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NUCLEAR REGULATORY COMMISSION

[10 CFR Part 20]

Advance Notice of Rulemaking

on Certification of Personnel Dosimetry Processors

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Advance notice of rulemaking to improve accuracy in personnel dosimetry.

SUMMARY: Tests have indicated that a significant percentage of personnel dosimetry processors may not be performing with an appropriate degree of accuracy. Alternatives for action to correct this situation are presented. Interested persons are invited to submit comments on these alternatives.

DATES: Comment should be received by

ADDRESSES: Comments or suggestions for consideration in connection with these alternatives may be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Alexander, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-5975.

SUPPLEMENTARY INFORMATION: Recent tests indicate that a significant percentage of the personnel dosimetry processors in the United States are not performing with a degree of accuracy acceptable to the NRC when compared against a consensus standard prepared under the auspices of the American National Standards Institute.* To the extent that these test results are representative of routine field conditions, the results indicate that the dose received by occupationally exposed personnel may often be considerably different from the dose reported by the dosimetry processor. Where complete reliance for individual dose determinations is placed on personnel dosimeters, control of individual radiation exposures may not be accomplished as well as is indicated, and compliance with regulatory dose limits may not, in fact, be achieved. The test results indicate that individual doses may be over or understated. Further, these incorrect measurements could become a source of error when the dosimetry data are used in epidemiological studies intended to investigate the dose-effect relationship.

The principal causes of the inconsistent test measurements that have been observed are not well understood. There is some evidence that the inconsistencies are due primarily to differences between the dosimeter irradiation techniques used by the tester and the calibration methods used by the processors; this possibility is discussed in the following paragraph. However, actual inaccuracies may arise because of inadequate quality control in dosimeter manufacturing or in a few cases because of ineptitude on the part of the processor. These different problems would

*Pilot study conducted for the NRC by the University of Michigan.

require different solutions, so that appropriate regulatory corrective action is very dependent on a better understanding of the causes of the problem.

Regarding the adoption of methods for correcting this problem, it is evident from at least two important considerations that caution should be exercised. First, as previously mentioned, the inconsistent test measurements refer to differences between the amount of radiation delivered to a dosimeter, under highly controlled laboratory conditions, by the individuals conducting the test, and the amount of radiation subsequently reported by the processor. These tests do not necessarily measure the difference between the radiation delivered to a dosimeter worn by a worker and the radiation subsequently reported by the processor. For example, the radiation source used by the processor to calibrate the dosimeter may emit radiation of the same or very similar quality as the radiation to which the worker is exposed, but may be quite different from the radiation used by the tester to irradiate the processor's test dosimeters. Thus, standardization of calibration techniques among U.S. processors, which may be essential for achieving good performance in a test program, could in some cases produce apparent improved accuracy while actually introducing greater errors in the personnel dose measurement process.** This consideration is an integral part of the personnel dosimetry problem and must receive full consideration in corrective action planning.

**For example, a processor may calibrate beta dosimeters for workers at a uranium fuel fabrication plant using a uranium slab; the tester may use a strontium-90 source. The processor could then measure the workers' doses accurately but could fail the performance test.

Secondly, any regulatory action taken must be handled in a manner to ensure that sufficient personnel dosimetry services remain available. Unnecessarily severe or improper corrective action could reduce the number of available processors to the extent that the dose determinations for some workers could be adversely affected.

One of the major sources of error in personnel dosimetry is known to be the potential difference between the actual dose received by the dosimeter and the actual dose received by the wearer. Such differences can, for example, be due to shielding of the dosimeter by the body when the worker is not facing the source of radiation or due to different irradiation of the part of the body on which the dosimeter is worn than of other parts of the body. These sources of error are recognized but are not part of the dosimeter processing problem that is being considered for correction.

A Federal Interagency Policy Committee on Personnel Dosimetry Performance has been formed to guide and coordinate correction of the dosimetry processor performance problem. Represented on this Committee are: the Bureau of Radiological Health (HEW), the Department of Defense, the Department of Energy, the Environmental Protection Agency, the National Bureau of Standards (NBS), the Nuclear Regulatory Commission, the Occupational Safety and Health Administration (DOL), and the Conference of Radiation Control Program Directors (States). Dosimetry processors and users have indicated agreement that some corrective action is appropriate. A working group of the Health Physics Society Standards Committee (HPSSC) has developed and the American National Standards Institute (ANSI) has published a draft standard for dosimetry performance (N13.11, July 1978). This standard is considered to be the most important element in a corrective

program. An industry committee (Personnel Dosimetry Overview Committee) has been formed to assist in ensuring that any proposed regulatory action is effective and appropriate to the need. However, agreement has not been reached as to the specific action that should be taken. Alternative corrective actions under consideration are discussed below.

