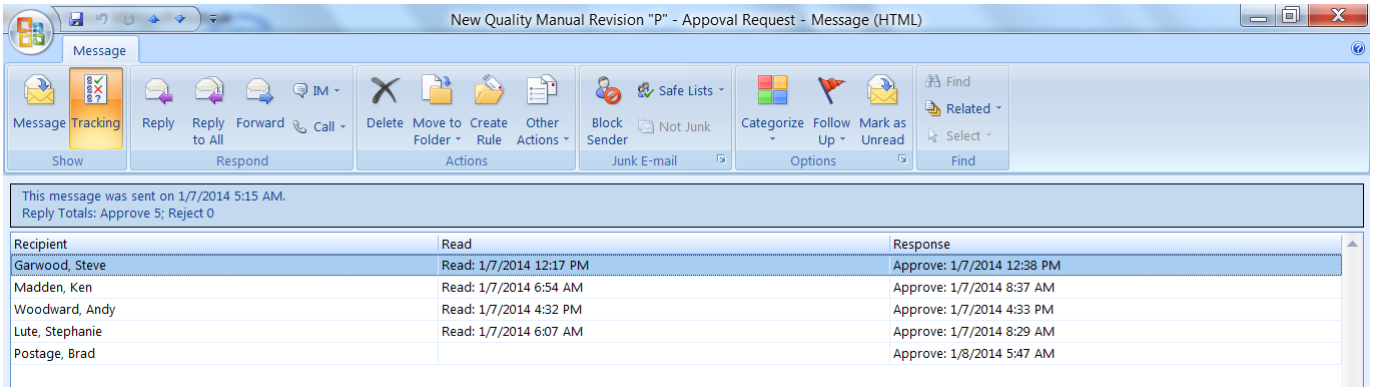
Approvals:

VP of Global Engineering
VP of Global Operations
VP of Sales
Director of Global Human Resources
Quality Manager, NA Operations



0. General

0.1 Purpose of the Manual

The purpose of this manual is to serve as the single source document for the management and improvement of the Vernay Quality System based on ISO/TS 16949 and ISO 13485. This manual covers the quality system policies and procedures for all North American Vernay facilities: Vernay Laboratories, Inc. (VL or VYS), in Yellow Springs, Ohio, Vernay Manufacturing (VM or VGR), located in Griffin, Georgia, and Vernay Manufacturing (VX or VMI), located in Milledgeville, Georgia.

0.2 Approval of the Manual

The North American (NA) Leadership Team hereby declare by evidence of their approval as authorization of this manual and commitment to enforcing the contents of this Quality Manual and the associated Quality Assurance Procedures and Work Instructions. We will actively support and guide the organization in line with the **Quality Policy** and the contents of this document.

0.3 Release and Distribution of the Quality Manual

Effective October 2004, approval may occur electronically and a tracking record of approval responses is maintained as part of the document. The Quality Systems Engineer then publishes the approved Quality Manual on the Vernay Infobase. The published copy is the latest revision and is available to all Vernay personnel.

0.4 Revision Record

--	Original, Ken Weaver, 06/19/96
Rev A	Changed, Ken Weaver, 10/14/96
Rev B	Changed, 12/03/96, Ken Weaver
Rev C	Changed, 08/20/97, Ken Weaver
Rev D	Changed, Ken Weaver, 03/31/99
Rev E	Changed, Ken Weaver, 06/07/00
Rev F	Changed, Ginny Grooms, 07/13/01
Rev G	Changed, Ginny Grooms, 05/29/02
Rev H	Changed, Ginny Grooms, 07/30/02
Rev I	Changed, Corinne Scott, 12/04/02
Rev J	Changed, Corinne Scott, 7/3/03
Rev K	Changed, Corinne Scott, 01/13/04 Removed from sign-off cover page: President & CEO, Sr VP Global Business Development, CFO, VP Advanced Technology, VL Plant Mgr, VM Plant Mgr, VS

	Plant Mgr, VX Plant Mgr; changed General Manager NA to VP & General Manager NA; added Director Manufacturing, Director Sales
0.2	Changed "The Officers and Directors of Vernay Laboratories, Inc., the Manager Quality System Improvement NA, and Plant Managers of the North American manufacturing sites" to "The North American Operations Team" NOTE: NA Management Team and VL Management Team changed to NA Operations Team throughout document
0.3	Changed printed copies to printed copy
0.9	Changed 600 professionals to 500 personnel
0.10	Changed Corporate Council comprised of officers to comprised of Corporate Executives and managers; added Pacific Rim SBU; defined the NA Operations Team as comprising of VP & GM NA and direct reports; deleted the Leadership Team participating in Management Reviews
0.11	Deleted "VM and VX do not perform product development but do participate in the development process for products that are intended to be manufactured at VM and VX. VS can perform limited product development which is conducted in a similar manner as corporate." Deleted that VL,VM, VX, and VS jointly approve any revisions to the manual. Changed QAP's and WI's "may be" location specific from "are"
1.2	Deleted corporate goals and objectives are established "by the Vernay North American SBU" Removed listed "Responsible" functions after Reference listing (also throughout entire document)
1.4.1	Deleted the records of reviews are maintained in the VL Leadership meeting minutes; changed "Selected indicators are sent to VL and are included as part of the VL Management Review" to "Selected indicators are included as part of the NA QMS Review"
1.4.3	Changed reviews from monthly to quarterly
1.6.3	Updated to reflect current Management Organization Reporting Relationships
3	Added Production Coordinators
4	Deleted from NPD Team: Manager Advanced Quality Development
6	Added QAP-2.4-VX, QAP-6.2-VX, QAP-6.4-VX
7	Removed "When applicable, Vernay uses the same receiving inspection process as described in QAP-10.2-VL / QAP-10.2-VM / QAP-10.1-VS for assuring the quality of customer-supplied products."
8	Added QAP-9.8-VS
9	Added QAP-9.8-VS, QAP-9.9-VS, QAP-9.9-VX, QAP-9.13-VX
10	Added QAP-9.8-VS, QAP-9.6-VX, QAP-9.7-VX, QAP-9.9-VX, QAP-9.10-VX
12	Added QAP-9.8-VS
13	Added QAP-9.8-VS, QAP-2.4-VX
14	Changed QAP-9.1-VX to QAP-9.8-VX; changed QAP-9.1-VS to QAP-9.9-VS
17	Replaced QAP-17.1-VL/VM/VS/VX with QAP-17-1-CORP
21	Added QAP-2.2-VX
22	Added QAP-9.13-VX

23	Added QAP-9.9-VS and QAP-9.8-VX
Rev L	Changed, Corinne Scott, 11/28/05 Changed Director of Human Resources to Manager Human Resources NA, also throughout document; changed sign-off cover sheet to electronic approval tracking page
0.1	Deleted references to ISO/QS9000, FDA's Quality System Regulation as a basis for this manual; also in sections 1.5 and 6
0.2	Changed the evidence of authorization from a signature to approval
0.3	Changed the references of printed hard copies with approval signatures to electronic approval and tracking; changed Manager/Lead Auditor, Quality and Environmental Systems NA to Manager, Quality and Environmental Systems, also throughout document
0.7	Deleted scanning electron microscope and x-ray defraction as analytical tests
0.9	Changed Vernay employs "over 500 personnel to "personnel"
0.11	Changed the reference of "VL Leadership Team" to "NA Operations Team;" also section 1.4.2 and 1.5
0.12	Added paragraph describing the relationship between the SBU's
1.3	Replaced the table format with the input/output listing
1.6.3	Updated to reflect current Management Organization Reporting Relationships
1.6.4	Added new section
1.8	Deleted from References: QAP-1.1-VL, QAP-1.1-VX, QAP-1.1-VS; added QAP-1.1-CORP
2.2	Deleted from References: QAP-4.1-VL, QAP-4.1-VM, QAP-4.1-VX, QAP-4.1-VS; added QAP-4.1-CORP, QAP-2.3-VX
3	Deleted statement about Ford, GM, DaimlerChrysler requirements specified in Section II of QS-9000; deleted from References: QAP-4.1-VL, QAP-5.2-VL, QAP-5.4-VL, QAP-9.14-VL, QAP-4.1-VM, QAP-5.2-VM, QAP-4.1-VX, QAP-4.1-VS; added to References: QAP-4.1-CORP, QAP-5.2-CORP
5	Deleted from References: QAP-5.2-VL, QAP-5.4-VL, QAP-5.6-VL, QAP-5.2-VM; added to References: QAP-5.2-CORP
6	Changed "Quality" maintains an Approved Supplier List to "Vernay;" changed Vernay expects "100% on time" delivery to "on-time" delivery
7	Changed title of section from "Control of Customer-Supplied Product" to "Control of Customer Property", also throughout section; added "…or other documentation. Customer property may include inserts, test equipment, manufacturing equipment, software, etc."; deleted from References: QAP-4.1-VL, QAP-7.1-VL, QAP-10.2-VL, QAP-4.1-VM, QAP-7.1-VM, QAP-4.1-VX, QAP-4.1-VS, QAP-7.1-VS; added to References: QAP-4.1-CORP, QAP-7.1-CORP, QAP-9.2-VX
8	Deleted from References: QAP-8.2-VL; added to References: QAP-8.2-CORP, QAP-9.17-VX
9	Changed references of QAP-18.1-VL/QAP-18.1-VM, QAP-18.1-VX/QAP-18.1-VS to QAP-18.1-CORP (also in section 18); deleted from References: QAP-4.1-VL, QAP-5.4-VL, QAP-9.1-VL, QAP-9.2-VL, QAP-9.3-VL, QAP-9.4-VL, QAP-9.5-VL, QAP-9.6-VL, QAP-9.7-VL, QAP-9.8-VL, QAP-9.9-VL, QAP-9.16-VL, QAP-9.13-VL, QAP-

