



**VNA Business Management System
Supplier Quality Manual**

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Approvals:

Manager, Quality Systems/Improvements NA
Purchasing Manager



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Overview

Purpose of Manual

The purpose of this manual is to communicate the requirements and expectations of all North American facilities of Vernay Laboratories, Inc. and Vernay Manufacturing to our partners—our suppliers. The demand for excellence, combined with a close working relationship, will enable us both to continuously improve and become a world-class supply base to all of our customers.

This manual is divided into six main sections. The first section reviews the purpose of the manual, the Vernay supplier development philosophy, the approval of the manual, and the manual change procedure. The next three sections explain our pre-production, sample submission, and production requirements. The fifth section of the manual describes Vernay's expectations on continuous improvement and how we will monitor the progress being made by our key suppliers. The final section of the manual details the revision records.



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Vernay Supplier Development Philosophy

The Vernay Mission Statement identifies our suppliers as one of five stakeholders and states Vernay will **“provide suppliers with the opportunity for long-term commitment and mutually beneficial relationships.”** Our Quality Policy states **“Vernay is committed to the highest level of quality and service. We focus on continual improvement and innovation in all areas of our business and accomplish these goals through our quality system.”** These documented statements confirm Vernay’s commitment to both our suppliers and our customers.

Vernay supplies products and services to customers in the automotive, speciality, and medical markets. Many of these customers are now recommending, and in some cases requiring, that we use designated quality system standards, including ISO/IATF 16949 and Quality System Regulation (QSR). As a result, we have adopted these standards and have developed a quality system that is in compliance with them.

The automotive standard ISO/IATF 16949 requires that Vernay use these standards as our “fundamental quality system requirement” for the development of our suppliers. We believe these standards are fundamentally sound and any organization can benefit from them if properly used. Vernay will be using the ISO/IATF 16949 goal of supplier conformity for future assessment of current and potential suppliers. The prioritization of suppliers for development depends upon the supplier's quality performance and the importance of the product supplied.

Vernay is internally organized to support and work with suppliers. Purchasing plays a key role in the quality system and handles all commercial issues; the chemists, new product development engineers, and quality engineers work with suppliers on new materials and products. The Manager QS/I NA is responsible for quality assessment and the Quality Engineers coordinate receiving inspection activities.

Product-specific quality and performance is dependent on a pre-production preparation process to prevent issues and a post-production process to resolve issues and prevent repeat occurrences. This manual is organized to clearly define expectations in each area.



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Manual Change Procedure

This manual is included as a part of the Vernay Quality System documentation and is controlled per BMP-7.5.3-VNA Control of Documented Information BMP .

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

A copy of this manual is also posted electronically at www.vernay.com/misc.html. Suppliers, both current and potential, are expected to review this manual to ensure compliance to the stated requirements. Approved suppliers will be notified of changes to this manual; however, hard copies of the manual will not be distributed or otherwise maintained.



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AIAG Reference Manuals

All Vernay suppliers should maintain copies of, and use as a guideline, the following manuals from the Automotive Industry Action Group (AIAG). Vernay's requirements are based on either the ISO/IATF 16949 Standard or the referenced manuals.

- Advanced Product Quality Planning and Control Plan (APQP)
- Failure Mode and Effects Analysis (FMEA)
- Statistical Process Control (SPC)
- Measurement Systems Analysis—MSA (Gage R&R)
- Production Part Approval Process (PPAP)
- Quality System Assessment (QSA)
- Quality System Requirements (QS-9000)
- ISO/IATF 16949

Copies of these manuals can be obtained from:

Automotive Industry Action Group
26200 Lahser Road, Suite 200
Southfield, Michigan 48034

Telephone: (248) 358-3570
Fax: (248) 358-3253

Advanced Quality Planning

Advanced Quality Planning (AQP) describes the methodology and tools that help prepare a team to design and launch a product at planned performance levels. The major elements of AQP are described in this section of the manual. (Refer to the Advanced Product Quality Planning and Control Plan Manual available from AIAG.)

Process Flowchart

The process flowchart is an AQP tool that should be created early in the design process to depict the anticipated manufacturing process for a product. It is a visual approach to describing and developing sequential or related work activities. It provides a means of communication and analysis for planning, development activities, and manufacturing processes.

Process flowcharts are required for all custom components.

Failure Mode and Effects Analysis (FMEA)

The Failure Mode and Effects Analysis (FMEA) is a tool used in both the design and process preparation stages to hypothesize and risk-rank what might go wrong to affect the product. Pro-active work can then be done to prevent potential issues from occurring. (Refer to the Failure Mode and Effects Analysis Manual available from AIAG.)

