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EVALUATION OF THE TRIAL INSPECTION PROGRAM INVOLVING STATISTICAL SAMPLING INSPECTION TECHNIQUES CONDUCTED AT METROPOLITAN EDISON COMPANY'S THREE MILE ISLAND UNIT 1

BY THE

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1. ABSTRACT

A one-year trial inspection program involving statistical sampling inspection techniques was initiated on July 1, 1975 at an operating reactor facility. The objective of the trial program was to evaluate the feasibility of utilizing statistical sampling inspection concepts which would reflect a numerical measure of confidence regarding the capability of the NRC inspection program to detect a licensee who was in noncompliance with NRC requirements. It has been concluded that the statistical sampling inspection concept is not a viable technique for broad application to the NRC inspection process in that the costs associated with implementation of such a program would outweigh significantly the benefits. The concept does have application in specific areas of the inspection program.

CONTENTS

2. INTRODUCTION

During the latter part of Calendar Year 1974, a review of the existing reactor inspection program was initiated by Sandia Laboratories at the request of the Directorate of Regulatory Operations (now the Office of Inspection and Enforcement). The objective of this review was to determine the feasibility of utilizing statistical techniques to establish a numerical measure of confidence regarding the capability of the existing inspection program to determine whether a licensee was operating his facility safely. During the review process it was concluded that measurement of the safety of operations was not quantifiable because the discrete elements that ensure safety of operations are not universally agreed upon, nor is the individual impact of each on safety known. It was further concluded that measurement of compliance might be quantifiable, but not under the existing program. It was subsequently decided to determine the feasibility of utilizing statistical sampling inspection techniques in an inspection program which would reflect a numerical measure of confidence regarding the ability of the program to detect licensees who are in noncompliance with NRC requirements. The approach was to have application to inspection of construction, preoperational testing and operational phase activities at commercial nuclear power reactors licensed by the Atomic Energy Commission (now Nuclear Regulatory Commission). Early in development of an inspection program to test the feasibility, it was concluded that the initial effort should be limited to the inspection of operating power reactors. This decision was based on the existence of more specific NRC requirements applicable to operating reactors than to reactors in the other phases of activity, therefore providing a broader base from which to develop the elements to be inspected. If the concept were found to be viable for application to operating reactors, it might then be expanded to the other phases of the NRC inspection program.

The goal was to develop a trial inspection program which would provide a basis for a confidence level statement regarding the ability of the inspection program to detect a licensee who is in noncompliance with NRC requirements. The resultant inspection program would also recognize that the NRC requirements do not all have a consistent relationship to safety. The following type of statement resulted: "The NRC inspection program is such that there is at least an X% probability of detecting any licensee who is less than Y% in compliance with NRC requirements over the period of a facility year." In order to develop the basis for such a statement, the following actions were necessary:

a. Selection of the trial facility.

b. Development of the population of inspectable elements based on regulatory requirements established in NRC regulations and the facility technical specifications.

c. Stratification of the population in accordance with safety importance.

(1) Stratum A -- Significant Safety Requirements -- Those inspectable regulatory requirements having a major impact on safe reactor operations; e.g., limiting conditions for operation having the stated purpose of ensuring safe reactor operation; requirements which identify and prohibit certain modes of operation; requirements designed to ensure the safe shutdown margin established in the technical specifications; requirements pertaining to off-site radiological releases.

(2) Stratum B -- Safety Requirements -- Those inspectable regulatory requirements which have an impact on safe reactor operations; e.g., surveillance requirements directly related to safety limits and limiting conditions for operation, other than those pertaining to nonradiological environmental matters; surveillance requirements designed to ensure the functional integrity of engineered safety feature mechanical and electrical components; requirements establishing the design features delineated in the technical specifications; requirements pertaining to radiological environmental monitoring; requirements that establish the criteria for physical protection of the facility and attendant nuclear materials.

(3) Stratum C -- Safety-Related Requirements -- Those inspectable regulatory requirements that could impact on safe reactor operations; e.g., requirements pertaining to record keeping; reporting and organizational procedures; requirements pertaining to nonradiological environmental monitoring; all other license and technical specifications not included as a significant safety requirement or safety requirement.

d. Independent verification of the stratified population by NRC personnel.

e. Selection of the confidence level to be associated with each safety stratum.

f. Generation of the random sample of inspection elements to be examined from the stratified inspection population.

g. Development of inspection procedures for the inspection elements selected in the sample.