	9.15-VL, QAP-18.1-VL, QAP-4.1-VM, QAP-9.5-VM, QAP-9.11-VM, QAP-18.1-VM, QAP-9.5-VX, QAP-9.13-VX, QAP-18.1-VX, QAP-9.5-VS, QAP-18.1-VS; added to References: QAP-4.1-CORP, QAP-935-CORP, QAP-9.16-CORP, QAP-9.13-CORP, QAP-18.1-CORP, QAP-2.2-VX, QAP-2.4-VX, QAP-9.17-VX, QAP-2.2-VS
10	Deleted from References: QAP-10.1-VL, QAP-10.2-VL, QAP-10.3-VL, QAP-10.4-VL, QAP-10.5-VL; added to References: QAP-9.17-VX
11	Changed "Process gage calibration is maintained…to control the process by the Maintenance Department." to "…to control the process." Deleted from References: QAP-9.1-VL, QAP-11.1-VL, QAP-11.3-VM
12	Deleted from References: QAP-12.1-VL; added QAP-9.17-VX
13	Deleted from References: QAP-13.1-VL; added QAP-10.2-VM, QAP-9.17-VX
14	Changed title of QAP-2.3-VX "Quality Planning" to "Advanced Quality Planning", also in section 20, 21
15	Deleted from References: QAP-9.8-VL, QAP-15.1-VL
19	Changed section from not being applicable
21	Added to References: QAP-2.3-VX, QAP-2.4-VX
22	Deleted from References: QAP-9.5-VL, QAP-9.13-VL, QAP-9.5-VM, QAP-9.5-VX, QAP-9.5-VS; added to References: QAP-9.5-CORP, QAP-9.13-CORP
23	Deleted from References: QAP-9.4-VL, QAP-9.6-VL, QAP-9.7-VL, QAP-9.11-VL, QAP-9.11-VM; added to References: QAP-9.16-CORP
24	Added new section
Rev. M	Changed, Cheryl Nadzam, 12/18/2009
0.1	Deleted references to Vernay's Marion Plant (closed 4/1/09) and throughout document.
0.2	Changed operations team to leadership team to prevent confusion with Operations group (i.e. one of business processes) and throughout the document.
0.3	Changed "Manager, Quality and Environmental Systems (MQES)" to "Quality and Manufacturing Systems Manager (QMSM) or designee" and throughout the document.
0.10	Added sealing components to mission statement, consistent with the 2009-2013 strategic plan
0.11	Changed Pacific Rim business unit to Asia Pacific business unit and throughout the document.
1.1	Updated quality policy.
1.2	Updated QAP references.
1.4.1	Local management reviews are combined into single NA management review.
1.4.3	Updated QAP references.
1.5	Changed management representative for VL and overall system maintenance to Quality & Manufacturing Systems Manager (QMSM). The Operations Manager replaces Plant Managers as management representative for VM and VX.
1.6.3	Revised org chart
1.8	Updated QAP references
2.2	Updated QAP references
3	Updated QAP references
4	Updated QAP references

5	Updated QAP references, eliminated separate document control system for visual inspection standards
6	Updated QAP references
7	Updated QAP references
8	Updated QAP references
9	Updated QAP references
10	Updated QAP references
11	Updated QAP references
12	Updated QAP references
13	Updated QAP references
14	Updated QAP references
15	Updated QAP references
16	Updated QAP references
17	Updated QAP references
20	Updated QAP references
21	Updated QAP references
22	Updated QAP references
23	Updated QAP references

Rev. N Changes, Brad Postage, 01/23/2013

0.1	Added references to VYS, VGR, and VMI for new three letter designations.
0.9	Added China manufacturing location.
0.12	Modified references to VYS, VGR, and VMI; Added three letter designation references to VOL, VAS, and corporate Vernay offices in Atlanta (VAT).
1.4	Added KPI reviews to section as 1.4.4 and removed VX/VM nomenclature
1.5	Removed VX/VM reference and added site location names
1.6.3	Corrected titles and reporting relationships; removed VX/VM references
Page 11	Removed “Reference appropriate QAP” editing box in left hand column

Rev. O Changes, Brad Postage, 9/30/2013

1.1	Modified Quality Policy to include achieving ISO 13485
1.4.4	Modified VL to VYS acronym and added reference to ISO 13485 for VGR.
1.4.5	Updated Supply Chain Director and moved Customer Service Rep under Sales/Marketing
4	Added references to medical validations for medical components, QAP-11.4-VGR Medical Validation Plan, and QAP-2.9-VGR Risk Management
9	Changed MRP to ERP
12	Added reference to QAP-10.1-VGR, Final Inspection and Test
15	Added reference to QAP-15.1-VGR, Environmental Controls
21	Added references to QAP-10.2-VGR, Receiving Verification and QAP-10.3-CORP, Annual Recertification
25	Added ISO 13485 Cross Reference Table Updated reference from VM to VGR and VX to VMI acronym in QAP links as appropriate.

Rev. P Changes, Brad Postage, 11/14/2013

18	Updated section to state installation activities, sterilization activities, active implantable, and implantable medical devices are not part of the business profile.
1.1	Modified Quality Policy to include ISO 13485
0.1	Added reference to ISO 13485
0.6	Added reference to Printing and Small Engine markets
0.9	Updated sales locations
0.11	Removed General Manager, NA and removed Europe council reference
1.6.3	Updated functional nomenclature

0.5 Who is Vernay?

Vernay is a global company. We are committed to help meet the challenges of our customers through the co-development and manufacture of elastomeric fluid control components.

Sergius Vernet's invention of the wax expansion element in 1938, which revolutionized the automotive thermostat, set the original direction of innovation and creativity for the company. The creation of our V-Tip Needle product line, in the early sixties, has been our in-road to the industrialized world markets. Since then, we have been working with customers in the automotive, medical, appliance, and specialty industries worldwide to optimize the quality and performance of their products.

The following brief overview outlines the technical aspects of Vernay's dedication to innovation, as well as our commitment to our customers.

0.6 Product Applications

Vernay has made its mark across the globe, working hand-in-hand with its customers' engineers to design and develop over 2,000 unique elastomeric products for:

Automotive:	Vacuum systems Fuel systems Emission control systems Safety and comfort control systems Transmission and engine control systems
Medical:	Intravenous infusion systems Enteral and parenteral nutritious systems Urologic and wound drainage systems Hemodynamic control devices
Appliances:	Water level control systems Water mixing valve systems Anti-siphon devices Flow control/metering devices
Specialty:	Dynamic flow control devices Valves and diaphragms Static and dynamic seals Custom developed components

Printing
Small Engine

Over fifty years of knowledge, research, and testing provide Vernay with the expertise to custom design and manufacture critical elastomeric components for many industries. Thousands of elastomeric compounds are mixed and tested each year in our laboratory, where we specialize in rubber product development for precision components.

