THERMALOGIC CORPORATION

QUALITY ASSURANCE MANUAL

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Chief Executive Officer: Jeremy H. DuBois

President: Joe Grein

Quality Assurance Manager: Ralph Tenaglia

THERMALOGIC

QUALITY ASSURANCE MANUAL

TABLE OF CONTENTS

A. OBJECTIVES OF THE QUALITY ASSURANCE DEPARTMENT

A-1 GENERAL

The Quality Assurance Department is maintained and supervised by the Quality Assurance Manager, who reports to the President. This manual has been prepared under the direction of the Quality Assurance Manager. The manual will be reviewed periodically and, if necessary, changed and updated at intervals no larger than 6 months. The THERMALOGIC Quality Assurance Department is organized and administered to assure uniform high quality in all products. All items produced by THERMALOGIC or procured from outside sources are subject to inspection, test and/or other quality assurance procedures to assure maintenance of the required high quality level.

A-2 SPECIFIC

It is the objective of the THERMALOGIC Quality Assurance Department to:

1. Assure the highest quality at the lowest cost for all products;
2. Insure that all customer requirements are complied with;
3. Reduce the rejection rate of material at all levels;
4. Reduce the cost of Quality;
5. Insure that the Reliability of all products meet customer requirements to promote the reputation of THERMALOGIC in the industry.

To insure that the above objectives are achieved , the Quality Assurance Department is responsible for the following functions:

1. Prepare inspection planning documents and Quality Assurance procedures;
2. Verify company adherence to test, engineering, manufacturing, and government or customer specifications and contracts;
3. Prepare and institute necessary paperwork used in the above;
4. Obtain prompt, effective corrective action of any condition that may lead to the production of defective material;
5. Make periodic oral and written reports to

THERMALOGIC's management of the quality trend of products, mentioning significant factors that may tend to affect quality;

6. Maintain Quality Assurance surveillance of operational tests and test equipment;

7. If a unit fails the test procedure, a reject tag is put on by the test technician. When all the units of a manufacturing batch are completely tested, then all rejected units if any, are verified for failure by Quality Assurance. If found defective, the unit is sent back for rework. Q.A. checks the reworked unit against the test procedure, at this point the reject tag is removed by Q.A. if the unit works correctly;

8. Maintain liaison between the Quality Assurance Department and THERMALOGIC departments;

9. The Quality Assurance Department responsibilities relate to the six functional tasks listed below. Details of the procedures are listed in subsequent sections of the Quality Assurance Manual;

    a. Document Control Procedures

    b. Purchasing Procedure

    c. Receiving Inspection Procedure

    d. In-Process Procedure

    e. Final Inspection Procedure

    f. Facilities and Test Equipment Maintenance Procedure.

A-3 Document Control Procedures

All Documents generated for Engineering or Production will have a category number which is encompassed by Thermalogic's Part Numbering System.

Since all documents are generated by Engineering, the Engineering Manager will issue or oversee the documentation numbering or revision number.

On Engineering notification/modification issues, the Engineering

Manager will note all the changes or corrective actions in a formal Engineering memo, which will be circulated to Management, Production and Quality Assurance.

Production notification/modification issues are formally noted by the V. P. of Manufacturing and circulated to the same above departments.

Quality Assurance notification/modification issues are formally noted by the Q. A. Manager and circulated to the same above departments. Changes which will affect the Q.A. Manual are filed by Q.A. Manager and periodically (at least every 6 months) incorporated into the Q.A. Manual with associated rev. level change.

A-4 DOCUMENT REVIEW

The owner or contractor of a product will be granted the right to inspect all Thermalogic Q.A. documentation on request, for that product(s). This right specifically excludes Thermalogic purchasing or other proprietary documentation. Inspection rights to proprietary documentation will be considered on a case-by-case basis when requested. Thermalogic reserves the right to delete proprietary information from any documents offered for inspection.