3. TRIAL PROGRAM DESCRIPTION

Metropolitan Edison Company's Three Mile Island Unit No. 1 facility, near Harrisburg, Pennsylvania, was selected as the appropriate site for the trial inspection program because it was a recently licensed facility representative of the new generation of nuclear power plants. Stratification of the identified population was accomplished in accordance with the criteria delineated in Section 2.c.

For the trial program, the population of inspection elements, sample size and resultant confidence level statement for each safety strata were established as follows:

Strata	Population of Inspection Elements	Inspection Sample	Confidence Level
A	854	266	95/99
B	966	58	95/95
C	724	22	90/90
Overall	2544	74	95/96

Consistent with estimated manpower resource requirements and the gradation of the inspection effort to safety importance, the confidence levels for strata A, B and C were established as delineated above. It should be noted that the overall confidence level statement was limited to the 95/96 level by the occurrence of the 22nd inspection sample for Stratum C during the random sample selection process. Selection of an overall confidence level statement was not predetermined.

Inspection procedures were developed for each of the inspection elements identified in the inspection sample. Since the statistical sampling inspection program (SSIP) was essentially limited to a review of facility records associated with licensee activities, it was augmented with portions of the normal inspection program (MC 2515). This augmentation included facility tours and witnessing of on-going activities. It should be noted that whereas the MC 2515 inspection program is based on examination of compliance with numerous regulatory requirements associated with a specific functional activity, it was necessary from the statistical validity standpoint to develop the statistical sampling inspection program such that each inspectable element was independent of the other inspectable elements from a compliance standpoint.

Following a meeting with Metropolitan Edison Company to inform them that Three Mile Island Unit No. 1 had been selected for a trial inspection program involving statistical sampling inspection techniques, the trial inspection program covering the reactor operating period July 1, 1975 to June 30, 1976 was initiated.

4. TRIAL INSPECTION RESULTS

4.1 Inspection Coverage and Effectiveness

The Statistical Sampling Inspection Program (SSIP) is a highly defined inspection program which is limited to inspection of the legal regulatory requirements established in the Rules and Regulations, Facility License, Technical Specifications, Emergency Plan, Security Plan, and the Licensee's Quality Assurance Program for Operation. The normal NRC Inspection Program (MC 2515) is more extensive in that it also requires that NRC inspectors review safety-related matters which may not be fully covered by specific regulatory requirements, thereby enhancing the feedback of information necessary for optimization of the overall regulatory process. As a result of the difference in inspection coverage, NRC inspectors have expressed a higher degree of confidence regarding their evaluation of the safety of the licensee's operation utilizing MC 2515 as compared to the SSIP. Because the SSIP samples were selected randomly, some areas were not adequately covered by the sample. The following table denotes examples of the disparity in inspection coverage during the trial program:

	Program Manhours	
	MC 2515	SSIP - Sample
Security	40 Hrs.	3 Hrs.
Emergency Planning	22 Hrs.	0 Hrs.
Environmental	32 Hrs.	6 Hrs.
Refueling	50 Hrs.	3 Hrs.

The MC 2515 hours indicate the average time spent per facility per year in the respective area. The SSIP hours reflect the time required to complete the inspection procedures selected in the random sample for the trial inspection program. On the other hand, the sample size of the SSIP elements were found to be excessively large in some areas. As an example, the inspector was required to inspect all design changes initiated in a sample period of two months to ensure that licensee evaluations required by 10 CFR 50.59 had been completed. Although this would normally be an acceptable sample size, there happened to be approximately 100 design changes during the two month period. The resulting effort was much less efficient and less productive than reviewing several significant design changes to ascertain whether all regulatory requirements had been satisified in the sample selected.

4.2 Noncompliance Identification

A comparison of the total number of items of noncompliance identified within the SSIP program at Three Mile Island with those identified during MC 2515 inspection efforts at the same facility and at other facilities with B&W reactors over the same time period is as follows:

Table A *

Facility	Items of Noncompliance			Onsite Inspect. Man-Days	Man-Days Per Item of Noncompliance
	Infractions	Deficiencies	Total		
Arkansas 1	14	9	23	74.0	3.21
Oconee 1	17	7	24	49.9	2.08
Oconee 2	16	6	22	49.8	2.26
Oconee 3	16	4	20	32.3	1.61
Rancho Seco	6	5	11	60.6	5.51
Average of B&W Facilities (above)	12.4	6.2	18.6	53.3	2.86
Three Mile Island					
SSIP	7	3	10	75.2	7.52
2515	12	10	22	112.5	5.11

* It is noted that these data are dependent in part on the quality of the licensee's management control systems for operation of the respective facilities. Therefore, care should be exercised in the review, evaluation and further use of these data.

