Quality Management System
Policy and Manual

“Listen Empathize Apologize Deliver”

To achieve

"Total Customer Satisfaction"

Author: Matonia “Toni” Widger, EHS Mgr.
Approver: Management Team
Information:


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Issuer: Matonia Widger, EHS and Quality Manager

Organization: OctoChem, Inc.
2090 Wagner Street
Vandalia, IL 62471

Approved by: Management Team

Mark Langston
President/CEO

Denny Grant
General Manager

Cathy Kinkead
Human Resources Manager

Matonia Widger
EHS & Quality Manager

Mark Carroll
Warehouse 2 & 3 Manager

Julie Nickel
Customer Service Manager
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CORPORATE PROFILE

OVERVIEW:
Incorporated in the State of Illinois, OctoChem, Inc. is a privately-owned, chemical sample company specializing in the storage and procurement of raw chemicals while offering intermediate consignee services. These chemicals are used for a wide variety of research and development including but not limited to industrial, cosmetic, food grade, and pharmaceutical grade products.

Founded in 1995, OctoChem, Inc. has a rich history and has been responsible for procuring and shipping samples of various raw chemicals all over the world. In order to remain successful and support the wide variety of our Customer’s requirements as well as regulations, OctoChem prides itself on its commitment to "Total Customer Satisfaction" by extensive reinvestment in experienced personnel and automated equipment. Located in the southern region of Illinois, we have a facility that is over 100,000 sq. ft., housing the necessary personnel and resources for sales, procurement, sampling, and shipping of all product lines as well as hazmat materials to help meet the growing demand of our Customers. All processes are performed under quality systems in accordance with ISO 9001, ISO 22000, NACD, CSA Z299.3, and GMP as well as all federal and international regulations outlined under the Quality Section of this profile. It is our firm belief that this extensive investment allows for control over the entire sampling process and provides for systems that can accurately, quickly and efficiently handle Customer/Customer inquiries, delivery requirements, product quality, and unique Customer requirements or requests.

To effectively service the various Customers, focused departments have been established containing dedicated customer service, inventory, logistics, and procurement personnel that are supported by the main OctoChem infrastructure. All departments comply with the rules and regulations of OctoChem, Inc.’s quality management systems.

These divisions include:

- Customer Service:
  (Customer specific trained representatives ensuring proper customer service for each Customer)
- Inventory:
  (Customer specifically trained representatives to ensure proper customer service for each Customer)
- Operations (All hazmat trained)
- Logistics:
  (Shipping/Packaging trained to handle all DOT/IATA packaging and hazard requirements)
- Shared Support:
  (Assist all areas of the business and includes HR, EHS, Finance, IT, and Acct. Coord.)
- Leadership (Lead Management)
BUSINESS CLASSIFICATION AND STATEMENTS OF COMPLIANCE:

OctoChem, Inc. complies and/or can be identified according to the following characteristics:

1) Is a small business, which currently employs approximately 60 people.
2) Is a privately owned, sampling company incorporated in the State of Illinois.
3) Is an equal opportunity employer that posts EEO notices in our facility.
4) Complies with all requirements associated with EPA regulations.
6) Has never been on the EPA List of Violating Facilities.
7) Meets all local, State and Federal environmental laws and regulations.
8) Is entirely US owned and operated.
9) Operates a drug-free workplace.
10) Has not used federally appropriated funds for the purpose of influencing any government employee.
12) Has not provided, attempted to provide, offered, solicited or accepted any kickback.
13) Is not currently and has never been debarred, suspended, proposed for debarment or declared ineligible for award of public contracts or grants by any federal agency.
14) Has not been convicted of or had a judgment rendered against it or been indicted for commission of fraud or criminal offense connected with a public contract or violation of federal or state antitrust statutes or similar criminal offenses.
15) Has never defaulted on any public contract, grant or loan.
16) Prices its products independently without agreement with any other supplier or competitor of a public solicitation.
17) Does not use in any process or manufacture any products, which contain ozone-depleting substances as identified by state requirements.
18) Is an open shop with no union affiliations.
19) Complies with all applicable OSHA, DOT, FAA, EPA, FDA, USP, CWC, DEA, TSCA, NACD Responsible Distribution, CSA Z299.3, and FIFRA regulations.
Internal Structure:
OctoChem, Inc. has implemented an integrated facility, which includes most steps from initial sale to product shipment. This continuous reinvestment into the facility and equipment provides a high degree of self-sufficiency and offers flexible sampling, fast procurement, and customization services to meet Customer/Customer needs. Following is a detailed description of OctoChem’s equipment and facilities.

