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Performance Testing of Personnel Dosimetry Services: Alternatives and Recommendations for a Personnel Dosimetry Testing Program

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ABSTRACT

The Nuclear Regulatory Commission (NRC) is considering an amendment to 10 CFR Part 20 that would require their licensees to use only processors of personnel dosimetry devices (e.g., film badges and thermoluminescent dosimeters) that have been certified. Although this action would have a direct effect only on those processors that service NRC licensees, it would most likely lead indirectly to a nationally-recognized certification program for all dosimetry processors.

The objectives of this Report are to consider a variety of alternatives that would influence a certification program, to consider the advantages and disadvantages, values and impacts, of each alternative, and to make a recommendation for each alternative. Among the considerations discussed are:

1. Is a certification program necessary?
2. What standard should be used for a testing program?
3. What type of organization should test dosimetry processors?
4. How often should a processor be retested?
5. What appeals procedures should be available to a processor?
6. What are realistic estimates of the costs of a testing program?

SUMMARY

Values of the Proposed Action

1. A nationally-recognized dosimetry testing program will give credibility to a processor that passes.

2. A dosimetry testing program will encourage processors to correct major problems in their procedures (e.g., inappropriate calibration factors, dosimeter variability, clerical errors, and accident dose calibrations).

3. A dosimetry testing program, together with other relevant actions (e.g., adequate quality control procedures, use of uniform terminology), will lead to an improvement in the quality of personnel dose measurements.

Impacts of the Proposed Action

1. A dosimetry testing program will cost approximately $800,000 to initiate and about the same amount annually.

2. Some processors could view the passing of a dosimetry testing program as their only objective, which would lead to the use of improper calibration factors (and therefore incorrect assigned doses) for the radiation workers they serve.

3. If a processor makes substantial changes in the calibration factors used for his regular users due to changes in his procedures required to pass a testing program, the credibility of his past dosimetry may be lost.

Table of Contents

Table of Contents (cont.)

INTRODUCTION

From October, 1977 to December, 1979, we at The University of Michigan (UM) conducted a pilot study of a dosimetry performance testing standard, ANSI N13.11.[1] The pilot study was sponsored by the U.S. Nuclear Regulatory Commission (NRC) as part of a long-range plan to require performance testing of processors that supply personnel dosimetry to their licensees. The results of the pilot study are described in three major reports: a Procedures Manual,[2] a Final Report,[3] and a Supplementary Report.[4]

It was, and still is, the hope of many people that other Government agencies (e.g., Department of Energy (DOE), Department of Defense, Bureau of Radiological Health, Department of Labor, the States) will also amend their requirements so that all dosimetry processors in the United States will someday be required to demonstrate competency on a periodic basis.

The contract between the UM and the NRC was extended until February 15, 1981, in part so we could assist the NRC in the preparation of a Value/Impact Statement for a proposed rule to require NRC licensees to use acceptable (i.e., certified) processors. As part of our effort to provide this assistance, we invited all processors that participated in the pilot study and all other processors known to us to attend a one-day meeting with their peers to discuss values and impacts to them of a dosimetry performance testing program. Three separate meetings were

held in Ann Arbor, Michigan, one for private in-house processors (nuclear power plants, medical facilities, universities, etc.), one for Government-affiliated in-house processors (National Laboratories, prime DOE contractors, the military, etc.), and one for commercial processors. Table 1 shows the organizations that sent representatives to these meetings. No one from a regulatory agency was invited to these meetings. We believed this format offered several advantages:

1. Small meetings provide ample opportunities for everyone to participate.
2. The absence of regulatory people enable frank, often brutal, discussions.
3. Each of the three groups has its own values and impacts that, in some cases, differ considerably from those of the other groups.

The disadvantage of this format is that participants in each group were not able to hear the discussions that occurred in the other two groups.

Several processors submitted written statements expressing their opinions on various topics relevant to a dosimetry testing program. These statements have been forwarded to the NRC.

This report has two parts, each with its own objective. PART I is a summary of the comments and ideas generated during the three one-day meetings held in Ann Arbor. The format for PART I is similar to the format required for the Value/Impact Statement. Various alternatives are considered, including the alternative of no testing program, and advantages and disadvantages of each alternative are given. This summary

Table 1. Processors represented at one-day meetings to discuss values and impacts to them of a dosimetry testing program, Ann Arbor, Michigan.

Private In-House Processors
April 23, 1980

Bethlehem Steel Corporation
Carolina Power & Light Co.
Consumers Power Co.
Duke Power Co.
Duquesne Light Co.
Florida Power & Light Co.
Gulf Oil Co.
Houston Power & Light Co.
Jersey Central Power & Light Co.
New Brunswick Electric Power Co.
New England Nuclear
Omaha Public Power District
Ontario Hydro
Public Service Electric & Gas Co.
Tennessee Valley Authority
University of Utah
Virginia Electric & Power Co.
Washington Public Power System
Yankee Atomic Electric Co.

