BAITY SCREW
MACHINE
PRODUCTS
QUALITY MANUAL
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>SECTION</th>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Company Introduction</td>
<td>4</td>
</tr>
<tr>
<td>0</td>
<td>Organizational Chart</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>Scope</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>Related Documents</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Terminology</td>
<td>7</td>
</tr>
<tr>
<td>4</td>
<td>Quality Management System</td>
<td>8</td>
</tr>
<tr>
<td>4.1</td>
<td>General Requirements</td>
<td>8</td>
</tr>
<tr>
<td>4.2</td>
<td>Documentation Requirements</td>
<td>9</td>
</tr>
<tr>
<td>4.2.1</td>
<td>General</td>
<td>9</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Quality Manual</td>
<td>9</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Control of Documents</td>
<td>10</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Control of Records</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>Management Responsibility</td>
<td>13</td>
</tr>
<tr>
<td>5.1</td>
<td>Management Commitment</td>
<td>13</td>
</tr>
<tr>
<td>5.2</td>
<td>Customer Focus</td>
<td>13</td>
</tr>
<tr>
<td>5.3</td>
<td>Quality Policy</td>
<td>14</td>
</tr>
<tr>
<td>5.4</td>
<td>Planning</td>
<td>14</td>
</tr>
<tr>
<td>5.4.1</td>
<td>Quality Objectives</td>
<td>14</td>
</tr>
<tr>
<td>5.4.2</td>
<td>Quality Management System Planning</td>
<td>15</td>
</tr>
<tr>
<td>5.5</td>
<td>Responsibility, Authority and Communication</td>
<td>15</td>
</tr>
<tr>
<td>5.5.1</td>
<td>Responsibility and Authority</td>
<td>15</td>
</tr>
<tr>
<td>5.5.2</td>
<td>Management Representative</td>
<td>15</td>
</tr>
<tr>
<td>5.5.3</td>
<td>Internal Communication</td>
<td>15</td>
</tr>
<tr>
<td>5.6</td>
<td>Management Review</td>
<td>16</td>
</tr>
<tr>
<td>5.6.1</td>
<td>General</td>
<td>16</td>
</tr>
<tr>
<td>5.6.2</td>
<td>Review Input</td>
<td>16</td>
</tr>
<tr>
<td>5.6.3</td>
<td>Review Output</td>
<td>16</td>
</tr>
<tr>
<td>6</td>
<td>Resource Management</td>
<td>17</td>
</tr>
<tr>
<td>6.1</td>
<td>Provision of Resources</td>
<td>17</td>
</tr>
<tr>
<td>6.2</td>
<td>Human Resources</td>
<td>17</td>
</tr>
<tr>
<td>6.2.1</td>
<td>General</td>
<td>17</td>
</tr>
<tr>
<td>6.2.2</td>
<td>Competence, Awareness and Training</td>
<td>17</td>
</tr>
<tr>
<td>6.3</td>
<td>Infrastructure</td>
<td>18</td>
</tr>
<tr>
<td>6.4</td>
<td>Work Environment</td>
<td>18</td>
</tr>
<tr>
<td>7</td>
<td>Product Realization</td>
<td>19</td>
</tr>
<tr>
<td>7.1</td>
<td>Planning of Product Realization</td>
<td>19</td>
</tr>
<tr>
<td>7.2</td>
<td>Customer Related Processes</td>
<td>19</td>
</tr>
<tr>
<td>7.2.1</td>
<td>Determination of Requirements Related to the Product</td>
<td>19</td>
</tr>
<tr>
<td>7.2.2</td>
<td>Review of Requirements Related to the Product</td>
<td>20</td>
</tr>
</tbody>
</table>
Introduction

Since 1947, Baity Screw Machine Products has provided high quality machining services to the Automotive, Oil & Gas, Refrigeration, and Agriculture industries at a competitive cost. Baity Screw Machine Products has the capability to machine parts from many types of materials such as Stainless Steel, Cold-Rolled Steel, Brass, Copper, and Aluminum.

