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The National Personnel Radiation Dosimetry Accreditation Program

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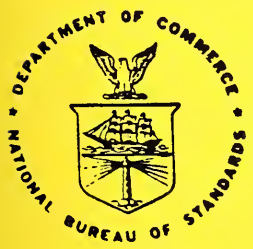

U.S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS

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U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, *Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

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INTRODUCTION

An estimated 1.3 million workers are occupationally exposed to ionizing radiation in the United States and must be monitored for exposure via personnel dosimetry [1]. Accurate measurements of the radiation doses received by workers are needed because of the health, economic, and legal consequences of exposures to radiation. For three decades there has been general concern about the reliability of the reported doses.

Prior to 1973, government and industry groups made several attempts to establish dosimetry performance standards. Those attempts were unsuccessful mainly because the standards addressed performance of the dosimeter only and not the equally important issue of the performance of dosimetry processors.

In 1973, the Conference of Radiation Control Program Directors (CRCPD) held a workshop on personnel dosimetry evaluation and control. The workshop report stated that the necessary degree of reliability of dosimetry services was not being achieved, in spite of attempts to provide reliability testing of those services [2]. The report's principal recommendation was "that the Conference designate an impartial federal agency, such as the National Bureau of Standards (NBS), to direct a continuing performance testing program which includes all personnel dosimetry services identified by responsible state and federal agencies." The report also recommended that the criteria for performance of personnel dosimetry services be based on recognized standards, and that the Conference establish a task force to meet with interested federal agencies for the purpose of implementing the recommendations.

All of the workshop recommendations were accepted by the Conference and eventually implemented by various agencies. A first draft of a performance criteria document was prepared by Dr. Margarete Ehrlich of NBS (with partial support from the Food and Drug Administration). In 1975, the Health Physics Society established a working group chaired by Dr. Ehrlich to develop a suitable consensus standard based on her draft. The resulting document was eventually published as ANSI N13.11-1983, Criteria for Testing Personnel Dosimetry Performance [3].

In a parallel effort, federal liaisons to the CRCPD task force formed a policy committee that coordinated development of a national performance testing program. In 1980 this group considered various alternatives for administering a national program and concluded that the best choice would be the NBS National Voluntary Laboratory Accreditation Program (NVLAP). In 1982, the Nuclear Regulatory Commission (NRC) formally requested that NVLAP develop a laboratory accreditation program for dosimetry processors (Dosimetry LAP) incorporating ANSI N13.11 as the performance criteria. The program was established with financial support from the NRC and became operational on January 1, 1984.

Numbers in brackets refer to literature references listed at the end of this report.

This paper describes the accreditation program offered to personnel dosimeter processors by NBS and presents results of proficiency testing performed by organizations seeking accreditation. Proficiency testing is an essential element in the evaluation of processors to determine competence to perform radiation measurements in accordance with the accreditation criteria.

NVLAP OVERVIEW

Accreditation is offered by NVLAP to laboratories and other organizations that perform standard test methods and provide test data in accordance with those methods. Commercial testing services, in-house quality assurance laboratories, government laboratories, and academic institutions are eligible for accreditation. Accreditation is granted to organizations found competent to perform specified test methods in specific technical areas. NVLAP currently has laboratory accreditation programs (LAPs) for organizations that provide testing services in the fields of concrete, carpet, wood stoves, thermal insulation, paint, paper, building seals and sealants, photographic film, environmental acoustics and personnel dosimetry processing. NVLAP is administered by NBS but all administrative and technical operations are funded entirely by fees paid by organizations participating in the program.

NVLAP is a nationally and internationally recognized system. All NVLAP accredited organizations are listed in an annual directory and other NVLAP publications [4]. Information dissemination about each organization's accreditation status and scope of accreditation aids potential users of technical services in selecting competent service organizations.

Participation in NVLAP is voluntary. However, other organizations such as code groups, regulatory agencies, or specification writers may require NVLAP accreditation as a condition for the acceptance of test data used in making procurement, licensing, or other contractual decisions. Participation provides a means for organization management to monitor quality assurance and obtain assistance from recognized technical experts to improve laboratory performance.

NVLAP uses technical experts (TEs) to perform on-site assessments. They are selected on the basis of their professional and academic achievements, experience in the appropriate field of testing, management experience, and ability to work with people. Their services are contracted by NVLAP; they are not NVLAP staff members.

TEs are assigned to do assessments based on their knowledge of the equipment in use at the individual sites and on freedom from conflict-of-interest. An individual TE's expertise should provide enough versatility to accommodate the uniqueness of each laboratory.

NVLAP accreditation is based on a process that includes five basic steps; application, proficiency testing, on-site assessment, evaluation and accreditation. Two steps, proficiency testing and on-site assessment, form the technical basis of the accreditation.

Application: An Application Package, sent on request, includes: instructions, an Application Form, Test Method Selection Form, Fee Calculation Form, Registration Form for NVLAP Proficiency Testing, and a LAP Handbook that describes administrative, technical, and proficiency testing requirements for accreditation [5]. Payment of fees at the time of application is prerequisite to initiating the process.

Proficiency Testing: Proficiency testing is the method by which NVLAP evaluates the ability of a participant to conduct specified test methods by actual demonstration.

On-Site Assessment: Each participant is visited by a technical expert who determines the organization's capability to meet the NVLAP criteria. The assessment is conducted using a NVLAP designed checklist to assure that each participant receives a uniform and equitable assessment.

Evaluation: After the processor has completed all the technical requirements of the LAP and is ready for accreditation action, a final technical evaluation is conducted by technical experts (TEs) selected for their particular experience and knowledge. They review records on the applicant processor and base their evaluation on:

- information provided in the application;
- on-site assessment reports;
- actions taken by the processor to correct deficiencies;
- results of proficiency testing; and
- information from any monitoring visit to the facility.

Accreditation: After technical evaluations are completed, NVLAP staff prepares an administrative recommendation regarding accreditation. The recommendation is based on the evaluations of all available information to assure that all NVLAP technical, financial, and administrative criteria have been satisfied.

THE DOSIMETRY LAP

Accreditation in the Dosimetry LAP is awarded for a period of two years after which the participant must apply for renewal. Both the on-site assessment of the processing facilities and proficiency testing are performed on the same two year cycle. Proficiency testing is conducted in accordance with ANSI N13.11 which defines eight radiation test categories.

Accreditation is limited to those types or models of dosimeters which document whole body and skin dose. Processors may gain accreditation for as many different dosimeter models or types as they wish, provided that they demonstrate ability to meet the criteria. The program is not applicable to extremity dosimeters, pocket ionization chambers, or environmental monitors.

Participation

As of December 1985, the number of accredited processors was 35 and an additional 14 were seeking accreditation. The 49 processors represent the following interests:

- utilities (36);
- commercial processors (6);
- U.S. military (5); and
- other (2).

Some processors are accredited for only one dosimeter model while others are accredited for as many as seven models. The dosimeter types include thermoluminescent detectors (TLDs), photographic film, and plastics. Almost half of the processors seek accreditation for all eight test categories.

