May 11, 2001

David Morris, President
iTi Qualitek, Inc.
267 Boston Post Road
N. Billerica, MA 01862-2310

SUBJECT: Registry Certificate NR-1128-D-101-E

Dear Mr. Morris:

Based on the information submitted in your letter dated April 12, 2000, and subsequent letters, with enclosures thereto, we conclude the Models Leakmeter 120 and Q200 Leakmeter ECD detectors continue to be acceptable for licensing purposes. Your application stated that as of January 2000, Ion Track Instruments became an independent company and agreed to transfer the distribution of the Model Q200 Leakmeter to iTi Qualitek, Inc. Accordingly we have given you the new registry certificate number NR-1128-D-101-E (enclosed).

Please be advised that you must manufacture and distribute the licensed product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in these registration certificates. As a general rule, you must request and obtain an amendment to the certificate before you make changes to the products or modifications to the information submitted to obtain the certificates.

Please read over the enclosed registration certificates in their entirety and notify us immediately if there are any errors or omissions.

Please be aware that, as a holder of an NRC registration certificate, you may be subject to the NRC's licensing fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-6096.

If you have any questions, please contact me at (301) 415-6140 or Michele Burgess at (301) 415-5868.

Sincerely,

/RA/

Anthony S. Kirkwood, Health Physicist
Materials Safety & Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: NR-1128-D-101-E
Distribution:
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DATE	May 10, 2001		May 14, 2001		May 14, 2001					

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001
(formerly NR-0399-D-103-E)

DEVICE TYPE: ECD Detector

MODEL: Leakmeter 120 and **Q200 Leakmeter** (**formerly** Leakmeter 200)

DISTRIBUTOR: **iTi Qualitek, Inc. (formerly part of Ion Track Instruments, Inc.)**
267 Boston Road
North Billerica, MA 01862

MANUFACTURER: Ai **Qualitek**
London Road
Pampisford, Cambridge, **England** CB2 4EF

SEALED SOURCE MODEL DESIGNATION: DuPont NER-004

ISOTOPE:
Nickel-63

MAXIMUM ACTIVITY:
10 millicuries (370 MBq)

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (N) Ion Generators, Chromatography

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY
EVALUATION OF DEVICE

(formerly NR-0399-D-103-E)

DEVICE TYPE: ECD Detector

DESCRIPTION:

The Leakmeter 120 and **Q200** Leakmeter are hand-held devices for measuring the leakage of gases such as sulfur hexafluoride and refrigerants from their normal containments. The devices work on the principle of electron capture, utilizing a small radioactive source. The Model 120 Leakmeter**, which was distributed by Ion Track Instruments and registered as NR-0399-D-103-E, has not been** manufactured or distributed **since 1994.** The Model **Q200** Leakmeter is a replacement for the Model 120 Leakmeter.

The devices are intended for either industrial or field use. The hand-held sensing probe is 13.8" (35 cm) long overall, and is attached to the carrying case containing the electronics console by a cable 11 feet (3.5 m) long. The probe weighs 2 lb (0.9 kg). The only physical difference between the Leakmeter 120 and the **Q200** Leakmeter is that the **Q200** Leakmeter has an outer casing made of higher-strength plastic than that used in the Leakmeter 120. There are several differences in the electronics associated with the two probes, but these have no significance to their radiation safety. The electrical portions also control a heater which surrounds the detector body, and is designed to maintain the detector temperature at 122°F (50°C).

The gas being analyzed is sucked into the probe by a pump located in the probe, and the gas interacts with an electric field in the vicinity of the cylindrical foil source inside the detector body. The readout is provided on the electronic display on the rear of the probe. The dimensions of the carrying case for the electronics are 17 in x 16 in x 9 in (43 cm x 40 cm x 23 cm), and it weighs 30.8 lb (14 kg). The electronics include a temperature control for the electric heater wrapped around the detector body.

