



# NEWT/NETT Quality MANUAL

ISO 9001:2015 / ISO 13485:2016

## **New England Wire Technologies Corp**

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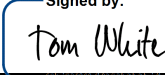
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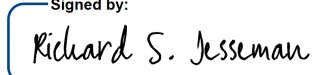
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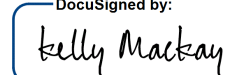
## Authorizations

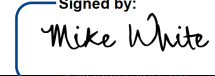
**Effective Date:** September 11, 2026

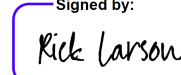
The following Senior Managers have reviewed the quality manual and approve it for adequacy:

Authorizer:  Signed by: Thomas White, President Date: 9/11/2026

Agree:  Signed by: Richard Jesseman, Executive Vice President Date: 9/16/2026

Agree:  DocuSigned by: Kelly Mackay, Sales and Marketing Director Date: 9/16/2026

Agree:  Signed by: Michael White, Vice President of Operations Date: 9/16/2026

Agree:  Signed by: Richard Larson, Research & Development Director Date: 9/17/2026

The Quality Manager has reviewed the quality manual and approves it for adequacy.

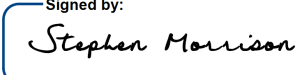
Originator:  Signed by: Stephen Morrison, Quality Manager / Management Representative Date: 9/11/2026

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## Amendments:

|            |           |                                                                                                                                                                                                                     |
|------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | Issue 1-3 | Obsolete                                                                                                                                                                                                            |
| 02/19/2016 | Issue 4   | Amended Section 3 with the new wording for the Mission Statement. Amended Section 4.2 and 4.3 wording because of the format change in the Mission Statement. The goals are no longer listed with separate sections. |
| 01/15/2017 | Issue 5   | Amended to address ISO9001:2015                                                                                                                                                                                     |
| 02/05/2018 | Issue 6   | Amended to address the name change from New England Catheter Corporation to New England Tubing Technologies Corp. (Section 1.1.2) and incidences of initials throughout.                                            |
| 03/05/2021 | Issue 7   | Amended 1.2 Scope to include medical tubing and sections 2 Quality Policy and 4.8 Quality Policy Posting to include the phrase "customer requirements".                                                             |
| 06/07/2024 | Issue 8   | Added 4.3 Climate Control Assessment to 4.3.6. This includes the General Policy on Climate Change 4.3.3; This caused renumbering of the subsection 4.                                                               |
| 11/11/2025 | Issue 9   | Amended to incorporate ISO13485:2016                                                                                                                                                                                |
| 12/09/2025 | Issue 10  | Added 2.2 – Reporting to Regulatory Authorities & 5.1 – Internal & External Issues and other formatting Corrections                                                                                                 |
| 12/29/2025 | Issue 11  | Revised quality policy and clarified its communication & added references to documented procedures                                                                                                                  |
| 05/26/2026 | Issue 12  | Updated scope to match ISO cert, added design exclusions & updated production Process Details                                                                                                                       |
| 07/01/2026 | Issue 13  | Changed 1.4 from exceptions to non-applicable & updated Matrix, added 1.5.1 & 2.1, updated 2.2 as a result of stage 2 ISO13485 audit                                                                                |
| 09/11/2026 | Issue 14  | Added Section 5 Changes to QMS Processes                                                                                                                                                                            |

## New England Wire Technologies Corp (NEWT) Overview

Founded in 1898 New England Wire quickly became a key contributor to the growth in the infant telephone industry. At that time, it was hard to get quality insulated wire needed for use in the telephone's construction. New England Wire solved the supply and quality problems by producing insulated wire on newly invented machines. We have continued serving our customers with innovative technology ever since.

As commercial demand for wire of all types grew, the company expanded its capabilities to include braiding, stranding, drawing and plastic extrusion, producing copper and copper alloy-based wire with unique characteristics manufactured to exacting specifications. Decades of research, testing, and development combined with a continuing commitment to expand and improve upon our manufacturing processes, have positioned us as the leader for the custom manufacturing of specialty wire and cable. Today, the company enjoys the dedicated loyalty of a workforce of technicians, craftsmen and support personnel working in modern manufacturing facilities encompassing over 385,000 square feet at Lisbon and 80,000 square feet at Littleton.

### Quality Manual Prologue

#### **The Quality Manual is a Customer Satisfaction Manual**

The NEWT/NETT quality system is established for the purpose of satisfying customers. We depend upon our customers being satisfied for our success. This Quality Manual is created to organize NEWT/NETT's processes and resources, using the documented procedures listed in Master Procedure Log (Log14), to meet customer requirements and to achieve customer satisfaction. The Quality Management System is comprised of documented information containing SOPs, Work Instructions, Forms, Lists, and Charts.

#### **Customer Focus**

Since the quality system is established to satisfy customers, it is important to have an understanding of customers. All companies exist because of the demand for their products. Demand is derived from the customer's use of the product not the supplier's offering of the product. Customers have a need to be competitive and they expect suppliers to aid them in being competitive. Customers have many choices of products. They demand value and support suppliers who provide value in product innovation, product quality, delivery, and customer support services. The NEWT/NETT quality system must accept the role of the customer and focus on the customer in order to achieve customer satisfaction.

# **1. Scope**

## **1.1. Introduction**

### **1.1.1. NEWT**

This Quality Manual is issued and controlled by New England Wire Technologies Corp (NEWT) located in Lisbon, New Hampshire with a manufacturing location in Littleton, NH. This manual describes the NEWT Quality System. It provides the authorization and control of related activities and the associated documentation.

### **1.1.2. NETT**

At the same Lisbon, NH location is the NEWT subsidiary New England Tubing Technologies Corp. (NETT). NETT is listed on the Certificate as a manufacturing location. This Quality Manual applies to NETT and all references to NEWT should be construed to include NETT as well as NEWT.

## **1.2. Scope of Registration**

### **1.2.1. ISO9001:2015**

Manufacture of Wire and Cable, Medical Tubing, other Specialty Products for Medical, Automotive, Commercial and Industrial Applications.

### **1.2.2. ISO13485:2016**

Manufacture of Wire and Cable, Medical Tubing, other Specialty Products for Medical Applications

## **1.3. Responsibility**

The Quality Manual and the NEWT Quality Policy are issued under the authority of the President of New England Wire Technologies Corp. Top Management is responsible for ensuring that the Quality Management System is implemented and maintained to meet the requirements of the Quality Manual. The Management Representative will aid Top Management with ensuring that the quality system meets the requirements of ISO9001:2015 & ISO13485: 2016. NEWT documentation defines who has the responsibility for implementation of tasks to ensure conformance to the sections of the standard.

**1.4. Declared Non-Applicable**

The NEWT Quality Management System has been designed to be compliant to ISO9001:2015 & ISO13485:2016 in all aspects that apply to the organization's operations and needs. Being compliant does not detract from the ability or responsibility to provide product that fulfills customer and regulatory requirements. Listed below are the declared non-applicable between NEWT's Quality Management System and the standards.

| <b>ISO 9001 Elements</b>  | <b>Title</b>                                                                                           | <b>Justification</b>                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.3                       | Design and Development of Products and Services                                                        | NEWT's Quality Management System does not address the sub-sections of the standard within Operation dealing with "Design Responsible" for custom products                                                                                                                                                                                                                                |
| 8.5.5                     | Post-Delivery activities<br><br>C – the nature, use and intended lifetime of its products and services | NEWT's Quality Management System does not address the sub-section of the standard within Operation dealing with "service provision" in the aspects of post delivery service of product field service, such as installation, training or repair. NEWT products are of a nature that there is no field service option for our products<br><br>The intended lifetime of products is unknown |
| <b>ISO 13485 Elements</b> | <b>Title</b>                                                                                           | <b>Justification</b>                                                                                                                                                                                                                                                                                                                                                                     |
| 7.5.3                     | Installation Activities                                                                                | NEWT does not participate in installation activities.                                                                                                                                                                                                                                                                                                                                    |
| 7.5.4                     | Servicing Activities                                                                                   | NEWT does not participate in servicing activities.                                                                                                                                                                                                                                                                                                                                       |
| 7.5.5                     | Particular Requirements for Sterile Medical Devices                                                    | NEWT does not produce product in sterilized environments. Sterilization is not a customer requirement.                                                                                                                                                                                                                                                                                   |
| 7.5.7                     | Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems      | NEWT does not produce product in sterilized environments. Sterilization is not a customer requirement.                                                                                                                                                                                                                                                                                   |
| 7.3                       | Design and Development                                                                                 | NEWT does not participate in design and development activities for medical device components.                                                                                                                                                                                                                                                                                            |

## **1.5. Design Responsible Limit**

- 1.5.1. NEWT *Does Not Get Involved In “Suitability for Use”*
- 1.5.2. NEWT does not recommend or specify product or material for specific use in a customer’s product. The customer alone must decide about “suitability for use.”
- 1.5.3. NEWT does make recommendations and designs products for general applications. These general applications are characteristics of our product and in no way should anyone construe these general applications to include a suitability of use statement for a specific application, use, or end use.
- 1.5.4. For example: NEWT can recommend or design wire for a general application such as good flex life at a high temperature but would not recommend or design wire specifically for use in bringing power to a commercial pizza oven door. The customer would have to determine suitability for use of the NEWT product in the oven door application. NEWT would only provide material for customer evaluation in a specific application at the customer’s request. The decision that the wire is suitable for use in the door is the customer’s responsibility.

