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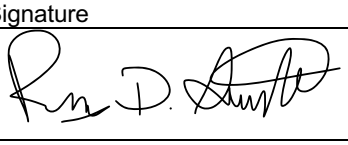
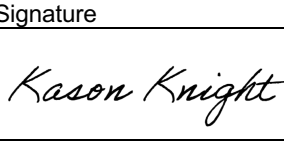
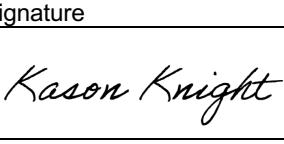
Signature: 	Signature: 	Signature: 
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REVISION HISTORY

Revision Number	Effective Date	Revision Summary (Brief Description)	Author
00	08-Nov-2024	Initial release	**Ross Smith**
01	22-Jul-2025	4.1.3 – added QMS-026 as a method for Internal Issues 4.3.1 – revised address to new company location Figure 3 - added examples to level iii and iv documents Corrected titles of QMS-007 and QMS-023 throughout Added references to newly created QMS-031 SOP	**Ross Smith**
02	29-Sep-2025	- Added management review to section 4.1.3 - Added environmental and climate change monitoring as a - method to table in 4.1.3 for external issues - Changed title of QMS-030 to “Continual” Improvement - throughout	**Ross Smith**
03	9-Feb-2026	- Revise Added reference to ISO 9000 for framework as foundation (2.1) - Corrected title of QMS-002 throughout - Added notification to registrars of significant changes (4.2.2)	**Ross Smith**
04	13-Apr-2026	- Revise to expand the QMS scope to include medical device contract manufacturing per quality plan PLN-003 - Minor verbiage and grammatical adjustments throughout	**Ross Smith**

i-SOLIDS
DIGITAL MANUFACTURING

Quality Manual

i-SOLIDS QUALITY POLICY

We are committed to delivering high-quality, safe, and effective products that meet applicable customer, statutory and regulatory requirements through innovation and continuous improvement. i-SOLIDS will:

- Maintain the suitability and effectiveness of our Quality Management System through ongoing monitoring and improvement.
- Establish clear and measurable quality objectives to guide our performance and ensure accountability.
- Conduct periodic reviews of quality objectives by Top Management to drive strategic enhancements.
- Empower our teams with technology and training to optimize production capabilities and quality.
- Exceed customer expectations by transforming innovative ideas into exceptional products across diverse industries.

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1. i-SOLIDS INTRODUCTION

Company Background

Founded in 2016, i-SOLIDS began as a modest operation with a single 3D printer and a bold vision; to revolutionize manufacturing. Our journey was driven by a commitment to providing "creative control" to businesses that felt constrained by the high costs and lengthy timelines of traditional manufacturing processes. Over the years, we have evolved into a specialized team of engineers, designers, and programmers, dedicated to delivering comprehensive technical consulting, prototyping and turnkey manufacturing solutions across a variety of industries. Our extensive services range from industrial end-use additive manufacturing (e.g., 3D printing), rapid prototyping, mechanical and industrial design, to engineering services, and project management, making i-SOLIDS a trusted partner for a multitude of product development projects.

At i-SOLIDS, we celebrate our rich and diverse background encompassing mechanical engineering, CAD modeling, electrical design, software programming, patent protection, and manufacturing technologies. This foundation allows us to approach every project holistically, ensuring that we treat each development with the attention to detail it deserves. We operate one of the largest and most varied fleets of industrial additive manufacturing technologies in the United States, boasting over 150 printers capable of utilizing a vast array of engineering-grade materials. This unique infrastructure empowers us to tackle even the most complex supply chain and manufacturing challenges, providing innovative and cost-effective solutions that span from prototyping to high-volume production.

Our commitment to innovation goes beyond simply using advanced hardware; we seamlessly integrate cutting-edge machine learning and artificial intelligence into our workflows. This approach significantly enhances our production capabilities while upholding rigorous quality standards, resulting in an industry-leading quality performance that exceeds 99%. As we navigate the challenges of producing thousands of unique parts, our state-of-the-art inspection system—featuring vision, sorting, and logic modules—allows us to streamline operations and optimize quality outcomes. By leveraging our extensive experience and knowledge across various projects and industries, i-SOLIDS remains dedicated to transforming innovative ideas into tangible, functional products, consistently delivering exceptional results at competitive rates.

Join i-SOLIDS as we continue to push the boundaries of what’s possible in digital manufacturing!

i-SOLIDS Vision

Enable custom manufacturing solutions that transform ideas into exceptional products with the highest quality standards.

i-SOLIDS Mission

We are committed to addressing unique customer challenges through revolutionary digital manufacturing. By combining cutting-edge technologies with exceptional processes, we deliver high-quality, economical solutions. Our core purpose is to cultivate deep, meaningful relationships with our customers, enabling us to fully understand their distinct needs. Through these partnerships, we tailor innovative strategies to drive their success. As we push boundaries, we aim to establish i-SOLIDS as a leading manufacturing company, enriching our employees, customers, and the industry.

i-SOLIDS Company Values

1. **Integrity** – Always doing the right thing and maintaining ethical standards in all interactions and decisions.

2. **Quality** – Committing to the highest standards in products and services, ensuring exceptional outcomes for our customers.