DEVICE TYPE: ECD Detector

DESCRIPTION: (Cont'd)

The source is enclosed by the detector body and electrodes, all of which are made of stainless steel. The metal gas flow tubes are too small to permit human access, and bends in them block any direct radiation path from the source. The source itself consists of nickel-63 plated on a metal foil which lines a cylindrical area inside the detector body. The source can be accessed only by use of a special tool, which is not provided to users. The outer body of the probe is made of rigid polyurethane, which provides some additional, but not essential, protection to the source housing.

LABELING:

The devices are labeled in conformance with Section **20.1905** of 10 CFR Part 20. One label made of velvet polycarbonate is attached to the outside of the device with adhesive. This label contains the company name, address, and telephone number, and measures 0.43 in x 1.7 in (11 mm x 44 mm). Also attached with adhesive to the outside of the probe, below the readout display, is a plastic label with the radiation symbol, 370 MBq, and Ni-63.

An additional label stating the exempt license requirements of Section 32.29 of 10 CFR 32 is provided on the outside of the point of sale packaging.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

DEVICE TYPE: ECD Detector

LABELING: (Cont'd)

Within the device probe, there is a label attached by a twisted wire to a metal tube going into the detector cell. This label has black lettering on yellow background. The label contains the radiation symbol, and the following words: CAUTION - Radioactive Material, 370 MBq Ni 63, Serial No., Date, and the warning "Do not dismantle. See instrument manual before operating this device. Analytical Instruments, Ltd." There is an additional label (shown on Attachment 3) engraved on the end of the ECD body.

DIAGRAM:

See Attachments 1, 2, and 3.

CONDITIONS OF NORMAL USE:

These devices are designed for use in either an industrial setting or for field use. They are a rugged design, with adequate provisions to protect the source from mechanical damage or access by unauthorized persons.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001
(formerly NR-0399-D-103-E)

DEVICE TYPE: ECD Detector

PROTOTYPE TESTING:

A prototype of the Model Leakmeter 200 was constructed and subjected to the tests listed below. The manufacturer states that no malfunction that compromised radiological safety occurred, and that there was no was loss of shielding efficiency after the tests. The pump for obtaining samples had a reduced flow rate following the drop tests.

Impact . . . . . Dropped six times from a height of 1 meter onto six sides of device

Temperature tests were not necessary, since this device is hand held, and an engineering analysis indicates that it can withstand temperatures suitable for human activities. The design of the two models are so similar that results of the tests above would be expected to be similar for the Leakmeter 120. More damage may occur to the outer body of the Leakmeter 120, but this would not compromise its radiological safety.

The sealed sources used in the probe detector assembly passed tests conducted by Amersham International on similar nickel-63 foil sources, type NBCK 7074, manufactured by Amersham. Those sources received the classification 77C32313 based on ANSI N542-1977.

EXTERNAL RADIATION LEVELS:

No primary radiation is detectable from outside the device, since the source is a soft beta emitter. The source is surrounded on all sides by material of such thickness that no direct radiation from the source will reach the outside of the sensor probe. Therefore, accumulation of quantities of the devices in distribution will not significantly increase the radiation in the vicinity.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

DEVICE TYPE: ECD Detector

QUALITY ASSURANCE AND CONTROL:

As devices are assembled, the serial number of each foil source is etched onto the label wired to the ECD assembly. After assembly, each detector cell is given a wet wipe test for external contamination.

iTi Qualitek, maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Leakmeter 120 and **Q200** Leakmeter devices may be distributed to any person who is exempt from the requirements for a license in accordance with Section 30.20 of 10 CFR Part 30.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The Model 120 **has not been** manufactured or distributed **since 1994. iTi Qualitek** will continue to service and calibrate these devices.

Based on our review of the information and test data cited below, we conclude that the product is designed and manufactured so that:

DEVICE TYPE: ECD Detector

SAFETY ANALYSIS SUMMARY: (Cont'd)

- In normal use and disposal of a single exempt unit, and in the normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the following table.