The On-site Assessment

Although the assessment does have elements of the traditional audit of files, documentation, and procedures, the emphasis of the assessment is on the technical aspects of the operation. The resulting assessment is therefore an exchange between the NVLAP assessor and in-house technical personnel which offers considerable helpful advice to participants.

One of the key benefits of the assessment is that the assessor relates the results of the proficiency testing to the normal processing done by the participant. This is to assure that the same equipment and procedures are used for normal operations that were used for the proficiency test, as well as to evaluate the participant's ability to measure radiation fields of a different type than those covered by the radiation categories in ANSI N13.11.

The major problems found to date as a result of on-site assessments are:

- lack of established procedures;
- poor recordkeeping;
- inadequate calibration techniques;
- insufficient number of quality assurance dosimeters used;
- inadequate number of personnel;
- lack of proper training of personnel; and
- need for additional equipment.

ANSI N13.11 - The Basis of Proficiency Testing

The current standard defines eight radiation categories with irradiation ranges and tolerance levels for deep and shallow dose equivalent as shown below [3].

Table 1. Test Categories, Irradiation Range, and Tolerance Levels.

Test Category	Test Irradiation Range	Tolerance Level (L)	
		Deep	Shallow
I. Accidents, low-energy photons (NBS technique MFI)	10 to 500 rad	0.3	No test
II. Accidents, high-energy photons (Cs-137 gamma radiation)	10 to 500 rad	0.3	No test
III. Low-energy photons (NBS techniques LG, LI, LK, MFC, MFG, MFI)	0.03 to 10 rem	0.5	0.5
IV. High-energy photons (Cs-137 gamma radiation)	0.03 to 10 rem	0.5	No test
V. Beta particles (Sr-90/Y-90)	0.15 to 10 rem	No test	0.5
VI. Photon mixtures (Any combination of categories III and IV)	0.05 to 5 rem	0.5	0.5
VII. Mixtures, photons and beta particles (Any combination of categories IV and V)	0.20 to 5 rem	0.5	0.5
VIII. Mixtures, Cf-252 fission neutrons, moderated by 15 cm of D_2O covered with cadmium and high-energy photons (category IV)	0.15 to 5 rem	0.5	No test

To determine the performance of a particular dosimeter model in a radiation category, 15 identical dosimeters are irradiated to 15 different known values and returned to the processor for reading. The data are evaluated using the following equations.

The performance quotient for the i(th) dosimeter is defined by

$$P_i = \frac{H_i' - H_i}{H_i} \qquad i = 1,\ldots,15$$

where H_i is the dose equivalent applied by the testing laboratory to the irradiated dosimeter, and H_i' is the corresponding dose equivalent reported by the processor.

An average performance quotient is determined from the performance quotients for 15 dosimeters by

$$\bar{P} = \frac{1}{15} \sum_{1}^{15} P_i$$

The standard deviation of the 15 P_i values is

$$S = \sqrt{\frac{(P_i - \bar{P})^2}{n - 1}}$$

Performance in a given category is considered to be adequate if the specified tolerance level, L, is not exceeded by the sum of the absolute value of the average performance quotient and the standard deviation; that is if

$$|\bar{P}| + S \leq L .$$

The Proficiency Testing Laboratory

Irradiation of test dosimeters is performed by a proficiency testing laboratory (PTL) under contract to NVLAP. Procedures have been developed to assure that the radiation fields used to irradiate test dosimeters are accurately characterized by the PTL. The procedures include:

- calibration by NBS of the PTL's ionization chambers used to standardize the x-ray and gamma-ray fields;
- calibration of the beta radiation source by both NBS and the PTL;
- calibration by NBS of the neutron source; and determination of corrections for photon emission and room return.

Additional procedures for assuring adequate performance by the PTL include an on-site assessment and review of the laboratory's procedures, and periodic performance tests conducted by the NBS Center for Radiation Research to demonstrate that the PTL can irradiate dosimeters with adequate accuracy.

In addition to the specific actions taken by NBS to assure the validity of processor proficiency tests, the PTL is required to implement an internal quality assurance program. This program is subject to review and approval by NBS. Although some flexibility is allowed, general requirements include:

- a written laboratory protocol that specifies operational procedures and conditions for testing in all eight radiation categories;
- quality control procedures;
- redundant measurement systems and techniques for calibration, verification, and quality control; and
- suitable records of routine quality control actions.

Proficiency Testing Procedures

Each participant must demonstrate proficiency according to the criteria of ANSI N13.11 for each dosimeter model in each radiation category for which accreditation is sought. The testing program requires that a participant supply a total of 15 dosimeters of the type used for each category to the PTL. Each month, for three consecutive months, the PTL irradiates 5 dosimeters to a controlled value (unknown to the participant) and returns them to the

participant for reading. The readings obtained by the participant are returned to the PTL where they are compared to the values applied to each dosimeter by the PTL. At the end of the testing period, a report is sent by the PTL to NVLAP and to the participant. The report gives H_i', H_i, and P_i for the fifteen dosimeters, the average performance quotient for the set, $\bar{P}$, and the standard deviation, S. The performance criterion is applied to determine whether the participant has passed or failed. NVLAP staff analyzes the proficiency test data to provide an evaluation of the performance of participants individually and as a group.

The results of analyses are given to the TEs for use during the on-site assessment to aid in identifying and correcting problem areas. In the case of test failure, NVLAP and the TEs provide extra help to the processor to correct problems. Problems identified have included clerical errors, calculational errors, calibration errors, algorithm errors, and instrument failure.

Proficiency Testing Results

A summary of test results for 1984 and the first two quarters of 1985 is given in Table 2 below. A total of 39 dosimeter processors performed a total of 316 category tests. Some of the category tests attempted were failed and later retested; these results are included in the summary. Thus far, all retests attempted have been passed.

Table 2. Proficiency Test Results for Six Calendar Quarters (1984-85)

Radiation Test Category	Number of Dosimeter Processors	Number of Category Tests Performed	Number of Category Tests Passed	Number of Category Tests Failed
I	25	32	26	9
II	36	42	42	0
III	28	35	31	4
IV	36	48	48	0
V	32	41	39	2
VI	30	38	33	5
VII	35	45	43	2
VIII	28	35	34	1

All of the test results were reviewed by NVLAP with the intent of gaining information for use by the TEs during their on-site assessments and learning more about the test procedures. In addition to the basic pass/fail characteristic, the data for each participant in each category test were examined for the following characteristics:

- Average performance quotient, $\bar{P}$.

  A large magnitude of $\bar{P}$ indicates a bias in the data. A positive $\bar{P}$ means the processor's reported dose equivalent is higher than the delivered dose, and a negative $\bar{P}$ means that the reported value is too small. If $\bar{P}$ is systematically too high or too low, it may indicate calibration or algorithm errors.

- Standard deviation, S.

  If the value of S is large, a lack of precision is indicated. This may appear as outlying values of P_i, month-to-month variations, or large random scatter in the data.

