

werfen

**POL01. Integrated Quality &
Information Security Policy**

Version Control

Versions			
Version	Date	Author	Modifications
02	09/02/2021	S. Blemings	Updated to Corporate format (sections 6-9 added), Appendix A added. Annual Review: No updates to content as per agreement during ISO Committee meeting held 25.01.2021 (recorded within minutes of meeting).
03	13/07/2021	S. Blemings	Updated into new corporate format (Werfen Branding change), no content change.
04	05/07/2022	S. Blemings	Annual Review: Objectives (section 4) updated to align with agreed DRC-215 Objectives Monitoring Spreadsheet – 2022. Section 1 updated to include correct scope wording and version of SoA. Appendix A – Financial Controller updated to Financial Manager (Ariadna Cañellas) replacing Xavier Soler. Supply Chain Manager added – Stewart Taylor Jessica Worswick added to Internal Auditors
05	29/09/2023	S. Blemings	Annual Review: Font colour change from blue to black. APPENDIX A: Haemostasis BUM changed from Andy Smith to Sue Stafford. Financial Manager changed from Ariadna Cañellas to Jordi Llobet. INTERNAL Auditors – Removal of Daniel Maud and Brigitte Campbell, addition of Naomi Thompson (AUT).
06	13/05/2024	F. McSharry	Appendix A: Transfusion & Transplant added under Roles & Responsibility. Internal Auditors added - James Ash, Kayleigh Lacey & Thomas Staniforth. ANNUAL REVIEW performed (RW Action number 878).
	14/05/2024	S. Blemings	ISO Standard section updated: Updated reference of Annex A Control reference from 2013 standard to 2022 standard reference. APPENDIX A: Customer Support removed from HR and added to Contracts Manager responsibility. Quality Administrator & Audit Supervisor role added to Appendix A.

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Document ownership and status

Document owner	Issuing department	IMS Process
Quality & Regulatory Manager	Quality	Integrated Management System

Document status	APPROVED
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Distribution list

Areas/Departments
Werfen in the UK (all departments)

ISO standard section:

ISO Standard Clause	Description
5.2 (ISO 9001:2015)	Quality policy
5.2 (ISO IEC 27001:2022)	Policy
<p><i>This document has been prepared using the following ISO 27001 standard controls as reference.</i></p>	
A.5.1	Policies for information security
A.5.2	Information security roles and responsibilities
<p>Previously (Annex A Control A.5 – ISO 27001:2013)</p>	

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1. Scope and applicability

Werfen have assessed, determined, and implemented the impacts & expectations of its internal & external influences and interested parties to determine the Integrated Management Systems (IMS) scope and to ensure that all interested parties have a clear and unequivocal understanding of the systems, processes and accompanying policies and procedures that make up Werfen's **Integrated Management System**.

SCOPE: Procurement, sales, installation, warehouse, shipping, maintenance, technical and scientific support within the UK, of medical analytical solutions and IT systems for the healthcare sector. Statement of applicability version 1.n.

This policy applies to all employees and associates of **Werfen Ltd (UK)**.

2. Policy statement

Werfen Ltd is committed to providing products & services that always meet and where possible exceed the expectations of our customers and other interested parties as well as complying to all legal & regulatory requirements.

The security and legal admissibility of information owned and managed by Werfen Ltd is of great importance to continuing operations. Failure in these areas can result in damage to Werfen's reputation, financial loss as well as legal action against the confidentiality, integrity, and availability of Werfen information assets.

Adherence to this policy will help to protect Werfen Ltd, its customers and staff from information security threats, whether internal or external, deliberate, or accidental. It will ensure a consistent approach to security and legal admissibility throughout Werfen.

In support of this, Werfen Ltd operates an Integrated Management System (IMS) that complies with the requirements of both **ISO 9001** and **ISO IEC 27001** standards.

This is fundamental to the successful operation of the organisation and dedication to continual improvement of the IMS.

3. Roles, responsibilities and authority

This policy is produced by the senior management team of Werfen in the UK and is approved by the General Manager and the Quality and Regulatory Manager.

4. Policy objectives

Senior management provide clear focus on priorities by establishing business direction, these form the foundation of our IMS system, in brief.

Integrated Management System - Objectives	
QUALITY	INFORMATION SECURITY
To maintain a robust but dynamic company structure to support the growing needs of our customer base	Manage our information assets securely
To grow the sales to our current and future customers	Investigate and manage security incidents
To have high levels of customer satisfaction	Actively manage and reduce security risks and support continual improvement
To exceed shipping of goods expectations to our customers	Provide assurances to customers over the security of their information
To continue to grow and develop our employees	Comply with NHS Data Protection and Security Toolkit / Health and Social Care (HSCN) network connection requirements

5. General

- The framework of provisions for quality and information security management, and the related responsibilities, processes are set out in the IMS.
- Senior management are responsible for ensuring that the IMS continues to be suitable, adequate, and effective and, as part of this, shall review the policies, objectives, and legislative requirements regularly.
- Employees are responsible for carrying out their duties in line with the requirements of the IMS and shall receive training to enable them to perform these activities.
- Employees shall report to senior management any conditions, activities or occurrences that may render the IMS ineffective and therefore jeopardising the quality of service to our customers.