0.7 Compounding Capabilities

Vernay has developed over 23,000 proprietary elastomeric formulations. All formulations are stored in a database for quick retrieval. Our compound families cover the entire elastomer spectrum from natural rubber (NR) to silicone (LSR/VMQ) and from nitrile (NBR) to fluorosilicone (FVMQ) and fluorocarbon (FKM). Vernay's technical capabilities are the result of the collective talents of skilled mechanical, chemical, and production engineers focusing on the component's function in the end application and cost and quality during manufacturing. State-of-the-art analytical testing includes gas chromatography, thermogravimetric analysis, rheology testing, infrared spectroscopy, and differential scanning calorimetry. For dimensional and functional testing, Vernay has dedicated measuring and test equipment.

0.8 Precision and Quality

Vernay's commitment to innovation involves more than product design and testing. We strive for quality in every area, from component / sub-assembly to integrated, high volume manufacturing.

We use a variety of precision elastomeric molding processes, including transfer, injection, compression, and continuous molding. Pre- and post-molding processes include:

- Cryogenic deflashing for high volume flash free parts
- Automatic functional testing of components and assemblies
- Precision grinding for smooth surfaces and close tolerances
- Proprietary surface treatments for low stickiness and chemical integrity
- Component assembly with additional metal and plastic sub-components
- Die-cutting of seals and valves
- Controlled environment manufacturing
- Proprietary bonding methods for inserted products

Vernay's success in achieving stringent tolerance specifications is known industry-wide and is second to none.

0.9 Global Commitment

Vernay employs personnel who believe that customer satisfaction determines Vernay's success. They are dedicated to providing the best customer support and technical service possible.

Established operations are located in North America, Europe, and Asia. Vernay provides products to the entire industrialized world through its sales and/or manufacturing facilities in Ohio, Georgia, The Netherlands, Italy, Japan, China, Singapore, France, Germany, and Brazil.

0.10 Mission Statement

While pursuing excellence in our products and services, Vernay will differentiate by applying our global resources to deliver adaptive solutions for customer's elastomeric fluid control and sealing needs.

Vernay, in its global operations, will lead by providing:

CUSTOMERS with quality solutions, products, and services which promote success in their markets.

EMPLOYEES with an environment that promotes teamwork, participation, safety, creativity, job satisfaction, personal development, and security through mutual success.

SHAREHOLDERS with competitive return, management of risk, and pride in ownership while maintaining the financial strength to support market requirements.

SUPPLIERS with the opportunity for long-term commitment and mutually beneficial relationships.

COMMUNITY with leadership, support, employment stability, and demonstrated environmental responsibility.

Vernay will optimize rewards to its stakeholders for their efforts in support of the company. Rewards will be generated through the generation of wealth, not its redistribution. This mission will be accomplished through planned growth while maintaining the highest business ethics throughout the Vernay global operations.

0.11 Corporate Profile and Structure

The Corporate Council, comprised of corporate executives and managers from the North American SBU provides the goals and major objectives for the corporation and coordinates the worldwide programs to achieve them. These programs are critical to the Vernay mission and help to focus our resources on initiatives that benefit and improve the organization as a whole.

The NA Leadership Team, comprised of the President & CEO, VP's and direct reports, provides the goals and objectives for the North American business and are responsible for the business plan for North America.

The SBU's are autonomous in their geography, marketing, sales, product, technology, development, and manufacturing.

The corporate support functions are to serve the global synergism in technology / innovation and quality by coordinating corporate activities.

Material technology is centralized in Yellow Springs, Ohio, USA.

0.12 Relationship between Vernay Laboratories and Subsidiaries (Vernay Manufacturing: Griffin and Milledgeville, Georgia).

Vernay Laboratories has in Yellow Springs, Ohio, is the corporate headquarters of Vernay. Vernay Manufacturing Operations (VGR, VMI) are subsidiaries of Vernay Laboratories that are located in Griffin and Milledgeville, Georgia. VGR and VMI are primarily manufacturing operations. VYS with offices also located in Atlanta, Georgia (VAT) supports many of the activities and functions at subsidiaries, such as compounding, sales quotation, purchasing, human resources, payroll, etc.

The relationship between the Vernay North America SBU, the European SBU (VE/VI or VOL/VAS) and the Asia Pacific SBU (VAP) is that of a customer-supplier arrangement.

VYS, VGR, and VMI share this Quality Manual. Quality Assurance Procedures (QAP's) and Work Instructions (WI's) may be location specific. However, in any case where there is shared responsibility between the locations, the QAP defines the location responsibilities and authorities and a representative(s) from each location approves the associated QAP's and any subsequent revisions. QAP's referenced throughout this manual will have a VL (VYS), VM (VGR), VX (VMI), or CORP suffix, which indicates the owning and controlling location.

1. Management Responsibility

1.1 Quality Policy

- **Vernay is committed to the highest level of quality and service to our customers. We focus on innovation and continuous improvement in all areas of our business and accomplish these goals through our quality management system.**
- **Maintain our existing quality certifications (ISO/TS-16949, ISO 9001, and ISO 13485).**

Vernay is committed to the philosophy of continuous improvement. Product quality is achieved through the stabilization and improvement of processes and activities that impact quality. Quality is the responsibility of all employees, and Vernay will ensure that every employee understands the Quality Policy and the relevant quality requirements documented in the Quality

Manual, Quality Assurance Procedures, and Work Instructions. Every employee is empowered to take actions that can help us achieve higher levels of customer satisfaction.

1.2 Business Planning

Vernay conducts annual strategic planning at each SBU. Corporate goals and objectives are established and include both a short-and long-term strategic plans. The plan is based on customer, company-level, and competitive data and information and is aimed at meeting the needs of all stakeholders identified in the Mission Statement.

Reference: QAP-1.2-CORP North American Business Planning

1.3 Process and Quality Improvement Planning

On an annual basis, a cross-functional group of employees from all areas of the company is used in the planning process for the identification and selection of improvement activities. The following lists the inputs and outputs of this process:

Inputs:

- Business Plan Assumptions (Sales [dollars], Cost assumptions, Profit/Loss [Income Statement])
- Strategic Plan
- Environmental Management System (EMS) feedback
- Quality Management System (QMS) feedback

Outputs:

- Kaizen activities
- Improvement Team projects
- Individual/personal Objectives

1.4 Management Reviews

1.4.1 Quality System

The NA Leadership Team reviews the results of internal audits and other established measurables for the Quality System on at least an annual basis. These reviews determine the effectiveness of the system and any corrective action that must be taken. Appropriate metrics are broken down by plant. Records of the reviews are maintained and any assigned corrective action activities are put on a task list for future follow-up. Local management teams for Griffin and Milledgeville participate in this management review process.

1.4.2 Quality Improvement Teams / Projects

The NA Leadership Team and the VGR and VMI Management Teams conduct at least one or more reviews annually of all team-based improvement activities to monitor progress, ensure the team is on track, remove any roadblocks, and ensure the team is properly resourced for success.

1.4.3 Operating System

The NA Leadership Team reviews operational performance indicators such as on-time delivery, productivity, scrap, complaints, new product development cycle time, sales, and cost for trend analysis on at least an annual basis and takes appropriate corrective action when necessary.

0.6.1 Key Performance Indicators

The NA Manufacturing facilities, Griffin and Milledgeville, review KPI's (Key Performance Indicators) on at least a quarterly basis. This involves review of Safety, Quality, Delivery, and Cost metrics for each facility.

Reference: QAP-1.3-CORP, Quality Management System Review

1.5 Management Representative

The NA Operations Team has appointed the Quality Systems Manager as the management representative for VYS and has pledged its support in the effort to maintain a Quality System which meets the needs of our customers and the requirements set forth in ISO 9001/TS 16949 upon which the Vernay Quality System is based.

The management representative is responsible for the overall health of the Quality System, for the internal auditing system, and for reporting appropriate data regarding the Quality System to the NA Leadership Team for their review, corrective action, and as a basis for improvement of the Quality System. The management representative is given full authority by the President & CEO to execute the responsibilities stated above.