Baity Screw Machine Products strives to provide the highest quality product, on time, at the lowest possible cost. We realize to remain successful we must continue to create strong partnerships and maintain clear and concise communications with our customers and suppliers.

Our customers and suppliers are the reason Baity Screw Machine Products exists, and the reason for our success, and no one associated with Baity Screw Machine Products ever forgets it. We present this quality manual as a demonstration of our commitment to our customers.

Approved By: Richard C. Pace

President

Robert C. Pace
Sales Manager

James S. Pace
Q.A. Manager

Todd Bingham
Production Manager

Mike K. Pace
Warehouse Manager
1 SCOPE

The Quality Management System described within this manual establishes Baity Screw Machine Products total quality policy. This manual reflects Baity Screw Machine Products intent to adhere to the requirements of ISO 9001:2000 except for the exclusions shown, with justification, in the table below:

EXCLUSION TABLE

<table>
<thead>
<tr>
<th>Clause or Sub-clause</th>
<th>Exclusion</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3</td>
<td>Design and Development</td>
<td>Baity Screw Machine Products manufactures product to a customer supplied design. We do not perform design activities.</td>
</tr>
<tr>
<td>7.5.1</td>
<td>Service Provision</td>
<td>Baity Screw Machine Products does not perform service activities.</td>
</tr>
</tbody>
</table>

This manual contains the necessary criteria and methods required to implement the policy.

2 RELATED DOCUMENTS

Documents related to this policy document include:

- Process Control Plans or Process Work Orders that directly impact our product and processes.
- Forms and Support documents necessary for providing information to or collecting information from the Quality Management System.
3 Terminology

3.1 Quality Manual
Document describing the operational methods of the quality management system.

3.2 Quality Policy
Overall intentions and direction of the quality management system.

3.3 Process Control Plan
Detailed description of activities and tasks performed within a process.

3.4 Failure Mode Effects Analysis (FMEA)
Document that recognizes and evaluates potential failure of a product and/or process while identifying actions to reduce the occurrence of the potential failure.

3.5 Production Part Approval Process (PPAP)
Process to determine if all customer specification requirements are understood and that the process has the potential to produce product consistently to these requirements during an actual production run.

3.6 Measurement Systems Analysis (MSA)
Process to determine measurement device repeatability, reproducibility and variation (GR&R).

3.7 Statistical Process Control (SPC)
Method for determining system, process, and product predictability, capability and performance.

3.8 Form
Document used to collect information from the quality management system.

3.9 Support Document
Electronic document that provides information for the quality management system.

3.10 Records
Documents that provide evidence and historical data of quality management system activities.
4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

This quality management system and the processes within it have been created, are maintained and implemented and its effectiveness continually managed and improved to achieve compliance with ISO 9001:2000 and all customer requirements and expectations.

The order and interaction of the quality management system processes are as follows:

Start
Sales receives customer order or quote and determines if the order or quote can be fulfilled.

Quality Assurance receives, and if necessary, creates product and/or processing documentation.

Management personnel order raw products and/or services as necessary.

Receiving processes purchased product and places in storage or forwards to production.

Management personnel provide necessary equipment and employee needs for manufacturing of product.

Production manufactures product to customer requirements.

Quality Assurance and/or Production personnel perform all necessary inspection and/or tests on product.

Production forwards completed product to shipping area.

Shipping packages product and forwards to customer or to storage.

Sales determines customer satisfaction with supplied product.

Management personnel review system performance and institute necessary actions to ensure continual system improvement.

End
Further, specific procedures, criteria and methods for effective control, monitoring and operation and interaction of processes are found within this manual and related quality system documentation. Resources for effective operation of the quality management system are provided as needed as determined by management personnel. Upon the completion of measurement and monitoring of products, processes and the quality management system the data will be analyzed and appropriate action taken to ensure intentions are achieved and opportunities for improvement are acted on.

Outsourced processes, having impact on the achievement of product or service requirements are controlled as described in section 7.4 of this manual.

