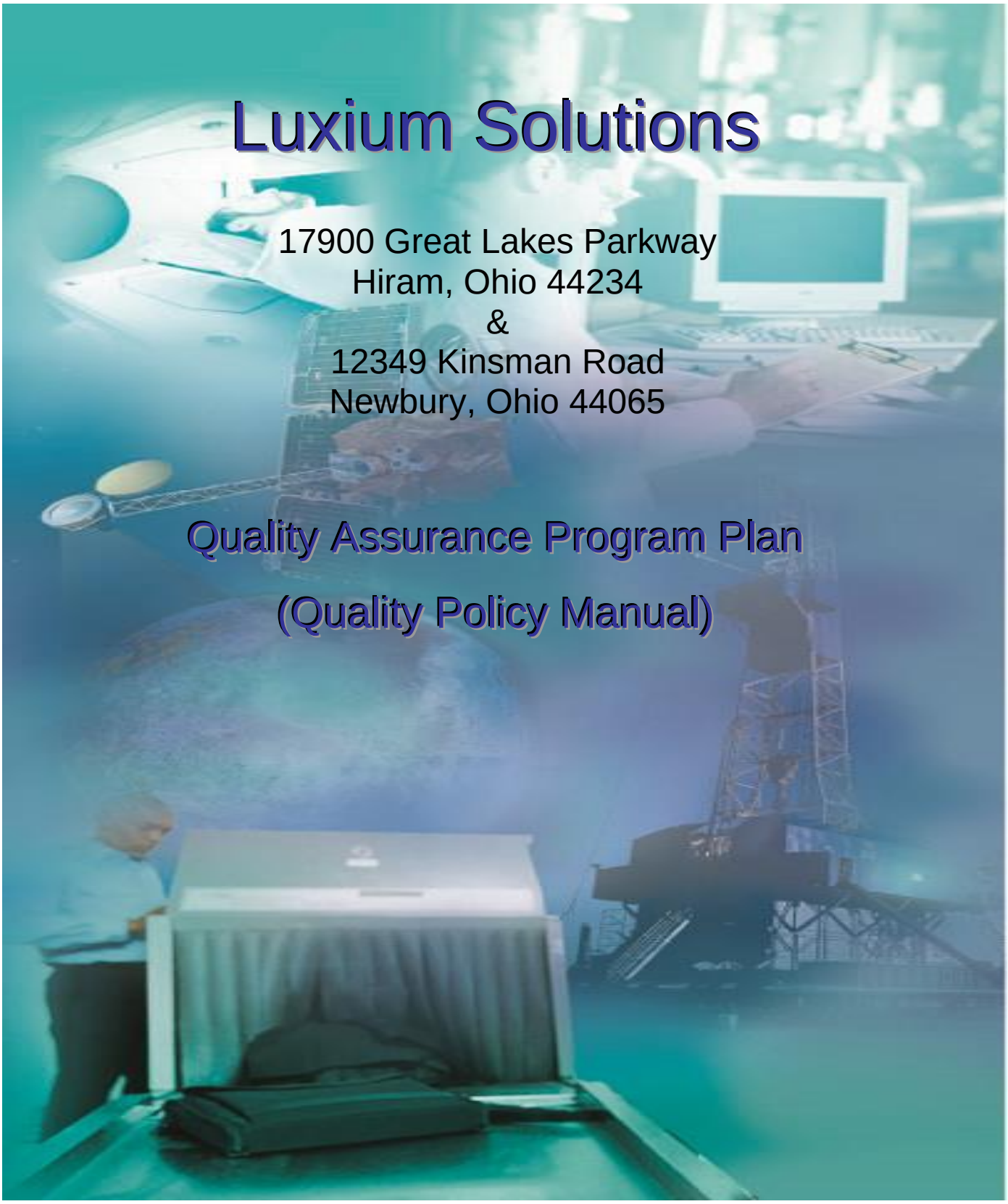

Luxium Solutions

17900 Great Lakes Parkway
Hiram, Ohio 44234
&
12349 Kinsman Road
Newbury, Ohio 44065

Quality Assurance Program Plan

(Quality Policy Manual)

Quality Policy Manual Review and Approval Page

Plant Manager

_____ _____

Troy Kinleyside **Date**

Operational Excellence Manager (Management Representative)

_____ _____

William Harder **Date**

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1.0 TABLE OF CONTENTS

To be consistent with the numbering scheme of the Standard, previous QSM Sections 1.0 through 3.0 have been eliminated from the Table of Contents, but incorporated into various Quality Policy Manual sections

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4.0 Context of the organization

4.1 Understanding the organization and its context

Luxium Solutions has identified the external and internal issues relevant to its purpose, strategic direction, and those that affect our ability to achieve the intended results of our quality management system as…

Internal / External Sources	Internal / External Issues from the identified sources may include but are not limited to…
Customers	Not complying with Customer Specific Requirements (NC Product or Service related issues), and Poor Customer Satisfaction Survey Results
Suppliers	Supplier Performance as it relates to On Time Delivery and Quality Issues affecting Luxium Solutions or its Customers
Product End Users	NC Products (Field Failures)
Internal Operations	Producing NC Products, Late Deliveries, Safety Related Issues
Stakeholders & Management Personnel	Lack of Business Growth, Competition in Marketplace, and Economic Environments
Statutory and/or Regulatory Agencies	Not complying with applicable Legal and / or Regulatory requirements
Employees	Injuries on the Job, Not having appropriate information on how to process jobs (information on Work Orders, lack of training)

Luxium Solutions monitors and reviews information regarding these external and internal issues as part of…

- the quarterly Management Review Meetings in which the following is discussed…
  - review of Customer Complaints and Corrective Actions
  - review of Customer Satisfaction Data
  - review of Supplier Performance
- scheduled Internal Audit activities

The overall purpose and **Strategic Direction** of the organization is broken out via measures on the Goals and Objectives Matrix and are most typically identified as…

- Continuing to satisfy customers
- Expanding existing Customer Base
- Continuing to be profitable
- Maintaining Quality Management System Registration
- Reducing Internal Nonconformances by improving Internal Process Operations

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on Luxium Solutions ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization has determined:

a) the interested parties that are relevant to the quality management system;

- End Users
- Customers
- Suppliers
- Staff and Employees
- Stakeholders
- Statutory and / or Regulatory Agencies

b) the requirements of these interested parties that are relevant to the quality management system have been identified as follows…

Interested Parties may include, but are not limited to…	**Requirements of the Interested Parties may include, but are not limited to…**
End Users	▪ Products that meet agreed upon specifications
Customers	▪ Products that meet agreed upon specifications ▪ Timely delivery of products to their intended destination ▪ Timely resolution of any issues which do not conform to customer requirements ▪ Competitive Price
Suppliers	▪ adequate planning information in order to enable suppliers to meet Luxium Solutions Requirements for quality and delivery ▪ timely resolution of any issues which do not conform to Luxium Solutions Requirements
Staff & Employees	▪ Company growth to ensure job stability ▪ Safe Working Environment ▪ Effective Training to ensure continued competencies in assigned tasks
Stakeholders	▪ Company growth ▪ Profitability
Statutory and/or Regulatory Agencies	▪ See comments below…

- With respect to Statutory and/or Regulatory requirements, the following comments were noted…

  Statutory and/or Regulatory requirements which are currently applicable to Luxium Solutions have been identified and are controlled as follows…

  - BWC
  - OSHA
  - NFPA (Natural Fire Protection Act)

- SDS / Global Harmonization
- HAZMAT and related Safety Requirements
- EPA
- Bureau of Radiation Protection (Ohio Department of Health)
- Federal Requirements (e.g. EEOC, Minimum Wage Act, Hand Gun Regulations, Smoke Free Workplace)
- Local Requirements (e.g. Building Codes, Fire Marshall)

The identification of new and changed Statutory and Regulatory Requirements will be identified during the Design, Quotation, and Contract Review Processes, but may also be identified through the following…

- Involvement with various Statutory and Regulatory Groups
- General communications with Customers,
- Facility Personnel's involvement with Industrial, Local, State and Federal Groups
- Updates received through any government and other contracted organizations
- Internal and External Auditor communications
- Internet references (subscriptions to various web-sites)
- Lessons Learned

If the new or changed requirements identified affect Luxium Solutions, the new and/or updated requirements will be reviewed by appropriate personnel in accordance with the review activities defined in LS 7.5-1, which includes directions on determining and implementing appropriate actions, and communicating changes throughout the organization.

The Documented Information Procedure (LS 7.5-1) includes provisions on how Statutory and Regulatory, as well as Customer Requirements will be managed and controlled.

The combination of the Customer Service, Quality, Purchasing, Human Resources, and Production Personnel are responsible for monitoring and reviewing information regarding the identified interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

Luxium Solutions has determined the boundaries and applicability of the quality management system in order to establish its scope.

