

UNITED STATES  
NUCLEAR REGULATORY COMMISSION

**INFORMATION REPORT**

August 29, 1975

SECY-75-486

#13

For: The Commissioners

Thru: Executive Director for Operations *[Signature]*

Subject: UTILIZATION OF THE RANDOM SAMPLE INSPECTION TECHNIQUE  
AS A METHOD OF QUANTIFYING THE NRC INSPECTION PROGRAM

Purpose: To inform the Commission of utility reaction to the trial program and to provide responses to anticipated questions regarding the trial program as requested by the Commission during the briefing on June 18, 1975.\*

Discussion: The Metropolitan Edison Company was notified during a meeting of Office of Inspection and Enforcement representatives with Mr. R. Arnold, Vice President-Operations, on July 30, 1975, that the Three Mile Island Unit 1 facility had been selected as the facility at which the subject inspection program would be implemented on a trial basis. Mr. Arnold stated that the company does not like to participate in trial programs such as this. He expressed concern that the statistical approach used in this trial program may not be valid and the results could be used improperly to adversely affect the Metropolitan Edison Company image. Mr. Arnold was informed that the NRC would make every effort to ensure that the results of the trial program would not impact the Metropolitan Edison Company image. There is a possibility that the Metropolitan Edison Company will direct a written communication expressing their concern to the NRC.

Briefing on the Study of the Feasibility of a Quantitative Inspection Program.

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The Chairman requested that the Office of Inspection and Enforcement prepare answers to the types of questions which may be asked by the public as a result of implementing a trial inspection program utilizing a random sampling inspection technique. Anticipated questions and the appropriate NRC responses are enclosed.

Coordination:

The Office of Policy Evaluation reviewed the questions and responses in draft form. Their comments have been incorporated in the enclosed questions and responses. The Executive Legal Director has no legal objections to the responses to the questions.

*Donald F. Knuth*

Donald F. Knuth, Director  
Office of Inspection and  
Enforcement

Enclosure:  
Anticipated Questions  
and Responses

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TRIAL PROGRAM UTILIZING  
STATISTICAL SAMPLING INSPECTION TECHNIQUE

ANTICIPATED QUESTIONS AND RESPONSES

1. QUESTION: What is the purpose of the trial inspection program utilizing the statistical sampling technique?

RESPONSE: The existing NRC inspection program is a sampling inspection program in which the selection of the items to be inspected depends largely on the judgment of the inspector.

The purpose of the trial program is to ascertain whether the statistical sampling inspection technique is a viable approach to utilize in the conduct of the inspection program. We recognize that such a technique is widely utilized by various industries in inspection programs associated with acceptance of hardware items, however, such a technique has not been extensively applied to an inspection program wherein determination of compliance with requirements is based, to a large extent, on examining the ongoing actions of personnel.

2. QUESTION: Why is a statistical sampling inspection program necessary?  
Isn't the existing NRC inspection program adequate?

RESPONSE: Consistent with the NRC ongoing efforts to improve the inspection process and inform the public of the results of our regulatory activities, we are exploring on a trial basis the feasibility of utilizing the statistical sampling inspection technique in our inspection process.

Within the scope of this trial program, the selection of items to be inspected will be on a random basis. Utilizing a given amount of inspection effort, we intend to determine if there is an optimum balance between utilization of the random sample technique and allowing the selection of the sample to be based on the judgment of our inspectors.

A byproduct of the random sampling technique could be the capability of the NRC to make a statement regarding the probability of our inspection program to detect a licensee who is in noncompliance with the NRC requirements. Likewise, as the result of utilizing a random sampling technique, we may be able to arrive at a quantitative judgment regarding the actual degree of compliance (or noncompliance) attributable to a licensee. The feasibility of being able to arrive at

such a conclusion will be evaluated during the trial program. Utilizing our current inspection program, we are unable to make such a quantitative evaluation.

The present technique for selecting items to be examined by the NRC inspectors relies on the judgment of the individual inspector as tempered by guidance contained in IE inspection procedures. The scope and technical detail of the NRC inspection activities under the trial program remain unchanged from that of our existing inspection program. Both programs are based on the NRC Regulations and requirements set forth in the Operating License.