Government In-House Processors
April 25, 1980

Argonne National Laboratory
Battelle Pacific Northwest Laboratories
Bettis Atomic Power Laboratory
Charleston Naval Shipyard
Department of Energy, Idaho Operations Office
Lawrence Radiation Laboratory
Lexington-Bluegrass Army Depot
Los Alamos Scientific Laboratory
Mason & Hanger
Monsanto Research Corporation
Naval Research Laboratory
Oak Ridge National Laboratory
Portsmouth Naval Shipyard
Reynolds Electric & Engineering Co.
Sandia Laboratories
Savannah River Plant
United States Air Force, Brooks AFB

Commercial Processors
April 29, 1980

Eberline Instrument Corporation
ICN Pharmaceuticals
Landauer, R.S., Jr. and Co.
Radiation Management Corporation
Searle Analytic
Teledyne Isotopes

should provide information necessary for the NRC to prepare a Value/ Impact Statement. In PART II of this report, we assume that a testing program will become a reality, and our recommendations are given for the design for what we believe would be the most effective program possible. These recommendations are based on the advantages and disadvantages of the alternatives considered in PART I, our experience with the two-year pilot study, and the comments received from the processors that met with us in Ann Arbor during April, 1980.

PART I: ALTERNATIVES TO BE CONSIDERED IN THE VALUE/IMPACT STATEMENT

PROPOSED ACTION

Description of the Proposed Action

On March 28, 1980, the NRC published a notice in the Federal Register (Vol. 45, No. 62) titled, "Advanced notice of rulemaking to improve accuracy in personnel dosimetry." The notice proposed that, "... 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."

This proposed action contains two key ideas: (1) an improvement in the accuracy of personnel dosimetry is required, and (2) the testing laboratory must be approved or specified by the NRC. Both of these ideas will be discussed at length in this report.

Need: Pilot Study

A major argument in favor of the hypothesis that the quality of personnel dosimetry in the United States is poor and requires improvement is the results of the pilot study. The 59 processors that participated

in the pilot study account for about 90% of the personnel dosimeters used in the United States. Each processor was permitted to be tested twice during the pilot study with a minimum of three months between the tests during which time they could make corrections in their procedures as required. Among all the radiation categories tested for all the processors, only 23% were passed in Test #1 and 35% were passed in Test #2. Although this represents some improvement, the results suggested that two-thirds of the category-tests attempted in a future testing program would be failed.

After the pilot study was concluded, the Standard was revised by the Health Physics Society committee that prepared the draft Standard used for the pilot study. A detailed discussion of the revisions made is given in the Supplementary Report.[4] The statistical method used to determine if a processor passes or fails was revised based, in part, on the high failure rate of the processors during the pilot study. Had the revised statistical method been used for the pilot study, the passing rates for Tests #1 and #2 would have been 48% and 62%, respectively. These results suggest that, at most, only about one-third of the category-tests attempted in a future testing program would be failed. The actual failure rate would probably be less as processors become used to the procedures required by the Standard.

Several major reasons for the high failure rate of the pilot study are identifiable and must be considered in a discussion of the state-of-the-art of personnel dosimetry.

1. Calibration Factors

Only a few radiation sources were used to irradiate dosimeters tested during the pilot study. These sources were selected and used according to the specifications of ANSI N13.11. The sources were different than those used by many processors for the original calibration of their dosimeters. Since no personnel dosimeter gives dose equivalent directly (film dosimeters provide optical density and thermoluminescent dosimeters, TLDs, provide light), calibration factors must be provided for each type of dosimeter (i.e., combinations of a radiation sensitive element and associated filters) so the processor can convert the output from optical density or light to dose equivalent. These calibration factors are usually highly dependent on the type of radiation used.

Few processors began Test #1 with the calibration factors required for all the radiation sources used during the pilot study. Those processors that made a concerted effort to produce the appropriate calibration factors showed a noticeable improvement in their performance from Test #1 to Test #2. However, few processors bothered to produce the necessary calibration factors before the end of Test #2. Therefore, it is not unreasonable that the failure rates of the two tests of the pilot study were high.

Some processors maintain that their dosimeters are calibrated to sources other than those specified in ANSI N13.11 because these other

sources simulate the working conditions of the radiation workers that use their dosimeters. These processors have two choices. They can either generate one set of calibration factors for a testing program and a second set of factors for their users, or they can produce only the calibration factors necessary to pass the testing program. If they do the former, then the testing program may only test their ability to produce calibration factors. If they do the latter, then the testing program may actually cause a worsening of dosimeter accuracy. Neither case is a good argument for a testing program.

During the two-year pilot study, we had many telephone conversations and correspondences with the 59 processors that participated, and we were able to visit a few of the processors. Our observations suggest that although it is physically possible to produce the necessary calibration factors for each type of dosimeter in use, a few processors do not have the knowledge to do so. Unless these processors obtain the necessary knowledge, they will never be able to pass a test of their ability to generate proper calibration factors. These processors are few in number (approximately a half dozen) and account for a small fraction of radiation workers in the United States (approximately one half of one percent). In addition, we suspect that they cater primarily to workers who receive little or no exposure (e.g., dental X-ray technicians). Therefore, a national testing program to protect society from these processors may not be justifiable.

2. Dosimeter Variability

Dosimetry film supplied by Kodak (the only supplier in the United States) appears to be fairly constant in quality from batch to batch. Processors that use film generally follow good quality control procedures to examine each batch that they purchase.

Processors that use thermoluminescent chips must develop and follow sophisticated quality control procedures before they accept these chips from a manufacturer for use in a dosimeter. If these chips are not carefully screened by a processor, the average bias among a large number of chips may be small, but the variability in sensitivity may cause the processor to fail a testing program. (As a result of the pilot study, some processors discovered that some of their chips were completely insensitive to the type of radiation for which they were purchased.)

3. Clerical Errors

Many processors failed portions of the pilot study tests because of clerical errors. These errors included misplaced decimals and transposed numbers.

