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NUCLEAR REGULATORY COMMISSION

IN THE MATTER OF:

THREE MILE ISLAND
SPECIAL INTERVIEWS

DEPOSITION OF WALTER P. HAASS

Place - Bethesda, Maryland

Date - Wednesday, September 19, 1979 Pages 1 - 130

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NUCLEAR REGULATORY COMMISSION

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DEPOSITION OF WALTER P. HAASS

Room 9109
Maryland National Bank
Building,
Bethesda, Maryland

Wednesday, September 19, 1979
9:10 a.m.

APPEARANCES:

For the Nuclear Regulatory Commission:

WAYNE LANNING, NRC/TMI Special Inquiry Group
WILLIAM PARLER, NRC/TMI Special Inquiry Group

C O N T E N T S

WITNESS:	DIRECT
Walter P. Haass	2

E X H I B I T S

COMMISSION EXHIBITS:	IDENTIFIED
1086	2
1087	4
1088	25
1089	33
1090	45
1091	53
1092	58
1093	71
1094	102
1095	109
1096	109
1097	120
1098	122

pv DAR

PROCEEDINGS

Whereupon,

WALTER P. HAASS

was called as a witness and, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. LANNING:

Q Would you please state your full name?

A Walter P. Haass.

Q I have marked as Exhibit 1086 a letter from Mr. Rogovin, director, NRC-TMI Special Inquiry Group to Mr. Walter P. Haass, dated August 30, 1979.

(NRC-1086 identified.)

BY MR. LANNING:

Q Mr. Haass, I show you what has been marked for identification as Exhibit 1086. Is this a photocopy of a letter sent to you by Mr. Rogovin confirming your deposition here today under oath?

A Yes.

Q Have you read this document in full?

A Yes.

Q Do you understand the information set forth in this letter including the general nature of the NRC-TMI Special Inquiry Group, your right to have an attorney present here today as your representative, and the fact that

pv DAR

the information you provide here may eventually become public?

A I believe I do.

Q Is counsel representing you personally here today?

A No.

MR. LANNING: I would like to note for the record that the witness is not represented by counsel here today.

BY MR. LANNING:

Q Mr. Haass, if at any time during the course of this interview you feel you would like to be represented by counsel and have counsel present, please advise us, and we will adjourn these proceedings to afford you the opportunity to make the necessary arrangemnts.

Is this procedure agreeable to you?

A Fine.

Q You should be aware that the testimony that you give has the same force and effect as if you were testifying in a court of law. Our questions and your responses are being taken down, and they will later be transcribed. You will be given the opportunity to look at the transcript and make changes that you deem necessary.

However, to the extent that your subsequent changes are significant, those changes may be viewed as affecting your credibility. So please be as complete and accurate as you can in responding to our questions.

pv DAR

Did you brin a copy of your resume with you?

A Yes, I did.

Q I have marked as Exhibit 1087 a two-page resume of Mr. Walter P. Haass, professional qualifications division of project management, office of nuclear reactor regulation, U.S. Nuclear Regulatory Commission.

(NRC-1087 identified.)

BY MR. LANNING:

Q What is your present position with the NRC?

A I am the chief of the quality assurance branch in the division of project manager, office of nuclear reactor regulation.

Q How many NRC employees report to you?

A At the present time I have eight professional men and two secretarial.

Q And what review responsibilities does your branch have?

A We have responsibility to review the areas of quality assurance conduct of operations and initial test programs, as described in certain sections of applicants safety analysis report submitted in support of construction permits and application licenses -- and operating licenses -- excuse me.

Q When did you assume the position of branch chief?

A In June of 1978.

pv DAR

Q Did you work in the area of quality assurance or conduct, initial test programs, prior to that time?

A My experience in the quality assurance area was limited to some early work in approximately 1970-71, when Appendix B to 10 CFR Part 50 was first promulgated. I was a project manager at that time in charge of one or more project reviews, and I was assigned to a special task force to develop specific guidelines for implementation of Appendix B on CP and OL reviews. That was the extent of my working with quality assurance.

I had, as a project manager, of course, back then when the reviews -- when a large part of the reviews of CP and OLs were performed by the project manager, we also had some reviews of conduct of operations and initial test programs as well as quality assurance.

Q Of the total of eight employees, can you give us a breakdown of how many of those review quality assurance programs, how many review the conduct of the operations, and how many of those review the initial test programs?

A We have a total of five men associated with the quality assurance reviews, one of whom is the group leader. We have two men associated with initial review of initial test programs, and one man who handles the conduct of operations reviews.

Q Is the conduct of operation review the same as

pv DAR

determining the technical qualification of the applicant?

A Yes, that is part of the review of conduct of operations.

Q Would you explain which parts of the applicants quality assurance program are contained in the SAR, safety analysis report?

A We require that the applicant describe the quality assurance program that he professes to implement for designing construction under a CP applicant and under an OL application. The program will consist of the part that the utility plays in that program, as well as his major contractors. By "major contractors," we define that as the reactor vendor, the architect engineer, and construction manager.

The commitments that are made by the applicant in that program are also transferred down to other lower-tier suppliers and vendors who contribute to the design and construction and subsequent operation of the plant.

Q Is it true that a large part of the quality assurance program is not documented in the SAR?

A We require that the applicant provide a description of his quality assurance program and a description is intended to demonstrate that the ultimate program developed will meet the requirements of Appendix B to Part 50. Therefore, the program itself, other than the

description, would appear in the quality assurance manual that the applicant would develop at some subsequent time, and that manual would consist of all the policies and procedures that would be required in order to implement the quality assurance program.

Q Does your branch review implementing procedures for the quality assurance program?

A We do not.

Q Have you ever in the past reviewed any detail in any administrative procedures?

A You mean quality assurance procedures?

A Yes.

Q To my knowledge, the branch has not done that. Now, we do interact with our I&E counterparts who are responsible for reviewing those, the specifics of the quality assurance program. And in the context of the QA manual, we participate in some of the inspections they perform, and, in that sense, we do get a chance to look at some of the procedures in the quality assurance manual as it's prepared.

MR. PARLER: What is this "quality assurance manual"? Has that been clearly identified for the record? Is that the applicant's quality assurance manual or what?

THE WITNESS: Yes, it is.

MR. PARLER: Okay.

pv DAR

BY MR. LANNING:

Q After the quality assurance branch has reviewed and approved the quality assurance program, would you identify the requirements — what requirements govern the changes to this approved program?

A As part of our review, we have — we require that the applicant commit to a requirement that he inform us of programmatic changes that he proposes to make to that program in advance of their being made. Organizational changes that he tell us within 30 days after the original change has been announced. These are provided -- this information is provided to us in the form of amendments to the PSAR.

There is a complication after, for example, after a construction permit is issued. At that point -- in other words, up until the CP is issued, he provides us with amendments, and subsequenty to that point he is now required to report changes under it. I think it is 5059, changes to the construction permit. And his — the applicant's responsibility is to initially determine whether the change is of safety significance. If it is safety-significant and constitutes an unreviewed safety question, then he is required to submit that to us prior to him making that change. If it is not, then he is free to make the change and proceed as normal.

pv DAR

Now, I think, in practice what we had seen — and like I say, I have only been in this branch about a year and a half -- but what we have seen is when I&E inspectors visit the applicant and perform QA inspections, they sometimes find differences between the base for inspection, which is the PSAR, and what the applicant is actually doing. And occasionally they have cited the applicant.

And to avoid this kind of problem, the applicant often informs us by a letter that he has made certain changes. And, in fact, we have established a policy whereby he should submit those changes to us. And that's normally done as part of the OL review, although sometimes before we review them for acceptability to assure that what they are doing is consistent with our requirements.

Q Does the same procedure provide for operating licenses?

A Now, for an operating license, again -- and it would be submitted during the OL review, subsequent to the OL issuance -- they would be required to report changes under 5059.

Q Now, are these changes only those that are an unresolved safety question, or are they changes in such things as the implementation procedures or changes to the QA program as identified in the SAR?

A Well, we are concerned about the -- about changes

pv DAR

to the QA program description as described in the FSAR. And so if he makes any changes to those, then he has to decide if it is initially -- whether it is an unresolved safety question, and then respond accordingly, if he modifies his procedures.

If that effect has an impact upon the commitments made in the FSAR, then he would again treat that under 5059. Otherwise, he is free to make those changes; they would be judged to be in his opinion to be less than significant and therefore not required to be reported. Of course, he has to document them, revision to procedures and that sort of thing.

Q Would changes to the list of equipment to which Appendix B applies, sometimes referred to as a "Q list," would changes to the Q list be reported to the NRC?

A Again, they should be -- changes should be reviewed in accordance with the provisions of 5059. You're talking again after the OL.

Q After the OL is issued.

A Again, should be in accordance with 5059 and appropriate notification to the staff should be made.

Q Have you processed such changes? Have you reviewed the Q list or deletions to the Q list of an applicant?

A I have not, since I have been in the branch. I

pv DAR

have not seen any. I can't verify whether this has come up before. And I guess my opinion would be that it has not, but I don't know that for sure.

Q After the operating license is issued, should there be a change to the quality assurance program, would it require an amendment to the operating license?

A No.

Q Why is that?

A The quality assurance program is not a condition of the operating license, and therefore it would not affect the OL.

Q In your opinion, why isn't the quality assurance program part of the license or part of the tech spec, technical specifications?

A I'm not sure I can understand that. My understanding was that there was some effort made back two or more years ago to accomplish that specific objective. And I don't think I can answer or provide the reasons as to why it did not proceed that way. I don't know.

Q Does the quality assurance program contribute to the defense-in-depth concept?

A Yes, I would say it does, in a way. The defense-in-depth concept is one in which the staff has required a multiplicity of systems and structures and components, redundancy, to meet the single-failure criterion

pv DAR

that provide high assurance that in the event a system is required to perform under certain conditions and failures do occur, that the capability is available to accomplish what is necessary to be accomplished.

Now, the quality assurance program would provide the assurance that indeed the various systems, structures, and components necessary to be available are indeed available. I think, in that sense, the QA program contributes to the defense-in-depth.

Q Does the quality assurance program contribute to the reliability of the equipment to perform their function?

A Yes, I would say it does. We don't perform any specific functions directly aimed at reliability, but my understanding would be that the provisions of Appendix B, the QA requirements that we have included in our standard review plan and that we use in regulatory guides as they endorse ANSI standards, would contribute to assurance that systems and components and structures would perform their functions under conditions under which they are required to.

Q Well, in your opinion, should the QA program be part of the operating license? Is it important enough to constitute recognition in the operating license?

MR. PARLER: That is, should it be a condition in the operating license, such as, for example, the various conditions that have to be met during the operational

pv DAR

testing phase and the various other conditions that are deemed by someone, a group in the regulatory process, to be significant enough so that they are included explicitly as conditions in the operating license?

THE WITNESS: I am having difficulty answering "Yes" or "No." And the main reason is that I have not really, in the year and a half that I have been in the branch, I have not really focused on that issue. So I can see some pros and cons.

If you make it a conditional license, then I can see where we would -- we would be informed on a better basis regarding how things were being done, whether changes were being made or not.

On the other hand, a con would be that it would -- it would not require the applicant to report all these changes, and some of which -- many of which -- would not be very significant. I think it would create a lot of paperwork and probably be unnecessary considerations.

I guess my bottom line is that from what I have thought about it, that I don't see that that would have an overriding significance, when I think of other things that are a part of the plant -- my understanding -- are not part of license, either.

So, I am not sure I would be in a position to specifically select quality assurance as an item that ought

pv DAR

to be a condition of the license. But I'd like to qualify that by saying I would have to do some more thinking about it and be familiar with all the aspects of it.

BY MR. LANNING:

Q What other areas are you knowledgeable of that are not included in the license?

A Well, again, I guess I'm not qualified to really talk about this, but I would think there are other aspects of system design that we review in the FSAR, other branches review in the FSAR that would not be the details of which would not be specifically included in the license or in the tech specs.

Q Can you be a little more specific?

MR. PARLER: Well, as one example, maybe you're talking about or maybe you have in mind interactions between the balance of plant systems that are not reviewed in depth by the NRC and the nuclear steam supply system that perhaps such interactions which may be significant may not all be covered by conditions of the license.

Would that be an example?

THE WITNESS: Well, I wasn't thinking of that so much. That could be part of it, but I was thinking more in terms of the details of a system design. I am really a fish out of water here. I don't think I can answer the question too well.

pv DAR

BY MR. LANNING:

Q Well, what I was getting at, were there other equipment or other provisions within the provisions of NRC which include safety-related equipment or equipment which perform a safety function which seem to be vital to the staff operation of a nuclear power plant? Are there other examples besides the quality assurance program that exist?

A I don't think I can answer that.

MR. PARLER: The responsibility for the development of technical specifications, I gather, is not in your branch?

THE WITNESS: No, it is not.

MR. PARLER: Where is that responsibility; can you tell us?

THE WITNESS: There is a tech spec group that I believe is part of the division of operating reactors that handles that.

MR. PARLER: And that organization presumably would have the responsibility or at least a part of the responsibility for evaluating whether various things should be included as a condition in the license, at least in the form of technical specifications; is that right?

THE WITNESS: I would guess so, yes.

Let me add one more thing: that the basis of our license review process is that the applicant is responsible for the

pv DAR

safe design, construction, and operation of his plant. And the reviews that we perform, while we certainly consider them to be important, they are not all-encompassing. They don't cover all areas; they don't cover full depth. It is sort of a -- it's a review of significant areas, and the point being that the applicant and/or the licensee is ultimately responsible for the safety of his plant and many design aspects, many decisions that go into the design and construction and operation of a plant are made by the applicant.

And through our review process, we feel that we have engendered in that applicant the significance of accomplishing a safe design and construction and safe operation of the plant.

MR. PARLER: I assume from Mr. Lanning's questions to you and from your responses, that the quality assurance requirements are not included as conditions in an operating license, whether or not there are other things that are of comparable significance to quality assurance is not included. Is that something that you believe, but as far as specifics you would have to defer to others? Am I correct? Am I understanding that?

THE WITNESS: Yes.

MR. PARLER: Now, a question I would like to ask you is: Have you, in your capacity as the head of the

pv DAR

quality assurance branch, received any feedback for -- from the NRC inspectors in which these inspectors have expressed difficulty in carrying out their responsibility in the quality assurance area because of the fact that quality assurance is not a condition in an operating license?

Or, to put it simply, are you aware of concerns being expressed that because of the fact that quality assurance is not a condition in the license, that that makes the job of the inspector much more difficult?

THE WITNESS: I personally am not aware of that.

Now, like I have said before, that may be one of the aspects that was considered in the part of the -- my becoming the branch chief. I really can't answer that.

BY MR. LANNING:

Q As part of reviewing the applicant's QA program, do you also review the applicant of vendor's quality assurance programs?

A We look at quality assurance programs of the principal contractors; namely, the NMSS supplier, the architect engineer, and the construction manager.

Q Now, if equipment is not manufactured by either of these three principal contractors yet it falls under the criteria of Appendix B, is that vendor QA programmed review approved by NRC?

A No, it's not.

pv DAR

Q Are you familiar with the I&E vendors inspection program?

A Yes.

Q Insomuch as the majority of equipment that goes into construction of a nuclear power plant is constructed off site and is constructed at what we would classify as a sub-tier contractor, in your opinion, should these contractors' QA program be subjected to NRC review?

pv DAR

A Up till now, we have -- our requirement is that the applicant and his major contractors determine in their purchase specs and other design documents what QA requirements should be imposed on their sub-tier vendors and suppliers.

In that way, the requirements, the appropriate requirements, of Appendix B are passed down to the lower-tier suppliers and vendors.

Back several years ago we did initiate a program that was -- that was to request industry, if they were interested in submitting topical reports at that level of activity, to submit them for the NRC staff for review. So there were -- they were permitted to do that at that point, and, as my understanding is, we got two responses, one of which is still an active topical report. And I'm not sure what happened to the other one.

