RECORD #175

TITLE: Acceptability of New Technology Respirator Fit Testing Devices

FICHE:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

HPP ?

APR 10 1989

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THRU: James E. Wigginton, Section Chief, RPB, DREP, NRR

FROM: Roger L. Pedersen, Sr. HP, RPB, DREP, NRR

SUBJECT: ACCEPTABILITY OF NEW TECHNOLOGY RESPIRATOR FIT TESTING DEVICES

Recently the Radiation Protection Branch has been queried on the acceptability of the new respirator fit testing devices on the market (see Enclosure 1). Enclosure 2 is a letter sent to John Hale in response to his question regarding the PORTACOUNT device. Note that the response was general in nature and intended to apply to any fit testing device and/or protocol. When making a determinant that a method is technically adequate an inspector should keep in mind that:

° Fit Factors (FF) determined by any quantitative fit test are not protection factors and cannot be used as such.

° Acceptance Criteria for FF should be set at least ten times the protection factor of the mask being fit (i.e., to show a proper fit on a mask with a protection factor of 50, a FF of at least 500 should be measures).

° Testing methods should reasonably simulate use conditions.

° An adequate bases for correlating the parameter being measured (aerosol concentration, pressure drop, etc.) to a FF, should be established.

It is our understanding that the QUANTAFIT device (see Enclosure 1) requires the subject to be absolutely still with no facial movement. Apparently the momentary breaks in the face seal, cause by facial movement, fail this test. This type of leakage is well known even in a good fitting respirator and it is a major contributor to the overall leakage (or fit) of the mask. If our information is correct it is difficult to see how this method can adequately measure the respirator fit.

Also it is our understanding that Region I has an open item concerning the calibration of the PORTACOUNT system used by one of their licensees.

We will keep you informed of further development regarding these devices.

Original signed by

Roger L. Pedersen, Sr. HP, RPB, DREP, NRR

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QUANTAFIT

High accuracy fit testing without the high cost.

Dynatech Frontier now offers an easy to use, low cost alternative to conventional aerosol fit test systems. By using computerized leak decay testing, Quantafit™ accurately and repeatably provides a numerical fit factor for the wearer's own respirator.

PRODUCT PROFILE

Quantafit™ uses a computer and special pressure conversion module to provide an instantaneous indication of pressure conditions in the respirator cavity. Quantafit™ can be used with your IBM PC/XT/AT (or compatible) or can be ordered installed from the factory.

To be tested, the subject dons the respirator with the specially engineered, non-destructive chucks installed and follows the on-screen prompts. While the subject holds his/her breath, the operator creates a slight negative pressure in the respirator by means of a draw on a syringe. The internal pressure is monitored for five to ten seconds and is automatically displayed graphically on the screen.

The result is a "leak slope" that is uniquely related to the fit of the respirator and that is extremely repeatable. This "leak slope" is then compared to a leak slope generated by inserting a calibrated leak into the test chuck. By comparing the two leak slopes and the calibrated leak orifice, we can accurately measure the unknown leak . . . we call this the "equivalent leak diameter."

This value represents the leak as though it occurs in one site and is round in geometry. From this equivalent leak diameter, we can convert to what is known as a "fit factor."

Fit factor is defined as the ratio of contaminant outside versus inside the breathing zone. For the Quantafit™, we use the same principle and look at the ratio of clean air entering the breathing zone through the filters versus contaminated air entering through the leak.

FEATURES

NON-INVASIVE PROBE

For the first time ever, quantitative fit testing requires no destructive probe into the respirator. The subject can be tested in his or her actual respirator without damage to the respirator.

SHORT TEST TIME

No longer do we just analyze the result of the fit. Instead, the Quantafit™ technology can measure leakage directly, and it only takes a few seconds.

NO AEROSOL REQUIRED

Eliminates the cumbersome booth and generator associated with conventional aerosol fit tests.

NO MAINTENANCE REQUIRED

Quantafit's™ simple electronic design eliminates the need for routine maintenance..

EXTREMELY PORTABLE

The Quantafit™ is lightweight, and compact.