4.2 Documentation Requirements

4.2.1 General

The following documents are included within the quality management system:

- Statements of quality policy and quality objectives
- This quality manual
- Documents referred to in this quality manual
- Documents needed to ensure effective planning, operation and control of processes
- Records

4.2.2 Quality Manual

This quality manual contains:

- Scope statement with exclusions
- Procedures Criteria and methods to achieve planned results
- References the documents that describe the quality management system
4.2.3 Control of Documents

The control of internal documents is performed as follows:

Creating Internal Document

Start

Create document and submit with request form.

Determine if document is necessary for system operation.

Affect system operation?

Yes

No

Review document for adequacy.

Document adequate?

No

Yes

Sign and date document and/or request form. Record revision level on document and add document to document log.

Make copy of master document and distribute copy. File request record.

End

Document will not be controlled. Notify requester of decision.

Review criteria is:
1. Necessary information
2. Document I.D.
3. Revision level assigned

End

Editing Internal Document

Start

Make copy of controlled document. Mark copy with requested change and submit with request form.

Determine if change to document is necessary for system operation.

Change necessary?

Yes

No

Document will not be changed. Notify requester of decision.

Review criteria is:
1. Necessary information
2. Document I.D.
3. Revision level assigned

Create revised document to reflect requested change. Review document for adequacy.

Document adequate?

No

Yes

Sign and date document and/or request form. Revise revision level on document and document log.


End

Signature and date on document and/or request form constitute approval of change.
The control of external documents is performed as follows:

All controlled documents will be identified by title and/or number and be listed on the Controlled Document Log. Changes to internal documents that require information to be **added** will be identified as follows:

- **Quality Manual and Process Control Plans or Process Work Order:** Information will be underlined.

- **Forms:** Changes identified with request form.

- **Support Documents:** Will not be identified.

Changes to internal documents that require information to be **deleted** will be identified as follows:

- **Quality Manual, Process Control Plans or Process Work Order and Forms:** Changes identified with request form.

- **Support Documents:** Will not be identified.

The Quality Assurance Manager is responsible for all activities of the document control process. All controlled documents will be reviewed and require approval by the Sales, Production, Quality Assurance and Warehouse Managers for
adequacy prior to issue. All controlled documents are available to all employees for use. Documents will be replaced if they become unreadable or cannot be identified. Documents that become obsolete will either be disposed of or retained. If retained, they will be identified by placing them in obsolete folders or stamping “OBSOLETE” on them. Records of document approval and change are maintained as described in section 4.2.4 of this manual.

4.2.4 Control of Records

The control of records is performed as follows:

Start

- Determine if record will reflect system performance.
  - Reflect system performance? No → Record will not be controlled.
  - Yes → Review record for adequacy.
    - Review criteria is:
      1. Legibility
      2. Necessary information
      3. Record name assigned
    - Document adequate? No → Document adequate?
      - Yes → Determine record storage point, retention time and disposition method.
        - Record the record name, storage point, retention time and disposition method on the record log.
          - Develop filing system that ensures that the record will be protected against loss, deterioration and can be retrieved with ease.

End
All controlled records will be identified by title and/or number. The Quality Assurance Manager is responsible for all record control activities. Placement of a record on the Controlled Record Log by the Quality Assurance Manager constitutes approval of the record.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment
The following are expressions of management’s commitment to develop, implement and improve the effectiveness of the quality management system:

- Communication about the importance of fulfilling customer legal and regulatory requirements occurs throughout the company. That communication happens through the use of:
  - General and product specific training
  - Retraining when and where shortfalls appear
  - Periodic verbal and documented communications
  - Provided documentation

- Quality policy
- Quality objectives
- Management review records
- Availability of resources

5.2 Customer Focus
Management assures that all customer requirements are determined and implemented for all necessary processes of the quality management system as described in section 7.2 of this manual. Through all of the policies, objectives and processes described within this quality manual, management assures the needed environment to consistently fulfill the customer requirements. By routinely assessing customer satisfaction as described in section 8.2.1 of this manual, the likelihood of achieving customer satisfaction increases.
5.3 Quality Policy

