval with UKAS EMS Mark (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Mar 13	P Wesson	Initial issue.

Lloyd's Register Quality Assurance System Approval with UKAS QMS Mark (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Mar 13	P Wesson	Initial issue.

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Version	**Date**	**Approved**	**Description**
1.0	Apr 08	IMS RUK ToE	Initial issue within IMS-02-02-RUK.

LRQA Quality and Environmental Management System Approvals (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Mar 13	P Wesson	Initial issue.

NSAI Guidelines (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Apr 08	IMS RUK ToE	Initial issue within IMS-02-02-RUK.

PG&P Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**
1.3	Jun 18	L McClements	Updated.
1.2	Feb 15	B Loade	Updated.

Planning & Logistics Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**
1.2	Jul 18	D Flynn T Galvin B Fay	Updated.
1.1	Sep 13	B Loade	Updated.

Retail Management Critical Process Maps (see attachment)			
Version	**Date**	**Approved**	**Description**
1.1	Sep 15	I Reynor	Updated

SHEQ Critical Process Maps (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Aug 14	B Loade	Initial issue.

Sureserve Critical Process Map			
Version	**Date**	**Approved**	**Description**
1.6	Jul 18	D Browne	Updated.
1.5	Sep 16	P Wesson	Updated.

Test Shop Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**
1.1	Sep 13	B Loade	Updated.

TMM Critical Process Map (see attachment)			
Version	**Date**	**Approved**	**Description**

1.2	Sept 15	P Hughes	Updated.

Onsites Process Map			
Version	**Date**	**Approved**	**Description**
1.4	Jun 18	P Laffan S Dunne B Loade	Updated.
1.3	Sept 15	B Loade	Updated.
1.3	Sept 15	B Loade	Updated.

UKAS Environmental Management System Approval (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Apr 08	IMS RUK ToE	Initial issue within IMS-02-02-RUK.

UKAS Quality Management System Approval (see attachment)			
Version	**Date**	**Approved**	**Description**
1.0	Apr 08	IMS RUK ToE	Initial issue within IMS-02-02-RUK.

Sureserve E-Call Handling Procedure			
Version	**Date**	**Approved**	**Description**
1.5	Sep 16	P Wesson	Updated

Learning and Assessment Guide

IMS-02-02-RUK : Management System and Standards for RBU UK and Ireland

Prerequisites

As a result of training in the content of this document you will be able to:	Learning method:	Assessment method:	Reference:
Describe the structure of the management system.	Self-study	Traccess Test	Whole Document