We have had calls -- I have had calls since I have been the branch chief from several vendors interested in doing that, that our present policy, mostly because of the extensive necessity of that work, that there are hundreds, thousands, of suppliers of supplier and vendors that might be interested in doing that. And it would take a very large amount of manpower on the part of NRC to review all their programs.

Our policy at the moment is not to allow that kind of

pv DAR

activity. I would say -- I would say the system we presently have is probably a sufficient system. My understanding is that it has worked fairly well and before one decides whether to open the door, so to speak, to a QA program of the sub-tier vendors and suppliers, I think that a further study would be required to determine just the benefit relevative to the impact on manpower to do that job.

MR. PARLER: Is my understanding correct that even though the NRC does not review the QA program of the sub-tier contractors, that it does require its licensee -- that is, the utility -- to assure that the quality assurance principles of Appendix B to Part 50 are imposed on the sub-tier contractors?

THE WITNESS: Yes. That is what I mean when I refer to the fact that we require the applicant and his principal contractors to pass on to the lower-tier suppliers and vendors the appropriate requirements of Appendix B.

MR. PARLER: So what the NRC does not do is to review the detailed programs of the sub-tier contractors, which, I assume, in voluminous detail say how the principles in Appendix B as well as other principles actually be carried out. Is that true?

THE WITNESS: Yes, that's true.

Now, I might add that as part of the LCVI program conducted by I&E -- licensed contractor and vendor

pv DAR

inspection program -- out of Region IV, they do this several -- they visit, for example, ASME shops, and in addition to nuclear systems suppliers and architect engineers, so there is an I&E inspection function of certain vendors and suppliers.

And again, my understanding is that the selection is based on the significance of the item that is being produced by that shop, because necessarily the manpower is limited and all such sub-tier vendors and suppliers cannot be inspected.

BY MR. LANNING:

Q Do you receive licensee's event report?

A In our branch we receive a computer printout -- I think it comes from MPA -- that lists the LERs that have been received by NRC over a certain period of time. They are categorized by components or systems -- I can't recall specifically now -- and it is a document that comes through periodically. It might be an inch thick.

And we use it to review areas where -- that may pop out at us as being areas of weakness that require additional work. If we see consistent programs in QA, then we would like to feed that back into our process to make appropriate corrections.

Yes, we do.

Q Do you recollect any examples, particular events

pv DAR

or shortcomings that have been identified in LERs, that have resulted in a change in review process or review requirements?

A In the year and a half I have been in the branch, I cannot recall any specifics, no.

Q Are there requirements in Appendix B addressing maintenance of equipment?

A Yes.

Q Would you refer me to the particular criteria in Appendix B?

A If you look at the first paragraph of the introduction to Appendix B, the very last sentence -- it runs about 10 lines or so. Toward the end of the sentence it talks about the various activities that may be involved in the safety-related functions of structures, systems, ad components; and one of those is maintaining.

Q That's in the introduction. Now, does an introduction constitute the same weight as the remaining criteria?

MR. PARLER: I think that in part -- asks for a legal-type conclusion on Mr. Hughes' part, which, at least for the record, we shouldn't ask them him to give.

But with that qualification, you should answer the question from just your understanding as the head of the quality assurance branch.

pv DAR

THE WITNESS: We require Appendix B to be implemented on all the activities that are identified in the introduction.

MR. LANNING: Let's go off the record a minute.

(Discussion off the record.)

MR. LANNING: Back on the record.

BY MR. LANNING:

Q Would you explain which criteria contained in Appendix B reflect maintenance requirements?

A Well, there are several criteria that, in my view, would be applicable to maintenance, the maintenance activities. And they could include items like procurement document control, if spare parts have to be procured. That would be criterion 4.

There might be special instruments and procedures that apply to that maintenance activity, in which criterion 5 comes into play. Documents would be involved -- that is criterion 6. There would be requirements for identification of controlled materials, parts, and components, criteria 8.

If there is a special process involved in performing the maintenance, such as welding or some kind of coating operation, that is criterion 9.

Criterion 10 covers inspection activities during and subsequent to the maintenance activities.

If a test is required, criterion 11 would come into play,

pv DAR

and so on. There may be others.

MR. PARLER: I believe that what Mr. Lanning was getting at in the question is whether there are any requirements for maintenance in the Appendix B to the Part 50.

Now, my understanding of the discussion that has just taken place is that there are in the Appendix B to the Part 50 certain quality assurance principles that would have to be complied with if certain types of maintenance were carried out.

I wonder if the distinction which I am trying to make is a correct distinction?

THE WITNESS: Yes, the Appendix B would not dictate as to when maintenance functions or what kind of maintenance functions should be performed, but it provides the criteria that would -- or the requirements that would govern the performance of the maintenance so that it is performed correctly.

Now, that is true of all the activities, quality assurance only assures that the activities that you're undertaking, that they are performed correctly.

MR. LANNING: I would like to mark as Exhibit 1088 a memorandum from Harold Denton to Commissioner Kennedy. The subject is: "Preventive maintenance." It's dated August 8, 1979.

pv DAR

(NRC-1088 identified.)

BY MR. LANNING:

Q Mr. Hughes, have you reviewed this memorandum, and, in particular, the third paragraph on the first page there? First off, I do not see that you concurred in this memorandum." Is that true?

A That's correct.

MR. PARLER: Well, I think that, again, for clarification on the record, was the memorandum even submitted to you for your concurrence?

THE WITNESS: No, it was not.

MR. PARLER: Okay.

BY MR. LANNING:

Q On the first page, the third paragraph, there it states that a detailed preventive maintenance program currently is not required by the regulatory staff. This implies to me that the NRC does not have requirements for a preventive maintenance program.

Now, am I misinterpreting the context of this letter, or could you clarify what your understanding of this letter is trying to address?

A Well, focusing on the third paragraph on the first page -- and let me hasten to add here that I have not specifically looked at these particular references with regard to these -- to the comments that are made here. But

pv DAR

my understanding is that the -- apparently the ANSI standard would -- requires that a preventive maintenance program be established for safety-related components.

The quality assurance branch, in turn, would require, consistent with the requirements of Appendix B, that those activities would be conducted in accordance with the QA programmatic requirements.

Q Do you recall, is that the standard review plan which addresses maintenance requirements?

A I believe the standard review plan again identifies the various activities that could be conducted at a nuclear power plant, and maintenance would be one of those.

MR. PARLER: Let's go off the record while he is looking for his document.

(Discussion off the record.)

MR. PARLER: On the record.

THE WITNESS: Specifically, in section 17.2 of the standard review plan, under subsection (1), entitled "Areas of Review," at the last sentence in the first paragraph it refers to the various activities to which the QA controls would be applied, and maintaining is one of those activities.

BY MR. LANNING:

Q Are there also qualification requirements for

pv DAR

personnel performing maintenance?

MR. PARLER: That is NRC qualification requirements.

THE WITNESS: To my knowledge, we require that personnel that perform maintenance activities -- we are talking now about the QA aspect of maintenance activities as well as the QA aspects of any other activity, would require the use of personnel qualified in the area in which they are performing that work.

And I believe there are several references to that. I can't cite them specifically right now, but I believe they are in the ANSI standard, the 18.7. And I believe that's where they are, yes.

BY MR. LANNING:

Q Are you aware of any I&E concerns regarding the requirements for maintenance in an approved quality assurance program and the lack of qualifications, explicit qualifications, for personnel performing maintenance functions, testing, repair functions?

A No.

Q In other words, you have not been contacted by I&E headquarters, for example, to resolve any issues raised by regional I&E inspectors?

A Regarding qualifications of people?

Q Regarding qualifications of people or regarding

pv DAR

the need for explicit requirements for maintenance.

A No, not to my knowledge.

Q Is there a requirement in the standard review plan or the standard format or any other regulatory guidance requiring licensees or applicants to provide a list of equipment on the Q list, to be included in his SAR?

A Yes, sir.

Q Where is that requirement?

A Requirement is identified in the criterion 2 of Appendix B to 10 CFR Part 50; specifically, the third sentence of the first paragraph.

Q Would you read that?

A "The applicant shall identify the structures, systems, and components to be covered by the quality assurance program." And then it goes on to another subject and major organizations participating in the program together with the designated functions of these organizations.

Q And this list are identifications of the structures, systems, and components, are submitted to the NRC as part of Chapter 17?

A Most generally, the listing is provided in Chapter 3, and it is referenced, that list is referenced in Chapter 17.

Q What is the criterion for equipment or systems to

pv DAR

be included on this list?

A The criterion we use is, again, contained in Appendix B, which states that Appendix B applies to safety-related -- to safety-related functions of systems, structures, and components. And "safety-related" is defined as those systems, structures, and components that are required to prevent and mitigate or mitigate the effects -- to prevent or mitigate the conseuqences of postulated accidents that could cause undue risk to the health and safety of the public.

Q Is that a definition of safety-related equipment?

A That is the definition of the staff and industry, to my knowledge, have utilized in determining what items are included on the Q list.

Q Well, what would constitute undue risk?

MR. PARLER: What was the question? What would constitute an undue risk?

MR. LANNING: Yes.

MR. PARLER: Again, that is a question that could involve legal considerations. But taking the statement I just made into account, what, from your perspective and responsibility could constitute undue risk, strictly from a technical standpoint?

THE WITNESS: Well, in the context of the sentence I just read out of the introduction of Appendix B, I would

pv DAR

interpret undue risk as being related to accidents -- and we talk here in terms of significant accidents -- that could result in dose levels to the public that may approach part-100 limits, and therefore I would say that undue risk here is related to those kinds of accidents.

Now, again, don't feel particularly qualified to respond to that.

BY MR. LANNING:

Q Did I understand you correctly to say that the NRC and industry have been using this definition that you quoted?

A Yes.

Q Is it your understanding that that's a uniformly accepted definition within the industry and the NRC?

A I don't believe it is. I have been involved in this now for a year and a half, as I said, and I talked to quite a number of licensees and applicants in the context of the QA program. And this topic has come up in several conversations, and based on those conversations I would say that is pretty uniformly accepted.

There is a dichotomy in the staff, however, where -- in which there are some segments that believe that Appendix B applies to all systems and components and structures that could be identified from the general design criteria given in Appendix A.

pv DAR

However, since the promulgation of Appendix B approximately 10 years ago, it is my understanding that this -- that the NRC staff and industry have implemented the requirements of Appendix B in the context that there was a difference between safety-related systems, structures, and components, and the systems, structures, and components identified as important to safety under Appendix A.

And therefore, the Q list has grown out of that definition, and it is now the listing of systems, components, and structures to which Appendix B applies.

MR. PARLER: The difference between the various -- or the two views of the -- within the NRC, I guess, what the two positions are, and the reasons for those two positions, as you understand them -- I am not too sure that I understand that.

Go off the record, please.

(Discussion off the record.)

MR. PARLER: Back on the record.

MR. LANNING: Back on the record.

BY MR. LANNING:

Q The words that you have been quoting from Appendix B, is that a definition of safety-related equipment which perform a safety function, or is that a statement of what Appendix B applies to?

A The introduction to Appendix B -- specifically,

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the first paragraph -- talks about safety-related functions of structures, systems, and components that prevent or mitigate the consequences of postulated accidents. And I am paraphrasing here a little bit.

But when you read the introduction of the first paragraph, section (b), this is the gist of what you get out of it. We are talking here specifically about systems, structures, and components that are necessary to prevent or mitigate the consequences of an accident.

That paragraph now talks in terms of the safety-related functions of those structures, systems, and components. And my understanding is that if a system has a safety-related function, it can now be considered a safety-related system. And therefore, I dont' distinguish to any degree between the functions and the system itself.

If a system has a function that is safety-related, then the system is safety-related; and therefore, looking at the context of that whole paragraph, it's my understanding -- is my understanding of how Appendix B come to be applied to safety-related systems, structure, and components, and safety-related is specifically identified as those items that prevent or mitigate the effects, the consequences of postulated accidents.

Q As a participant in the NRC interoffice task force, wasn't one of the duties to define what is meant by

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"safety-related" or "important to safety" or "safety-graded equipment"?

A I believe that was one of the issues raised at some earlier meeting, prior to my coming to this job. We have had one meeting of that task force since I have been on the job, and that was the subject at that meeting.

MR. LANNING: I would like to mark as Exhibit 1089 a memorandum from Walter P. Haass to W. M. Morrison, the subject is: "QAB Comments on Proposed Regulatory Guide 1.XXX (RS-70404)."

(NRC-1089 identified.)

BY MR. LANNING:

Q Does this memorandum in effect provide comments as a result of that last meeting of the task force?

A This comment -- this memo comments on the -- on a proposed regulatory guide, which was advanced at the meeting of the interoffice QA task force on June 6, 1979, as an approach to resolving the dichotomy that exists between the applicability of Appendix B to items identified in Appendix A.

Q That would imply to me that it does not -- that there does not exist a formal definition of what is meant by "safety grade" or "systems which perform safety functions."

A I think one can say there is not a clear definition of what is meant by "safety-related" and what is

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meant by "important to safety." In other words, there is no specific line item in the regulations that says "safety-related means," "important to safety means." One has to read from the various portions of the regulations in order to make the interpretation as to what those specific terms mean.

Q Exhibit 1089 commented on the guide in attempting to establish equivalency between the definitions of "important to safety," which appears in the first paragraph, introduction to Appendix A, and "safety-related," which appears in the introduction to Appendix B.

Can you distinguish your understanding of the difference between the definitions of "important to safety" and "safety-related" in Appendix A and B?

A Yes. I think that -- well, we went through the definition as one can derive from the introduction of Appendix B.

If we now go to the introduction of Appendix A, again referring to the first paragraph -- specifically, the last sentence of that first paragraph -- which says that the principal design criteria establishes design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated

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without undue risk to the health and safety of the public."

MR. PARLER: Of course, that definition would appear to be as broad as the basic finding that has to be made to permit a plant to be licensed.

THE WITNESS: Yes.

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MR. PARLER: In other words, the reasonable assurance of no undue risk finding that those that have been involved in this regulatory program are familiar with, so I guess a question that could be asked is, is such a definition from the practical standpoint useful?

THE WITNESS: Well, again, you read the provisions of Appendix A and Appendix B which basically provide the regulatory support for the staff review process on -- in the various areas that we have determined are necessary for review as described in an SAR.

In other words, Appendix A covers all those areas, and, yes, important to safety would be judged as a broad, or the definition of Appendix A would be judged as an all encompassing kind of definition that covers all the systems, structures, and components that one could say -- use for want of other terminology -- that affects safety.

MR. PARLER: Excuse me, go ahead.

THE WITNESS: And what has happened now since the promulgation of Appendix B is that people have read the definition of "safety related" as being some elite grouping of systems, structures, and components which have some greater significance t safety because they are required to prevent or mitigate the effects of an accident as opposed to other items in the plant, that maybe they're just -- because that we are concerned about them because they affect safety

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and it could be at some lower level, so that you have a two level kind of system -- safety-related being the more significant to safety as opposed to the remaining items in Appendix B as being not quite as important to safety, not quite as significant to safety.

MR. PARLER: Now where are these items, the items that are more significant for safety than others? Where are they identified? Are they the items that are identified on the Q List?

THE WITNESS: Yes.

MR. PARLER: Now beyond the words that are associated with safety-related in the Appendix B to Part 50, are there any other criteria that you are aware of which are associated with the identification of items that have this special safety significance? Is my question clear to you?

THE WITNESS: Maybe we could repeat it again.

MR. PARLER: Well, what are the criteria beyond the words in the Appendix B to Part 50, which relate to the identification and the choice of those systems which do have special significance from the standpoint of safety?

THE WITNESS: I don't think --

MR. PARLER: In other words, those that arise above all of the systems that are covered by the Appendix A to Part 50 which are important to safety, which I understand you have been saying is for Appendix A purposes. There are

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some systems which are more important to safety than others. And what I'm trying to ask you is where are the criteria which will identify such systems which are more important to safety than others?