The following represents comparison of the time required to complete the trial inspection program at Three Mile Island Unit No. 1 with the average inspection effort at other operating facilities:

Table B

Facility	Preparation Time Man-Days	Onsite Inspection Time Man-Days/Year
Three Mile Island		
SSIP	14.0	75.2
2515	17.5	112.5
SSIP & 2525	31.5	187.7
* NRC 1-2515	Unknown	120.1

As indicated in Table A, a total of ten items of noncompliance were identified within the SSIP while an additional twenty-two items were detected during the MC 2515 inspection effort at Three Mile Island Unit No. 1. The ten items of noncompliance detected under the SSIP consisted of seven infractions (70%) and three deficiencies (30%) while the twenty-two items of noncompliance detected under MC 2515 consisted of twelve infractions (55%) and ten deficiencies (45%).

The results indicate that the higher yield of infractions as compared to deficiencies detected during the SSIP resulted from the fact that the SSIP inspection sample was weighted with elements involving more significant safety requirements, i.e., made up of 266 Stratum A elements (76.9%), 59 Stratum B elements (16.8%), and 22 Stratum C elements (6.3%). It should be noted that results are in good agreement with the noncompliance history at other B&W facilities inspected against MC 2515 requirements where infractions ranged from 61% to 80% with an average of 68% and the deficiencies ranged from 20% to 45% with an average of 32%. Items of noncompliance involving violations were not detected at any of the facilities discussed above.

* Nine operating facilities in NRC-1 that had the same basic operating cycle, including a refueling outage.

While items of noncompliance and man-days of inspection effort per item of noncompliance are interesting parameters, they are not considered to be reliable indicators of the overall effectivenss of a licensee's operation as related to safety. This is based in part on the variation in NRC requirements from facility to facility, variability in inspectors, and lack of direct correlation of NRC requirements to a measurement of safe operations.

In order to verify that items of noncompliance were not overlooked or misinterpreted, an independent review by experienced inspectors was completed using the same procedures employed by the trial program inspectors. The audit involved 27 of the inspection procedures, and reflected no disagreement with the trial inspector's findings.

It should be noted that documentation of preparation time identified in Table B is unique to the trial inspection program and is not required to be recorded for the MC 2515 inspection at all operating facilities.

The as-found confidence level data associated with the SSIP are as follows:

Table C

Strata	Items of Noncompliance Detected			Total	Compliance Factor
	Violations	Infractions	Deficiencies		
A	0	6	2	8	95/96
B	0	1	1	2	95/90
C	0	0	0	0	90/90

If it is assumed that the inspection elements were randomly selected from the total population rather than from each stratum, these data translate into the following overall confidence level statement: "The NRC is 95% confident that Three Mile Island Unit No. 1 was operated in compliance with at least 95% of the NRC requirements during the trial inspection program."

4.3 Inspection Effectiveness

A review of the actual time required for completion of both portions (SSIP and MC 2515) of the trial inspection program as described in Section 4.2 Table B, indicate that the SSIP required 40% of the combined inspection effort while MC 2515 required 60%. A review of related inspection reports and inspector comments relating to the trial inspection program indicate that the inspectors are less effective under the SSIP than under MC 2515. This reduction in inspection effectiveness is considered to be caused by the following:

a. By requiring review of all data associated with a single regulatory requirement during a specific time interval, less effort can be expended in determining the technical adequacy of the most important aspects associated with the functional activity addressed by the regulatory requirement.

b. The SSIP elements selected as the sample did not require the depth of inspection normally conducted under the MC 2515 program. This difference resulted from the fact that it was necessary to limit each SSIP element to a single regulatory requirement in order to facilitate the random sampling process. The MC 2515 inspection procedures are generally based on the aggregate of regulatory requirements associated with a specific licensee activity.

c. The SSIP elements in looking at only one legal requirement per inspection procedure, e.g., 50.59 evaluation completed, or procedure exists, or change reviewed by the on-site review committee, reduce the inspectors' ability to determine the overall adequacy of the licensee's program in the area being inspected.

d. Due to the requisite historical nature of the SSIP, the majority of the inspection effort was expended in paper review and little in inspection of on-going activities.

e. The SSIP sample is independent of current events. In selecting the random sample at the beginning of each annual inspection period, the computer has no input to allow the selection to be tailored to changes in plant conditions, unexpected problems, or significant schedule changes. This approach allows known significant events to pass uninspected.