4. Accident Dose Calibrations

Several processors do not calibrate for accident doses (greater than 10 rem) or have inadequate procedures for handling accident doses. Some of these processors maintain that they have no need for such calibrations since it is physically impossible for their users to receive accident doses (e.g., dental X-ray technicians).

Some processors that have special, off-line, procedures for processing dosimeters exposed to accident doses never completed their special procedures. Thus, when no dose was assigned to a dosimeter, the processor reported zero instead of a correct value that ranged up to 800 rad.

Need: Epidemiological Studies

There is considerable interest today in low-dose effects of ionizing radiation. Since a large number of workers are exposed to low doses, it is tempting for some organizations to attempt to correlate dose to effect. A nationally-recognized testing program would help many people to understand and document the accuracy and limitations of personnel dosimeters which, in turn, would probably help the interpretation of dose/effect investigations.

Need: Appropriate Calibrations

Many radiation workers are using dosimeters that have not been calibrated for their special needs. Commercial processors must generally calibrate for what they perceive to be average radiation energies for their users, although they have the technical capability to provide custom calibrations if asked. A dosimetry testing program will require a processor to develop calibration factors necessary to pass the test. This effort may, in turn, focus attention on the use of calibration factors appropriate for the needs of the radiation workers served by the processor.

Need: Uniformity

Many processors have developed a dosimetry language that only they can understand, and sometimes even they are confused. For example, ANSI N13.11 clearly defines shallow and deep depths, but many processors report doses with descriptions such as beta and gamma, skin and whole body, non-penetrating and penetrating. A standardized testing program would probably lead to a standardized vocabulary. Cumulative doses assigned to radiation workers that frequently change jobs, and therefore change processors, would probably be more accurate if all processors subscribed to the same set of dosimetry definitions.

Need: Summary

The primary question that must be addressed is: Are improvements in personnel dosimetry necessary? Based on the needs discussed above, the answer appears to be yes. The major problems identified in the pilot study (appropriate calibration factors, dosimeter variability, clerical errors, and accident dose calibrations) probably exist in the routine operation of most dosimetry processors. Although it is doubtful that these problems constitute a major health hazard to the majority of radiation workers in the United States, there is little doubt that these problems can be corrected and, in general, at a minor cost to the dosimetry industry.

A secondary question is: Will a dosimetry testing program, whether it covers only NRC licensees or all radiation workers, actually improve dosimetry? The answer to this question would be an unqualified yes provided that all processors could be tested without their knowledge (blind testing), and if they could be tested with radiation sources that simulate the needs of their users. In such a blind test, a processor would treat the testing laboratory exactly like their users, and their performance during the blind test could be equated with their performance to their users. However, blind testing on a large and continuing scale is virtually impossible for all but the major commercial processors. No evidence exists that this group deserves to be tested more than any other group of processors.

If the processor knows they are being tested, the ability of the testing program to improve dosimetry decreases significantly. It is

possible in an open test, wherein the processor knows they are being tested, for a processor to use carefully generated calibration factors for the test dosimeters and totally ignore the needs of their regular users. A processor can send carefully screened dosimeters to the testing laboratory, but use unscreened dosimeters for their regular users. A processor can check and recheck for clerical errors among test dosimeters, but pay little attention to similar errors in the processing of regular dosimeters. And a processor can treat accident dosimeters and other potential sources of error with greater care for test dosimeters than for dosimeters sent to their regular users. Thus, an open testing program can only demonstrate that a processor has the ability to meet the demands of the test. It cannot, by itself, insure that a processor applies this ability to their regular users.

Values of the Proposed Action

The major value of a testing program as perceived by all three groups of processors is credibility. Due in part to a nation-wide hysteria concerning biological effects of ionizing radiation, lawsuits against employers of radiation workers abound. Dosimetry processors feel an increasing need to demonstrate their ability to measure doses to people accurately. Self-designed and self-administered testing and quality control programs do not carry the legal credibility of a nationally-recognized certification program. Maximum credibility will be realized if the testing program is sanctioned by appropriate Government agencies.

Some individuals responsible for in-house dosimetry within their organization clearly recognize the limitations of their equipment and procedures. They often find it difficult or impossible to secure the funds from their management to make necessary improvements. They believe a testing program would be of value to them in that a poor performance, either demonstrated or anticipated, would increase their operating budget and thus the quality of their service.

Some commercial processors believe a testing program would have some advertising value to them, provided that their performance was better than that of their competitors. Some commercial processors insist that this value would be minimized if all commercial processors were passing the test regularly. Given the demands of a competitive market, it is probably correct to assume that the testing program would have some advertising value to the commercial processors that performed well, although the technical value to their customers would not follow automatically.

Commercial processors are tested continuously by their customers. One value to these processors of a nationally-recognized testing program would probably be a reduction in the number of customer-organized tests, many of which are improperly designed and implemented.

Impacts of the Proposed Action

The most obvious impact of a testing program is its cost. If a testing program is self supported, a fee will have to be levied on each participating processor by the testing laboratory. The magnitude of this fee will depend on several things. If one testing laboratory services all processors in the United States, the fee to each processor will be less than if several testing laboratories exist, each servicing only a few processors. The commercial processors believe that all processors should be treated equally in determining the fee structure. The in-house processors believe that the testing fees should be assessed according to the size of each processor. This disagreement alone represents an uncertainty of four orders of magnitude in the estimated testing fee.