THE WITNESS: I would cite the --

MR. PARLER: I'm familiar with the general words that are in the Appendix B regarding safety-related and the general words that are in Appendix A regarding "important to safety", but beyond that what are the criteria -- let's go off the record while he's looking for this.

(Discussion off the record.)

MR. PARLER: Back on the record. I would cite the regulatory position given in the Regulatory Guide 1.29 entitled "Seismic Design Application" as being an additional guidance to determine those systems, structures, and components that would fall under Appendix B.

BY MR. LANNING:

Q Is that guidance, or is that the only definitive criteria that you know exists for including equipment that is subject to the requirements of Appendix B?

A Well, the Regulatory Guide is guidance. Other than my citing the initial paragraphs of Appendices A and B, I cannot cite any other definition.

Q Were you implying that there exists a graded Q and A program?

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A Yes, the applicant is free to grade the QA requirements for specific systems, structures, or components in accordance with the importance to safety.

MR. PARLER: In whose judgment? The applicant's judgment or the NRC's judgment?

THE WITNESS: In the applicant's judgment.

MR. PARLER: Excuse me.

BY MR. LANNING:

Q Are you saying that Appendix B is applied to equipment, other than the equipment which satisfies the definition which you previously stated?

MR. PARLER: Which definition, "safety-related" or "important to safety"?

BY MR. LANNING:

Q Important to safety.

A Let's see. I'd have to hear that question again. Can you repeat that?

Q Let me state it differently. It was my understanding that Appendix B only applied to those equipment or components or systems which were important to safety, safety-related.

A Safety-related.

Q Safety-relted. Okay. My question is, does Appendix B also apply to other equipment and systems which are important to safety but which are not safety-related?

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A The QA requirements for items which can be identified from Appendix A as important to safety but are not included on the Q List are called out in General Design Criterion Number 1 of Appendix A.

MR. PARLER: Did you say "called out" or "culled out"?

THE WITNESS: Called, C-A.

BY MR. LANNING:

Q In other words, Criterion 1 states that everything in the plant -- there should be some suitable quality assurance applied?

A Yes, yes. See, you can see -- maybe I can add here that what has happened over the years is that this elite class of systems, structures, and components has been culled, c-u-l, culled out of the listing of Appendix A items and Appendix B requirements have been applied to those items because they are more significant to safety than others. But yet there still remains a QA requirement for the remaining items, namely that given in GDC Number 1.

Q How do you review the degree of the QA program which applies to all those other components?

MR. PARLER: That are covered by Criterion 1 in Appendix A.

THE WITNESS: Up to now, that has not been reviewed. We are now in the process of developing a

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specific QA umbrella of requirements that we believe to be appropriate for those Appendix A items that are not covered by Appendix B.

MR. PARLER: Who is that, your Branch, or Standards, or Task Force?

THE WITNESS: It would be a combination of Standards and QAB.

MR. PARLER: Is that what's starting, or well along the way?

THE WITNESS: It is starting.

MR. PARLER: Something, say, within the last several months or this year?

THE WITNESS: Within the last several weeks.

MR. PARLER: Within the last several weeks?

THE WITNESS: Yes, yes. We have obtained agreement from Standards based on the memor you cited before, Exhibit 1089, to proceed in that direction.

MR. PARLER: Who is heading that effort? Is that you or Mr. Morrison's people?

THE WITNESS: It is Standards --

MR. PARLER: That is Mr. Morrison?

THE WITNESS: It comes under Bill Morrison, yes. We have volunteered to make some -- to begin the effort in defining what the umorella requirements will be for those Appendix A items. We recognize that we will be heavily

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involved in any regulation change or regulatory guide or any other criteria that might evolve from this area, and so we feel -- we see a need to initiate an effort in our branch to define these areas.

MR. PARLER: Although the regulatory effort in the area that you are talking about, that is the quality assurance program, that is referred to in General Design Criterion Number 1, although the regulatory effort to define that program is just beginning, do you have any information or knowledge as to how the nuclear industry, say for example the vendors, have applied this General Design Criterion 1 over the years?

I realize that is a general question, but the point is, there has been a lack of activity in the regulatory arena, presumably up to now, and the point of my question is, I wonder whether there has been a similar lack of response in the nuclear industry?

THE WITNESS: I believe I addressed that issue in Exhibit 1089, and in our conversation with several of the applicants and licensees, we have determined that there is a wide spectrum of what they are doing in that area that ranges from very little to something which they have not really defined.

The answer that I can give you is that we have no details regarding that.

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MR. PARLER: Okay. Fine, fine.

BY MR. LANNING:

Q Are you familiar with efforts made several years ago by Westinghouse and Commercial Engineering to formulate or establish a graded QA program?

A From what you have said, it doesn't strike a bell. I don't know anything about it.

Q Exhibit 1089 indicates that the proposed guide attempts to modify the meaning of the regulations by changing the meaning of the perceived definition. Is not the lack of specific definition for "safety-related" and "important to safety" one of the major shortcomings in the applicability of Appendix B?

A I would say yes. The lack of clear definition is, or the lack of a clear intent on the part of the regulation, is to say that Appendix B, indeed, applies to all Appendix A items, is a difficulty.

Q Do you forsee a need to change the regulations in order to clarify --

A Yes, I do.

MR. PARLER: Now is the regulatory change a part of this recently initiated task that you have been talking about?

THE WITNESS: Yes.

MR. PARLER: I see.

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BY MR. LANNING:

Q What organization has the responsbility of approving the Q List?

A QAB is responsible for assuring that the quality assurance program description, as given in Chapter 17 of NSAR, has tied in with it a Q List. However, the details of determining whether that Q List itself is adequate, acceptable, what have you, is really a function of the review areas who review the specific items within their area of responsibility as they appear on that Q List.

We have recently initiated -- this goes back to early this year and discussion late last year regarding a change and how we accomplish the determination of whether that Q List is acceptable or not.

Our present process now requires that we ask several of the review branches to review the items on the Q List that fall within their area of responsibility to make that determination as to whether that list is complete or not, and that's the way we are doing things now.

If you go back prior to that initiation of this new program, the list, it's my understanding, was basically reviewed within the QA Branch by comparing the applicants' list against the list which had been developed within the branch as being an acceptable list. Prior to that time, and I can't really say how long that particular review process

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was in vogue, but prior to that time there seems to be a question as to whether the Q List was really reviewed in detail at all. I can't give you anymore specifics on that, so it has evolved from that early time to the present time which I personally believe is the proper way to do it.

It asks the people who are most familiar with the functions of the systems, structures, and components in the context of their safety functions to determine whether the Q List is acceptable or not.

MR. PARLER: When was the present practice initiated of having the technical, or reviewers presumably who are in the Division of Safety Systems — when was that practice initiated approximately? Do you have any idea?

THE WITNESS: It was -- it was formally identified as a problem in a memo dated February 8, 1979, from Mr. Skovholt or Mr. DeYoung and Mattson, where a procedure was identified -- the procedure was identified for accomplishing the review of the Q List for acceptablity.

MR. PARLER: Do you have it? Could I make a copy of that, please?

BY MR. LANNING:

Q We'll mark that as Exhibit 1090.

(Exhibit 1090 was marked for identification.)

Does this procedure apply to new applications that are

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docketed, or does it also apply to existing plants? Review of the Q List?

MR. PARLER: What are you talking about? Backfitting the Q List? Is that the point?

THE WITNESS: Maybe I can explain it. We -- by the way, let's first of all say that the proposed procedure as described in this memo has been accepted for use, and we are now using the procedure. It applies to new applications as well as applications that are in-house at the moment. And necessarily judgments have to be made if we are about to issue an OL or a CP, the review is basically complete. We have not applied it, but those as far as the latter with ANSI are complete because we have had delays due to the TMI accident. We have gone back to the procedure --

MR. PARLER: But would this procedure have any applicability to a plant which has already been licensed to operate?

THE WITNESS: No. That would not be our prerogative. We don't handle those plants.

BY MR. LANNING:

Q When you say, "we don't handle those plants" --

A QAB does not.

Q It does not address operating activities?

A No, they come under DOR.

MR. PARLER: You mean that once the responsibility

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for a plant is transferred to DOR that the Quality Assurance Branch has no further involvement with that plant at all?

THE WITNESS: Only when requested.

MR. PARLER: Only when requested by DOR?

THE WITNESS: Yes, it has its own capability. To my understanding, they have referred most of their QA review questions or review areas to us for review, and I can recall two instances which involved a full term operating license determination where we raised this very question, whether the -- to DOR -- should we be looking for guidance to them, should we be applying this procedure for the review of the Q List in that full term operating license?

And I know on one occasion the response -- and maybe on both -- was that it would be considered in the context of the systematic evaluation program.

Let me clarify here. We are not talking about backfitting. We are talking about future activities, and in the context of an operating plant, it's activities involved in maintaining and modifying, repairing items, that are presently in the plant.

We're not proposing that a licensee go back and develop the pedigree for a particular item, which we are now, under the new procedure, have been including on the Q List. And up to them was not included. We are not asking for that. We are saying, in the future, if you do any work, you have

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to replace that item, maintain the repair, what have you, any work on that item. If it is now on the Q List, it now falls under the Appendix B QA program.

MR. PARLER: Well, with that explanation, the explanations you have just given, it's rather puzzling to me why the issue that we are talking about, that is that is covered by this Exhibit 1090, should be associated with the systematic evaluation programs for operating reactors.

I would just make that comment. It is rather puzzling to me.

THE WITNESS: Well, my understanding is that the DOR is saying that there are certain issues that would be addressed in the context of the SEP, and I am not privy to how these decisions are made. All I can tell you is -- I raised the question in QAB when we did those reviews for DOR, and that was the response we got. And as far I'm concerned, they are responsible. And I raised the issue.

BY MR. LANNING:

Q Back to Exhibit 1089, would you explain your recommendation concerning a graded quality assurance program? I guess, primarily, how would one determine which equipment is more important than others, yet all equipment are considered important to safety? How do you determine which systems, components, are more important to safety than others?

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A Well, first of all, under this proposed approach, we would be categorizing all systems, structures, and components that affect safety into two areas. One would be those that we now call safety-related and to which Appendix B applies. And the other would be those remaining items from Appendix A, not on that Q List, but judged to be important to safety and to which GDC-1 would apply.

And a we discussed before, we are proposing that we develop an umbrella of QA requirements for those items which remain in Appendix A that are not on the Q List, in accordance with GDC-1.

Now within the context of those two umbrellas, the Appendix B on the one and Appendix A on the other hand, the applicant is free to apply a program which we would call a graded program to a specific item that falls either under the Appendix B list or under the Appendix A list, depending upon the importance of safety to that particular item, and that is identified -- that concept is identified in Appendix B, specifically under Criterion 2.

And I will read the sentence. It says: "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent consistent with their importance to safety."

mgcDA.? Q That implies to me that Appendix B was intended to apply to various levels of equipment?

A Let me continue. If I go now to Criterion I of Appendix A, again the first sentence: "Structures, sytems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed."

In other words, in both Appendices A and B, there is the concept of applying QA requirements consistent with the importance to safety of that item, and we term that a "graded" approach -- applying QA requirements so the applicant is free within the context of these two umbrellas, and we don't have it yet, of course, for the Appendix A items to apply the QA requirements that in his judgment are consistent with that item's importance to safety.

Q When a system, as a reactor coolant system, reactor protection system, is identified on the Q List, does this mean that all the components of the system are safety grade?

A Not necessarily. There may be certain aspects of those systems that in the applicant's determination, based on his application of the commitments that have been made in the SAR as a result of our review, basically Chapters 4 and 15 and 7 -- others are involved -- whereby the functioning

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of that system with regard to safety is clearly identified. There may be items on that system that one could judge are not safety-related. An example might be the loose parts monitor, part of the reactor coolant system. That is an instrument that up to now has not been a Q Listed item. It is part of the system, but in the judgment of the staff, at the moment, has not been judged to be an item that is a safety-related item that is necessary to prevent or mitigate the effects of an accident.

Now that could change in the future, but up to now it has not been that way.

BY MR. LANNING:

Q Have you been involved with any discussions between I&E personnel who have raised the concern about the flexibility of the applicant or the licensee has with regard to changing the quantity or the list of components or systems that appear on the Q List?

A I don't recall any conversations along those lines.

Tape4.1
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Q. Have you been involved in any discussions addressing consumables as to whether or not they should be included on the Q List?

A. Yes.

Q. Can you explain under what circumstances?

A. Yes. It was in the context of the revised procedures for determining the acceptability of the Q List. We had identified items other than specific systems, structures and components that ought to be on the Q List. Consumables is one of those.

There were also items such as data taking, when the applicant is investigating a site, determing the meteorology, the geology, the seismology, the foundation characteristics of the site, all of which can be related to, are used in the design of structures of the meteorology, for example, affects how you design your emergency plans. The geology, seismology, determines how you design your structures, what kind of safety-- what kind of initial assumptions are assumed. These are important for the design of those items and, therefore, the obtaining of that data. We feel, and of course the final judgement is not ours -- it belongs to the reviewing branch -- we feel those items ought to be part of the Q List.

Q. How was the issue brought to your attention?

A. Well, as I said before in the context of our

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establishing a revised procedure for determining the acceptability of the Q List.

Q This is the procedure identified in Exhibit 1090?

A Yes.

Q I want to mark as Exhibit 1091 a memorandum from Harold Denton to Commissioner Kennedy. The subject is "Quality Assurance Programs for Nuclear Power Plants", dated April 16, 1979.

(Exhibit 1091 was marked for identification.)

Did you originate that memorandum?

A I originated part of it. It was actually a combination of input from Quality Assurance Branch which, as I recall, was basically the first page and inputs from I&E which I think were basically the rest of it -- certainly the second page and maybe some more.

Q Okay. Was the first page -- I would like to discuss -- it states that --

MR. PARLER: Excuse me. Do you have a copy of that before you, or do you want a copy before you as he is reading that?

THE WITNESS: Let me figure it out here.

MR. PARLER: Off the record for a second.

(Discussion off the record.)

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BY MR. LANNING:

Q This memorandum states on the first page that "sufficient quality assurance programmatic requirements and controls are already imposed on applicants." What is the basis for this conclusion?

A The basis for that conclusion is our extensive knowledge of the QA programmatic requirements and the review of I & E inspection reports and licensee-vendor reports given to us i us in the computer printout, which indicate to us that there's really -- there is no need for additional programmatic requirements in the areas where we find difficulties -- that they're primarily a matter of implemention, that the applicant has not implemented the programmatic requirements properly. That there are errors in procedures or maybe design review aren't conducted properly, or inspections are not done right.

But we have not found the need for identifying any more programmatic requirements.

MR. PARLER: At this point, what do you mean by programmatic requirements?

THE WITNESS: The 18 or so criteria in Appendix B, as expanded by the acceptance criteria in Standard Review Plan, section 17-1 and 17-2, and the Regulatory Guides and enforced standars that are referenced in those Standard Review Plans.

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BY MR. LANNING:

Q Does the basis for this conclusion also include being able to ascertain the effectiveness of a quality assurance program? In general?

A No. I would say -- well, other than -- I have to say no, other than a qualitative assessment of effectiveness. Effectiveness of a quality assurance program is rather difficult to quantify. But we can take -- make an assessment of how the program is being conducted by our review of I&E inspection reports and licensee event reports, discussions with I&E inspectors.

Basically the feedback -- that is basically the feedback that we get that tells us how things are going.

Q Well, shouldn't the LERs and the reliablity data collection system for equipment failures provide you a basis for judging the effectiveness of the program?

A I guess I don't feel qualified to respond to that. I would say in a qualified way that I'm sure that those pieces of information would help, but to my knowledge, nobody has actually gone that far to actually say what the -- to assess the effectiveness of a program.

MR. PARLER: I gather that an assessment of the effectiveness of the quality assurance program of any particular licensee for a nuclear power plant or types of licensees is not a part of the responsibility of the Quality

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Assurance Branch? Is that right?