The NA Leadership Team has appointed an Operations Manager as management representative for Griffin and Milledgeville. The NA Leadership Team has pledged to support these sites in their effort to meet the needs of its customers and the requirements set forth in ISO 9001, ISO/TS 16949 and ISO 13485 for VGR and ISO 9001, ISO/TS 16949 for VMI. The Operations Manager is responsible for maintenance, reporting, and improvement of the Quality System and is given full authority to execute the responsibilities of the position.

The respective management representative is responsible for notifying their certification body/registrar in writing within five (5) working days when a customer places the site in any of the following statuses: DaimlerChrysler “Needs Improvement;” Ford “Q-1 Revocation;” or General Motors “Level II Containment,” or "New Business Hold-Quality" following Level II Containment.

1.6 Responsibility and Authority

1.6.1 Responsibility

The responsibility for quality is shared by all employees. The following chart shows how quality management responsibilities and quality support responsibilities come together cross-functionally to affect the Vernay business cycle from marketing of applications through distribution of products. This team-based approach assures communication and co-ordination in technical functions throughout the development process.

The NA Leadership Team is responsible for all aspects of the North American Operations of Vernay and strives to meet the needs of all five Vernay stakeholders as identified in the Mission Statement.

The chart below demonstrates the organizational interfaces of the different functions within Vernay by showing areas of Quality Management and Quality Support responsibilities during our business cycle.

Quality Management Responsibility		Business Cycle Flow		Quality Support Responsibility
◆ Sales ◆ Marketing	→	Marketing of Applications ▼	←	◆ Management Information Systems ◆ Materials Technology ◆ New Product Development Engineering
◆ Sales ◆ New Product Development Engineering ◆ Manufacturing Engineering	→	Product Definition (Specification) ▼	←	◆ Materials Technology ◆ Quality Engineering ◆ Materials Management
◆ Sales ◆ New Product Development Engineering ◆ Manufacturing Engineering	→	Product Design ▼	←	◆ Quality Engineering ◆ Design ◆ Tool Engineering
◆ New Product Development Engineering ◆ Materials Technology ◆ Manufacturing Engineering	→	Product and Process Development ▼	←	◆ Quality ◆ Maintenance ◆ Purchasing ◆ Sales
◆ New Product Development Engineering ◆ Quality Engineering ◆ Manufacturing Engineering	→	Product Verification and Validation ▼	←	◆ Production Management ◆ Maintenance ◆ Dimensional Inspection
◆ Manufacturing Engineering ◆ Quality Engineering ◆ Customer Service Planners ◆ Production Management ◆ Maintenance	→	Production ▼	←	◆ Materials Management ◆ Purchasing ◆ Finance ◆ Management Information Systems ◆ Quality
◆ Materials Management ◆ Production Management	→	Packaging and Distribution ▼	←	◆ Management Information Systems ◆ Quality
◆ Manufacturing Engineering ◆ Quality ◆ Customer Service Planners ◆ Production Management	→	Customer Complaints ▼	←	◆ New Product Development Engineering

1.6.2 Authority

Authority on product quality decisions belongs to the Quality organization, including Quality Assurance and Quality Control. Quality personnel may delegate authority to qualified employees as necessary to facilitate timely decisions on production parts.

In the case of absence of the responsible employee, the replacing authority is either arranged for within the employee's functional discipline or moves automatically up to the next line of responsibility.

The NA Leadership Team is given their authority by the Board of Directors of Vernay Laboratories Inc.

1.6.3 Management Organization Reporting Relationships

Note: Indented functions report to the function above.

Board of Directors
- President & Chief Executive Officer

President & Chief Executive Officer
- VP Global Sales & Marketing
- VP Global R&D
- VP Global Operations
- VP Global Finance
- VP Global Engineering
- Director of Global HR Policy

VP Global Sales & Marketing
- MBU Teams
- Customer Service Rep.

VP Global Finance
- Manager of Accounting
- Senior Accountant

VP Global R&D
- Senior Materials Chemists
- Lab Technicians
- Manager Advanced Product Development
  - Test Engineer

VP Global Operations

Operations Manager
- Production Managers
  - Manufacturing Engineers
- Production Employees
- Quality Manager
  - Quality Engineers
  - Dimensional Lab
  - Quality Technicians
  - Audit Leader
- Maintenance Technicians
- Tooling Technicians
- Environmental Affairs and Safety Manager
- Supply Chain Director
  - Planner
  - Buyer

VP Global Engineering
- Manager Tool Engineering & Design
- Tool Designers
- NPD Engineers

Director of Global HR Policy
- Human Resource Manager
- Payroll Administrator

1.6.4 Internal Communications

Vernay is committed to ensuring all employees are aware of their roles in the quality management system. Such communications may take the form of newsletters, postings and announcements, company e-mails, or regular monthly/quarterly employee meetings. For any unusual or significant issues, a special employee meeting may be conducted so that all employees receive the information in a timely manner. Management at Vernay practices an open door policy in which employees are encouraged to seek the answers to any questions they may have.

1.7 Availability of Human and Financial Resources

Management is committed to making available the human and financial means for enhancing the Quality System and supporting the Quality Improvement programs. This includes the availability of adequate statistical and other process / product control techniques and the required

equipment to be a leader in our industry. Management is also committed to hiring and retaining highly qualified employees, providing the training necessary for employee development, paying an industry competitive salary / wage, and sharing the financial success of the company with all employees.

1.8 Customer Satisfaction

Customer satisfaction is critical to the long-term success of Vernay. Measures of customer satisfaction and dissatisfaction are monitored for trends and used as input in the annual planning process. Periodically, a customer survey is conducted which identifies levels of customer satisfaction and benchmarking information on our competitors.

Reference: **QAP-1.1-CORP, Customer Satisfaction**
QAP-1.2-CORP,-North American Business Planning
QAP-1.3-CORP, Quality Management System Review

2. Quality System

2.1 Quality Documentation Structure

The document system used to support the Quality System is a three tier system comprised of the Quality Manual, Quality Assurance Procedures (QAP's), and Work Instructions (WI's).

The Quality Manual is the first tier of documentation. It contains the history and mission, states the Quality Policy, and describes the policies and structure of the organization and the Quality System.

The QAP's comprise the second tier of documentation. These procedures are required to describe the purpose and scope of an interdepartmental process; what shall be done and by whom; when, where, and how it shall be done; what materials, equipment, and documents shall be used; and how it shall be controlled and recorded.

The WI's are the third tier of documentation. These documents are required when the activity is intra-departmental. These instructions are generally part specific or process specific, e.g. travelers and process sheets.

Reference: **QAP-2.1-CORP, Creation and Control of Quality System Documents**

2.2 Quality Planning for New Products

Advanced Quality Planning (AQP) methods are used starting with the feasibility assessment of a new product and ending with the successful transfer of the part into production. The product

must first have a thorough product definition. Once the product is defined, a cross-functional team uses AQP tools such as the process flow diagram, failure mode and effects analysis (FMEA), and the control plan during different stages of the development process to identify and prevent potential product / process problems. All special characteristics are finalized during the advanced product quality planning process and are included in the control plan. Appropriate process controls are established for all special characteristics to assure their control during production. Vernay designates special characteristics on their production part drawings.

Once the development is complete, special characteristics identified by the customer or Vernay are validated for statistical process capability. The production control plan and development results are translated into the work instructions (shop floor documents) necessary for production. Production samples with supporting documentation, as required by PPAP and/or the customer, are then submitted to the customer for approval and release.

Reference: **QAP-2.2-CORP, Production Part Approval Process**
QAP-2.3-CORP, Advanced Quality Planning
QAP-2.5-CORP, Special Characteristics
QAP-3.1-CORP, Contract Review / Request for Quotation
QAP-4.1-CORP, New Product Development

AIAG reference manuals:
- Advanced Product Quality Planning and Control Plan
- Failure Mode and Effects Analysis
- Measurement Systems Analysis—Gage R&R
- Production Part Approval Process
- Statistical Process Control (SPC)

3. Contract Review and Control

Customer contracts include requests for quotes, long-term supply agreements, purchase orders for prototype parts, tools, or equipment, and ongoing regular or blanket purchase orders for production parts or associated tooling or equipment. Contract reviews include feasibility assessments for all part specific specifications included with the Request for Quotation, delivery requirements, and any customer requirements specified in any supplier quality requirement manual provided by the customer. Resolutions of any differences are required before the order is accepted to assure requirements are adequately defined and the capability exists to meet all customer requirements.