3. **Continuous Improvement** – Embracing a culture of learning and development to constantly enhance processes and solutions.

4. **Innovation** – Pioneering the use of advanced technologies and creative approaches to stay at the forefront of the manufacturing industry.

5. **Customer Enablement** – Providing businesses with the tools and support they need to achieve their goals and realize their visions.

6. **Collaboration** – Building strong relationships with partners, customers, and team members to nurture success and mutual growth.

7. **Employee Development** – Offering continuous learning and growth opportunities that empower employees to advance their skills and reach their full potential.

8. **Community Impact** – Striving to create geographical manufacturing opportunities that contribute positively to local communities and beyond.

2. PURPOSE

2.1. This Quality Manual, hereafter referred to as "Manual," outlines the scope and structure of the i-SOLIDS Quality Management System, hereafter referred to as "QMS," in order to ensure compliance to applicable requirements, statues, regulations, and standards. The QMS is designed to be compliant with the ISO 9001 and ISO 13485 standards, and FDA Quality Management System Regulation (QMSR), while using the framework of ISO 9000 to establish a QMS foundation, and ISO 14971 for medical device risk management.

2.2. This Manual, and documented information within the QMS, are designed to be as simplified as possible. This approach affords i-SOLIDS the best opportunity to establish, execute, audit, maintain, and improve the QMS to maximize its effectiveness. As the overall QMS is designed to be compliant with ISO 9001, ISO 13485, and the QSMR, this Manual avoids repetitive language from ISO and FDA, to more importantly describe (or refer to) how each clause is established. This Manual aligns with ISO 9001 clause numbering.

2.3. The approval of this Manual establishes the overall quality plan, which defines the quality practices, resources, and activities relevant to products and services that are provided by i-SOLIDS. It also establishes how the requirements for quality will be met, and establishes the structure and documentation used for the QMS.

3. ACRONYMS, TERMS and DEFINITIONS

3.1. Refer to the i-SOLIDS QMS Glossary (QMS-003) for a list of Acronyms, Terms, and Definitions.

4. CONTEXT of the ORGANIZATION

4.1. Understanding the Organization and its Context

4.1.1. i-SOLIDS overarching purpose and strategic direction are outlined in the company Vision, Mission, and Values statements on page 4 of this Manual.

4.1.2. i-SOLIDS has determined that the following internal and external sources are key issues related to the purpose and strategic direction of the company.

4.1.3. i-SOLIDS monitors these sources and reviews them while carrying out QMS activities, and during management review, to ensure the intended results of the QMS are achieved.

External Issues	**Monitor and Review Methods**
Understanding and fulfilling customer needs	Product and Service Requirements (QMS-015) Post-Delivery Activities (QMS-021) Customer Satisfaction (QMS-025) Management Review (QMS-028)
Business development	Sales reviews Marketing engagement reviews News and social media monitoring Customer Satisfaction (QMS-025)
Competitor analysis	Periodic pricing comparisons Competitive marketing analysis News and social media monitoring
Socio-economic factors (local, national, international)	News and social media monitoring Environment and climate change monitoring
Supply chain	News and social media monitoring Purchasing and Supplier Control (QMS-016)

Technology advancements	Information from equipment developers Technology research News and social media monitoring
Digital manufacturing opportunities	Information from industry News and social media monitoring
Regulatory and statutory obligations	Internal audits (QMS-027) Management Review (QMS-028)
Legal vulnerabilities and obligations	Annual insurance review Management Review (QMS-028)

Internal Issues	**Monitor and Review Methods**
Goals and objectives	Management Review (QMS-028)
Resources	Training, Competence and Awareness (QMS-010) Management Review (QMS-028)
Roles and responsibilities	Training, Competence and Awareness (QMS-010) Management Review (QMS-028)
Communication and culture	Quality Objectives for QMS (QMS-002) Training, Competence and Awareness (QMS-010) Communication (QMS-011)
Knowledge management	Organizational Knowledge (QMS-009)
Process workflow	Operational Planning and Control (QMS-014) Production Operation (QMS-017 and QMS-032)
Operational performance	Performance Monitoring and Measurement (QMS-024) Data Analysis and Evaluation (QMS-026) Management Review (QMS-028)
QMS health	Internal Audit (QMS-027) Management Review (QMS-028)
Continuous improvement	Continual Improvement (QMS-030)

4.2. Understanding the Needs and Expectations of Interested Parties

4.2.1. i-SOLIDS has determined the following parties to be relevant to the QMS.

4.2.2. Information relating to interested parties will be presented and reviewed during management review as described in section 9.3 of this Manual.

Relevant Parties	**Requirements of Each Party**
Customers	Competitive pricing Order accuracy Quality products and services Responsiveness and delivery promptness Part traceability (if required)
Suppliers	Clear specifications Accurate and timely order placement Prompt payment
Employees	Clear job expectations and streamlined processes Training Development opportunities Mission-driven purpose Safe work environment Competitive compensation
Consultants	Access to work required per contract Prompt payment
Regulators	Compliance with applicable statutes and regulations

Registrars	Compliance with requirements for certification Audit transparency Notification of significant changes impacting the QMS Prompt payment

4.3. Determining the Scope of the Quality Management System

4.3.1. This Manual applies to the QMS for i-SOLIDS, a digital manufacturer in Texas. QMS processes are documented and conducted in their sole location at 21602 E. Hardy Road, Houston, Texas, 77073.

