OH 506-1

Telephone 617 366-9011
TWX
710-390-0739

YANKEE ATOMIC ELECTRIC COMPANY

B.1.1.1
WYC 80-23

20 Turnpike Road Westborough, Massachusetts 01581

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DOCKET NUMBER
PROPOSED RULE PR-20 (50)
(45 FR 20493)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing & Service Branch

Subject: Comments on Advance Notification of Rulemaking on Certification of Personnel Dosimetry Processors (45FR20493-3/28/80)

Dear Sir:

Yankee Atomic Electric Company appreciates the opportunity to comment on the subject advance notice of rulemaking. Yankee Atomic owns and operates a nuclear power generating plant in Rowe, Massachusetts. The Yankee Nuclear Services Division also provides engineering services for other nuclear power plants in the northeast including Vermont Yankee, Maine Yankee, and Seabrook 1 and 2.

Yankee Atomic participated in the pilot study (testing program) of ANSI N13.11 and recently participated in the public meetings held on May 27 and 28, 1980. Through our participation we have become concerned that this rulemaking may be hurried and therefore adopted before a sound certification program has been established. Our comments on how a test and certification program should be established and conducted are attached for your consideration.

If you have any questions regarding our comments, please contact us.

Very truly yours,

YANKEE ATOMIC ELECTRIC COMPANY

D. W. Edwards

D. W. Edwards, Director
Operational Projects

JHM/kaf

Attachment

L-4-1, Pt. 20

Acknowledged by card. 7/14/80 mdv

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Standardization of Calibration Techniques

Yankee Atomic Electric Company (YAEC) concurs that the use of well defined calibration techniques and radiation sources is necessary to properly implement a dosimetry testing standard. The proposed regulations for dosimetry processors should specifically recognize that a dosimetry users radiation environment may not be the same as the radiation sources used in testing for the performance standard. Thus, a dosimetry processor should be allowed (and encouraged) to apply response calibration factors to dosimetry results that will equate dosimetry results to absorbed dose under routine operating conditions.

In addition, a dosimetry processor may choose to calibrate its dosimetry system to radiation sources that are not generic to either the testing standard or the dosimetry user. In these cases the dosimetry processor will need to use response calibration factors when equating absorbed dose for both the testing standard and its dosimetry users. Calibration factors, equating dosimetry response to absorbed dose, are an absolute necessity when beta and neutron exposures are being evaluated.

Standardization of calibration techniques is considered, by YAEC, to be an integral part of a dosimetry processors quality assurance program. Essential elements of a quality assurance program are outlined later in this attachment.

Impact of the Proposed Certification of Personnel Dosimetry Processors on the Availability of Personnel Dosimetry Services

Yankee Atomic Electric Company (YAEC) realizes that caution must be utilized in the implementation of corrective actions for testing failure such as Certification removal in order to ensure that sufficient personnel dosimetry services remain available thus minimizing the affect on dose determinations for some workers. However, care must also be taken to ensure that "lack of available dosimetry" does not become an overriding factor in the maintenance of a processor's certification; that is, full certification may be maintained, even after failure to perform satisfactorily in the testing program, solely due to the large number of dosimeters processed by an individual processor. It should also be recognized that inaccuracy on the part of a large processor may have a more significant impact on the prediction of the total exposure for a large group of workers than the lack of accuracy of a small processor.

Therefore, YAEC recommends the adoption of successive levels of Certification such as PASS, PROBATION, and FAIL for <u>each</u> category in which a processor is evaluated. The performance criterion established in the revised ANSI N13.11 could be the basis by which movement from one level to another is determined. The use of the PROBATION level will provide the users (particularly NRC licensees) of a processor's service with 1) a mechanism by which they may be made aware of problems within

the processor's services and 2) the time to prepare alternative sources of dosimetry if they so desire. In addition, the PROBATION level will provide the Certification and Appeals Board more flexibility to deal with the obvious problem of dosimetry availability without fully certifying a processor.

Adequacy of ANSI Standard N13.11

Yankee Atomic Electric Company (YAEC) considers ANSI N13.11 to be a good basis for establishing a standardized method of testing personnel dosimetry processors. YAEC had noted problems with the use of the ANSI during the pilot study and these were presented, in detail, at the public meeting held May 27 and 28, 1980 in Washington, D.C.