Customer Service: The customer service staff has 28 full time employees dedicated to sales and customer service: approximately 15 in Domestic Sales, 5 in International Sales, and 8 additional support personnel. This combined sales force serves as an efficient vehicle for supporting existing products as well as new Customer products.

Inventory: The inventory staff consists of 8 full-time employees. Approximately 6 of the employees are dedicated to replenishment and receiving, while 2 full-time support personnel are dedicated to waste consolidation, conversions, and cycle counts. All personnel rely heavily on tools such as SAP, OctoChem’s ERP, and WM systems. In addition, OctoChem’s WMS tools allow accurate documentation and updates in real time ensuring customer service and our Customer’s have live data at all times.

Operations: Utilizing approximately 2/3 of the facility and typically operating at 50% capacity, exceptional capability exists in storage and sampling. The operational staff consists of 16 full-time employees with two shifts, totaling 14 personnel dedicated to procurement and 2 dedicated to receiving new or replenished products. Other operational capabilities include but are not limited to: dry ice handling, mixing, clean room services, and nitrogen blanketing.

Logistics: The logistics staff consists of 6 full-time personnel that are hazmat trained. Approximately 2 of the employees are dedicated to shipping samples under DOT and FAA regulations. While 4 employees are responsible for packaging all samples under DOT and FAA regulations.

Shared Support: Approximately 10 personnel are utilized for various administrative and support functions, which include human resources, EHS, account management, purchasing, accounting, and information technology.

Leadership: The Leadership team has 6 full-time management level employees who offer guidance to all departments as well as approving all new Customers and facility updates as well as changes.

Each employee’s job responsibilities and work instructions define the methods by which they support the customer needs, their direct supervisor and/or Leadership Team member supports each employee.
QUALITY:
Although OctoChem is not ISO or GMP certified, the quality assurance system is written to the International Quality Standards, ISO9001 and ISO22000 as well as current GMP standards. These standards provide a model for chemical quality assurance in customer service, inventory, and operations. Compliance with all applicable policies is mandatory for all personnel and training on this manual is required for all OctoChem employees regardless of their role. OctoChem is FDA registered and complies with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 as well as the Food Safety Modernization Act of 2011.

In addition, the facility complies with NACD and CSA Z299.3 and is a supplier to the Nuclear Power industry in accordance with applicable requirements and has implemented system requirements providing Customers with products compliant to 29 CFR, 40CFR, and 49 CFR regarding use of hazardous substances and their disposal. Furthermore, all calibration standards used within the facility are traceable, at a minimum, to NIST Standards.

FINANCIAL:
Fiscal year is January 1 to December 31. OctoChem will provide additional corporate financial, financial institution, and/or business references only in response to qualified requests on company letterhead.

Federal Taxpayer Identification Number: OctoChem, Inc. 23-2817849
Internet Address: www.octochem.com E-Mail Address: sales@octochem.com
Normal Payment Terms: Net 30
SECTION 1: INTRODUCTION
This quality process manual describes OctoChem, Inc.’s quality management system, the processes involved in the operation of our quality management system, the interaction of these processes within the system, and our established policies as they relate to applicable Quality Management System Requirements.

The interaction of processes have been defined to demonstrate how a change in one process may have an impact on another process that in the long term could result in sub-optimization within our organization. Our quality management system is focused on process management and we have identified critical core processes as well as support processes. In addition, we have determined how to monitor and measure these processes. Review of data from these measurements enables us to make informed decisions on correcting and preventing nonconformities, while providing opportunities for continual improvement of the quality management system.

SECTION 2: SCOPE
Due to the nature of our business, this Quality Policy Manual addresses our entire quality management system and the applicable requirements, ISO9001, ISO22000, NACD, CSA Z299.3, and GMP standards. Those requirements not addressed in this manual are covered in related supporting policies.

SECTION 3: DOCUMENTATION STRUCTURE OF THE QUALITY MANAGEMENT SYSTEM
The quality management system of OctoChem, Inc. is documented in the following manner and access to this documentation is made available to all employees of the facility involved in operations essential to the effective functioning of the system.

- The quality management system (QSM) policy manual is considered the top-level document of OctoChem, Inc. quality management system. The manual defines our quality policy and objectives; top management's commitment to quality and the identification of our processes and their owner’s. The manual is revised accordingly to keep it up to date with our processes as they are continually improved upon. Policy manual revisions are maintained by a document control system. Obsolete or superseded printed controlled copies of this document are retrieved and destroyed. Current uncontrolled copies are available from the Quality Assurance management representative upon request. A reference is attached to identify the supporting policies that are linked to the related processes identified in this manual. The EHS Manager controls and maintains this document.