THE WITNESS: I would say, that's correct without looking at a detailed description of responsibility of the QAB.

MR. PARLER: I'm talking about in practical terms as that branch understands and carries out its responsiblities on a day to day basis. It doesn't really get into the area of assessment of the effectiveness of quality assurance programs too much. Is that right?

THE WITNESS: That's right. That's right.

MR. PARLER: I wonder who does that?

THE WITNESS: Well, I have heard -- what I can say is that I have heard people in I&E --

MR. PARLER: Yes?

THE WITNESS: -- talk about attempting to do this, and they're sort of searching for ways to do it.

MR. PARLER: Yes?

THE WITNESS: And to my knowledge, nothing has been done in that regard.

BY MR. LANNING:

Q On page two of Exhibit 1091, it states, in effect, that the balance between regulatory effort versus industry effort has been considered acceptable by the Commission and staff in view of the Three Mile Island accident. However, the acceptability of this balance has clearly been upset,

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and additional high level reviews appear to be immanent. Can you explain the meaning of those words or what has resulted from the Three Mile Island incident which tends to upset the balance between regulatory and industry's effort?

A I guess what I can say at this point is that this was provided by I&E, and recognizing the dates, this was written probably within a couple of weeks after the accident at Three Mile Island and at which time not a lot was known, and maybe this was more speculation than fact, because since that time, we're not aware of any specific -- well, let me say not aware of any specific of any Q and A programmatic deficiencies that could be one of the root causes of the Three Miles Island accident.

What this is trying to say here is that there was a balance, there was a balance between what NRC does and what the industry does with respect to inspection activity and verification, that kind of thing. And they were speculating at that point that maybe something has to change in that balance that's not correct, but I'm not aware at this point -- and this is several months since this -- that there would be any significant change along those lines.

Q Are you aware of any quality assurance deficiencies which impacted on the recovery from the accident as opposed to causing the accident?

A Gee, I don't know of any. You said deficiencies

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that impacted on the recovery?

Q Yes. Previously you had stated that you had not determined -- you had determined that there were no QA deficiencies which caused the accident. I'm just following up on that to determine if there were QA deficiencies which may have either contributed or hindered recovery efforts.

A Well, we did have a man up at Three Mile Island. John Gilray was up there to work on the alternate cooling system which was, I guess, eventually installed. So he covered the QA aspect of it. So he was reviewing what Westinghouse and others were doing with regard to the activity. And we were satisfied with what they were doing.

MR. LANNING: Okay. Shall we take a short recess?

MR. PARLER: If you don't ming.

(Brief recess.)

MR. LANNING: I'll mark as Exhibit 1092 a letter from Dave Moeller to Marcus A. Rowden, who's the Chairman of the U.S. NRD. The subject is "Report on Nuclear Reactor Inspection Data", dated May 19,1976.

(Exhibit 1092 was marked for identification.)

BY MR. LANNING:

Q Mr. Haass, have you seen that letter previously?

MR. PARLER: Let him examine it.

THE WITNESS: This is an ACRS letter?

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MR. LANNING: Yes.

THE WITNESS: I don't recall seeing this. No.

BY MR. LANNING:

Q On page three of that letter, it recommends increased efforts to develop better criteria and codes for standards for electrical systems and other safety-related components.

In addition to this QA Task Force, are you aware of any other staff action which has been initiated in response to ACRS concerns?

MR. PARLER: You mean in the area that you're talking about?

MR. LANNING: In the area of QA, yes.

MR. PARLER: Not in the area of ACRS generally?

THE WITNESS: No, I'm not.

BY MR. LANNING:

Q Are you knowledgeable of any issues raised by the ACRS concerning quality assurance requirements?

A No.

Q The next paragraph there on page three discusses the concept of a third party inspection program. Criterion 10 of Appendix B has a similar requirement for an inspection of processes by an independent person.

Would you review that discussion and see if it is the same as contained in Criterion 10?

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A And then compare this with 10?

MR. PARLER: Sure. Just take your time.

THE WITNESS: Well, if I understand your question correctly, you're asking -- does this third paragraph in this letter reflect the requirements of Criterion 10? Is that basically the question?

MR. LANNING: Yes.

BY MR. LANNING:

Q Is that a new concern that is being raised by the ACRS? Or in your opinion does Criterion 10 adequately reflect this third party inspection requirement, quality assurance programs.

MR. PARLER: Why don't you just look at it whilst he is out?

THE WITNESS: Let me go off the record here for a minute.

MR. PARLER: Off the record.

(Discussion off the record.)

MR. PARLER: Back on the record now.

THE WITNESS: The difference I see between the Criterion 10 and this third paragraph in Exhibit 1092 are that the Criterion 10 describes the principles that should be applied to the performance of inspection activities and for the personnel selected to perform those activities, whereas this third paragraph is -- I don't believe quarrels

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with that at all, with the Criterion 10, but seems to add another aspect, and that is that the results of inspections ought to be analyzed with regard to their frequency of occurrence of unacceptable results, repetition of substandard results, in order to assess that the QA program is operating properly or is defined properly.

BY MR. LANNING:

Q As part of the review of an applicant's QA program for conformance to Criterion 10, how is the review performed to ascertain that inspections for such activities as surveillance testing, returning from a locked out status of equipment, in service inspection or plant modifications, performed?

A The question is how are the inspections performed?

Q In your review of applicants' QA programs, do you require a commitment from the applicant to identify the activities the inspections are applied to, or do you just get a commitment in general terms to Criterion 10?

A Our standard review plan identifies several acceptance criteria that we utilize in judging the acceptability of the applicants' commitments with regard to meeting the requirements of Criterion 10.

As examples, we require that the applicant describe the scope of the inspection program and that he has established an effective program, that the procedures provide criteria

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for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are required or defined how and when inspections are performed.

We look for the organizational responsibilities for inspections, and here we get specifically into some of the items in Criterian 10 -- the fact that the individuals that perform the inspections, other than those who perform or directly supervise the activity being inspected -- we look for commitment regarding the qualification program for inspectors, such as NDT personnel, and that the qualifications and certifications are kept current.

We look for inspection procedures, instructions, or checklists to be sure they are provided and include items such as identification of characteristics and activities to be inspected, the description of the method of inspection, the identification of the individuals or groups responsible for performing the inspection, the criteria for acceptance or rejection, the required procedures, drawings, and specifications that should be utilized in the inspection, recording of inspector data and results of the inspection operation and equipment that is required including accuracy requirements.

We look for procedures to establish and describe that, identify the documents, the mandatory inspection hold point, and the fact that finally the inspection results are

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evaluated and their acceptability determined by responsible individuals or groups.

Q How does the reviewing of QAB determine which activities criteria can apply? Is there a list provided by the applicant, identifying the activities with which this third party inspection will be performed for?

For example, specifically, is there a requirement for inspection of surveillance testing?

A I believe that there is a requirement for -- yes, there would be a requirement for inspecting and auditing inspection requirements, but it may not be done specifically by QA personnel. It may be done by other personnel within the organization of the person who is actually doing the surveillance -- but not by the person who did the surveillance, somebody else in accordance with Criterion 10.

Q You're talking about the applicant's personnel now?

A Yes, yes.

Q I'm still having a problem understanding how the NRC reviewer ascertains what activities these inspection criteria apply to.

A We look for a commitment that the applicant will apply the -- all the commitments to all the activities identified in the introduction to Appendix B, but the application of criteria to a specific activity on a specific

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component would be left up to the discretion of the applicant or the licensee.

Q So in other words there is really no effort to identify the specific activities with which inspection criteria apply? Is that true?

A We do not go through the specific QA requirements for a specific component, let's say, with regard to all the activities that may be conducted on that component. The QA program description is intended to convey the concepts to the applicant that the criteria, that the application of all the criteria and all the commitments that it makes in the SAR are considered and appropriately applied to each of the activities that would be performed on each of the systems, structures, and components that are identified in the Q List.

And finally the determination of what the applicant actually does is his discretion and, of course, subject to inspection by I&E.

Q Since assuming the position of Branch Chief, do you recollect any comparison being made to the Standard Review Plan quality assurance programs for existing plans or plants that have already been licensed or for plants which have not been licensed but are submitting an amendment to the SAR, prior to receiving the operating license?

MR. PARLER: Do you understand the question?

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THE WITNESS: I'm not sure I understand if.

BY MR. LANNING:

Q Has there ever, during your position as Branch Chief, been an attempt to compare the requirements set forth in the Standard Review Plan --

A Which one now are you talking about? The original or the revision?

Q Either.

A Either one, okay.

Q Comparing those requirements to previous requirements.

A Well, go ahead.

Q For any plant.

A For an operating plant?

Q Any plant.

A No, no. We have the -- let me elaborate on that a little bit. The QA requirements, I can say with almost 100 percent assurance, have never been backfitted. I think you are referring to backfitting. With the exception of the original promulgation of Appendix B, when that came out, my understanding is that we did go back to the plant and assure ourselves that the proper QA programs were being developed and implemented in accordance with Appendix B.

But over the years new regulations have been issued, new standards have come out. We have come out with a Standard

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Review Plan. We have modified it each time additional QA requirements have been developed and included, and we have never gone back to older plants — and by that I mean plants that are either operational or for which reviews have been completed — to implement anything new, because, in our judgment, those new things were not determined to be of such significance as to require backfitting.

MR. PARLER: Well, I thought the question went to whether there was a comparison made in the quality assurance area between the requirements of the Standard Review Plan and, say, some other requirements that had been imposed. First of all -- is that right?

THE WITNESS: Previously, right.

MR. PARLER: Now in the absence of such a comparison being made, what is the basis for one's conclusion that the differences in the quality assurance requirements are not of such significance as to require backfit? Is it something that people just know without actually making a comparison, or what?

THE WITNESS: Yes, I guess you can say it's an educated determination in the view of the experts that are involved in these review that the significance of the new requirement is not that great as to warrant making this comparison.

I think people already understand that there are

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differences, but I'm not going to go back to a specific plant to say, "Hey, this plant does not meet this requirement and doesn't meet this requirement." But people know that the vintage plants did not generally meet the category requirements, but it might add that.

Often these -- like topical reports and amendments come in that we -- and I&E is active in this area where new requirements are pointed out to applicants, and they very often are willing to update to the new requirements.

Now there is no requirement to do that. So there has been some updating, but I can't say it is consistent.

MR. PARLER: What do you mean the regional inspector will bring some new provisions or new development to the attention of a licensee, and at that level or under those circumstances the licensee may agree to go along with it?

THE WITNESS: Yes, yes.

MR. PARLER: Why?

THE WITNESS: You recognize that we do have the Regulatory Requirements Review Committee, and all new requirements come -- new regulations or revision to the existing ones pass through that Committee. And the determinations result from those determinations that decide whether a new requirement is of sufficient importance as to warrant backfitting or not.

MR. PARLER: Excuse me. Generally, I think records have been made elsewhere as to what the Regulatory Requirements Review Commi'tee does. But without getting into that general background, since you have mentioned that Committee, are there any items that relate, let's say specifically or predominantly, to a new quality assurance program that have come before that Committee that you're aware of?

THE WITNESS: Yes. Before we issued Revision 1 to the Standard Review Plan, which included several changes resulting over what, three, four years of the use of the original SRP, provision was sent to the Regulatory Review Committee, but the recommendation was that they did not see significant changes that would require backfitting. And as a result of the discussion, they agreed that that was correct, and that's the way that we have been implementing Revision 1. We have not gone back to backfitting.

BY MR. PARLER:

Q. Revision 1 covers things other than the quality assurance?

A. Yes. I am only talking about 17-1 and chapter 17-2.

Q. And in chapter 17 of the Revision 1 that you are talking about, that the staff's recommendation was, backfitting wasn't required, and I gather that the Review Committee went along with the staff's position?

A. Yes.

Q. Now, are there any other examples that you know about in the quality assurance area where some issuer has been brought before the Regulatory Requirements Review Committee?

A. Yes, I believe all new reg guides and revisions to existing reg guides that endorse ANSI standards have gone through the Regulatory Requirements Review Committee, and none of those have required backfitting.

Q. And Regulatory Requirements Review Committee's decision in that regard, that is, not to require backfitting, was in accord with the staff's recommendations to that Committee?

A. Yes, yes, that is my understanding, without going back to specific cases. But I don't know of any QA new requirement that was of significance that it required backfitting.

BY MR. LANNING:

Q. Has the draft guide which provides guidance for implementing Appendix B been reviewed by -- the draft guide -- I'm sorry. It's my understanding that there has been a draft guide on the applicability and implementing --

A. No, it has not.

MR. PARLER: The draft guide that you are talking about has been marked for identification as Exhibit 1089, isn't that right?

MR. LANNING: That's right.

THE WITNESS: No, this is the memo that refers to the draft guide.

MR. PARLER: But the draft guide is referred to in that memo that has been marked for identification 1089?

BY MR. LANNING:

Q. How long has the effort on this guide that you are aware of --

A. I think it goes back, I guess, I would guess two or three years, maybe longer, four years. I'm not sure.

Q. Are you familiar with the major obstacles of getting this guide out for comment?

A. I guess vaguely. There was a task group established to develop a guide, and I'm not familiar with all the aspects of it. One area they bogged down in, I think, was in developing a listing of items, systems, structures and components. I really can't add any more to it.

Q. This is a list of components which should be included on the Q list?

A. Yes, yes, yes. And you see, the complication arises because you have several different reactor vendors and architect-engineering firms, so all plants differ somewhat, and they come up with -- and to come up with a generic list is difficult.

Q. Are you aware of any other efforts to develop a generic list of equipment which should appear on the Q list?

A. Well, there was a reg guide at one point, XYZ, that was being worked on. Also, I think that was involved in here also, but I can't really give you the details of how it was worked.

Q. Are you aware of any efforts of staff members within the QAB to upgrade the quality assurance program at Three Mile Island Unit 2?

A. Not since I was at the branch.

Q. What is the relationship between the technical qualifications of the applicant and the QA programmatic requirements?

A. Well, technical qualification of the applicant covers many areas. I think we made a listing of about seven, as I recall, seven areas. And the quality assurance program is one of those.

MR. PARLER: Why don't you consult your documents? Take your time.

(Discussion off the record.)

MR. PARLER: Back on the record.

BY MR. LANNING:

Q. I'll mark as Exhibit 1093 a memorandum from Walter Haass to Roger Boyd, assignment: to assignment and documentation of review responsibility for technical qualifications, dated December 15, 1978.

(Exhibit No. 1093 identified.)

BY MR. LANNING:

Q. As I understood your response, the QA program is included as part of determining the technical qualifications of the applicant; is that a correct understanding?

A. Yes. Attached to the memo is a table that gives a listing of 11 areas of review that comprise the determination of technical qualifications. And on that list, Item 6 is identified as the scope and content of the applicant's quality assurance program, and it's the responsibility of QAB to do that review. And we basically use Section 17-1 and 17-2 of the Standard Review Plan to conduct that review.

Q. In other words, if he has an acceptable QA program, that is one acceptance criteria for determining that he's technically qualified --

A. Yes.

Q. -- to operate the nuclear power plant?

A. Design, construct and operate.

Q. What are the other criteria for determining the technical qualifications of an applicant?

A. Well, as I mentioned before, we have identified 11 on this table. The first one talks with the completeness, adequacy and basis of the technical design and related information described in the SAR.

Q. And how does your branch make that determination?

A. We're not responsible for that. That is done by

the licensing project manager of DPM.

Q. Okay.

BY MR. PARLER:

Q. What is the licensing manager of DPM, do you know?

A. He, during the course of the review of a CP or an OL, he would, the licensing manager would have to make a determination regarding the completeness and adequacy and basic design of it and the information described in the SAR. It's conducted over the whole period of time, which normally takes about two years for each of those.