In addition to direct fees levied by the testing laboratory, each processor will incur additional costs due to the extra labor required to participate in a testing program. Most processors will require a major expenditure of capital and labor to develop the initial calibration procedures required to pass a testing program. For some small processors, the number of dosimeters required for testing amounts to 25% or more of the number of dosimeters they process regularly.

An obvious, but undetermined, impact to all processors is the consequence of failing one or more of the radiation categories of a test. This impact is difficult to assess since no procedures have been pro-

posed concerning notification of users of a failure, probationary periods for retesting, etc.

Commercial processors are concerned that insurance companies will view participation in a testing program as a risk, since failure is a considerable threat to business. Thus, it is likely that insurance premiums will go up, and this added cost will be passed along to the customers.

If the cost of dosimeters provided by commercial processors increases substantially, many users who are not legally required to wear dosimeters but do so voluntarily will probably terminate their contracts. Not only does this represent a loss of business for the commercial processors, but it will represent a decrease in radiation protection among a substantial number of workers.

Our estimates of the costs associated with a personnel dosimetry testing program are given in the Appendix.

Unless sensible provisions are made to give a processor an opportunity to correct problems following a failure, chaos will result. Commercial processors will face immediate cancellation of contracts they have with their clients. A client who cancels must secure dosimetry elsewhere, either from another commercial processor or with their own in-house service. Most commercial processors maintain that a minimum of 60 days is required to add a new customer. A customer would probably require at least a year to begin doing their own dosimetry.

Most processors have calibrated their dosimeters to radiation sources other than those specified in ANSI N13.11. If a processor changes calibration sources because of the requirements of the testing program, this could cause a noticeable increase or decrease in the doses he regularly reports to his users. This could result in a serious impact on the processor if his users challenge his past calibration efforts. A noticeable increase in assigned doses could imply past uncertainties that resulted in an underestimate of true doses. A noticeable decrease in assigned doses could imply a new effort to reduce doses artificially. Either sharp change in assigned doses could be viewed with suspicion by the users.

Several processors speculated that one impact of a testing program would be the discouragement of new developments in personnel dosimetry. They fear that the goal of dosimetry will be to pass the test. A processor with a dosimeter that will pass the test has little incentive to research and develop new types of dosimeters.

TECHNICAL ALTERNATIVES

If a dosimetry testing program is determined to be potentially desirable, several standards are available from which to choose.

The International Organization for Standardization (ISO) has a few standards completed or in preparation that have some bearing on personnel dosimetry. However, these standards deal either with one type of dosimeter (film or TLDs), or they deal with the engineering specifications of equipment such as TLD readers. No processor expressed a desire to subscribe to an ISO standard in place of one developed in the United States.

The National Sanitation Foundation (NSF) has had a dosimetry performance standard since 1966.[5] Two disadvantages of this standard are recognized. First, it represents a state-of-the-art standard instead of one that addresses health physics needs. Second, due to previous political and technical problems, the NSF service, including the NSF Standard, are unacceptable to many processors.

Finally, the advantages and disadvantages of ANSI N13.11 were discussed at length among the processors and are summarized below.

Advantages of ANSI N13.11

1. It will eventually have the endorsement of the Health Physics Society and the American National Standard Institute (ANSI). These two organizations offer considerable credibility to the document and, therefore, to those processors that pass a test administered according to this Standard.

2. It represents health physics needs, although tempered by the state-of-the-art of personnel dosimetry.

3. The radiation sources, number of dosimeters required for testing, tolerance limits, and dose ranges are, in general, realistic.

4. The pilot study provided a thorough test of the Standard, although the Standard has since been revised.

5. It will be a consensus Standard, developed and approved by the industry it is intended to improve.

Disadvantages of ANSI N13.11

1. The draft of ANSI N13.11 used during the pilot study was altered by the committee that prepared the Standard after the pilot study was completed. The latest draft of the Standard is being reviewed by the Health Physics Society Standards Committee which is expected to decide whether or not to approve the Standard by the summer of 1980. The Standard will then go to ANSI, which is expected to reach a decision by the fall of 1981. Either organization could amend the Standard considerably. Copies of the latest draft of the Standard are currently unavailable which makes a detailed discussion of the document impossible.

2. Based on what knowledge is available concerning proposed revisions to the Standard, several potential problems with the document are perceived by dosimetry processors:

   a. The radiation sources required by the Standard are not realistic to simulate the needs of all radiation workers.

   b. Some processors believe that beta-particle sources with at least two different energies (e.g., thallium-204 and promethium-147), in addition to the strontium-90 source specified in the Standard, should be available. The right of a processor to choose from among several beta-particle sources is especially attractive since the revised Standard contains two different neutron spectra. However, if many radiation sources are available for each radiation category tested, the cost of a testing program will increase.

   c. Some processors are concerned that the photon contribution from a heavy-water-moderated californium-252 neutron source has not been documented.

   d. Some processors are disappointed that the revised Standard has no radiation category for neutrons only. Some dosimeters are used to measure only neutrons and will not be able to pass a test of neutron-plus-gamma.

e. The minimum dose tested by the Standard is 30 mrem. Most processors are able to document that their dosimeters can detect doses less than this value, some as low as 10 mrem. If processors are certified only down to 30 mrem, they will consider raising their minimum reported dose to 30 mrem. This will result in a minimum reported dose of 360 mrem/yr for workers that exchange dosimeters monthly, which will be viewed by many people as an unacceptably high minimum. This problem is most significant for the beta-particle category in which the minimum dose tested is 150 mrem.