Sales or Customer Service Planners review amendments to any contract or purchase order requirement. Once approved, the amendment is documented either through changes to the purchase order or referenced drawing / specification. Records of all reviews and changes are maintained.

Reference: **QAP-3.1-CORP, Contract Review / Request for Quotation**
QAP-3.3-CORP, Customer Deviation
QAP-5.5-CORP, Control of Customer Requirements Manuals
QAP-16.1-VL, Quality Records
QAP-16.1-VGR, Quality Records
QAP-16.1-VMI, Quality Records

4. Design Control

At Vernay, the production part and its manufacturing process are developed concurrently and sometimes in conjunction with customer development of the application. This highly interactive process requires an integrated design and development process, involving the customer, engineering, material development chemists, sales, manufacturing, purchasing, quality, and other supporting resources as necessary. Project plans are developed for every new part by a New Product Development (NPD) Team which typically includes NPD Engineering, Chemists, Sales, Quality, Manufacturing Engineering, and others as required depending on the complexity of the project. The development process starts with analyzing the customer's requirements and evaluating available prints and specifications during the Contract Review / Request For Quotation process. The process finds its completion in the transferring of the fully developed production part and process to manufacturing.

Vernay applies, in the earliest stage possible, advanced quality planning (AQP) to assure that the design meets the required and expected quality. AQP methods allow Vernay to identify, prevent, and/or control potential problems in the design of the part and its process. AQP includes the use of process flowcharts, failure mode & effects analysis, control plans, capability analysis, application of statistical methods, measurement systems analysis, and AQP checklists. All special characteristics are identified and finalized during the AQP process.

The NPD Team is responsible for developing a safe, capable, and cost-effective process using the right combination of rubber materials, inserts, tooling, equipment, and human resources.

The engineering disciplines used in the development of the part and its process include Design of Experiment (DOE), Design FMEA (normally supplied by the customer, if available), Computer Aided Design (CAD), Design for Manufacturing (DFM), Design for Assembly (DFA), Geometric Dimensioning and Tolerancing (GD&T), Finite Element Analysis (FEA), Measurement and Testing Analysis, Equipment Validation, Risk Management (Medical Components), etc. The new part is verified at appropriate stages of its development and validated according to the PPAP reference manual and/or Medical Validation during the new production part (NPP) stage of development.

The NPD Team, along with other technical resources, conduct design reviews at appropriate stages of the development process, when necessary, that are independent of the design. The most rigorous of these reviews occurs at the end of the NPP development stage, before the approval submission package / samples are sent to the customer and before the part is released to production. Design review records are maintained.

The control of important documents during the prototyping stage is accomplished through Print Evaluation, a documented system for pre-production prints and specifications. As new parts move into the final NPP stage, part and process documents are controlled under the Engineering Change System. Tool drawings are controlled under the Tool Drawings System. These three systems assure strict control of all drawings, specifications, and work instructions from initial customer contact through the life of the product.

Design output documents include all engineering drawings, material specifications, and work instructions including the mill riders, travelers, process sheets, standard procedures, visual inspection standards, etc., that are necessary to ensure the production process is consistently controlled.

Reference:

QAP-2.2-CORP, Production Part Approval Process
QAP-2.3-CORP, Advanced Quality Planning
QAP-2.8-VL, Process Validation
QAP-2.9-VGR, Risk Management
QAP-3.1-CORP, Contract Review / Request for Quotation
QAP-4.1-CORP, New Product Development
QAP-5.1-CORP, Engineering Change System
QAP-5.2-CORP, Print Evaluation
QAP-5.3-VL, Control of Tool Drawings
QAP-10.6-VL, Product Functional Testing
QAP-11.4-VGR, Medical Validation Plan
QAP-16.1-VL, Quality Records
QAP-5.3-VGR, Control of Tool Drawings
QAP-16.1-VGR, Quality Records
QAP-16.1-VMI, Quality Records

AIAG reference manuals
- Advanced Product Quality Planning and Control Plan
- Failure Mode & Effects Analysis
- Measurement Systems Analysis—Gage R&R
- Production Part Approval Process
- Statistical Process Control

5. Document Control

Document control is applied to secure a closed-loop system, which provides the users of all types of controlled documentation with the valid versions. Customer drawings and specifications, Vernay tool drawings, part drawings, travelers, process sheets, specifications, standard procedures, visual inspection standards, and the Quality Manual and procedures are the main groups of controlled documentation.

Separate control systems are used for pre-production (Print Evaluation), production (Engineering Change), tool drawings, and Quality System documents. These systems cover the initiation, evaluation, approval, and implementation of the desired change including, where applicable, an approval loop with the customer.

Reference:
QAP-2.1-CORP, Creation and Control of Quality System Documents
QAP-2.4-CORP, Customer Notification / Approval of Process Change
QAP-5.1-CORP, Engineering Change System
QAP-5.2-CORP, Print Evaluation
QAP-5.3-VL, Control of Tool Drawings
QAP-5.5-CORP, Control of Customer Requirements Manuals
QAP-5.3-VGR, Control of Tool Drawings

6. Purchasing Control

Vernay documents its requirements for all purchased products used in the manufacture of production parts and communicates those requirements to our suppliers as a part of the ordering process. Vernay assures that all products purchased will meet our requirements and satisfy any governmental safety constraints or restrictions for toxic and hazardous materials. Vernay requires Material Safety Data Sheets for all purchased materials.

The Supplier Quality Manual is used to document and communicate the Vernay Quality System requirements to the affected suppliers. This manual is based on ISO/TS 16949 and defines our fundamental quality requirements.

Vernay requires process change notification, prior to implementation, from our suppliers and has a defined process for evaluating and dispositioning the change request.

As needed, supplier audits are conducted to evaluate a supplier's conformance to Vernay quality requirements, determine their ability to meet product requirements, and/or to select new suppliers. Vernay maintains an Approved Supplier List.

Vernay expects on-time delivery from our suppliers and therefore provides them with appropriate planning information and purchasing commitments, and monitors their delivery performance.

Reference: **QAP-2.4-CORP, Customer Notification / Approval of Process Change**
QAP-6.1-CORP, Purchasing and Supplier Development Activity
Supplier Quality Manual

7. Control of Customer-Property and Software

Vernay performs very little manufacturing using customer-property. If there are any special customer requirements for handling their property, those requirements are appropriately documented on the traveler, process sheet, or other documentation. Customer property may include inserts, test equipment, manufacturing equipment, software, etc.

Customer-owned tooling is controlled and managed by Vernay. Any loss or damage that makes them unsuitable for use is reported to the customer.

Returnable packaging provided by the customer is controlled by Vernay. Any loss or damage that makes them unsuitable for use is reported to the customer.

Software validation is verified through the maintanence PM schedule.

Reference: **QAP-4.1-CORP, New Product Development**
QAP-7.1-CORP, Control of Customer Property and Software
QAP-10.2-VGR, Receiving Verification
QAP-9.2-VMI, Receiving Verification / Raw Material Inventory

8. Product Identification and Traceability

Vernay provides a system that meets all applicable customer expectations either through our standard identification and traceability procedure or through special arrangements as agreed upon by the customer.

Reference: **QAP-8.2-CORP, Control of Compound and Part Identification Numbers**
QAP-8.1-VGR, Product Identification and Traceability
QAP-9.2-VMI, Receiving Verification / Raw Material Inventory
QAP-9.3-VMI, Weigh, Mix, and Mill Activity
QAP-9.4-VMI, Test Lab Activity

QAP-9.6-VMI, Rubber Preform Activity
QAP-9.7-VMI, Stripcure Activity
QAP-9.9-VMI, Flow Control Activity
QAP-9.10-VMI, V-Ball Activity
QAP-9.17-VMI, Injection Molding Activity

9. Process Control

Production is planned and scheduled using an ERP software system in conjunction with pull systems and synchronous manufacturing techniques whenever possible. Production orders are reviewed and entered into the ERP system, which triggers the ordering of raw materials and the scheduling of the production process. Inventory control is also accomplished with an ERP system.

