B-Tec Solutions Quality Manual

Quality Manual

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Company Profile:

B-Tec Solutions Incorporated is a manufacturing solutions supplier, providing services to the avionics, automotive, heavy equipment, commercial, electronics and medical industries. Currently, B-Tec Solutions operates one division located in Croydon, Pennsylvania.

Approval:

President of B-Tec Solutions Corporation:

Designated Management Representative:

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Revision History:

Revision	Change Description	Revision Date
F	Entire Re-Write to ANSI/ISO/ASQ Q9001-2000, SAE: AS9100, and Customer Requirement Changes.	05/31/02
G	Revised Quality Policy, Add paragraphs 4.2.3.1, 4.2.3.2, 4.2.3.3, remove revisions from referenced Standards.	06/20/02
H	Added Paragraph 5.5.1.1 “Executive Management Responsibility”	10/01/02
I	Revised 5.3 Quality Policy to read: “Continuously improve the way we meet our customers’ expectations.” 5.5.2 corrected Title of Management Representative	03/11/03
J	1. All References to Brenner Tool Inc. changed to B-Tec Solutions. 2. Company Profile updated to reflect current Business Plan. 3. President & Management Representative updated to current. 4. Removed D6-82479 from Section 2.0 Normative References. 5. Revised flowchart showing sequence and interaction of Quality Management processes to reflect current. 6. Section 5 updated to current. 7. Various grammatical and spelling errors corrected.	07/15/03
K	1. Adjusted page #’s in table of contents for new additions. 2. Moved Section 4.2.3.3 Configuration Management to Section 4.3 3. Adjustment of Scope to include current work scope. 4. Format of 5.3 & 5.4.1 to refer to Appendix C for Quality Policy & Objectives. Ability to change more frequently without updating entire QM. 5. Added Design to Scope of Activities & addition of 7.3 in its entirety.	05/05/05
L	Amended Paragraph 5.6.1 from quarterly to annual.	09/05/07
M	Amended Section 1.2 to include Eastern Welding Program Exclusion	09/18/08
N	Revised to bring document into compliance with ISO9001:2008	07/19/10
O	Remove references to AS9100	11/03/11
P	General update and editing to include and/or reinstate references to AS9100C.	02/05/16

Distribution List

See Document Control Administrator for Controlled Quality System Documents.
Any Quality System Documentation printed, or outside of B-Tec Solutions is “Uncontrolled”.

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Section 1: Scope:

1.1 General

The B-Tec Solutions quality manual establishes and specifies our policies, procedures and requirements of the Quality Management System. The scope of our activities is as follows:

Contract Manufacturing including: Tool & Die Build, Production Stamping, EDM, Precision Machining & Outsource Management.

This system is structured to comply with ISO9001:2008, SAE: AS9100C, and applicable statutory, regulatory and contractual requirements. Our Quality Management System utilizes eight basic principles for managing and obtaining objectives for improved performance of the organization. They are:

- Customer Focus – Understanding current and future customer needs and continually striving to improve the way we meet their expectations;
- Leadership – Creating and maintaining the internal environment where people become fully involved in achieving B-Tec Solution's objectives;
- Involvement of People – All levels of the organization involvement enabling their abilities used for the company's benefit;
- Process Approach – Efficiently managing interrelated resources to manage the processes;
- System Approach to Management – Identify, understanding and managing interrelated process as a system;
- Continual Improvement – A permanent objective of B-Tec Solutions;
- Factual Approach to Decision Making – Based upon the analysis of data and information;
- Mutually Beneficial Supplier Relationships – Mutually beneficial relationships to enhance the ability of both to create value.

1.2 Application

This manual is applicable to product which is intended for or required by a customer or for any intended output resulting from the product realization process. The following requirements are not applicable to B-Tec Solution's operations.

Our system excludes:

- Service - Our system does not require warranty and after market support.
- Design and Development – B-TEC Solutions builds and manufactures to customers design; B-TEC Solutions does not have customer design authority.
- Eastern Welding Program – This service was added as to support our customer's overflow of welding work they cannot accomplish in-house. They have certified these welders to their own specifications, which we are not privy to. This equipment may only be used to support this program and no other. The work occurring in this cell does not fall under B-Tec Solutions Quality System.

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- These excluded activities have no affect on B-Tec Solution's ability to provide products and services meeting customer, statutory and regulatory requirements.
- Sample products produced to prove out methods of production.

Section 2: Normative Reference

2.0 Quality Management System References

These documents were consulted during the preparation of B-Tec Solution's Quality Management System:

- **International Standard ISO 9000:2005,**
  Quality Management Systems – Fundamentals and Vocabulary.
- **International Standard ISO 9001:2008**
  Quality Management Systems – Requirements.
- **American National Standard ANSI/ISO/ASQ Q9004-2000, Quality Management Systems – Guidelines for Performance Improvements.**
- **SAE: AS9100C Quality Systems - AEROSPACE**

These documents are indispensible for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Section 3: Terms and Definitions

3.0 Quality Management System Definitions

- The terms and definitions given in ISO 9000:2008, and SAE: AS9100C apply to B-Tec Solution's Quality Management System. Any differences or addition to terminology in B-Tec Solution's system is stated below.

