

103

RECORD #103

TITLE: ... Clarification of Guidance Regarding Physicians Detion  
for Physical Qualification of Respirator Equipment Users. (Also  
see record #61)

FICHE: 67978-353



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

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enclosures  
7-22-85

JUL 19 1985

MEMORANDUM FOR: M. M. Shanbaky, Chief  
PWR Radiation Protection Section, Region I

FROM: Dennis A. Allison, Chief, Section B  
Engineering and Generic Communications Branch  
Division of Emergency Preparedness and  
Engineering Response  
Office of Inspection and Enforcement

SUBJECT: REQUEST FOR CLARIFICATION OF GUIDANCE REGARDING  
PHYSICIANS DETERMINATION FOR PHYSICAL QUALIFICATION  
OF RESPIRATORY EQUIPMENT USERS

I am writing in response to your June 24, 1985 memorandum to L. J. Cunningham on the above subject (Enclosure 1) which requested clarification regarding physician's signatures on individual fitness determinations.

The Fisher-Hall memorandum (Enclosure 2) did not concur with the Region 4 position that "...a physician must review and sign the forms..." that document the final determination of individual fitness for wearing respirators. We did agree that "...a physician must make the final determination of fitness for each individual."

We do not wish to provide regulatory guidance which could be needlessly prescriptive and possibly lead to a lack of inspector/licensee flexibility. For determining compliance with the 10 CFR 20.103.c.(2) requirement, who physically signs the "fitness" forms seems of secondary importance. Also, we believe that "liability questions" you mention are outside our regulatory purview and focus on after-the-fact health problems of the respirator user. The intent of having a physician make the medical determination was an effort to effectively screen out people with health problems before respirator use.

We can envision an acceptable compliance situation where a trained nurse physically administers testing, and documents and signs the required forms. As long as the individual's medical test results are within a pre-approved (by physician) envelope, and the physician agrees to retain full responsibility, we believe the intent of the regulation is met. If physical parameters fall outside the acceptable range, then this individual's case could be referred to the physician for more direct attention/testing. In summary, all forms should be reviewed by the physician, but whether the physician signs appears to be non-substantive.

Contact: Jim Wigginton  
(301)492-4967

The inspector should focus on the degree of involvement of the responsible physician. Based upon the limited information provided concerning the Ginna Station, it appears that the "responsible physician" is not involved in any direct oversight/review function of physical screening results for each individual. Assuming no other involvement by the company physician, we would recommend the licensee upgrade the physician's direct involvement to meet the requirements of 10 CFR 20.103.c.(2).

In summary, we do not believe that each form must necessarily be signed by a physician. However, the physician should be involved in the supervising and overseeing the fitness determination program such as by reviewing overall results, reviewing individual cases that fall outside certain physical parameters and general supervision/oversight of the personnel performing the tests. Simply setting up rules at the beginning, with no further involvement, is not adequate. If you have any questions concerning this clarification, please call me or Jim Wigginton.

Dennis A. Allison, Chief, Section B  
Engineering and Generic  
Communications Branch  
Division of Emergency Preparedness and  
Engineering Response  
Office of Inspection and Enforcement

- Enclosures:
1. Shanbaky-Cunningham Memo (6/24/85)
  2. Fisher-Hall Memo (2/1/84)
  3. Hall-Cunningham Memo (10/31/83)

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
631 PARK AVENUE  
KING OF PRUSSIA, PENNSYLVANIA 19406

JUN 24 1985

MEMORANDUM FOR: L. J. Cunningham, Chief, Engineering and Generic  
Communication Branch, IE

FROM: M. M. Shanbaky, Chief, PWR Radiation Protection  
Section, Region I

SUBJECT: REQUEST FOR CLARIFICATION OF I & E GUIDANCE REGARDING  
PHYSICIANS SIGNATURE REQUIREMENTS DURING PHYSICAL  
QUALIFICATION OF RESPIRATOR USERS

In a letter dated February 1, 1984 your office concurred with the Region IV position that a physician must review and sign the forms that provide the results of medical screening of respirator users. However, you also state that a physician's designee may sign these results for administrative convenience.