4.3.2. The following sections are not applicable to i-SOLIDS and are excluded from this QMS:

4.3.2.1. ISO 9001 clause 8.3 – Design and development of products and services. Design and development activities are carried out by i-SOLIDS customers who are responsible for all design and development processes and documentation.
4.3.2.2. ISO 13485 clause 4.2.3 – Medical device file. The medical device file is established and maintained by i-SOLIDS customers who own the product designs.
4.3.2.3. ISO 13485 clause 4.2.5 – Control of records; confidential health information. Records in i-SOLIDS possession will not contain confidential health information, as this is established and maintained by i-SOLIDS customers who own the product designs and handle customer complaints containing confidential health information.
4.3.2.4. ISO 13485 clause 5.6.3.b – Review output; product improvements. Improvements of products based on customer requirements are carried out by i-SOLIDS customers, who own the product designs and all customer requirement information.
4.3.2.5. ISO 13485 clause 6.4.2 – Contamination control; sterile medical devices. Sterilization is not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.6. ISO 13485 clause 7.2.2.d – Review of requirements related to product; user training. User training for end customers is carried out by i-SOLIDS customers, who own the product designs and finished device instructions for use.
4.3.2.7. ISO 13485 clause 7.2.3.d – Communication; advisory notices. Communicating advisory notices is carried out by i-SOLIDS customers, who own the product designs and their distribution in the market.
4.3.2.8. ISO 13485 clause 7.3 – Design and development. Design and development activities are carried out by i-SOLIDS customers who are responsible for all design and development processes and documentation.
4.3.2.9. ISO 13485 clause 7.5.2 – Cleanliness of product. Product cleaning and contamination controls for medical devices are not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.10. ISO 13485 7.5.3 – Installation activities. Installation is not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.11. ISO 13485 7.5.4 – Servicing activities. Servicing is not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.12. ISO 13485 7.5.5 – Particular requirements for sterile medical devices. Sterilization is not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.13. ISO 13485 7.5.7 – Particular requirements for validation of processes for sterilization and sterile barrier systems. Sterilization is not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.14. ISO 13485 7.5.9.2 – Particular requirements for implantable medical devices. Implantable medical devices are not applicable to i-SOLIDS manufactured products or QMS.
4.3.2.15. ISO 13485 clause 7.5.11.a-b – Preservation of product; additional protections. Additional product protections for finished devices are the responsibility of i-SOLIDS customers, who own the product designs and finished product use information.

4.3.2.16. ISO 13485 clause 8.2.2 – Complaint handling. Complaints from medical device customers and patients are handled by i-SOLIDS customers who engage i-SOLIDS for investigation and remediation activities, as they own the product designs and are responsible for distributing their products in the market. All complaints related to i-SOLIDS other products are handled per section 8.5.5.

4.3.2.17. ISO 13485 clause 8.2.3 – Reporting to regulatory authorities. Notification to regulatory authorities (adverse events and advisory notices) is carried out by i-SOLIDS customers, who own the product designs and handle complaint-related reporting.

4.3.2.18. ISO 13485 8.2.6 – Monitoring and measurement of product; implantable medical devices. Implantable medical devices are not applicable to i-SOLIDS manufactured products or QMS.

4.3.2.19. ISO 13485 clause 8.3.3 – Actions in response to nonconforming product detected after delivery. Advisory notices are issued by i-SOLIDS customers, as they are responsible for distributing their products in the market. All nonconforming product detected after delivery related to i-SOLIDS other products are handled per section 8.7.

4.3.2.20. ISO 13485 clause 8.5.1 – Improvement general; medical device safety and performance, and post market surveillance. Maintaining medical device safety and performance, and conducting post market surveillance is the responsibility of i-SOLIDS customers, who own the product designs and their distribution in the market.

4.3.2.21. FDA QMSR 820.35 (a) – Control of records; records of complaints. Complaints from medical device customers and patients are handled by i-SOLIDS customers who engage i-SOLIDS for investigation and remediation activities, as they own the product designs and their distributing in the market. All complaints related to i-SOLIDS other products are handled per section 8.5.5.

4.3.2.22. FDA QMSR 820.35 (b) – Control of records; records of servicing activities. Servicing is not applicable to i-SOLIDS manufactured products or QMS.

4.3.3. As a manufacturer of products for other companies, activities related to and supporting manufacturing operations are primarily performed in-house with some activities externally provided by suppliers, as described in section 8.4 of this Manual.

4.3.4. Typical products and services provided to i-SOLIDS customers include:

Services and Technologies	**Industries**
Design Support Services • 3D scanning • 3D modeling • Design for Additive Manufacturing (DfAM) optimization	• Automotive • Consumer • Education / research • Energy • Industrial • Medical • Telecommunications • Unmanned Arial Vehicles
Digital Manufacturing • Desktop Fused Deposition Modeling (FDM) • Industrial Fused Deposition Modeling (FDM) • HP Multi Jet Fusion (MJF) • Selective Laser Sintering (SLS) • Stereolithography (SLA)	
Post-Processing • Assembly and threading • Painting & coating • Surface polishing • Vapor smoothing	
Finished Product Manufacturing • Washing	

• Cleaning • Painting • Cutting • Assembling • Applying components	

4.4. Quality Management System and its Processes

4.4.1. Quality Management System

4.4.1.1. i-SOLIDS has established the QMS structure as described within this Manual and referenced documents, with processes and interactions illustrated in **Figure 1**.