Recent Federal Government Action

Some time ago, on November 30 and December 1, 1976, the Nuclear Regulatory Commission and other Federal agencies conducted a public meeting at which the personnel dosimetry performance problem was discussed in an open forum by personnel dosimetry processors, dosimetry users, and representatives of State governments and Federal agencies. Other co-sponsors of this meeting were the Energy Research and Development Administration (now the Department of Energy) and the Bureau of Radiological Health. These discussions revealed general agreement that a personnel dosimetry problem does exist and that the problem is sufficiently broad in scope that it should be addressed by the Federal government. However, many of the attendees cautioned against precipitous action and strongly recommended a pilot study (1) to evaluate the draft HPSSC/ANSI standard and (2) to provide processors the opportunity to take any necessary corrective actions in their operations prior to the implementation of new Federal regulations on the dosimetry performance problem. These recommendations were accepted, and the Nuclear Regulatory Commission (NRC) subsequently issued a contract to the University of Michigan (UM) to conduct a two-year pilot study. The objectives of this study were:

(1) to determine whether the draft HPSSC/ANSI standard provides an adequate and practical test of dosimetry performance;

(2) to give processors an opportunity to correct any problems that are uncovered;

(3) to develop operational and administrative procedures to be used later by a permanent testing laboratory.

The study was completed December 31, 1979.

Conditions of the contract included a provision that any personnel dosimetry processor in the United States would be allowed to participate in the study on a strictly voluntary basis, provided only that the dosimeters tested be restricted to those used to provide the permanent record of occupational exposures. Processors were told that the UM would keep test results confidential (i.e., that no organization other than the UM would be able to associate specific results with the name of a processor), that all results would be published (in coded form), that the UM would charge no fee for participation, that the new HPSSC/ANSI standard would be used to evaluate their performance, that each participant would be given the opportunity to be tested twice and would also be given an opportunity to discuss with UM personnel the possible reasons for any poor performance prior to the second round of tests, and that the accuracy of the irradiations provided by the UM would be verified by the NBS, and that UM facilities and equipment would be open to inspection by the participants prior to the beginning of the tests. An open house was conducted for the latter purpose by the UM on April 20, 1978. Fifty-nine processors participated in the study; it is believed that very few U.S. processors did not participate. During the course of this study, the UM submitted monthly

progress reports to the NRC. These reports are available for inspection or copying in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. Copies may also be obtained by contacting the Public Document Room, (202) 634-3273. The final report for the study, NUREG/CR-1064, may be purchased from National Technical Information Service, Springfield, Virginia 22161.

The draft standard allowed processors to be tested in eight different radiation categories. The term "category" refers to the type of radiation being measured. For example, Category 1 is gamma radiation, Category 2 is high energy X-radiation, Category 3 is low energy X-radiation, etc. Within each category of the draft standard were several dose ranges called intervals. The consensus standard used in the pilot study evaluated a processor's ability to consistently and accurately perform within a specific tolerance limit for each interval. Failure to pass one interval within the category would cause a processor to fail the entire category test. A performance index, P, was calculated for each dosimeter as (reported dose minus the delivered dose) divided by the delivered dose. For each interval, the average performance index, $\bar{P}$, and its standard deviation, S, were calculated. The draft standard incorporated a statistical test, $\bar{P} + 2S$ equal to or less than a specific tolerance value. The tolerance value for any given interval was a function of the average delivered dose and varied from 0.3 to 2.0. A processor could only pass a given category if all intervals of a respective category were passed.

At the conclusion of the first round of testing, the results were examined by the NRC staff, by the Interagency Policy Committee on Personnel

Dosimetry Performance, and by the industry's Personnel Dosimetry Overview Committee. The results indicated poor performance on the part of many processors. Only 23% of the category tests attempted by the processors were passed, using the criteria in the HPSSC/ANSI standard. None of the processors passed all of the tests attempted in the first round, but every category test was passed by at least one processor. These facts indicate that the standard is achievable and suggest that the problem may lie with the processor and/or with differences in irradiation techniques used by the UM and those used by the processors during their calibration procedures. The participants' performance in the first round was also evaluated used a simple percentage-passed basis (as opposed to the more complicated statistical formula of the standard). Again, generally poor performance was indicated. Using a simple ±30% pass-fail criterion for each and every dosimeter in a category during the first round of tests, the weighted average of all the processors reveals 7% of the category tests were passed (i.e., all dosimeters tested in all intervals of the category fell within the ±30% criterion). Using a ±50% criterion in the same manner, 21% of the category tests were passed. Thus, the results using the draft standard are similar to those using the ±50% criterion.

It had been anticipated at the beginning of the pilot study that processors who performed poorly during the first round of testing would be able to take corrective action prior to the second round and would improve their performance. The second-round results did indicate improvement over the first round. Approximately 35% of the category tests were passed. Using a simple ±30% pass-fail criterion for each dosimeter in a category during the second round of tests, the weighted average of all the processors reveals 19% of the category tests were passed (i.e.,

all dosimeters tested in all intervals of the category fell within ±30% criterion). Using a ±50% criterion in the same manner, 32% of the the category tests were passed.