## **2. Medical Device File**

**2.1.** NEWT does not manufacture Medical Devices, however, we do produce and sell products to customers who manufacture Medical Devices. For this reason, NEWT maintains a product file and does not have Medical Device files.

**2.2.** The contents of NEWTC product file are as follows:

- RFQ
- Quote
- Exceptions
- Customer Specifications
- NEWT Drawings
- MES/ Quality records
- D365 Records
- Quality Orders
- Test reports
- NCR records

- Customer Complaints

### **2.3. Reporting to Regulatory Authorities**

NEWT is not registered with the U.S. FDA and, as a subcontractor manufacturing components of medical devices, is not required to submit regulatory reports to any competent authorities.

## **3. Quality Policy**

New England Wire Technologies Corp is a company striving for quality and excellence in everything we do. The first responsibility of NEWT/NETT employees is the satisfaction of our customers who buy and use our products. In order to provide total customer satisfaction, we must...

Meet Customer & applicable Regulatory requirements,

Continuously improve the quality of our products.

Deliver the highest level of service possible.

Sell our products at competitive prices.

This goal of supplying our customers with the highest quality products at competitive prices is achieved through our continuous improvement and commitment to maintain the effectiveness of the Quality Management System.

(The standards and procedures contained in this manual assist us in meeting customer requirements by providing the best quality and reliability to our customers.

## **4. Mission Statement**

The Mission Statement has been prepared, documented, and approved by the Senior Management Committee and copies have been posted throughout the facility for employee review.

### **MISSION STATEMENT**

New England Wire Technologies is committed to being the premier custom manufacturer of choice for customers in existing and emerging worldwide specialty cable markets. This is accomplished by providing exceptional service from design through manufacturing, leveraging flexible capabilities and innovative solutions. We will continuously operate on a sound financial basis, foster profitable growth, and steadily increase the value for our shareholders.

New England Wire Technologies prides itself on sustaining an organization dedicated to serving its employees and their families in a responsible manner. We will continue to ensure multi-generational stability for the greater community through the manufacture of highly specialized products serving critical technological advancements around the world.

Our customers...our employees...our products...the future!

- 5.** The organization ensures that changes to the Quality Management System (QMS) are planned, reviewed, implemented, and maintained in a controlled manner. Changes to QMS processes are evaluated for their potential impact on the effectiveness of the QMS, the safety, and compliance with applicable regulatory requirements before implementation.

**5.1.** The following procedures go into detail on Changes:

- 5.1.1. SOP405 – Document Data and Quality Records
- 5.1.2. ENG1899 – The Change Case Process
- 5.1.3. QA1963 – Equipment Validation
- 5.1.4. QA1503 – Software Validation Procedure
- 5.1.5. SOP1454 – Process Validation
- 5.1.6. ENG2108 – General Project Management
- 5.1.7. SOP2175 – Risk Management Procedure

## **6. About the Internal & External Issues, Interested Parties, Climate Control, Quality Policy, and Mission Statement**

- 6.1.** NEWT has identified the following Internal & External Issues, which are reviewed during Management Review Meetings:

**6.1.1.** Internal Issues

- Values and Culture
- Company Knowledge
- Opportunity for employee growth
- Safety

**6.1.2.** External Issues

- Economic Factors
- Labor Market
- Cyber Security threats
- Legal & Regulatory requirements
- Sustainability

- 6.2.** The Climate Change Assessment, Quality Policy and Mission Statement is directed to our interested parties:

| <b>Interested Party</b> | <b>Requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>QMS Processes</b>                                                                                                                                                                                                                                                                 | <b>Some Outputs</b>                                                                                                                                                                                                                                                                                                                   |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Customers               | <ul style="list-style-type: none"> <li>• Meet Customer Requirements</li> <li>• Continual Improvement</li> <li>• Customer Satisfaction</li> <li>• Product Quality and Reliability</li> <li>• Competitive Prices</li> <li>• Customer Service</li> <li>• World Markets</li> <li>• Leveraging flexible capabilities and innovative solutions</li> <li>• Provide highly specialized products</li> <li>• Serving critical technological advancements around the world</li> </ul> | <ul style="list-style-type: none"> <li>• Management</li> <li>• Strategic Planning</li> <li>• Sales</li> <li>• Product Planning</li> <li>• Production Planning</li> <li>• Materials</li> <li>• Production</li> <li>• Improvement and Abatement</li> <li>• Controls/Records</li> </ul> | <ul style="list-style-type: none"> <li>• Innovative designs</li> <li>• Quotes</li> <li>• Lead times</li> <li>• Custom products</li> <li>• Product availability</li> <li>• Meet customer's requirements</li> <li>• Sales orders</li> <li>• Test reports</li> <li>• COC</li> <li>• On time delivery</li> <li>• Product value</li> </ul> |
| Employees               | <ul style="list-style-type: none"> <li>• Continual Improvement</li> <li>• Operate on a sound financial basis</li> <li>• Sustaining the organization</li> <li>• Serving its employees and their families</li> <li>• Multi-generational stability</li> </ul>                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• Management</li> <li>• Controls/Records</li> <li>• Strategic Planning</li> <li>• Improvement and Abatement</li> </ul>                                                                                                                        | <ul style="list-style-type: none"> <li>• Pay Checks</li> <li>• EOP</li> <li>• Job Security</li> <li>• Training</li> <li>• Benefits</li> <li>• Opportunities for Employees and families</li> </ul>                                                                                                                                     |
| Owners                  | <ul style="list-style-type: none"> <li>• Operate on a sound financial basis</li> <li>• Sustaining the organization</li> <li>• Foster profitable growth</li> <li>• Steadily increase the value</li> </ul>                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Management</li> <li>• Controls/Records</li> <li>• Strategic Planning</li> <li>• Sales</li> </ul>                                                                                                                                            | <ul style="list-style-type: none"> <li>• Profits</li> <li>• Remain in business</li> <li>• Gain in equity</li> </ul>                                                                                                                                                                                                                   |