COMPLETE DATA STORAGE CAPABILITIES

The Quantafit™ full function software provides accurate and complete storage of fit test results plus management of your employee database.

MENU DRIVEN SOFTWARE

Subject and operator are given easy to follow on-screen prompts guiding him/her through the fit test.

LOW COST

See price list to learn how affordable true quantitative fit testing can be!

DYNATECH FRONTIER CORPORATION

The Leader in Quantitative Fit Testing

5655 Jefferson NE • Albuquerque, NM 87109 • 505-345-3611

High-accuracy fit testing without the high cost.

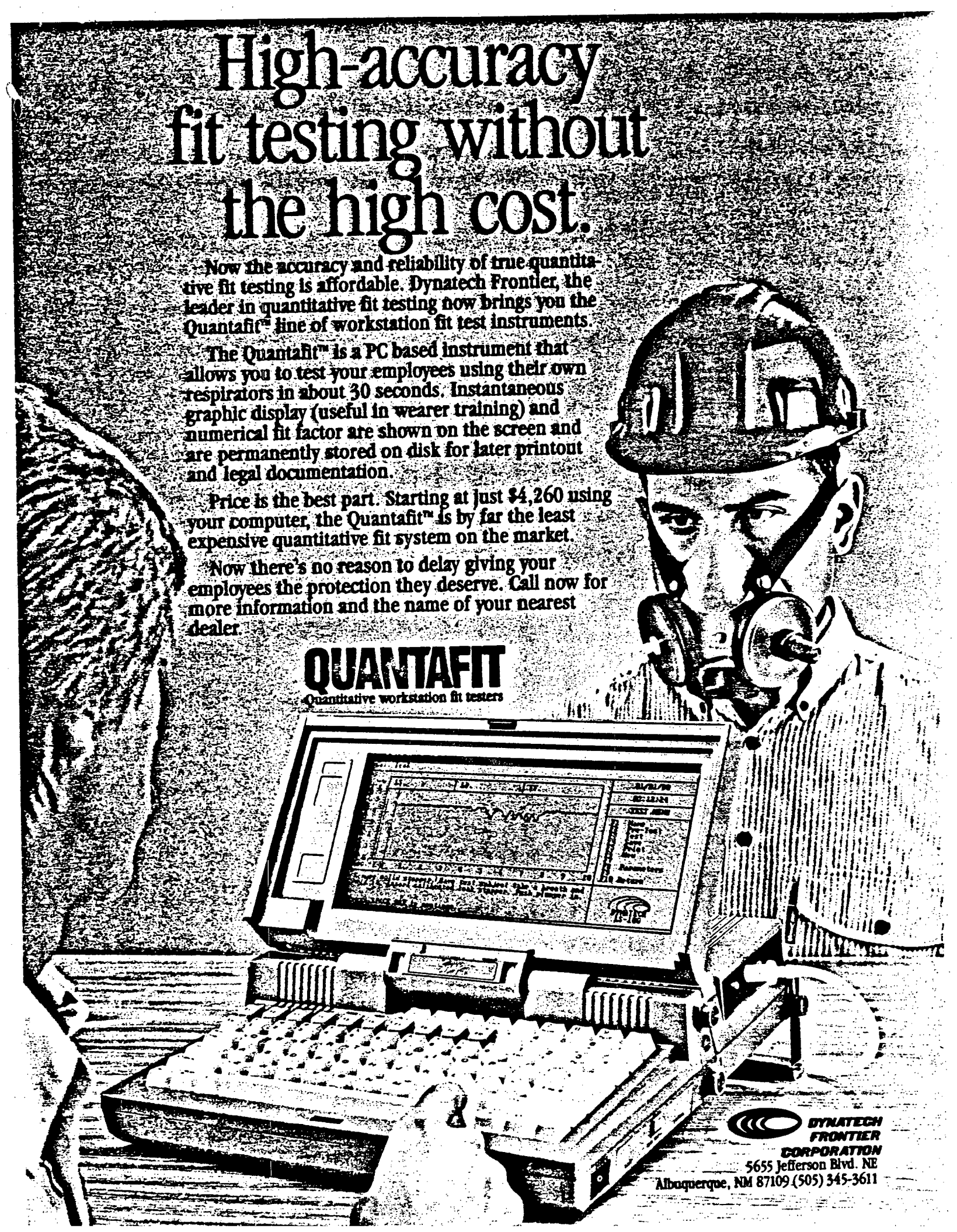
Now the accuracy and reliability of true quantitative fit testing is affordable. Dynatech Frontier, the leader in quantitative fit testing now brings you the Quantafit™ line of workstation fit test instruments.