3.1 Risk

B-Tec Solutions Management Representative is responsible for the coordination and control of the Risk Management process. Supervisors and Quality personnel are responsible for the implementation of the Process Failure Mode Effect Analysis (PFMEA) associated with their applicable sections. The Director of Quality and the Operations Manager is authorized to approve all PFMEA's.

3.2 Special Requirements

Requirements identified by the customer, or determined by the organization, which have high risk to being achieved, require their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity.

Examples of special requirements include performance imposed by the customers that are at the limit of the industry capability, or requirements determined by B-Tec Solutions to be at the limit of its technical or process capabilities.

3.3 Critical Items

B-Tec Solutions identifies those items, e.g. function, parts, software, characteristics, processes having significant effect on the product realization and use of the product; including safety, performance, form, fit, producibility, service life that require specific actions to ensure they are adequately managed.

Examples of critical items include:

- Safety critical items
- Fracture critical items
- Mission critical items
- Key Characteristics

3.4 Key Characteristics

The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

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Section 4: Quality Management System

4.1. General Requirements

B-Tec Solution's documented Quality Management System is maintained, implemented and continually improved by:

- Determining the processes needed for the Quality Management System and application of processes throughout the organization;
- Determining the sequences and interactions of these processes;
- Establishing criteria and methods to ensure operations and control of the processes are effective;
- Ensuring the availability of resources and information to achieve planned results and the continual improvement of these processes;
- Monitoring, measuring where applicable and analyzing our processes;
- And implementing actions to achieve planned results and the continual improvement of the processes.

B-Tec Solutions manages the processes in accordance with the requirements of ISO9001:2008 and SAE: AS9100C.

Our system includes control of processes outsourced affecting product conformity to requirements. Control of outsource processes is identified in section 7.4 of this manual.

4.2. Documentation Requirements

4.2.1 General

Our Quality Management System documentation includes:

- Quality Policy and Objectives;
- This Quality Manual;
- Documented Procedures and records;
- Documents, including records for planning, operating, and controlling processes;
- And Quality system requirements imposed by regulatory authorities

For a list of procedures, see Appendix A at the end of this manual.

We ensure personnel have access and are aware of relevant procedures in the Quality Management System documentation. Customer and/or regulatory authority representatives have access to quality management system documentation upon request.

4.2.2 Quality Manual

This Quality Manual describes the B-Tec Solution's Quality Management System. The scope and permissible exclusions of the QMS are described in section one. A reference to lower level procedures is located in Appendix A. The Process Flow Diagram at the end of section four provides a description of the interactions between the processes and the Quality Management System.

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4.2.3 Control of Documents

Quality Management System documents are controlled in accordance with the Document Control procedure. It defines the process to:

- Review, revise, and approve/re-approve documents prior to issue;
- Ensure changes and current revision status are identified;
- Ensure versions of applicable documents are available at points of use;
- Ensure documents remain legible and readily identifiable;
- Ensure documents of external origin that have been determined to be necessary for the planning and operation of the QMS are identified and distribution controlled;
- Prevent the unintended use of obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified;
- And, customer furnished data used for production and/or inspection, is controlled.

B-Tec Solutions coordinates documented changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

4.2.3.1 Document and Data Approval and Issue

Before the release, authorized personnel review and approve documents. Once approved, records are updated identifying the current revision status of documents to preclude the use of invalid and/or obsolete documents.

4.2.3.2 Document and Data Changes:

Changes of document and data are reviewed and approved by the same functions/organizations that performed the original review and approval, unless specified in a lower level procedure. Personnel who review changes have access to pertinent historical information to base their review and approval. As required, the nature of the change is identified in the document or appropriate attachments.

All changes such as drawings, specifications, planning, etc. are reviewed in a timely manner, distributed, implemented, and maintained. B-Tec Solutions maintains a record of changes incorporated and, when required, coordinates these changes with customer and/or regulatory authorities.

4.2.4 Control of Records

Records established to provide evidence of conformity to the requirements and effective operation of the quality management system are controlled according to the procedure for Control of Quality Records.

Our records remain legible, readily identifiable and retrievable. Stored records are identified, protected, and retrievalble. Retention times are for a minimum of seven years or unless otherwise specified by contractual requirements. After records are retained for the designated time, they are disposition in accordance with customer requirements.

Records from our suppliers are considered part of our record control.
Records are available to our customers and regulatory agencies upon request.