Process FMEA is required for all custom components.

Product Technical Requirements

Vernay is responsible for clearly communicating our requirements for each purchased compound or component. The Buyers fulfills this requirement by sending copies of internally controlled drawings or specifications to the supplier or by stating the requirements on the purchase order. Vernay Quality personnel may communicate additional requirements.

The supplier, working closely with Vernay, is responsible for ensuring that:

- The latest drawing or specification is on-site at the supplier.
- The product being shipped represents the proper engineering change level.
- The drawing or specification does not conflict with the control plan (if applicable).
- A Vernay deviation is in place whenever there is a discrepancy between the products being shipped and the drawing or specification.

Special Characteristics Designation

Special characteristics are product characteristics that have been identified because they are particularly important to the safe operation of the customer's product, their impact on form, fit, or function, or their effect on Vernay's or the customer's manufacturing process.

Vernay uses the following two levels of special characteristic designations as identified on the drawing by an oval shape around the characteristic with a one (1) or two (2) inside it.

- **Critical:** The number one (1) inside the oval means the process capability must meet or exceed a Ppk of 1.67 for process potential studies and a Cpk of 1.33 for ongoing process capability. Statistical process control charts for these characteristics is required and they must be addressed on the control plan.
- **Control:** The number two (2) inside the oval means the control of the characteristic must be addressed on the control plan. No specific capability requirements apply to control characteristics beyond the need to meet specifications.

Control Plans

Vernay requires the development of a control plan for all custom-made components (developed after January 1, 1994) provided by our suppliers. The purpose of the control plan is to aid in the manufacture of quality products by providing a structured approach for the design, selection, and implementation of value-added control methods. A control plan provides a written summary description of the systems used in minimizing process and product variation, and for the detection of non-conformities and the prevention of unacceptable product from being supplied to Vernay. Control plans are meant to be living documents so they must be maintained throughout the life of the product. Vernay must be notified for approval of any change to control plans for custom-made components prior to shipment of product produced under the change.

The supplier is required to document the control plan methodology using the Automotive Industry Action Group (AIAG) form or any other form with equivalent information. (Refer to the Advanced Product Quality Planning and Control Plan Manual available from AIAG).

Process Capability and Gage R&R

A capability assessment is required for special characteristics designated as "critical." All capability assessments must initially begin with gage repeatability and reproducibility study (gage R&R) to assure that the measurement system provides meaningful data. (Refer to the Measurement Systems Analysis Manual (MSA) available from AIAG.) Vernay requires a gage R&R not to exceed 30% of tolerance for all critical characteristics.



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Before capability can be meaningfully expressed using an index such as Ppk or Cpk, the stability of the process must be demonstrated. A capability run includes the use of a control chart for assessing stability and should be sufficient in length to collect enough time ordered samples for at least 25 subgroups of 5 pieces each.

Once the measurement system has been analyzed, found to be acceptable, and process stability demonstrated, capability can then be calculated. Vernay requires a critical characteristic capability of $Ppk \geq 1.67$ and $Cpk \geq 1.33$. (Refer to the Production Part Approval Process Manual and Fundamental Statistical Process Control Manual available from AIAG for a more complete description of capability assessment methodology.)

Packaging Instructions

Any special packaging requirements for our products will be mutually developed and initially agreed upon by Vernay and the supplier during the pre-production stage. These requirements will be carried forward to production and will be called out on purchase orders or otherwise documented by Purchasing. Any changes to these requirements will require advanced mutual agreement between Vernay and the supplier. The supplier must adhere to these requirements to prevent contamination or damage during handling and shipment.



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Sample Submission

Vernay has adopted the Production Part Approval Process (PPAP) as its requirement for sample submission. Level 3 is the default submission level for all custom-made components. As part of the level 3 requirements, a material report may be required with each PPAP submission. Any modifications to these requirements must be approved in advance by Quality Engineering for new products or existing production products or processes.

Sample submissions are required for new products and before changes are made on existing products or processes. All suppliers are required to notify Vernay Purchasing in advance of product or process changes. This includes changes in form, chemical changes, changes in the manufacturing process, changes in the sequence of the process, changes in sub-contractors, changes in manufacturing location, and any other change that can affect Vernay's or our customer's manufacturing process or the form, fit, or function of the custom-made component or compound, including the durability of the end product. Vernay encourages continuous improvement and recognizes that change is necessary to obtain improvement. Vernay will work with the supplier to quickly qualify the change whenever possible; recognizing that any such change may also require our customer's approval.