4.4 Inspector Awareness

The collective evaluation by the inspectors involved and Region I supervisory personnel was that under the SSIP the inspector was less familiar with activities at the facility. This reduction in familiarity was caused by the SSIP technique of inspection to verify one specific requirement as compared to a programmatic approach as utilized under MC 2515. Even with the inspection narrowed to a specific requirement, (e.g., 50.59 evaluation performed), the depth of the inspection effort was not sufficient (e.g., no adequacy of evaluation), to provide the inspector with the desired overview of the effectiveness of the licensee's management control systems in the area inspected. Another example of this is associated with review of operating procedures wherein technical adequacy of a specific procedure was not addressed within the sample that is designed to verify that a procedure has been reviewed and approved by the licensee. It should be noted, however, that other inspection elements required the inspector to ascertain whether the content of the related procedure was adequate for its intended function. These elements were not necessarily part of the selected sample due to the randomness of the selection process.

4.5 Management of Program

The effort required to schedule and maintain status of the SSIP during the trial program was approximately 300 man-hours per year. This is the time expended by the principal inspector in inspection scheduling, data verification and orientation of specialist inspectors regarding the SSIP. It is noted that the average principal inspector requires about 200 man-hours per year per facility for this effort in connection with the MC 2515 inspection program.

The SSIP as currently structured would be administratively impractical if implemented at all operating facilities. This is caused, in part, by inspection elements being tied to the specific requirements delineated in the technical specifications, 10 CFR, security plan and QA program for operations. Since many of these requirements are not standardized, the inspection program at each facility would continue to be unique. It is recognized that inspection elements associated with certain 10 CFR requirements, Regulatory Guides, and industry standards referenced in technical specifications would be common to some facilities. These uniform requirements are counterbalanced by the other facility-unique requirements to an extent that only a modest reduction in manpower/reactor to manage the SSIP could be achieved in expanding the SSIP to many facilities.

It is noted that a total of 96 changes to requirements in the Three Mile Island Technical Specifications were approved by the Office of Nuclear Reactor Regulation (NRR), during the trial inspection program. Based on current practices, these revisions are effective on the date of issuance. Under the SSIP, associated inspection procedures would have to be revised to reflect the technical specification changes. This action would necessiate a new inspection sample and result in a perturbation in the overall management of the program for the facility.

4.6 Support Functions

The effort required to develop and support an on-going SSIP at all operating facilities may be quantified as follows:

a. Developing and maintaining inspection population

A part of the cost involved in implementing a SSIP for the inspection of nuclear reactors would be that required to develop and maintain a population of inspectable elements for each reactor facility. It is from these populations that samples would be drawn to provide the basis for NRC inspections. The population development for the trial inspection program included a three-step process which resulted in expenditure of the following effort:

Population generation:

Generation of the trial program population required four man-weeks of effort. It is estimated that a reduction to three man-weeks could be effected after the fifth population. If standard technical specifications (STS) become available, a further reduction is considered possible. This premise is based on the fact that once elements based on documents other than technical specifications (CFR, Regulatory Guides, etc.) have been defined, they can be used for all populations.

Population verification:

Verification of the population requires a thorough examination of the population to assure that all requirements are covered and that population elements are properly defined and stratified. This effort required four man-weeks for the trial program. It is estimated that this effort can be reduced to three man-weeks after the first five populations and that further reduction can be expected if STS are available.

Preparation of procedures:

Preparation of procedures selected for the trial inspection program sample required thirty-eight man-weeks of effort. It should be noted that the sample selected was equivalent to one-sixth of the total population. Therefore, approximately two hundred man-weeks would be required to develop procedures for the complete population. It is estimated that approximately 25% of the inspection requirements presently are facility-unique. Therefore, approximately 50 man-weeks would be required to develop the inspection procedures applicable to each facility.