4.4.1.2. Processes required to carry out QMS activities are listed in section 11 (References) of this Manual.

4.4.1.3. i-SOLIDS implements, maintains, and continually improves the QMS by:

a) Describing process inputs and outputs within process documents, considering the methodology illustrated in **Figure 2**.

b) Identifying process sequence and interactions in **Figure 1**, and within process documents.

c) Outlining criteria and methods for monitoring and measuring against process performance indicators, as described in section 9 of this Manual.

d) Defining resource needs and ensuring their availability, as described in sections 7.1-7.3 of this Manual.

e) Assigning responsibility and authority to carry out processes, as described in section 5.3 of this Manual.

f) Managing risks and opportunities, as described in section 6.1 of this Manual.

g) Evaluating processes and implementing changes to ensure they continue to achieve intended results, as described in sections 7, 9, and 10 of this Manual.

h) Continually improving processes, as described in section 10 of this Manual.

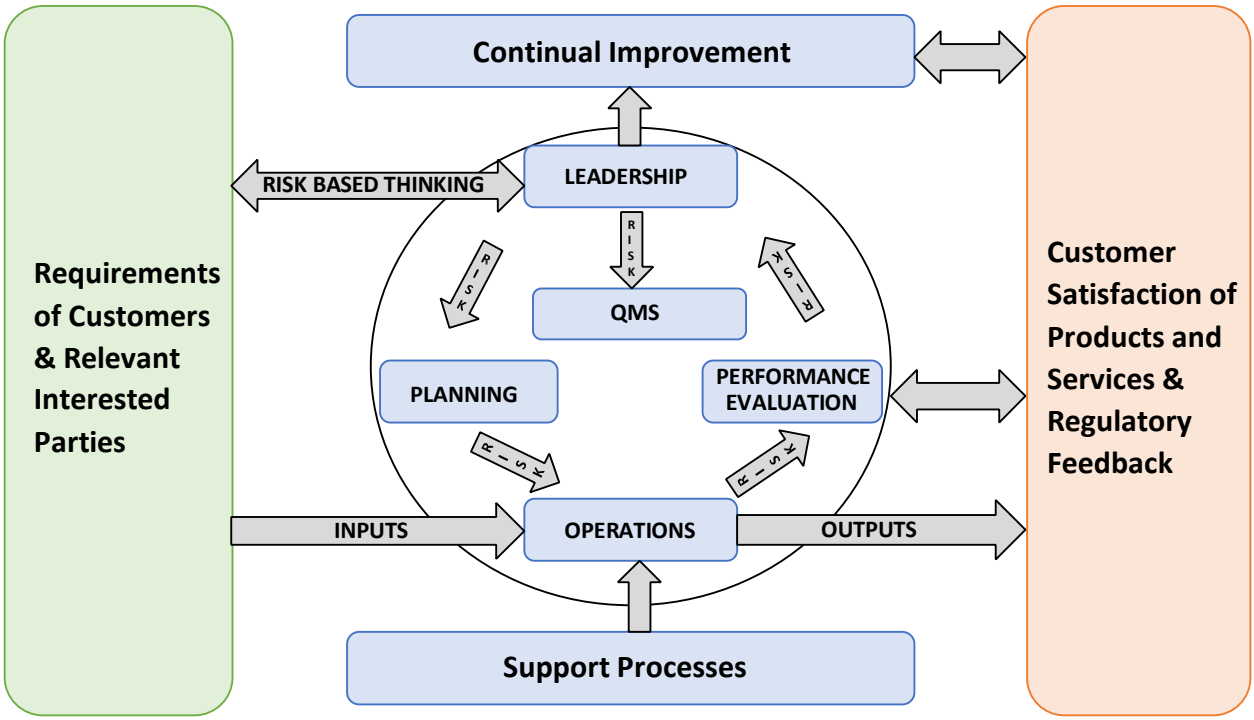

Figure 1 – Quality Management System Processes and Interactions

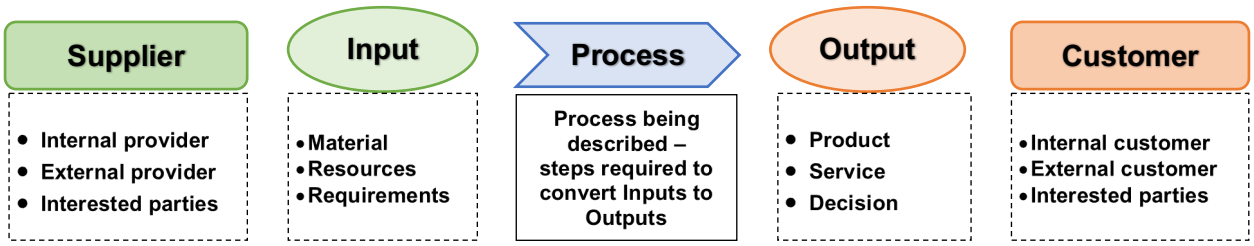

Figure 2 – Elements of a Single Process
(as a SIPOC [Supplier-Input-Process-Output-Customer] diagram)

4.4.2. Documented Information

4.4.2.1. I-SOLIDS maintains and retains documented information to ensure and demonstrate QMS effectiveness, as described in section 7.5 of this Manual.

