

May 5, 2003

Mr. David Morris
Director of Product Management
ITI Qualitek, Inc.
13 Alexander Road
Suite 2B
Billerica, MA 01821

SUBJECT: REQUEST FOR COMPANY OWNERSHIP CHANGE AND RELOCATION,
REGISTRATION NUMBER NR-1128-D-101-E, FOR THE MODEL NOS. Q200
LEAKMETER AND LEAKMETER 120

Dear Ms. Morris:

We have received your request dated February 14, 2003, for a change to company ownership and relocation, with respect to registration NR-1128-D-101-E, for the Model Nos. Q200 Leakmeter and Leakmeter 120. In order to proceed with this action, we need the following information:

- A. Delineate the facility's name and location where the products are manufactured;
- B. Specify the serial number of the last unit that was distributed by ITI Qualitek, Inc. prior to March 1, 2003, and the number of completed units that were transferred to be distributed by Uson LP, and by Roper Industries;
- C. Change of ownership information discussing transfer of assets, products, records custody, contractual arrangements, and servicing arrangements for products previously distributed;
- D. Provide a new label for the devices indicating the new company name and the effective date of the label change;
- E. Confirm that no changes were made to the product since its initial registration or last amendment;
- F. Verify that there are no changes to previous commitments that have been made from a previous sealed source and device review for the continued service, repair and calibration of the Model No. 120 Leakmeter as stated in a letter from you to Anthony Kirkwood of the NRC dated March 21, 2001; and
- G. Provide details regarding the quality assurance program at the new location.

D. Morris

-2-

The information requested by this letter should be submitted in a written response within 30 days of the date of this letter. If a written response is not received within this time period, the staff will consider the application as "abandoned" for failure to provide the requested information "without prejudice" to the re submission of the request.

If you have any questions regarding this matter, we would be pleased to meet with you and your staff. I may be contacted at (301) 415-6195.

Sincerely,

David Tiktinsky, Senior Project Manager
Regulatory Guidance Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: Rosalyn Jones

D. Morris

-2-

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/RA/

David Tiktinsky, Senior Project Manager
Regulatory Guidance Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: Rosalyn Jones

SS&D Case FILE 03-29

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