At the Ginna Station a specially trained nurse conducts the screening, reviews the results, and signs the authorization for respirator use by a worker. The corporate physician is responsible for this program but does not review individual screening results nor sign any document. The Region I position is that a physician must eventually review the screening results, concur with the nurse's evaluation, and sign an appropriate form. We believe that a physician designee may sign the initial results for administrative convenience, however, to satisfy the regulatory requirements and liability questions, a physician must review and approve the final records.

Please provide clarification on the physician's signature requirement.

A handwritten signature in cursive script that reads "M. M. Shanbaky".

M. M. Shanbaky, Chief  
PWR Radiation Protector Section

cc: K. Barr, R II  
R. Greger, R, III  
B. Murray, R IV  
C. Yuhas, R V

FEB 1 1984

MEMORANDUM FOR: Ramon E. Hall, Chief  
Technical Program Branch  
Division of Vendor and Technical Programs  
Region IV

FROM: William L. Fisher, Chief, Section B  
Engineering and Generic  
Communications Branch  
Division of Emergency Preparedness  
and Engineering Response  
Office of Inspection and Enforcement

SUBJECT: REQUESTED GUIDANCE REGARDING PHYSICIANS DETERMINATION FOR  
PHYSICAL QUALIFICATION OF RESPIRATORY EQUIPMENT USERS

As requested in your October 31, 1983 memorandum (copy enclosed), we have reviewed the Region IV licensee's respirator users physical qualification proposal. We cannot support the licensee's proposal. We do support the stated Region IV position that a physician must make the final determination of fitness for each individual. It is not acceptable for a physician to establish criteria for a program and then have the licensee (or any other designee) use these criteria to determine an individual's qualification.

Our position does not mean the physician must personally administer each medical history questionnaire or physical test. Nor should we preclude the physician's medical designee (e.g., a nurse) from signing the medical approval/denial form for the physician, as long as the designee's signature is clearly for administrative convenience and the physician has not relinquished any responsibility for the fitness determination.

We have coordinated this response with Lynnette Hendricks, ORPB, RES. If you have any questions, please contact Jim Wigginton.

William L. Fisher, Chief, Section B  
Engineering and Generic  
Communications Branch  
Division of Emergency Preparedness  
and Engineering Response, IE

Enclosure: see page 2

CONTACT: J. E. Wigginton, IE  
49-24967



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
611 RYAN PLAZA DRIVE, SUITE 1000  
ARLINGTON, TEXAS 76011

31 OCT 1983

MEMORANDUM FOR: L. J. Cunningham, Chief, Section B, Engineering and Generic  
Communication Branch, IE

FROM: R. E. Hall, Chief, Technical Program Branch

SUBJECT: REQUEST IE GUIDANCE REGARDING PHYSICIAN'S DETERMINATION FOR  
RESPIRATORY EQUIPMENT USERS

During a recent inspection of a licensee's respiratory protection program, the interpretation of 10 CFR Part 20.103.c.(2) was discussed. 10 CFR Part 20.103.c.(2) states, in part:

. . . "and determination by a physician prior to initial use of respirators and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protective equipment."

In our case, a physician assisted the licensee in the development of pass/fail acceptance criteria for the personnel screening checklist and pulmonary function tests. The licensee is responsible for actually performing the screening and function tests. The licensee maintains the position that since a physician had input regarding the acceptance criteria, it is not necessary to have a physician directly involved in the review and concurrence of the initial or followup examinations; once the testing parameters have been established, the licensee can independently accept or reject a prospective respiratory user based on the test results.

The Region IV position has been that it is acceptable for the licensee to conduct the initial and followup tests, but a physician must review the results and acknowledge this review by signing the appropriate forms.