During the public meeting several changes which will be implemented in ANSI N13.11 were presented. These changes involve: a) replacing the ^{60}Co photon source with ^{137}Cs, b) adding a category of moderated ^{252}Cf neutrons, c) eliminating the intervals within each testing category d) increasing the number of test dosimeters within a category from ten to fifteen and e) modification of the performance criteria from $B \pm 2S$ to $B \pm S$. YAEC concurs with these recommended changes and requests their implementation in ANSI N13.11.

YAEC has recognized a discrepancy between the requirements of ANSI N13.11 and NRC Form-5. Depth dose monitoring for the ANSI is accomplished at $1000 mg\text{-}cm^{-2}$, whereas, NRC Form-5 instructions require depth dose monitoring at $300 mg\text{-}cm^{-2}$ when eye protection is not worn. This conflict can result in dosimetry processors having to use two different badge designs for responding to ANSI N13.11 and maintaining compliance with NRC Form-5 requirements. This conflict would void the intent of the ANSI to use the same dosimetry as used for personnel monitoring. YAEC requests resolution of this problem.

YAEC will reserve additional comments on the adequacy of ANSI N13.11 pending receipt of a revised draft and notification of any changes the Nuclear Regulatory Commission intends to make with regard to implementation of ANSI N13.11.

Certification Process

A single Certification and Appeals Board should be established with a mandate to issue initial certification, resolve differences of opinion between any parties involved in the certification program and remove certifications if required. This board should be composed of individuals involved with each facet of dosimetry measurements and should be composed of members from: a) one or more federal regulatory agencies (NRC, EPA, etc.), b) the National Bureau of Standards, c) a National Laboratory involved in routine dosimetry production, d) a commercial dosimetry processor and e) the testing laboratory.

The inital certification of a processor in each category should be awarded based on: a) dosimetry testing results, b) a review of the processors quality assurance program, and if necessary, c) an on site evaluation of the processor's program. Since the first year of testing will be a learning experience for the testing laboratory personnel as well as the individual processors, it is recommended that certifications should not be issued based upon data collected during the first testing cycle.

Adoption of ANSI N13.11 as a Performance Standard

Yankee Atomic Electric Company (YAEC) encourages the adoption of ANSI N13.11 as a performance standard for dosimetry processors for two particular reasons. First, the ANSI will be endorsed by the Health Physics Society and American National Standards Institute. Second, most dosimetry processors have had some experience in responding to requirements of the ANSI. However, the changes to the ANSI, as described at the meeting of May 27 and 28, 1980, lead YAEC to recommend that at least one additional pilot study incorporating all anticipated changes be underwritten by the Nuclear Regulatory Commission.

ANSI N13.11, as presently written, includes requirements for performing angularity testing of processors dosimetry. However, no criteria are placed on this testing. There are many factors, in addition to angularity response, that have an equal effect on the response of dosimetry. Including a study of angularity respone with no criteria or apparent intent in a performance standard is inappropriate. YAEC requests that this requirement be removed from the standard.

Frequency of Testing for Continuance of Certification

After having participated in the pilot study of ANSI N13.11, Yankee Atomic Electric Company (YAEC) believes that yearly testing is probably the most viable testing frequency. The yearly testing, it is presumed, would be performed in a manner similar to the schedule established by the University of Michigan. This schedule called for monthly testing for three consecutive months once a year.

This frequency of testing would not have a dramatic impact upon man-hour requirements of a processor and is spread over a period of time that would allow the testing to be blended into a processor's routine production requirements.

Notification to NRC Licensees of Dosimetry Processors' Status

Prompt awareness of a change in the status of a certified dosimetry processor is an absolute necessity for NRC licensees. At the Public Meeting on the Subject of Personnel Dosimetry (Washington, D.C., May 28 and 29, 1980) the NRC staff indicated that such notification could come through the Federal Register. Yankee Atomic Electric Company agrees with the principle of notification through the Federal Register. The information which should be contained in such a notification would be the name of the processor, status of each category for which that processor is certified (i.e. PASS, PROBATION, or FAIL) and a notation on any change of status for the processor. In addition to the publication of a list of certified processors, each certified processor should be required to provide written notification to any NRC licencees serviced by the processor of any change in a category status which may adversely affect the accuracy of dosimetry results.