- The quality assurance manual (QAM) policies and flow charts define the primary responsibilities within each of the documented processes. This company wide documentation supports and links the policies established in this policy manual to the documentation. The departmental procedure manuals support the quality assurance procedures and flow charts. This is required for consistently performing the execution of specific tasks on a routine basis. A document contains instructions and requirements or other means of ensuring consistent communication of information necessary for performing procedural tasks. Process owners and management, are responsible for creating, coordinating, maintaining, and improving these policies and SOP’s. Level of detail is commensurate with the complexity of the task. Control of this documentation is maintained by the Quality Assurance Manager.

SECTION 4: QUALITY POLICY STATEMENT
The OctoChem Management Team has selected the following statement to convey the OctoChem Quality Policy:

"It is the policy of OctoChem, Inc. to do whatever is necessary to realize our vision of “TOTAL CUSTOMER SATISFACTION” by incorporating the initiative of “LEAD” (Listen, Empathize, Apologize, and Deliver). We have selected the expression TOTAL CUSTOMER SATISFACTION in order to communicate this policy. Our quality management system and metrics ensure the goal and vision of “TOTAL CUSTOMER SATISFACTION” is consistently achieved.”

The Management Team is dedicated and committed to continual improvement of the corporate quality objectives identified below. Our "primal" quality objectives are:
The Management Teams conduct Management Review of the OctoChem Quality System on an annual basis or as changes are made throughout the year. These reviews include, at a minimum, policy review, primal objectives (listed above), the results of internal and external audits, Customer complaints, and feedback, process and product conformity, recommendations for improvements, corrective, and proactive actions, matters arising from previous reviews, review of calibration service, and status of personnel training. Supporting records for these criteria are available from the EHS Manager upon request. We trust that these items satisfy both our internal needs and the expectations of our Customers/Customer.

In an effort to reach our goal of TOTAL CUSTOMER SATISFACTION, if at any time, any of the requirements of the OctoChem Quality System cannot be conducted, the Management Team will determine the appropriate effective action that will best serve our Customer or Customer's needs.

All OctoChem personnel are required to understand our goal of “TOTAL CUSTOMER SATISFACTION”, to familiarize themselves with the quality documentation, and to follow the policies as well as procedures applicable to their work.

In addition to this Quality Policy for both manufacturing and service activities, the Management Team is committed to good professional practice.

SECTION 5: MISSION STATEMENT
The Management Team has published the following mission statement. The quality policy and OctoChem policies as well as this statement combine to form the basis for our company.

"To continuously improve our Customer's ability to efficiently manage their marketing efforts. We will continue to invent new services and capabilities that monitor every aspect of the sample lifecycle. By carefully listening to our Customers, we are able to enhance the Customer experience and deliver real cost saving that will positively impact the bottom line."

SECTION 6: QUALITY MANAGEMENT SYSTEM DEVELOPMENT
The approach used to develop, implement and maintain our quality management system is influenced by various factors. We have determined the needs and expectations of our Customers, interested parties, suppliers, our community, and our employees and have established a quality policy and objectives for our organization. We have identified our processes and responsibilities necessary to achieve our quality objectives. These processes have documented policies that define the process owner(s) and related responsibilities. The process owners are responsible for ensuring supporting process instructions and SOP’s are properly documented, coordinated, and maintained.

Resources necessary for each functional area are identified for review by top management. Top management dispositions the resource requirement according to the impact on the quality management system. Each Process owner is responsible for establishing methods to measure the efficiency and effectiveness of their processes and any related sub-processes. The results of these measurements are subject for review by top management during management review. The process owner is responsible for utilizing process measurements for preventing nonconformities and eliminating their causes as well as identifying root causes as well as completing a written analysis for the nonconformity or customer complaint so corrective action can be implemented. All process owners are responsible for establishing and implementing our organizational approach to continual improvement. Continual improvement is defined as recurring activity to increase our ability to fulfill requirements more efficiently.
SECTION 7: CONTINUAL IMPROVEMENT
Continual improvement activity is used to increase our ability to meet Customer requirements and our corporate objectives. Two fundamental ways continual improvement is conducted is by projects leading to revision of existing processes resulting in significant cost savings, and/or ongoing improvement activities conducted within existing processes by process owners. These improvements are usually based on the analysis of data provided by the specific process measurements.

