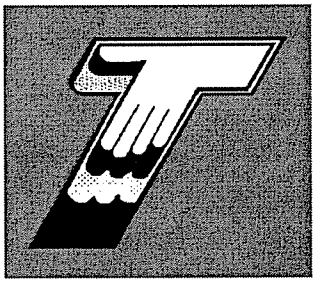
SUPPLIER QUALITY AUDIT QUESTIONNAIRE



Therma Corporation
408-347-3400

Revisions

Rev	DCR	DESCRIPTION	REVISION DATE
0	05022	Initial Release	

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1. GENERAL INFORMATION:		
Company Name:		
Street Address:		
City, State, Zip Code:		
Phone Number:		
Fax Number:		
Form Completed By & Title:		
Date Form Completed:		
Email Address:		
Date of Last Survey:		

Complete each section listed below. Once all fields have been completed, please sign the last page of the survey and return the entire form with additional information (if applicable) to Therma Corporation, Quality Assurance Department.

Contact Person: Karen Lee, P.E. Email Address: klee@therma.com

Fax Number: 408-347-3405 Mail: 1601 Las Plumas Avenue, San Jose, Ca 95133-1613

2. TYPE OF MANUFACTURE OR SERVICE PROVIDED FOR THERMA CORP.:

3. TYPE OF PRODUCT(S) PROVIDED FOR THERMA CORP.:

4. BUSINESS INFORMATION:		
4.1	How long in business?	
4.2	Annual sales?	
4.3	Manufacturing Locations (if other than above address)	
4.4	President's Name:	
4.5	Operations Manager's Name:	
4.6	Quality Assurance Manager's Name:	

5. FACILITY DESCRIPTION:		
5.1	Size of building(s) in square feet:	

6. NUMBER OF EMPLOYEES:		
6.1	Manufacturing:	
6.2	Quality Assurance / Quality Control:	
6.3	Research and Development:	
6.4	Technical Support/Customer Service:	
6.5	Administrative/Other:	

7. MAJOR EQUIPMENT/CAPACITY:

8. QUALITY SYSTEM DESCRIPTION:			
8.1	Is your facility ISO certified?	☐ Yes	☐ No (If no, skip to Question 8.5.)
8.2	What ISO certification(s) do you have? Note: Please forward a copy of ISO certificate(s) with this response.		
8.3	What are the certification expiration dates?		
8.4	Who is the Notified Body?		
8.5	Is your facility registered with the FDA?	☐ Yes	☐ No (If no, skip to Question 8.8.)
8.6	Date of most recent inspection:		
8.7	Issued 483 or warning letter?	☐ Yes	☐ No
8.8	Is there a Quality Manual in place? Note: If yes, please forward a copy of quality manual with this response.	☐ Yes	☐ No
8.9	Is there a written policy for roles and responsibilities of quality control and quality assurance units? Note: If yes, please forward a copy of the policy with this response.	☐ Yes	☐ No
8.10	Is there an organization chart that defines responsibility, authority, and interrelation of personnel who manage, perform, and verify work? Note: If yes, please forward a copy of the organization chart with this response.	☐ Yes	☐ No
8.11	Does your company have any other registrations, licenses or certifications?	☐ Yes	☐ No
	If yes, please list.		
For Therma Use Only: Deficiencies*: ☐ None ☐ Minor ☐ Major			

9. DOCUMENT AND CHANGE CONTROL:			
9.1	Does your company have document control program?	☐ Yes	☐ No
	If yes, please forward a copy of the document control procedure with this response.		
9.2	Does your company have a change control program or procedure?	☐ Yes	☐ No
	If yes, please forward a copy of the program or procedure with this response.		
For Therma Use Only: Deficiencies*: ☐ None ☐ Minor ☐ Major			

10. PROCESS CONTROL / INSPECTION AND TESTING:			
10.1	Does your company have process control/inspection and testing procedures?	☐ Yes	☐ No
	If yes, please forward a copy of the procedures with this response.		
10.2	If inspected, does your company have a procedure to address inspection parameters?	☐ Yes	☐ No
10.3	If certification is used to accept incoming material or components, describe how your company performs the process.		
10.4	Does your company have process and final inspection testing procedures?	☐ Yes	☐ No
	If yes, please forward a copy of the procedure with this response.		
10.5	Are the results of all inspections and testing documented with dates and signatures of individual involved?	☐ Yes	☐ No
For Therma Use Only: Deficiencies*: ☐ None ☐ Minor ☐ Major			