5. LEADERSHIP

5.1. Leadership and Commitment

5.1.1. General

5.1.1.1. i-SOLIDS Top Management establish leadership and commitment to the QMS by:

a) Demonstrating accountability for QMS effectiveness through implementing and carrying out activities described in this Manual, and specifically per sections 6.2 and 9.3.

b) Ensuring the Quality Policy and Quality Objectives are established, supporting the context and strategic direction of the company, per sections 5.2, 6.2 and 7.4 of this Manual.

c) Ensuring that QMS requirements are integrated into business processes through implementing and carrying out the activities described in this Manual, and specifically per sections 5.3, 7.1, and 7.3-7.5.

d) Promoting a process approach and risk-based thinking through implementing and carrying out the activities described in this Manual, and specifically per sections 4.4, 5.3, 6.1, 7.1-7.3, 8.1, 8.4-8.5, 9.1, and 9.3.

e) Ensuring that required resources to establish, implement, maintain, and improve the QMS are available, per section 7.1 of this Manual.

f) Communicating the importance of effective quality management, meeting customer needs, and conforming to requirements of the QMS, per sections 7.3-7.4 of this Manual.

g) Ensuring that the QMS achieves its intended results, as described in sections 6.2 and 9.3 of this Manual.

h) Engaging, directing, and supporting the organization to contribute to an effective QMS, per sections 7.1-7.4 of this Manual.

i) Promoting continuous improvement, per sections 6, 9, and 10 of this Manual.

j) Supporting relevant management roles to demonstrate their leadership, per sections 5.3 and 7.1-7.2 of this Manual.

5.1.2. Customer Focus

5.1.2.1. i-SOLIDS Top Management establish leadership and commitment to customers by:

a) Ensuring that customer, and applicable statutory and regulatory requirements are determined, understood, and met, per sections 5.2-5.3, 6.1-6.2, 7.1, 8, 9.1-9.2, and 10.1 of this Manual.

b) Ensuring that risks and opportunities that may affect product and service conformity, or enhance customer satisfaction, are determined and addressed, per sections 5.3, 6.1, 9.1, 9.3, and 10 of this Manual.

c) Maintaining focus to enhance customer satisfaction, per sections 6.1-6.2, 9.1, 9.3, and 10 of this Manual.

5.2. Quality Policy

5.2.1. Establishing the Quality Policy

5.2.1.1. I-SOLIDS Quality Policy is established on page 1 of this Manual.

5.2.2. Communicating the Quality Policy

5.2.2.1. i-SOLIDS maintains, and makes available to interested parties, the Quality Policy as a feature of this Manual, per page 1.

5.2.2.2. i-SOLIDS ensures the Quality Policy is communicated, understood, and applied across the company per Communication SOP (QMS-011).

5.3. Organizational Roles, Responsibilities, and Authorities

5.3.1. i-SOLIDS Top Management ensures that responsibility and authority for company roles are assigned, communicated, and understood by designating these within the Organizational Chart (QMS-F001), QMS procedures, and related job descriptions.

5.3.2. i-SOLIDS Top Management assigns responsibility and authority to the Management Representative, irrespective of other responsibilities, and as designated on the company Organization Chart (QMS-F001) for the following activities:

a) Ensuring the QMS is documented and conforms to requirements.

b) Ensuring that QMS processes deliver their intended outputs.

c) Reporting QMS performance and opportunities for improvement to Top Management.

d) Promoting customer focus and requirements awareness throughout the organization.

e) Ensuring that QMS integrity is maintained when planning or implementing changes.

6. PLANNING

6.1. Actions to Address Risks and Opportunities

6.1.1. Risk and Opportunity Actions

6.1.1.1. i-SOLIDS determines risks and opportunities that need to be addressed per Risk Management SOP (QMS-004).

6.1.2. Risk and Opportunity Planning

6.1.2.1. i-SOLIDS plans actions to address risks and opportunities per Risk Management SOP (QMS-004).

6.2. Quality Objectives and Planning to Achieve Them

6.2.1. i-SOLIDS has established and documented quality objectives per Quality Objectives for QMS (QMS-002).

6.3. Planning of Changes

6.3.1. i-SOLIDS carries out changes to the QMS per Change Management SOP (QMS-005).

7. SUPPORT

7.1. Resources

7.1.1. General

7.1.1.1. i-SOLIDS determines and provides resources to establish, implement, maintain, and improve the QMS, including meeting applicable regulatory and customer requirements, as described in sections 7.1.2-7.1.6, and 8.4.

7.1.1.2. i-SOLIDS Top Management periodically assesses the adequacy of capability and constraints for these resources as described in section 9.3.

7.1.2. People

7.1.2.1. i-SOLIDS determines and provides the necessary personnel for effective QMS performance as outlined in the Organizational Chart (QMS-F001).

7.1.3. Infrastructure

7.1.3.1. i-SOLIDS determines, provides, and maintains the necessary infrastructure for QMS effectiveness, and product and service conformity (including validating equipment and QMS software) per Infrastructure and Maintenance SOP (QMS-006).