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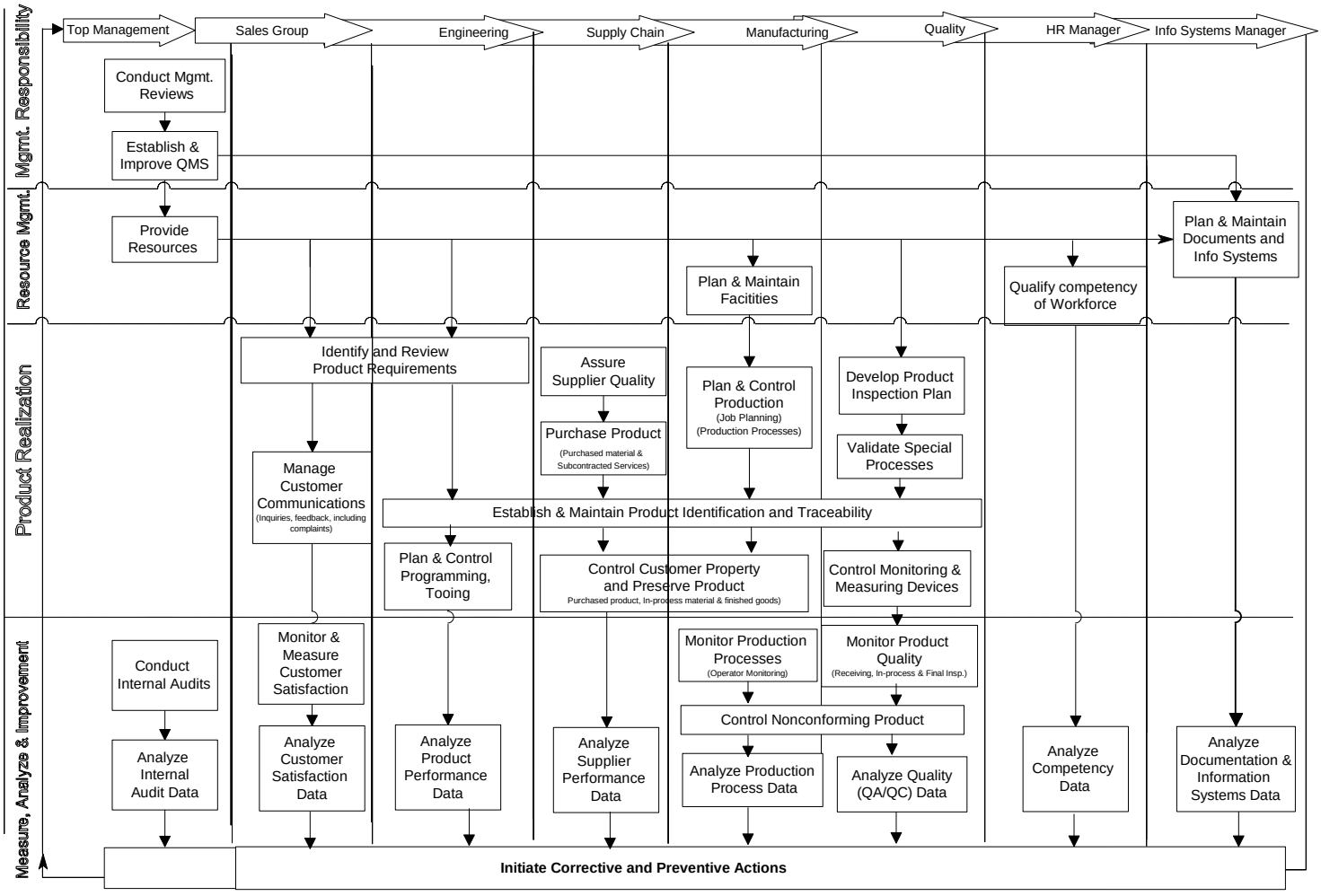
Sequence and Interaction of Quality management System Processes



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Section 5: Management Responsibility

5.1 Management Commitment

Top management is actively involved in development and implementation of the Quality Management System. They are continuously pursuing improvements in the Quality Management System.

Their leadership and commitment actions include:

- Communicating the importance of meeting customer, statutory, and regulatory requirements;
- Establishing the quality policy and objectives;
- Conducting quarterly management reviews;
- And ensuring resource availability.

For details on B-Tec Solution's organizational structure refer to Appendix B at the end of this manual.

5.2 Customer Focus

B-Tec Solutions management ensures customer requirements are determined and met with the aim to current and future customer needs, while aiming to enhance customer satisfaction.

B-Tec Solutions ensures that product conformity and on-time delivery performance are measured and that appropriate action is taken when results are not achieved.

5.3 Quality Policy

The quality policy has been developed and approved by Top Management. This policy and relevant procedures is available to all employees. The policy is audited regularly to ensure its distribution and ongoing overall awareness of it, by employees. During management review, the quality policy is reviewed for continual suitability. The quality policy is contained inside the quality manual, the quality policy may also be issued as a stand-alone document; in this occurrence it is uncontrolled if printed. Top management communicates the quality policy to all employees.

For details of the Quality Policy & objectives of B-Tec Solutions, please refer to Appendix C at the end of this manual.

The policy is:

- Applicable to internal and external customers;
- Committed to continuous improvement;
- Provides a framework for establishing and reviewing quality objectives;
- Reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

Our Quality objectives are established to support B-Tec Solution's efforts to achieve our quality policy. Objectives are reviewed at the Management Meetings. As objectives are addressed they are translated to lower levels and become more specific and tactical in nature. These lower level objectives are available in Appendix C at the end of this manual.