Many Vernay customers require periodic PPAP submissions. Where this is a requirement or where deemed otherwise important to Vernay, the supplier will be required to periodically submit a PPAP and samples per the PPAP Manual.



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Certification Requirements

Raw material and compound suppliers are required to submit a certification with test data that verifies the material meets the purchasing specification. Vernay requires the certification for each receipt.

Suppliers of custom-made components are required to provide material certifications on an as requested basis.

Notification of Change Requirements

This procedure applies to specific suppliers defined as those whom provide “engineered” components or compounds to Vernay. This includes providers of metal and/or plastic inserts or services which are defined by a Vernay print and/or specification. It also would include providers of compounds where Vernay provides specific formulations and/or specifications.

Vernay Laboratories, Inc provides components into the Automotive and Medical market place where very strict policies are in place relative to any product changes. Many of these end products and devices are registered and regulated by various Government agencies and very little leeway is provided for exceptions to those policies. Failure to adhere to their requirements may lead to discontinuation of the business relationship. It must be noted that many of our customers not in these specific markets are adopting the same practices.

Each manufacturer is responsible for exercising control over its suppliers and each supplier to its sub-contractors. Specifically, it is essential that changes proposed by suppliers or sub-suppliers are communicated in writing and approved prior to implementation of the change. These changes include: material or process changes which may affect form, fit or function, reliability, serviceability, performance, approved part quality plans, functional interchangeability, regulatory compliance, safety or options or spare parts interchangeability. This may include but is not limited to: changes of sources of materials or parts: changes in manufacturing processes, tooling, test procedures, manufacturing locations, relocation or displacement of equipment and or any similar changes that are anticipated by suppliers or sub-suppliers. No such change will be made without Vernay’s prior written consent. .

As Vernay and our customers are required to validate these changes to assure specific requirements will continue to be met, the change request must be accompanied by an appropriate validation test program or rationale. Changes must be announced sufficiently in advance of implementation such that all validation studies can be conducted. The minimum time-frame for these notifications is 1 year as many re-qualifications can take up to a year.

Change notifications and appropriate validation documentation if available are to be submitted to Vernay Purchasing, NA



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Nonconforming Material Reporting

Timely reporting and resolution of quality problems is critically important, especially as we decrease our inventory levels and move toward just-in-time delivery systems. Vernay expects our suppliers to deliver 100% conforming product at all times; however, we understand that quality problems sometimes occur. How we react to those problems is very important. We must work together to resolve them promptly and effectively.

When nonconformances are detected, whether at receiving, in process, or in application, the Quality Engineer will notify the supplier and issue a Nonconforming Material Report (NMR). If it is necessary to return the product, the Quality Engineer will request authorization to do so.

Each issued NMR requires written corrective action by the supplier. The use of 8D or similar problem-solving methods is recommended and in some cases may be required. The supplier is requested to communicate frequently during the resolution of the problem, at the minimum including information on containment, root cause analysis, and effective corrective and preventive action.

Vernay will issue an NMR for any failure to meet our requirements, including problems with labeling, certifications, packaging, and product problems. An effective corrective action system prevents problems from recurring, so we must be persistent and thorough in resolving quality problems. The Quality Engineer will follow-up to assure corrective action responses are received, verified to be effective, and the NMR is closed.

Based on the severity and urgency of the quality problem, the Quality Engineer will determine appropriate corrective action response times and document those dates on the NMR.

Vernay monitors the number of supplier quality problems. An excessive number of problems or poor responses can lead to removal from the Approved Supplier List.



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Supplier Assessments

The Manager QS/INA and Purchasing Manager determine the appropriate type of assessment for potential new suppliers, which may include an on-site audit, a self-assessment, a technical assessment by our Laboratory or engineering or other options as appropriate. Vernay may not require a full self-assessment from those suppliers who are ISO 9000 and/or ISO/TS 16949 certified.

Assessments for ongoing suppliers will be based on the Quality System Assessment (QSA) Manual published by AIAG. In some cases, suppliers may be requested to complete a self-assessment on a periodic basis. For suppliers of some critical products or those with repetitive quality problems, on-site assessments may be necessary.

Second party audits are utilized to fulfill duties within the supplier management spectrum. Their duties may include but aren't limited to: supplier assessment, supplier monitoring, supplier development, product audits and process audits. The frequency of Second Party Audits is: Tier 1 suppliers – One audit every 3 years due to their compliance to ISO 9001 or IATF 16949 certifications. Tier 2 and Tier 3 Suppliers for cause per our Vernay Vendor Score Card Rating. A second party audit will be warranted if any vendor scores a 2 or lower.