Vernay uses a new product development system which identifies special characteristics for both process and product parameters. Special characteristic capability is established during the NPD stage of development. Ongoing process performance is monitored during production using SPC techniques as specified on the control plan. Corrective action is taken when an unstable process or product characteristic is identified or when we fail to meet the ongoing capability requirements on customer-designated special characteristics. These special characteristics are transferred from the control plan to the work instructions used during production. The part or process specific work instructions are referred to as mill riders, travelers, process sheets, and standard procedures. These documents are operator instructions that detail the part or process specific information necessary to set-up and run any specific process defined in the routed process. In addition, we use operator instructions called Safe Operating Procedures (SOP's), for designated pieces of equipment that define critical equipment and safe operating instructions. Visual inspection standards are also used to define the acceptance criteria for visual defects.

Work instructions are not written to cover common practices or system requirements defined in QAP's. These issues are handled through operator training done during the new employee orientation and probation period, or through on-the-job training done when an operator transfers from one job classification to another (QAP-18.1-CORP).

Important parameters in the mixing and molding processes are monitored continuously in real-time on the equipment that has automatic process monitoring capability. An extensive set-up process verifies both the process settings and product characteristics that have been identified. Process and product auditing is also used as a process control when appropriate.

Preventive maintenance on both equipment and tooling is a critical part of an overall stable processing system. All critical equipment is on a scheduled preventive maintenance program and production molds are periodically evaluated and graded to prevent unexpected tooling problems.

Process changes are defined and controlled through the Engineering Change System. Allowable temporary process changes and the control of experiments run in production are controlled by a QAP. When required, the customer is either notified of the change or their approval is requested.

Process changes, that require notification/approval for other Vernay locations, are communicated and executed according to defined procedures to assure uninterrupted service to our customers. Inter-company job transfers are coordinated between plants by using procedures that assure product quality, delivery and customer notification / approval.

Informal studies / experiments / data collection during production, for the purpose of improving the process, are encouraged and can be requested through the production supervisor by Engineering, the Lab, or Quality. Work instructions are not required but production management is responsible for controlling the parts processed during the trial to assure product compliance with customer requirements.

Vernay has a program to assure compliance with all applicable government safety and environmental regulations including those concerning handling, recycling, eliminating, or disposing of hazardous materials. The Manager of Environmental Affairs & Safety who ensures that we meet all OSHA and EPA requirements administers the Safety/Environmental program.

Vernay performs capacity and process planning for production operation and maintains contingency plans in case of disruptions or forced shut down of operations.

Reference:

QAP-2.3-CORP, Advanced Quality Planning
QAP-2.4-CORP, Customer Notification / Approval of Process Change
QAP-2.5-CORP, Special Characteristics
QAP-2.6-VL, Intercompany Change Notification
QAP-2.7-VL, Intercompany Job Transfer
QAP-2.9-VGR, Risk Management
QAP-4.1-CORP, New Product Development
QAP-9.5-CORP, Temporary Process Change
QAP-9.12-CORP, Contingency Plans
QAP-9.13-CORP, Production Trials / Experiments
QAP-9.16-CORP, Process Planning for Existing Operations
QAP-18.1-CORP, Training
QAP-20.1-VL, SPC and Ongoing Process Capability in Manufacturing
QAP-9.2-VGR, Environmental Controls
QAP-9.3-VGR, Process Controls
QAP-9.4-VGR, Tooling Preventive Maintenance
QAP-9.6-VGR, Tool Management
QAP-9.7-VGR, Identification and Repair of Damaged Cavities
QAP-9.8-VGR, Scheduling, Inventory and Delivery Control
QAP-9.17-VGR, Medical Molding Activity
QAP-9.18-VGR, Medical Mill Activity

QAP-9.19-VGR, Post Molding Inspection
QAP-10.6-VM, Set-Up Inspection
QAP-20.1-VGR, SPC and Ongoing Process Capability in Manufacturing
QAP-9.3-VMI, Weigh, Mix, and Mill Activity
QAP-9.4-VMI, Test Lab Activity
QAP-9.6-VMI, Rubber Preform Activity
QAP-9.7-VMI, Stripcure Activity
QAP-9.8-VMI, Tooling Management Activity
QAP-9.9-VMI, Flow Control Activity
QAP-9.10-VMI, V-Ball Activity
QAP-9.11-VMI, Scheduling, Inventory, and Delivery Control
QAP-9.17-VMI, Injection Molding Activity
Statistical Process Control manual from AIAG

10. Inspection and Testing

Appropriate methods of verifying product requirements are used throughout the production process. Vernay maintains a laboratory for raw material testing and works with our suppliers to achieve certification on critical product components.

In-process and final inspection testing of product are used, when appropriate, to verify the products meet specified requirements. Records of critical inspections and tests are maintained as evidence of product compliance.

Positive recall methods are used whenever materials are released to be used prior to their full approval. Positive recall methods are applicable for purchased materials, for the release of preforms to molding departments, and for the release of a job set-up.

When required, periodic layouts and functional testing are performed to verify product characteristics.

Reference:
QAP-10.6-VL, Product Functional Testing
QAP-10.1-VGR, Final Inspection and Test
QAP-10.2-VGR, Receiving Verification
QAP-10.3-CORP, Annual Recertification
QAP-10.4-VGR, In-Process Inspection and Testing
QAP-10.5-VGR, Dimensional Inspection
QAP-10.6-VM, Set-Up Inspection
QAP-9.2-VMI, Receiving Verification / Raw Materials Activity
QAP-9.4-VMI, Test Lab Activity
QAP-9.6-VMI, Rubber Preform Activity
QAP-9.7-VMI, Stripcure Activity
QAP-9.9-VMI, Flow Control Activity

QAP-9.10-VMI, V-Ball Activity
QAP-9.17-VMI, Injection Molding Activity
QAP-9.17-VGR, Medical Molding Activity
QAP-9.18-VGR, Medical Mill Activity
Laboratory Quality System Manual, Policies and Procedures

11. Control of Inspection, Measuring, and Test Equipment

Vernay maintains a calibration system for all gages and test equipment that are used to assess product quality characteristics. The system assures both initial and ongoing reliability and accuracy. Appropriate measurement system analysis is performed for special characteristics and other standard measuring and test systems.

Process gage calibration is maintained for all designated equipment gages that are used to control the process.

Guidelines from recognized standards are used which allow traceability to the National Institute of Standards and Traceability (NIST), whenever possible.

Software validation is verified through the maintenance PM schedule.

Reference:
QAP-11.2-CORP, Measurement Systems Analysis
QAP-9.1-CORP, Preventive Maintenance
QAP-11.1-CORP, Gage Calibration and Control
QAP-7.1-CORP, Control of Customer Property and Software

12. Inspection and Test Status

The status of inspection and testing is maintained on all raw materials and product in any stage of production. Procedures define how this is done from receival of raw materials through shipment of finished product.

Reference:
QAP-12.1-VGR, Inspection and Test Status
QAP-10.1-VGR, Final Inspection and Test
QAP-9.2-VMI, Receiving Verification / Raw Materials Inventory
QAP-9.3-VMI, Weigh, Mix, and Mill Activity
QAP-9.4-VMI, Test Lab Activity
QAP-9.6-VMI, Rubber Preform Activity
QAP-9.7-VMI, Stripcure Activity
QAP-9.9-VMI, Flow Control Activity
QAP-9.10-VMI, V-Ball Activity
QAP-9.17-VMI, Injection Molding Activity

13. Control of Nonconforming Product

All products which fails to meet specified requirements is segregated from conforming product or appropriately tagged to prevent unintended use or shipment. According to procedures, nonconforming product is dispositioned and, when required, the customer is notified for authorization to release nonconforming product or any product made using an unapproved process. A scrap system is used to collect scrap information. Scrap reports are used for scrap control and reduction.

Rework is controlled and a prioritized plan to reduce the amount of nonconforming product is developed, implemented, and tracked.