Higher Level Objectives:

- Customer Satisfaction
- Reduction of Non-Conformances
- Reduction of Cycle Times
- Improve Delivery Performance
- Reduction of Complaints

Quality objectives are measurable, and reviewed to assure performance demonstrate continual improvement at each management review meeting.

5.4.2 Quality Management System Planning

Top Management ensures the quality management system continues to meet the requirements of ANSI/ISO/ASQ Q9001: 2008 and SAE: AS9100C. Planned changes to the Quality Management System are effectively implemented for continuous compliance.

Documented policies and procedures were reviewed prior to implementation. Management ensures the QMS is maintained when changes to the QMS are planned and implemented. Subsequent major changes that may affect the performance, quality or reliability of the product will be identified, reviewed and approved and the QMS documentation will be updated.

The QMS documentation acts as the overall quality plan for B-TEC Solutions. As required, specific quality processes may be developed for individual products; these plans include the information given above. In such cases, the appropriate department manager (with support from Quality Management) has overall responsibility for the development of quality plans.

5.5 Responsibilities, Authority and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibility are defined and communicated throughout the organization. The organizational chart defines the basic management structure of B-TEC Solutions. In all cases, the appropriate person has been granted both the responsibility and authority for the duties of their position, which further defines within position specific job descriptions. Training and job assignment are the responsibility of department managers.

5.5.1.1 Executive Management Responsibility

President/CEO

- Direction and development of the company and overall strategic business planning
- Acquisitions of the capital investments
- Facility Maintenance

Operations Manager

- Oversees the daily activities of the company
- Oversees the manufacturing and engineering operations

Director of Quality

Quality Assurance Manager

- Control and maintenance of the Quality Management System
- ISO/AS designated representative
- Facility qualifications
- Product Quality Activities

Supply Chain Manager

- Purchasing activities
- Supplier control in conjunction with quality
- Shipping/Receiving functions

Production Control Manager

- Planning and scheduling of production
- Customer Relations

CFO

- Finance
- Human Resource
- Safety

Sales Management

- Management of Sales and Support functions

5.5.2 Management Representative

Quality System Management Representative Appointment

The Director of Quality is appointed as Management Representative. As Management Representative, the Quality Director and/or his designate, the Quality Assurance Manager is responsible for ensuring the proper implementation of the quality system, as well as, for overseeing the maintenance of the system, reporting on its effectiveness during management review, and discussion of matters relating to the quality management system with customers, registrars and other concerned parties.

The management representative and/or designee are responsible for facilitation of these policies and procedures. The management representative has the responsibility and authority

to resolve matters relative to quality in products, processes and service from internal and external sources.

Quality may suspend internal and external processes and/or shipments that do not meet requirements until appropriate correction is implemented on and expedited, high priority basis. The Quality Director reports to the President/CEO and has unrestricted access to top management. The Quality Assurance Manager, Inspectors, and Auditors report directly to the Quality Director. In addition, the Management Representative and/or designee ensure the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal Communication

Top Management ensures that the appropriate communication processes are established between various levels and functions within the organization and that communication takes place regarding the effectiveness of the quality management system. Communication and effectiveness of the quality management system is through the use of, but not limited to:

- Departmental and Management meetings;
- Use of Company bulletin boards.

5.6 Management Review

5.6.1 General

Top Management conducts annual Management Review Meetings. It assesses the continuing suitability, adequacy and effectiveness of the Quality Policy and Quality Objectives. These meetings identify opportunities for improvement and needed changes.

- Meeting records are maintained.

5.6.2 Review Input

Reviews are based on: (As applicable)

- Action items assigned in last review meeting – Follow up
- Customer feedback and complaints
- Internal or external audit results
- Continual improvement projects or recommendations
- Corrective and preventative actions
- Resource needs
- Changes that could affect the quality system
- Product conformity (scrap, rework)
- Changes in quality policy or objectives
- Customer satisfaction progress
- Company level data (KPI's Metrics)

5.6.3 Review Output

Management identifies decisions and actions resulting from the quality management meetings relating to the following:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Section 6: Resource Management

6.1 Provision of Resources

Resource assessment initiated through, but not limited to, management reviews, business planning and quality system performance reviews

B-Tec Solutions identifies and provides adequate resources for the assignment of trained personnel:

- To implement, maintain, and continually improve the effectiveness of the quality management system
- Enhance customer satisfaction by meeting customer requirements

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are competent based upon their education, training, and/or experience.

6.2.2 Competence, Training and Awareness

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. The effectiveness of training is evaluated through testing results, and certification of training completion.

B-Tec Solutions maintains documented procedures for identifying training needs and provides for the training of all personnel performing activities affecting conformity to product requirements. When applicable B-Tec Solutions provides training or takes alternate actions to assure that personnel achieve the necessary competence.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

Training records for personnel are on file.