Having given due consideration to the following:

- Purpose of Baity Screw Machine Products
- Commitment for compliance to requirements
- Commitment to continually improve the effectiveness of the quality management system
- Continual compatibility with quality objectives

The management of Baity Screw Machine Products formulated the following quality policy statement:

```
Baity Screw Machine Products will meet the needs of customers while continually improving quality system performance
Rev. (A) 2008
```

All employees realize their responsibility for not only knowing the content of the quality policy, but also their responsibility for fulfilling the requirements of this policy in all of their work related efforts and decisions. The quality policy is reviewed during management review meetings for suitability.

5.4 Planning

5.4.1 Quality Objectives

The following measurable quality objectives have been formulated by the management of Baity Screw Machine Products:

1. Continually Improve Customer Satisfaction
2. Continually Improve Product and Process Performance
3. Continually Improve Supplier Performance

Baity Screw Machine Products has communicated to all employees their responsibility in achieving these quality management system objectives.
5.4.2 Quality Management System Planning
Formal planning for new products, processes or customers will be conducted by the management personnel and, as necessary, appropriate employees. Through formal planning the integrity of the quality management system is maintained. Quality planning will be recorded on the Quality Planning form. Records of quality planning are maintained as described in section 4.2.4 of this manual.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority
The responsibilities and authorities of management personnel are described throughout this manual in detail. Communication of responsibilities and authorities for employees occurs during training.

5.5.2 Management Representative
The Sales Manager serves the role of the primary management representative. In his absence, the Quality Assurance Manager accepts this role. The Sales Manager ensures that the processes needed for the quality management system are established, implemented, and maintained. The representative schedules management meetings and reports to all employees on the performance of the quality management system and any need for improvements. The representative has and will continue to ensure the promotion of awareness of customer requirements to all employees.

5.5.3 Internal Communication
Management personnel communicate verbally and with posted metrics on a regular basis to all employees regarding the performance of the quality management system. Customer requirements and information are communicated to employees through verbal conversations, meetings, and quality management system documentation.
5.6 Management Review

5.6.1 General

The Sales, Production, Quality Assurance, and Warehouse Managers review the performance of the quality management system once every year (1-year) to ensure its continuing suitability, adequacy, and effectiveness. The review assesses opportunities for improvement and the need for changes, including the quality policy and objectives. Meeting activities are recorded on the Management Review form. Records of management review are maintained as described in section 4.2.4 of this manual.

5.6.2 Review Input

Quarterly performance and opportunities for improvement are determined by reviewing the following:

- Audit results
- Customer feedback
- Process performance and product conformity
- Preventive and corrective action status
- Supplier performance
- Changes that affect the quality management system
- Recommendations for improvement
- Follow-up actions from previous review meetings

5.6.3 Review Output

Actions and decisions associated with the following are included in the output from management review:

- Improvement of effectiveness of the processes
- Overall improvement of the quality management system effectiveness
- Improvements upon product associated with customer requirements
- Resource needs
6 RESOURCE MANAGEMENT

6.1 Provision of Resources
Management personnel determine and provide the necessary resources for:
• Implementing and maintaining the quality management system
• Continually improving quality management system effectiveness
• Ensuring customer satisfaction through achievement of customer requirements

6.2 Human Resources
6.2.1 General
Employees performing work affecting product quality have been and will continue to be competent on the basis of appropriate education, training, skills, and experience. Employees are encouraged to verbally request any necessary training needed to enhance their job performance. Management personnel will consider all requests and determine if requested training is needed.

All Baity Screw Machine Products employees performing job tasks prior to the original release date of this manual are grandfathered into their past and current job tasks as determined by the management of Baity Screw Machine Products.