f. The Standard contains a table of dose conversion factors (rem/roentgen) for shallow and deep depths. These values are exceedingly important for credible dose calculations, yet there is little confidence among the processors that these factors are accurate. Processors do not want these factors to change once a testing program begins.

g. The dose conversion factors (rem/roentgen) given in the Standard are for frontal beams of photons delivered with the dosimeters facing the radiation source. Dose conversion factors for isotropic irradiations, the typical irradiation geometry for most workers, are about 40% less than those given in the Standard.

h. The Standard does not permit the testing laboratory to divulge the type of radiation to which each dosimeter was irradiated, except for the accident categories. Many processors, including a few commercial, argue that they know the type of radiation to which their users are exposed and, therefore, the Standard is unjustifiably restrictive. However, many of these processors concede that although this is true most of the time, situations do arise where their dosimeters are required to help identify the type of radiation to which the user was exposed.

i. The Standard requires a study of the angular response of dosimeters. Although all the characteristics of each processor's dosimeters should be known, the Standard should involve only tests and not studies.

j. The depths at which doses must be determined are not the same in the Standard as on the NRC's Form 5, the permanent record for doses of NRC licensees.

k. Most processors believe that the Standard should state specifically that the correction factors applied by a processor for test dosimeters can differ from those applied to dosimeters sent to regular users if the processor can document that separate correction factors are justified.

1. Some processors believe that shallow doses should represent the average dose to the skin (between 7 and 1000 mg/cm^2) instead of the maximum dose to the skin (at 7 mg/cm^2).

PROCEDURAL ALTERNATIVES

Frequency of Testing

During the discussion with the three groups of processors, it was assumed that, if ANSI N13.11 were used for a testing program, a complete test would cover a three-month period as was done during the pilot study. The commercial and private in-house processors generally feel that to pass one test per year is sufficient to demonstrate competency and to provide a measure of credibility to their users. The Government in-house processors desire a testing frequency as infrequent as possible, preferably once every three to five years.

If the majority of processors are tested on an infrequent basis (e.g., three to five years), this will cause practical problems for a testing laboratory. Equipment, procedures, and personnel that are used infrequently tend to become ineffective.

Number of Testing Laboratories

Two alternatives for the number of testing laboratories are practical to consider at this time assuming that a testing program will be required: one laboratory or more than one. Several advantages exist in favor of one nationally-recognized laboratory.

1. It could receive considerable individualized supervision and assistance from a monitoring agency such as the National Bureau of Standards (NBS).

2. The cost of establishing and operating a single testing laboratory, when distributed among all dosimetry processors in the United States by testing fees, would minimize the cost to each processor. The radiation sources, buildings, and other equipment required of a testing laboratory will cost essentially the same whether the laboratory tests one processor or all the processors.

3. A single laboratory would provide common reference sources for all processors.

The disadvantage of having only one testing laboratory is that if it goes out of business, a considerable amount of the time would be required to establish a new laboratory.

If more than one testing laboratory is created (e.g., one sanctioned by the NRC, one sanctioned by the DOE, etc.), the advantages and disadvantages are essentially the reverse of those discussed above for a single testing laboratory. An additional point, which can be viewed as potentially both an advantage and disadvantage, is that the various testing laboratories will have to be reproducible among themselves.

Most processors feel that the multiple testing laboratory approach is undesirable for a variety of reasons.

1. Testing fees assessed to each processor will be high if each testing laboratory services only a few processors.

2. Processors will tend to polarize around their testing laboratory. This will resurrect old bureaucratic problems with NRC licensees subscribing to one testing laboratory and DOE contractors subscribing to another.

3. Some processors provide dosimeters to NRC licensees, DOE contractors, and licensees of other regulatory agencies. If each agency has its own testing program and its own testing laboratory, these processors will have to be tested redundantly.

4. A monitoring agency, such as the NBS, will be required to provide redundant services to several testing laboratories to insure the high quality of each.

Type of Testing Laboratory

In considering each of various types of organizations that could serve as a dosimetry testing laboratory, several general questions must be answered satisfactorily.

1. Would this activity constitute a conflict of interest for this type of organization? This question would be of special concern for organizations that process dosimeters.

2. Would this activity constitute a conflict of purpose (i.e., the reason for being) for this type of organization?

3. Does this type of organization have the number and quality of people required to be a testing laboratory?

4. Does this type of organization have the technical facilities necessary to be a testing laboratory?

Several types of organizations are considered below.

Laboratory Operated by the NRC. This alternative would have the advantage for the NRC of providing a testing laboratory that was totally under the control of the NRC. This control would include staff, equipment, radiation

sources, financing, etc. The major disadvantage of this alternative is that the NRC does not currently operate laboratories. This is probably not a serious disadvantage, but it would represent a unique situation for the NRC.

Laboratory Operated by a National Laboratory. There is no question that most, if not all, of the National Laboratories have the expertize and facilities necessary to be a dosimetry testing laboratory. However, the major disadvantage of this alternative is that most National Laboratories process dosimeters for their own employees, which could represent a conflict of interest for their own certification.

Laboratory Operated by Another Government Agency. A common desire among many processors is for the NBS to be the testing laboratory. There is no higher authority for standards in the United States. The only disadvantage of this alternative is that this effort would be a conflict of purpose for them. Since this has been stated repeatedly and vehemently by the NBS management, there seems to be little possibility that the NBS would agree to become a testing laboratory.