BY MR. LANNING:

Q. What other responsibility does the project manager have with respect to determining the technical qualifications?

A. The other items that he has to look at are -- we have identified an area which is called an applicant's competency in technical discussions with the staff. Again, this is an implicit finding by the LPM which is based on his daily interface with the applicants at the meetings, on telephone conversations, his submittals to him.

Again, he has to make an evaluation and include that in his final determination.

Another item is the applicant's responsiveness and resources in the resolution of technical issues that come up during the licensing review process, and that is conducted in a similar fashion.

So it is those four areas that we identify in this table as being the responsibility of the licensing project manager.

Now, in addition, there are other items that QAB does and some that I&E does, and also there's the potential for input from DOR. All of these are fed into the project manager and it's his responsibility to make an overall assessment in the safety evaluation report of the applicant's technical qualifications.

Q. The exhibit recommends that the areas for which the licensing project manager is responsible be documented either in the project manager's handbook or in the Standard Review Plan, which implies that these responsibilities of the project manager have not really clearly been defined and accepted by the project management. Is that a true statement?

A. I would say that they have not been, at this moment in time they have not been specifically defined other than what this memo says.

Q. In other words, you have attempted to --

A. But I have no knowledge that they have not accepted. I think they do accept these requirements, but they have not been implemented in a formal document.

Q. In other words, do you know if there exists acceptance criteria for which the project manager uses to make his determination?

A. I'm not aware of any particular documented acceptance

criteria.

Q. Well, prior to this memorandum dated December 15, '78, how was the technical qualification of an applicant determined?

MR. PARLER: By the NRC doing this review of the application.

THE WITNESS: Well, I can -- I guess I can respond to the QAB responsibility and say that basically we used our -- we use our Section 13-1, which consists of two parts, 13-1-1 and 13-1-2, and Section 17-1 and 17-2. And those are identified as Items 2 through 6 of this table attached to the memo.

I really don't think I'm qualified to talk about how other people have done their portions of it.

BY MR. LANNING:

Q. Well, doesn't your SER input for chapter 13 essentially approve the technical qualifications of the applicant in general?

A. It addresses the aspects that we review as identified in SRP Sections 13-1-1 and 13-1-2. And the QA program, excuse me. I think maybe what you are referring to is the fact that this was not particularly well organized previously, and that perhaps these other items that we're identifying here are not really included in that technical qualification.

I really don't have specific knowledge, but I suspect that the QAB input on technical qualifications basically served as the input into the safety evaluation report. And other items

were not included. but when we finally went into -- we looked at it in a more organized way, we identified other areas, and now are saying that these other areas should be factored into an overall assessment of the technical qualifications.

BY MR. PARLER:

Q. Well, in any event, even -- either before December the 15th, 1978, which is the date of your memorandum which has been marked for identification as Exhibit 1093, or after that date, in the area of technical qualifications it's my understanding from what you have said that the Quality Assurance Branch only provides input on technical qualifications and does not itself reach a decision one way or the other regarding the adequacy of the technical qualifications of an applicant.

A. Yes.

Q. Is that what you have said?

A. Yes.

Q. Now --

A. In other words, QAB by itself cannot draw that final conclusion.

Q. But I realize that in areas that are not your responsibility you may not be familiar with and you may not care to speak to. But is it your understanding now that, with the input that you have talked about from QAB and perhaps input from others, such as inspectors or maybe other people

in NRC, that it is the project manager that is supposed to make the determination about the adequacy of an applicant's technical qualifications? Is that your understanding?

A. Yes, yes. The project manager should -- I think that is described in this summary paragraph in the memo. It says, "QAB will provide its conclusions to the LPM regarding the technical qualifications of the applicant for the areas so identified in the attached table. Utilizing the QAB conclusions as well as I&E and DOR inputs, the LPM can develop its findings, including the basis for presentation in the SER."

BY MR. LANNING:

Q. How is the applicant's experience considered in determining its technical qualifications?

A. Okay. That is described in SRP Section 13.1.1, entitled "Management and Technical Support Organization." Specifically, in subsection 1(a) it talks about staff review of the applicant's past experience in the design and construction of nuclear power plants and past experience and activities of a similar scope and complexity.

And for cases where the applicant may not have been involved in a nuclear power plant, we look at the applicant's management, engineering and technical support organization, the charts, that the organizational charts that reflect his headquarters and engineering structure, the modification that would result because the nuclear power plant have been added. Well, it's

these kinds of things that are described in this section that we look at.

BY MR. PARLER:

Q. Before you move on into other areas, I want to ask another question or so about this Exhibit 1093. That exhibit may be self-explanatory as to why your memorandum was written, which provides further guidance on the various items which should be considered in the area of technical qualifications.

Is, or are the reasons for that memorandum set forth in the memorandum? For example, the issue of technical qualifications being raised in hearings and things along that line?

A. Yes.

Q. Now, others have represented to us that I believe about this time, because of the issue of technical qualifications being raised in hearings, such as the Pilgrim hearing, if my recollection is correct, that the work was initiated to try to provide better guidance in the area.

Now, would my understanding be correct if you assume that this Exhibit 1093, your memorandum to Mr. Boyd, is the product if a suggestion that either you or someone else made for additional guidance in this area?

A. Well, as I recall the history here, there were some hearings where this issue came up. Pilgrim, I believe, was one of them. And Shearon Harris came up subsequent to that. And prior to my coming on the QAB scene, there was an

effort to try to organize and structure this in a better way. And as far as I was concerned, it was bogged down because we were attempting to convince people that they ought to do certain things. And in my discussions with my boss, Mr. Scovholt, I convinced him that I would like to take the monkey off my back by simply writing this memo to people who are affected and tell them where their responsibilities are and what QAB was going to do.

Everybody agreed on that anyhow, and this was the mechanism that did it. In other words, now the ball is in LPM's lap and I&E. We have done our part.

If you look at this table, the parts that we are responsible for are described in appropriate documents, SRP sections, and we are doing them. We are implementing them. So we are doing our part.

You will notice in other areas there is no reference document. Something is required. And it is not our QAB responsibility to do that.

Q. What has happened in these other areas, as far as you are aware? That is, these other areas that are not QAB's responsibility.

A. Okay. We followed up with a meeting with I&E people subsequent to issuance of this memo. I believe it was early in 1979, where we were asking I&E to develop a specific procedure that would address how they would gather information

from the numerous inspectors that are involved in the design and construction of a power plant or the operation of a plant. They rotate their people so that an inspector may be on the job no more than two years. That's my understanding. So that during the course of the design and construction, and because you have several disciplines, you could have as many as 30 or 40 inspectors involved in the design and construction of a plant.

Now, one of the items we looked for in this table is feedback from implementation of the applicant's quality assurance program as determined by I&E. So they would have to, I&E people would have to talk to their various inspectors and get their views as to how the applicant was conducting his QA program.

So a procedure was needed to gather these views and assimilate them into a single view that could be used in assessing the overall technical qualifications of the applicant. So we had that kind of a meeting. We had several discussions with DPM personnel who would be -- where the LPMs reside, because QAB is in there, also. But to inform them as to what we thought their areas were. And I have had requests from several LPMs, and they indicate they were going to use this procedure or these requirements to write their overall technical qualifications. But that's the extent of it.

Q How about the I&E meeting? Which part of the I&E

organization was that with, or which individual, if you recall?

A. That involved Frank Nolan of the operations end, and I believe Mark Perinich was there from the design and construction end.

Now, in the meantime, of course, the Three Mile Island accident intervened. So I'm not sure what has happened in that regard.

Q. Your memoranda which has been marked as Exhibit 1093 was issued in early December of 1978. You had the meetings that you referred to early in 1979. The Three Mile Island accident happened on March the 28th, 1979. And as far as you are aware, there hasn't been much else, if anything, done on your memorandum other than these meetings that you refer to?

A. Yes. And other than statements by LPM where they intended to address all these issues in their determination of technical qualifications --

BY MR. LANNING:

Q. Has the applicant's capability to respond to an emergency situation been part of the requirements for determining the technical qualifications?

A. Up 'til now, no.

BY MR. PARLER:

Q. When you say up to now, do you mean now or March 28, 1979?

A. No, up to the present time. You are aware that we

are embarking on a program to evaluate their capability to respond?

Q. Right, right.

BY MR. LANNING:

Q. Part 5034 --

A. Let me qualify that prior comment. They may be part of the emergency plans that get involved in an applicant's response to accidents. But your question was in terms of technical qualification?

Q. Yes.

A. Yes, that answers it, then.

Q. 10 CFR 5034 requires that SARs include the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

What specific activities are requested? Would you just clarify what is meant by that language in 5034?

A. Could you locate it for me?

Q. 5034(b)(7) or -- just a second. One is (a)(7), paragraph (a)(7).

A. (a)(7) is the QAB program.

MR. PARLER: That is WA program.

THE WITNESS: Now, wait a minute. What page are you on?

MR. PARLER: Let's go off the record.

(Discussion off the record.)

THE WITNESS: The activities would be those described in the safety analysis report, namely, in the case of 54, 5034(a)(9), would involve the activities, all the activities in design and construction of the plant; and in the case of 5034(b)(7), would be involved in the activities involved in the operation of the plant.

BY MR. LANNING:

Q. That implies to me that the NRC makes a determination about concerning the technical qualifications of all activities related to the design, construction, operation of power plants?

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A. Yes.

Q. I personally don't see how that's accomplished. There must be some activities which are more important than others, which would review the technical qualifications of the person involved. And I was just trying to get to some examples of the activities which the QA -- the Quality Assurance Branch reviews in determining the technical qualifications of the applicant.

A. I think we are talking here basically about a difference in level of detail. We are not going back to each of the specific activities, say a design function or a procurement function or a construction function or -- when we look at the technical qualifications, we are looking at the applicant's overall experience in the design and construction of nuclear power plants: What part did he play in it, how well did the

job come out --

Q. Suppose he had no power?

A. That's basically --

Q. Suppose he had no prior experience, no nuclear power plant experience?

A. That's what I addressed before. We look at his past experience in activities of similar scope and complexity, and this demonstrates to us he has the capability, the qualifications to handle complex design, construction and operation activities.

Q. Is it correct that there does not exist a list of activities which are considered by the NRC staff in determining the technical qualifications of the applicant?

A. Yes, I would say there is no specific listing I can point to, other than to say the activities that are basically described in the report, which cover many, many areas.

Q. That could include anything from meteorology to water samples to --

A. Yes.

Q. -- to --

A. All the things necessary to design, construct and operate the plant, yes. Many things.

BY MR. PARLER:

Q. I think a question that could be asked as a follow-up

question here is similar to the exchange which occurred earlier, I suppose, in the quality assurance area, in which there was a comparison of what was meant by "safety-related" in the Appendix B to Part 50 and "of importance to safety" in the Appendix A.

And during that discussion you pointed out that in the safety area there were some things that could be viewed as more important than others. And I think that the same sort of question could be asked here. The language that Mr. Lanning has referred to, which appears in Section 5034 A, could be interpreted very broadly, and probably is, as meaning everything that is involved in the design, construction and operation of a nuclear power plant.

But in our review or in the NRC's review, are there some things in this overall process that are more important than others, which the staff singles out and takes a real hard look at in assessing the technical qualifications of an applicant?

I believe in the final analysis, that is where the question is directed and is headed.

A. Well, I guess I can refer to our table in this Exhibit 109 that identifies specific areas. We point out the quality assurance program as being a significant area. We point out the organizational structure of the applicant as being a significant area. We identify the technical staff,

the breadth and level of experience and available manpower as being a significant area. His past experience in the design and construction of projects of similar scope, including nuclear power plants.

Q. Does that past experience mean also past performance, prior performance? For example, if the prior performance of a utility in the nuclear area was not so good?

A. Yes.

Q. Would that make a difference?

A. Yes, I think it would.

Q. In the evaluation which QAB conducts?

A. I think that comes more into play for I&E.

Q. And their input to the project manager?

A. Yes. But also, I think it would be hard for us to avoid any knowledge of prior experience -- let's say, on a past nuclear power plant that a utility has designed and constructed, and as we now know, there is deficiencies or were, I think we would be in a position to raise questions regarding how those deficiencies were corrected and can we expect them in the future, and that sort of thing.

Q. I would assume that would be the case. I suppose what I was trying to get to was whether in fact in such cases that was done, as far as you are aware. I realize we could do it and perhaps it should be done, but is it done?

A. Well, I guess my experience in the branch is not

that long to be able to answer that, other than to say it's in our Standard Review Plan, so the guidance to the reviewer is that he should consider that.

Q. The Standard Review Plan provides that what past performance should be taken into account?

A. Yes, applicant's past experience in the design and construction of nuclear power plants.

Q. Would you happen to know whether the Standard Review Plan also provides for the past performance of vendors and architect-engineers? For example, I can recall in the architect-engineer area, there have been some performances which, at least on the surface, would appear to be not as good as other performances.

Off the record.

(Discussion off the record.)

THE WITNESS: Yes, it includes the management and technical organizations of not only the applicant, but also major contractors, including the reactor vendor and architect-engineer.

BY MR. PARLER:

Q. And their past performance, is that right?

A. I don't see a specific item here that says past performance.

Just a moment.

Q. It's not clear to me what the policy is regarding

the consideration of past performance. It's my understanding that you have said that the Standard Review Plan does say to take that into account.

Off the record.

(Discussion off the record.)

MR. PAPLER: Back on the record.

THE WITNESS: Now, in the last paragraph of subsection 1(a) of Section 13.1.1 of the Standard Review Plan, the CP review stage of the NSSS and AE organizations and applicant's for a manufacturing license and the review of standardized design, includes a review of their technical staff to perform the activities related to the application.

"The information submitted should include a description of the specific activity, including scope, to be engaged in, organizational description and charts reflecting their lines of authority and responsibility for the project, the number of persons assigned to the project, and qualification requirements for principal management positions related to the project. For those NSSS and AE organizations with extensive experience, a detailed description of this experience may be provided in lieu of the details of their organization as evidence of technical capability."

BY MR. LANNING:

Q. Are there acceptance criteria for determining the acceptability of these personnel?

A. Yes, but they are rather subjective. We look for substantive breadth and level of experience, available of manpower. That's basically it. There is really not too many acceptance criteria.

Q. There is no minimal qualifications, for example?

A. No, no.

BY MR. PARLER:

Q. Have you ever received anything from Inspection & Enforcement which comments on the past performance, say, of a vendor or an architect-engineer and recommends that that past performance be taken into consideration in any future reviews of applications involving such parties?

A. No, I don't recall any. The subject came up in the context of the Shearon Harris hearing, where I believe there was a construction company that was involved and they had some -- I guess questionable performance on another project for a different utility.

And as I recall, the determination at that point was that we didn't feel it was appropriate to consider what happened on another project, because the situation was different. There are different people. They might be doing different work. You would have to look in the contract to see what they were involved in.

We were concerned only with their commitment and how they were performing on the project we were now looking at.

Q. Well, that means to me, then, that past performance of a contractor, and perhaps even of a utility, would not be too much of a factor?

A. Yes, yes.

Q. Certainly it would seem that the language that you quoted from the Standard Review Plan would leave it to the utility and the vendor and the architect-engineer in the first instance to provide themselves the information on their past performance, and I would assume, generally speaking, that that input would usually reflect a good performance, and the input on the below average performance, whatever that means, would be from our inspectors, an Inspection & Enforcement person, and it might be input from other projects that may involve -- however, the same utility, or may involve a different utility, but the same architect-engineer or the same vendor or the same constructor.

A. Well, I think our Standard Review Plan is fairly clear. It does say that we should consider that experience, and I guess what I'm saying when I talk about the Shearon Harris hearing is that there seems to be a question as to what was appropriate to consider. I really -- I guess my experience in this area, since being with the QA Branch, is that I can't really cite specific instances where we have gone back to look at those areas. And I have to say, of course, there has been no -- I guess there have been no new CPs that we have

worked on.

The issue never came up since I have been here.