| <b>Interested Party</b>                     | <b>Requirements</b>                                                                                                                                                                                                                                                                                                                             | <b>QMS Processes</b>                                                                                            | <b>Some Outputs</b>                                                                                                                                                                                                         |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suppliers                                   | <ul style="list-style-type: none"> <li>• Product Quality and Reliability</li> <li>• Foster profitable growth</li> <li>• Innovative solutions</li> <li>• World Markets</li> <li>• Provide highly specialized products</li> <li>• Serving critical technological advancements around the world</li> <li>• Multi-generational stability</li> </ul> | <ul style="list-style-type: none"> <li>• Materials</li> <li>• Strategic Planning</li> </ul>                     | <ul style="list-style-type: none"> <li>• Approved Suppliers</li> <li>• Worldwide markets</li> <li>• Pay bills</li> <li>• Appreciation of innovation</li> <li>• Stability</li> </ul>                                         |
| Community                                   | <ul style="list-style-type: none"> <li>• Multi-generational stability for the greater community</li> <li>• Serving its employees and their families</li> <li>• Serving critical technological advancements around the world</li> </ul>                                                                                                          | <ul style="list-style-type: none"> <li>• Management</li> <li>• Strategic Planning</li> </ul>                    | <ul style="list-style-type: none"> <li>• Jobs for community members</li> <li>• Charitable outreach</li> <li>• Blood Drawing</li> <li>• Business Round Table</li> <li>• Support of School and Colleges</li> </ul>            |
| Schools and Colleges                        | <ul style="list-style-type: none"> <li>• Serving critical technological advancements around the world</li> <li>• Serving its employees and their families</li> </ul>                                                                                                                                                                            | <ul style="list-style-type: none"> <li>• Strategic Planning</li> </ul>                                          | <ul style="list-style-type: none"> <li>• Summer Students</li> <li>• Interns</li> <li>• Technology tours and discussions</li> <li>• Industry awareness tours for local school</li> </ul>                                     |
| Regulatory Bodies Including Law Enforcement | <ul style="list-style-type: none"> <li>• Meet Customer Requirements</li> <li>• Customer Satisfaction</li> <li>• World Markets</li> <li>• Product Quality and Reliability</li> <li>• Sustaining the organization</li> </ul>                                                                                                                      | <ul style="list-style-type: none"> <li>• Product Planning</li> <li>• Materials</li> <li>• Production</li> </ul> | <ul style="list-style-type: none"> <li>• UL</li> <li>• CSA</li> <li>• VDE</li> <li>• Export compliance</li> <li>• EHS</li> <li>• Laws for improvement of society</li> <li>• Taxes</li> <li>• Environmental/Green</li> </ul> |

**6.3.** Interested party's risks and opportunities are handled by Management Review.

#### **6.4. Assessment on Climate Change**

6.4.1. NEWT makes no assertions on climate change but is aware of the assertions being made through media and government.

6.4.2. The main area of climate change consideration are facilities, operations, and climate change mitigating products.

##### **6.4.3. General Policy on Climate Change**

NEWT general policy on climate change is that projects and activities which have a connection to reasonable assertions on climate change will be viewed as "doing good". These projects and activities will be acted upon with favor and afforded reasonable concessions such as capital appropriations with extended return on investment requirements or emphasized market desirability. Examples of capital appropriations would be energy efficiency and scrap reduction projects. Examples of emphasized market desirability would be electric vehicle cables, miniaturized cables, wind power cables, and charging station cables.

6.4.4. NEWT acts on government climate change assertions by complying with laws and regulations. We may also participate in incentive programs.

6.4.5. NEWT is using the following media assertions for the causes of climate change.

#### **Commonly Listed Causes of Climate Change from Media**

- Generating power using fossil fuels  
NEWT does not generate power. Our manufacturing buildings are older and were not designed to withstand the additional weight of solar panels. Any future buildings or additions will consider the advantages of adding solar panels and be designed with energy efficiency in mind.
- Manufacturing goods  
NEWT does manufacture goods and many of our products are related to energy efficiency, alternate power sources, and alternative transportation modes.
- Cutting down forests  
NEWT does not cut down forests. We plant trees and other vegetation on our property. NEWT does use materials which could require tree and vegetation destruction such as mining. NEWT depends upon affected countries governments to control these activities in a responsible way.
- Transportation  
NEWT uses transportation. Our employees travel to and from work, employees engage in business travel, we utilize shipping to receive materials and ship

products, and customers and regulators travel to visit. NEWT has some work at home employees, uses video conferencing to eliminate some visits or trips and uses consolidated shipping.

- Producing food

NEWT does not produce food.

- Powering buildings

NEWT does use power for its buildings. We are committed to reducing our consumption by using energy efficient lighting, heating and cooling. We also work with utility companies to limit our usage during peak demand hours. This helps NEWT economically and aids in reducing the power companies production to satisfy the standby needs to support start up surges.

- Excess consumption

NEWT addresses excess consumption through projects that reduce scrap, allow miniaturization of products, reducing packaging and efficiency improvements.

6.4.6. Interested parties and Climate Change are addressed in the management review report.

**6.5.** Senior Management has set the quality policy and recorded it in the quality manual. The quality policy stresses NEWT's understanding that satisfied customers are the key to NEWT's success. The Quality Policy contains important statements of purpose, strategic direction, and commitment. In the Quality Policy are the quality goals that provide the framework for establishing the quality objectives (Chart 3047 – Quality Objectives).

**6.6.** Senior Management has recorded three mission goals in the quality manual. These goals include economic, manufacturing/marketing, and social missions. The mission statement is dependent on the quality policy, and they are approved by the Senior Management Team. NEWT believes that only by following the quality policy and thus satisfying the needs and expectations of the customer are the mission goals obtainable.

**6.7.** The Business Plan's long term and short-term objectives are structured to support the Company's mission statement and detail the planned course of action. These quality and operational objectives contained in the Business Plan are shaped by the quality policy because of NEWT's conviction that only by satisfying the customer will the mission goals be successful.

**6.8.** NEWT ensures that the quality policy is communicated, understood, implemented, and maintained at all levels of the company: **a)** The quality policy is presented to each employee and its importance to the success of NEWT is emphasized during on-boarding. **b)** The quality policy is posted throughout the facility, as well as on the back of employee badges. **c)** Employees are trained annually, and when updates are made to the quality policy. **d)** The quality policy

and its goals, especially continuous improvement, high customer service and remaining competitive are openly discussed in the day-to-day, employee to employee, routine of doing business at NEWT.

- 6.9.** NEWT ensures that the quality policy is communicated to interested parties by posting it on our web site, <http://www.newenglandwire.com>.

The Quality Policy is also available in our Quality Manual for appropriate interested parties and as New England Wire Technologies' Quality Policy and Mission Statement, Chart 2026 and List 2097.

- 6.10.** Senior Management reviews the Quality Policy during management review for continuing suitability and will update as deemed necessary.

## **7. Organizational Interfaces**

### **7.1. Cross Functional and Multi-disciplinary approach**

NEWT uses a cross functional or multi-disciplinary approach for decision-making. This approach involves the use of meetings to seek input, posting procedures for all to review and comment on and, in general, sharing information and intentions with others while being guided by their input.

### **7.2. The Good Tenets:**

The various functions and departments at NEWT are required to follow the good tenets: (This includes working with customers, between individuals, inter-functionally, and inter-departmentally.)

#### **7.2.1. Don't work in a vacuum:**

- Seek input,
- Give notification of intent,
- Give notice of direction,
- Give notification of start

#### **7.2.2. Be friendly:**

- Cooperate with other departments, programs, and people;
- When presented with something reasonable acknowledge it and act accordingly.

#### **7.2.3. Acknowledge substantial equivalence:**

- Recognize when the presented and the expected are the same within reason.