- Outlying values of P_i.

  Outliers may be identified using standard tests [6] after assuming that the 15 P_i values are normally distributed. Since ANSI N13.11 does not address the problem of outliers, they must be included in calculations of $\bar{P}$ and S. They may be due to clerical errors, processing inconsistencies, inadequate or incorrect algorithms, roundoff of very low doses, or random events.

- Month-to-month variations.

  If the three sets of five dosimeters used for monthly tests are considered independently, there may be appreciable differences in the P_i values within a set and the average performance quotients for the sets may differ significantly. One "bad" set, when combined with two "good" sets to calculate the overall $\bar{P}$ and S, could cause failure of a category test. Such variations among sets may be due to calibration changes, temporary external influences, technician performance, equipment malfunction, or doses received in transit.

- Outlying performance.

  Values of $\bar{P}$ and S that differ significantly from those of the group of participating processors indicate performance that deviates from the norm. Large magnitudes of $\bar{P}$ or S that are outlying from the group, even though the test was passed, suggest a need to review the process.

Data Analysis

Analysis of the test data yields information that enables individual participants to compare their performance with the performance of others, and provides support for upgrading and improving the national dosimetry program. Figure 1 is an example of an analysis performed to evaluate the individual processor performance for each category test. The figure shows 15 P_i values for one category, plotted in the order in which they were reported. While the test data shown in the figure would pass the 0.5 tolerance level criterion, the data for the three groups of five dosimeters vary. The first

group of five is close to $\bar{P} = 0$ and has only a small spread. The second group is 30% low and has a large spread while the third group is back near zero but with a large spread. Also, one of the P_i values in the second month shows a reading more than 50% low. This view of the data indicates that this participant is having problems keeping its process in control.

Figures 2 through 12 show the proficiency testing results for all participating processors in each of the eight test categories. Each figure is a plot of the performance quotient, $\bar{P}$, versus the standard deviation, S, where each square symbol represents one processor. The large triangle encloses the area bounded by $|\bar{P}| + S = L$, which is the area within which passing results lie for the particular category. Shallow and deep doses are shown separately for categories III, VI, and VII.

These figures seem to indicate that, for the categories which include low-energy photons, poor performance is primarily due to large values of the performance quotient, $\bar{P}$. For the other categories, it appears that a large standard deviation is the primary reason for failure. Examination of the data shows that a large standard deviation is most often caused by outlying P_i values, and is less frequently due to large random variations or month-to-month variations. If failing data, outliers, and data for a single month that are inconsistent with the other two months are removed, and the standard deviation is recalculated, the new maximum value of S that can be expected from the typical processing system may be determined. The results are shown in Table 3.

Table 3. Expected maximum standard deviation, S, and the number of category tests (n), included.

Category	I	II	III	IV	V	VI	VII	VIII
S, Deep dose	0.15	0.12	0.15	0.15		0.15	0.15	0.16
n	(21)	(41)	(30)	(47)		(32)	(42)	(33)
S, Shallow dose			0.15		0.15	0.16	0.16	
n			(29)		(38)	(33)	(41)	

This analysis indicates that a typical processor should be able to produce test results for 15 dosimeters with a standard deviation less than 0.20 for any category. Figures 2 through 12 support that conclusion.

EVALUATION OF THE NATIONAL PROGRAM

After two years of operation, the NVLAP program has been quite successful despite the limitations imposed by ANSI-N13.11. Now that the basic concept has been shown to be feasible it is appropriate to consider increasing the scope of the program.

Value to Dosimetry Users and Dosimetry Processors

The benefit to radiation workers of using NVLAP accredited processors is the increased assurance of the quality and reliability of radiation monitoring. Various regulatory authorities, including individual states, the Nuclear Regulatory Commission [7], and the Department of Transportation, are in the process of amending their regulations to require the use of accredited dosimetry processors to monitor workers.

Participating processors receive national recognition from NVLAP and from the resultant publicity in various media. They receive direct benefits during the on-site assessment due to the advice they receive from the NVLAP Technical Experts. The Technical Experts may also provide suggestions for improving conditions beyond the requirements for accreditation.

Impact on Measurement Technology

The goal of the national program continues to be assurance of satisfactory quality for personnel dosimetry. One essential element of the program is processor performance, which is tested and accredited by NVLAP. An equally important element is performance of the dosimeter itself, and subsequent improvement of that technology. The NVLAP testing process has already identified limitations of the present technology, such as problems of angular dependence in some dosimeter designs. It is expected that other problems will be identified, and that they will be solved by improvements of the technology and related research.

Upgrading and Improvement

Based on two years of NVLAP experience, input from interested parties, and consideration by the federal policy committee, revision of ANSI N13.11 should be considered. The standard prescribes the basic conditions and criteria for performance testing and must be revised in order for NVLAP to increase the scope of the program. The authors recommend that the following be considered in any revision of the standard:

- The number of radiation test categories should be increased to reflect a broader representation of radiation sources and energy spectra encountered in the field.

- Individual tolerance levels should be adopted for the average performance quotient and the standard deviation. This would, in effect, remove the corners from the triangles in Figures 2 through 12 (so poor performers can't "hide" in them).

- Present tolerance levels should be adjusted based on the results of existing test data. For example, the data would apparently support a lower value of L for Category IV, high-energy photons.

- The use of other than normal incidence for test irradiations should be considered, since normal incidence does not adequately represent field conditions.

Model for Other National Programs

This program has been successful because all concerned parties were involved by consensus in its development. As a result, the program is widely accepted and supported in the private, state, and federal sectors. Now that the model exists, it could be adapted to other national programs in related areas. An example is a program for assuring the quality of bioassay services, where a draft performance testing standard has been prepared [8].