Private Laboratory. The pilot study demonstrated that a private laboratory, such as a foundation or university, that does not process their own dosimeters can administer a dosimetry testing program following the requirements of ANSI N13.11. If the private laboratory were well supervised technically as discussed below, it should be acceptable to any Government agency that elects to initiate a dosimetry testing program.

Technical Supervision of the Testing Laboratory

If a nationally-recognized dosimetry testing program is initiated, the consequences of a processor failing a test will be severe. The least problem facing a processor that fails will be the expenses of taking corrective action, explaining the circumstances to users of their service, and being retested. Their greatest problem will be total termination of business. There is little doubt that a processor, especially a large commercial processor, will take legal action against everyone involved to prevent the termination of their business. It is essential, therefore, that the testing laboratory be sufficiently competent to defend any challenge to the delivered doses it assigned to each dosimeter. The National Bureau of Standards is the best alternative for the technical supervision of the testing laboratory.

Appeals Procedures

There is no doubt that the testing laboratory will become involved in disputes with the processors on numerous occasions. The primary reasons for these disputes are:

1. A processor will disagree with the testing laboratory on the delivered dose assigned to a particular dosimeter.

2. A processor will want to change their reported dose for a particular dosimeter or void the dosimeter after they are told the reported dose. Most of these requests will be because the processor discovered a clerical error they made in the reported dose.

It will therefore be necessary for the testing laboratory and the challenging processor to have a method of appealing a dispute.

Since any one person would probably not be willing to accept the authority nor would they be granted the authority to settle a dispute, this duty will fall to a committee. Two alternatives for the composition of the appeals committee are considered below; peer review and Government agency.

Peer Review. For this alternative, the appeals committee would be formed of individuals recognized by their peers to have theoretical knowledge and practical experience in dosimeter processing. By virtue of their knowledge and their experience, they would be able to determine if a processor has a legitimate complaint or if the processor is simply producing a smoke screen to cover their incompetency. A disadvantage of this alternative is that most, if not all, individuals selected for a peer-review committee would have some affiliation with one or more processors. This disadvantage could probably be overcome by establishing a procedure to disqualify such an individual when appropriate.

Government Agency. For this alternative, the appeals committee would be formed of individuals selected from one or more Government agencies. The advantage of this alternative is that it would emphasize the authority of the agency certifying a processor. The disadvantage is that this alternative could result in a separate appeals committee for each regulatory agency that required dosimetry testing. Thus, a processor might be certified by one agency, but would not be acceptable to other agencies.

PART II: RECOMMENDATIONS FOR THE DESIGN OF A DOSIMETRY TESTING PROGRAM

NEED FOR A TESTING PROGRAM

At the conclusion of each of the three meetings of processors held in Ann Arbor, we asked the processors for their opinion as to whether there should be a mandatory testing program, a voluntary testing program, or no testing program at all. Although there was no where near a unanimous opinion for any option, there was a general consensus on several points.

1. Most processors believe there should be some sort of testing program. They believe the needs for a program, especially the need for demonstrated credibility, outweigh the arguments against a testing program. To a certain degree, they also believe the testing program is inevitable, and so the real issue is to how to make it as useful as possible.

2. Although some processors favor a voluntary testing program, most believe that is an unrealistic option. If the NRC and other Government agencies pressure processors to participate in a voluntary program, then the program should not be referred to as voluntary. Experience with previous voluntary testing programs shows that only a few processors would actually participate with any regularity.

3. A mandatory testing program, hopefully for all processors and not just those that serve NRC licensees, would probably have more advantages

than disadvantages. This conclusion depends heavily on the frequency and structure of the testing program. If Government agencies are too inflexible, especially during the first few years of a mandatory testing program, processors would violently oppose the effort. Otherwise, the majority of all the processors in the United States would make an honest effort to cooperate in a mandatory testing program.

Although a variety of reasons is given in this report to support and refute the need for a dosimetry testing program, we believe the following are the major considerations.

In Favor of Testing

1. The results of the pilot study show that, even with the statistical method of the revised ANSI N13.11 Standard, one-third of the category-tests were failed in Test #2. Thus, there are demonstrated inaccuracies in personnel dosimetry (see the four major problems identified during the pilot study as discussed on pages 7 through 10 of this report).

2. The major problems identified during the pilot study (improper calibration factors, dosimeter variability, clerical errors, and accident dose calibrations) can be corrected and, for at least some processors, will result in improved accuracy for their regular users.

3. A processor that passes a nationally-recognized testing program will gain credibility.

Against Testing

1. The inaccuracies that exist with personnel dosimeters probably do not constitute a major health hazard. At a time of rising costs and increasing regulations, more of each is undesirable.

2. Even if processors can pass a test, there is no guarantee that a testing program will document or improve the quality of a processor's service to their regular users.

Based on the considerations given above, we believe a dosimetry testing program would serve a useful purpose, but only if two problems are recognized and dealt with properly. First, a testing program will only test the ability of a processor to perform within the limits of a standard, and will not determine if the processor actually treats their regular users with the same competence accorded the testing laboratory. Therefore, it will be necessary to supplement the testing program with checks of a processor's quality control, calibration, and administrative procedures. Second, the testing program must include all dosimetry processors in the United States to provide credibility to those processors that do well in the program. In order for this to be accomplished, the

testing laboratory, the standard used, and all the procedures followed must be acceptable to all the Government agencies involved.