B. PURCHASING PROCEDURE

B-1 GENERAL

THERMALOGIC Quality Assurance Department is responsible for assuring that all supplies and services procured from our suppliers (sub-contractors and vendors) conform to internal and/or contract requirements. The Purchasing Department will coordinate with the Quality Assurance Department on plans for obtaining new suppliers. On terms of question and major consequence, the Quality Assurance Department may, in advance of production, conduct a survey to determine satisfactory evidence of inspection and Quality Assurance for maintaining THERMALOGIC Corporation standards.

B-2 SPECIFIC

Where no Quality History exists, sub-contractors and vendors will be approved by the Quality Assurance Department by one or more of the following methods:

1. The Quality Assurance Department will conduct an initial quality survey (or have one conducted by an independent service) where possible, and conduct periodic resurveys to review the suppliers quality efforts, dependent on the products supplied;

2. Request a written Quality System manual and verify the quality of their products by objective and receiving evidence;

3. When Thermalogic Corporation subcontracts all pertinent documents including, but not limited to manufacturing, testing and shipping procedures are given to the subcontractor contracted for such services.

C. RECEIVING INSPECTION PROCEDURE

C-1 GENERAL

Materials and parts purchased from contractors and suppliers or supplied to Thermalogic Corp. by the customer or one of its suppliers, are received and held for incoming inspection to assure conformance to customer requirements. Material will be inspected and/or tested (as required: to drawings, specifications or catalogs).

C-2 SPECIFIC

Inspections will consist of the following:

1. Check of material to specific drawings, specifications and purchase orders to determine compliance with all quality requirements;

2. Review of a "Certificate of Compliance" (if applicable) accompanying material;

3. Procedure for non conforming material. Incoming inspector will randomly test a certain number of items based on lot size for acceptance, see table 1;

   Should this sample batch of the lot fail, all the items in this lot will be 100% tested. The out of specification item(s) are segregated to a holding area identified with a rejection tag describing the item(s), part number, job number, date of inspection, discrepancy and authorization for rejection. All non-complying material will be held in a segregated area until Quality Assurance notifies the Purchasing department and outlines the corrective action to take.

4. Notification by the Quality Assurance Engineer to Purchasing Department and Management of non-conformance;

5. All approved material is to be routed to stock with notification to Purchasing and Accounting Departments.

All purchase requisitions and subsequent purchase orders for raw materials and manufactured parts will indicate:

1. Clear definition of desired part or material as to description and/or catalog designation;

2. Applicable specifications: THERMALOGIC, Military and customer;

3. Required test reports and certification. The Quality Assurance Engineer will have the responsibility of making oral (and/or written) reports to THERMALOGIC Management regarding the status of approved or conditional approved vendors.

D. IN PROCESS PROCEDURE

D-1 GENERAL

THERMALOGIC's in-process procedures for high level quality assurance of products consist of: First Piece Inspection and Station Inspection. The Quality Assurance Engineer will have the responsibility of supervising these procedures. All inspections stations and manufacturing facilities will have documented instructions either for the manufacturing, the inspection or the test to be performed. These documents will include, as a minimum; when an inspection or test is required, and/or the accept or reject criteria.

D-2 SPECIFIC

First Piece Inspection

1. The Manufacturing Department will submit the first piece produced to the Quality Assurance Department for inspection along with the correct test fixture(s)/jig(s) to test the unit with. Thus verifying the proper operating condition of the fixture(s)/jig(s);

2. The Quality Assurance Department will test the first piece in accordance with the applicable print and detailed test procedure;

3. A First Piece Inspection form, designating approval, will be filled out and notice given to the Manufacturing Department to proceed with manufacturing the remainder of the lot;

4. If the part is disapproved by the inspector, the part is returned to the operator; the shop foreman is then notified to take the necessary steps for corrective action.

Station Inspection

Where applicable, the Quality Assurance Engineer will establish station inspection schedules as outlined below:

1. The Inspector will review the part for previous operations;

2. The part will be inspected to the applicable print, specifications and inspection instructions for the respective station;

3. Upon completion of inspection, inspector will identify rejected parts and inform the Quality Assurance Engineer; (see page 4 step 7)

4. Defective parts will be rejected or submitted for rework;

5. Accepted units will be routed to the next operation.

E. FINAL INSPECTION PROCEDURE

E-1 GENERAL

The Quality Assurance Department will have the responsibility for final inspection of manufactured goods. All THERMALOGIC manufactured units will receive 100% mechanical and electrical final inspection per applicable test procedures.