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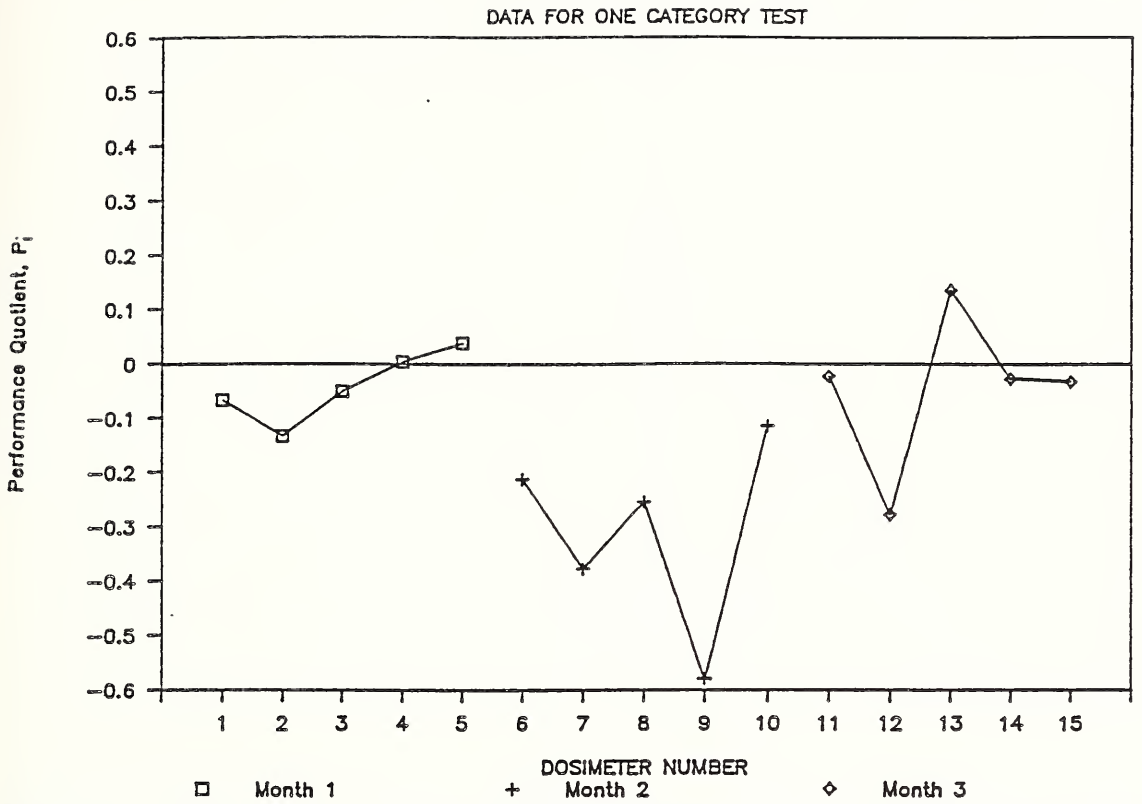

Figure 1. Data for one category test showing variability in individual performance quotients.

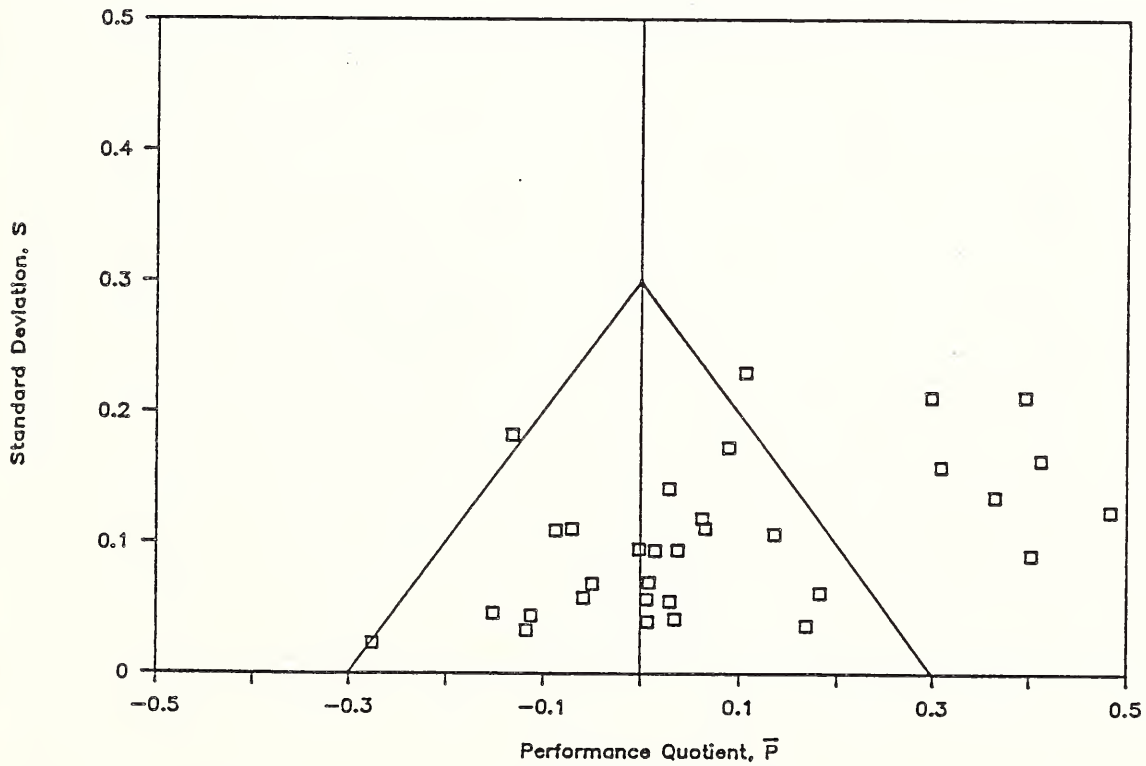

Figure 2. Test results for Category I, low-energy photons, accident levels.

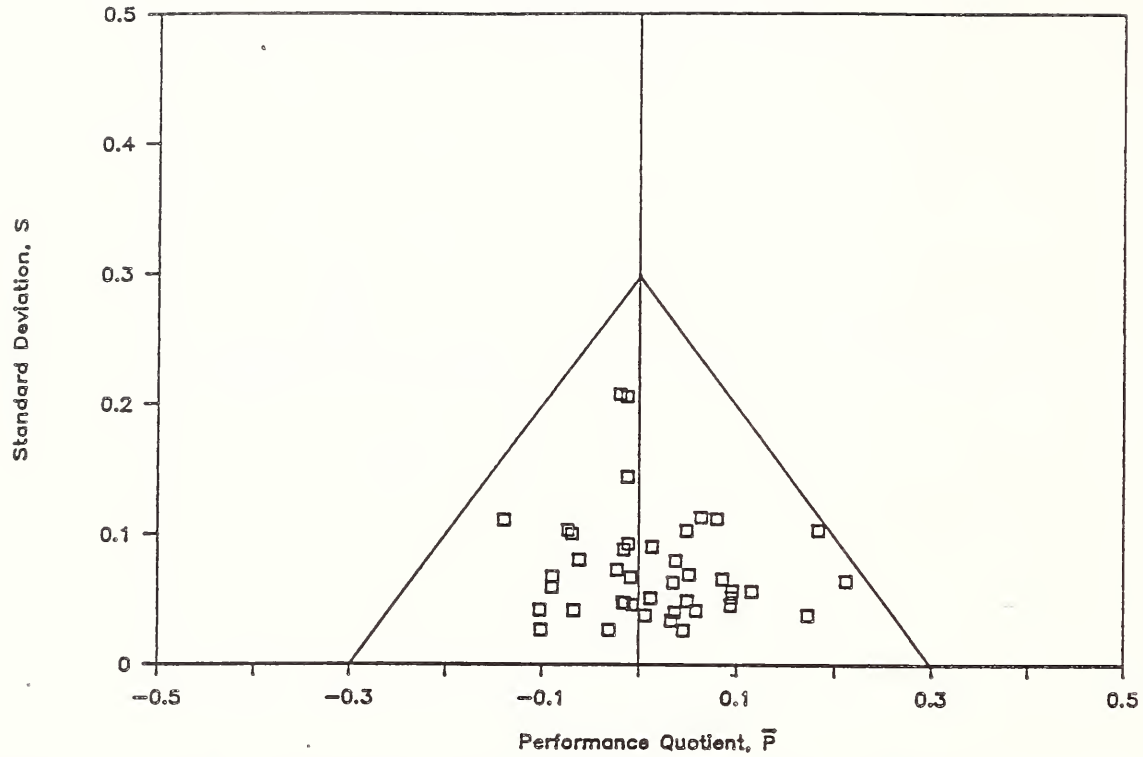

Figure 3. Test results for Category II, high-energy photons, accident levels.