6.2.2 Competence, Awareness and Training
Management personnel determine the necessary competence needed as new processes evolve and existing ones change. When training is required to aid in the achievement of the required competence, one or more of the following will occur:
• Classroom training (internal or external) will be scheduled
• On-the-job training will be delivered

If on-the-job training is conducted, selected employees will conduct the training for an appropriate amount of time and then observe the trainee performing all of the required activities. If the trainee performs the activities in an acceptable manner, the trainer will complete a Training Certification Log form and forward to
management personnel for placement within the trainees training file. If the trainee does not perform the activities in an acceptable manner, the trainer will provide additional training to the trainee until such time that the trainee can demonstrate the activities in an acceptable manner or report the results of the training effort to management personnel for consideration of placing the trainee in a different job.

One or more of the following will be used for evaluating the effectiveness of the training and other actions taken:

- Certificate of completion
- Operator certification
- Monitoring of product, process, and system results

Management personnel communicate to all employees the relevance and importance of their activities and how they contribute to the achievement of the quality management system objectives. Records of training are maintained as described in section 4.2.4 of this manual.

6.3 **Infrastructure**

Management personnel determine infrastructure needs for new or existing products or processes informally (single need items) or formally (new projects) during quality planning as described in section 5.4.2 of this manual. Considerations include the building, workspace, and facilities associated with the building or workspace, equipment, hardware, software, and support services. When all needs have been identified, they will be considered for approval and implementation. Equipment maintenance will be performed as planned. Records of equipment maintenance are maintained as described in section 4.2.4 of this manual.

6.4 **Work Environment**

Management personnel ensure that all employees maintain a safe and clean work environment for achieving product requirements.
7 PRODUCT REALIZATION

7.1 Planning of Product Realization

As Baity Screw Machine Products prepares for new products or processes, the following is determined, as necessary:

- Specific quality objectives as described in section 5.4.1 of this manual
- Product requirements as described in section 7.2.1 of this manual
- Process, verification, validation, monitoring, inspection/test, and product acceptance criteria as described in section 5.4.2 and 7.5.2 of this manual
- Documentation requirements as described in section 4.2 of this manual
- Infrastructure requirements as described in section 6.3 of this manual
- Training requirements as described in section 6.2 of this manual
- Resource requirements as described in section 6.1 of this manual

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

In an effort to thoroughly identify all customer requirements, the following are considered by management as they communicate with the customer and as the product development takes place:

- Product specifications provided by the customer
- Product performance requirements provided by the customer
- Customer stated availability requirements
- Customer stated delivery requirements
- Customer stated support needs
- Determination of application related requirements provided by the customer
- Determination of relevant legal requirements if any
- Determination of relevant environmental requirements if any
- Determination of any other relevant requirements
7.2.2 **Review of Requirements Related to the Product**

Upon receipt of a customer order or quote, the President and/or Sales Manager review all identified customer product requirements prior to acceptance of new business using the Product Requirement Review form. The completed document ensures that product requirements are defined, order requirements are clearly understood, and that Baity Screw Machine Products has the ability to meet all of the defined order requirements. If the customer does not specify order requirements, the President and/or Sales Manager will ensure that order requirements are understood and documented prior to acceptance of the customer order. Where order requirements are changed, the President and/or Sales Manager will update the review form to reflect the changes and will communicate all necessary changes to the appropriate employees. Records of product requirement review are maintained as described in section 4.2.4 of this manual.

7.2.3 **Customer Communication**

Communication activities regarding product information, inquiries, contracts, and order handling, including changes to such are established and implemented as described in section 7.2.2 of this manual. Customer feedback, including customer complaints, regardless of how it is received, is reviewed and appropriate actions are taken as described in section 8.2.1 of this manual.
7.4 Purchasing

7.4.1 Purchasing Process

Purchasing product or service is performed as follows:

Suppliers that do not meet management expectations are removed from the Approved Supplier Log. The President, Sales, Production, Quality Assurance, and Warehouse Managers all have the authority to add or remove suppliers from the
Approved Supplier Log. The application of the above process is dependent upon the impact of the purchased product or service on subsequent product realization or final product.