Reference:

QAP-2.4-CORP, Customer Notification / Approval of Process Change
QAP-3.3-CORP, Customer Deviation
QAP-13.2-CORP, Control of Scrap Codes
QAP-10.2-VGR, Receiving Verification
QAP-13.1-VGR, Control of Nonconforming Product
QAP-3.1-CORP, Contract Review Activity
QAP-9.2-VMI, Receiving Verification / Raw Materials Inventory
QAP-9.3-VMI, Weigh, Mix, and Mill Activity
QAP-9.4-VMI, Test Lab Activity
QAP-9.6-VMI, Rubber Preform Activity
QAP-9.7-VMI, Stripcure Activity
QAP-9.9-VMI, Flow Control Activity
QAP-9.10-VMI, V-Ball Activity
QAP-9.17-VMI, Injection Molding Activity
QAP-9.17-VGR, Medical Molding Activity
QAP-9.18-VGR, Medical Mill Activity
QAP-9.19-VM, Post Molding Inspection

14. Corrective and Preventive Action

Corrective action for both externally and internally identified nonconformances is responded to using appropriate problem-solving techniques. Thorough investigation, containment, and root cause analysis is done for correction of problems and prevention of their future recurrence. Changes to the process, that are made to correct a nonconformance, are documented on the appropriate procedure or work instruction to make the corrective action permanent. Past due corrective action responses are tracked and are escalated to the next level of management for resolution to assure closure.

Vernay responds to customer problems quickly and effectively according to their specified requirements. Returned product is thoroughly tested and analyzed. Vernay emphasizes prevention versus detection as the primary solution to quality problems.

Corrective action activities included in the Vernay Quality System include both externally and internally identified nonconformities as described below:

A. Externally identified:
QAP-14.1-CORP, Record of Customer Complaint
QAP-14.8-CORP, Preventive Actions

B. Internally identified:
QAP-14.8-CORP, Preventive Actions
QAP-14.9-CORP, Internal Corrective Action
QAP-9.4-VMI, Test Lab Activity
QAP-14.9-CORP, Internal Corrective Actions

Corrective action data is submitted for management review per **QAP-1.3-CORP, Quality Management System Review.**

Preventive action activities included in the Vernay Quality System are listed below along with references to the QAPs:

A.	Process FMEA	**QAP-2.3-CORP, Advanced Quality Planning**
B.	Process Capability Studies	**QAP-2.3-CORP, Advanced Quality Planning**
C.	Statistical Process Control	**QAP-20.1-VL, SPC and Ongoing Process Capability in Manufacturing** **QAP-20.1-VGR, SPC and Ongoing Process Capability in Manufacturing**
D.	Process Monitoring	**QAP-9.3-VGR, Process Controls**
E.	Proactive Maintenance of Equipment	**QAP-9.1-CORP, Preventive Maintenance**
F.	Proactive Maintenance of Tooling	**QAP-9.4-VL, Tooling Preventive Maintenance** **QAP-9.4-VGR, Tooling Preventive Maintenance** **QAP-9.8-VMI, Tooling Management Activity**

Preventive action data is subject to management review per **QAP-1.3-CORP, Quality Management System Review.**

15. Handling, Storage, Packaging, Preservation, and Delivery

Adequate procedures are in effect for proper handling of the products during their routing in production. Storage of raw materials, compounds, and products are done in designated areas that are adequate to protect them from contamination. The packaging materials and methods of packing provide the required protection of the products during transportation.

Vernay uses an order-driven scheduling system that is computerized and allows for on-line transmittal of advanced shipping notices. Vernay is committed to on-time delivery that will meet customer production and service requirements 100% of the time.

Reference: **QAP-9.8-VGR, Scheduling, Inventory, and Delivery Control**
QAP-15.1-VGR, Handling, Storage, Packaging, and Preservation
QAP-15.1-VMI, Handling, Storage, Packaging, and Preservation
QAP-15.2-VMI, Delivery/Shipping
QAP-9.2-VGR, Environmental Controls

16. Quality Records

Vernay quality records provide critical objective evidence as to the fulfillment of requirements for the products or the Quality System.

These documents are identified by procedure and retained according to customer-specified requirements, when available, or according to the Vernay procedure. Quality records are legible and are stored in a manner to prevent damage, deterioration, or loss.

Reference: **QAP-16.1-VL, Quality Records**
QAP-16.1-VGR, Quality Records
QAP-16.1-VMI, Quality Records

17. Internal Quality Auditing

Vernay has an adequate number of certified internal auditors who are managed by the Quality Systems Engineer. Internal audits are scheduled and performed based on the importance of the activity being audited and are carried out by auditors who are independent of those having responsibility for the activity being audited. Audit nonconformances are corrected in a timely fashion by the management personnel responsible for the area audited. Past due corrective action reports are escalated to the next level of management for follow-up to ensure closure. Effectiveness of the corrective action is determined through follow-up audit activities, when appropriate.

The NA Operations Team reviews the results of internal auditing activities on at least a quarterly basis as a part of the management review process.

Reference: **QAP-1.3-CORP, Quality Management System Review**
QAP-17.1-CORP, Internal Quality Audits

18. Training and Education

Vernay is dedicated to assuring that all employees have the necessary skills and know-how so they can be successful in performing their responsibilities. To do this, skills, knowledge, and/or experience required for each position or job function are periodically evaluated. As a result, training needs are identified, training plans are developed, and training is then budgeted and implemented.

Reference: **QAP-18.1-CORP, Training**

19. Servicing, Installation, Sterilization, and Implantable medical devices

Vernay has a process for communicating information on service concerns to manufacturing, engineering, and design activities. This process involves, but is not limited to, feedback from customer complaints, approval/rejection/deviation of sample/production part submissions, and from sales calls. At this time, it is not part of Vernay's business profile to establish any service agreements, installation agreements, or sterilization agreements with customers. It is also not part of Vernay’s business profile to manufacture any active implantable medical devices or implantable medical devices.

20. Statistical Techniques

Vernay uses statistical methods such as SPC charts, histograms, pareto analysis, design of experiments, sampling, etc., wherever their application helps in the analysis of data or the control / improvement of processes. The advanced quality planning process identifies statistical applications during new product development. There are also some applications that are used by production to help control processes. Statistical sampling techniques are also used widely throughout the production environment.

We believe in the use of statistical techniques by all functional areas including administrative, service, or support functions as well as production.

Reference:
QAP-2.3-CORP, Advanced Quality Planning
QAP-20.1-VL, SPC and Ongoing Process Capability in Manufacturing
QAP-20.2-VL, Standard Sampling Procedures
QAP-20.1-VGR, SPC and Ongoing Process Capability in Manufacturing
QAP-20.2-VGR, Standard Sampling Procedures
QAP-9.4-VMI, Test Lab Activity

21. Production Part Approval Process (PPAP)

Vernay follows all customer requirements regarding the submission of quality documents and samples for customer approval. Changes to approved parts, processes, or materials are controlled by Vernay and submitted for re-approval if required by the customer.

Reference:
QAP-2.2-CORP, Production Part Approval Process
QAP-2.4-CORP, Customer Notification / Approval of Process Change
QAP-6.1-CORP, Purchasing and Supplier Development Activity
QAP-9.2-VMI, Receiving Verification / Raw Materials Inventory
QAP-9.3-VMI, Weigh, Mix, and Mill Activity
QAP-9.4-VMI, Test Lab Activity
QAP-10.2-VGR, Receiving Verification
QAP-10.3-CORP, Annual Recertification

22. Continuous Improvement

The improvement planning process described in section 1.3 of this manual provides a formal, structured approach to continuous improvement. But, this is not the only method used at Vernay. All employees are encouraged and empowered to take risks and try new things. The only caution is that experimenting needs to be done in a controlled fashion so the customer is protected from changes that have not been validated or approved. There are also less formal departmental improvement

strategies employed in each production area. These improvement activities may be aimed at part quality, but often are focused toward cost savings; mistake proofing, reduced rework, and elimination of non-value added steps of the process.

Reference: **QAP-1.2-CORP, North American Business Planning**
QAP-9.5-CORP, Temporary Process Change
QAP-9.13-CORP, Production Trials / Experiments

23. Manufacturing Capabilities

The new product development process includes, when appropriate, a plan for facilities utilization including lean manufacturing concepts such as waste reduction, single minute exchange of dies, mistake proofing, synchronous flow, and value-added use of floor space. Lean manufacturing is also being used in existing production areas to reduce cost and improve quality.