- It is unlikely that there will be a significant reduction in the effectiveness of containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

- In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table below, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table below.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

DEVICE TYPE: ECD Detector

SAFETY ANALYSIS SUMMARY: (Cont'd)

TABLE OF ORGAN DOSES (Rem)

Part of the body	Col. I	Col. II	Col. III
WB, head, trunk, gonads, eyes	0.005	0.5	15
Extremities, skin	**0**.075	7.5	200
Other organs	0.015	1.5	50

Based on review of the Models Leakmeter 120 and **Q200** Leakmeter devices, and the information and test data cited below, we conclude that these devices are acceptable for licensing purposes.

Furthermore, we conclude that the Models Leakmeter 120 and **Q200** Leakmeter devices would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001
(formerly NR-0399-D-103-E)

DEVICE TYPE: ECD Detector

REFERENCES:

The following supporting documents for the Models Leakmeter 120 and **Q200** Leakmeter devices are hereby incorporated by reference and are made a part of this registry document **(formerly NR-0399-D-103-E)**.

- Ion Track Instruments letters dated June 21, 1995, June 13, 1995, May 12, 1995, and September 27, 1994, with enclosures thereto.
- Ion Track Instruments application dated March 21, 1994, with enclosures thereto, requesting device registration.
- Telephone conversation record dated May 30, 1995 from Robert Waterfield, Jupiter Corporation, to David Morris, Ion Trac**k** Instruments, clarifying the model number.
- **iTi** Qualitek letters dated January 9, 1997 (address change only), **April 12, 2000, September 20, 2000, November 14, 2000, December 18, 2000, and March 21, 2001, with enclosures thereto.**
- **iTi Qualitek facsimiles dated May 1, 2001, May 10, 2001 (concerning proprietary information) and May 10, 2001 (concerning registry commitments).**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: May 11, 2001 Reviewer: Michele L. Burgess

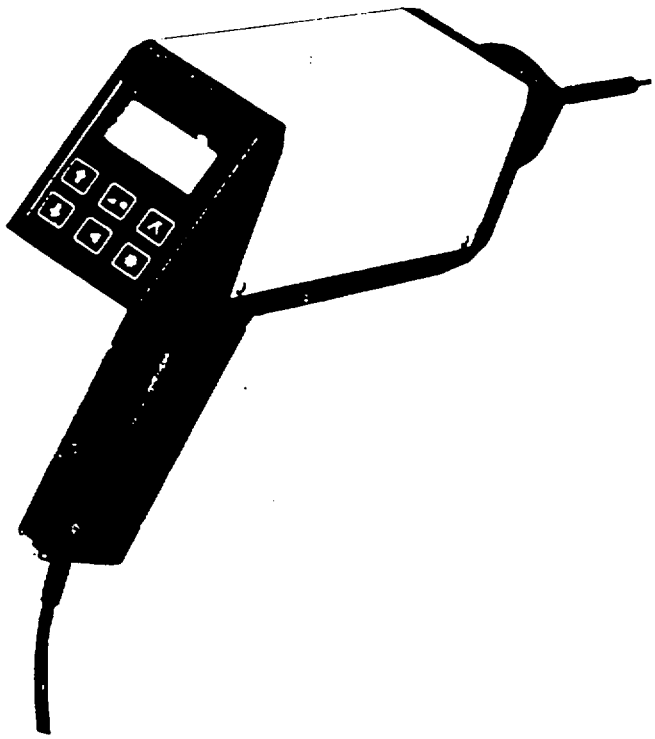
Date: May 11, 2001 Concurrence: John P. Jankovich

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001 ATTACHMENT 1 OF 3
(formerly NR-0339-D-103-E)

