

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

## Version Control

Versions			
Version	Date	Author	Modifications
02	09/02/2021	S. Blemings	<p><i>Updated to Corporate format (sections 6-9 added), Appendix A added.</i></p> <p><b>Annual Review:</b> No updates to content as per agreement during ISO Committee meeting held 25.01.2021 (recorded within minutes of meeting).</p>

## Distribution list

Areas/Departments
Werfen UK

Document owner	Issuing department	IMS Process
Quality Manager	Quality	Management System

Document status	<b>APPROVED</b>
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ISO Standard Clause	Description
5.2 (ISO 9001:2015) 5.2 (ISO IEC 27001:2013)	Quality Policy Information Security Policy
<p><i>This document has been prepared using the following ISO 27001:2013 standard controls as reference.</i></p>	
ISO Annex A Control	Description
A.5.1	Management direction for information security

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## 1. Scope and Applicability

Werfen UK 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 UK IMS.

**SCOPE: Procurement, sales, installation, maintenance, technical and scientific support within the UK, of medical analytical solutions and IT systems for the healthcare sector. Statement of applicability version 4.n.**

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

## 2. Policy

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 9001:2015 and ISO IEC 27001:2013 standards.

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

## 3. Responsibility and Authority

This policy is produced by the senior management team of Werfen UK and is approved by the General Manager and the Quality 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	
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 ensure the integrity of our customer's information	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

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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 for employees to review and on display within the Reception area.

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

## 7. Risks and Opportunities

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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

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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

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Document Reference	Document Name
GQD-MC-01	Werfen UK Integrated Management System Manual
POL49	Disciplinary Procedure
PR02	Staff Training Procedure

**For and on behalf of Werfen UK Limited**

**Signed:** 

**Date:** 9<sup>th</sup> February 2021

**Name:** Fiona McSharry, Quality Manager

**Signed:** 

**Date:** 9<sup>th</sup> February 2021

**Name:** Richard Hames, General Manager

## Appendix A – Quality & Information Security Roles

Quality Role	Information Security Role	Name
<b>General Manager</b> Overall responsible person but delegates management of the QMS to the Quality Manager	<b>(*) General Manager</b> Overall responsible person but delegates management of the ISMS to the Quality Manager	Richard Hames (*)
<b>Quality Manager</b> <i>(ISO Committee Chair)</i> Oversees Werfen UK Integrated Management System (QMS) Representative for Quality, Regulatory, Compliance & Health & Safety	<b>Quality Manager</b> <i>(ISO Committee Chair)</i> Oversees Werfen UK Integrated Management System (ISMS) <b>Data Protection Delegate</b> <b>Compliance Delegate</b>	Fiona McSharry (*)
<b>Technical Service Manager</b> Representative for Field Service Engineering, Technical Support (Helpline) and Internal IT <b>Processes: Preventive Maintenance, Reactive Support, Equipment Installation, Calibration &amp; Internal IT Infrastructure</b>	<b>Senior Information Risk Owner (SIRO)</b> <b>Asset Owner</b> for Technical Service and Internal IT	Kiran Naidu (*)
<b>Haemostasis Business Unit Manager</b> Representative for Haemostasis division <b>Processes: Division Management, Product Management, Sales and User Training</b>	<b>Asset Owner</b> for Haemostasis	Andy Smith (*)
<b>Autoimmune and Infectious Disease Business Unit Manager</b> Representative for AIID division <b>Processes: Division Management, Product Management, Sales and User Training</b>	<b>Asset Owner</b> for Autoimmune and Infectious Disease	Julie Chatman (*)
<b>Acute Care Diagnostics Business Unit Manager</b> Representative for ACD division <b>Processes: Division Management, Product Management, Sales and User Training</b>	<b>Asset Owner</b> for Acute Care Diagnostics	David Wheeler (*)
<b>IT Business Unit Manager</b> Representative for IT <b>Processes: Division Management, IT Product Management, Sales &amp; External IT Infrastructure</b>	<b>Asset Owner</b> for External IT	Richard Hobman (*)
<b>Head of HR &amp; Customer Support Manager</b> Representative for Human Resources and Customer Support <b>Processes: HR, Staff Competence, Awareness and Training &amp; Customer Service</b>	<b>Asset Owner</b> for HR and Customer Support	Joanne Bennicke (*)
<b>Financial Controller</b> Representative for Finance & Supply Chain (Warehouse) <b>Processes: Purchasing &amp; Suppliers, Warehousing, Storage &amp; Shipping</b>	<b>Asset Owner</b> for Finance & Supply Chain	Xavier Soler (*)
<b>QA Administrator and Audit Supervisor</b> <i>(ISO Committee – minute taker)</i> Administrator for the QMS	<b>QA Administrator and Audit Supervisor</b> <i>(ISO Committee – minute taker)</i> Administrator for the ISMS	Sharon Blemings (*)

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

<b>Internal Auditors</b>	
	Fiona McSharry
	Sharon Blemings
	Brigitte Campbell
	Abigail Welsh
	Daniel Maud

(\*) Members of the ISO Committee