3. QUESTION: What is the probability that the statistical sampling inspection program will detect all of the noncompliance which exists at a facility?

RESPONSE: This probability is essentially zero for a sampling program. However, due to inspector error, the same statement may be made for a 100% inspection program. The effectiveness of the inspection program lies in the follow-on investigation and enforcement action. Since most noncompliance will arise from a few causes, the elimination of these causes, through detection of a portion of the noncompliance and subsequent enforcement actions, will have a major impact on the subsequent operations at a facility. Quality Assurance programs rely quite heavily on this approach.



4. QUESTION: Is a 95/99 probability statement good enough? Why not design the inspection program for a 99/99 statement?

RESPONSE: The selection of the numerical value for the probability statement is predicated on balancing the level of noncompliance the inspection program will detect against the manpower required to detect a licensee operating at a specified level of noncompliance with NRC requirements. Actual manpower requirements for various probability levels will be evaluated during the trial program.

To compare the 95/99 detection probability to programs involving high reliability requirements, NASA and DOD inspection techniques were reviewed. Where sampling inspection for hardware acceptance is used, MIL-STD-105D is generally used as the basis for determining sampling rates. The IE inspection program sampling plan for significant safety requirements incumbent upon the trial facility compares to normal and tightened level inspection plans from MIL-STD-105D as follows:

	<u>IE Inspection Program</u>	<u>Tightened MIL-STD-105D</u>	<u>Normal MIL-STD-105D</u>
Lot Size	854	854	854
Sample Size	252	125	80
Probability of Detection	95/99	95/97.6	95/96.3
or	90/99.3	90/98.2	90/97.2

The differences in inspectable characteristics between a compliance



inspection program and hardware lot acceptance programs are recognized as decreasing the absolute meaningfulness of such a comparison, but it does give a good indication of how the probability statement selected for the trial program compares to recognized sampling programs employed by other agencies.

5. QUESTION: If a licensee is found to be only 95 percent in compliance with NRC requirements, what action will you take? At what point will the facility be required to shut down?

RESPONSE: Action taken by the NRC as a result of detection of noncompliance is contingent upon the actual items of noncompliance that are detected and the conditions under which they are detected. Therefore, at this time it is not appropriate to specify a specific numerical level of noncompliance at which the facility operations will be terminated.

Appropriate enforcement action will be taken for all items of noncompliance detected; however, the actual significance of the noncompliance and the resultant enforcement action will be based upon evaluation of each specific case, utilizing established enforcement criteria.

The enforcement action available to the NRC falls into three general categories: notice of violation, civil monetary penalty, and order to modify, suspend or revoke a license. Whereas a written notice of violation may be appropriate enforcement action for noncompliance performance that is readily correctable and does not constitute a serious threat to personnel health or safety, an order to suspend a license may be warranted when continued non-compliance would constitute a serious threat to personnel health or safety.

6. QUESTION: How does the probability statement relate to reactor safety?

RESPONSE: As in our current inspection program, emphasis is placed on those NRC requirements most closely associated with assuring the safe operation of the nuclear power plants. In the trial program we have graded the regulatory requirements incumbent upon the specific nuclear facility into three categories of safety importance. The resultant probability statements reflect the difference in NRC inspection effort applied to the three (3) categories of regulatory requirements established for this trial program.

Although the regulatory requirements are designed to assure safe operation of the nuclear power plant, a quantifiable correlation between safety of operations and compliance with regulatory requirements has not been established.

7. QUESTION: What is the rationale for basing a confidence level statement on a review of licensee documentation?

RESPONSE: The confidence level statement is based upon the degree of compliance indicated by the inspection process. The validity of the statement depends upon the accuracy of the compliance/noncompliance determinations made by the inspector and his supervisor during the inspection process. These decisions are to a large extent based upon review of licensee documentation and it is therefore a primary determinant in arriving at the confidence statement. However, it is not correct to infer that the confidence statement is based entirely upon documentation review. The confidence statement is based upon the sum of the inspection decisions, and these decisions are based upon documentation review, interviews with licensee personnel, and observation of plant conditions and operations in progress.

8. QUESTION: How can the subjective evaluation of the IE inspectors provide the basis for a quantitative statement about the inspection program?