E-2 SPECIFIC

1. Inspector will match ship order to customer order. Review for completion of all operations;

2. Units will be subjected to such individual tests and inspections as specified by below enumerated steps:

   A) Unit checked against Maximum/Minimum tolerance sheet, ie. on/off points CW & CCW.

   B) Ship with list.

   C) Customer specification sheet.

   D) An optional check list of above steps will be activated in writing when Management is under a contractual agreement to do so.

   E) Sections A - C are the standard procedures for all controls and sensors. The only difference, **No PAPER CHECK LIST IS GENERATED**, to lower cost.

3. Upon completion of inspection, defective units will be identified and Quality Assurance Engineer notified;

4. Accepted units will be sent to shipping;

5. The Manufacturing Department will be notified as to results of final inspection and need for rework.

E-3 NON-CONFORMING ITEM

Thermalogic Corporation or the customer from time to time may exercise their mutual right to discuss the acceptance of a product(s) that may not conform 100% to specification.

In time of necessity, if the customer approves the Q.A. non conformal form which outlines the out of conforming part(s) or parameter(s), then the Q.A. Manager will sign off the form which will then act as a formal document to release the product to the shipping department for delivery.

F. FACILITIES AND TEST EQUIPMENT MAINTENANCE PROCEDURE

F-1 GENERAL

THERMALOGIC's Quality Assurance Department will have the responsibility for monitoring the facilities and test equipment used in the manufacture and inspection of parts. The objective will be to assure that inspection and test equipment is adjusted, replaced or repaired before if becomes inaccurate.

F-2 SPECIFIC

1. A log on all inspection and test equipment will be kept showing, as a minimum, date of calibration, condition, due date of next calibration and serial number;

2. Instruments used for quantitative measurement are calibrated at least once every year;

3. Standards are checked and certified annually. Certification is performed by a laboratory with standards certified by or traceable to the National Bureau of Standards;

4. When necessary, instruments are recalibrated more frequently than specified above;

5. When justifiable, calibration intervals may be extended. Written justification will be maintained by the Quality Assurance Engineer;

6. Instruments found to be defective will be so identified and removed from further use until repaired or replaced;

7. After calibration, a sticker or tag is applied to the instrument showing date calibrated, date of next calibration and person who performed the calibration;

8. If instruments do not require calibration, a sticker stating "Not subject to periodic calibration" will be affixed to the device;

9. To preclude the use of worn, faulty or inaccurate tools, gauges and test equipment, a system of periodic re-inspection and recalibration of such devices will be provided.

G. QUALITY ASSURANCE RECORD

G-1 GENERAL

In addition to Sections QAM-D and QAM-E, the Quality Assurance Program assigns individual batch and serial numbers for each control manufactured. These are logged onto a "Production Control Record", which travels with the order in manufacturing, testing and, finally, to shipping. This record includes a sign off with names of the test technician(s) and Quality Assurance Manager for every lot. This record is saved in the customer's file for future tracking of all controls shipped.

G-2 SPECIFIC

This system was devised as a management tool for pinpointing problems or potential situations which need to be amended. The below check point outline the system.

1. The Production Control Record Sheet is generated for each batch of control(s)/sensor(s)manufactured by Thermalogic. This sheet is filled out by the production floor supervisor. Stating the customer, model number, batch code and invoice number;

2. The Record Sheet from step 1 is then given to the assembler who will be doing the assembling along with the build instructions;

3. Once the assembler builds a complete batch, the batch is then forwarded to the test technician assigned to test them or placed in the holding area. At this point, P.C.R. Sheet will have the signature of the person who performed the assembling of this control(s)/sensor(s);

4. The test technician will test all the controls and place a unique batch/serial number on each one as well as check off that number as being tested and note any assembly or operational problems if any. The technician will now place his/her signature on P.C.R. Sheet;

5. The tested batch is then forwarded to Q.A. for inspection. If the batch is of the variety to be encapsulated in epoxy, step 6 will be performed after the curing process is complete.