When determining the scope, consideration was given to:

a) the external and internal issues referred to in section 4.1 of this Quality Policy Manual;
b) the requirements of relevant interested parties referred to in 4.2 of this Quality Policy Manual;
c) the products and services of the organization.

Luxium Solutions has applied all the requirements of this International Standard (as applicable) in order to determine the scope of its quality management system.

The scope states the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

The following details have been provided with respect to the boundaries and applicability of the scope and Quality Management System…

- The scope includes all activities and operations performed at our 109,000 square foot facility headquarters located at 17900 Great Lakes Parkway, Hiram, Ohio 44234 and our 26,000 square foot support manufacturing facility located at 12345 Kinsman Road, Newbury, Ohio 44065

- Luxium Solutions is considered to be the global leader in scintillation technology and is the largest producer of sodium iodide crystals and plastic scintillators in the world.

- The objective of Luxium Solutions is to take a proven technology forward to meet tomorrow's needs.

- Luxium Solutions has successfully developed many commercial applications in the nuclear medicine, oil exploration, health physics, and security/safeguards industries.

- Luxium Solutions continues to make a significant contribution by working with OEM customers to develop medical, industrial, and high-energy physics detectors to meet new specifications for innovative applications.

- All products are manufactured in accordance with our documented Quality Management System and Customer Specific Requirements

- Our Customer Service, Quality, and Production Team Members are committed to ensuring all product specifications and parameters are met, including any customer specific, statutory, and/or regulatory requirements

- For more information regarding Luxium Solutions, please visit our web site at www.luxiumsolutions.com

ISO 9001 Registration

- Luxium Solutions achieved ISO 9001 Quality Management System Registration on October 30, 2007 and continues to successfully maintain the Quality Management System through the performance of Internal and Third Party Audit activities.

- The Scope of Registration, as stated on the Certificate of Registration reads,

  "Design and manufacturing of chemical compounds, crystals, and detectors for the Geophysical, Medical, Security, and other industries."

  SIC Code: 2819
  IAF Code: 12
  NACE Code: DG24.1
  Description: Industrial inorganic chemicals, not elsewhere classified

Exclusions of the Quality Management System

No Exclusions have been recognized with respect to our Quality Management System in accordance with the ISO 9001:2015 Standard requirements

The scope of the organization's quality management system will be made available as documented information through this Quality Policy Manual and the company website.

4.4 Quality Management System and its Processes

4.4.1 Luxium Solutions has established, documented, implemented, maintains, and continually improves their quality management system.

This includes the identification of QMS Processes and their interactions in accordance with the requirements of this International Standard.

Luxium Solutions has determined and identified the processes needed for the quality management system and their application throughout the organization as…

1) Management Team
2) Documents and Records
3) Sales
4) Materials Management
5) Design and Development
6) Product Planning
7) Human Resources,
8) Manufacturing

    ⇒ Organic (Machining)
    ⇒ Nuclear Medicine,
    ⇒ Geophysical,
    ⇒ Radiance,
    ⇒ Cutting,
    ⇒ Inorganic Crystal Growth*
    ⇒ Organic Chemical Operations*

9) Shipping
10) Quality Assurance
11) Calibration / Preventative Maintenance
12) Internal Audits
13) Corrective Action

Processes identified with an '*' are considered 'special processes' – see 8.5.1f

Key Processes are consistently referenced on the following documents…

- System Process Model Diagram (F 4.4.1-1)
- Process Matrix (F 4.4.1-3)
- Risk Assessment Matrix (F 6.1-1)
- Goals and Objectives Matrix (F 6.2-1)
- Internal Audit Schedule (F 9.2-1)

As part of the identification and continued management of these Key Processes, Luxium Solutions …

a) has determined the inputs required and the outputs expected from these processes via the System Process Model Diagram (F 4.4.1-1) as well as the documented information defined below;

Identified Key Processes	Inputs may include, but are not limited to…	Outputs may include, but are not limited to…
Management Team	Receive Organized Information and Data with respect to… • Customer Satisfaction, • Internal Audits, • Corrective Actions, • Customer Complaints, • Continual Improvement, • Quality Objectives, • NC Data, • Resource Needs	• Management Review Meeting Minutes • Development of new and/or updates to… ➢ Quality Planning Projects ➢ Continual Improvements ➢ Corrective Actions ➢ Goals and Objectives ➢ Action associated with Goals and Objectives ➢ Nonconformances • Application of resources to be applied back into the QMS
Documents and Records	• Document Change Forms • Internal and/or External Audit Findings • Corrective Actions • Continual Improvements	• Updated Quality Management System Documents • Completed Document Change Forms • Updates to the Document Master List • Updates to the Records Matrix • Release of Controlled Copies of applicable QMS Documents
Sales	• Requests for Quotes from the Customers • Customer Purchase Orders • Customer Part Prints • Customer Specific Requirements • Customer Report Cards and other Satisfaction Data	• Quotations to the Customers • Acceptable Contracts between the Customer and Saint-Gobain Crystals • Risk Assessments • Quality Planning Checklists • Sales / Work Orders to initiate Production Activities • Customer Satisfaction Data
Materials Management	• Information to qualify new Suppliers • Data regarding Quality and Delivery performance to monitor existing Suppliers • Information related to Material and / or Service Demands • Receipt of materials needed to complete Customer Orders	• Quotations from Suppliers • Supplier Qualification Documents • Purchase Orders • Receiving Records • Communication Records with the Customer regarding damaged, lost, or unsuitable for use Customer Supplied Property

Identified Key Processes	Inputs may include, but are not limited to…	Outputs may include, but are not limited to…
Design and Development	• Requests for Quotes from the Customers • Customer Purchase Orders • Customer Part Prints • Customer Product Samples • Knowledge from previous Design activities • Customer Specific Requirements	• Samples to the Customers • Designs • Information communicated to other departments via Sales / Work Orders • Design & Process FMEA's • MOC's
Product Planning	• New Products • Modified Products • New Processes • Modified Processes • Customer Specific Requirements • Continual Improvements • Design Information • QMS Documents	• Updated QMS Documents • Training Records (as applicable) • Updated PM Program
Human Resources	• Top Management feedback with respect to resource needs • Employee Requests for Training • Equipment needs based on PM Data and Customer Orders	• Quality Planning Checklists • Training Records • Employee Competencies • Training Effectiveness Evaluations
Manufacturing	• Sales / Work Orders • Raw Materials • Components • Part Prints • Customer Specific Requirements • Inspection Records • QMS Documents	• Products to be sent for outside processing • Finished Goods • Completed Inspection Documentation and Records • Calibration Records • Preventative Maintenance Records • Nonconformance Reports • Corrective Actions
Shipping	• Sales / Work Orders • Pick Lists • Finished Goods • Products requiring outside processing • Customer Specific Requirements • Inspection Records • QMS Documents	• Completed Shipments • Completed Inspection Documentation and Records • Complete Packaging and Shipping Records

Identified Key Processes	Inputs may include, but are not limited to…	Outputs may include, but are not limited to…
Calibration & Preventative Maintenance	Calibration • New Measurement Devices • Calibration Schedule • Employee Communications with respect to device issues or loss Preventative Maintenance • Preventative Maintenance Schedule • Unscheduled Work Order Requests	Calibration • Updated Calibration Records displaying complying results • Out of Tolerance Investigations • Updated Calibration Stickers • Certificates of Calibration from external calibration sources Preventative Maintenance • Updated Preventative Maintenance Records • Evidence of completed Work Order Requests • Copies of External Service PM Reports
Internal Audits	• Internal Audit Schedule • Scope of Internal Audits • Internal Audit Note and Record Sheets	• Completed Internal Audit Reports • Corrective Actions (as necessary) • Updated Internal Audit Schedule
Corrective Action	• Customer Complaints • Customer Satisfaction Data • Audit Schedules • Inspection Requirements and associated documents • Initiated Nonconformance Reports • Initiated Corrective Actions • Initiated Continual Improvements • Raw Data for analysis	• Completed Inspection Documentation and Records • Completed Nonconformance Reports • Completed Corrective Actions • Completed Internal Audit Reports • Completed Continual Improvement Projects

b) has determined the sequence and interaction of these processes via the System Process Model Diagram (F 4.4.1-1)

c) has determined and have applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes throughout the documented QMS (i.e. Quality Policy Manual, Quality System Procedures, Work Instructions, Forms, and any related Reference Documents)

d) has determined the resources needed for these processes and ensure their availability through conversations and actions resulting from Management Review Meetings, Contract Review activities, Corrective Actions (including Customer Complaints, Internal Nonconformances, Internal and External Audit results), Documentation Changes, and any Quality and/or Product Planning activities

e) has assigned responsibilities and authorities for these processes via the Organizational Chart (F 4.4.1-2) and the Responsibilities Matrix (F 5.3-1)

The key processes of the system are managed by representatives of Top Management who provide information, instruction, and support to their employees.

f) continually addresses the risks and opportunities as identified and determined in accordance with the requirements of section 6.1 of this Quality Policy Manual

g) continually evaluates the Key Processes and implements any changes needed to ensure that these processes achieve their intended results via the review of the Goals and Objectives Matrix (F 6.2-1), Internal Audit activities, Customer Feedback, Management Review Meeting discussions, and day to day activities;

h) continually applies methodologies to improve the processes and the quality management system. Actions are taken as necessary when planned results are not achieved.