11. MATERIAL HANDLING AND CONTROL:

Please indicate if there are written procedures or policies for the following material processes:

11.1	Handling?	☐ Yes	☐ No
11.2	Storage?	☐ Yes	☐ No
11.3	Lot Control?	☐ Yes	☐ No
11.4	Marking/Identification?	☐ Yes	☐ No
11.5	Packaging?	☐ Yes	☐ No
11.6	Shipping?	☐ Yes	☐ No
11.7	Non-conformance?	☐ Yes	☐ No
11.8	Restocking?	☐ Yes	☐ No

For Therma Use Only:

Deficiencies*: ☐ None ☐ Minor ☐ Major

12. NON-CONFORMING MATERIAL:

12.1	Does your company have any non-conforming material?	☐ Yes	☐ No
	If yes, please describe the disposition of non-conforming material (or reference and attach procedure):		

For Therma Use Only:

Deficiencies*: ☐ None ☐ Minor ☐ Major

13. TRACEABILITY:

13.1	Does your company have a procedure to trace raw material/component?	☐ Yes	☐ No
	If yes, please forward a copy of procedure with this response.		

For Therma Use Only:

Deficiencies*: ☐ None ☐ Minor ☐ Major

14. CORRECTIVE AND PREVENTIVE ACTION:			
14.1	Does your company have an internal system for corrective and preventive action?	☐ Yes	☐ No
	If yes, please forward a copy of procedure with this response.		
14.2	Does your company have a formal complaint system with written records for each complaint and investigation?	☐ Yes	☐ No
	If yes, please forward a copy of procedure with this response.		
14.3	Brief describe how to handle customer's complaints. Describe who is responsible for the system, what records are maintained, if and how evaluations are performed.		
14.4	Does your company perform failure investigation and trend analysis of customer's complaints?	☐ Yes	☐ No
14.5	Can you describe your system to ensure linkage of customer's complaints to positive corrective and maintenance action?		
14.6	Do you provide feedback to your customers on all complaints with respect to corrective and preventive action taken?	☐ Yes	☐ No
14.7	Does your company have a recall program?	☐ Yes	☐ No
	If yes, please forward a copy of the program with this response.		
14.8	Does your company have a procedure for handling returned goods?	☐ Yes	☐ No
	If yes, please forward a copy of return procedure with this response.		
For Therma Use Only:			
Deficiencies*: ☐ None ☐ Minor ☐ Major			

15. TEST OR MEASUREMENT VERIFICATION:			
15.1	Does your company have calibration program policy for measurement devices?	☐ Yes	☐ No
	If yes, please forward a copy of program with this response.		
15.2	Does your company maintain a system to ensure that measuring devices and test equipment are calibrated within specified frequencies?	☐ Yes	☐ No
15.3	Are tools and test equipment marked with:		
	15.3.a. Identification Number?	☐ Yes	☐ No
	15.3.b. Calibration Date?	☐ Yes	☐ No
	15.3.c. Calibration Due Date?	☐ Yes	☐ No
15.4	Are calibration devices traceable to National Institute of Standards and Technology (NIST) or a recognized government standards certification body?	☐ Yes	☐ No
	If yes, and not NIST, please list name of certification body.		
15.5	Please describe your procedure how to handle out of calibration results.		
For Therma Use Only: Deficiencies*: ☐ None ☐ Minor ☐ Major			

16. QUALITY SYSTEM AUDIT:			
16.1	Does your company have annual quality audit policy/procedure?	☐ Yes	☐ No
	If yes, please forward a copy of the procedure with this response.		
16.2	What department is responsible for audits?		
For Therma Use Only: Deficiencies*: ☐ None ☐ Minor ☐ Major			

17. OTHER COMMENTS:

18. REFERENCES: Provide three references if available

19. OVERALL QUALIFICATION RATNG: For Therma Use Only			
Deficiencies*:	☐ None	☐ Minor	☐ Major
Qualification**:	☐ Qualified	☐ Unqualified	

* See Therma's SOP 1.002 for major and minor deficiency definitions
** See Therma's SOP 1.002 for qualified and unqualified rating description.

This signature below certifies that the information contained in this document accurately reflects the current status of our company.

Name (Printed):	
Title:	
Signature:	
Date:	