With regard to TS modifications, a total of five TS changes involving 96 inspection elements were approved during the trial program. Because actual procedure preparation was approximately 4 hours per procedure, it can be assumed that forty-eight man-days or ten man-weeks would have been required to prepare revised procedures. Over the forty year operating life, this number can most likely be reduced to an average of one man-week per facility/year.

b. Computerized Support

A computerized program was not utilized for management of the trial inspection program. It appears that such a program would be compatible with the Module Tracking System (MTS) program which was developed for the current Light Water Reactor Inspection Program. It is estimated that two man-years of effort/year would be required to manage the computerized aspects of the program for all operating facilities.

c. Other Manpower Considerations

Headquarters effort:

One Headquarters individual was assigned responsibility for review and evaluation of on-going trial program activities. The manpower required for this effort was equivalent to eight man-weeks of effort. A similar function would be required for any future program. However, the manpower required could be reduced to approximately two man-weeks/reactor facility/year.

Regional office effort:

The extra managerial effort for the trial program is discussed in section 4.5. Management of Program.

4.7 Impact on the Licensee

A total of 61 and 49 licensee events were reported to the NRC by the trial facility licensee during the years ending July 1, 1975 and July 1, 1976, respectively. The effect, if any, of the SSIP on the number of Licensee Event Reports (LER) is not obvious. The number of LER were impacted by facility technical specifications and by the changes in reporting requirements put into effect in 1975. The number is also affected by such things as the quality of the licensee's training program, preventive maintenance programs, procedure quality, time since licensing and management attention.

The licensee's evaluation of the effect of the SSIP as compared to the MC 2515 inspection program was requested during a special meeting with onsite licensee management at the conclusion of the trial inspection program. The licensee's evaluation was as follows:

a. The statistical approach appears to provide a distorted view which would have an adverse impact on the industry. This distortion results from:

   - The positive and negative nature of the findings, i.e., if 99% of data were satisfactory, but 1% not satisfactory, it would be a negative finding.

   - The necessary paper orientation of SSIP slights two important aspects of an inspection program, personnel performance and hardware performance. This paper orientation is caused by the statistical approach of looking at historical data.

   - The narrow focus of the program could cause areas significant to safety to be completely missed.

b. The regional inspection staff has observed indications that under the SSIP, key licensee supervisory personnel tend to be less involved in systematic problem review. The tendency caused by the historical approach of the SSIP is for the licersee supervisory personnel to spend more time in their offices reviewing data to ensure the blanks are filled in and less time in the plant looking for programmatic problems. Likewise, the NRC inspectors are less involved with supervisory personnel due to the increased time spent on specific data review and less time on programmatic adequacy and quality of operations.

5. SUMMARY AND CONCLUSIONS

5.1 Benefits

a. The SSIP provides a means to quantify the effect of changes in inspection intensity upon the ability to detect noncompliance.

b. If NRC requirements were applied uniformly to all facilities, the SSIP concept would provide a basis for comparative evaluation of licensee performance as related to compliance with NRC requirements.

c. The SSIP provides a means to adjust inspection emphasis by changing strata or confidence levels.

5.2 Costs

a. The cost of identifying noncompliance in terms of man-days per item was approximately 1.5 times the routine program at the same facility.

b. The SSIP relies almost exclusively upon record review at the expense of direct observations.

c. The resources required for establishing a SSIP for current operating facilities would be 70 man-years.

d. The resources required for implementing a SSIP at current operating facilities would be 1.35 man-years/reactor/year.

5.3 Conclusions

a. The SSIP does not appear to be a viable inspection concept by itself. However, the SSIP could be used in concert with a more comprehensive inspection program such as the current inspection program. The value of the SSIP portion of the program would be the provision of a statistical statement. The value of the SSIP in terms of significant preventive enforcement and facility improvement is limited.

b. For the SSIP to be a viable management concept, it would require adoption of standard technical specifications for all operating facilities. This action appears necessary to minimize the manpower required for development and management of the Program by IE. Based on hardware differences and site considerations, it is questionable whether standard technical specifications can ever be developed.

c. The SSIP limits significantly the inspector's ability to determine the overall adequacy of the licensee's operation.

d. The SSIP relies primarily on record review; therefore, areas significant to safety are missed.

e. A broad range of confidence level statements can be developed for use with inspection populations which are most likely to be encountered during inspections of construction and operations phase activities at all nuclear power plants, for example, preparation of a simple table which relates the number of weld radiographs which must be examined with a wide range of confidence level values.

f. The SSIP concept is not compatible with observation of on-going licensee activities because of the random nature of the inspection sample.

6. RECOMMENDATIONS

It is recommended that:

a. Expenditure of further developmental effort for the SSIP be terminated.

b. Confidence level statements associated with a wide range of populations and sample sizes be developed for possible application to discrete portions of the inspection and investigation programs.