7.1.4. Environment for the Operation of Processes

7.1.4.1. i-SOLIDS determines, provides, and maintains the necessary environment (including contamination controls) for QMS effectiveness, and product and service conformity per Operating Environment SOP (QMS-007).

7.1.5. Monitoring and Measuring Resources

7.1.5.1. General

i-SOLIDS determines and provides the necessary monitoring and measuring resources to ensure valid and reliable results for verifying product and service conformity per Monitoring and Measuring Resources SOP (QMS-008).

7.1.5.2. Measurement Traceability

i-SOLIDS ensures that valid measurement results are achieved from measuring equipment (if required) per Monitoring and Measuring Resources SOP (QMS-008).

7.1.6. Organizational Knowledge

7.1.6.1. i-SOLIDS determines, maintains, and makes available the necessary knowledge for QMS effectiveness, and product and service conformity, per Organizational Knowledge SOP (QMS-009).

7.2. Competence

7.2.1. i-SOLIDS determines, ensures, acquires, and retains records for the necessary personnel competence for QMS effectiveness, and product and service conformity, per Training, Competence and Awareness SOP (QMS-010).

7.3. Awareness

7.3.1. i-SOLIDS ensures that personnel (internal and external) working within the QMS are aware of the Quality Policy, Quality Objectives, the importance of their contributions and the

implications of nonconformance for effective QMS operation per Training, Competence and Awareness SOP (QMS-010).

7.4. Communication

7.4.1. i-SOLIDS determines relevant communications (internal and external) necessary for effective QMS operation per Communication SOP (QMS-011).

7.5. Documented Information

7.5.1. General

7.5.1.1. i-SOLIDS QMS includes documented information necessary for effective QMS operation per Document Control SOP (QMS-012) and Record Control SOP (QMS-013); using the QMS document hierarchy illustrated in **Figure 3**.

7.5.2. Creating and Updating

7.5.2.1. i-SOLIDS ensures appropriate controls when creating and updating documented information necessary for effective QMS operation per Document Control SOP (QMS-012) and Record Control SOP (QMS-013).

7.5.3. Control of Documented Information

7.5.3.1. i-SOLIDS ensures the availability, suitability, integrity, security, and protection of documented information necessary for effective QMS operation per Document Control SOP (QMS-012) and Record Control SOP (QMS-013).

7.5.3.2. i-SOLIDS ensures the appropriate identification, distribution, access, retrieval, use, storage, preservation, version control, retention, and disposition of documented information necessary for effective QMS operation per Document Control SOP (QMS-012) and Record Control SOP (QMS-013).

7.5.3.3. i-SOLIDS identifies and controls documents of external origin necessary for effective QMS operation per Document Control SOP (QMS-012).

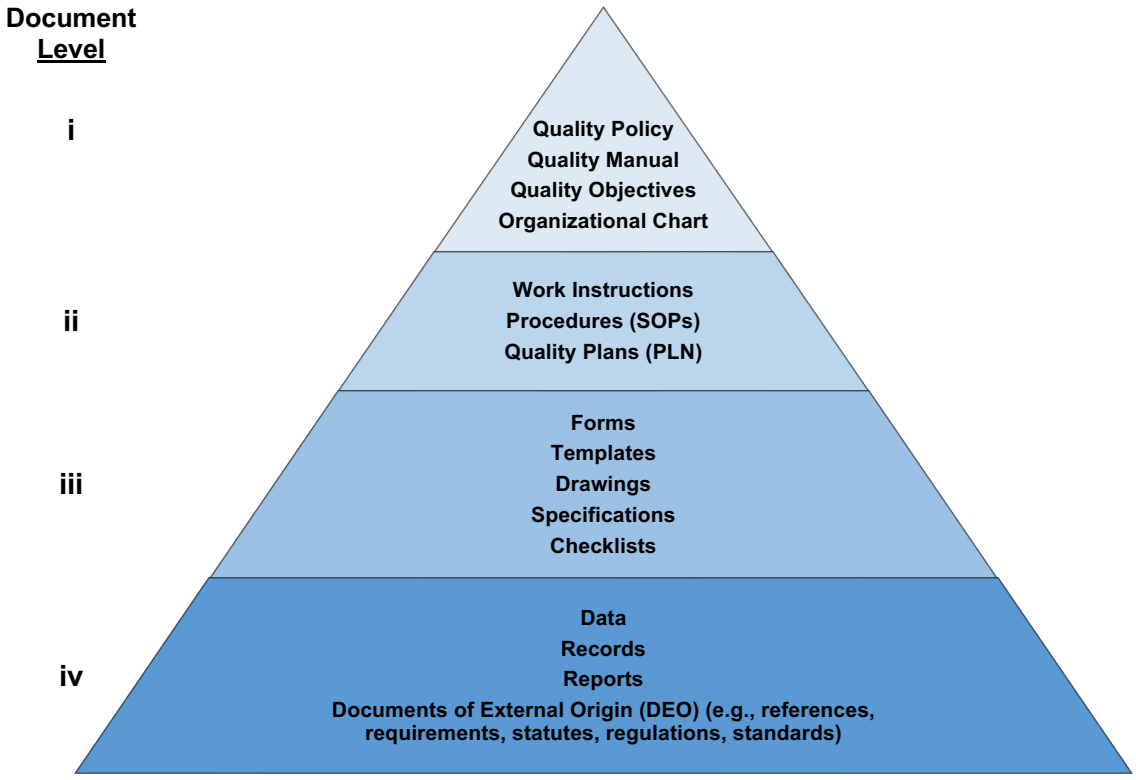

Figure 3 – Quality Management System Document Hierarchy

8. OPERATION

8.1. Operational Planning and Control

8.1.1. i-SOLIDS plans, implements, and controls processes (including process validation) necessary to meet product and service requirements, and implement section 6 Planning activities per Operational Planning and Control SOP (QMS-014).