Basic actions for continual improvement are outlined in the following steps:

- Identifying areas for improvement by reviewing process data, interviewing people performing the process and possibly benchmarking activities.
- Establishing improvement objectives and determining if the improvement provides cost savings, eliminates a production problem, enhances compliance with Customer requirements, or improves our quality management system.
- Providing possible solutions to the established objectives.
- Reviewing possible solutions to determine that the desired outcome is achievable.
- Implementing the recommended change and training employees accordingly.
- Verifying the implemented changes to determine if the improvement has achieved planned results. If not then return to the beginning of the continual improvement process.
- When the implemented changes are determined to be effective, the changes are formalized, documents updated, related processes are reviewed to determine impact, and employees are trained on the revised

Although OctoChem is continually trying to improve processes and procedures our policies rarely change as they are set forth and in place per client requirements. If a change is to be made during the course of a year they are done so with the leadership and involvement of the EHS department and Management Team as well as our clients. In regards to SOP’s, they are created with direct involvement of the client and cannot be changed per contractual agreement.

SECTION 8: QUALITY MANAGEMENT SYSTEM
OctoChem, Inc. Management has adopted a process management approach for operation and has established a Customer-oriented environment of systems and processes that are continually improved upon for effectiveness and efficiency. Policies and metrics as well as corresponding data are used to determine the satisfactory performance of our quality management system. All policies reviewed annually and updated as required by changes in processes. Each policy must be version controlled with a document number and signed by EHS as well as approved by the CEO.

SECTION 9: GENERAL REQUIREMENTS
OctoChem, Inc. has established, documented, implemented, maintains, and continually improves a quality management system that meets the requirements of ISO9001, ISO22000, NACD, CSA Z299.3, and GMP standards. This has been accomplished by identifying processes needed for the quality management system, their application, sequence, and interaction throughout the organization. Our processes have defined criteria and methods to ensure effective operation and control. Top management ensures all processes have adequate resources and information availability for supporting operations. All process metrics are analyzed to determine action plans that ensure the operations achieve planned results and identify areas for continual improvement. All identified processes are managed in accordance with the requirements of these standards.

SECTION 10: DOCUMENTATION REQUIREMENTS
Quality Management documentation includes this Quality Policy Manual which states our Quality Policy and Quality Objectives, policies, procedures, any additional Customer quality requirements, applicable statutory and/or regulatory authority requirements, additional documents needed to ensure consistent and effective planning, operation, and control of processes. All OctoChem, Inc. personnel have access to system documentation and are trained in relevant policies. Documentation is available to Customers and/or regulatory authorities through subsequent control structures.
Our Quality Policy Manual includes the scope of the Quality Management System and defines any exclusion to standards in the scope portion of this manual. All supporting policies and SOP’s are directly related to specific requirements of the governing International Standards.

OctoChem, Inc. has documented policies defining the controls over internal and external documents as well as data that relate to our Quality Management System. These controls include the review, signed approval, prompt revision and revision control, issuance, obsolescence, and availability at point of use. Signed approval includes titles/roles, printed names, and wet ink signatures by the approval panels. Documents are readily identifiable using policy numbers, legible, and retrievable with a requirement to have the date format as the mmm/dd/yyyy on all policies as well as page numbering that must be formatted as page x of y to insure clarity. Obsolete documents are suitably identified if retained for any purpose. Document revisions are coordinated as Customers and/or statutory/regulatory authorities require an update.

Record control is established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. Documented policies exist defining the controls needed for identification, storage, protection, retrieval, retention time and disposition of legible and retrievable records. Control procedures exist governing records that are created by and/or retained by suppliers when required by Customer contract. Records are available for review by customers and/or statutory/regulatory authorities per contractual requirements. All prior records are retained by the EHS department, this is considered an equivalent solution, so that obsolete versions are available to compare against upon request or during policy updating.

SECTION 11: MANAGEMENT RESPONSIBILITY
The basis of our Quality Management System is leadership, commitment, and involvement of our Management team. Management established vision, policies, and strategic objectives promotes continuous improvement and ensures the effectiveness of our Quality Management System while creating an environment that encourages involvement and development of employees.

SECTION 12: MANAGEMENT COMMITMENT
The Management Team of OctoChem, Inc. is committed to the development, implementation, and continual improvement of our Quality Management System. This commitment is provided by communicating to the organization

- The importance of meeting all Customer, statutory, and regulatory requirements
- The establishment of our quality policy and quality objectives
- Reviewing and ensuring resource requirements necessary to meet Customer and product requirements
- Conducting management reviews at defined intervals to ensure the effectiveness and efficiency of the Quality Management System.

SECTION 13: CUSTOMER FOCUS
Management ensures that all Customer requirements are determined and met with the main focus of improving Customer satisfaction. This is accomplished by identifying, understanding, and satisfying current and future needs and expectations of our Customers. These needs and expectations are communicated and translated throughout the organization into improving the processes used to realize Customer product and services. Management conducts appropriate action in the event Quality Objective performance is not achieved.