CHOICE OF A STANDARD

The Standard used during the two-year pilot study, ANSI N13.11, was found, in general, to be effective as a minimum performance standard. The Standard is currently in the process of being revised and reevaluated by the Health Physics Society and by the ANSI. Once it is endorsed by these two organizations, it will represent a consensus standard. It is the only dosimetry testing standard that presently stands a chance of being accepted and used by a majority of processors and Government agencies.

In general, the processors favor the ANSI N13.11 Standard. This is probably the only realistic Standard available, but it is difficult to evaluate the Standard conclusively until it is finalized.

TESTING PROCEDURES

We believe that if the following procedures are followed, a dosimetry testing program will have the best chance of being useful to the pro-

cessors, to the Government agencies, and to the users of personnel dosimeters.

1. There should be only one testing laboratory.

2. Funding for the testing laboratory should be derived from fees levied on each participating processor. The fee for each radiation category should be the same regardless of the size of the processor. The testing laboratory should operate on a non-profit basis since, if there is only one laboratory, it will be a monopoly with captive clients.

3. The testing laboratory should be selected by the NBS on the basis of technical and administrative competence. The NBS should also consider the fee the laboratory will charge for each radiation category tested.

4. The testing laboratory should be required to satisfy the NBS that the dose delivered to each dosimeter tested is accurate to within ±5%, the accuracy specified in ANSI N13.11.

5. The testing laboratory should not be affiliated in any way with a dosimetry processor.

6. The testing laboratory should be recognized as such by all relevant Government agencies.

7. The testing laboratory should offer four three-month tests each year.

8. Each processor should certify to the testing laboratory that the dosimeters, calibration procedures, and handling techniques used in the testing program are the same as those used for the processor's regular users. If a processor does treat the testing laboratory differently than their regular users (e.g., unique calibration factors), these differences should be documented by the processor.

9. At the completion of a three-month test, the testing laboratory should report all statistical information described in ANSI N13.11 only to the processor for which the information was generated. This information includes an error term for each dosimeter, P, and a measure of the bias, $\bar{P}$, standard deviation, S, and total accuracy, $|\bar{P}| + S$, for each radiation category. The testing laboratory should not label the performance of any processor as "pass" or "fail."

10. Any test results generated by the testing laboratory for a processor should be confidential. It should be the responsibility of each processor to report their results to the appropriate government agency.

11. The testing laboratory should periodically (once or twice a year) publish the detailed test results of each processor that has been tested since the last summary publication. These publications should

contain the code numbers but not the names of the processors tested. These publications would enable interested parties to compare the performances of many processors while protecting the identity of each processor.

12. Each Government agency should determine the appropriate frequency of testing and the acceptable accuracy for the processors within its jurisdiction. It is assumed that the most common testing frequency will be annually, and the most common accuracy limits will be those specified in ANSI N13.11.

13. A peer-review committee should be created to handle disputes arising between the testing laboratory and a processor. The decisions of the peer-review committee should be sent only to the testing laboratory and the processor involved. It should be the responsibility of each processor to report the decisions of the peer-review committee to the appropriate regulatory agency.

14. A processor that desires to be retested in one or more radiation categories should be permitted to do so on an accelerated schedule. A retest should be started as soon as the processor is ready, and it should be completed in one month instead of the regular three-month period.

15. It is expected that, due to occasional problems, every processor will eventually fail one or more radiation categories. Procedures should be developed to permit a processor that fails to continue operating during a probationary period until the processor can be retested.

The approach outlined above should make the testing laboratory acceptable to all relevant Government agencies. The approach would enable each Government agency to specify the testing frequency and tolerance limits acceptable for the processors under its control. In addition, the approach would result in all dosimetry processors in the United States demonstrating minimum competency as defined by a commonly accepted testing program. Thus, the protection afforded a radiation worker would be approximately the same regardless of the Government agency that regulates his dosimetry processor.

The first year or two of a mandatory testing program will be expensive and painful for the processors, the testing laboratory, and the Government agencies. During this initial period, we recommend that participation in the testing program be mandatory, but no penalties be assessed for failures. Some processors will require considerable lead time to complete the necessary changes in their procedures. In some cases, initial failures of a processor will be required to convince their management that changes are necessary. Since ANSI N13.11 is not expected to be adopted in the final form by the ANSI until late in 1981, a mandatory testing program could begin in early 1982 provided that Government agencies are flexible concerning penalties for failure as the program begins.

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*Also available for purchase from the NRC/GPO Sales Program, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

APPENDIX

Cost estimates of a dosimetry testing program

INTRODUCTION

The following are estimated costs of establishing a testing laboratory, operating the laboratory, processor participation in the testing program, processor failure in the testing program, and operating a Certification Board and an Appeals Board. We believe these are the major categories of costs which will be realized.

This analysis is divided into three sections: I) Costs to the testing laboratory; II) Costs to a typical processor; and III) Costs of the Certification Board and the Appeals Board.

I. COSTS TO THE TESTING LABORATORY

The testing laboratory will have initial costs and annual operating costs. For this estimate, the costs for equipment are shown as both an initial cost and an annual replacement cost.

Operating Costs: Labor

Director, half time	$20,900/year
Assistant Director	24,000
Two technicians @ $15,000/year each	30,000
Secretary, quarter time	2,500
	$77,400
Overhead* and fringe benefits, 100% of salaries	77,400
TOTAL	$154,800/year

*NOTE: Overhead includes rental charges for existing floor space, electricity, heating, etc.