8.2. Requirements for Products and Services

8.2.1. Customer Communication

8.2.1.1. i-SOLIDS communicates with customers to ensure product and service requirements will be met per Product and Service Requirements SOP (QMS-015).

8.2.2. Determining the Requirements for Products and Services

8.2.2.1. i-SOLIDS determines product and service requirements necessary to ensure customer, statutory, regulatory, internal, and claims requirements will be met per Product and Service Requirements SOP (QMS-015).

8.2.3. Review of the requirements for Products and Services

8.2.3.1. i-SOLIDS reviews and confirms customer orders to ensure product and service requirements will be met per Product and Service Requirements SOP (QMS-015).

8.2.3.2. i-SOLIDS retains documented information on the results of customer order reviews and new requirements per Product and Service Requirements SOP (QMS-015).

8.2.4. Changes to Requirements for Products and Services

8.2.4.1. i-SOLIDS ensures that when changes to requirements occur, relevant records are amended and relevant personnel are made aware of the changes per Product and Service Requirements SOP (QMS-015).

8.3. Design and Development of Products and Services

8.3.1. Design and Development activities are excluded from this QMS as described in section 4.3 of this Manual.

8.4. Control of Externally Provided Processes, Products, and Services

8.4.1. General

8.4.1.1. i-SOLIDS ensures that externally provided processes, products, and services conform to requirements by determining and applying the necessary controls, including retaining records, per Purchasing and Supplier Control SOP (QMS-016).

8.4.2. Type and Extent of Control

8.4.2.1. i-SOLIDS determines and applies the type and extent of risk-based controls necessary to ensure that externally provided processes, products, and services have no adverse impact on QMS effectiveness, and its ability to deliver conforming products and services to customers, per Purchasing and Supplier Control SOP (QMS-016).

8.4.3. Information for External Providers

8.4.3.1. i-SOLIDS ensures that process, product, and service requirements are adequate to deliver conforming products and services to customers prior to communicating the requirements to suppliers per Purchasing and Supplier Control SOP (QMS-016).

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

8.5.1.1. I-SOLIDS ensures that the production and service provision is implemented under controlled conditions per Production Operation SOP (QMS-017) and Medical Device Production Operation SOP (QMS-032).

8.5.2. Identification and Traceability

8.5.2.1. i-SOLIDS identifies the product and status of outputs, throughout the production and service provision, to ensure product and service conformity per Identification and Traceability SOP (QMS-018).

8.5.2.2. i-SOLIDS controls the unique identification of products and outputs when traceability is a requirement, including retaining records, per Identification and Traceability SOP (QMS-018).

8.5.3. Property Belonging to Customers or External Providers

8.5.3.1. i-SOLIDS exercises care with customer and supplier property that is being used by or under the organization's control, by identifying, verifying, protecting, and safeguarding this property per Customer and Supplier Property SOP (QMS-019).

8.5.3.2. i-SOLIDS reports issues to customers and suppliers when their property is lost, damaged, or unsuitable for use, including retaining records, per Customer and Supplier Property SOP (QMS-019).

8.5.4. Preservation

8.5.4.1. i-SOLIDS preserves the product and outputs, during the production and service provision (including processing, storage, handling, and distribution), necessary to ensure conformity to requirements per Preservation SOP (QMS-020), Packaging and Shipping SOP (QMS-031), and Medical Device Production Operation SOP (QMS-032).

8.5.5. Post-Delivery Activities

8.5.5.1. i-SOLIDS considers the extent of activities related to products and services necessary to ensure that post-delivery requirements will be, or have been, met (including feedback and complaints) per Post-Delivery Activities SOP (QMS-021).

8.5.6. Control of Changes

8.5.6.1. i-SOLIDS reviews and controls changes related to the production and service provision necessary to ensure conformity to requirements, including retaining records, per Change Management SOP (QMS-005).

8.6. Release of Products and Services

8.6.1. i-SOLIDS ensures products and services are only released to customers after they have been verified to meet requirements, or approved by relevant parties, including retaining records, per Product Acceptance and Release SOP (QMS-022) and Medical Device Production Operation SOP (QMS-032).

8.7. Control of Nonconforming Outputs

8.7.1. i-SOLIDS ensures that nonconforming products and services are identified and controlled to prevent unintended use or delivery, and risk-based action taken, including detection post-delivery, per Nonconformance Control SOP (QMS-023).

8.7.2. i-SOLIDS retains records of nonconforming products and services that document the nonconformity, evaluations, investigations, actions, concessions, decision rationale, rework, and approvals per Nonconformance Control SOP (QMS-023).