The Quantafit™ is a PC based instrument that allows you to test your employees using their own respirators in about 30 seconds. Instantaneous graphic display (useful in wearer training) and numerical fit factor are shown on the screen and are permanently stored on disk for later printout and legal documentation.

Price is the best part. Starting at just $4,260 using your computer, the Quantafit™ is by far the least expensive quantitative fit system on the market.

Now there's no reason to delay giving your employees the protection they deserve. Call now for more information and the name of your nearest dealer.

QUANTAFIT
Quantitative workstation fit testers



DYNATECH FRONTIER CORPORATION
5655 Jefferson Blvd. NE
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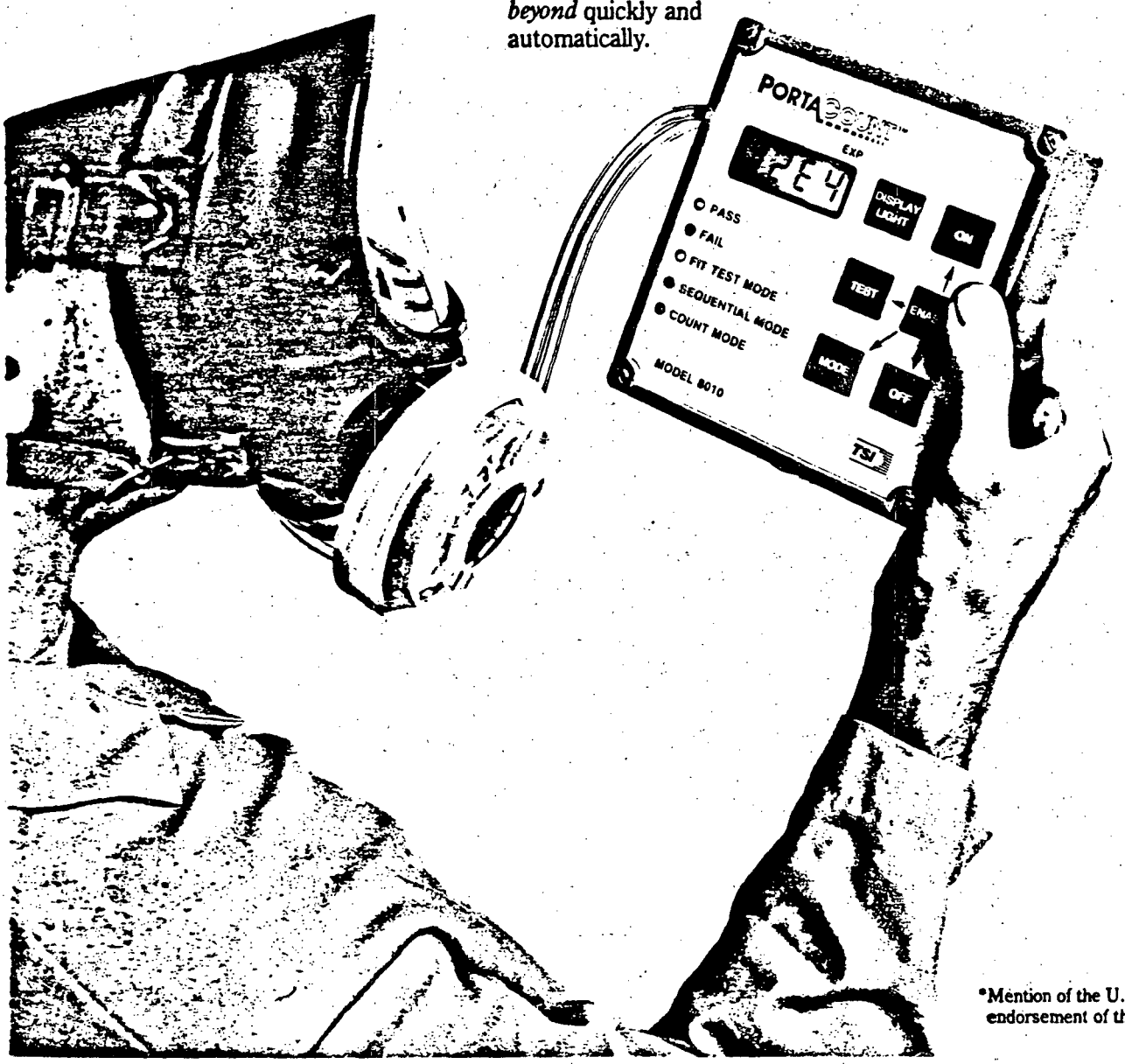
PORTACOUNT – An Innovative Approach to Quantitative Respirator Fit Testing