6. Q.A. will now randomly choose a number of controls/sensors and proceed with a full functional test for that product;

7. Q.A. will note on the back of the P.C.R. Sheet the unique batch numbers that were randomly tested and officially signed off to shipping;

8. The last step for P.C.R. Sheet is, for all the data on it to be logged into a spread sheet for analytical purposes. Then all the P.C.R. Sheets are sent to be filed in the appropriate customer files.

H. MATERIAL MANUFACTURING FLOW AND STORAGE

Each component received from supplier/subcontractor is handled by section QAM-6. The component is then placed in the stock room(s). A portion of commonly used resistors, capacitors, transistors etc., etc. are placed in the production line bins for assemblers to draw from.

Special or job dependent components are drawn directly from the stock room by the stock room overseer for specific manufacturing runs.

All stocked components used in the manufacture of temperature controls and or sensors are periodically inspected for valid shelf life to ascertain if it is in acceptable condition for manufacturing use. This is done once per year at inventory time.

Once the units are completely assembled, (printed circuit boards), they are placed in non conductive tote bins and stored in a holding area until a test technician is assigned to test them.

I. PACKAGING AND SHIPPING PACKAGING

Thermalogic manufactures a large variety of temperature controls in many configurations and sizes. Virtually all of these controls are manufactured to withstand shock and vibration similar to or greater than that which would be experienced during commercial shipping carriage. As a result, the emphasis for packaging is to establish and maintain control over: 1) item separation and identification, 2) cosmetic protection, 3) clear and complete labeling, and 4) An ESD environment and labeling appropriate to the product being shipped.

Generic packaging and shipping instructions, applicable where specific requirements do not accompany an order, are given in Thermalogic drawing #711-174. A copy of this drawing is posted and filed in the shipping department for day to day procedures.

Additional and special consideration is always given to specific shipping circumstances required by individual product contracts. Any such requirements will be identified and, if necessary, amplified on a shipping instructions document entered into the Thermalogic drawing system. This drawing will accompany the invoice/shipping order when special requirements exist. It will be the authorization for purchase of any special shipping materials and will be followed by the shipping department in the actual shipping procedure.

SHIPPING

The preferred Thermalogic common carrier is United Parcel Service and will be used where there exist no instructions to the contrary. Priority or overnight shipments will normally be made by either United Parcel or Federal Express where there exist no instructions to the contrary.

Special shipment instructions from the customer or contract will be specified directly on the invoice/shipment order or will be referred to on this document through a shipping instruction document number under the Thermalogic drawing system.

TABLE 1

Lot or Batch size	Sample size	Acceptable Quality Levels	
		AC	RE
2 to 8	2	0	1
9 to 15	3	0	1
16 to 25	5	0	1
26 to 50	8	0	1
51 to 90	13	0	1
91 to 150	20	0	1
151 to 280	32	1	2
281 to 500	50	1	2
501 to 1200	80	2	3
1201 to 3200	125	3	4
3201 to 10000	200	5	6
10001 to 35000	315	7	8
35001 to 150000	500	10	11
150001 to 500000	800	14	15
500001 and over	1250	21	22

Notes: AC - Acceptable number
RE - Rejection number

J. RETURNED PRODUCT FOR MODIFICATION/REPAIR

All product being returned will have a Return Authorization Number which will allow it to be accepted by the Thermalogic Receiving department.

The returned item(s) is then placed in a segregated holding area after it is confirmed with Thermalogic Customer Service that this RAN has arrived and will be scheduled for repair.

The control's serial batch number is inputted into our computerized RMA system to check if this control was returned previously. If no record is found, a new record is opened with the test results as well as repair information. Testing is done according to section E in this manual.

K. FORMS SECTION

A) QUALITY CONTROL RECORD FORM
B) INTERNAL CHANGE REQUEST/ AGENCY NOTIFICATION FORM