SECTION 14: QUALITY POLICY
Management has defined a Quality Policy that is appropriate to the purpose of our organization and includes a commitment to continuous improvement. The Quality Policy addresses our commitment to comply with Customer requirements and is communicated and understood throughout the organization. The Quality Policy is reviewed for continuing suitability during management review and all Department Managers are responsible for communicating how the Quality Policy applies to each employee's specific function. The Quality policy is the basis for creating our organizational Quality Objectives and each area creates goals relevant to the support of these objectives.
SECTION 15: PLANNING
Management has defined quality objectives, including those needed to meet requirements for product, which are established at relevant functions and levels within the organization. These objectives are measurable, tracked, and reviewed during our management review activities. Management plans the quality management system in order to define objectives and requirements. When system revisions are proposed or implemented to the quality management system, the advance planning ensures the integrity of the system is maintained.

SECTION 16: RESPONSIBILITY, AUTHORITY, AND COMMUNICATION
Management defines and communicates the responsibilities and authorities necessary to implement, maintain, and improve the effectiveness of the quality management system. The Management Team as well as the EHS Manager are responsible for resolving all matters pertaining to quality. These managers are:

- Denny Grant, General Manager
- Cathy Kinkead, HR, Purchasing, and Shipping/Receiving Manager
- Mark Carroll, Operations Manager
- Julie Nickel, Customer Service Manager
- Matonia Widger, EHS Manager

Irrespective of other responsibilities, these representatives have the responsibility and authority for reporting on the performance of the quality management system including ensuring required system processes are established, implemented, and maintained and any need for improvements while promoting the awareness of Customer requirements throughout the organization. Management has defined various channels of communication within the organization regarding the effectiveness of the quality management system, including but not limited to:

- Email
- Phone
- Facility Meetings
- Memos and policy updates
- Employee Scorecards
- Error reporting

SECTION 17: MANAGEMENT REVIEW
Management reviews the quality management system at planned intervals ensuring it’s continued suitability, adequacy, and overall effectiveness. This review assesses opportunities for improvement, the need for changes in the system, and the continued validity of the quality policy and established objectives. The schedule for management review activity is coordinated with the timely submission of new policies as well as metrics to facilitate the strategic planning process. Outputs of management review are communicated to appropriate personnel in the organization to flow-down to appropriate levels required to implement changes.

Input for our management review activities is generated from various sources including, but not limited to, reviewing the results of internal and external audits, Customer feedback, status of corrective and preventive actions, improvement actions, process measurements and controls, performance toward objectives, supplier performance, competitive market analysis, items or actions from previous reviews, financial effects of quality related activities, and changes that could affect the quality management system. The output from our management review activities include decisions and actions related to the improvement of the quality management system and its processes, improvements of the product related to Customer requirements, and associated resource needs.

SECTION 18: RESOURCE MANAGEMENT
Top management ensures that resources necessary for the effective implementation of our business strategy and the achievement of our quality objectives are identified and made available.
SECTION 19: PROVISION OF RESOURCES
Department Managers identify resources needed to implement, maintain, and improve the effectiveness of their processes within the quality management system and to enhance their ability to meet customer requirements. Identified resource needs are submitted to Management for their review and approval.

SECTION 20: HUMAN RESOURCES
OctoChem, Inc. ensures that training needs are identified per job description and training provided to all personnel performing activities affecting quality. This is controlled by the EHS department and deemed as a sufficient solution for training needs as the EHS department keeps all training records, training documents, and a spreadsheet of all trained employees which auto sends an email for employees falling due on recurring OSHA or EPA training. Personnel are also required to sign their name and initials for proper internal identification during the training process with EHS. The signed copies will be kept with the hard copy of the Quality Manual all times in the EHS office. Personnel are qualified based upon appropriate education, skills, training, and/or experience. Necessary competence is determined and individual training is developed. Education and training to achieve the required level of performance is conducted. The results of the training are evaluated to determine effectiveness. Employees are made aware of the relevance and importance of their assigned responsibilities and how they support the quality objectives and contribute to the success of the organization. As stated above, records of employee training, education, experience and skills are maintained by EHS.

SECTION 21: INFRASTRUCTURE
When determining, providing and maintaining the infrastructure needed to achieve product conformity consideration is given to the objective, function, performance, availability, and associated cost. Preventive Maintenance methods are in place to ensure the infrastructure continues to meet our needs. The infrastructure is evaluated during management review to determine the continued suitability to meet customer requirements.