All suppliers that have supplied Baity Screw Machine Products with products or services prior to the original release date of this manual are grandfathered onto the Approved Supplier Log. Records of supplier evaluations are maintained as described in section 4.2.4 of this manual.

7.4.2 Purchasing Information
Purchase documents will contain the following information, as applicable:

- Supplier name
- Identification of product or service ordered
- Quantity ordered
- Price
- Delivery date
- Requirements that product or service must meet

All purchasing documents are reviewed for adequacy and approved prior to their release to a supplier. The President, Sales, Production, Quality Assurance, and Warehouse Managers all have the authority to create, review and approve purchasing documents. Records of purchasing documents are maintained as described in section 4.2.4 of this manual.

7.4.3 Verification of Purchased Product
The Sales Manager ensures that purchased product and service conforms to purchase requirements. Receiving inspections and/or tests are performed to determine whether purchased product or service met the purchasing requirements. Results are recorded on the Purchase Order. Product that does not meet the purchase order requirements is controlled as described in section 8.3 of this
manual. Records of receiving inspections and/or tests are maintained as described in section 4.2.4 of this manual.

When Baity Screw Machine Products stipulates in any contract that purchased product or service is subject to source inspection by Baity Screw Machine Products or their customer at the supplier’s premises, the details for such an inspection and subsequent release of accepted material will be stated in the purchasing document.

7.5 Production Provision

7.5.1 Control of Production

The control of production activities is assured by:

- Providing process control plans or process work orders and drawings for product
- Providing necessary training to personnel
- Use of suitable maintained equipment
- Use of calibrated measuring devices
- Performing necessary inspection and/or test activities
- Control of nonconforming product
- Performing effective release, delivery and post-delivery activities

7.5.2 Validation of Processes for Production

Processes, whose outcomes are not verifiable at reasonable cost, are validated to ensure that requirements are met. This also applies to processes used for products that may experience premature failure. The validation includes, as necessary:

- Process approval realized through validation of first piece(s), measurement of product characteristics, destructive testing, reliability and qualification testing, and measurement of process parameters
- Conducting PPAP, FMEA, MSA, and SPC activities when required by the customer
- Equipment and equipment set-up approval through first piece approval, calibration and maintenance
- Employee training and/or certification
- Required documentation
- Re-validation of process as necessary

Records of process validation are maintained as described in section 4.2.4 of this manual.

7.5.3 Identification and Traceability

In order to prevent the misuse or misapplication and to maintain identity of purchased material, work-in-process, and completed product, the following methods are applied:

- Received products are identified by part number and/or product description. Product that is nonconforming is identified with a Reject Tag attached to the product or product container. Scraped product is placed in an identified scrap container. The processing status of the product is reflected within the purchasing documents. Traceability, if required, is attached to the product or product container.

- Product located within the production processes is identified by part number and/or product description. Product that is nonconforming is identified with a Reject Tag attached to the product or product container. Product that is scrap is placed in an identified scrap container. The processing status of the product is reflected within the Product Inspection form. Traceability, if required, is recorded within the processing documents.

- Product awaiting shipment to a customer is identified by part number and/or product description. Product that is nonconforming is identified with a Reject Tag attached to the product or product container. Scraped product is placed in an identified scrap container. The processing status of the product is reflected within the Product Inspection form. Traceability, if required, is established by assigning the Customer Purchase Order number to the product container.
7.5.4 Customer Property
The Sales Manager ensures that customer property is, as necessary, identified, inspected and/or tested, calibrated, protected, maintained and not damaged or lost. Customer property is inspected and/or tested upon receipt. Results of the inspection and/or test are recorded within the customer supplied documentation. If customer product is found to be unsuitable for use, it will be controlled as described in section 8.3 of this manual and the customer will be notified of such by the Sales Manager. Records of inspections and/or tests and customer notification are maintained as described in section 4.2.4 of this manual.