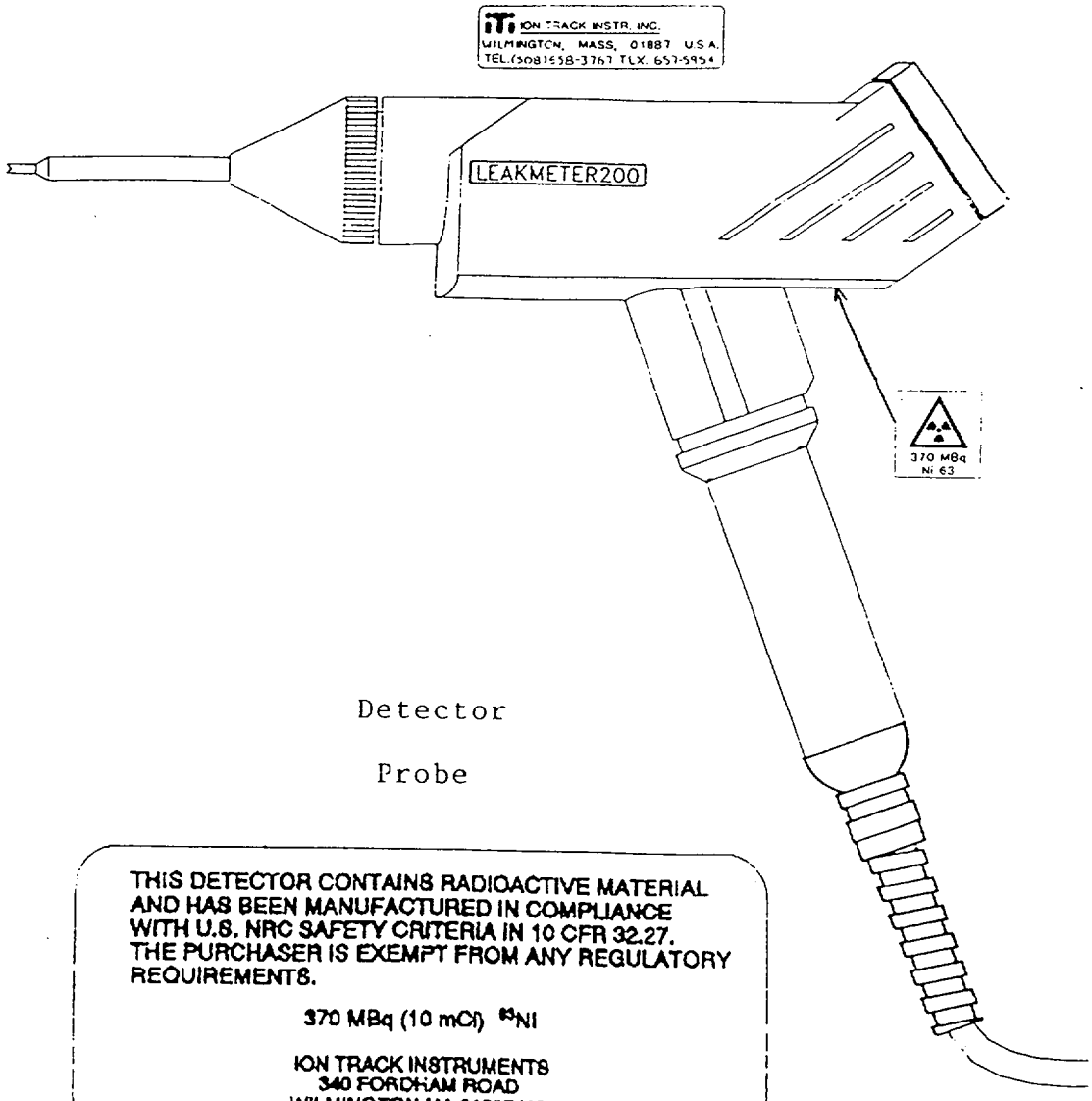
Leakmeter 120

Detector Probe



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001 ATTACHMENT 2 OF 3
(formerly NR-0339-D-103-E)



Detector

Probe

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

370 MBq (10 mCi) ^{63}Ni

ION TRACK INSTRUMENTS
340 FORDHAM ROAD
WILMINGTON MA 01887 USA

LABEL, RADIOACTIVE CAUTION,
CASE, LEAKMETER 200

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-1128-D-101-E DATE: May 11, 2001 ATTACHMENT 3 OF 3
(formerly NR-0339-D-103-E)