Establishment of a Testing Laboratory

Yankee Atomic Electric Company believes that establishing the testing laboratory as a NRC-contracted laboratory is the most attractive method of implementing the testing program. Initial funding of the laboratory should come from the NRC. Testing fees can be imposed after the first year of operation to make the laboratory self-sustaining. Fee schedules should be based on the number of categories in which a dosimetry processor participates and the volume of dosimetry routinely processed. This arrangement will allow processors to be charged fees that are commensurate with their operating budgets. The laboratory should be operated by personnel with little vested interest in dosimetry processing.

The laboratory should be permitted to obtain radiation sources and provide testing outside the confines of ANSI N13.11 after the first year of operation. This will allow the laboratory to expand its services and obtain additional income based on fees established for these increased services.

Monitoring of the Testing Laboratory by the National Bureau of Standards (NBS)

Yankee Atomic Electric Company concurs that monitoring and certification of the testing laboratory by NBS is an absolute necessity. This will ensure unbiased exposure techniques and lend credibility to any testing program. The NBS should be totally involved with the areas of a) source selection, b) source, dosimeter, and phantom configuration, c) exposure delivery procedures, and d) definition of delivered exposures.

Removal and Reinstatement of Dosimetry Processor Certification

The Federal Register notice did not publish any intended rule-making on the certification procedures for dosimetry processors. However, Yankee Atomic Electric Company is taking this opportunity to present a suggested outline for removal and reinstatement of processor certification.

The testing laboratory would notify the Certification and Appeals Board (CAB) of the failure of any one category by a dosimetry processor. The CAB would automatically notify the processor that he has been placed on "Probation" in the failed category and must submit dosimetry for retest within a predetermined period of time. In addition, the processor will be required to present to the CAB the results of an investigation as to the cause(s) of failure. If the processor passes the retest, certification would be reinstated.

Failure of the retest will cause the CAB to require the processor to present arguments as to why his certification, for the category, should not be removed. The minimum action allowed for the CAB would be keeping the processor on probation until sucessfully passing the failed category. If the CAB votes to remove a processors certification, it must be decided by a near-unanimous vote of the CAB.

A processor who applies for re-certification, after having failed a testing category, must have a comprehensive review of his quality assurance program performed by the CAB. This review may include onsite visits to the processor's facilities.

Quality Assurance

Adequate confidence in dosimetry results produced by any processor, on a routine basis, cannot be established solely on the basis of satisfactory performance in an evaluation program under a set of extremely well defined conditions which may or may not reflect the conditions encountered in a licensee's routine operations. However, satisfactory performance may be indicative of the manner in which a processor conducts the measurement of routine dosimetry. The Certification and Appeals Board should be able to determine the adequacy of a processors program for the processing of routine personnel dosimetry by a review of the key elements of the processors quality assurance program.

It must be stressed that the quality assurance programs of most processors are extremely complex and detailed. Thus, a review of all of the details of a processors quality assurance program could be time consuming, confusing, and would most likely shed no more light on the manner in which a processor conducts his routine operation.

The outline below depicts some of the essential elements of quality assurance as applied to dosimetry data.

I. Selection of Key Personnel

- A. Hightest available quality,
- B. Knowledgeable about dosimetry needs,
- C. Aware of complex interactions required in a functional dosimetry program and
- D. Responsible for delineation of the entire program

II. Facility Design (Direct Bearing on Quality)

- A. Large enough to accomodate planned quantity of dosimetry processing
- B. Each separate processing area must have adequate and proper:

    1. Space
    2. Lighting
    3. Heating and ventilation
    4. Temperature and electrical power regulation
    5. Ambient radiation levels

III. Awareness of Exposure Parameters

- A. Type of radiation to be measured
- B. Energy spectrum for each type
- C. Expected exposure levels

IV. Selection of Analytical Techniques

- A. Balanced blend of quality and quantity
- B. Well known and/or well documented techniques
- C. Based on a working knowledge of the measurement system and technique(s) under evaluation
- D. Technique uncertainties and limitation
- E. Comparison of <u>expected</u> accuracy and precision for various anticipated methodologies

V. Selection of Analytical Equipment

- A. Partially governed by choice of analytical methodology
- B. Several points to investigate when choosing instrumentation

1. Suitable for measuring required quantity
2. Reliablity
3. Reproducibility
4. Operating Parameters
5. Maintenance required
6. Availability of equipment
7. List of users
8. User oriented