6.3 Infrastructure

B-Tec Solutions Manufacturing has determined, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Documentation is in the form of Maintenance and calibration records. The infrastructure has been provided, and includes:

- Buildings, workspace, utilities;
- Process equipment including hardware and software;
- Supporting services (such as transportation, communication or information systems).

B-Tec Solutions has established a production facility with the necessary environmental controls for factors including temperature, humidity, lighting, and cleanliness. Facilities undergo routine preventative maintenance by skilled maintenance personnel.

B-Tec Solutions internal server is equipped with a battery backup system preventing loss of power and data in the event of a power outage. In the event of a sustained power outage, loss of data is prevented through regular backups and prevention of loss.

6.4 Work Environment

B-Tec Solution's has determined and manages the work environment, including noise, temperature, humidity, and lighting, needed to achieve conformity (if applicable) to product requirements. The work environment is periodically reviewed during internal audits and work environment-related resource requirements are regularly reviewed during management review. The working environment is maintained based upon planning activities of product realization and top management input.

Section 7: Product Realization

7.1 Planning of Product Realization

B-Tec Solutions plans and develops the processes and documents needed for product realization. The product planning process is consistent with the requirements of the other processes of the quality management system. During this planning, personnel determine (as appropriate):

- The quality objectives and requirements for the product;
- Processes, documentation and resources to support operation and maintenance, specific to the product;
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product, and criteria for product acceptance;
- Records needed to provide evidence that products meet requirements;

7.1.1 Project Management

Project management is a process designed to ensure customer requirements are met. During project management, managers plan and manage product realization is a structured and controlled manner. Resource needs and scheduled constraints are considered and adjusted as needed. Appropriate actions are taken to mitigate risk as they are determined.. These processes are further defined in sections 7.1.2, 7.1.3, 7.2, and 7.5.

7.1.2 Risk Management

Risk management is essential in meeting customer requirements. Managers, and/or the delegates, communicate with customers, obtaining information that may not be stated in contracts of purchase orders.

Management is responsible for risk management and taking action to mitigate risks. Factors Such as labor, equipment, material, scheduling, and outside processes are identified throughout contract review, purchasing, planning, production, and inspection processes. Documents are created or revised, and meetings are held as needed to address and communicate risk that have been identified. Internal preventive and corrective action is closely intergrated into risk management. As risks are identified these actions may be used to mitigate and resolve risks (see 8.5.2 and 8.5.3).

Prior to acceptance of contract or purchase order, relevant risk criteria are assessed to identify risk and determine feasibility.

Criteria may include but are not limited to:

- Engineering data (e.g. drawings, models, specification, etc.) are made available
- Customer supplied quality requirements.
- Configuration plan
- Quantity and delivery schedule
- Requirements for customer approved suppliers
- Lead time and cost for raw material and/or hardware items
- Lead time and cost for outside processing (e.g. heat treat, plating etc.)
- Cost of any non-recurring charges
- Labor hours and skill
- Equipment (e.g. tooling, fixtures, and resources)
- Inspection and test plans
- Any special requirements and expectations not stated in request

7.1.3 Configuration Management

Configuration management includes planning, identification, change control, status of accounting, and auditing. Configuration audits are conducted during internal audits. Contracts for new products and changes to existing products are processed in accordance with section 7.2.

Part configuration is provided in the customer's engineering specifications. Configuration is identified on the Process Sheet and subsequent shipping documents. When the product requirements change, the manufacturing plan is revised and appropriate personnel are informed of the change. This process is further defined in section 7.5.

7.1.4 Control of Work Transfers

When planning to temporarily transfer work, B-Tec Solutions defines the process to control and validate the quality of work per customer requirements.

- The outsourced service provider must be an approved supplier according to requirements of section 7.4.
- The supplier is required to notify B-Tec Solutions of any process changes, any nonconformity, or other issues.
- The supplier will be subject to corrective action system, as defined in section 8.5.2.
- Work must be conducted on the article(s) according to any specification listed on the purchase order.

This process is controlled through purchasing and resultant receiving documentation. Product and quality requirements are flowed down in purchase orders as described in section 7.4.2.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements related to the Product

B-Tec Solutions captures all contractual and special requirements, monitoring and measuring requirements, applicable statutory or regulatory requirements, and/or any necessary, unstated requirements as part of the contract review.

7.2.2 Review of Requirements related to the Product

B-Tec Solutions reviews requirements related to the product before order commitment.

Our review ensures:

- Product requirements are defined;
- Differences between the contract, order, or tender requirements are resolved;
- Our ability to meet the defined requirements;
- The risk associated with new technology and/or short delivery time scale is evaluated.

Records of review activities are maintained showing the results and actions.

When the customer provides no documented statement of requirements,

B-Tec Solutions confirms these requirements prior to acceptance.

Changes to product requirements are communicated to relevant personnel. B-Tec Solutions ensures these changes to product requirements are documented.

7.2.3 Customer Communication

B-Tec Solutions uses an effective process for communicating with customers relating to:

- Product Information
- Enquiry's, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development (Exclusion)

- Design and Development – B-TEC Solutions builds and manufactures to customers design; B-TEC Solutions does not have customer design authority.