9. PERFORMANCE EVALUATION

9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

9.1.1.1. i-SOLIDS determines what, when, and the methods needed, to monitor and measure QMS processes and QMS effectiveness, and product and service

conformity, including retaining records, per Performance Monitoring and Measurement SOP (QMS-024).

9.1.2. Customer Satisfaction

9.1.2.1. i-SOLIDS determines the methods for obtaining, monitoring, and reviewing customer perceptions necessary to monitor the effectiveness of fulfilling their needs and expectations per Customer Satisfaction SOP (QMS-025).

9.1.3. Analysis and Evaluation

9.1.3.1. i-SOLIDS analyzes and evaluates data, and information from monitoring and measurement activities, necessary to ensure valid results for QMS suitability, adequacy, and effectiveness, product and service conformity, feedback and customer satisfaction, process and product outputs, planning effectiveness, risk mitigation, supplier performance, audits, and continuous improvement per Data Analysis and Evaluation SOP (QMS-026).

9.2. Internal Audit

9.2.1. i-SOLIDS conducts internal audits at planned intervals necessary to ensure conformance to internal and external requirements, and to confirm the QMS is effectively implemented and maintained per Internal Audit SOP (QMS-027).

9.2.2. i-SOLIDS plans, establishes, implements, and maintains an audit program. The program defines the criteria and scope for audits, ensures auditors are qualified, and audits are objective and impartial, ensures that audit results are reported to management, and that correction and corrective actions are taken without delay, including retaining records, per Internal Audit SOP (QMS-027).

9.3. Management Review

9.3.1. General

9.3.1.1. i-SOLIDS Top Management reviews the QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with i-SOLIDS strategic direction per Management Review SOP (QMS-028).

9.3.2. Management Review Inputs

9.3.2.1. i-SOLIDS plans and carries out management reviews considering previous management review actions, changes to internal and external issues, QMS performance and effectiveness, resources, risk management, and opportunities for improvement, per Management Review SOP (QMS-028).

9.3.3. Management Review Outputs

9.3.3.1. i-SOLIDS management review results in decisions and actions relating to opportunities for QMS improvement, QMS changes, changes relating to new or revised regulatory requirements, and resource needs, including retaining records, per Management Review SOP (QMS-028).

10. IMPROVEMENT

10.1. General

10.1.1. i-SOLIDS determines, selects, and implements actions focused on opportunities for improvement to meet customer requirements and enhance customer satisfaction, as described in sections 7.1, 8, 9, and 10.2-10.3 of this Manual.

10.2. Nonconformity and Corrective Action

10.2.1. i-SOLIDS controls and corrects nonconformities, and potential nonconformities, including customer complaints, to eliminate the causes in order to prevent occurrence or recurrence, and to ensure QMS effectiveness, and product and service conformity, including retaining records, per Corrective and Preventive Action SOP (QMS-029).

10.3. Continual Improvement

10.3.1. i-SOLIDS determines the needs and opportunities for continual improvement through the use of the quality policy and quality objectives, and by assessing results from analysis and evaluation, audits, and management review, necessary to continually improve the suitability, adequacy, and effectiveness of the QMS per Continual Improvement SOP (QMS-030).

11. REFERENCES

- **ISO 9000** – Quality Management Systems – Fundamentals and Vocabulary
- **ISO 9001** – Quality Management Systems – Requirements
- **ISO 13485** – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- **ISO 14971** – Medical Devices – Application of Risk Management to Medical Devices
- **21 CFR Part 820** (subparts A & B) – U.S. FDA Quality Management System Regulation (QSMR)
- **QMS-F001** – Organizational Chart
- **QMS-002** – Quality Objectives for QMS
- **QMS-003** – QMS Glossary
- **QMS-004** – Risk Management
- **QMS-005** – Change Management
- **QMS-006** – Infrastructure and Maintenance
- **QMS-007** – Operating Environment
- **QMS-008** – Monitoring and Measuring Resources
- **QMS-009** – Organizational Knowledge
- **QMS-010** – Training, Competence and Awareness
- **QMS-011** – Communication
- **QMS-012** – Document Control
- **QMS-013** – Record Control
- **QMS-014** – Operational Planning and Control
- **QMS-015** – Product and Service Requirements
- **QMS-016** – Purchasing and Supplier Control
- **QMS-017** – Production Operation
- **QMS-018** – Identification and Traceability
- **QMS-019** – Customer and Supplier Property
- **QMS-020** – Preservation
- **QMS-021** – Post-Delivery Activities
- **QMS-022** – Product Acceptance and Release
- **QMS-023** – Nonconformance Control
- **QMS-024** – Performance Monitoring and Measurement
- **QMS-025** – Customer Satisfaction
- **QMS-026** – Data Analysis and Evaluation
- **QMS-027** – Internal Audit
- **QMS-028** – Management Review
- **QMS-029** – Corrective and Preventive Action
- **QMS-030** – Continual Improvement
- **QMS-031** – Packaging and Shipping
- **QMS-032** – Medical Device Production Operation

References Note: The organization conforms with statutory and regulatory requirements where applicable, including, but not limited to, the references in this section. External documents are listed without revision levels, and are understood to refer to the latest revision of the document, or as referenced within QMS documents.