SECTION 22: WORK ENVIRONMENT
Department Managers ensure the work environment has a positive influence on employee motivation and satisfaction. A suitable work environment considers ergonomics, workplace location, hygiene, cleanliness, temperature, humidity, lighting, protection from electrostatic discharge, creative work methods, and workplace safety. The proper work environment contributes to the organization’s ability to achieve conformity to product requirements. OctoChem maintains documented policies defining required manufacturing controls of environmental conditions for maintaining product protection, integrity and conformity during manufacturing, assembly, and logistical operations.

SECTION 23: PRODUCT REALIZATION
Management ensures the effective and efficient operations of realization and support processes, the interrelations of these processes and their impact on the ability and capacity to satisfy the requirements of all interested parties.

SECTION 24: PLANNING OF PRODUCT REALIZATION
OctoChem, Inc. plans and develops the processes needed to procure the product that meets customer requirements. Planning of product realization is consistent with the requirements of other processes in the quality management system. In planning the product realization processes, consideration is given to associated support processes, process inputs and outputs, key actions, configuration management, process measures, linked processes, and required resources. Planning also considers the quality objectives and requirements of the customer, the necessary documents/records, inspection requirements, and process verification as well as validation. The output of the planning activity is in a format suitable with our method of operation. Consistent with the OctoChem, Inc. Quality Policy, the planning activity commits subsequent customer service and application engineering resources and user manuals to support the proper operation and maintenance of all products.

SECTION 25: PROJECT MANAGEMENT
As deemed appropriate for quality management system processes of OctoChem, Inc., product realization is planned and managed in a structured and controlled manner taking into account risk, resources and identified constraints.
SECTION 26: RISK MANAGEMENT
OctoChem has established, implemented, and maintains appropriate processes for managing risk in achieving compliance to product requirements. Risk management responsibilities and corresponding criteria are identified, defined, assessed, and communicated throughout product realization. Actions taken to mitigate risks that exceed defined risk acceptance criteria are identified and implemented; including acceptance of risks remaining after implementation of mitigating actions.

SECTION 27: CUSTOMER RELATED PROCESSES
OctoChem, Inc. ensures requirements received from the Customer are fully understood and the capability exists to meet aspects of the customer requirements prior to acceptance of the contract. Customer requirements are fully understood, including requirements for delivery as well as post delivery activities and requirements not stated by the customer but necessary for the specified use of the products are identified. Any additional statutory, regulatory, or technical requirements are identified and included in quality planning activities.

Requirements are reviewed prior to acceptance of the contract or order. This review ensures all verbal or documented special requirements, including any associated risks, are adequately defined, documented, and agreed upon before their acceptance. Requirements differing from original quotes are resolved prior to contract acceptance. Appropriate personnel are notified when contract changes occur. Contract amendments are reviewed, approved, and affected functions are advised of the impact. Account Coordination is the primary function designated for communicating with the customer in relation to product information and requirements, changes to requirements, and customer feedback including but not limited to customer complaints.

SECTION 28: PURCHASING
OctoChem, Inc. maintains documented policies to ensure products and services obtained from outside suppliers conform to specified requirements. OctoChem maintains responsibility for the quality of all products purchased from any supplier or customer-designated source. Supplier control depends upon the type of product, impact on product quality, and previous history of supplier. OctoChem, Inc. ensures customer-approved special process sources are used when specified. OctoChem allows no non-conforming material to be supplied or changes in product and/or process definition unless prior approval is obtained. OctoChem requires all suppliers to allow right of access to facilities and records by our organization and corresponding customers as well as associated authorities. Verification that products conform to specified purchasing requirements is ensured prior to their use or processing. Verification is achieved through receiving inspections with review and evaluation of objective evidence for product compliance received in the form of certifications, test reports, and other supporting documentation. Product verification may also take place at supplier premises through audit, inspection, and documentation review. Purchased product is not used unless verification to specified requirements is completed and accepted.

Per contractual agreement, the Customer, or a representative, reserves the right to verify subcontracted product conformance at its supplier’s premises. Customer verification does not prove supplier quality, absolve OctoChem of the responsibility to ensure acceptable product nor preclude subsequent product rejection by the Customer.

SECTION 29: PRODUCTION AND SERVICE PROVISION
Where key characteristics have been identified, OctoChem has established process controls and developed control plans for measurement qualification. In-process verification points have been identified where conformance measurement cannot be obtained at subsequent product realization stages. Processes are carried out under controlled conditions such as:

- Processes
- Availability of information describing the characteristics of the product
- Documented policies accessible at operator work stations for operation and process monitoring
- Correct monitoring and measuring devices available for use
- Proper process measurements to control critical process parameters
- Implementation and control of product release
Delivery and post-delivery activities

Accountability of product is maintained during procurement operations. Engineering and manufacturing controls provide for prevention, detection, and removal of foreign objects or contamination. Utilities and supplies are monitored and controlled to minimize any effect on product quality. Standard Operating Policies provide clear and practical criteria for procurement quality and form the basis for operation control.