RESPONSE: The validity of numerical statements regarding the detection capability of any sampling inspection program rests on the accuracy of the inspectors' decisions.

These decisions are admittedly subjective to some degree. The accuracy of the decision depends upon the inspector's judgment (stemming from his training and experience) and the program guidance (provided by inspection procedures, criteria for assigning noncompliance, etc.). In the case of the Statistical Sampling Inspection Program, the program guidance provided is considered to be sufficiently detailed so that the judgment which must be applied is within the capabilities of the IE inspectors. As a result, inspection error should not be large enough to invalidate the program statement. Adequacy of the program guidance will be evaluated by an independent review of inspection results during the trial program.

9. QUESTION: What criteria were used in selecting the population of elements to be inspected?

RESPONSE: The inspection program is based upon requirements established in the NRC regulations, Operating License, and Technical Specifications. All regulatory requirements pertaining to the operational aspects of the trial facility were subdivided into inspectable elements, thus comprising the inspectable population.

Each element was defined such that, when it is inspected, either zero or one noncompliance will be assigned to the results. The sampling theory upon which the program is based is valid only if the elements of the population have this "zero/one" characteristic.

The time period assigned to each inspectable element was considered in establishing the population. To demonstrate compliance with a regulatory requirement, a sufficient time period must be considered to evidence proper action by the licensee or condition of the facility. For example, the time period used for an element consisting of a licensee activity must be long enough to include the output of different operations, and affects of variation of performance

with time, thus demonstrating whether the facility is truly in compliance with the requirement.

Other criteria utilized in defining an inspectable element were:

- a. Each element was required to be independent from other inspectable elements, i.e., compliance of the element is not contingent upon also being in compliance with a different element.
- b. Each element was to be inspectable in a reasonable amount of time, preferably about one hour.
- c. An element was to be as homogeneous as practical, i.e., be concerned with one activity, performed by one group of people, in accordance with one procedure.



10. QUESTION: Why was the Three Mile Island facility selected for the trial program?

RESPONSE: Three Mile Island was selected as the facility for this trial inspection technique because it is a recently licensed facility representative of the current generation of nuclear power plants. Administrative criteria such as availability of IE personnel for development of the trial program, geographic proximity of the facility to our Regional and Headquarters offices and the number of operational units at the site also entered into our selection.

11. QUESTION: Why isn't the statistical sampling technique applied to other operating power plants?

RESPONSE: The present inspection program at the Three Mile Island Unit One facility is employing the statistical sampling inspection technique on a trial basis. Upon completion of the cost-benefit analysis associated with this trial program, the NRC will make a decision regarding the application of this technique to other operating nuclear power plants. The cost-benefit analysis is scheduled for completion in October 1976.

12. QUESTION: Why hasn't a resident inspector been assigned to the Three Mile Island facility?

RESPONSE: The statistical sampling inspection technique is not dependent upon assignment of a resident inspector. To facilitate comparison of the effectiveness of this trial program to that of the current inspection program, it was decided that the concept of resident inspection should not be employed as a part of this trial program. A separate resident inspection program is being employed at several sites on a trial basis.

13. QUESTION: Will the trial program be discriminatory in any way with respect to Three Mile Island?

RESPONSE: Insofar as inspection and enforcement activities are concerned, the trial program is not discriminatory against Three Mile Island. The basis for the trial inspection program is the same as the routine inspection program and the areas inspected under both programs are the same. The difference between the programs lies in the way in which the items to be inspected on a given inspection are selected. Under the trial program these are selected at random, rather than depending primarily on the judgment of the inspector for the selection. Since most inspections are routinely conducted on an unannounced basis, the licensee does not have prior knowledge of the items to be inspected under either program. Consequently, it is unlikely that the licensee would recognize any difference under the trial program if he were not aware that the program was being carried out. When items of noncompliance are identified under the trial program, the routine enforcement procedures will be followed. Thus, the trial inspection program does not give Three Mile Island any advantage or place them at a disadvantage with respect to inspection and enforcement activities.

The trial program is expected to provide the Nuclear Regulatory Commission with data on Three Mile Island which can be analyzed statistically, and in this respect the Three Mile Island inspection program results will be unique. Care will be taken to ensure that the results of any statistical analyses are not used in a manner which will discriminate against Three Mile Island.

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