7.4 Purchasing

7.4.1 Purchasing Process

B-Tec Solutions ensures procured materials and services are conforming to specified requirements and assume responsibility for their quality, including customer-designated sources.

Evaluation/Control of Suppliers:

B-Tec Solutions:

a) Evaluates and selects suppliers based upon their ability to meet our flow-down requirements;
b) Evaluates/re-evaluates suppliers;
c) Defines the necessary action to take when dealing with suppliers that do not meet requirements;

d) Establishes and maintains a register of acceptable suppliers (e.g. AVL or Approved Vendors List) and their scope of approval;
e) Ensures, where required, the use customer-approved special process sources;
f) Ensures that the purchasing and quality departments approves suppliers quality systems and has the authority to disapprove the use of suppliers;
g) Periodically reviews supplier's performance. Records of these reviews are maintained and used as a basis for establishing the level of supplier controls to be implemented;

7.4.2 Purchasing Information

Purchasing information describes the product to be acquired including, where applicable:

a) Requirements for approval or qualification of product, procedures, processes, equipment and personnel, and quality management system requirements;
b) The title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data;
c) Design, test examination, inspection and related instructions for acceptance by the organization;
d) Right of access by B-Tec Solutions, our customer, and regulatory authorities to all facilities involved in the order and all applicable records;
e) Requirements for test specimens (production method, number, storage conditions etc.) for design approval, inspection, investigation, or auditing;
f) Requirements relative to the notification of non-conforming material, and arrangements for approval of supplier nonconforming material;
g) Requirements for notification of changes in product, and/or process definition and, where required, obtain approval;
h) And, sub-tier suppliers requirements to flow down of applicable requirements in the purchasing documents, including key characteristics where required.

B-Tec Solutions ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

B-Tec Solution's purchased products verification methods may include:

a) Obtaining objective evidence of the product's quality from suppliers (e.g. accompanying documentation, certificates of conformity, test reports, statistical records, process control);
b) Inspection and audit at supplier's premises;
c) Review of the required documentation;
d) Inspection of products upon receipt;
e) Delegation of verification to the supplier, or supplier certification.

When delegation is used, B-Tec Solutions defines the requirements for delegation and maintains a list of delegations.

Should B-Tec Solutions propose to verify purchased product on the supplier's premises, B-Tec Solutions will specify the verification arrangements and methods of product release in our purchase order.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless released under positive recall process. When the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. B-Tec Solutions periodically validates test reports for raw material.

Where required by contract, B-Tec Solution's customer or their representatives will have the right to verify at the supplier's premises and B-Tec Solution's premises that subcontracted product conform to specified requirements. B-Tec Solutions does not use these verifications as evidence of effective control of quality by the supplier. Customer verifications do not absolve B-Tec Solutions of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by our customer.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

B-Tec Solutions plans and carries out production provisions under controlled conditions.

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring equipment
- The implementation of monitoring and measurement
- The implementation of product release, delivery and post-delivery activities
- The establishment of process controls and development of control plans where key characteristics have been identified
- The accountability for all product during manufacture (such as quantity, split orders, and nonconforming product)
- Evidence that all manufacturing and inspection operations have been completed as planned or as otherwise documented and authorized
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and special processes
- Provision for the prevention, detection, and removal of foreign objects, (FOD).
- Monitoring and controlling of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality
- Criteria for workmanship, which shall be stipulated in the clearest practical manner

Planning shall consider, as appropriate:

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified.
- Manufacturing and using tooling to measure variable data.
- Identifying in-process inspection/verification points when adequate verification of conformance cannot be performed in later stages of realization
- Special processes (See 7.5.2).

7.5.1.1 Production Process Verification

B-Tec Solutions Manufacturing uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing the parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results. These changes can include, but not be limited to:

- Engineering Changes
- Manufacturing process changes
- Tooling changes
- Raw material changes
- Special process changes

7.5.1.2 Control of Production Process Changes

B-Tec Manufacturing identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and programs are documented. Procedures exist to control their implementation.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

The President/CEO, Director of Quality, Quality Assurance Manager, Production Control Manager, and the Operations Manager are authorized to approve changes to production process.

B-Tec Solutions Manufacturing controls and documents changes affecting

- Processes
- Production equipment
- Tools
- Software programs

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools, and software programs used to automate control/monitor product realization processes are validated prior to release for production and are maintained for review and future recall.

Storage requirements, including periodic preservation/condition checks are defined for production equipment or tooling in storage.

7.5.1.4 Post-Delivery Support

Post delivery support is provided as applicable for the following:

- Collection of analysis of service data
- Actions to be taken, including investigation and reporting, when problems are detected after delivery
- Controlling and updating of technical documentation
- Approval, control and use of repair schemes
- Controls required for off-site work as B-Tec Solutions Manufacturing's work undertaken at customer's facility.

7.5.2 Validation of Processes for Production Provision

B-Tec Solutions validates any processes for production provision where subsequent monitoring or measurement cannot verify the resulting output and as a consequence deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

B-Tec Solution's Manufacturing establishes arrangements for these processes including, as applicable.