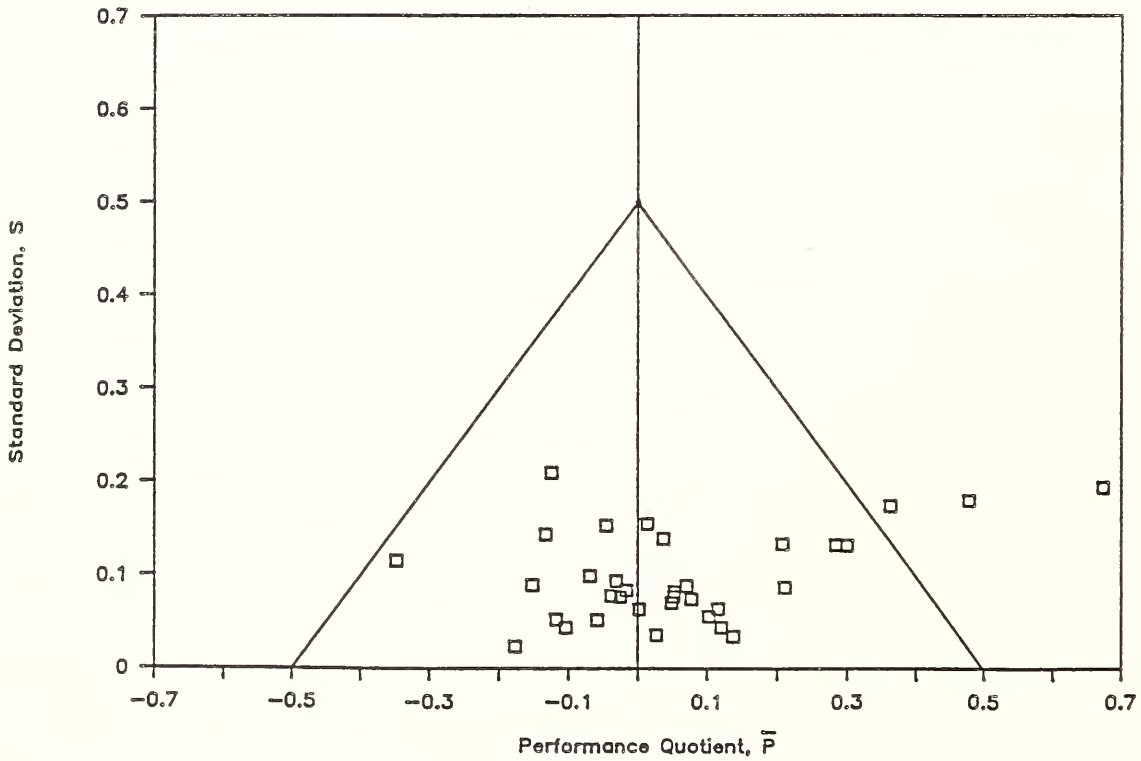

Figure 4. Test results for Category III, low-energy photons, deep dose. One test result is beyond the limits of the plot.

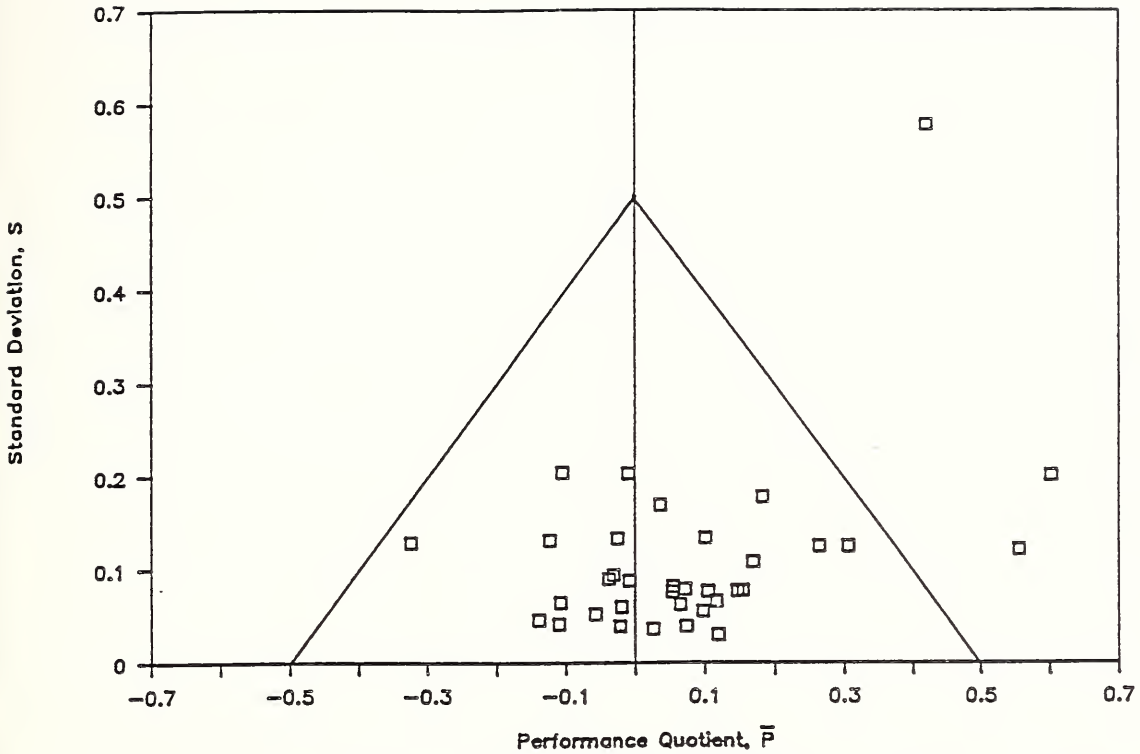

Figure 5. Test results for Category III, low-energy photons, shallow dose.