Operating Costs: Supplies

Duplicating	$1,000/year
Postage	2,000
Telephone	2,000
Maintenance of equipment	5,000
Travel	3,000
Calibrations with NBS	3,000
Computer time	2,000
TOTAL	$18,000/year

Operating Costs: Equipment

Type of Equipment	Initial Cost	Life(yrs)	Cost/yr
One X-ray machine	$40,000	10	$4,000
One 400 Ci Cs-137 source	12,000	10	1,200
One 20 Ci Cs-137 source	6,000	10	600
One Sr-90 source	3,000	10	300
Two Cf-252 sources @ $6,000 each	12,000	2	6,000
Two shipping casks for Cf-252 sources	4,000	30	100
Heavy water for one Cf-252 source	6,000	10	600
Sphere for Cf-252 moderator	2,000	30	700
Beam Monitors for all sources	8,000	10	800
Phantoms	1,000	30	100
TOTAL	$94,000		$14,400/year

Total yearly operating costs

Labor	$154,800
Supplies	18,000
Equipment	14,400
	$187,200/year

Initial cost for testing laboratory

Equipment	$94,000
One person-year labor for source procurement and calibration	36,000
TOTAL	$130,000

Testing Fee

The testing fee will be based on the categories in which the processor is tested. Categories I through V require one radiation source each, and we believe will have a charge of $300 each. Categories VI through IX require two radiation sources each, and we believe the testing fee will be $600 per category.

Category	Fee/Category		Fee to Test All Categories
I - V	$300		$1,500
VI - IX	600		2,400
		TOTAL	$3,900

During the pilot study, the average processor chose to be tested in 60% of the categories. Thus, the total fee to the average processor is expected to be about $2,340/year. If the assumption is made that 80 processors will participate in a mandatory testing program, the income to the testing laboratory will be $187,200/year.

II. COSTS TO PROCESSOR

There will be two major types of costs incurred by the processor: Normal testing costs, and costs for failure of the tests. We believe the normal testing costs for the processor will be as follows:

Testing fee	$2,340/year
Labor: 3 person-weeks, including overhead and fringe benefits	3,660
	$6,000/year

We believe there will be an initial cost of approximately $8,000 for the processor to make his dosimetry system compatible with the standard. This initial calibration cost should be a one-time cost, and will vary greatly from processor to processor.

Additional costs will be incurred by processors that fail one or more of the categories tested. The estimates given below are based on a processor failing two categories; one single-source category and one double-source category.

Costs for processors that fail

Testing fee for two categories	$ 900
Three person-weeks for recalibrations	3,660
Consulting service (irradiations)	1,040
Legal fees, 1 week at $50,000/yr	1,000
Travel	1,000
TOTAL	$7,600/year

This estimate does not include the loss of business to a commercial processor that fails one or more categories.

III. COSTS OF THE CERTIFICATION BOARD AND APPEALS BOARD

We assume that a Certification Board and an Appeals Board will be formed. Although several alternate plans are currently being considered for the composition and activities of these Boards, we assume that about 14 people will serve on the Boards, that these people will meet periodically, that they will have to travel to the meetings and to some of the processors, and that the Boards will require the support of a clerical and legal staff. We estimate the following expenses for these Boards:

14 people, 20% effort, $35,000/yr each	$98,000
One secretary/recorder	15,000
One full time lawyer	50,000
Miscellaneous (office supplies, telephone bills, etc.)	5,000
Travel expenses for 14 people	20,000
TOTAL	$188,000/year

IV. SUMMARY

The following is a summary of the costs involved in a mandatory testing program based on the assumptions given above.

I. Costs to Testing Laboratory

A. Initial costs	$130,000
B. Operational costs	$180,400/year

II. Costs to the Processors

A.	Normal costs	$6,000/year
B.	Initial calibration costs	8,000
C.	Failure costs	7,600/failure

III. Costs of Certification Board and Appeals Board

A.	Operating costs	$188,000/year

If 80 processors participate in a testing program, they will spend a total of about 80 x $8,000 = $640,000 initially to make their dosimetry system compatable with the Standard. In addition, the testing laboratory will spend about $130,000 initially to prepare for the testing program. The processors will spend about 80 x $6,000 = $480,000 per year to participate in the testing program excluding costs for failure. If 10 processors fail one or more categories each year, the combined costs to them will be about 10 x $7,600 = $76,000 per year. The costs for the Certification Board and the Appeals Board will be about $188,000 per year. Thus, the total cost for the testing program is expected to be about $770,000 initially and $744,000 per year.

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16. ABSTRACT *(200 words or less)*

The Nuclear Regulatory Commission (NRC) is considering an amendment to 10 CFR Part 20 that would require their licensees to use only processors of personnel dosimetry devices (e.g., film badges and thermoluminescent dosimeters) that have been certified. Although this action would have a direct effect only on those processors that service NRC licensees, it would most likely lead indirectly to a nationally-recognized certification program for all dosimetry processors.

The objectives of this Report are to consider a variety of alternatives that would influence a certification program, to consider the advantages and disadvantages, values and impacts, of each alternative, and to make a recommendation for each alternative. Among the considerations discussed are:

1. Is a certification program necessary?
2. What standard should be used for a testing program?
3. What type of organization should test dosimetry processors?
4. How often should a processor be retested?
5. What appeals procedures should be available to a processor?
6. What are realistic estimates of the costs of a testing program?

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