4.4.2 Luxium Solutionshas…

a) maintained documented information to support the operation of its processes;

The Quality Management System Documentation structure has been defied as follows…

Tier I Quality Policy Manual (QPM)

The governing document that defines the scope and processes of the Quality Management System.

Tier II Quality System Procedures (LS)

Documents that define Who, What, and When

Tier III Work Instructions (WI)

Documents that specifically define how to complete an assigned task

Additional Instructions and records are available electronically via various database systems.

Tier IV Forms (F)

Documents that promote the recording of data and information.

Tier V Controlled Reference Materials

Documents that provide information on how to complete tasks but do not require the recording of any data.

Other documents that are controlled but are not considered part of this five tier structure include Documents of External Origin.

External Documents are those documents that Luxium Solutions has no authority to update or revise.

These documents may include but are not limited…

- the ISO 9001 Standard,
- Industry Specifications,
- Test Methods,
- Reference Manuals, and
- Customer Drawings.

b) retained documented information in order to support compliance with external and internal requirements, and to provide Luxium Solutions confidence that the processes are being carried out as planned. See the associated Records Matrix (F 7.5-4)

5.0 Leadership

5.1 Leadership and commitment

5.1.1 General

Luxium Solutions has defined the Leadership Team / Management Team as the following staff members:

- Plant Manager
- Operational Excellence Manager / Management Representative
- Engineering Manager
- Director of Sales Americas
- Human Resources Director
- Customer Service Manager
- Purchasing Manager
- HSE Manager
- Manufacturing Manager
- Planning Manager

The additional staff members identified below may provide input as deemed necessary to assure adherence to the Quality Policy, the documented Quality Management System, and the Goals and Objectives Matrix (F 6.2-1)

- Production Supervision
- MIS/Telecommunications Manager
- Milford Key Process Managers

Top Management demonstrates their leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system by taking or assigning actions as a result of Internal and External Audits, as well as any action items generated during Management Review Meetings;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization (see section 5.2 of this Quality Policy Manual)

c) ensuring the integration of the quality management system requirements into the organization's business processes via the documented Quality Management System documents
d) promoting the use of the process approach and risk-based thinking per section 6.1 of this Quality Policy Manual
e) ensuring that the resources needed for the quality management system are available per section 7.1 of this Quality Policy Manual
f) communicating the importance of effective quality management and of conformance to the quality management system requirements through distributed documents, meetings, and a variety of postings;

Top Management has established and maintains appropriate communication channels as defined in the System Process Model Diagram (F 4.4.1-1) and the Organizational Chart (F 4.4.1-2) to support the effectiveness of the Quality Management System.

At the conclusion of each Management Review Meeting, Top Management will summarize the results and provide the employees within the organization with a breakdown of the overall suitability and effectiveness of the Quality Management System (F 5.1.1-1). This is normally accomplished through employee meetings or postings throughout the facility.

g) ensuring that the quality management system achieves its intended results through the management of the Goals and Objectives Matrix, as well as involvement with both Internal and External Audit activities;
h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system through the release of QMS documents, training programs, and various meetings;
i) promoting improvement through the empowering of employees to offer suggestions to improve the organization and processes, and the generation of related Continual Improvement Projects;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility by being readily available to answer any questions or assist in assigned projects

5.1.2 Customer focus

Top Management demonstrates its leadership and commitment with respect to customer focus by ensuring that:

a) Customer, as well as any applicable statutory and regulatory requirements are determined, understood, and consistently met;

- Customer Requirements are initially determined and clarified through Sales, Product Management, and Engineering activities and met through the completion of Work Orders Packages.

  Customer Specific Requirements are normally discussed during Management Review Meetings, Quality Planning sessions, or during updates or modifications to Designs or Contracts.
  Relevant information is communicated to the employees via…

  - Production Work Orders,
  - General Informative Postings throughout the facility,
  - Meetings with employees,

- Ongoing customer requirements will be determined, monitored, and measured for improvement based on the receipt of customer satisfaction and dis-satisfaction data.

- With respect to Statutory and Regulatory Requirements, see section 4.2b of this Quality Policy Manual

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

Information on Risks and Opportunities can be found in section 6.1 of this Quality System Manual as well as in LS 6.1

c) the focus on enhancing customer satisfaction is maintained.

Customer Satisfaction, as well as dis-satisfaction measures, are determined and evaluated through the use of Customer Surveys, Customer Report Cards (LS 9.1.2), the receipt of Customer Complaints (LS 10.2), and periodic on-site Customer Visits

5.2 Policy

5.2.1 Establishing the quality policy

Top Management has established, implemented, and maintains a quality policy that…

a) is appropriate to the purpose and context of the organization and supports its strategic direction based on discussions held during the Management Review Meetings (LS 9.3)

b) provides a framework for setting quality objectives (see section 6.2 of this Quality Policy Manual and the Goals and Objectives Matrix F 6.2-1)

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

With this, the Quality Policy of Luxium Solutions has been defined as follows:

Our Policy is to provide innovative products, on-time, that meet or exceed customer requirements and expectations, while striving for continual improvement in all products and processes along with providing stewardship in safety and environmental impacts.

In relation, our Mission Statement has been defined as…

VMVO provides Luxium Solutions with a strategic framework that supports our commitment to comply with and continually improve the effectiveness and efficiency of our quality management system.

Annual quality objectives are established, reviewed and driven through the leadership and organizational direction of VMVO.

5.2.2 Communicating the quality policy

The quality policy has been…

a) made available internally via internal postings. The Quality Policy Statement is controlled and maintained as documented information per QPM 5.2-1.

b) communicated, understood, and applied within the organization

The Quality Policy has been communicated to all employees via…

- initial employee orientation,
- employee meetings,
- internal audits, and
- a variety of handouts and postings.

Routine evaluations during the internal audit activities assure the implementation, understanding and application of the Quality Policy throughout the organization.

c) made available to relevant interested parties via…

- the company web-site
- postings throughout the facility

5.3 Organizational roles, responsibilities and authorities

Top Management ensures that the roles, responsibilities, and authorities for relevant positions are assigned, communicated, and understood within the organization through the following...

- the existing Quality Management System documents (i.e. Quality Policy Manual, Quality System Procedures, Work Instructions, and Forms),
- Position Descriptions,
- Training activities

While no longer a defined position of the ISO 9001:2015 Standard, Saint-Gobain Crystals has retained the position of Management Representative in order to…

- facilitate Internal and External Audit activities
- act as the liaison when discussing QMS issues with Customers or other interested parties
- ensure the overall suitability and effectiveness of the QMS
- provide assistance to any Luxium Solutions personnel with respect to implementing QMS requirements
- reporting on the performance of the system to all Luxium Solutions personnel

Top Management has assigned the responsibility and authority for following aspects of the Quality Management System…

a) the Quality Manager / Management Representative is responsible for ensuring that the quality management system conforms to the requirements of this International Standard;
b) all members of the Top Management Team are responsible for ensuring that the processes are delivering their intended outputs via the review of the Goals and Objectives Matrix (F 6.2-1);
c) the Quality Manager / Management Representative is responsible for reporting to Top Management, as well as all employees, with respect to…

- the performance of the quality management system
- opportunities for improvement, and

These communications typically take place via…

- Management Review Meetings,
- Postings,
- Involvement with Continual Improvement Projects,
- General Employee Meetings

d) the personnel within the Contract Review, Production, and Quality functions are responsible for ensuring the promotion of customer focus throughout the organization through associated communications, postings, and references to customer specific requirements on production documents
e) the personnel within the Top Management and Quality functions are responsible for ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented (see section 6.3 of this QPM and LS 7.5-1).

6.0 Planning

6.1 Actions to address risks and opportunities

6.1.1 As part of planning for the continued development of the quality management system, the organization will consider the issues referred to in Section 4.1 and the requirements referred to in Section 4.2 of this Quality Policy Manual, and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.

6.1.2 Luxium Solutions has incorporated Risk Assessment Methodologies in order to…

a) identify actions in order to address identified risks and opportunities;
b) determine the most effective methods to:

1) integrate and implement the actions into the quality management system processes, and
2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities will be proportionate to the potential impact on the conformity of products and services.