Process changes are controlled through the identification of authorized individuals to evaluate potential changes and provide approval. Any changes requiring customer or regulatory approval per contractual requirements are identified and acceptance properly acquired. Changes affecting processes, equipment, tools, and programs are documented, with policies in place to control their implementation. Results of changes to processes are assessed to confirm that the desired effect is achieved. All equipment, tools, and programs are validated prior to use and periodically thereafter through documented calibration and preventive maintenance procedures. Periodic preservation and condition checks of stored equipment and tools provide assurance that reliable replacements are available if needed. Controls exist to ensure the capability of any external entity to provide quality work or service temporarily transferred outside of OctoChem.

In house servicing operations provide collection and analysis of in-service data, investigation, reporting, and action plans all consistent to contractual and/or regulatory requirements. New processes and other associated equipment is properly tested and validated prior to usage. Special Processes are qualified and approved by Management with delegated authority to provide process qualification, approval, maintenance, and control. Process measurements are identified for monitoring and measurement and process data is analyzed to make necessary improvements or changes in processes to achieve planned results.

Systems are established to maintain identification of product through each stage of receipt, procurement, and delivery. Product traceability is established where required to record unique product identification as well as track product from receipt of raw materials to delivery to the customer. Product identification is maintained when required throughout product life by lot number and product code.

Traceability of raw material or batches provides record of product destinations including non-conforming material and rework when required. Documented policies define the processes used to control products and to ensure they are identified, verified, stored, and protected while under the responsibility of OctoChem, Inc. Unsuitable, lost, or damaged products are identified, their condition recorded, and immediately reported to the customer. Customer provided intellectual property, such as data furnished production (SAP/Lotus) and/or inspection purposes, is likewise safeguarded.

OctoChem, Inc. has documented policies to ensure that products are controlled through handling, storage, packaging, preservation, and delivery in such a manner that product integrity is maintained. Designated storage areas have been identified that utilize appropriate methods for preservation, segregation, receipt, and dispatch of materials. Inventory is periodically assessed for possible deterioration. Packaging, preservation, storage, and shipping processes are monitored and controlled to ensure compliance to Customer requirements. Regulated special handling protocols for sensitive or hazardous materials, including special markings, labeling, safety warning, shelf life, and stock rotation, are adhered to. Product documentation provided upon delivery is protected against loss or deterioration.

SECTION 30: CONTROL OF MONITORING AND MEASURING DEVICES

Defined processes are in place to ensure that inspection, measuring, and test equipment is controlled, calibrated, adjusted, handled, stored, and maintained. Environmental conditions are suitability controlled to provide accurate calibration, inspection, measurement, and test. Processes are defined for the calibration of inspection, measuring, and test equipment. Acceptance criteria and corrective action are included in this process. Inspection, measuring, and testing equipment is identified, calibrated, safeguarded from adjustments that would invalidate the accuracy, and adjusted at prescribed intervals or prior to use against certified equipment traceable to nationally recognized
standards. Prescribed intervals are established for each testing medium and records of results are maintained. If equipment is found to be out of calibration, validity of prior inspections is assessed and appropriate action is initiated. Handling, preservation, and storage practices ensure that accuracy is maintained. Calibration records are maintained.

SECTION 31: MEASUREMENT, ANALYSIS, AND IMPROVEMENT
Policy data is used for making fact-based decisions. This is accomplished by ensuring effective and efficient measurement, collection, and validation of data and its intended use for adding value to the organization.

OctoChem, Inc. plans and implements improvement processes by monitoring process measurements and analyzing process data. This method is used to demonstrate conformity of the product, the quality management system, and to continually improve the effectiveness of the system. We have determined the tools, methodology, and statistical techniques used to monitor and measure our processes, product, and services and the extent of their use. Statistical techniques may be used to support product from initial design through final inspection.

SECTION 32: MONITORING AND MEASUREMENT
Customer service monitors information relating to customer perception as to whether OctoChem, Inc. has fulfilled its customer requirements. This information is submitted for management review. Various methods are used such as: surveys, feedback relating to products, market needs, and customer requirements compared to contract information.