7.5.5 Preservation of Product
Product preservation is ensured through product identification, handling of product, packaging as instructed by the customer, storing product in an acceptable environment, and protecting product from damage using suitable containers and materials.

7.6 Control of Monitoring and Measuring Devices
Once product measurements are identified, the process of identifying the monitoring and measurement devices required to make effective measurements starts. Use of a monitoring and measurement device within the measurement process requires that there be sufficient confidence that the error of the measurement process (device, documentation and operator) will not alter the measurement to be made. Baity Screw Machine Products accommodates this need by selecting monitoring and measurement devices that meet or exceed measurement tolerances.

To ensure measurement capability consistency, Baity Screw Machine Products requires that monitoring and measurement devices are:
- Identified
- Calibrated periodically to NIST traceable standards
- Measurement System Analysis performed when required by the customer
• Safeguarded against inappropriate adjustment
• Handled, maintained, and stored properly

In the event that calibration reveals that measurement capability has been lost, corrective action will be taken as described in section 8.5.2 of this manual on the device, and any product affected by the device, as deemed necessary. The Quality Assurance Manager is responsible for the control of monitoring and measurement devices. Records of calibration are maintained as described in section 4.2.4 of this manual.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General
Measurement, monitoring, analysis, and improvement to demonstrate the conformity of the product is described in section 8.2.4 of this manual. Measurement, monitoring, analysis, and improvement to ensure the conformity of the quality management system and to continually improve its effectiveness are described throughout section 8 of this manual.

8.2 Monitoring and Measuring
8.2.1 Customer Satisfaction
The Sales Manager requests customer feedback through the use of the Customer Survey form. All customer feedback is reviewed and appropriate actions are taken, as necessary. If formal action is necessary, corrective and/or preventive action will be taken as described in section 8.5.2 and/or 8.5.3 of this manual. All actions taken will be communicated to the customer. Records of customer surveys are maintained as described in section 4.2.4 of this manual.
8.2.2 Internal Audit

Internal audits are performed as follows:

The Quality Assurance Manager is responsible for all internal audit activities and has the authority to approve or deny all necessary changes. Annually, all processes within the quality management system will have an internal audit performed on them. Selected processes may be audited more frequently due to
their impact on the system or due to their status as derived from audit history. Schedule adjustments are made as deemed necessary.

The audit scope is determined by identifying the process to be audited and defining the system requirement that will be verified for effectiveness within the identified process.

Internal auditors are selected based upon their independence of the process that is to audited. Auditors will not audit their own work. Internal and external auditors are considered qualified to perform audits if they have had auditor training. Records of internal audits are maintained as described in section 4.2.4 of this manual.

8.2.3 Monitoring and Measurement of Processes

Baity Screw Machine Products applies suitable methods for monitoring, and where applicable, measurement of quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, product is controlled as described in section 8.3 of this manual. Informal correction and/or formal corrective action, as appropriate, are performed to ensure conformity of the product. Processes are further measured through the internal audit process and as required by the customer as described in section 7.5.2 of this manual. Records of process measurements are maintained as described in section 4.2.4 of this manual.

8.2.4 Monitoring and Measurement of Product

In order to assure conformity to customer requirements as described in section 7.1 of this manual, process control plans or process work orders as well as other relevant documents contain the monitoring and measurement processes that are applied to the characteristics of each product or service at the appropriate levels of realization.
Measurements taken as well as the initials of the inspector are recorded on the Product Inspection form. Product that conforms to requirements is forwarded to the next relevant processing activity. If the product does not meet customer requirements it is controlled as described in section 8.3 of this manual.

Forwarding of product to the next relevant processing activity or delivery to the customer does not occur until all customer requirements are met unless approved by the customer. Records of product inspections and/or tests are maintained as described in section 4.2.4 of this manual.

8.3 Control of Nonconforming Product

All Baity Screw Machine Products employees share the responsibility for detecting and identifying nonconforming product. The Quality Assurance Manager is responsible for determining and approving the disposition of nonconforming product. In his absence, the Warehouse Manager has this responsibility and authority.