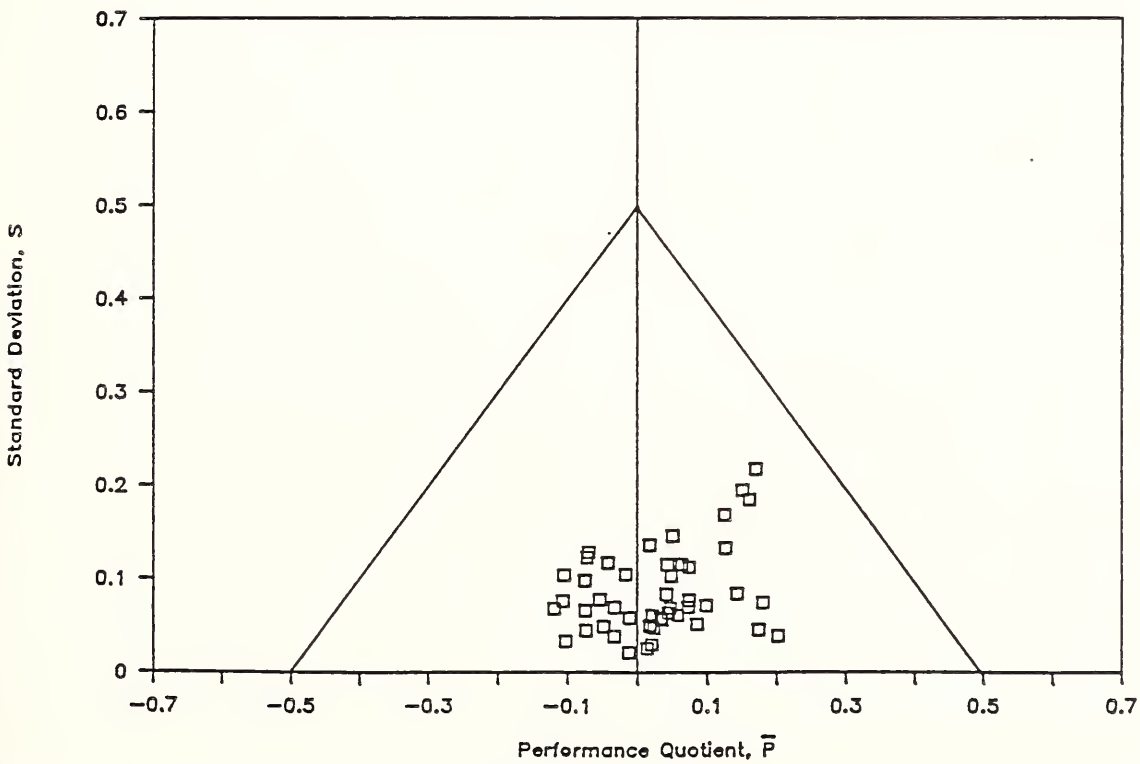

Figure 6. Test results for Category IV, high-energy photons.

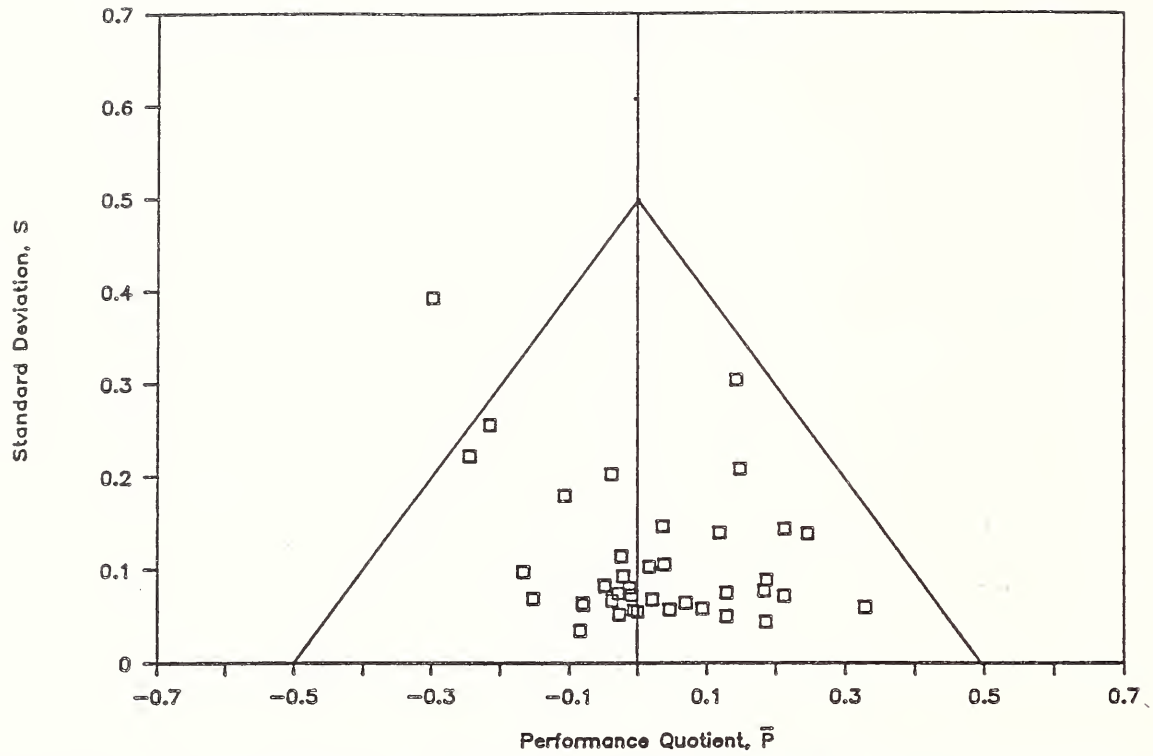

Figure 7. Test results for Category V, beta particles. One test result is beyond the limits of the plot.