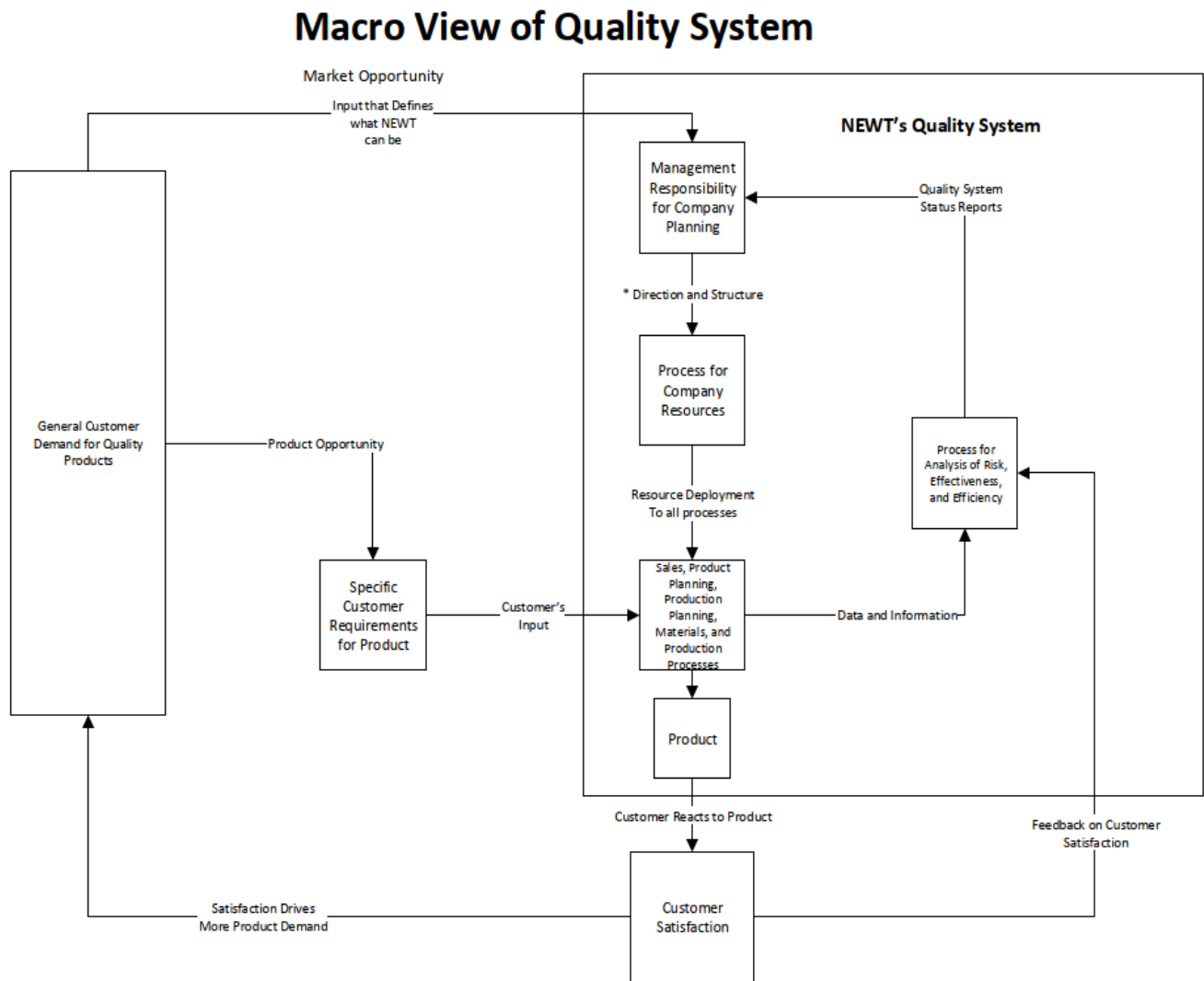
- Treat things that are substantially equivalent as an acceptable match.
- Don't get stuck in the minutia.

**7.2.4. Acknowledge that “jumping to the end” cannot be done:**

- Change requires a process;
- Transition periods are inevitable;
- While the future may be unclear in some aspects, this does not necessarily detract from the merit of the goal.
- The inertia of the previous culture, policy, or procedure must be overcome before change can make progress.

## 8. Macro View of Quality Management System

The quality system has hundreds of components to it, with many interconnections and interactions. This intricacy is needed to address the details of running an effective and efficient company. Controls are in place to make this intricacy work. While a certain level of complexity is necessary to show the micro view of the quality system, the macro view shows the fundamentals to be simple and straightforward.



\*Continuous improvement is accomplished through changes in plans by adjusting controls (training, documentation, software, and equipment) and as needed the structure of the company through the deployment of resources.

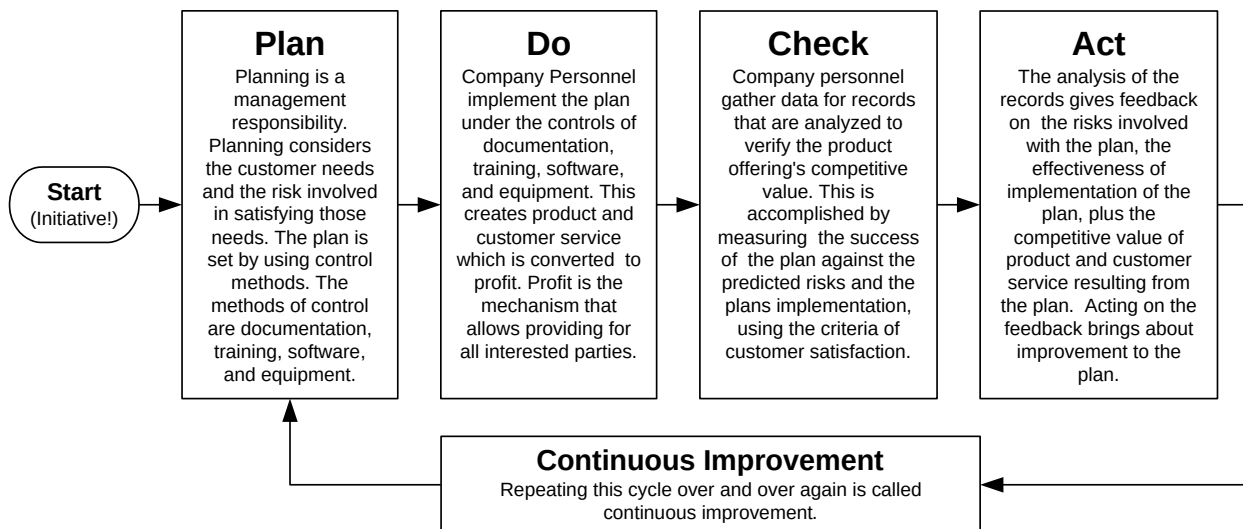
## 9. Management

Management has the responsibility to make the company successful. Management must provide the direction, commitment, resources, and structure for the company. These facets must be communicated throughout the organization and reviewed for effectiveness and efficiency while identifying, addressing, and monitoring risks.

### 9.1. Management and the Plan, Do, Check, and Act (PDCA) Cycle

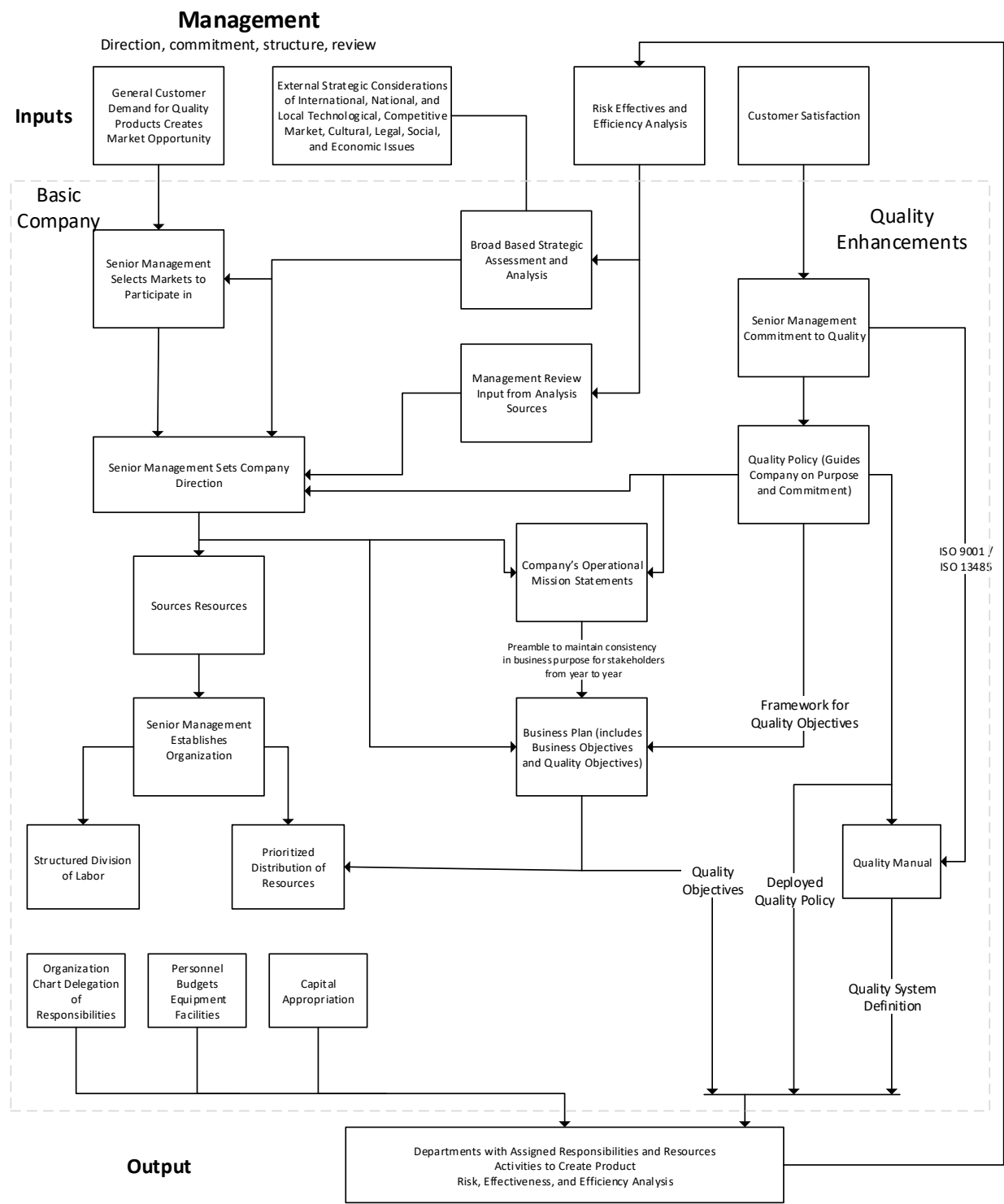
NEWT has a Senior Management team who is responsible for planning and carrying out the plan. PDCA cycles are incorporated into the plan to achieve reliably positive results through continuous improvement. Providing for continuous improvement through communication, review, and risk assessment is an important part of management responsibility.