Processor performance was not based on the percentage of dosimeters that individually passed the criteria set forth in the standard. Of the 23,000 individual dosimeters evaluated during the pilot study, 85% of the dosimeters tested passed round one of the tests and 90% of the dosimeters passed in the second round. Failure of the 15% and 10% of the dosimeters tested to meet minimum tolerances established by the HPSSC/ANSI in the standard .s an unsatisfactory level of performance when determining individual dose assessments. In the pilot study, for example, high doses (i.e., 600 rads) delivered to some of the test dosimeters were actually undetected by some of the processors.

One processor, whose results in the first round were very poor, worked with UM personnel to identify and effect the necessary changes in the process and then performed very well during the second round, passing all categories attempted but one. Another processor passed all eight of the categories. These facts provide rather strong indications that conformance with the standard is attainable, but that many processors have not made the necessary changes in their operations.

After considering this situation, the Interagency Committee on Personnel Dosimetry Performance made the following recommendations:

(1) The actual causes of the poor performance should be determined with a greater degree of certainty before finalizing plans for corrective action;

(2) A notice should be published in the Federal Register for the purpose of notifying all personnel dosimetry processors and the public that the Federal government is determined to take action as necessary to correct the personnel dosimetry problem.

Subsequently, the NRC staff authorized the UM to conduct a series of site visits with eight of the largest processors to try to determine the causes of poor performance. At the conclusion of these site visits, the UM personnel prepared a report which indicates four major causes:

(1) Inadequate calibration sources,

(2) Variability in the thermoluminescent dosimeter chips,

(3) Clerical errors,

(4) Lack of effort on the part of the processors to make the changes necessary to pass the tests.

This report, dated May 1979, is available in the Commission's Public Document Room in the file on personnel dosimetry performance testing.

Future Action

The pilot study was completed by the UM on December 31, 1979. Future action will be based in part on the final report. However, it is possible at this time to identify the following actions that the NRC has under consideration.

Processor Certification

According to this plan, the NRC would issue new regulations stating that personnel dosimetry results would be acceptable only if provided by

a processor who is certified by a testing (i.e., certifying) laboratory approved by, or specified by, the NRC.

These processors would have to obtain and maintain their certification by passing, at a specified frequency, performance tests conducted by the certifying laboratory. The certifying laboratory(s) would use performance criteria published by the American National Standards Institute (ANSI) and referenced in the new regulations. These regulations: (1) would adopt, possibly in modified form, the final ANSI standard evolving from draft ANSI standard N13.11; (2) would specify how frequently processors would have to demonstrate, through testing, their ability to comply with this standard; (3) would establish the procedure to be used by the NRC to let its licensees know which processors have been certified as well as those who have lost their certification; (4) would (except for one possibility noted below) name the testing and certification laboratory(s) required to be used; (5) would stipulate that the laboratory(s) would be monitored for technical competence by the National Bureau of Standards; and (6) would specify the procedure to be used for reinstating processors who have lost their certifications and have appealed.

Subsequently, other affected Federal and State agencies would be likely to consider adopting similar regulations. Although it is estimated that only about 15% of U.S. personnel occupationally exposed to measurable ionizing radiation (e.g., above 30 mrems per month) are engaged in NRC-licensed activities, it should be recognized that any NRC regulations in this area would affect a much larger percentage. This is true because most commercial processors serve customers other than NRC

licensees, and any improvements in their operations would be likely to benefit all of their customers rather than just the NRC licensees.

Several alternatives are possible as to the operation of the testing and certification laboratory(s):

(1) Unspecified Laboratory(s). This alternative would require an amendment to the NRC regulations as described above but without naming the testing laboratory(s). The processors and users would thereby be left to their own initiatives to establish one or more laboratories, which would have to be monitored by the NBS. The NRC would have no control over the laboratory(s), except through regulations applying to its licensees. However, if it is stipulated that the licensee must obtain personnel dosimetry results under conditions as described above (except for naming the testing and certification laboratory(s)), NRC licensees could only use a processor who complies with these conditions, including monitoring by the NBS.

(2) NRC-Operated Laboratory. This alternative would also require an amendment to the NRC regulations as described above, but the testing laboratory would be a Government facility managed and operated by NRC employees. By charging an appropriate testing fee, costs for establishing, maintaining, and operating the laboratory could be recovered.

(3) NRC-Contracted Laboratory. Similar regulation amendments would be needed for this alternative, but the laboratory would be operated by an NRC contractor, using the contractor's facilities. Funding would be provided by testing fees.

(4) Federal Government (non-NRC) Operated Laboratory. Similar regulation amendments would be needed for this alternative, but this testing laboratory would be operated by an agency of the Federal Government other than the NRC, preferably by one of the agencies experienced in laboratory testing work. Existing expertise could be utilized, or qualified personnel could be employed. The facilities would be Government-owned; funding would be provided by testing fees.

Invitation to Comment

Information pertaining to the personnel dosimetry problem discussed in this notice is invited, including comments on the alternative solutions described, suggestions of other alternatives, and estimates of costs anticipated in the process modifications necessary to permit successful passing of the ANSI standard criteria. Comments should be received by _____, 1980.

Dated at Washington, D.C., this 21st day of MARCH 1980.

For The Nuclear Regulatory Commission.

William J. Dircks
Acting Executive Director for Operations