- Defined criteria for review and approval of the process followed by qualification and approval of special processes prior to use.
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures in assuring control of significant operations and parameters of special processes in accordance with documented process.
- Requirements for records
- Revalidation

Special Processes

Special processes are carried out by qualified/certified operators and/or require continuous monitoring and control of process parameters ensuring that the specified requirements are met. Requirements for the qualification of process operations, including equipment and personnel are specified in lower level procedures. Records are maintained for qualified processes, equipment, and personnel

- Production processes classified as “special processes” are:

1) Identified and approved prior to use;
2) Controlled to applicable aspects of the special processes, as defined by the process specifications, this includes special process changes;
3) Defined significant operations and parameters in the process to be controlled during the production.

Special processes or processors used must be customer-approved as required by contract or other regulatory authority.

7.5.3 Identification and Traceability

7.5.3.1 B-Tec Solutions utilizes suitable methods of product identification and traceability; these methods may vary depending upon the stage of manufacture. The identification and traceability begins with the receipt of materials, through all stages of production, until delivered to the customer.

7.5.3.2 Based upon the extent of traceability requirements by the contract, B-Tec Solutions establishes and maintains unique identification of individual product or batches. The level of traceability required by contract, regulatory or other established requirements are maintained and recorded.

B-Tec Solution’s system provides for as necessary:

a. Identification to be maintained throughout the product life;
b. Identification of product status with respect to monitoring and measurement requirements throughout product realization;
c. All the product manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
d. For an assembly, the identification of its components and those of the next higher assembly to be traced;
e. For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

7.5.3.3 B-Tec Solutions maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration. When acceptance authority media are used (example: stamps, electronic signatures, passwords), the organization establishes and documents controls for the media.

7.5.3.4 If the identification and traceabililty of product has been lost, it is processed as non-conforming material.

7.5.4 Customer Property

B-Tec Solutions exercises care with customer property while it is under their control or being used by the organization. B-Tec Solutions controls, maintains, and stores, customer-supplied product provided for incorporation into the supplies or for related activities. Customers are notified of property, which is lost, damaged, or otherwise found unsuitable for use.

Customer-supplied product is identified, verified, inspected, tested, processed, recorded and stored in the same manner as regular product, unless specified differently by the customer and agreed upon by B-Tec Solutions.

When we receive or fabricate customer owned accountable-tools B-Tec Solutions controls those tools in accordance with the applicable customer tooling specification requirements.

7.5.5 Preservation of Product

B-Tec Solutions preserves the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable this preservation includes identification, handling, storage, packaging, protection, and delivery methods. Preservation also applies to constituent parts of a product.

Preservation of product includes, where applicable, in accordance with product specifications and/or applicable regulations, provisions for:

a) Cleaning;

b) Prevention, detection, and removal of foreign objects;

c) Special handling for sensitive products;

d) Marking and labeling including safety warning;

e) Shelf life control and stock rotation;

f) Special handling for hazardous materials.

B-Tec Solutions ensures that documents required by the contract/order accompany the product, are present at delivery and protected against loss and deterioration.

7.6 Control of Monitoring and Measuring Equipment

B-Tec Solutions determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the process used to ensure that monitoring and measuring can be and is carried out in a manner that is consistent with the monitoring and measurement requirements. A Database of these monitoring and measuring equipment, and the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria are maintained.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, where no such standards exist, the basis used for calibration or verification is recorded.
- Adjusted or re-adjusted as necessary;
- Identified to enable the calibration status to be determined;
- Recalled to a defined method when requiring calibration;
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage;

B-Tec Solutions ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

In addition, Quality assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. B-Tec Solutions takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

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

Section 8: Measurement, Analysis and Improvement

8.1 General

B-Tec Solutions plans and implements the monitoring, measurement, analysis and improvement processes as needed

- Demonstrating conformity to product requirements
- Ensuring conformity of the quality management system, and
- Continually improving the effectiveness of the quality management system.

These processes are identified in documented procedures to include determination of applicable methods, statistical techniques, and the extent of their use.

According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- Design verification (e.g. reliability, maintainability, safety)
- Process control
  - Selection and inspection of key characteristics
  - Process capability measurements
  - Statistical process control
  - Design of experiment
- Inspection – matching sampling rate to the criticality of the product and to the process capability
- Process Failure Mode Effect Analysis (PFMEA)

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8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

One measurement of the performance utilized is monitoring information relating to customer perception ensuring fulfillment of customer requirements. Methods used for determination of customer satisfaction include, but are not limited to: customer surveys, and review of customer supplier ratings.

Information to be monitored and used for evaluation of customer satisfaction is identified in APPENDIX (D).

8.2.2 Internal Audits

B-Tec Solutions conducts internal audits at planned intervals verifying the quality management system:

- Conforms to planned arrangements;
- Is effectively implemented and maintained;
- Conforms to customer quality requirements;
- And, meets contract and/or regulatory requirements.

Internal audits are scheduled based upon status; importance of the activity audited, and results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure.