See LS 6.1 for further information on Risk Assessment activities

6.2 Quality objectives and planning to achieve them

6.2.1 Luxium Solutions has established quality objectives at relevant functions, levels, and processes needed for the quality management system.

The Goals and Objectives Matrix (F 6.2-1) is the primary document that is populated and maintained with respect to Quality Objectives.

The quality objectives will be:

a) consistent with the quality policy;
b) measurable;
c) take into account applicable requirements;
d) relevant to conformity of products and services and to enhancement of customer satisfaction;
e) monitored;
f) communicated;
g) updated as appropriate.

6.2.2 As part of the Management Review Meetings, Top Management will review existing and define new objectives that will be utilized to measure the continued suitability and effectiveness of the Quality Policy.

When planning on how to achieve the identified quality objectives, Top Management personnel will determine:

a) what will be done;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

Evidence of these actions will be documented quarterly on the Goals and Objectives Matrix and reviewed in detail during the Management Review Meetings as a basis for continual improvements (QPM 9.3).

If goals and objectives are not met, either action items are assigned or statements justifying the non-action are recorded in the Management Review Meeting Minutes.

6.3 Planning of Changes (Systems Level Quality Planning)

When the organization determines the need for changes to the quality management system, the changes will be carried out in a planned manner consistent with the existing Quality Management System.

This level of planning (Systems Level Planning) is normally initiated during Management Review Meetings in which potential new or revised programs are introduced (i.e. plans for integrated accounting, manufacturing software, or updated ISO requirements).

Personnel responsible for each Planning Project will consider:

a) the purpose of the changes and their potential consequences;
b) the integrity of the quality management system;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

Quality System Planning activities and evidence of considerations being given to the various aspects of the Quality Management System may be captured on any of the following documents…

- Quality Planning Checklist (F 6.3-1)
- Management of Change document (WI 7.1.3-2)
- Management Review Meeting Minutes

Systems Level Quality Planning activities will be assigned to responsible individuals and be re-reviewed during Internal Audits and Management Review Meetings to ensure their effective implementation.

- Internal Auditors and Top Management Staff will ensure that the project(s) are being carried out in accordance with the general quality management system requirements (QPM section 4.4) and the established quality objectives (QPM section 6.2).

Upon completion of each Systems Level Planning activity, completed projects will be presented at Management Review Meetings in order to ensure the integrity of the Quality Management System.

Top Management will evaluate the overall adequacy and effectiveness of the new / updated system(s) and either officially close the project or provide direction with respect to additional actions necessary.

7.0 Support

7.1 Resources

7.1.1 General

The organization determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.

Resource requirements have been defined as equipment, manpower, and training needs.

Resource requirements are formally addressed and provided for during Management Review Meetings (LS 9.3) but may also be identified and provided for during normal day-to-day operations.

Any employee at Luxium Solutions may request additional resources while the Plant Manager, along with other members of Top Management, have the defined responsibility and authority to determine the need for the resources and ensure that, if required, the resources are provided.

During the decision making process, responsible Top Management personnel will consider:

a) the capabilities of, and constraints on, existing internal resources;
b) what needs to be obtained from external providers.

7.1.2 People

Top Management personnel will determine and provide the necessary personnel for the effective implementation of its quality management system and for the operation and control of its processes.

Determinations of required personnel are discussed during Management Review Meetings as well as day to day activities and events, based on Customer Requirements and Employee availability.

All Luxium Solutions personnel are trained and qualified to perform assigned tasks per Section 7.2 of this Quality Policy Manual.

7.1.3 Infrastructure

Top Management personnel will determine and continue to provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

The Plant Manager, along with other members of the Top Management Team, will determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements through Management Review Meetings (LS 9.3).

Infrastructure includes, as applicable…

a) buildings, workspace, and associated utilities
b) process equipment (including both hardware and software), and
c) transportation resources (internal as well as subcontracted resources)
d) information and communication technology (through Information Technology)

Facility Infrastructure is reviewed and determined through…

- Day to Day operations,
- Safety Committee activities (audits),
- Internal and External audit activities,
- Management Review Meetings (LS 9.3)

7.1.4 Environment for the operation of processes

Top Management will determine and continue to provide and maintain an environment necessary for the operation of its processes and to achieve conformity of products and services.

The Plant Manager, along with other members of Top Management and the Safety Committee, have determined and will continue to manage the work environment needed to achieve conformity to product requirements.

Work Environment considerations may include, but are not limited to aspects such as…

a) social (e.g. non-discriminator, calm, non-confrontational)
b) physical,
c) environmental,
d) noise,
e) temperature,
f) humidity,
g) lighting, or
h) weather, as appropriate.

- Eye Protection is required in all Luxium Solutions Production Areas
- For their safety, all visitors/vendors to Luxium Solutions will be offered ANSI approved glasses that comply with ANSI Z-87.

The condition of the work environment will be assessed for its ability to facilitate achievement of conformity to product requirements via…

- Safety Audits
- Internal Audits
- Employees Suggestions

All employees are encouraged to offer suggestions and/or solutions in an attempt to improve upon the existing work environment.

Results of the aforementioned activities are reviewed on a case by case basis, as well as during the Management Review Meetings, in order to identify potential negative situations and to determine whether or not additional actions will be required.

7.1.5 Monitoring and measuring resources (Calibration)

7.1.5.1 General

Operations Management have determined and continue to provide the necessary resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Luxium Solutions has established processes as defined in the Calibration Procedure (LS 7.1.5) to ensure that monitoring and measurement activities can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Operations Management will ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose.

Monitoring and Measuring Resources have been defined as…

- Monitoring and Measurement Equipment
- Personnel responsible for the calibration of Monitoring and Measurement Equipment

Records supporting the application of Monitoring and Measurement resources will be maintained (as appropriate) as part of the documented information to support evidence of fitness for purpose of the monitoring and measurement resources (See LS 7.5-2).

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by Luxium Solutions or its Customers to be an essential part of providing confidence in the validity of measurement results, measuring equipment will be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

In addition, Luxium Solutions will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Appropriate actions will be taken on the equipment and any product affected.

When software is utilized in the monitoring and measurement of specified requirements, the ability of the software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Records supporting Measurement Traceability will be maintained (as appropriate) as part of the documented information via LS 7.5-2

7.1.6 Organizational knowledge

Organizational Knowledge has been defined as…

- the knowledge specific to the organization which is normally gained through training and experience
- information that is used and shared in order to achieve the organizations objectives.

Personnel within the Resource Management Process, with assistance from other member of the Top Management Team, will determine and continue to update the organizational knowledge necessary for the operation of its processes and to achieve conformity of products and services.

Organizational Knowledge has been documented and maintained in an effort to safeguard the organization from any loss of knowledge through staff turnover, and/or failures in capturing and sharing vital operational information.

Organizational Knowledge is captured via…

- the Position Descriptions
- the existing QMS Documents
- Video Tape Process Presentations
- training activities

In order to assure against the lost knowledge and to ensure the effectiveness of continued operations, Luxium Solutions will continue to provide employees with documented information, training, and experience to successfully achieve operational goals.

- Relevant Operational Knowledge may be documented and obtained through…

  - On the Job Training (gained experience through on the job training)
  - Availability of QMS documents (e.g. Quality System Procedures, Work Instructions, Forms)
  - Training or other relevant learning activities (external courses, conferences, seminars, etc.)
  - Inputs from Customers or other External Sources

When addressing changing needs and trends, responsible managers will review their current Operational Knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

- Determining appropriate Organizational Knowledge may be based on…

  - Lessons Learned from failures and successful projects

    The system for capturing and communicating lessons learned is considered to be the Corrective Action Program

- capturing and sharing undocumented knowledge and experience

  On the Job Training and Mentoring Programs for new hires

- the results of improvements in processes, products, and services as demonstrated via postings of Goals and Objectives

Results of any additional knowledge requirements will be captured through training and/or the release of updated or new Quality Management System documents.

Operational Knowledge requirements will be maintained and made available to the extent necessary.

7.2 Competence

Luxium Solutions has developed and maintained a Human Resources Procedure (LS 7.2) in order to:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

   Competence has been defined as the employees' demonstrated ability to apply knowledge and skills.

   Competency requirements for personnel performing work affecting performance and effectiveness of the QMS have been defined through the Position Descriptions

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

   The Position Descriptions define the minimum qualifications (i.e. education, skills, and experience) as well as competencies required to perform assigned tasks and responsibilities of the position.

   Competencies of Luxium Solutions personnel will be determined and assessed via...

   - Electronic Employee Training and Qualification Matrix (F 7.2-1)
   - Previous Employment Skills (Grandfathered)

     Any employees hired prior to June 8, 2007 have been declared competent in their respective positions based on past performance and evaluations

     Competency Information from previous employment may be obtained through the review of the Employee's Résumé, Application, and any relevant Training Certificates presented

   - Witnessing the employee perform the task
   - Notations and Sign Offs on the Electronic Employee Training and Qualification Matrix (F 7.2-1)
   - Individual Training Log (F 7.2-3)
   - Annual Performance Evaluations (F 7.2-4)
   - One Point Lessons (F 7.2-8)
   - Practical Testing administered to attest to the transference of knowledge and skills
   - External Training Certificates
   - Positive effects on the Quality Objectives

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

Training Needs may be identified via...