Q. And in any event, along with that, the only policy guidance that you are aware of on the question is the Standard Review Plan that you referred to earlier and quoted from, is that right?

A. Yes, yes.

BY MR. LANNING:

Q. You indicated earlier that your branch had the review responsibility for the preoperational and start-up start programs?

A. Yes, yes.

Q. Are these plans reviewed in detail to determine the adequacy of the programs or is it more an audit review to confirm that certain tests be conducted?

A. Well, the applicant provides descriptions. He identifies tests that will be performed during preoperational and start-up, and he describes the tests that will be done, including the acceptance criteria. And we review those. We don't review the specific procedures that will be subsequently written to conduct the tests.

So again, it's analogous to our review of the quality assurance program, where we review a description of the program and we don't look at the details of the procedures.

BY MR. PARLER:

Q. Yes, but unlike the QA program, where you do have the principles or the criteria in the Appendix B, are there such criteria to evaluate the adequacy of the operational test program?

A. Basically, we use the information that's being provided by the applicant in the SAR. For example, we rely heavily on chapter 15, which talks about accidents and other malfunctions, that kind of thing, to help us and assess the adequacy of acceptance criteria. The applicant's conduct in the tests, is he subjecting the temperature to the proper range or limits of the exposure that should be -- in terms of flow and temperature and that kind of thing.

So we can assure ourselves that the system will indeed perform as the applicant claims it will in order to handle certain events that he describes in chapter 15.

So no, you won't find any specific criteria in the regulations other than that the applicant musthave test programs and that our review assures that the testing is appropriate to the expected performance of that system.

Q. Would such guidance be found in the Standard Review Plan?

A. Yes, the Standard Review Plan would certainly --

Q. So you did intend specifically to refer just to regulations?

A. Yes, other than identify the area of review in the regulations. But there is extensive guidance in Sections 14.1 and 14.2.

Q. Of the Standard Review Plan?

A. Of the Standard Review Plan. And they in turn refer to Reg Guide 1.68, which goes extensively into the identification of areas of testing that have to be accomplished during the various phases, preoperational through start-up.

BY MR. LANNING:

Q. In your current position, has there been a review of the preoperational testing programs and start-up for an applicant?

A. Yes.

Q. There are several pages of preoperational startup tests identified in Three Mile Island Unit 2 license as outstanding issues which require completion by certain phases of the start-up program.

My question is, do you have a feel for the number of preoperational and start-up test programs that are normally identified in the license when it is issued and which are not completed prior to issuance of the license?

A. I guess -- I don't have any direct experience in that area, but my understanding is that there are sometimes a few of the programs, a few items that remain that have to be done by certain -- before they reach certain power levels . But

I couldn't go beyond that.

Q. Just for discussion purposes, I'm going to use as a reference the licenses for Three Mile Island Unit 2, License No. DPR-37, in Appendix 2, the operating license, to examine the number of test procedures that are identified there. And in comparison with the applications that you have reviewed, how does this list compare to other licenses with which you are familiar? Is it a normal list? Is it an excessively large number of test procedures which needed to be completed after the issuance of the license?

A. See, this is a list that is made up at the time the OL is issued. And we have not -- since I have been in the QAB, there has not been an OL issued that I would have been involved in. And so I really can't answer the question. I don't know.

Q. I guess I misunderstood you previously.

A. We have been involved in reviews, but there is a bunch of the license reviews that are so-called near-term, ready for issuance, and had the Three Mile Island not come along, they would have been issued, in which case these lists would have been made up. But they have not been issued at this point and so I have not gone through that exercise.

So I really can't answer that, because we have a lot of OL reviews, but this is at the end. They are ready to issue the OL, and before you proceed to operational mode 4, you have

to do the following.

Q Who develops the list? Not which individual, but which organization at NRC develops the list of preoperational tests, start-up tests, and other items which must be completed? Is it your branch or is it -- or is it an area handled as technical specifications by some special group someplace else?

A Well, QAB would identify all the testing that had to be done, wherever it would be in the SAR, and we would review it to the point where we can agree with it.

All right. Now, the applicant proceeds and performs those tests. Now, when you get to the end, you are ready to issue the OL. It would be I&E's function to notify us, and I presume we would be involved in it, because we would have to assume somehow when they would be done. I&E would have those tests that haven't been completed. That is their function. But I think we would be involved in deciding when they should be done before you can go to a point in the start-up, before they should begin.

Q I am kind of confused. Maybe I'm mixing up different things in my mind.

I understood earlier there was the comment in areas such as the Q list that the adequacy of that list is not a determination that is made by QAB, but they have to rely very heavily on the input of the technical reviewers.

A. Yes.

Q. Now, if that is the case there, why does not QAB have to rely on input from some other place for the tests that are required for realistic time periods to conduct these tests, et cetera?

A. I understand your problem. Like when we first started, identified how many people we had in the different areas, we have three different areas in QAB. We have two people that are involved in the review of the preoperational startup test programs and these people are knowledgeable in systems, structures and components that make up the nuclear power plant, and therefore are in a position to assess the adequacy of the test program. They have to be knowledgeable in that area.

The -- we had five people involved in the quality assurance reviews, and those people are basically quality assurance experts. They know about QA, but they're not experts in the functions of systems, structures and components.

Q. Now, if we had enough people in the initial test program area, I suppose we could rely on those to help us determine the adequacy of the Q list. But we don't have that luxury, and they help us out when they can, but they are up to their ears in their reviews.

So now -- we have taken the approach for the Q list review to go to other branches that are also reviewing their systems. So I can understand where you are coming from, and that's the

answer to it.

MR. PARLER: Right, right.

I have a number of questions on the start-up program. Do you want me to them?

MR. LANNING: Go ahead and take them up now.

BY MR. PARLER:

Q. I gather from what you have said that the -- in essence, does the preoperational testing program, the start-up testing program, are proposed by the applicants, is that right?

A. Yes.

Q. What benchmarks, if any, are there which would suggest to the reviewer, to the NRC reviewer, whether these tests and start-up programs are realistic, whether they are within the ballpark.

When somebody evaluates something, I would assume they would have something to evaluate that something against.

A. If I understand you right, you're concerned with -- let's take -- consider a specific test, say the containment test.

Q. Yes.

A. Your question, as I understand it, is what guidance or what guides the reviewer, in determining whether the applicant's description of that test is really sufficient with regard to the intended capability of that containment system;

is that true?

Q That is a part of what I'm getting at, but also whether the time that is allowed for the tests, the evaluation of the test results, are adequate. It may well be that about the time that these tests are being conducted, that the utility is nearing the end of an 8 to 12-year process and may be very interested in having the project, which has been constructed, be placed in operation.

And so I'm interested not only in the aspects that you mention, but the other aspects also, such as regarding the adequacy of the tests, but the timing -- but the time that is set aside for the tests, how the test results are evaluated, and that sort of thing is what I'm getting at. Is that clear to you?

A Yes, yes.

Q All right.

MR. PARLER: Off the record.

(Discussion off the record.)

THE WITNESS: With regard to the test requirements, our reviewers, as part of their review process, must consider all the related information that's provided in the SAR. They look at the system description, its normal functioning as described in the individual chapter, and they go to the chapter 15. It talks about what unusual conditions it would have to be subjected to. And they make an evaluation of the

applicant's test program for that system, to make sure it demonstrates that the system will indeed perform as it's supposed to perform under the wide range of conditions.

With regard to the performance of the testing at the site, we look under SRP Section 14.2, and again I'm referring to Subsection 1, areas of review. We have requirements for review of the applicant's organization and staffing to make sure he has got the proper people -- well, of course, he identifies responsibilities and authorization and levels of staffing, the qualifications of principal participants, the participants of the operating and technical staff in the test program.

So we assure ourselves that he has got the right number of people and the right kinds of people involved.

Now, we also have a review area which addresses the test program schedule and sequence. That is, again, that is Item No. 10 in that same subsection.

e-6

MR. PARLER: This is the standard review plan, right?

THE WITNESS: Yes. We review the schedule for conducting each phase of the program relevant to the full date. So we are looking at how much time the applicant provides to accomplish certain things. We look at the anticipated schedule overlaps of the test program with test programs for other reactor facilities at the site to make sure you don't have a lot of things going on at once, you have enough people to handle all these things.

MR. PARLER: Does that go on to provide guidance also for the various levels or mods -- m-o-d-s -- for the power ascension program?

THE WITNESS: Well, my understanding is, in theory, you should accomplish certain tests prior to issuing an OL, and there are some, of course, that need to be later. You need fuel present to do the test. But my understanding is we sometimes issue an OL that is conditioned on performing certain items. In other words, he's ready to load fuel, but there are other things that he hasn't done because of the time, or what have you, so we will allow him to load fuel but not progress any further until he has performed some of these other items.

MR. PARLER: So that is not an unusual occurrence?

THE WITNESS: I think that happens fairly frequently. And, you know, it can be accommodated.

MR. PARLER: Now going on from there to power

power ascension levels, is there any guidance in that standard review plan on that?

Off the record for a second.

(Discussion off the record.)

THE WITNESS: To the best of my recollection, those kinds of issues are addressed by Reg. Guide 168, which goes through the various phases of conducting preoperational and start-up tests.

MR. PARLER: And that reg. guide, as you already said, to the best of your recollection, and you don't have the reg. guide here, is the guide, the document that we have -- the guidance document that we have on the various power tests. Is that right?

THE WITNESS: Yes.

MR. PARLER: And as far as you know, there is nothing else that NRC has, or nothing else that stands out in your mind at the present time?

THE WITNESS: Yes. I would say that is true. That reg. guide is referenced in section 14.2 of the SRP.

MR. PARLER: Now from the document that you're looking at, is the standard review plan. Do you have anything else to add about these tests -- the start-up tests and so forth that we have been talking about?

In other words, have you completed what you were looking at in that standard review plan? If ther is any other relevant

information that you happen to be able to recall right now, it may be useful if you would mention it.

THE WITNESS: No, I believe that is the extent of it.

MR. PARLER: I would like to mark for identification as Exhibit 1094 an article by a Mr. W. H. Spangler -- S-p-a-n-g-l-e-r -- manager, Nuclear Plant Start-up Services, Nuclear Power Generation Division, Lynchburg, Virginia.

The article is entitled start-up services and training activities during 1977.

xxx

(Exhibit No. 1094 was marked for identification.)

MR. PARLER: I cannot tell from this document that I have, whether the article from Mr. Spangler was published, but in any event, the article discusses -- the Babcock & Wilcox Company's start-up services participation during 1977 in the start-up of three plants: the Crystal River-3, Davis-Besse-1, and Three Mile Island-2.

Now, I realize, Mr. Haass, that this is not your article or, as far as I know, you have ever seen it before.

Have you ever seen it before?

THE WITNESS: No, I have not.

MR. PARLER: All right. With that understanding, I would like to use the article as a point of reference for some questions.

At the time this article was written, it's my understanding

from page 29 of the article, under Three Mile Island-2 start-up, that the start-up test of Three Mile Island-2 had not been completed. The article says that the RCS, which is what -- reactor coolant system, hydrostatic test, was completed on June 6, 1977, and fuel loading was scheduled for February 1, 1978.

As a matter of fact, I think the operating license was issued on or about February 8, 1978.

So with that background, I will proceed to the generic conclusions that Mr. Spangler reaches that are covered by page 30 in the lower right-hand column.

Mr. Spangler says that, "Based on experiences in 1977 --" And now he's talking about the experience with the three Babcock & Wilcox plants, the start-up of those plants at his Crystal River -- that is Crystal River-1, 3, and Davis-Besse-1, and Three Mile Island-2. He says that, "Two conclusions generic to the start-up of a nuclear steam system can be drawn."

And for the record I will read those, and after I read them, I will ask you for any comments that you may have on these conclusions.

From the regulatory perspective, it says, The first conclusion is "that the need for additional manpower at the job sites in the start-up period is continuing to grow because of expanding documentation requirements and the more extensive tests and programs now being required. Babcock & Wilcox is continuing to meet utility needs in these areas by making

available increased numbers of personnel with broadened scope of capability."

And then there is a reference to various tables which show the start-up assistance personnel assigned by the Babcock & Wilcox Company for these start-ups of three of the plants that I have already mentioned.

And another conclusion of Mr. Spangler's is that, "utilities continue to become committed to start-up schedules prepared earlier in the project that later prove to be unrealistic because of construction restraints. Loading fuel in the core prior to the time the plant is ready for criticality, severely limits access to complete construction.

"In addition, pressure on start-up personnel to achieve unrealistic schedules often results in serious mistakes being made that ultimately cause additional delays. Two recent examples of this type of mistake are flushing a demineralizer resin bed into the cooling water system, and contamination of the reactor vessel, internals, and transfer canal while shot blasting containment concrete surfaces. There needs to be an industry-wide effort to establish and maintain realism in project scheduling."

Now with regard to the adequacy of people, I believe, if my recollection is correct, you have already commented on that aspect of the situation. Isn't that right?

THE WITNESS: Yes.

MR. PARLER: And the thing that I'm interested in is Mr. Spangler's observation about the pressure on the start-up personnel to achieve unrealistic schedules. And what I am interested in is, from the regulatory standpoint, what is done to try to assure that the schedules are realistic?

I suppose that we have already discussed that to some extent, but, at this point, in view of Mr. Spangler's comments, presumably based on his company's experience with these three plants, do you have any comment from the regulatory perspective? Realizing, I'm not asking you to endose what Mr. Spangler has said, but just let's assume for the moment that his representation here is correct.

In that context, I will ask you for your comment.

THE WITNESS: Well, let me say that I am not overly familiar with this area, but my understanding is that the later stages of design and construction, when they're trying to complete certain construction activities and also perform certain preoperational testing, those stages are rather hectic and there are significant pressures to complete the work and get the plant on line.

Our review is concerned with assuring ourselves that the applicant has established a reasonable schedule, and I guess I have to say that we don't have acceptance criteria with regard to that. We don't have a document in the SRP. Our reviewers look for certain durations, and I don't have that information

at my fingertips.

We also look for numbers of people -- how many people do they plan to assign and what -- what level. So we attempt to get some kind of confidence that the applicant is going to satisfy enough time and enough people to do these tests.

On the other hand, as Mr. Spangler points out, very often these schedules are unrealistic, and because -- he talks of construction restraints. I presume there are delays in construction. So now things are going on simultaneously that weren't planned on initially, and yet they still try to maintain the same end date. So you are trying to squeeze things in when other things are going on. And, like I said before, it is a hectic period.

We, to some extent, rely on our I & E inspectors to be present on some of these -- during some of those periods, and I believe I have seen some inspectors' records of that, again, citing the same kind of difficulties.

MR. PARLER: The quality assurance branch people are routinely not at the site during these, are they?

THE WITNESS: No, they are not.

MR. PARLER: So we rely, as a regulatory organization, completely or certainly almost completely, on our inspectors. Is that right?

THE WITNESS: Yes. Though we are going to modify our program; we are going to send people to the site. We have plans

for that during the next fiscal year, which starts, I believe, October 1.

MR. PARLER: During the phase that we are talking about?

THE WITNESS: Yes, some of our test program people are at the site when tests are going on.

MR. PARLER: I wonder if doing these tests, if, for example, there is an equipment failure such as, oh, safety valves or something such as that, which have to be replaced, and then corrective action is undertaken and I suppose as a part of that corrective action, which may involve a replacement of the valve, the replacement valves may have to be sent someplace to be tested.

I'm just using this as an example. Who, if anyone, in the regulatory organization, would look at the reasonableness of the actions being taken from that standpoint? In other words, the time that is allowed for the replacement and the test for the replacement valve and things such as that?

THE WITNESS: I believe that would be, first of all, I think, depending on the significance, could be a licenses of events report. And, secondly, I & E would be involved, but there would be no direct involvement unless -- by QAB, unless called in by I & E.

MR. PARLER: So if there was a licensee event record, or I & E called in, or there was some eventual transfer of

responsibility from I & E to NRR?