6. Changes to this policy

We reserve the right to change this policy at any time, where minor changes are made, which do not significantly affect this policy we will notify individuals about those changes by email.

On significant or fundamental changes to this document, individuals will be expected to review and agree to be bound by its conditions. If training is required, this will be performed and recorded within SAP Training module.

Once agreed individuals are subject to the new conditions of use from that date forward but this does not form part of any employee’s contract of employment.

The policy will be freely available through SAP (WerfenDocs) for employees to review and is also available on our website <https://www.werfen.com/uk/en/quality-and-environment>.

This policy will be reviewed on an **annual** basis.

7. Risks and opportunities

As part of the Integrated Management System, Werfen Ltd have a Risk and Opportunities Register which is actively managed via Risk Wizard system and reviewed by senior management.


8. Policy non-compliance


Employees that do not adhere to this policy may be treated as misconduct and may be subject to disciplinary action under our Disciplinary Procedure (**POL49**).

9. Related documents

Document reference	Document name
GQD08	Integrated Management System
POL49	Disciplinary Procedure
PR02	Staff Training Procedure

For and on behalf of Werfen Ltd (UK)

Signed: 
Date: 13th May 2024
Name: **Fiona McSharry**
Title: Quality & Regulatory Manager

Signed: 
Date: 14th May 2024
Name: **Richard Hames**
Title: General Manager

Appendix A – Quality & Information Security Roles

Quality Role	Information Security Role	Name
General Manager Overall responsible person but delegates management of the QMS to the Quality Manager	(*) General Manager Overall responsible person but delegates management of the ISMS to the Quality & Regulatory Manager	Richard Hames (*)
Quality & Regulatory Manager <i>(ISO Committee Chair)</i> Oversees Werfen UK Integrated Management System (QMS) Representative for Quality, Regulatory, Compliance, Health & Safety and Facilities	Quality & Regulatory Manager <i>(ISO Committee Chair)</i> Oversees Werfen UK Integrated Management System (ISMS) Data Protection Delegate Compliance Delegate	Fiona McSharry (*)
Technical Service Manager Representative for Field Service Engineering, Technical Support (Helpline) and Internal IT Processes: Preventive Maintenance, Reactive Support, Equipment Installation, Calibration & Internal IT Infrastructure	Senior Information Risk Owner (SIRO) Asset & Risk Owner for Technical Service and Internal IT	Kiran Naidu (*)
Haemostasis Business Unit Manager Representative for Haemostasis division Processes: Division Management, Product Management, Sales and User Training	Asset & Risk Owner for Haemostasis	Sue Stafford (*)
Autoimmune and Infectious Disease Business Unit Manager Representative for AIID division Processes: Division Management, Product Management, Sales and User Training	Asset & Risk Owner for Autoimmune and Infectious Disease	Adam Senior (*)
Acute Care Diagnostics Business Unit Manager Representative for ACD division Processes: Division Management, Product Management, Sales and User Training	Asset & Risk Owner for Acute Care Diagnostics	David Wheeler (*)
Transfusion & Transplant General Manager Representative for T&T division Processes: Division Management, Product Management, Sales and User Training (under ISO transition)	Asset & Risk Owner for Transfusion & Transplant Diagnostics	Patrick Lynch (*)
HITS Business Unit Manager Representative for HITS Processes: Division Management, IT Product Management, Sales & External IT Infrastructure	Asset & Risk Owner for External IT	Richard Hobman (*)
Head of HR & Customer Support Manager Representative for Human Resources & Fleet Management Processes: HR, Staff Competence, Awareness and Training	Asset & Risk Owner for HR & Fleet Management	Joanne Bennicke (*)

Contracts Manager Representative for Customer Support Processes: Customer orders and pricing, customer contract management, GEM credits	Asset & Risk Owner for Customer Support & Customer Contract Management	Simon Rose
Finance Manager Representative for Finance Processes: Purchasing & Suppliers	Asset & Risk Owner for Finance	Jordi Llobet (*)
Supply Chain Manager Representative for Supply Chain (Warehouse) Processes: Warehousing, Storage & Shipping	Asset & Risk Owner for Supply Chain (Warehousing)	Stewart Taylor (*)
Quality Administrator & Audit Supervisor Oversees all administration of Werfen's Quality Management System (QMS) and management of internal audits.	Oversees all administration of Werfen's Information Security Management System (ISMS) and management of internal audits.	Sharon Blemings (*)

Information Governance Quality Leads (IGQL)	
Office Personnel including Warehouse	Joanne Bennicke
Autoimmune and Infectious Disease	Michael Woodworth
Acute Care Diagnostics	Stefano Tambalo
Haemostasis	Graham Burrows
Technical Service, IT & HITS	Jessica Worswick

Internal Auditors	
Lead Auditor	Fiona McSharry (*)
Lead Auditor	Sharon Blemings (*)
Auditor	Jessica Worswick
Auditor Under Training (AUT)	Naomi Thompson
Auditor Under Training (AUT)	James Ash
Auditor Under Training (AUT)	Kayleigh Lacey
Auditor Under Training (AUT)	Thomas Staniforth

(*) Members of the ISO Committee