Vernay maintains an Approved Supplier List. The approved supplier list is reviewed and updated quarterly. A supplier is selected from this list when Vernay issues a purchase order for a production item. A supplier may be removed from the Approved Supplier List for unsatisfactory performance or for other business reasons. Chronic quality problems, poor delivery performance, pricing issues, ineffective problem resolution, or lack of compliance with the requirements of this manual may also lead to removal of the supplier from the Approved Supplier List.

Continuous improvement is an integral part of our supply base philosophy. Without improvement activities, quality levels cannot improve and costs eventually threaten the competitive position of any organization. Plans for improvement should be pursued and the supplier should be able to demonstrate the results of past continuous improvement activities.

On-site assessments of current suppliers will include the applicability and effectiveness of the supplier's quality system, adherence to production control plan(s), and a review of quality issues and continuous improvement activities.

Product Quality Measurement System

Vernay monitors defective parts for suppliers of custom-made components. Vernay will issue Nonconforming Material Reports as appropriate (see the "Nonconforming Material Reporting" section on page 11).

Delivery Measurement System

Vernay monitors on-time delivery for suppliers of custom-made components.



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Vernay expects 100% on-time delivery from all suppliers.

Production Process Review

Vernay expects suppliers to be diligent in following a highly specified process. The AQP process defined in the AIAG manual contains a methodology to achieve the required process definition.

Process reviews or audits provide a means to verify the process is operating as designed and documented. To assure the actual process used to make Vernay products are in agreement with the documented process design (Process flow, FMEA, Control Plan, Work Instructions, Specifications, etc.), Vernay may request a Level 1 PPAP resubmission. The supplier is required to submit the PPAP and supply any updated/corrected documents for approval.

Vernay may visit suppliers to verify compliance to the documented manufacturing process.



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Rev --	Original, 08/20/96, Ken Weaver
Rev A	Revised, 11/26/96, Rodger Adkins
Rev B	Revised, 04/26/99, Ken Weaver & Rodger Adkins
Rev C	Changed, 01/28/00, Ken Weaver (Rev Class II)
Rev D	Changed, 08/20/01, Ginny Grooms (Rev Class II)
Section A	Replaced Purchasing Manager with Materials & Logistics Manager, added ISO/TS 16949 as a quality system standard used by Vernay, added Vernay will be using the QS-9000 "goal of subcontractor compliance" for future assessment of current and potential suppliers with minimum subcontractor compliance shall be certification by an accredited certification body to a current version of the ISO 9000 Quality Management Series of Standards (excluding ISO 9003), plus any additional requirements specified by the customer.
Section D	Deleted Quality Support / Technician notifies supplier by phone
Section E	Replaced Purchasing Manager with Materials & Logistics Manager, added ISO/TS 16949 certification as a basis for not requiring a self-assessment
Rev E	Changed, 11/08/05, Corinne Scott (Rev Class II) Changed sign-off cover sheet to electronic approval tracking page; replaced Director of Quality with Manager, QS/I NA (also throughout document); replaced VP&GM NA with Materials Manager and Purchasing Manager; adjusted the page numbers to reflect the elimination of blank/unused sections
Section A	Changed Purpose from Vernay Laboratories, Inc. to all North American facilities; updated the Quality Policy statement; deleted all references to QS9000 as being the basis for this manual (also throughout document); changed "subcontractor" to "supplier;" changed "Quality Support / Technician" to "Quality Engineers" (also throughout document); changed QAP-2.1-VL to QAP-2.1-CORP; added section concerning electronic approval and tracking; changed statement about controlled copy distribution to that of copies may be sent to suppliers.
Section C	Changed the approval responsibility of changes to existing production products or processes from the Director of Quality to the Quality Engineer.
Section D	Deleted the statement concerning the faxing of test certifications to the QS/T
Section E	Changed section on Product Quality Measurement System from " For suppliers of custom-made products, Vernay tracks defective parts per million (DPPM) and provides a quarterly report. Nonconforming product is charged against receipts based on the actual number nonconforming, the sample inspection data, or 10% for in-process problems if the percent is not known. If the percent is not known when a lot is rejected and returned, it is counted as 100% unless the supplier reports the actual number or percentage back to Vernay." Deleted from section on Delivery Measurement System that monthly reports are sent; changed Vernay expects "100% on-time" delivery to "on-time" delivery. Changed Production Process Review section to state that Vernay "may" send a process review questionnaire and "may" periodically visit suppliers.