VI. Selection and Training of Analytical Staff

A. Degree of experience dependent on program needs
B. Training

1. Initial

a. Technique familiarization to include theoretical considerations
b. Processing routine matrices
c. Qualification by processing replicate irradiated unknowns
d. Processing of submitted dosimetry

2. Retraining

a. Dependent on qualifications of individual
b. Requalification by processing irradiated unknowns (yearly)
c. Yearly review of pertinent procedures

VII. Establishment of Chain of Custody for Dosimetry

A. Establish a knowledge of dosimetry location at all times

1. Establish the normal flow of dosimeters for the measurement process
2. Establish a system for issuing and receiving dosimeters
3. Notification to contractee of missing dosimetry

VIII. Establishment of Quality Control Criteria

A. Adequate criteria must be established
B. Recognize key parameters

1. Accuracy (Bias)
2. Precision

C. How accurate or precise?

1. Pure guess
2. Educated estimate
3. Estimates based on total knowledge of measurement system and related uncertainties. (Preferable)

D. Choosing an operating criteria

1. Utilize an existing criteria from another facility?
2. Evaluate current measurement processes
3. Modify criteria to meet needs
4. Test criteria and modify if necessary
5. Adopt criteria for routine operations

The Certification and Appeal Board can assure themselves of the viability of a processors quality assurance program through a review of that program with respect to the following points:

1. Has the emphasis on quality been established among all staff members?
2. Has a thorough procedure manual dealing with all aspects of the measurement and reporting process been established and maintained?
3. Are well known or proven methodologies utilized? If the methodologies are developed in-house, have all facets of the method been tested, verified, and documented?
4. Has a viable training program which includes initial training and subsequent retraining been established and maintained?
5. Is the analytical staff thoroughly familiar with the dosimetry measurement systems being utilized and are they able to recognize and correct inadequate performance?
6. Is a calibration schedule and calibration documentation maintained?
7. Are instrumentation calibration checks performed utilizing well characterized dosimeters and radiation sources which truly reflect the operation of the system under consideration?
8. Does the processor perform standard measurements during each series of exposure determinations?
9. Are control charts or tables for recording instrument status checks utilized and are the criteria for acceptability clearly apparent?
10. Is a "chain of custody" system for the tracking of dosimeters throughout the issuing/processing cycle in place and operating?
11. Has a record keeping system, which will lend itself to ease of use and data retrievability, been established? Is this system capable of checking the validity of key data inputs from the analytical calculations? Remember - in all production type endeavors in which quality plays an important consideration - record keeping will occupy 40 to 50 percent of the work effort.
12. Are all aspects of the computer programs documented and validated Are a percentage of all calculations verified?
13. Is a complete instrument history maintained on the instrumentation utilized in the laboratory?
14. Does the processor conduct a mandatory data review by individuals knowledgeable of the dosimetry measurement program?
15. Does the processor expedite data review for quality control dosimetry as soon as known data is available?
16. Are appropriate actions taken based upon the acceptance or rejection of quality control data when compared to established criteria?

Once the framework of the quality assurance program is in place, satisfactory performance within the established quality control criteria must be maintained by determining the major uncertainties related to each analytical process, maintaining these uncertainties below their estimated upper bounds, and establishing a sufficient number of checks to ensure the quality of data on a day to day basis. Included among these checks must be several types of dosimetry which will test the system under various circumstances. These types of dosimetry are outlined below:

I. Intralaboratory Process Checks

- A. Known levels
- B. Prepared in-house
- C. Agreement with established criteria immediately known
- D. Does not indicate system bias

*II. Replicate Irradiation Program

- A. Excellent indicator of precision for truly replicate irradiations
- B. Preferrably controlled by the contractee
- C. Require notification of all results (acceptable and unacceptable).

III. Independent Evaluations (ANSI N13.11)

- A. Third party objectivity
- B. Agreement with criteria not immediately known
- C. Measurement of system bias
- D. National program preferrable
- E. Informal programs should be encouraged.

IV. Control Dosimeters

- A. Dosimeters processed which reflect intransit and storage dose evaluations during issue period
- B. Utilize viable percentage
- C. Processed with each exposure processing
- D. Irradiated controls may be viable

V. System Background Checks

- A. Check of well characterized background level
- B. Maintain system integrity

To ensure the continued adequacy of the quality assurance program audits of the entire process should be conducted at some predetermined frequency. The responsibility for these audits should rest with the licensees and not the processor.