Reworked product is re-inspected and/or tested and must meet the original requirements and intended function in accordance with customer needs. Results of such inspection and/or test are recorded on the Nonconforming Material form. The Sales Manager is responsible for obtaining customer concessions.

Discovery of nonconforming product after delivery is immediately followed by formal corrective action by the Quality Assurance Manager as described in section 8.5.2 of this manual. The Sales Manager is responsible for contacting the affected customer immediately upon detection of this circumstance and determining and coordinating a suitable method for containment and/or recall of affected product. Records of nonconforming product and actions taken are maintained as described in section 4.2.4 of this manual.
Control of nonconforming product is performed as follows:

Start

Identify nonconforming product as described in section 7.5.3 of this manual. Record product information on the Nonconforming Material form.

Determine cause of nonconformance.

Formal action necessary?

Yes

Contact Q.A. Manager. Perform corrective/preventive action as described in section 8.5.2/8.5.3 of this manual.

No

Perform informal correction and inspect and/or test as necessary.

Product meet requirements?

No

Disposition methods include:
1. Scrap product
2. Rework product
3. Use as is (customer concession required)
4. Return product to supplier
5. Regrade product

Yes

Contact Q.A. Manager for determination and approval of disposition of nonconforming product.

Record and approve disposition information on the Nonconforming Material form.

End
8.4 Analysis of Data

Baity Screw Machine Products collects data through quality management system documentation. The collected data is analyzed by the Quality Assurance Manager and used to determine the suitability, effectiveness and opportunities for improvement of the quality management system. The data analysis objectives for Baity Screw Machine Products are:

- Assess customer satisfaction levels and fulfillment of customer needs
- Assess trends associated with products and processes
- Assess the performance of suppliers

8.5 Improvement

8.5.1 Continual Improvement

At Baity Screw Machine Products, the process for continual improvement is:

- A part of the quality policy
- Reflected in the quality objectives
- A part of the actions taken upon audit results
- Driven by opportunities surfacing from data analysis
- A result of corrective and preventive action
- An output from management review

8.5.2 Corrective Action

Baity Screw Machine Products takes actions to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. The management of Baity Screw Machine Products determines when formal corrective action is necessary. The Quality Assurance Manager is responsible for maintaining the corrective and preventive action process. The management of Baity Screw Machine Products is responsible for ensuring that corrective and preventive actions are performed in an effective and expeditious manner.
Corrective and Preventive action is performed as follows:

**Start**

Identify and review problem. If deemed necessary, record actual or potential problem on a Corrective or Preventive Action Request form (CAR/PAR form).

**Record CAR/PAR Log**

Information on log. Review and issue CAR or PAR form to recipient.

**Internal recipient?**

- **No**
  - Await receipt of completed CAR or PAR form from external recipient.

- **Yes**
  - Determine actual or potential cause(s) of problem. Record on CAR or PAR form.

  **Determine solution(s) to eliminate actual or potential cause(s). Implement solution(s) and record solution(s) implemented on CAR or PAR form.**

  **Perform follow-up audit to ensure that solution(s) implemented eliminated actual or potential cause(s). Record results on CAR or PAR form.**

  **Problem eliminated?**

  - **No**
    - Review results with recipient and re-issue CAR or PAR form.

  - **Yes**
    - **Record CAR or PAR status as closed on CAR/PAR log. File CAR or PAR record.**

**End**
Corrective and Preventive action may result from information derived from customer feedback (includes complaints, needs, and expectations), internal audit, external audit, process and/or product inspection and/or test, outputs from management review meeting, outputs from data analysis, FMEA, PPAP, MSA, SPC, and supplier evaluation. Records of corrective and preventive action are maintained as described in section 4.2.4 of this manual.

8.5.3 Preventive Action
Baity Screw Machine Products determines action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of potential problems as determined by the management of Baity Screw Machine Products. Preventive action is performed as described in section 8.5.2 of this manual.