### Continuous Improvement and the PDCA Cycle



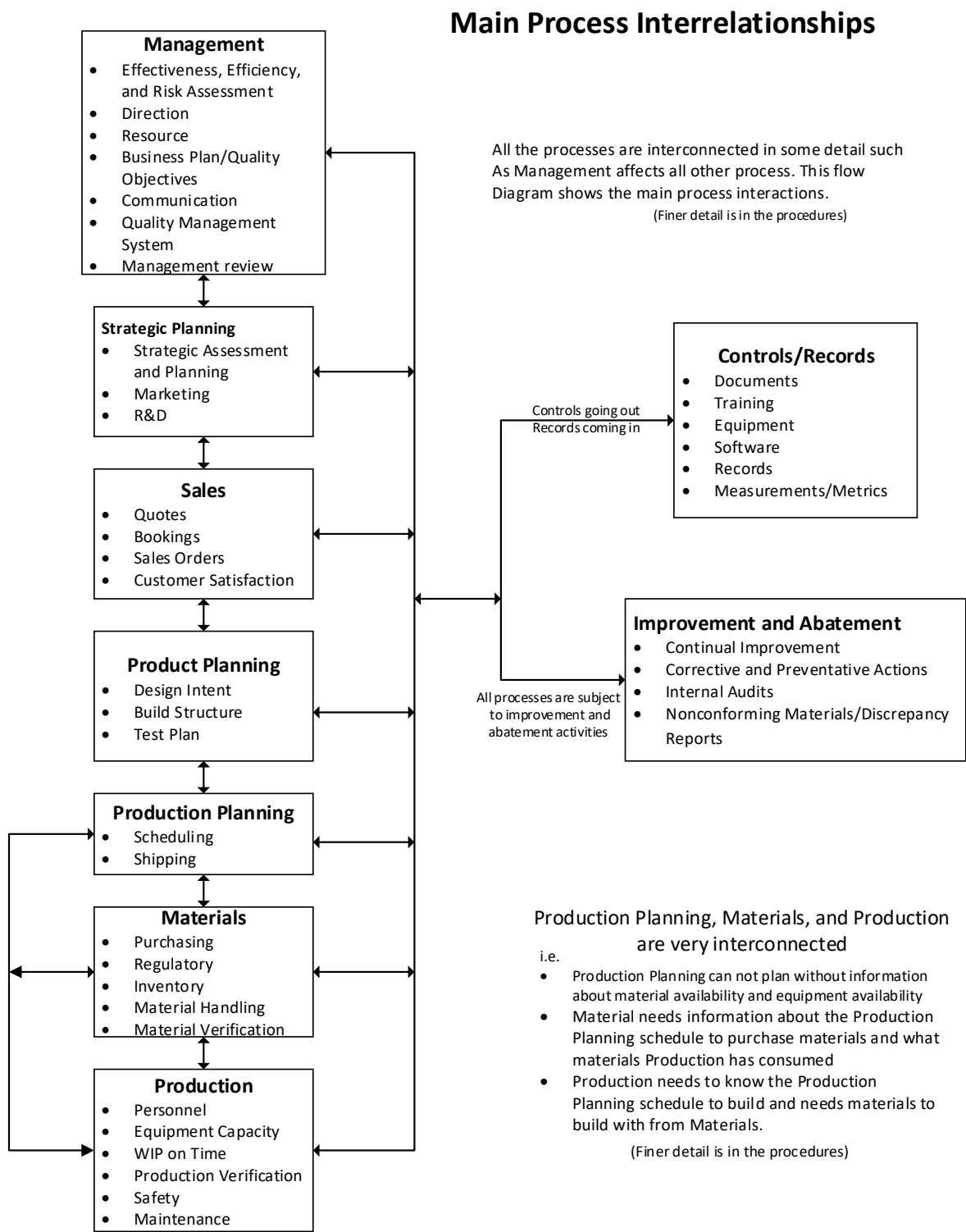
### 9.2. Quality Enhancements to Basic Company Structure

Management is responsible for the basic company structure and quality enhancements that lead to a more robust quality system and greater sustainable success.



## **10. Main Processes**

Management is responsible for establishment of the main processes and their subordinate processes that enable NEWT to conduct business using an organized approach (ISO9001 & ISO13485) to achieve intended results.



## **11. Company Resources and Controls**

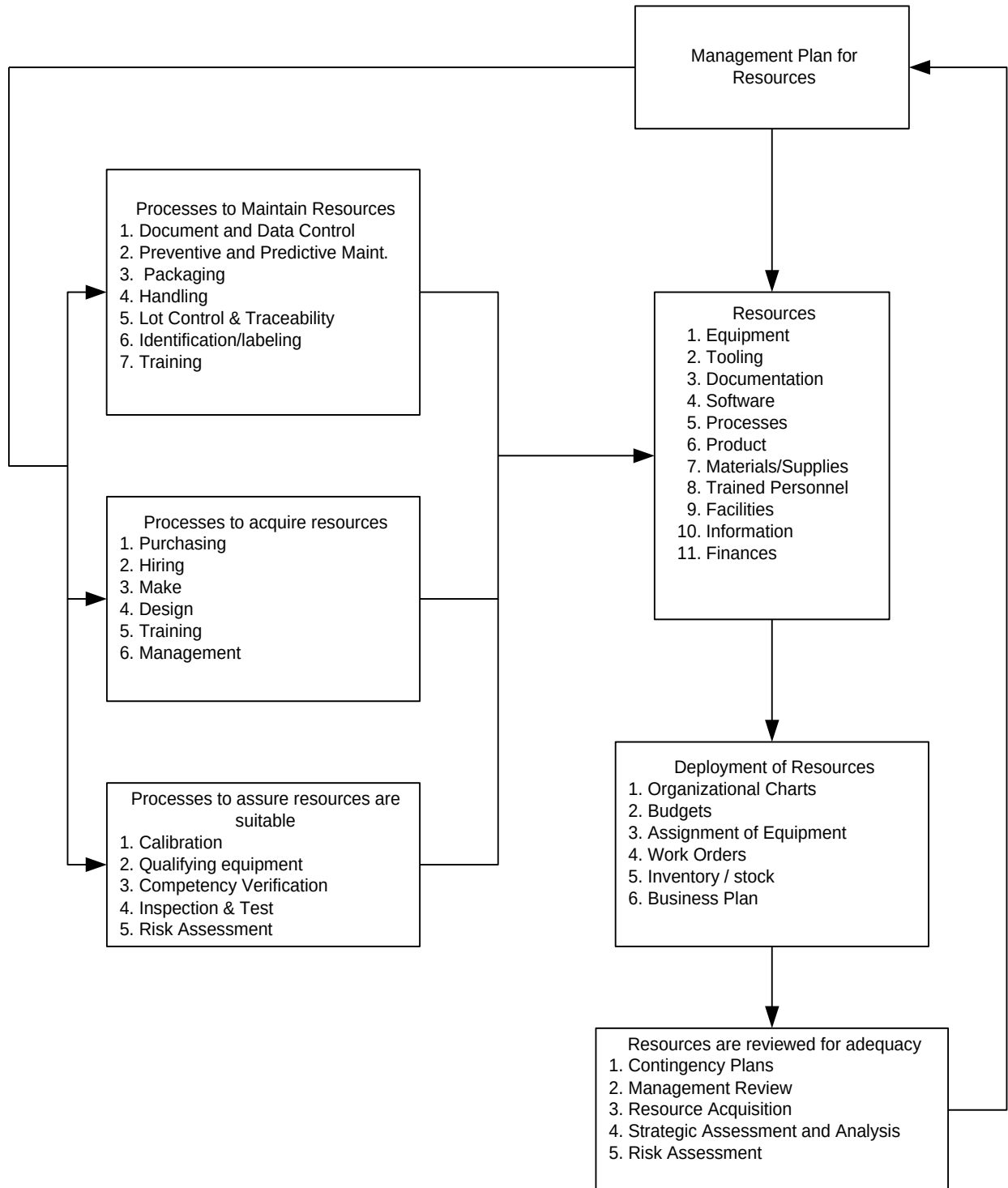
NEWT works hard to secure and maintain top quality resources. We firmly believe that trained personnel, use of technology and documented innovation keeps us competitive, and the customers satisfied.