THE WITNESS: Yes, because as far as we are concerned in QAB, we have reviewed the test requirement for that program, and if something goes wrong because the applicant has to fix it and applies the QA program to fix it and then resumes the test, as originally committed. So he has already made the commitments on what to do. It's a matter of going ahead and doing it.

MR. PARLER: All right. Now, off the record.

(Discussion off the record.)

MR. PARLER: Back on the record.

BY MR. LANNING:

Q Has there been any significant changes in the test program requirements in recent years?

MR. PARLER: As far as you are aware.

THE WITNESS: I am aware of a question with Reg. Guide 168.1 and 168.2. I think 168 has gone to a second revision. It's probably the most significant ones; they are, basically, prior to my time,

MR. PARLER: The review of the Three Mile Island-2 application for -- from the standpoint of the adequacy of the initial test program, start-up tests and the like, I gather occurred prior to your assumption of responsibilities for the quality assurance branch in June of 1978. Is that right?

THE WITNESS: Yes.

MR. PARLER: Since the Three Mile Island accident on

March 28th of this year, have you had the occasion to go back over all those -- well, the records that were involved in the review of this application?

In other words, the results of the branch's review of that application?

THE WITNESS: We looked back in the quality assurance area to identify any specific items that we thought might be -- well, just to take a quick look at the program and see whether, how does it stack up. And we found it stacks up pretty well.

MR. PARLER: Right.

THE WITNESS: I myself did not look back at the initial test program area, but I suspect Bob McDermott did, but I don't have any firm knowledge of that.

MR. PARLER: Now, Mr. McDermott addressed a memo to you on May the 22nd, 1979, subject: recommendations for improvements to initial test program review in light of the Three Mile Island-2 incident.

I will mark -- I will mark that memorandum for identification as Exhibit 1095, and you responded to that memo in the form of memorandum for Mr. Donald J. Skovhalt -- that's S-k-o-v-h-a-l-t, on May 24, 1979.

I will mark your response as Exhibit 1069 for identification.

xxx (Exhibits 1095 and 1096 marked for identification.)

MR. PARLER: Now, the question that I want to ask you -- you have a copy of each of those memorandum right?

THE WITNESS: Yes.

MR. PARLER: Is, in general -- what is your understanding of the significant points that Mr. McDermott was recommending to you regarding the initial test programs?

THE WITNESS: To answer that, let me go back a little bit into the history. Bob McDermott was assigned to work on a task force connected with the Three Mile Island accident a few weeks after the accident occurred, and he was heavily involved in analyzing the performance and design requirements of certain systems that were involved in the accident. And, in fact, he looked at -- he and others -- looked at similar -- the same systems at other nuclear power plants.

So, when his work was completed, he wrote down what he viewed to be necessary improvements for the review of the initial test programs, other test programs for other projects. And so these are basically his view of considerations that came out of the Three Mile Island Unit 2 accident.

So my memo now has taken it one step further, and that is, I have analyzed each of the items present and placed them into categories, and it is described in my memorandum. So, basically, these items are recommendations that the QAB branch says should be considered in the review of initial test programs or all projects.

MR. PARLER: Off the record.

(Discussion off the record.)

MR. PARLER: Back on the record.

Your memorandum to Mr. Skovhalt, which was marked as Exhibit 1096, refers to initial test program/conduct of operation group within the QAB. Have you already commented on what that group was engaged in?

THE WITNESS: Yes. That is a -- when Bob McDermott was here, he was the leader of that group. We combined two of the three areas into one group. The third area was QA. We have three areas, but two group leaders.

MR. PARLER: Oh, this just describes an operational function within your branch. Is that right?

THE WITNESS: Yes.

MR. PARLER: Is that what it describes?

THE WITNESS: Yes. This is Bob McDermott's group which has developed.

MR. PARLER: I have that. Now for that exhibit, the 1069, after you wrote the memorandum to Mr. Skovhalt, what happened next on Mr. McDermott's recommendations? Can you tell me?

THE WITNESS: I believe Don Skovhalt factored this into the lessons learned task force, but I'm not certain on that.

MR. PARLER: You haven't seen any document --

THE WITNESS: No, I don t recall seeing any return on it. It certainly is appropriate to lessons learned.

MR. PARLER: Okay.

BY MR. LANNING:

Q. In the past, have there been preoperational tests required for the auxiliary feed water system?

A. Yes.

Q. What parts of the system did that test procedure exercise? What purpose?

A. Well, without going back into the details, and I don't think Reg. Guide 168 would satisfy all the details, but basically, we would require that the applicant test the entire system to demonstrate its performance requirements, redundancy, capability of producing the required flow within the required time, that kine of thing.

Q. Mr. McDermott's memorandum indicates that Reg. Guide 168 does not state specifically what tests should be performed for auxiliary feed water system?

A. Yes. That is what I was just saying, that the Reg. Guide 168, I would guess, simply identifies the auxiliary feed water system as a system that should be tested; but in his prior statement, prior to what you're quoting from, he is identifying other details like the full flow tests, low flow/ high head or shut-off. In other words, he's going into the details as to specifically what should be done, because he is saying, in the auxiliary feed water systems, those valves were closed.

Now, when you turn on a pump, you want to make sure you don't ruin the pump. So you have to shut off the head, make sure it still runs, so when you finally open the valves, you haven't ruined the system.

Q Does Reg. Guide 168 lack specificity regarding the types of tests required for the certain systems?

A Yes. In fact, let me check here again. I might have that here.

MR. PARLER: Off the record for a second while he is checking.

(Discussion off the record.)

THE WITNESS: Well, let's take an example. Here's one on residual or decay heat removal systems. It says, "Verify operability of systems and design features provided or relied on to disipate or channel thermal energy from the reactor to the atmosphere or to the main condenser or other systems following off-normal conditions or anticipated transients, including reactor scram; verify operability of systems and design features provided for makeup of coolant to dissipate residual heat, to cool the reactor down to a cold shutdown condition, and to maintain long-term cooling.

"Tests should be conducted as appropriate to verify redundancy and electrical independence.

"The following list is illustrative of the systems and components that should be tested.

1) turbine by-pass valves; 2) system line atmospheric dump valves; 3) relief valves; 4) safety valves; 5) decay or residual heat removal system; 6) reactor core isolation cooling system; 7) main system isolation valves, branch system isolation valves, and non-return valves; 8) auxiliary feed water systems.

Testing should include demonstrations that the systems will meet design performance requirements at approximately normal operating primary and secondary coolant systems pressures and temperatures and over the range of expected system generator levels.

Operation of --" and they list a bunch of components -- "should be demonstrated."

See? It doesn't get into the detail of saying that you should have a fuel flow test and you should have a low flow/ test. He is saying that is an outcome of Three Mile Island and let's modify whatever lists we have to include that.

end T-7

Item 3, I have included even part of my memo, which says, "Hey, we have to develop a technical position," and then, that is documented either as branch or a modification to a reg. guide. So we are saying there is a potential here for modifying Reg. Guide 1.68 -- to modify that.

BY MR. LANNING:

Q. You previously stated, I believe, that Reg. Guide 168 served as your primary tool for determining acceptability of a preoperational start-up program.

A. Yes. It is one of my primary tools. Yes.

Q. And, just based on the example you chose, in the decay heat removal system, that description of the preoperational test doesn't really include any performance requirements of the system. I guess I'm wondering --

A. Well, you mean specific performance requirements or --

Q. Yes, you are going to do a test of the system; it would seem to me that you want to test it to determine its performance with respect to something.

A. Well, see, that would be covered in the standard review plan. This simply says, this is guidance as to what you should test for.

Q. Okay. I understand.

A. Now, when you get to a specific test criteria, you either have to go back to SAR, which says the system is supposed to produce so much flow --

Q Or a cool-down rate?

A Yes. In other words, specific numbers have to come out of the SAR, and the standard review plan would say, when you review this particular test, you should assure yourself that appropriate criteria tests are met.

So it is a combination of all these things.

MR. PARLER: Do you happen to know the extent to which the experience of the intial test, the start-up test of TMI-1, the extent to which that experience was taken into account in reviewing and approving the same tests, or the same kinds of tests for TMI-2?

THE WITNESS: Gee, that's again before my time. I would guess that even though the OLs were issued at different times for Unit 1 and Unit 2, the test programs, aside from scheduling requirements, were probably reviewed as a single item for both units. And, in other words, they provided one description of the test for both units, and we reviewed it, and it was applied to both units.

I would guess that was the way it was conducted. Obviously, there would be different requirements.

MR. PARLER: Are the test programs largely the product of the vendor? Is that the way it works?

THE WITNESS: Yes, yes. Well, do you mean the NSSS vendor?

MR. PARLER: Yes.

THE WITNESS: Well, it depends on the system. If it is a reactor system, then it would come from B & W, the reactor vendor. But if it is a feed water system or a turbine by-pass system, something in the balance of the plan that could come from the architect-engineer, the containment would come from the engineer.

MR. PARLER: I asked the question because you said these tests may well have been presented as one program, I gather?

THE WITNESS: Yes.

MR. PARLER: For both of the plants? Especially since it is my understanding that initially these plants were supposed to come on the line in a much more narrow -- in time than they actually did, because of other events.

But I gather that the test program, as far as the NRC is concerned, regardless of who supplies the various components of the test program, it is a program which is submitted by the applicant, that is, by the utility?

THE WITNESS: Yes, yes.

MR. PARLER: How about any information that you might be familiar with as to how test programs are handled in some foreign countries, particularly France? Have you -- are you aware of that at all?

THE WITNESS: I couldn't address that, no. Some of my people might be aware of that, but I am not.

MR. PARLER: I understand that.

BY MR. LANNING:

Q. Does your branch review the objectives of the surveillance testing requirements? Or is that part of the technical specifications?

A. No, that would be part of the tech specs.

MR. PARLER: So that's not within your branch?

THE WITNESS: No, no.

MR. PARLER: Does anyone know who reviews that? It would not be -- even though it's within tech spec, it would not be the little group in DOR that is responsible for the test?

THE WITNESS: No, I'm not familiar with how they are tested, but I think back to the various review branches, it would go back to the reactor systems branch, and make sure -- they have a standard tech spec, and they would go back to that branch and make sure everything is okay, and what the numbers are and that sort of thing.

MR. PARLER: During your tour of responsibility as a branch chief of quality assurance, are you aware of any directions from the commissioners being received which dealt primarily with the subject of quality assurance?

I'm talking about policy-type guidance.

THE WITNESS: None come to mind at the moment. I know we responded to several questions on QA from individual commissioners.

MR. PARLER: What I'm talking about is a -- something such as how we are doing in the QA area, or what is your opinion about the level of quality assurance in the industry and the adequacy of manpower or people power and all that sort of stuff.

THE WITNESS: No, no.

MR. PARLER: The same sort of question for the advisory committee on advisory safeguards?

THE WITNESS: No.

MR. PARLER: During the period of your responsibility in the quality assurance area, are you aware of any briefings of the committee in this area of technical qualifications, quality assurance, start-up procedures?

In other words, in the areas of your branch, that your branch has some responsibility for?

THE WITNESS: No, no, I'm not.

MR. PARLER: All right. Off the record.

(Discussion off the record.)

MR. PARLER: Are you aware of any quality assurance requirement that the Nuclear Regulatory Commission imposes on its own regulatory review and operation?

THE WITNESS: No, not specifically identified as a QA program. I think there are periodically -- I presume there would be checks by management levels as to how things were going on, but it is not identified as a specific Q&A program.

MR. PARLER: In any event, as far as you're concerned, there is nothing, as you have said, that identifies specifically as a QA program, and there has been, to the best of your knowledge, no organizational unit within the NRC which has such a specific responsibility?

THE WITNESS: I do not happen to know. No.

MR. PARLER: Okay. Go ahead.

BY MR. LANNING:

Q. Okay. Mark for identification Exhibit 1097, a report entitled, "A Study of the Nuclear Regulatory Commission Quality Assurance Program," conducted by Sandia Laboratories. The report number is PB-272 040. It is dated August 1977.

xxx

(Exhibit 1097 marked for identification.)

BY MR. LANNING:

Q. Mr. Haass, are you familiar with this exhibit and its contents?

A. Yes, I am to some extent.

Q. This study made a number of recommendations concerning changes to the way NRC reviews and implements the quality assurance programmatic requirements as set forth in B.

What I would like to know is, of the many recommendations they made there, beginning on page 8 -- are you familiar with that some attempt has been made to respond to the recommendations?

A. Well, let's see. We have -- recommendation 1 talks about standard review plan, and so we have updated our Chapter 17, Section 17.1 and 17.2, to reflect the latest guidance that we have available for program reviews.

Recommendation 2 -- so we were involved in that.

Recommendation 2 talks about the -- as I understand it, the Appendix A, Appendix B issue. Again, I think we discussed that extensively today, and we are clearly involved in that.

MR. PARLER: Right, right.

MR. LANNING: Let's go off the record for a second.

(Discussion off the record.)

MR. LANNING: Let's go back on the record.

BY MR. LANNING:

Q. Mr. Haass, I see you are reviewing some piece of documentation from your notes. Could you explain the subject of that?

A. Yes, what I have before me is a commission paper dated February 14, 1978, the subject of which is planned staff actions with respect to the Sandia study of the NRC quality assurance program.

This commission paper was prepared by Mr. Skovhalt, and -- as far as I'm able to tell at this brief review, the only areas I have been involved in are recommendations 1 and 2, as I previously described.

Q. All right. Let me mark that as Exhibit 1098.

(Exhibit 1098 marked for identification.)

MR. PARLER: I will make a copy of it.

Off the record.

(Discussion off the record.)

MR. LANNING: Let's go back on the record.

BY MR. LANNING:

Q. Besides the first two recommendations, are you knowledgeable in any efforts regarding including qualification testing required for design verification?

A. Off the record again.

(Discussion off the record.)

THE WITNESS: No, I'm not.

BY MR. LANNING:

Q. Are you familiar with any NRC efforts to adopt a method to address the human and hardware performance characteristics that are important to safety?

A. No, I'm not.

Q. Are -- the last recommendation in the report was that the quality assurance planning and evaluation function in NRC be assigned to a separate group.

Now, is the existence of your branch that separate group that they're referring to or is this more of a consolidation effort between the offices of standards and --

A. No, it would not be represented by any group. What

that recommendation covers is "the performance of continuing reviews of all assurance measures and standards, regulatory guides, and standard review plans for consistency and adequacy, and evaluating overall QA effectiveness, and recommending programmatic improvements when indicated and, also, developing and implementing quality assurance techniques."

Let's see, maybe I have to qualify my prior answer. As I recall, this response here, it's saying that it has already been dovered by the QA branch, and there is no need for additional organization.

Off the record a minute.

(Discussion off the record.)

THE WITNESS: Okay, back on the record.

The response in this commission paper points out that the recommendation does not consider the existing coordinating and concurrence mechanisms established to assure consistency, such as regulatory guide review process, inter-office QA task force, NRR-IE interface agreements and meetings, formal coordination on the development and interpretation of standards or the extensive discussion and coordination that occurs among the offices.

Additionally, it fails to note that a number of independent organizations, such as the ACRS, individual licensing boards, and the GAO, have looked at QA activities from an overview perspective.

Yes, as I understand the response here, it is saying that the proposal is to defer action on this recommendation in connection with its reference to recommendation 15, which talks about QA effectiveness through reliability studies.

And so this apparently is going to continue, but I'm not aware of how this is -- what's going on in this area.

MR. PARLER: Which organization in the NRC, in your judgment, has the primary responsibility to assure that licensees for commercial nuclear power plants appreciate the importance of meticulous attention to detail and the importance of safety from the top of the organization to the bottom?

Is that your branch, or is that some other organization?

THE WITNESS: I would say that's a responsibility of the entire review process. I don't think it can be assigned to one particular branch.

We, of course, look at those aspects from the quality assurance point of view and conduct of the operations. But it has to be -- has to come also from other review branches, who have their particular areas of responsibility.