Auditors are independent of those having direct responsibility for the activity being audited. The selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process.

Tools and techniques that may be utilized are check sheets, process flowcharts, or any similar methods supporting the audit of the quality management system requirements. Acceptability of the selected tools is measured against the effectiveness of the internal audit process and overall organization performance.

Audit results are brought to the area manager's attention having responsibility. They take timely corrective action on deficiencies found during the audit without undue delay to eliminate detected nonconformities and their causes. Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken.

8.2.3 Monitoring and Measurement of Processes

B-Tec Solutions applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate..

In the event of process nonconformity, B-Tec Solutions:

- Takes appropriate action to correct the nonconforming process;
- Evaluates whether the process nonconformity resulted in product nonconformity;
- Identifies and controls nonconforming product in accordance with the lower level procedure.

8.2.4 Monitoring and Measurement of Product

B-Tec Solutions monitors and measures product characteristics verifying the fulfillment of product requirements at appropriate stages of the product realization process in accordance with the planned arrangements.

Conformity acceptance criteria are maintained and records indicating the person authorizing release of product for delivery to the customer.

Product release and service delivery to the customer do not proceed until all planned arrangements are satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

When identified, key characteristics are monitored and controlled.

When B-Tec Solutions uses sampling inspection as a means of product acceptance, plans are statistically valid and appropriate for use. The plan precludes the acceptance of lots having known defects. As contractually required, the plan is submitted to the customer for approval prior to implementing sampling inspection.

8.2.4.1 Measurement requirements for product acceptance are documented, maintained and controlled. Some inspection documentation may be part of the manufacturing plan. This documentation includes:

- Criteria for acceptance and rejection
- Where in the sequence measurement and testing operations are performed
- Documents to record inspection results
- The type of measurement instruments required and any specific instructions associated with their use.

Test records show actual results when required by specification or acceptance test plan.

Where required, B-Tec Solutions demonstrates product qualification through the evidence of quality records showing where product meets the defined requirements.

8.2.4.2 First Article Inspection: B-Tec Solution's quality system provides a process for inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent changes invalidating the previous first article inspection results.

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8.3 Control of Nonconforming Product

Product not conforming to specified requirements is identified and controlled in order to prevent its unintended use or delivery. Non-Conforming material is reviewed and dispositioned; control, responsibility and disposition authority is specified in the lower level procedure.

Where applicable nonconforming product is dealt with one or more of the following ways:

a) Taking action to eliminate the detected nonconformity;

b) Authorizing its use, release or acceptance under concession by a relevant authority and where applicable, by the customer

c) Taking action to preclude its original intended use or application.

B-Tec Solutions does not use dispositions of “use-as-is” or “repair” unless specifically authorized by the customer if:

- The product is produced to customer design, or
- The nonconformity results in a departure from the contract requirements.

Product dispositioned as scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

B-Tec Solutions maintains records of the nature of nonconformities and any subsequent actions taken, including concessions obtained.

When nonconforming product is corrected it is subjected to re-verification to demonstrate conformity to the requirements.

B-Tec Solution’s non-conformance system provides timely reporting of non-conformities detected after delivery or use has started. B-Tec Solutions takes action appropriate to the effects or potential effects of the nonconformity in terms of reliability or safety. Our notification includes a clear description of the nonconformity, which includes a clear description of the non-conformance, including necessary parts affected, customer and/or internal part numbers, quantity, and date(s) delivered.

8.4 Analysis of Data

B-Tec Solutions determines, collects and analyses appropriate data demonstrating the suitability and effectiveness of the quality management system. We evaluate where continual improvement of the effectiveness of the quality management system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.
Analysis of data provides information relating to

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

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8.5 Improvement

8.5.1 Continual Improvement

B-Tec Solutions continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Every manager has the responsibility to continually improve their area of responsibility and to contribute to the improvement of the company as a whole.

8.5.2 Corrective Action

Corrective Actions are issued to eliminate the causes of non-conformities and prevent their recurrence. The manner in which they are dealt with is relative to the magnitude of problem and comparable with the risk encountered.

Corrective actions include:

a) The handling of customer complaints and reports of product non-conformities;
b) Investigation of the cause of non-conformities relating to product, process, and quality management system;
c) Evaluating the need for action to ensure that nonconformities do not recur;
d) Determining and implementing action need;
e) Records of the results of the actions taken:
f) Reviewing the effectiveness of corrective and preventive actions taken;
g) Flow down of the corrective action requirement(s) to a supplier, when it is determined that the supplier is responsible for the root cause;
h) Specific actions where timely and/or effective corrective actions are not achieved.
i) Determine if additional nonconforming product exists based on the causes of the nonconformities and taking further action, when required.

8.5.3 Preventive Action

B-Tec Solutions determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

Preventive Action includes:

a. Determining potential nonconformity's and their causes;
b. Evaluating the need for action to prevent occurrence of nonconformities;
c. Determination and implementing the action needed;
d. Records of results of action taken;
e. Reviewing preventive action taken.