### **11.1. Company Resource Process (Management, and Controls/Records)**

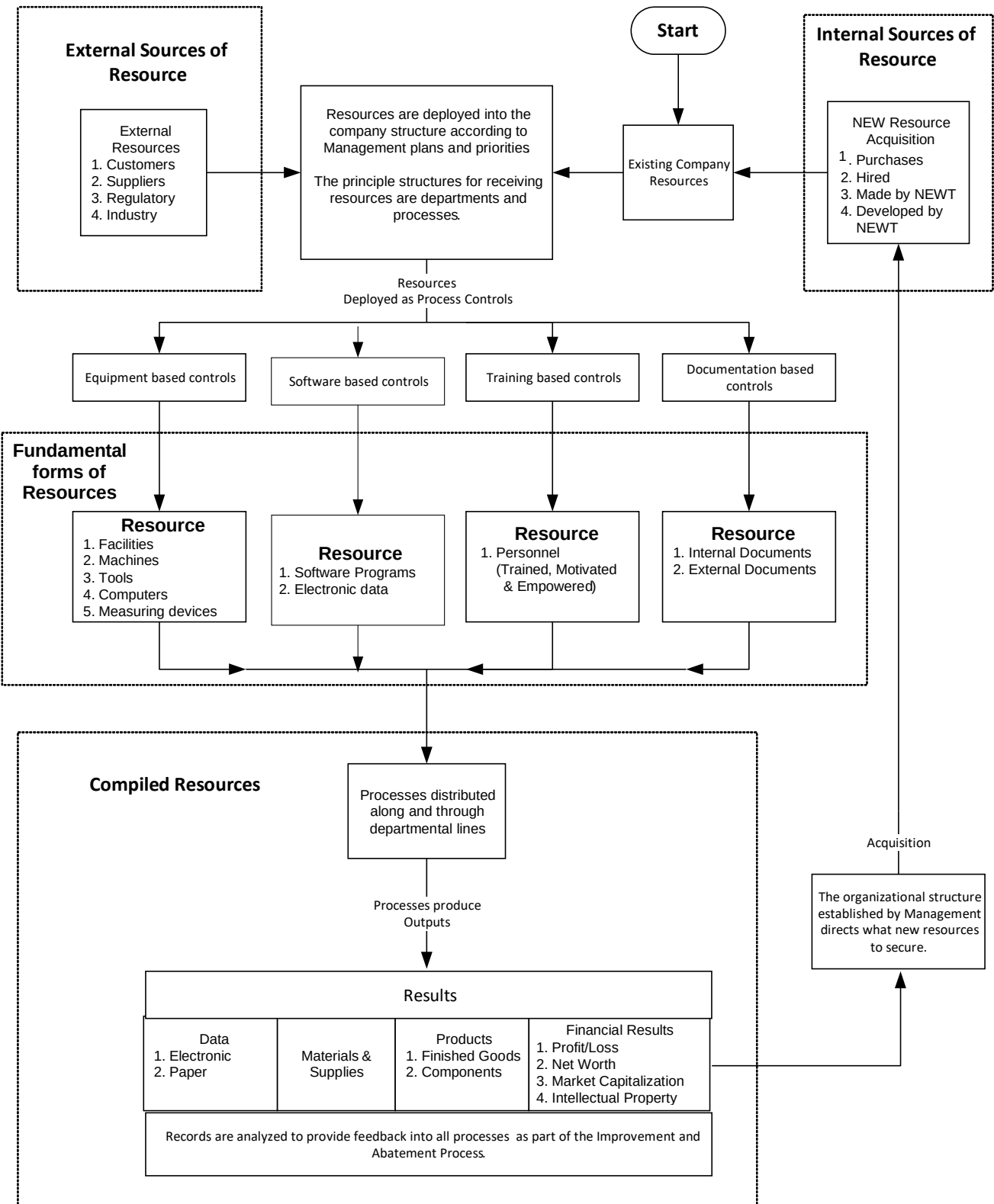
Resources must be managed with processes that provide the means to acquire, maintain, and assure resources are suitable.

Resources are deployed using process controls; Documentation based controls, Training based controls, Equipment based controls, and Software based controls.

## Support Processes for Resource Management



Company Resource Process



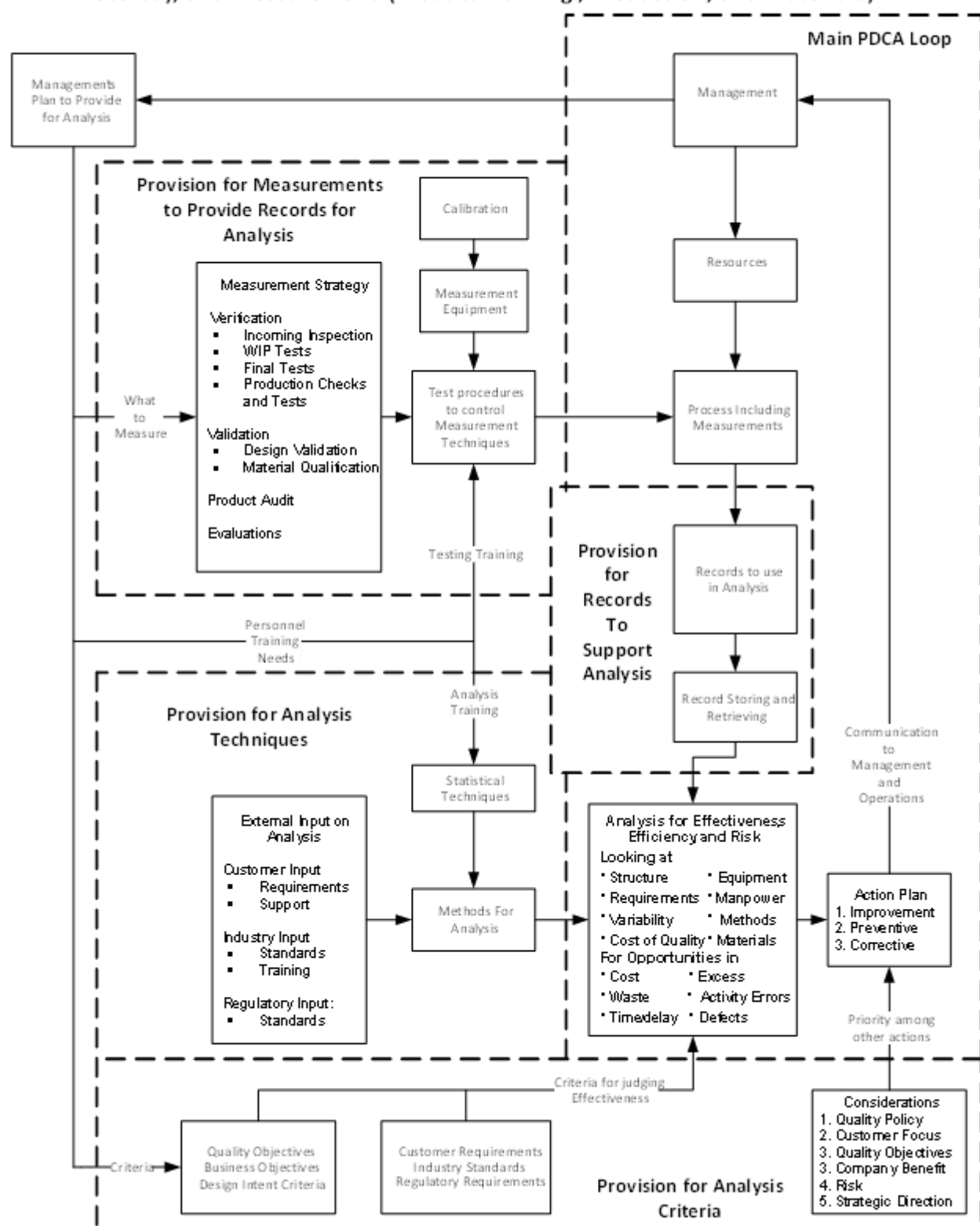
## **12. Interrelationships for Analysis (Improvement and Abatement), Records (Controls/Records), and Measurements (Product Planning, Production, and Materials)**

