PRECISION MEASUREMENTS, INC.	INTERNAL CORRECTIVE AND PREVENTIVE ACTION	QA-1414	Rev. 010
		Page 1 of 6	
APPROVALS	PRINT/SIGNATURE	ORIGINAL ISSUE	
ORIGINATOR	Robert Bahrs /	05/02/96	
PRESIDENT	Richard Ayala /	05/02/96	
MANAGEMENT REP.	Carlos Valdez /	05/02/96	
QA MANAGER	Robert Bahrs /	05/02/96	
DOC. CONTROL	Robert Bahrs /	05/02/96	

REVISION NO.	DESCRIPTION	DATE	PREPARED BY	APPROVED BY
001	Alignment to ANSI/ASQC Q9002-1994	01/31/97	R. Bahrs	CB
002	Update to expand detail of Preventive Action process.	09/30/97	R. Bahrs	CB
003	Revision to include referencing the ICAR Log form and the responsibility for maintenance of the form.	05/20/99	R. Bahrs	CB
004	Revision to clarify closure process and to specify limit for closing in ICAR (6.3 through 6.3.9).	10/20/00	R. Bahrs	CB
005	Revision to clarify responsibility, certain procedural steps, escalation (Sec. 6.3), Source information for Preventive Action and delete Addendum reference to Customer Feed back actions.	03/27/01	R. Bahrs	CB
006	Revision to establish ICAR response time limit. (6.3)	03/15/02	R. Bahrs	CB
007	Revision to more clearly outline preventative action (6.4)	01/10/03	R. Bahrs	CB
008	Addition of reference to the ISO standard	11/21/03	P. Kirsch	R. Ayala
009	Clarified 5.3.2.6 – ICAR Issue for Major discrepancies.	03/24/05	P. Kirsch	R. Ayala
010	Revised 6.2.3 to align it with section 9.2.2 e) of ISO 9001.	5/24/23	F. Loza 5/24/23	R. Ayala 5/24/23

INTERNAL CORRECTIVE AND PREVENTIVE ACTION

1.0 PURPOSE

1.1 To establish and maintain a systematic action process to address actual and potential PMI product quality, and/or Quality System nonconformities.

2.0 SCOPE

2.1 This procedure details the Internal Corrective and Preventive Action program in place at PMI to address product nonconformance issues which affect the ability of PMI to meet its quality goals and commitment. The elements of this program are as follows:

2.1.1 Identifying and classifying nonconformance.

2.1.2 Effective and timely documentation of nonconformance issues.

2.1.3 Effective resolution and follow-up of all product nonconformance issues.

2.1.4 Prevention of nonconformance recurrence.

2.1.5 Monitoring effectiveness of corrective actions.

2.1.6 Maintenance and retention of **ICAR** (nonconformance) history files.

2.1.7 Identification of potential nonconformities and implementation of required Preventive Action.

3.0 RESPONSIBILITY

3.1 The Quality Assurance (QA) Department is responsible for; and has the authority for the implementation and enforcement of the process outlined in this procedure.

3.2 QA is responsible for the maintenance of records relative to the Internal Corrective and Preventive Action Process.

3.3 The respective Functional and/or Department Managers or Supervisors are responsible for the timely response to **ICARs** addressed to them and the implementation of Corrective and Preventive Actions required.

3.4 Functional Managers / Supervisors are responsible for identifying the need for Preventive Action(s), and initiating process changes to effect the necessary Preventive Action(s).

4.0 REFERENCES

4.1 ISO 9001 (latest edition)

4.2 Quality Assurance Manual: QA-2000

4.2 Internal Corrective Action Request (ICAR): PM-CAR107

4.3 ICAR Log: PM-ICAR001

4.4 Internal Corrective Action Request: QAP-1114

4.4 Customer Feedback Process: QAP-0314

4.6 Control of Nonconforming Product: QA-0413

4.7 Inspection and Testing: QA-0410

5.0 DEFINITIONS

5.1 Originator: The individual initiating an Internal Corrective Action Request.

5.2 Resolver: The individual responsible for implementing corrective action to address the nonconformity.

5.3 Product Nonconformance: A discrepancy in the PMI service process, which adversely affects (or has potential for adversely affecting) PMI product (service) quality. Such discrepancies are classified as either **Minor** or **Major**.

5.3.1 **Minor** discrepancies are nonconformities of a non-repetitive nature, and include incorrect product identifying information, incorrect or insufficient service processing or service data, and product mislabeling, any (or all) of which are identified and corrected prior to product release.