OctoChem, Inc. has a documented process established for planning and performing internal audits. Internal audits are conducted annually to verify conformance to our quality management system and International Standards, as well as assess the operational effectiveness of the quality system. Audit plans give consideration to the status and importance of the activity to be audited, results of previous audits, and also incorporate contract and/or regulatory requirements. Each scheduled audit is supported by a checklist that guides the performance of the audit. The acceptability of the selected auditing tool is measured against the effectiveness of the audit process and overall organization performance. Audits are conducted by personnel who are independent of responsibility in the areas being audited and do not audit their own work. Documented policies describe the responsibility for planning, conducting, recording, and reporting the audit results. Audit results are communicated to management who are responsible for the area being audited and timely action is taken to eliminate the cause of identified non-conformity. Corrective action taken is documented and verified for effectiveness. Results of verification are recorded. Results of audit activities, corrective action taken and results of verification are submitted to the management representative to be included in management review activities. The internal auditing process is the primary method used to measure and determine the overall effectiveness of the quality management system. When system non-conformity is identified, corrective action is taken to ensure continued product conformity. If after evaluation of the non-conforming process it is determined that product non-conformity also resulted, the effected product is identified and controlled per documented non-conforming product policies.

OctoChem, Inc. maintains defined processes for inspection to verify that specified requirements for products and services are met. Where sampling inspection is implemented, all plans are statistically valid, appropriate for the inspection and preclude the acceptance of any lot with known non-conforming samples. Sample plans are submitted for customer approval, when required. Material is not released prior to verification unless positive recall is provided. No product is dispatched until all required inspections are carried out.

SECTION 33: CONTROL OF NON-CONFORMING PRODUCT
OctoChem, Inc. maintains documented policies to ensure that product that does not conform to specified requirements or is expired is controlled and prevented from unintended use. Control provides for identification, segregation (when practical), disposition, and notification of areas affected. Material review and disposition of non-conforming product or disposal product, and the decision process involved, are defined in documented policies.

The action taken by OctoChem, Inc. for dealing with non-conforming or disposal product is by one or more of the following ways:
• Taking action to eliminate the cause of non-conformity utilizing Doc. # O-507.
• Accepting the product as is provided customer authorization is obtained where required
• Rejecting or disposal of the product per Customer requirements and Attachment M of Doc. # O-503.

Dependant upon OctoChem or customer designed product and contractual obligations, OctoChem will disposition non-conforming product in accordance with customer contractual requirements. Product under customer-authorized deviation or waiver is properly identified and tracked per customer requirements. All product disposals are clearly and permanently marked and/or positively controlled. When required by the Customer, disposal product will be physically rendered unusable prior to disposal. Records of product non-conformities and the resulting actions are maintained. This includes concessions or waivers obtained from customers.

Appropriate action is taken in the event non-conforming product is detected after delivery or use. Affected parties (i.e. suppliers, customers, distributors, regulatory authorities) will be notified in a timely manner of any delivered non-conforming product. Notification will consist of a clear description of the non-conformity, including as necessary customer and/or OctoChem, Inc. part identification, quantity, traceability numbers, and delivery dates.

SECTION 34: ANALYSIS OF DATA
Processes are defined to collect and analyze system data from process monitoring and measurement as well as other relevant sources to demonstrate the suitability and effectiveness of the quality management system. Policy data used for continuous improvement analysis provides information relating to customer satisfaction, product conformance, suppliers, and trend to identify preventive actions.

SECTION 35: IMPROVEMENT
OctoChem, Inc. takes a proactive approach to continual improvement. We continually look for ways to improve our operations, rather than wait for a problem to occur and then implement system improvements. Our quality policy and objectives brings focus to our continual improvement efforts and through the use and proper analysis of audit results, process data, corrective, and preventive actions, as well as management appointed improvements are made in the system before problems occur. OctoChem, Inc. maintains documented policies for implementing corrective and preventive action. All actions taken are adequate with the problems identified and their impact.

Quality management system corrective actions include:
• Effective handling of Customer complaints and reports of non-conformities
• Investigation and documenting the causes of nonconformance and the action needed to prevent recurrence through our root cause analysis, #O-556, that is required for all customer complaints.
• The analysis of processes and operations, concessions, quality records, Customer complaints, and returned product failure analysis to detect and eliminate potential causes of the nonconformities
• Verification that corrective actions are taken and are effective.

Policies driving the process dictate specific action in the event that timely corrective action is not satisfactorily achieved. Additionally, when it is determined that a supplier is responsible for the root cause of non-conformity, requirements for addressing the issue are communicated to the customer.

Quality management system preventive actions include:
• Maintaining and utilizing information on performance to detect, analyze, and eliminate potential causes of nonconformities
• Determining and planning the steps needed to improve the process
• Obtaining customer approval where applicable
• Implementing the plan and verifying the results
• Submitting relevant information for management review activities
• Records of corrective and preventive action activities as well as results are maintained