- Management Review Meetings (Management Directives)
- Processing of Corrective Actions, Preventive Actions, Continual Improvements
- Internal and External Audit results
- Quality Planning
- Employee Requests
- Customer Complaints
- Customer, Statutory, and/or Regulatory Requirements
- Orientation
- Annual Performance Evaluation (F 7.2-4)

d) retain appropriate documented information as evidence of competence per LS 7.5-2.

Records of Training are captured on....

- Electronic Employee Training and Qualification Matrix (F 7.2-1)
- Orientation Checklists (QMS-1030-01F, QMS-1030-02F)
- Training Record Sheets (F 7.2-2)
- External Training Documentation (F 7.2-7)
- One-Point Lessons (F 7.2-8)
- Certificates from external training sources

7.3 Awareness

Luxium Solutions will ensure that persons doing work under the organization's control (internal and external) are aware of:

a) the quality policy through internal documents and postings and externally through the website;
b) relevant quality objectives through internal documents and postings and externally through communications with Customers and Suppliers as deemed necessary;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance internally via Orientation Training and ongoing training and meetings, and externally through communications with Customers and Suppliers as deemed necessary;
d) the implications of not conforming with the quality management system requirements via Orientation Training, ongoing training and meetings, and involvement with Internal Nonconformances and Corrective Actions.

See Training Procedure (LS 7.2) for further information

7.4 Communication

Top Management has determined the internal and external communications relevant to the quality management system. Communications aspects include:

a) what will be communicated;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.

To more easily address these requirements, the following chart has been developed…

Communication Topics may include, but are not limited to…	Communication Frequency	Communicated		Method of Communication	SG Personnel responsible for communicating the information
		Internally	Externally		
Customer Satisfaction	Annually	✓		Posting of the Customer Satisfaction Data / Results	Management Team
Customer Complaints	Annually	✓		Meetings and Postings associated with Customer Complaints	Quality Manager
Internal Nonconformances	As they occur	✓		Goals and Objectives and distribution of Quality Alerts	Manufacturing Manager
Internal and External Audit Activities and Results	As they occur	✓		Regular Employee Update / Meetings & Postings	Quality Manager

Communication Topics may include, but are not limited to…	Communication Frequency	Communicated		Method of Communication	SG Personnel responsible for communicating the information
		Internally	Externally		
Production Metrics	Quarterly	✓		Regular Employee Update / Meetings & Postings	Plant Manager
Quality Policy	Annually (at a minimum)	✓	✓	Postings, Meetings, Internal Audits, documented QMS, web-site	Management Team
Safety Related Topics	As necessary	✓		Meetings, Training, Postings	EHS Manager
New Customers, Statutory, Regulatory and Customer Requirements, Overall status of QMS	Annually	✓		Meetings, Training, & Postings	Management Team
Errors within Customer Documents (e.g. Prints, Specifications, Orders) (to Customers)	As they occur		✓	General Customer Communications, e-mails, marked up documents	Customer Service and/or Plant Manager
Supplier Performance (to Suppliers)	As issues arise		✓	Corrective Actions General Communications	Purchasing Manager

7.5 Documented information

7.5.1 General

The organization's quality management system includes:

a) documented information required by this International Standard;

Controlled Documents and Records will be maintained to support compliance with the sections of the ISO 9001:2015 Standard that specifically call out a requirement to maintain documented information. These sections have been identified as…

1) 4.3
2) 4.4.2
3) 5.2.2
4) 6.2.1
5) 7.1.5.1
6) 7.1.5.2
7) 7.2
8) 7.5.3.2
9) 8.1
10) 8.2.3.2
11) 8.2.4
12) 8.3.2
13) 8.3.3
14) 8.3.4
15) 8.3.5
16) 8.3.6
17) 8.4.1
18) 8.5.1
19) 8.5.2
20) 8.5.3
21) 8.5.6
22) 8.6
23) 8.7.2
24) 9.1.1
25) 9.2.2
26) 9.3.3
27) 10.2.2

b) documented information determined by Luxium Solutions as being necessary for the effectiveness of the quality management system.

These types of documents will be those not specifically required by the Standard, but required in order to support compliance with Luxium Solutions own internal policy and procedures.

The combination of the Document Master List (F 7.5-1) and Records Matrix (F 7.5-4) will identify the controls applied to each of the required documents and records, as well as those determined to be necessary by Luxium Solutions.

Documents under formal control include the…

- Quality Policy Manual,
- Quality System Procedures,
- Work Instructions,
- Forms, and
- External Documents.

See the Control of Documents Procedure (LS 7.5-1) and Control of Records Procedure (LS 7.5-2) for additional detail

7.5.2 Creating and updating

When creating and updating documented information, the Operational Excellence Manager / Management Representative will ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this International Standard will be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the combination of the Document Master List (F 7.5-1) and Records Matrix (F 7.5-4) address document…

a) distribution, access, retrieval and use;

Access implies permissions to view the documented information only, or the permission and authority to view and change the documented information.

b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.

Documented information of external origin determined by the Luxium Solutions to be necessary for the planning and operation of the quality management system has been identified and is controlled via the Document Master List F 7.5-1.

Documented information as defined on the Records Matrix (F 7.5-4) is retained as evidence of conformity shall be protected from unintended alterations.

8.0 Operation

8.1 Operational planning and control (Product / Process Level Quality Planning)

Luxium Solutions has planned, implemented, and controls the processes needed to meet the requirements for the provision of products, and to apply the risk assessment actions determined in Section 6 of this Quality Policy Manual.

Luxium Solutions has defined Operational Planning and Control as the day-to-day 'Product / Process' Level of Planning. To facilitate this planning, LS 8.1, Operational Planning and Control procedure is used to determine the design and its processes to meet our Customers' requirements and needs through the use of APQP.

'Product / Process' planning takes place when a new product or process is introduced, or if a product or process is significantly revised.

To ensure the consistent presentation of information and consistency with the established Quality Management System, the coordination and documentation of Product / Process Planning activities will be documented on the Quality Planning Checklist (F 6.3-1).

In planning the product / process realization, the Project Team will give consideration to the following, as appropriate:

a) determining the requirements for the products;
b) establishing criteria for:

1) the processes;
2) the acceptance of products;

c) determining the resources needed to achieve conformity to the product requirements;
d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining and retaining documented information to the extent necessary:

1) to have confidence that the processes have been carried out as planned;
2) to demonstrate the conformity of products to their requirements.

The organization will control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The output of this level of planning will be the generation of a new or revised Quality Management System documents suitable for the organization's operations.

With respect to Outsourced Processes, Saint-Gobain Crystals will ensure that outsourced processes are properly controlled through Section 8.4 of this Quality Policy Manual and LS 8.4.

8.2 Requirements for products (Contract Review)

8.2.1 Customer communication

Communication with customers will include:

a) providing information relating to products;

Product information is controlled by personnel within the Sales function and is communicated most commonly through the Interne and direct Customer contact.

b) handling enquiries, contracts or orders, including changes are communicated through Sales Personnel
c) obtaining customer feedback relating to products, including customer complaints;

See the Customer Satisfaction Procedure (LS 9.1.2) and Corrective Action Procedure (LS 10.2) for further information.

a) handling or controlling customer property (see Section 8.5.3 of this Quality Policy Manual);

f) establishing specific requirements for contingency actions, when relevant.

Contingency Plans have been prepared to reasonably protect the customer's supply of product in the event of emergency, such as utility interruptions, labor shortages, and key equipment failures.

The Contingency Plans include but are not limited to the following…

- Emergency Response Plan (SGCSP 102.0)
- Crisis Management Procedure (SGCSP 125.0)
- Business Continuity Management Plan (SGCSP 127.0)

The Contingency Plans will be reviewed and updated as necessary during the Management Review Meetings.

8.2.2 Determining the requirements for products

When determining the requirements for the products to be offered to customers, Sales Personnel will ensure that:

a) the requirements for the products are defined, including:

   1) any applicable statutory and regulatory requirements;
   2) those considered necessary by the organization;

b) the organization can meet the claims for the products it offers.

Initial requirements are normally identified during the Design and Quotation Phase of the operations (see LS 8.1, LS 8.2 and LS 8.3)

8.2.3 Review of the requirements for products

8.2.3.1 The Sales Personnel, will ensure that Saint-Gobain Crystals has the ability to meet the requirements for products to be offered to customers.