Vernay provides technical support for the design, fabrication, inspection, preventive maintenance, and repair of all molds and dies. Tooling management is accomplished through an organized storage and record system and any work that is sub-contracted is tracked to assure on-time delivery and quality.

Reference: **QAP-9.16-CORP, Process Planning**
QAP-9.4-VGR, Tooling Preventive Maintenance
QAP-9.6-VGR, Tool Management
QAP-9.7-VGR, Identification and Repair of Damaged Cavities
QAP-9.8-VMI, Tooling Management Activity

24. ISO/TS 16949:2009 Conversion Matrix

ISO / TS16949 Clause	Vernay Quality Manual
4 Quality management system (title only)	
4.1 General requirements	2
4.1.1 General requirements - supplemental	6
4.2 Documentation requirements (title only)	
4.2.1 General	2.1
4.2.2 Quality manual	2.1
4.2.3 Control of documents	5
4.2.4 Control of records	16
5 Management responsibility (title only)	
5.1 Management commitment	1.1
5.1.1 Process efficiency	1.4.1
5.2 Customer focus	3
5.3 Quality Policy	1.1
5.4 Planning (title only)	
5.4.1 Quality objectives	1.3, 1.4
5.4.2 Quality management system planning	1.3
5.5 Responsibility, authority, and communication (title only)	
5.5.1 Responsibility and authority	1.6.1, 1.6.2, 1.6.3
5.5.2 Management representative	1.5
5.5.3 Internal communication	1.6.4
5.6 Management Review (title only)	
5.6.1 General	1.4
5.6.2 Review input	1.4
5.6.3 Review output	1.4
6 Resource management (title only)	
6.1 Provision of resources	1.7
6.2 Human resources (title only)	
6.2.1 General	1.7
6.2.2 Competence, awareness, and training	18
6.3 Infrastructure	9
6.3.1 Plant, facility, and equipment planning	9
6.3.2 Contingency plans	9
6.4 Work environment	9
6.4.1 Personnel safety to achieve product quality	9
6.4.2 Cleanliness of premises	9
7 Product Realization (title only)	
7.1 Planning of product realization	2.2
7.1.1 Planning of product realization - supplemental	2.2
7.1.2 Acceptance criteria	2.2
7.1.3 Confidentiality	2.2
7.1.4 Change control	2.2, 4, 5

ISO / TS16949 Clause	Vernay Quality Manual
7.2 Customer-related processes (title only)	
7.2.2 Review of requirements related to the product	3
7.2.1 Determination of requirements related to the product	3, 4
7.2.3 Customer communication	3, 4
7.3 Design and development (title only)	
7.3.1 Design and development planning	4, 21
7.3.2 Design and development inputs	4, 21
7.3.3 Design and development outputs	4, 21
7.3.4 Design and development review	4, 21
7.3.5 Design and development verification	4, 21
7.3.6 Design and development validation	4, 21
7.3.7 Control of design and development changes	4, 5, 16, 21
7.4 Purchasing (title)	6, 10
7.4.1 Purchasing process	6
7.4.2 Purchasing information	6
7.4.3 Verification of purchased product	6, 10
7.5 Production and service provision (title only)	
7.5.1 Control of production and service provision	10, 19
7.5.2 Validation of processes for production and service provision	7,10,11
7.5.3 Identification and traceability	8
7.5.4 Customer property	7
7.5.5 Preservation of product	15
7.6 Control of monitoring and measuring devices	11
7.6.1 Measurement system analysis	11
7.6.2 Calibration/verification records	11, 16
7.6.3 Laboratory requirements	10
8 Measurement, analysis, and improvement (title only)	
8.1 General	10, 20
8.1.1 Identification of statistical tools	20
8.1.2 Knowledge of basic statistical tools	20
8.2 Monitoring and measurement (title only)	
8.2.1 Customer satisfaction	1.8
8.2.2 Internal audit	17
8.2.3 Monitoring and measurement of processes	10, 20
8.2.4 Monitoring and measurement of product	10, 20
8.3 Control of nonconforming product	13
8.3.1 Control of nonconforming product - supplemental	13
8.3.2 Control of reworked product	13
8.3.3 Customer information	13
8.3.4 Customer waiver	13
8.4 Analysis of data	20
8.4.1 Analysis and use of data	20
8.5 Improvement (title only)	14, 22
8.5.1 Continual improvement	22
8.5.2 Corrective action	14
8.5.3 Preventive action	14

25. ISO 13485:2003 Conversion Matrix

ISO 13485 Clause	Vernay Quality Manual
4 Quality management system (title only)	
4.1 General requirements	2, 6
4.2 Documentation requirements (title only)	
4.2.1 General	2.1
4.2.2 Quality manual	2.1
4.2.3 Control of documents	5
4.2.4 Control of records	16
5 Management responsibility (title only)	
5.1 Management commitment	1.1
5.2 Customer focus	3
5.3 Quality Policy	1.1
5.4 Planning (title only)	
5.4.1 Quality objectives	1.3, 1.4
5.4.2 Quality management system planning	1.3
5.5 Responsibility, authority, and communication (title only)	
5.5.1 Responsibility and authority	1.6.1, 1.6.2, 1.6.3
5.5.2 Management representative	1.5
5.5.3 Internal communication	1.6.4
5.6 Management Review (title only)	
5.6.1 General	1.4
5.6.2 Review input	1.4
5.6.3 Review output	1.4
6 Resource management (title only)	
6.1 Provision of resources	1.7
6.2 Human resources (title only)	
6.2.1 General	1.7
6.2.2 Competence, awareness, and training	18
6.3 Infrastructure	9
6.4 Work environment	9
7 Product Realization (title only)	
7.1 Planning of product realization	2.2, 4, 5
7.2 Customer-related processes (title only)	
7.2.1 Determination of requirements related to the product	3, 4
7.2.2 Review of requirements related to the produce	3, 4
7.2.3 Customer communication	3, 4
7.3 Design and development (title only)	
7.3.1 Design and development planning	4, 21
7.3.2 Design and development inputs	4, 21
7.3.3 Design and development outputs	4, 21
7.3.4 Design and development review	4, 21
7.3.5 Design and development verification	4, 21
7.3.6 Design and development validation	4, 21
7.3.7 Control of design and development changes	4, 5, 16, 21

7.4 Purchasing (title)	6, 10
7.4.1 Purchasing process	6
7.4.2 Purchasing information	6
7.4.3 Verification of purchased product	6, 10
7.5 Production and service provision (title only)	
7.5.1 Control of production and service provision	9, 10
7.5.1.1 General Requirements	9, 10
7.5.1.2 Control of production and service provision – Specific requirements	
7.5.1.2.1 Cleanliness of product and contamination control	9, 15
7.5.1.2.2 Installation activities	n/a (19)
7.5.1.2.3 Servicing activities	n/a (19)
7.5.1.3 Particular requirements for sterile medical devices	n/a (19)
7.5.2 Validation of processes for production and service provision (title only)	
7.5.2.1 General Requirements	7, 10, 11
7.5.2.2 Particular requirements for sterile medical devices	n/a (19)
7.5.3 Identification and traceability (title only)	
7.5.3.1 Identification	8
7.5.3.2 Traceability (title only)	
7.5.3.2.1 General	8
7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices	n/a (19)
7.5.3.3 Status Identification	8
7.5.4 Customer property	7
7.5.5 Preservation of product	15
7.6 Control of monitoring and measuring devices	11, 16, 10
8 Measurement, analysis, and improvement (title only)	
8.1 General	10, 20
8.2 Monitoring and measurement (title only)	
8.2.1 Feedback	1.8
8.2.2 Internal audit	17
8.2.3 Monitoring and measurement of processes	10, 20
8.2.4 Monitoring and measurement of product	10, 20
8.2.4.1 General requirements	10, 20
8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices	n/a (19)
8.3 Control of nonconforming product	13
8.4 Analysis of data	20
8.5 Improvement (title only)	14, 22
8.5.1 Continual improvement	22
8.5.2 Corrective action	14
8.5.3 Preventive action	14