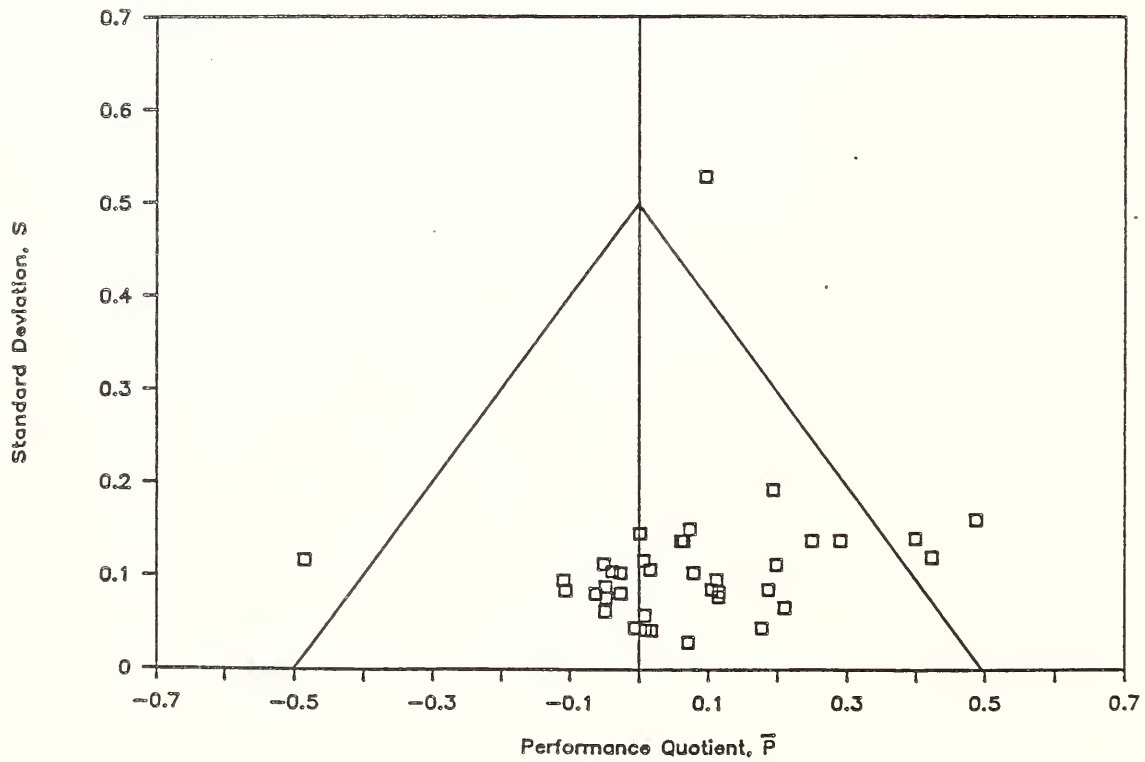

Figure 8. Test results for Category VI, photon mixture, deep dose.

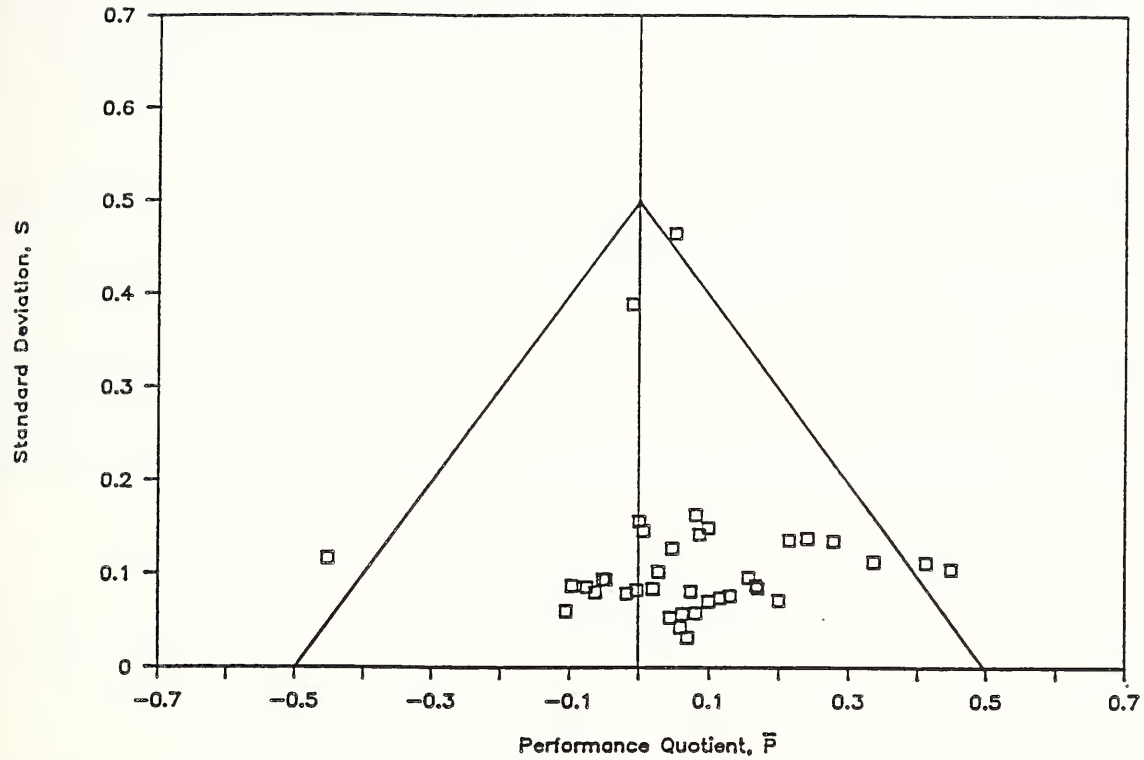

Figure 9. Test results for Category VI, photon mixture, shallow dose.

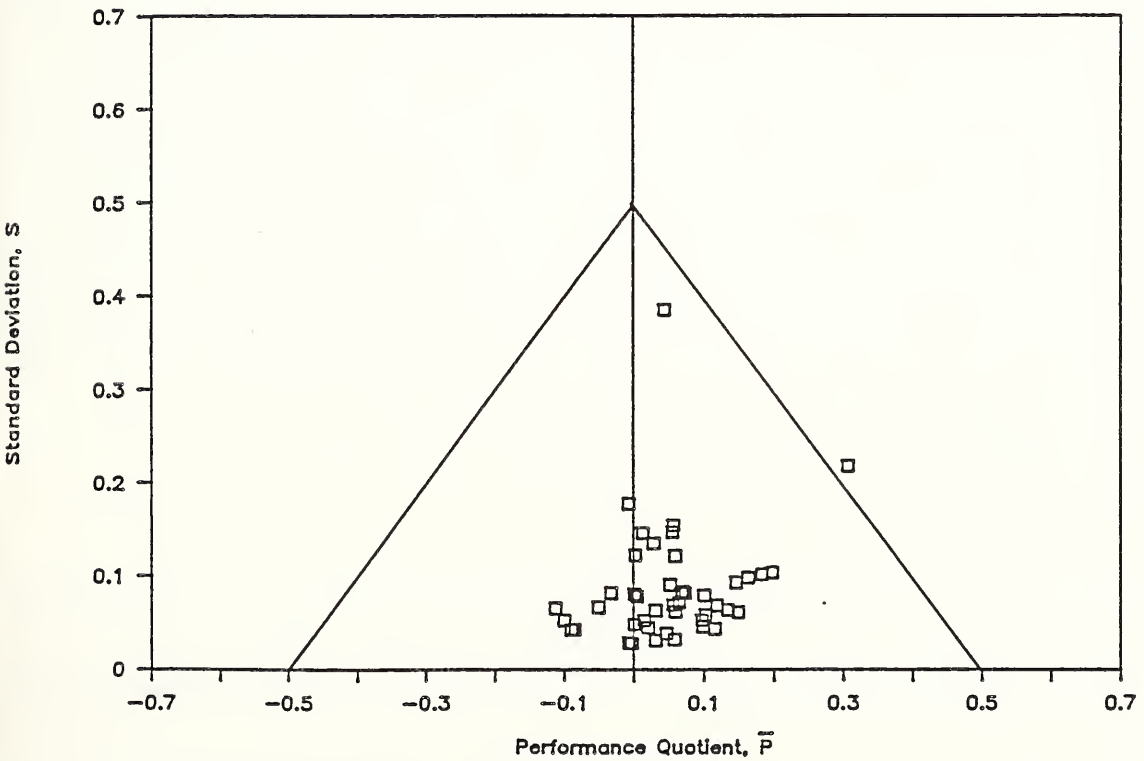

Figure 10. Test results for Category VII, photon and beta particle mixture, deep dose.