These individuals will conduct a review of the Customer Order before committing to supply products to the customer, which includes a review of:

a) requirements specified by the customer, including the requirements for delivery;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by the organization;
d) statutory and regulatory requirements applicable to the products;
e) contract or order requirements differing from those previously expressed.

These individuals will also ensure that contract or order requirements differing from those previously defined are resolved.

Where the Customer provides no documented statement of requirement (i.e. Customer places a verbal order), the Customer requirements shall be confirmed by the Sales Personnel prior to acceptance.

8.2.3.2 Sales Personnel are responsible for retaining documented information, as applicable to support:

a) the results of the review;
b) any new requirements for the products.

Records of the results of these reviews and actions arising from the reviews will be maintained in accordance with the Control of Records Procedure (LS 7.5-2).

8.2.4 Changes to requirements for products and services

Where product requirements are changed, the Sales Personnel will ensure that all relevant documents are amended and that relevant manufacturing personnel are made aware of the changed requirements.

Contract Review Procedure (LS 8.2) has been developed to further detail compliance with sections 8.2.2, 8.2.3, and 8.2.4 of this Quality Policy Manual

8.3 Design and development of products

8.3.1 General

Luxium Solutions has established, implemented, and maintains a process that is appropriate to ensure the subsequent provisions of products and ensure the proper planning, handling, communication, and overall control of product design and development activities (LS 8.3).

8.3.2 Design and development planning

Design and Development activities are initiated by Sales and Product Management, and then processed through completion by responsible Design Personnel.

Design Personnel are qualified and responsible for the timely completion of projects.

In determining the stages and controls for design and development, responsible Design Personnel consider:

a) the nature, duration and complexity of the design and development activities;
b) the required process stages, including applicable design and development reviews;
c) the required design and development verification and validation activities;
d) the responsibilities and authorities involved in the design and development process;
e) the internal and external resource needs for the design and development of products~~;~~
f) the need to control interfaces between persons involved in the design and development process;

   Dedicated Customer Teams assure the effective communications between various functions at Luxium Solutions and the Customer. Although the Designer is primarily responsible for the completion of the design project, other members of the team are expected to provide input requirements and participate as requested in resolving conflicting requirements.

g) the need for involvement of customers and users in the design and development process;
h) the requirements for subsequent provision of products;
i) the level of control expected for the design and development process by customers and other relevant interested parties;

   In the event design activities are subcontracted, Luxium Solutions will be responsible for controlling the subcontractors design activities and ensuring compliance with the requirements provided by the Customer and those contained within the ISO 9001 Standard.

j) the documented information needed to demonstrate that design and development requirements have been met.

   Planning output (specifications and drawings) will be documented and updated (as necessary) by the Designers as the design project progresses.

8.3.3 Design and development inputs

Inputs relating to the product requirements are obtained from the Customer and documented by either Sales or Customer Service Correspondents.

Design Inputs include, but are not limited to...

- Sales Information
- Samples
- Drawings
- Specifications

Responsible Design Personnel will determine the requirements essential for the specific types of products to be designed and developed.

The responsible Design personnel will consider:

a) functional and performance requirements;
b) information derived from previous similar design and development activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that the organization has committed to implement are defined within…

   - Design Procedure (LS 8.3)
   - Terms and Conditions outlined by either Saint-Gobain Crystals, and
   - Applicable Industry Standards

e) potential consequences of failure due to the nature of the products will be addressed as part of the risk assessment activities associated with the Customer Service and Design functions.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Designers will review input data for adequacy and ensure that any conflicting information is resolved prior to proceeding with any project.

- All input requirements will be complete, un-ambiguous, and not in conflict with any other requirements

Records of inputs and their reviews will be maintained in the design files per LS 7.5-2.

8.3.4 Design and development controls (Reviews)

Responsible Design Personnel will apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

   Design Reviews are completed at each phase of the design process and are captured via signatures and signoffs on various design documents

   Design Meetings, which are the responsibility of the Project Manager to schedule and document, are held in order to ensure all aspects of each Design Project are on track
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

   Design Verification has been defined as the internal approval of the Prototype Samples and the approval of the associated Design Outputs

d) validation activities are conducted to ensure that the resulting products meet the requirements for the specified application or intended use;

Design Validations has been defined as the Customer Evaluation and Approval of all related Design Outputs

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) documented information of these activities is retained in accordance with LS 7.5-2.

8.3.5 Design and development outputs

Responsible Design Personnel will ensure that design and development outputs:

a) meet the input requirements;
b) are adequate for the subsequent processes for the provision of products;
c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Outputs of the design and development activities include, but are not limited to…

- Drawings
- Specifications
- Design FMEA
- Process FMEA

Records of outputs and their reviews will be maintained in the design files per LS 7.5-2.

8.3.6 Design and development changes

Responsible Design Personnel will identify, review, and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Records of Design Changes will be maintained in accordance with LS 7.5-2 and will include information with respect to:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services (Evaluation of Suppliers)

8.4.1 General

Luxium Solutions ensures that any externally provided processes, products, and services conform to requirements.

Luxium Solutions has determined the controls to be applied to externally provided processes, products, and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;
b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The control of externally provided processes, products, and services is more clearly detailed in LS 8.4. This procedure addresses the criteria for...

- evaluation,
- selection,
- monitoring of performance, and
- re-evaluation of external providers

based on their ability to provide processes, products, and/or services in accordance with requirements.

In the event that Luxium Solutions chooses to outsource any process that affects product conformity with defined requirements and activities impacting the Quality Management System, the Materials Management, Quality Assurance, or Engineering functions will ensure control over such processes through the initial qualification and continual monitoring of outsourced service providers (LS 8.4 - Purchasing) and maintain documented information in accordance with the Control of Records Procedure (LS 7.5-2)

At the present time, Outsourced Processes, Products, and Services include, but are not limited to…

- Calibration Services
- Preventive Maintenance Services
- Secondary Manufacturing / Processing
    - Plating
    - Anodizing
    - Silk Screening

8.4.2 Type and extent of control

Luxium Solutions will ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

Purchasing and Quality Personnel will:

a) ensure that externally provided processes remain within the control of its quality management system;
b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output (see LS 8.4 and LS 8.6-1, old LS 8.2.4-1);
c) take into consideration:

    1) the potential impact of the externally provided processes, products, and services on Luxium Solutions ability to consistently meet customer and applicable statutory and regulatory requirements;

    2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

Luxium Solutions has established and implemented inspection activities necessary for ensuring that purchased product, materials, or services meets specified purchase requirements.

All purchased products and materials are subject to receiving inspection activities as defined in LS 8.6-1.

8.4.3 Information for external providers

Purchasing Personnel will ensure the adequacy of requirements prior to their communication to the external provider.

As applicable, Luxium Solutions Purchasing Personnel will communicate to external providers the requirements for:

a) the processes, products, and services to be provided;
b) the approval of:

   1) products and services;
   2) methods, processes and equipment;
   3) the release of products and services;

c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

   When Luxium Solutions or its Customer, intends to perform verification at the supplier's premises, Luxium Solutions Purchasing Personnel will state the intended verification arrangements and method of product release in the purchasing document.

Purchasing activities are more clearly defined in LS 8.4

8.5 Production provision

8.5.1 Control of production and service provision

Luxium Solutions has implemented production provisions under controlled conditions.

Controlled conditions will include, as applicable:

a) the availability of documented information that defines:

   1) the characteristics of the products to be produced, or the activities to be performed;
   2) the results to be achieved;

   This information is typically identified and available on the following production related documents…

- Work Instructions
- Production Schedules
- Manufacturing Work Orders
- Inspection Sheets
- Part Prints

b) the availability and use of suitable monitoring and measuring resources (see Section 7.1.5 of this Quality Policy Manual and LS 7.1.5);

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products, have been met;

d) the use of suitable infrastructure and environment for the operation of processes (see Sections 7.1.3 and 7.1.4 of this Quality Policy Manual, as well as the Preventative Maintenance Work Instruction WI 7.1.3-1, old WI 6.3 -1);

e) the appointment of competent persons, including any required qualification (see Sections 7.1.6 and 7.2 of this Quality Policy Manual, as well as the Training Procedure LS 7.2);

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

Saint-Gobain Crystals has identified the Organic and Inorganic Crystal Processes as 'Special Processes.'

These Processes have been identified as requiring additional monitoring per LS 8.5.1-2, (Organic and Inorganic Growth Processes), which outlines requirements for…

- Process Control, which includes references to Work Instructions that define the specific methods and procedures required for these processes to meet defined specifications
- Equipment Maintenance, WI 7.1.3-1.
- Monitoring and Measurement Device Calibration, LS 7.1.5
- The qualification of personnel
- Revalidation of the Organic and Inorganic Growth Processes
- Record retention, LS 7.5-2.

g) the implementation of actions to prevent human error;

Based on the hands on nature of our manufacturing processes, Luxium Solutions may never be able to eliminate the potential of human error.