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Rev F	Changed, 1/10/2009, Cheryl Nadzam (Rev Class II)
Section A	<p>Changed goal of supplier from compliance to conformity to ISO/TS 16949. Deleted minimum supplier compliance requirement for certification level and type. Added prioritization criteria for supplier development.</p> <p>Changed the title of the position responsible for publishing manual. Changed the method for notifying suppliers of changes to the Supplier Quality Manual and format it is available in, adding an electronic address for accessing current revision. Eliminated distribution and maintenance of hard copies</p>
Section B	<p>Changed wording from custom-made parts to custom-made components in Process flow, FMEA, Product Technical Requirements, and Control Plans requirements.</p> <p>Added impact on form and effect on customer's manufacturing process to list of items to be considered when establishing special characteristics.</p> <p>Changed SPC charting from recommended to required for Special Characteristics designated as Critical.</p> <p>Added clarifying statement for Special characteristics designated as Control indicating that capability requirements do not go beyond the need to meet specifications.</p> <p>Expanded purpose of Control Plan to include detection of non-conformities and the prevention of unacceptable product being shipped to Vernay. Included requirement for notifying Vernay of any change to control plans for custom-made components prior to shipment.</p> <p>Added Gage R&R requirement not to exceed 30% of tolerance for all critical characteristics.</p> <p>Added to Packaging Instructions requirements that any changes require advanced mutual agreement between Vernay and the supplier.</p>
Section C	<p>Changed wording from custom-made parts to custom-made components in Sample Submission requirements.</p> <p>Changed the requirements for a material report to accompany a Level 3 PPAP from required for each sample submission to may be required with each PPAP submission.</p> <p>Expanded list of changes requiring customer (Vernay) notification to include those that can impact our customer's manufacturing process or the form, fit, or function of the custom-made component or compound, including the durability for the end product.</p> <p>Expanded the requirements related to periodic PPAP submissions required by customers to include those deemed otherwise important to Vernay.</p>
Section D	<p>Changed Certification Requirements to include compound suppliers.</p> <p>Changed frequency of certification receipt from each receipt to each lot.</p> <p>Changed wording from custom-made parts to custom-made components in Certification Requirements.</p> <p>Expanded Nonconforming Material Reporting expectation to include prompt as well as effective quality problem resolution.</p> <p>Added in application to list of when nonconformities may be detected.</p> <p>Changed requirement for use of 8D or other problem-solving method to 8D or similar problem solving method.</p>



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- Section E
- Specified that the QE is to follow-up to assure verification of effectiveness of corrective action and closure of NMR's.
- Changed the wording from tracks to monitors the number of supplier quality problems.
- Changed wording for when full self-assessment is not required from will not to may not be required for those suppliers who are ISO 9000 and/or ISO/TS 16949 certified.
- Clarified when periodic self-assessments and on-site may be necessary or required.
- Added to conditions for removal from Approved Supplier List the wording, "or for other business reasons".
- Added pricing issues to the list of chronic conditions, which may lead to removal from the Approved Supplier List.
- Changed Continuous Improvement requirements from "must be" to "is" an integral part of our supply base philosophy. Also changed the requirements for plans for improvement from "must exist" to "should be pursued".
- Product Quality and Delivery Measurement System requirements changed from "tracks" to "monitors" "select "suppliers to "suppliers of custom-made components"
- Added 100% to on-time delivery expectation for all suppliers.
- Changed Production Process Review from sending out process review questionnaires to requesting Level 1 PPAP re-submission.
- Changed purpose of supplier visits from verifying compliance to completed questionnaire and corrective actions to compliance to documented manufacturing process.
- Rev G** Changed, 10/21/2010, John Livasy (Rev Class II)
- Section D Added Notification of Change Requirements
- Attachments Added Notification of Change Requirements Letter
- REV H Changed 06/02/2017 John Etheredge (Rev Class II)
Section E: Add verbiage regarding second party audits - Ref IATF section 8.4.2.4.1
- Rev I Changed, 01/26/2018, Odiri Ukuedojor (Rev Class II)
Updated Supplier Assessment section to include the following; The frequency of Second Party Audits is: Tier 1 suppliers – One audit every 3 years due to their compliance to ISO 9001 or ITAF 16949 certifications. Tier 2 and Tier 3 Suppliers for cause per our Vernay Vendor Score Card Rating. A second party audit will be warranted if any vendor scores a 2 or lower.

Attachments

[Notification of Change Requirements Letter](#)



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