### **12.1. Analysis Has to Do with Customer Satisfaction**

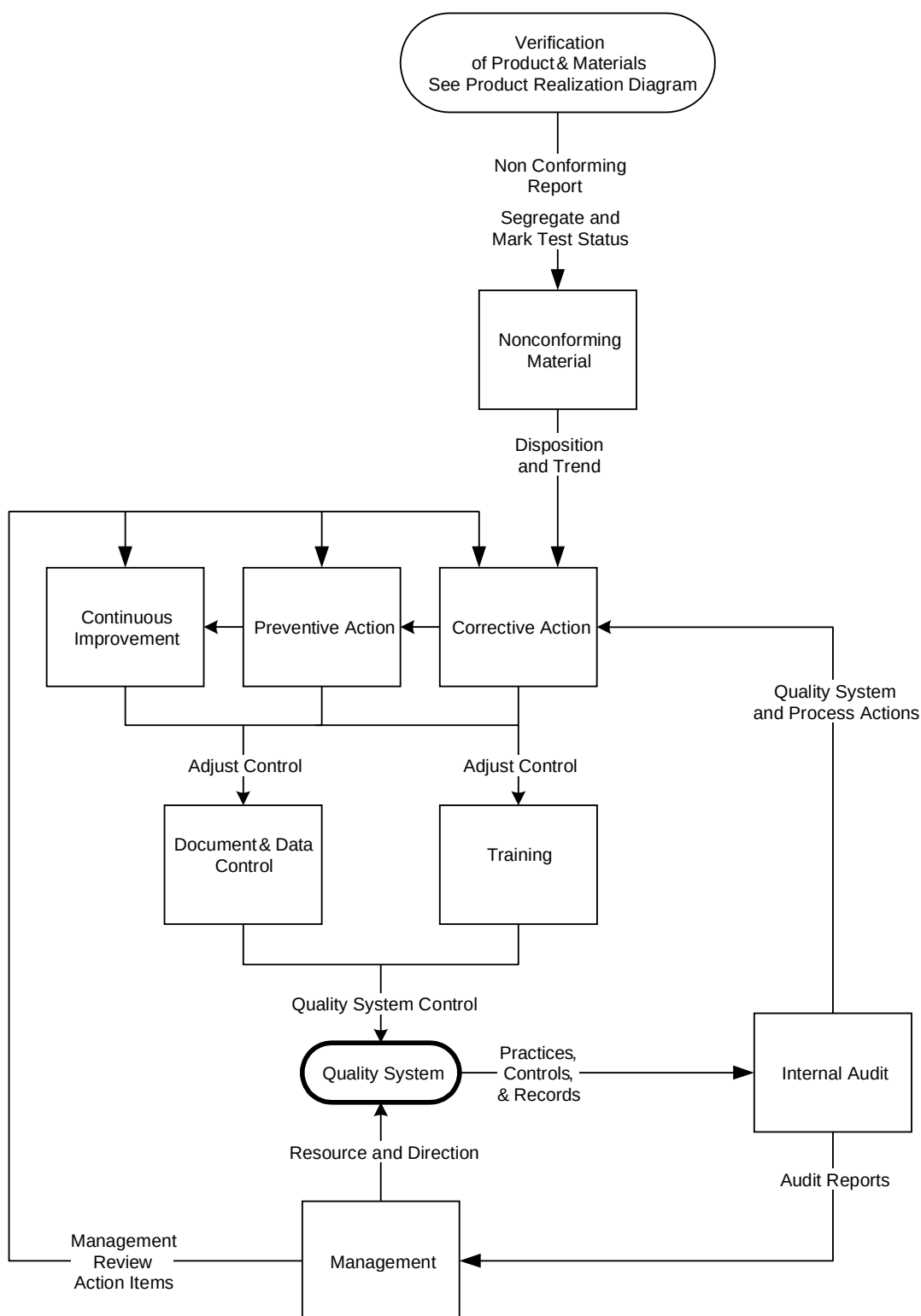
Results are important. Future results are even more important. Analysis is about verifying results and improving future results to achieve and maintain customer satisfaction. Analysis is the activity that gets this done.

Analysis cannot happen without planned arrangements and resources. Provision has to be made for analysis techniques, records, and criteria for making judgments.

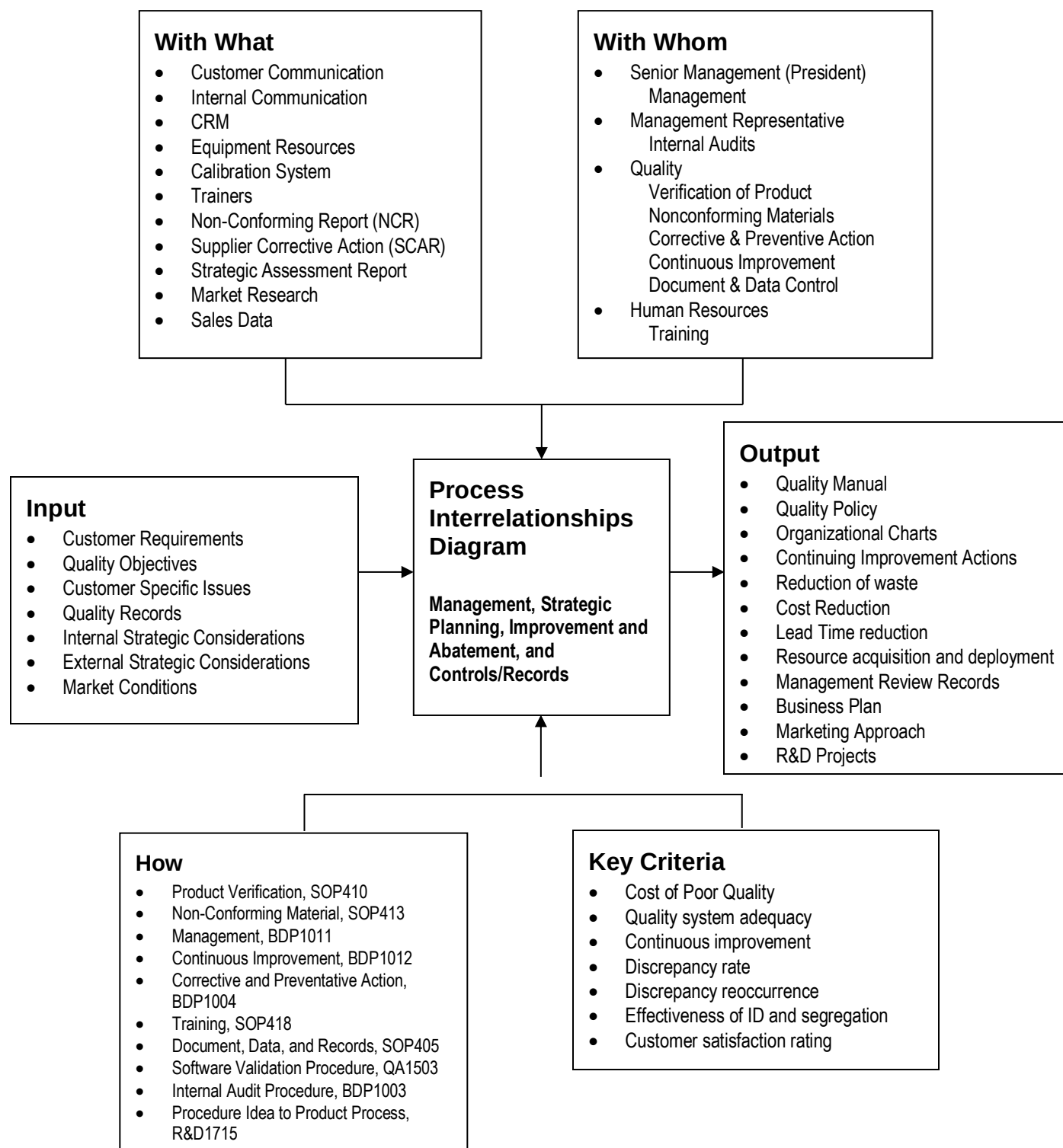
# Interrelationships for Analysis (Improvement and Abatement ), Records (Controls/ Records), and Measurement (Product Planning , Production, and Materials)