However, based on…

- the information established as part of the defined Organizational Knowledge,
- our documented Quality Management System,
- the ongoing Employee Training and Competency activities, and
- secondary checks and balance inspections performed by Supervisors and/or Quality Personnel

Luxium Solutions is confident that we have limited to potential of human error situations.

h) the implementation of release and delivery activities (see Section 8.6 of this Quality Policy Manual).

8.5.2 Identification and traceability

Luxium Solution has identified and utilizes suitable means in order to identify outputs when it is necessary to ensure the conformity of products.

All Production Personnel are tasked with…

- properly identifying the status of the outputs with respect to monitoring and measurement requirements throughout production provision through the use of…
  - travelers,
  - work orders,
  - tags,
  - labels,
  - product markings, and
  - vendor markings
- controlling the unique identification of the outputs when traceability is a requirement through the use of…
  - travelers, and
  - tags

When traceability is a specified Customer requirement, Luxium Solutions will control the unique identification of the product via the information contained on the Tags, through Product Markings, and other associated links back to Raw Material and certifications.

Records will be maintained per LS 7.5-2.

Products whose identification and inspection status cannot be verified will be handled in accordance with the Control of Nonconforming Product Procedure LS 8.7.

8.5.3 Property belonging to customers or external providers

Luxium Solutions will exercise care with property belonging to customers or external providers while under its control or while being utilized by Luxium Solutions.

For any property belonging to Customers or External providers, Luxium Solutions Crystals will identify, verify, protect, and safeguard the customers' or external providers' property provided for use or incorporation into the products.

Customer Property may include…

- returned goods
  - products for refurbishing,
  - warrantee and non-warrantee returns / repairs
- fixtures,
- components, or

- packaging

Intellectual property and personal data may also be considered customer property and are normally addressed with confidentiality agreements.

If any customer or external providers' property is lost, damaged, or otherwise found to be unsuitable for use, the situation will be evaluated and reported to customer or external provider and records maintained in accordance with the Control of Records Procedure LS 7.5-2.

Records will include a description of what has occurred and any related actions taken.

Control of Customer Property Procedure LS 8.5.3 further defines the control, identification, verification, protection and safeguarding of the Customer Owned Property

8.5.4 Preservation

Luxium Solutions will preserve the outputs during internal processing and availability for customer pickup, or when required by contract, delivery to the intended destination.

Detail provided within this Quality Policy Manual and Quality System Procedures ensures that preservation includes (as applicable)…

- the identification,
- handling,
- contamination control,
- packaging,
- storage,
- transportation, and
- protection of the outputs (products).

Luxium Solutions is not required to hold products to any defined cleanliness specifications.

See LS 8.5.4 for further information

8.5.5 Post-delivery activities

Luxium Solutions has determined the extent of post-delivery activities to be activities such as…

- warranty and non-warrantee returns and repairs,
- contractual obligations (i.e. maintenance and/or supplementary services such as recycling or final disposal)

During Post Delivery Services activities, consideration is given to the following…

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

8.5.6 Control of changes

The Supervisory Personnel responsible for production and service activities are also responsible for the review and control changes with respect to production and service provisions, to the extent necessary to ensure continuing conformity with requirements.

During actual processing, the Supervisory Personnel are authorized to approve marked up documents via initials and dates so as not to affect order requirements.

Once the job has been completed, Supervisory Personnel are required to communicate any marked up changes and approvals to the Quality Manager / Management Representative who is ultimately responsible for processing the official document changes.

The official document changes will be processed through the Control of Documents Procedure (LS 7.5-1) and the referenced Document Change Form (F 7.5-3)

Each Document Change will include provisions for…

- Review and approval of the new/updated document,
- assessing any other QMS documents that may be affected,
- assessing any requirements for training affected personnel,
- the removal of obsolete documents, and
- the distribution of the new/updated documents

The Production Personnel will then be responsible for the re-review, acceptance, implementation, and adherence to the updated document(s).

The Quality Manager / Management Representative is responsible for retaining documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products (Inspection and Test)

Luxium Solutions has implemented planned arrangements, at appropriate stages, to verify that the product requirements have been met.

- Quality and Production Personnel will monitor and measure the characteristics of the product to verify that product requirements have been met.

- Monitoring and Measuring activities will be carried out at appropriate stages of the product realization process in accordance with the planned arrangements defined within…

  - the System Process Model Diagram (F 4.4.1-1),
  - the Inspection and Testing Procedure, (LS 8.6-1),
  - the Organic Crystals Inspection and Testing Procedure (LS 8.6-2), and
  - other Process Control Documents (i.e. Work Order Packages, Part Prints, etc).

The release of product to the customer and delivery will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Evidence of conformity with the acceptance criteria, as well as the personnel authorizing the product release, will be maintained in accordance with LS 7.5-2.

The documented information will include:

a) evidence of conformity with the acceptance criteria via the Production Travelers (F 8.5.1-2);
b) traceability to the person(s) authorizing the product release via the Quality Assurance Form and associated Certificates of Conformance

8.7 Control of nonconforming outputs

8.7.1 Department Managers, Quality Assurance, and Production Personnel will…

- ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery
- take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.

When nonconforming product is detected after delivery or use has started, Luxium Solutions will take actions appropriate to the effects, or potential effects, of the nonconformity (see the Corrective Action Procedure LS 10.2).

Luxium Solutions will deal with nonconforming outputs in one or more of the following ways:

a) correction

   By taking action to eliminated the detected nonconformity - scrap, reject, re-work;

b) segregation, containment, return, or suspension of provision of products;
c) informing the customer;

   When nonconforming product is detected after delivery or use has started, Luxium Solutions will inform the customer and take actions appropriate to the effects, or potential effects, of the nonconformity (see LS 10.2 Corrective Action).

d) obtaining authorization for acceptance under concession

   By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the Customer (use as is);

Conformity to the requirements will be verified when nonconforming outputs are corrected.

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in LS 8.7.

8.7.2 Quality Assurance will retain documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

Records of the nonconformities and any subsequent actions taken, including concessions obtained, will be maintained in accordance with the Control of Records Procedure LS 7.5-2.

9.0 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Top Management Personnel have determined:

a) what needs to be monitored and measured (as defined on the Goals and Objectives Matrix – F 6.2-1);
b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.

Top Management continually evaluates the performance and the effectiveness of the quality management system through…

- the Goals and Objectives Matrix (F 6.2-1)

  The Goals & Objectives Matrix is utilized as a method for ensuring appropriate monitoring and measuring of the effectiveness and suitability of the Quality Management System processes.

  When planned results are not achieved, or data indicates a negative trend, either correction and/or corrective actions are established to adjust the resulting process measure, or statements justifying the non-action are recorded.

- Internal and External Audit results
- Customer Feedback (satisfaction and dissatisfaction)
- various meetings with internal and external sources
- Management Review Meetings

Evidence of these performance evaluations are retained as documented information to support evidence of the results per LS 7.5-2.

9.1.2 Customer Satisfaction

Luxium Solutions monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled.

- Customer Satisfaction may be obtained through...

  - Customer Surveys
  - Customer Report Cards
  - Sales Representative Communications with the Customer
  - Customer Complaints (dis-satisfaction measure)
  - Customer visits to Luxium Solutions or Luxium Solutions visits to the Customer facilities

- Customer Satisfaction data may be monitored and reviewed during…

  - Management Review Meetings
  - Meetings with the Customer(s)
  - The Goals and Objectives Matrix (F 6.2-1)
  - Customer Feedback (Positive Feedback or Complaints)

For additional information regarding Customer Satisfaction please refer to LS 9.1.2

9.1.3 Analysis and evaluation

Luxium Solutions analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are utilized to evaluate:

a) conformity of products through inspection and test activities, and Customer Feedback;
b) the degree of customer satisfaction per section 9.1.2 of this Quality Policy Manual and LS 9.1.2;
c) the performance and effectiveness of the quality management system per the Goals and Objectives Matrix (F 6.2-1), Internal and External Audit activities, and the Management Review Meetings;
d) if planning has been implemented effectively per sections 6.3 and 8.5.1 of this Quality Policy Manual;
e) the effectiveness of actions taken to address risks and opportunities (see section 6.1 of this Quality Policy Manual);
f) the performance of external providers (see section 8.4 of this Quality Policy Manual);
g) the need for improvements to the quality management system (see section 10.3 of this Quality Policy Manual).

In order to obtain collect and analyze this information, Top Management will determine the applicable collection methods, including any applicable statistical techniques and the extent of their use during Management Review Meetings

9.2 Internal Audit

9.2.1 Luxium Solutions will conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system;
2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 Responsible Internal Audit Personnel will:

a) plan, establish, implement and maintain an audit program including…

- the frequency,
- methods,
- responsibilities,
- planning requirements and
- reporting

At a minimum, each identified Key Process as identified on the System Process Model Diagram (F4.4.1-1) will be audited one time per year and support coverage of all applicable requirements of the ISO 9001 Standard.