*NOTE: Minor discrepancies do not require an **ICAR,** unless of a repetitive nature, as determined by the QA Manager.*

5.3.2 **Major** discrepancies include:

5.3.2.1 Repetitive service nonconformance identified during the Final Inspection Process.

5.3.2.2 Failure to follow documented procedures.

5.3.2.3 Failure to meet customer contractual requirements.

5.3.2.4 Customer feedback and complaints indicative of Quality System noncompliance.

5.3.2.5 Quality System noncompliance identified during an internal audit.

5.3.2.6 Mishandling of customer equipment including pick-up and delivery discrepancies.

*Note: **Major** discrepancies require an **ICAR** processing and closure.*

5.4 Internal Corrective Action Request **(ICAR):** The document used to initiate the resolution of any **Major** service quality issue, as defined (above), and to document a plan to prevent recurrence of the quality discrepancy. Any **ICAR** requires follow-up and closure by QA.

5.5 Preventive Action: Any action taken to eliminate a potential cause of a service quality nonconformity, or to identify and address a Quality System process which has potential for causing a product nonconformance.

6.0 PROCEDURES

6.1 Action(s) taken to correct, track, and prevent recurrence of **Minor** discrepancies (product nonconformance) are as follows:

6.1.1 **Minor** discrepancies are documented and corrected by either the individual responsible for the discrepancy or the QC Inspector prior to product release

6.1.2 The QA Manager reviews and analyzes Final Inspection Reports to identify repetitive discrepancies.

6.2 Action taken to correct, track, and prevent recurrence, of **Major** quality discrepancies is initiated by the generation of an **ICAR.**

6.2.1 An **ICAR** may be initiated by any employee identifying a quality discrepancy as defined herein.

6.2.2 An **ICAR** may be initiated because of customer complaint issues according the PMI Customer Feedback Process.

6.2.3 **ICAR(s)** are initiated by the PMI Internal Audit Team, without undue delay, for system and/or significant procedure vs. process discrepancies.

6.2.4 QA issues **ICAR (s)** for discrepancies classified as **Major** according to Final Inspection Report analysis.

6.3 Internal Corrective Action Request Process Outline and (Responsibility):

6.3.1 Identify and report the discrepancy through submittal of the **ICAR** to Quality Assurance *(originator).*

6.3.2 Determine severity of quality impact of the discrepancy, and whether resolution can take place and be effective by means other than through **ICAR** process *(Quality Assurance).*

6.3.3 Logging the ICAR on the ICAR Log form.

6.3.4 Establish the **ICAR** Response Due date *(Quality Assurance)*.

6.3.4.1 Response to the ICAR with the Corrective/Recurrence Prevention plan is due back to QA within five (5) working days unless indicated as sooner (on the ICAR).

6.3.5 Maintain records (copies) of open **ICAR(s)** *(Quality Assurance)*.

6.3.6 Forward the **ICAR** to the manager or supervisor of the Function (department) responsible for the discrepancy *(Quality Assurance)*.

6.3.7 Review of the ICAR response to evaluate the proposed corrective action and plan to prevent recurrence *(Quality Assurance)*.

6.3.7.1 Unsatisfactory or ambiguous responses are referred back to the responder for clarification and re-submittal.

6.3.7.2 Any ICAR not responded to within a maximum of ten (10) working days following the indicated Response Due Date is escalated to Executive Management for follow-up action.

6.3.8. Follow-up and verification that corrective action has taken place and that a preventive action plan has been implemented to prevent recurrence, and determined to be effective *(Quality Assurance)*.

6.3.8.1 Corrective and preventive actions not carried out according to the proposed plan or found to not be effective in addressing the issue(s) is either addressed directly by the QA Manager or referred to Executive Management.

6.3.8.2 Closure and filing of completed and satisfactorily addressed **ICARs** and annotating the ICAR Log indicating closure *(Quality Assurance)*.

6.4 Preventive Actions are implemented to identify potential nonconformities and prevent Occurrence and may be proposed by any PMI employee. Sources of information utilized to determine the need for Preventive Action include, but not necessarily limited to:

- Inspection and/or Test Records
- Audit Observations
- Results of Customer Satisfaction Surveys
- Customer Complaints
- Observations by staff personnel

- Supplier / Vendor Problems

6.4.1 Proposed Preventive Actions are documented and forwarded to Management for review and analysis.

6.4.2 Management determines if the proposed Preventive Action is appropriate, and if so, determines the methodology to effect implementation.

6.4.3 The Preventive Action is implemented, all affected personnel notified and the applicable documented procedure updated or initially written, as appropriate; and made available according to the PMI Controlled Document process.

6.4.4 Following implementation, the results of the Preventive Action is evaluated and verified for effectiveness. The period for this verification is approximately 90 days, or as needed.

6.4.5 Relevant information as to the effectiveness of each Preventive Action is reviewed as part of the next Management Review meeting.

7.0 ADDENDUM

7.1 Each Internal Corrective Action Request (**ICAR**) Form shall be numbered according to the following format and dated:

year - number (sequential)

(yy - xxx)

7.2 Instruction for **ICAR** Form initiation, routing, completion, filing and closure is contained in QAP- 1114.