TSI's PORTACOUNT represents a significant breakthrough in quantitative fit testing technology. PORTACOUNT is the first truly portable instrument designed to meet the respirator fit testing challenges you face today. The battery-powered PORTACOUNT performs fit tests without cumbersome chambers, tents or aerosol generators, for unmatched simplicity in quantitative fit testing.

Thanks to its excellent sensitivity, PORTACOUNT can utilize virtually any challenge media, including ambient air, making it convenient to operate in any location—in the laboratory, in the field, in the work place, anywhere you need to be assured of accurate respirator fit measurements. With PORTACOUNT, you can measure fit factors *up to 100,000 and beyond* quickly and automatically.

This instrument, initially developed through funding from the U.S. Army Chemical Research, Development and Engineering Center,* is now available commercially. It's a member of TSI's complete line of RESPOTRAC™ Respirator Testing Systems, designed to offer you more benefits and broader capabilities in respirator testing. Optional PORTACOUNT accessories can include a printer, data logger or microcomputer - everything you need to satisfy your testing requirements.



*Mention of the U.S. Army does not imply endorsement of the product.

ENCLOSURE 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DEC 11 1987

John P. Hale, Director
Respirator Programs
Darell Bevis Associates, Inc.
14640 Flint Lee Road, Suite D
Chantilly, Virginia 22021

Dear Mr. Hale:

I am responding to your letter to me concerning the acceptability of a new-type of quantitative respirator fit testing device. Specifically, you requested the "...official NRC Enforcement position regarding the acceptability of the use of ..." this instrument that can use air as the challenge atmosphere, rather than the particulate aerosols in relatively high concentrators used by the typical test devices.

As you and Jim Wigginton of my branch discussed in early November, the following background is pertinent to your questions regarding enforcement. The NRC regulations do require fit testing of users when a licensee wishes to take credit for the respirator's allowed protection factors (PF) listed in 10 CFR Part 20, Appendix A. While NUREG-0041 suggests that a quantitative fitting testing (QFT) program is preferred, clearly a properly conducted qualitative program meets the intent of the regulations. If a licensee does elect to use QFT, individual fit factors (generated during testing) that are in excess of the generally conservative PFs in Part 20 are not allowed to be used. Thus, in actual practice, the QFT results (fit factors) are not used to establish the assumed level of protection provided a worker.

Given the above and the informal feedback from several licensees (and your company's comparative testing) that the new device's results compare favorably with testing results from "established" aerosol QFT methods, we see no reason why licensees should not use this or any new technology that can be shown to be technically adequate, satisfies regulatory commitments and meets the intent of the regulatory requirements. As long as the testing protocol, equipment operation and maintenance guidelines, equipment operator training, etc. are incorporated into plant procedures, licensees should be meeting the 10 CFR 20 requirements.

key word

If you have any further questions concerning this matter, please call Jim Wigginton (301-492-4663) or me (301-492-4734).

LeMoine J. Cunningham, Chief
Radiation Protection Branch
Division of Radiation Protection
and Emergency Preparedness
Office of Nuclear Reactor Regulation