The Internal Audit Schedule will be based on the status and importance of the activity/process to be audited.

The audit frequency will be increased or decreased based on…

- performance data,
- management directives,
- changes affecting the organization,
- internal / external nonconformances, as well as
- the results of previous Internal Audits

b) define the audit criteria and scope for each audit;

The Auditor Criteria has been defined as…

- the ISO 9001:2015 Standard
- the documented Quality Management System
- any applicable Statutory and/or Regulatory Requirements
- any applicable Customer Specific Requirements

The Audit Scope for each audit activity has been defined on the Master Internal Audit Schedule F 9.2-1

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

Internal Audits will be carried out by personnel who are independent of those having direct responsibility for the activity/process being audited.

Personnel responsible for overseeing the Internal Audit Program (the Management Representative) will select independent auditors to perform objective and impartial audits, and ensure that Internal Auditors do not audit their own work.

d) ensure that the results of the audits are reported to relevant management;

Through the utilization of the Internal Audit Summary Reports

e) take appropriate correction and corrective actions without undue delay;

Depending on the nature of the Internal Audit Results, either Informal Actions or Formal Corrective Actions will be initiated and be addressed in accordance with the time frames stated on the Internal Audit Summary Reports or Corrective Action documents.

Follow-up activities will be performed and include the verification of the Corrective Actions taken and the reporting of verification results (see LS 10.2).

f) retain documented information as evidence of the implementation of the audit program and the audit results per LS 7.5-2

The Internal Audit Procedure LS 9.3 has been established to address all defined internal audit requirements.

9.3 Management Review

9.3.1 General

Top Management reviews the Quality Management System at a minimum of once per quarter to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review will be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:

    1) customer satisfaction and feedback from relevant interested parties;
    2) the extent to which quality objectives have been met;
    3) process performance and conformity of products;
    4) nonconformities and corrective actions;
    5) monitoring and measurement results;
    6) audit results;
    7) the performance of external providers;

d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities;
f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review will include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs,
d) alignment of QMS with the strategic direction of the organization

Records of the Management Review Meetings and any resulting actions will be retained as documented information in accordance with LS 7.5-2 in order to support evidence of the results of management reviews.

A detailed Quality Management System Procedure, LS 9.3 further defines the Management Review Meeting topics and the structured agenda.

10.0 Improvement

10.1 General

Luxium Solutions continues to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

Improvements may include, but are not limited to:

a) improving products to meet requirements as well as to address future needs and expectations;
b) correcting, preventing or reducing undesired effects;
c) improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, responsible Quality and Production personnel will:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;
2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity;
2) determining the causes of the nonconformity;
3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary.

A Corrective Action Procedure LS 10.2 has been established in order to more clearly define the requirements identified above

The following general statements have been identified with respect to processing corrective actions…

- Corrective actions initiated will be appropriate to the effects of the nonconformities encountered.
- Corrective Actions may be generated via…

  - Customer Complaints,
  - Internal Audits,
  - Supplier Nonconformances, or
  - any other Internally or Externally identified Nonconformance.

10.2.2 Records of Nonconformances and their resolution are retained as documented information per LS 7.5-2 as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

10.3 Continual improvement

Luxium Solutions will continually improve the suitability, adequacy, and effectiveness of the quality management system as defined in LS 10.3.

The Plant Manager along with Top Management, will determine, select, and implement actions to continually improve the effectiveness of the Quality Management System.

Continual improvement projects may be initiated via:

- the results of any analysis and evaluations,
- the review of the Quality Policy effectiveness,
- progress made towards achieving Quality Objectives,
- Internal and External Audit results,
- general analysis of data,
- Corrective Actions,
- outputs from Management Review Meetings, and
- Customer Feedback

All Continual Improvement Projects will be tracked and monitored for progress and completion.

Continual Improvement Projects may be documented via any of the following methods…

- Continual Improvement Log (F 10.3-1)
- Continual Improvement Form (F 10.3-2)
- WCM documents / records
- Management of Change records

11.0 Control of the Quality Policy Manual

The Quality Policy Manual will be reviewed and approved by the Luxium Solutions Plant Manager and Operational Excellence Manager / Management Representative.

A master hard copy of the Quality Policy Manual is maintained by the Operational Excellence Manager / Management Representative.

Controlled copies of the document are available electronically and accessible to all personnel.

Any distributed hard copies will be controlled as per the Master Document List (F 7.5-1).

Management Team personnel are responsible for ensuring that the content and requirements of the Quality Policy Manual are understood and complied with.

Any hard copies distributed to sources such as Customers or Registration Bodies are not considered controlled documents. These copies are provided for reference purposes only and are not subject to receiving updates as the document evolves.

Other Quality System Documents are available throughout the facility via controlled ‘hard copies’ and controlled electronic systems (i.e. - QAD and CMS).

These ‘systems’ are further defined in LS 7.5-1.

11.1 Quality Policy Manual Revision History

Revision Level	Date	Nature of Change
NEW	12/15/06	NEW issue to meet Quality Assurance Program Plan and QPM to meet the ISO 9001:2000 requirements.
Rev. A	02/19/07	Added page numbers to Table of Contents. Reformatted the page numbering scheme.
Rev. B	10/17/07	Added scope for registration purpose, section 2.0

Rev. C	07/28/08	Recognized the Hiram location as additional site under Registration, section 2.1.
Rev. D	08/11/09	Recognized changes for ISO 9001:2008 - 4.1a, 4.1, 4.2.1c, 4.2.2a, 6.2.2a, 7.1c, 7.2c, 7.2d, 7.2.2, 7.3.2, 7.3.3, 7.3.3b, 7.5.1d, 7.5.1f, 7.5.4, 7.6a, 7.6c, 8.1a, 8.2.2, 8.2.3, 8.2.4, 8.4c, 8.5.2, 8.5.2f, 8.5.3e
Rev. E	01/28/11	Recognized organizational change of Crystals General Manager from Director of Operations – i, 3.0, 4.1, 6.1, 6.3, 6.4. Recognized revision to Mission – 2.2 Recognized title revisions and additions to the Management Team; Crystals Global Supply Chain Manager from Materials Manager, Crystals Sales and Marketing Director from Director of Sales, added HSE Manager and Crystals General Manager.
Rev. F	08/29/11	Revised the defined Management Team Members; Section 5.0 Management Responsibility. Moved General Manager responsibilities to the Management Team; Section 3.0, paragraph 2, Section 4.1 paragraph 1.
Rev. G	09/10/14	Replaced General Manager with Director of Operations: page i and page 2, section 3, page 11 section 6.3 Revised the Management Team members: page 6, section 5.0.
Rev. H	11/23/15	Replace “PRMS” with QAD, the new ERP System.
Rev. I	6/15/16	DRAFT # 1 - Complete re-write and re-organization based on the updated requirements of the ISO 9001:2015 Standard
	8/30/16	DRAFT # 2 – Corrected mark ups provided with respect to the 6/15/16 version of the QPM
Rev. J	5/8/17	Revised the Newbury Mailing Address cover page. Corrected the use of QSP to QPM section 4.2 Key Process Design & Development, added Design & Process FMEA’s and MOC’s as outputs. Section 6.2, weekly changed to quarterly. Section 8.3.5, Product FMEA changed to Process FMEA
Rev. K	4/10/2018	Added Form F 4.4.1-3, Process Matrix to section 4.4.1
Rev. L	1/9/2019	Revised section 7.2 Competence: replace Skill Set-Matrix with Electronic Employee Training and Qualification Matrix, Orientation Checklists QMS-1030-01F and -02F replaced F 7.2-2, External Training Documentation replaced Temporary Employee Training Log, added One-Point Lesson form F 7.2-8
Rev. M	2/5/2020	Revised section 8.1 to include SGCN 8.1 Operational Planning and Control Procedure to determine the design and its processes to meet our Customers’ requirements and needs through the use of APQP.
Rev. N	3/22/2022	Revised Quality Manager to Operational Excellence Manager, section 5.1.1. Replaced “F 5.2-1 with QPM, section 5.2.1. Replaced F6.3-1 with WI 7.1.3-2. Replaced SGCN 8.4.1 with SGCN 8.1, sections 8.1 and 8.4.1. Replaced WI 8.5.1-1 with WI 7.1.3-1, section 8.5.1 d) and f).
Rev. O	5/9/2022	Revised Approval Page (2). Mohamed Chakroun now Plant Manager
Rev. P	8/1/2022	Revised Approval Page (2). Ryan Smith now Plant Manager

Rev. Q	03/06/2023	Replaced Saint-Gobain Crystals with Luxium Solutions. Revised SGCN to LS for level 1 procedures.

End of Document