## 13. Process Interrelationship, Management and Improvement and Abatement



### 13.1. Turtle Chart, Management, Strategic Planning, Controls/Records, and Improvement and Abatement



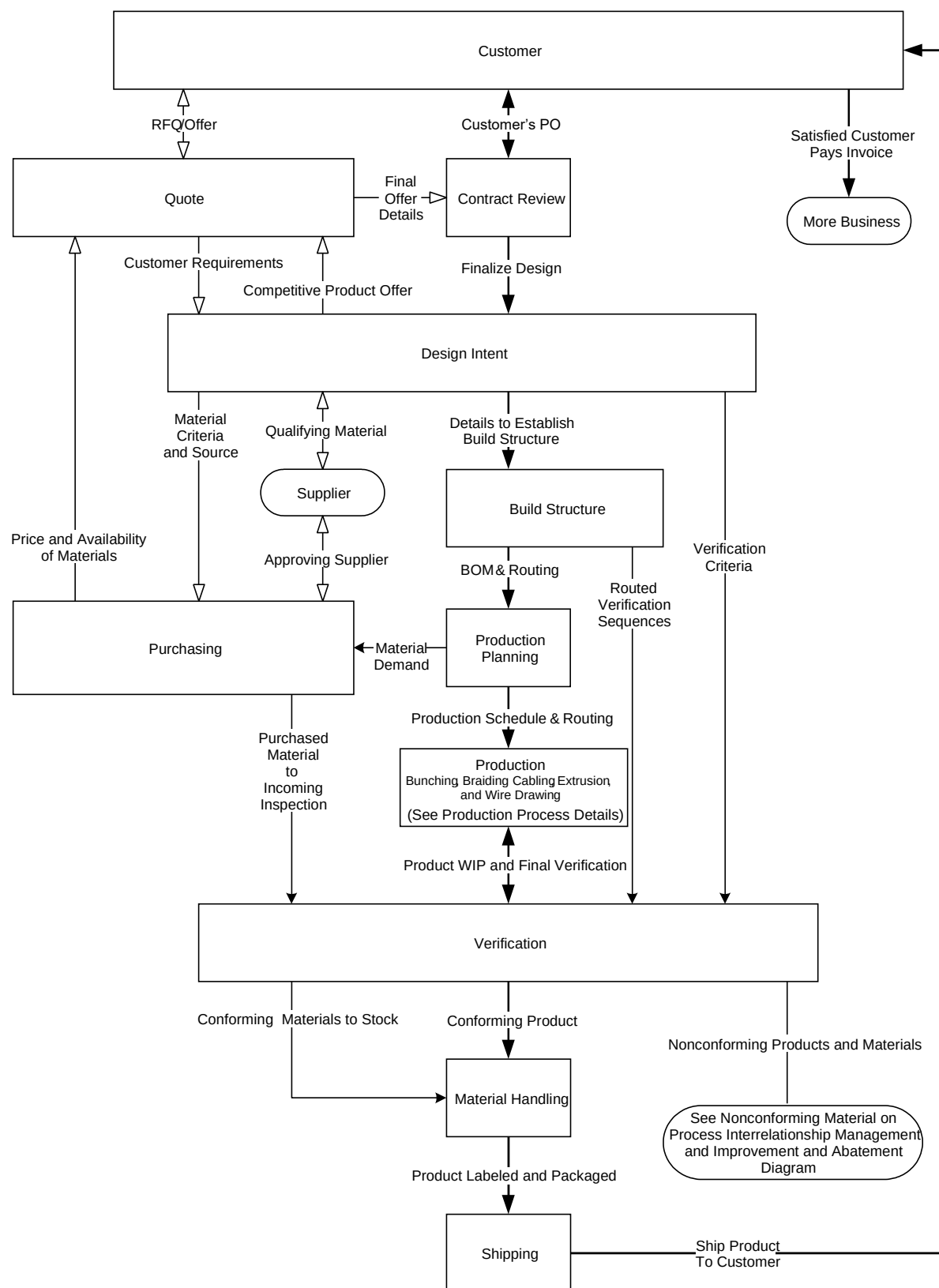
## **14. Quote to Shipping Processes: Sales, Product Planning, Production Planning, Material, and Product**

### **14.1. Interrelationship of Processes: Sales, Product Planning, Production Planning, Material, and Product**

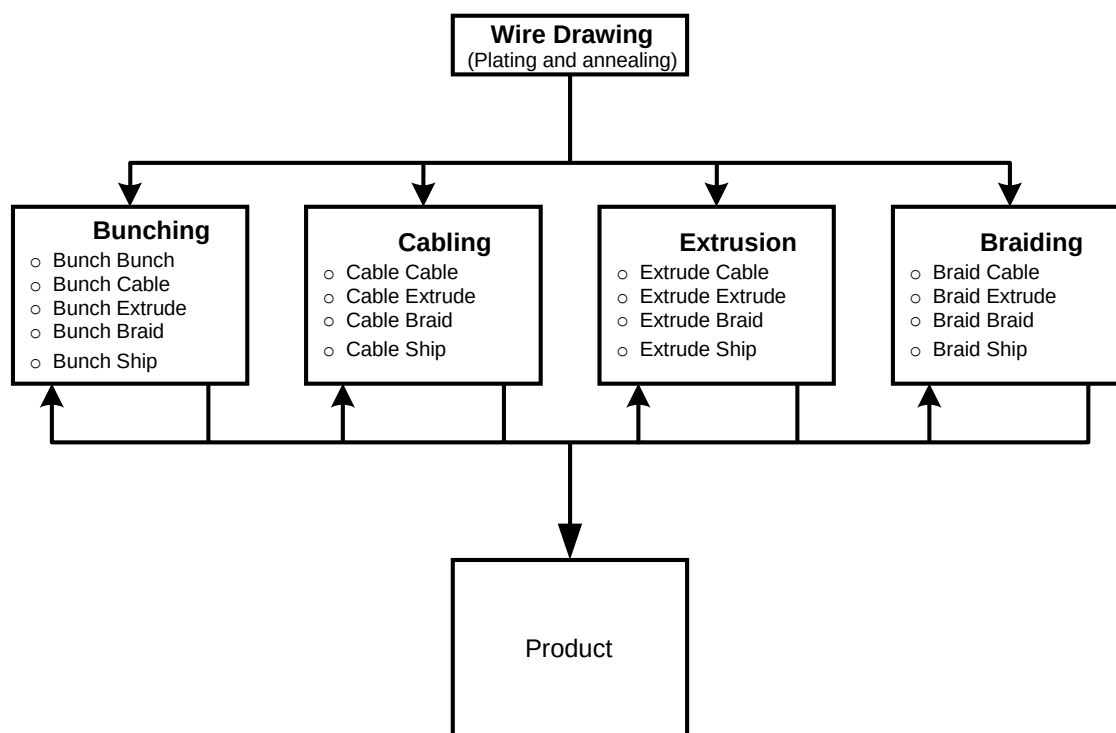
The following Interrelationship diagrams illustrate how NEWT has organized the Sales, Product Planning, Production Planning, Material, and Product processes. The processes start with the customer contact with the Sales Department and ends with the shipment of the product to the customer.

The Production Process Detail chart shows the interrelationships of the main production operation processes. Production operations are invoked by a Routing for the product and is controlled on the floor by the Routing.

### **14.2. Process Interrelationship Sales, Product Planning, Production Planning, Materials and Production**



### 14.3. Process Interrelationship, Production Process Detail



- Product is produced using the production processes controlled by the routing.
- Each sequence routes to a production process or its ancillary process.
- Product construction is such that any production process can precede or follow another process, repeating as necessary until all sequences are complete.
- A routing may call for any combination of production processes. This diagram only shows common interrelationships.

#### 14.4. Turtle Chart, Sales, Product Planning, Production Planning, Materials, and Production