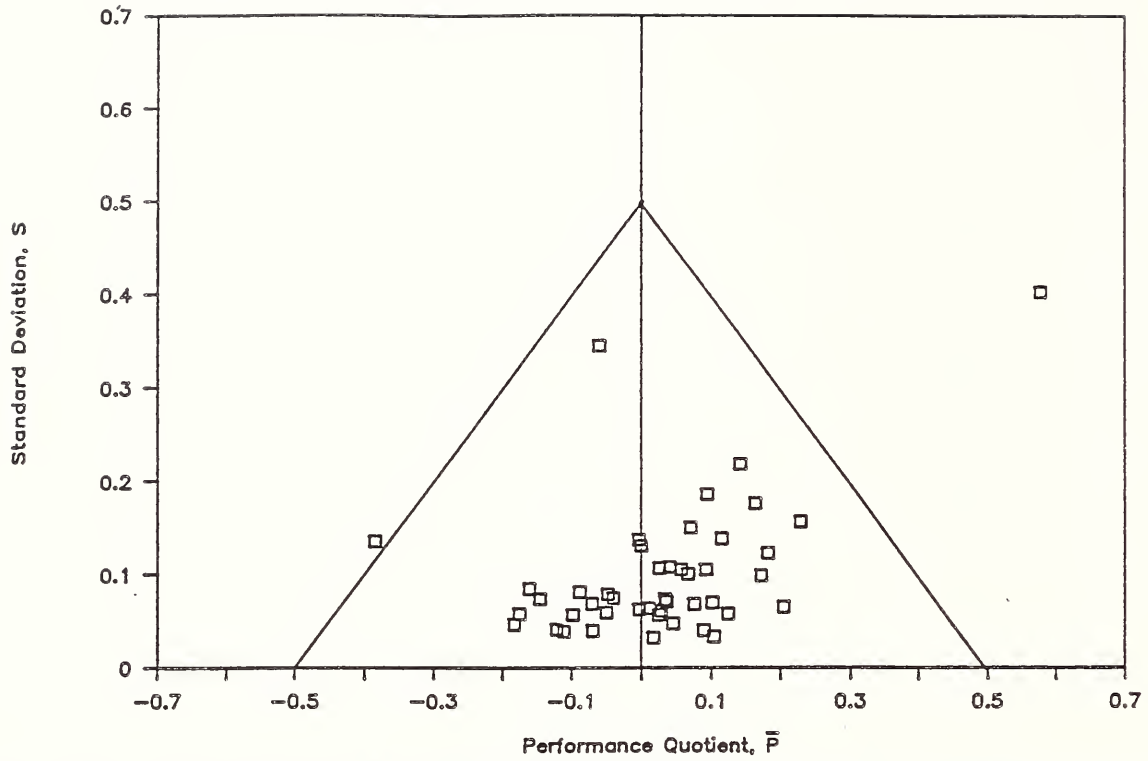

Figure 11. Test results for Category VII, photon and beta particle mixture, shallow dose.

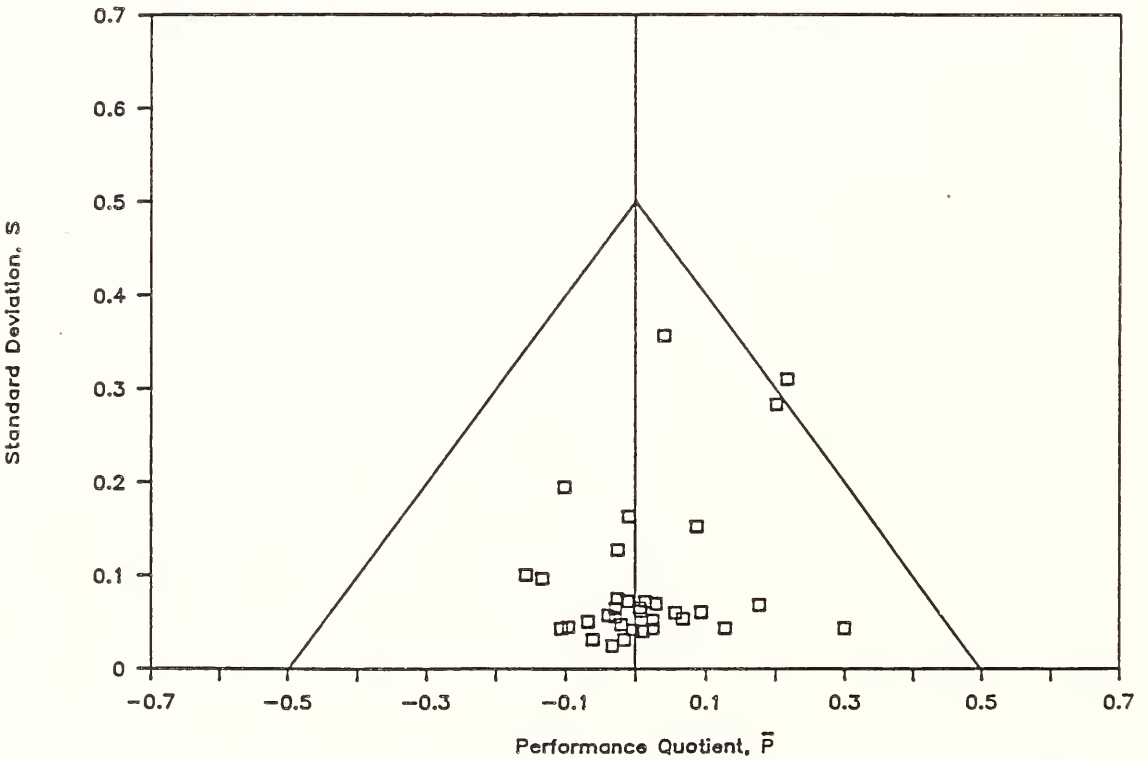

Figure 12. Test results for Category VIII, neutron and photon mixture.

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☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

For many years attempts have been made by various organizations to establish a national system to evaluate and upgrade personnel radiation dosimetry services in the United States. A system was established in 1984 under the National Voluntary Laboratory Accreditation Program (NVLAP). This paper describes how the NVLAP program evolved, how it operates, and the use of ANSI N13.11 to evaluate participant competence. Data and analyses from the NVLAP Proficiency Testing Program, based on ANSI N13.11, are presented. Problems found during on-site assessments of processor facilities and problems found as a result of proficiency testing are discussed. One significant observation is that the data seem to indicate that the NVLAP participating processors can make dose determinations to a higher degree of accuracy than specified in ANSI N13.11. Information presented in this paper will provide useful material for future revisions of ANSI N13.11.

12. KEY WORDS (Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)

accreditation; ANSI N13.11; dosimeter; evaluation; film badge; laboratory accreditation; NVLAP; personnel dosimetry; proficiency testing; TLD

13. AVAILABILITY

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