MR. PARLER: In certain organizations, industrial or utilities, I would assume that there is something like a safety office or a safety officer who has that mission. Is that right?

THE WITNESS: Yes, I believe that's generally true, but NRC is concerned with overall safety, so we can't have a

separate safety office. It would be NRC.

MR. PARLER: Now, do you have any other questions? At this point, I usually ask whether you have anything else to add which you think is a matter of substance, and the only reason why that has not come out in the interview thus far, is because of the question not being asked, or because of the way certain questions were asked.

Now with that little preliminary, do you have anything of your own that you would like to comment on in the quality assurance area or in any area about the licensing and regulatory process, or, indeed, about commercial nuclear power?

THE WITNESS: No, I don't think at this time.

BY MR. LANNING:

Q. Do you feel that quality assurance and technical qualifications of the applicant have received the attention and the review process that it deserves?

A. Well, I think I could always identify areas that -- and maybe this is because I'm fairly new in the branch, a year and a half; I don't have all the background that some other people would have -- areas that I would like to look into and that I am planning to in the future --

MR. PARLER: Are those the areas that you have already mentioned earlier, like the ongoing task force to try to accommodate the language and Appendix A and Appendix B and that sort of thing?

THE WITNESS: Those we have already identified, and we are working on those. But there may be others.

MR. PARLER: All right. There are others that you have identified? Would you mind mentioning them here?

THE WITNESS: Well, let me mention some work we did in the last year on QA controls for computer programs. We have -- there was a task force established to look into the specific QA controls that vendors and other contractors were employing on computer programs, and so we were part of that.

It was really run by the analysis branch, but we had some QA representatives on it. It raises the question -- and among other projects in my mind as to the adequacy of design reviews that are being conducted by people, by various organizations. What is the depth of the reviews, what people are doing them, what organizations are they coming from? And so I'm proposing that we look into that in more detail.

BY MR. LANNING:

Q. And so you're proposing to look into more of the quality control aspects?

A. Yes. How has it been implemented?

Q. And implementation?

A. Yes. Another area that comes to mine is something we skirted on before, and that is what kind of criteria should an applicant have to guide his people with regard to how he applies the graded approach.

In other words, you have a specific component. What QA requirements should be applied to that particular component? How does the engineer or QA man that's involved, how does he decide what QA requirements are applied?

I would like to look into that criteria applicants give their people. Do they have any? Should we have any? Things like that. There are several that -- others don't come to mind offhand, but I'm involved next week in a panel session with ASQC, and it is called a look-ahead panel, and it -- these are the things we talk about.

Q Do you feel that the quality assurance branch is properly located in the right division within NRC to be most effective?

MR. PARLER: Off the record for a second.

(Discussion off the record.)

THE WITNESS: On the record again.

Quality assurance branch is another review branch similar to many that exist in DSS, and I guess I would -- it would seem to me more appropriate to include QAB in that area, although I don't really have any strong feelings. We operate basically as another review branch, although we report to a different division director.

I guess operationally, I don't really see a significant difference.

BY MR. LANNING:

Q Do you have other information that may be of interest to the special inquiry group?

A Not that I am aware of.

MR. PARLER: How about have you happened to think about anything else in the start-up tests area? I'm sure that my colleagues that are particularly interested in that issue will want to be sure that the record does reflect all matters in that area that you think are of significance, especially in the context of the kinds of considerations that we discussed earlier, that were alluded to by Mr. Spangler in his article about the pressures and realistic times for the completion of the tests and some of the things that I guess I referred to, benchmarks for tests and the like?

I don't want to repeat any of that stuff, but have you -- do you have any -- did anything in addition occur to you?

THE WITNESS: No, I don't think I can add anything. We did mention briefly in another area the evaluation that we are doing now of utilities, management, and technical services. That's directly connected with Three Mile Island, and we are heavily involved with it, and it will be going on for the next several months.

MR. PARLER: Other than the Exhibit 1095, which is Mr. McDermott's memorandum to you about recommendations for changes in the initial test, in the light of the Three Mile Island-2 accident, are you aware of anything else that Mr.

McDermott might have prepared for you after March the 28th, 1979, which is concerned with the TMI-2 start-up test program?

THE WITNESS: No, unless there was something in the one memo he wrote in response to Denny Ross's request. I don't recall anything else specifically.

MR. PARLER: We have that, but other than that?

THE WITNESS: No, I don't. He wrote many things.

MR. PARLER: Well, the specific --

THE WITNESS: But this exhibit you're referring to is a summary of what he considered to be significant, presumably.

MR. PARLER: I grant, from earlier discussions in the interview, that after the accident on March 28th, that there was a look-see, say in the quality assurance area, to see how -- to see how in the judgment of the responsible members of the quality assurance branch staff, Metropolitan Edison, for Three Mile Island-2 stacked up in the quality assurance area, and I gather that your answer was, they were good, or, in any event, certainly there were no noticeable deficiencies.

Now, what I want to ask is, was there a similiar look-see in the start-up test area and the results of the start-up test that you are aware of by QAB?

THE WITNESS: I think I mentioned previously that Bob McDermott may have looked at this. I'm not aware of the details on that.

MR. PARLER: So any documents that you're aware of

would appear to deal with any such look-see by Mr. McDermott, would be either in this Exhibit 1096, or in the other documents that relate to the work of the bulletins and orders task force. Is that right?

THE WITNESS: Yes.

MR. LANNING: In conclusion, let me say that this is an ongoing investigation, and although we have completed the questions we have for you today, we may need to bring you back for further depositions.

We will, however, make every effort to avoid having to do so.

We will now recess this deposition rather than to terminate it. I wish to thank you for your time in being with us here today.

(Whereupon, at 2:15 p.m., the deposition was recessed.)

end T-8

Exhibits for CR

NRC/TMI Special Inquiry

9/19/79

Depo: HAASS

DAR

Exhibit 1086

August 30, 1979

In Reply Refer to:
NTFTM 790830-05

Mr. Walter P. Haass
Quality Assurance Branch
Division of Project Management
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Haass:

I am writing to confirm that your deposition under oath in connection with the accident at Three Mile Island is scheduled for September 10, 1979 at 2:00 p.m., in the Arlington Road offices of the TMI Special Inquiry Group. This will also confirm my request for you to bring with you a copy of your resume and any documents in your possession or control regarding TMI-2, the accident or precursor events which you have reason to believe may not be in official NRC files, including any diary or personal working file.

The deposition will be conducted by members of the NRC's Special Inquiry Group on Three Mile Island. This Group is being directed independently of the NRC by the law firm of Rogovin, Stern and Huge. It includes both NRC personnel who have been detailed to the Special Inquiry Staff, and outside staff and attorneys. Through a delegation of authority from the NRC under Section 161(c) of the Atomic Energy Act of 1954, as amended, the Special Inquiry Group has a broad mandate to inquire into the causes of the accident at Three Mile Island, to identify major problem areas and to make recommendations for change. At the conclusion of its investigation, the Group will issue a detailed public report setting forth its findings and recommendations.

Unless you have been served with a subpoena, your participation in the deposition is voluntary and there will be no effect on you if you decline to answer some or all of the questions asked you. However, the Special Inquiry has been given the power to subpoena witnesses to appear and testify under oath, or to appear and produce documents, or both, at any designated place. Any person deposed may have an attorney present or any other person he wishes accompany him at the deposition as his representative. The Office of the General Counsel of NRC has advised us that it is willing to send an NRC attorney to all depositions of NRC employees who will represent you as an individual rather than represent NRC. Since the NRC attorney may attend only at your affirmative request, you should notify Richard Mallory (634-3224) in the Office of the General Counsel as soon as practicable if you wish to have an NRC attorney present.

You should realize that while we will try to respect any requests for confidentiality in connection with the publication of our report, we can make no guarantees. Names of witnesses and the information they provide may eventually become public, inasmuch as the entire record of the Special Inquiry Group's investigation will be made available to the NRC for whatever uses it may deem appropriate. In time, this information may be made available to the public

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voluntarily, or become available to the public through the Freedom of Information Act. Moreover, other departments and agencies of government may request access to this information pursuant to the Privacy Act of 1974. The information may also be made available in whole or in part to committees or subcommittees of the U.S. Congress.

If you have testified previously with respect to the Three Mile Island accident, it would be useful if you could review any transcripts of your previous statement(s) prior to the deposition.

Thank you for your cooperation.

Sincerely,

Mitchell Rogovin, Director
NRC/TMI Special Inquiry Group

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March 1979
Exhibit 1087

WALTER P. HAASS

PROFESSIONAL QUALIFICATIONS
DIVISION OF PROJECT MANAGEMENT
OFFICE OF NUCLEAR REACTOR REGULATION
U.S. NUCLEAR REGULATORY COMMISSION

My name is Walter P. Haass. I am Chief, Quality Assurance Branch, U.S. Nuclear Regulatory Commission (NRC). My duties are to direct, supervise, and coordinate the review of nuclear power plant license applications and topical reports to determine compliance with the Commission's (1) quality assurance criteria stated in Appendix B to 10 CFR Part 50 for plant design, construction and operation; (2) preoperational and startup acceptance test program criteria; and (3) technical and administrative criteria for nuclear power plant operating organizations in order to promote protection of public health and safety.

I received a Bachelor of Science degree in Mechanical Engineering from Stevens Institute of Technology in 1952.

Upon graduation, I joined the Westinghouse Electric Corporation with an initial assignment on the Graduate Student Training Program. As part of this program, I spent one year at the Oak Ridge School of Reactor Technology. My next assignment was at the Atomic Power Division where I was engaged in the thermal-hydraulic aspects of the design of proposed nuclear power plants.

In 1959, I accepted a position at the Martin Marritta Corporation, Nuclear Division. My activities included project engineering work on the mechanical design aspects of the PM-1 and PM-3A portable nuclear power plants at Sundance, Wyoming and McMurdo Sound, respectively; and program management work for several radioisotopic SNAP programs including SNAP-11 and SNAP-13.

In 1968, I joined the Atomic Energy Commission's regulatory staff (now NRC) as a licensing program manager (LPM) responsible for overall management of the staff's review of several nuclear power plant applications for construction permits. I was also involved in the development of guidance for the review of quality assurance program descriptions based on the QA criteria given in Appendix B. In 1972, I became the Technical Assistant for Boiling Water Reactors, reporting to the Assistant Director for BWRS. In 1974, I was assigned to the position of Special Assistant for Standardization with the responsibility for developing the programmatic requirements for the licensing of standardized nuclear power plants.

In June 1978, I was appointed to my present position of Chief, Quality Assurance Branch, DPM.

g. Carter

Exhibit 1088

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 8 1979

MEMORANDUM FOR: Commissioner Kennedy

THRU: Executive Director for Operations (Signed) Lee V. Gossick

FROM: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Victor Stello, Jr., Director
Office of Inspection and Enforcement

SUBJECT: PREVENTIVE MAINTENANCE

Your memorandum of April 24, 1979 to Lee V. Gossick expressed concern that the preventive maintenance programs identified by two NSSS vendors as being inadequate for certain safety related equipment may be symptomatic of a generic weakness. You also mentioned that some of the surveillance requirements of the Technical Specifications may not encompass the full range of components and that augmented surveillance may not be the best way to improve the situation. You requested the staff's views on this and an assessment of the feasibility and desirability of requiring licensees to have a preventive maintenance program that has been approved by the staff.

With respect to the specific NSSS vendor concern, while we agree with the NSSS vendors that the proximate cause of the failure of the circuit breakers was inadequate preventive maintenance, we believe the breaker design was not the best and was also a contributing factor. The causes for failure were attributed to either binding within the linkage mechanism of the undervoltage trip device and trip shaft assembly or out-of-adjustment conditions in the same linkage mechanism and in each case cited by I&E, cleaning and relubricating the trip shaft mechanism within the circuit breaker corrected the problem. The preventive maintenance programs were judged to be inadequate because some programs did not identify these breakers as requiring maintenance and other programs did not have the level of detail now believed necessary.

[redacted] However, the need for a preventive maintenance program is recognized by the staff and typical implementing procedures for performing maintenance are described in Section 9 of Appendix A to Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)". This regulatory guide also endorses an ANSI standard (N 18.7-1976) ANS-3.2, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants". Licensees have made a commitment to comply with the regulatory position of the regulatory guide or equivalent which states that a preventive maintenance program shall be established for safety related components.

The staff through the Quality Assurance Program which is required by Appendix B to 10 CFR Part 50 assures that the technical disciplines and licensee organization exist that develop the programmatic maintenance requirements for the plant. The endorsed ANSI standard provides procedural control requirements. NRR currently does not verify or review the program or the detailed procedures during the licensing process. In general, the licensees' preventive maintenance schedules are expected to follow the vendors' recommendations for frequency and extent of maintenance. Implementation of the preventive maintenance program is verified by NRC inspections, both before plant licensing and during routine operations. Inspection of the preventive maintenance is included in the inspection procedures for review of licensees' maintenance programs.

At present, technical specifications with a specified testing frequency (surveillance requirement) are used to detect malfunctions and need for possible corrective maintenance. The inter-relationship of the testing frequency, time required to perform the test, the component or system configuration required to perform the test, and the desired reliability are all considered in establishing surveillance requirements but the emphasis has thus far been on performance rather than method. Attempts are being made to detect degraded or inferior performance of components or systems but quantification of failures is very difficult. You are aware of the discussions concerning the NPRDS, the LER system and the ongoing work by Research to estimate failure rate trends.

NRC approval of preventive maintenance programs for safety-related equipment would require verification of completeness of the licensee's list of components and then review of the appropriate vendor's manual to assure that the recommendations for each component had been addressed. Placing the NRC in an approval mode would require a substantial increase in NRC effort in this area from the present audit program. NRC approval of the preventive maintenance program would also complicate the licensees' ability to change component maintenance schedules and procedures based on operating experience or changes in vendors' recommendations. The scope of an NRC approval of preventive maintenance programs of each reactor licensee is estimated to be greater than the current effort on Technical Specifications at each plant.

One possible variation of reviewing the entire preventive maintenance program would be to have the staff identify during the review process those particular components which are believed to require augmented surveillance or preventive maintenance. This would be different than the present philosophy of the technical specifications which is to require system operability (as an LCO) and identification of only the performance acceptance criteria for key parameters. We believe that it is best to define the general performance requirement and give the licensee the flexibility to select the means of satisfying the requirement. We do not believe that it is practical or necessary to place a Technical Specification surveillance requirement on each safety-related component. However, we will consider a more detailed review of the preventive maintenance program during the CP and OL reviews.

We read with interest the letter to Comm. Ahearne from Hugh McCullough of "Logistic Management Institute" which he sent to us. We would welcome the opportunity to learn about establishing an effective maintenance program, but we believe the potential lesson is better learned by the licensees. Convincing the licensee that adopting a good maintenance program will reduce any reactor downtime and/or maximize plant availability (with the corresponding improved profits) might reap safety benefits more efficiently than by imposing an NRC requirement. We plan to contact the Atomic Industrial Forum and encourage them to arrange a briefing with LMI.

Our future action in the area of maintenance will be predicated on our assessment of the briefing by LMI and our evaluation of operating reactor data. Since we recognize that some components which are not specified as safety related in the design may play an important role in off-normal events, we expect we will encourage licensees, through the AIF meeting, to apply preventive maintenance to all plant components. We will keep you informed.

Original Signed by
H. R. Denton

Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Original signed by

Victor Stello, Jr., Director
Office of Inspection and Enforcement

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Bradford
Commissioner Ahearne
S. Chilk, SECY

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NRC FORM 318 (9-76) NRCM 0240 ☆ U.S. GOVERNMENT PRINTING OFFICE: 1978 - 265 - 769

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 24 1979

MEMORANDUM FOR: W. M. Morrison, Assistant Director for General Engineering Standards, Division of Engineering Standards, SD

FROM: Walter P. Haass, Chief, Quality Assurance Branch, Division of Project Management

SUBJECT: QAB COMMENTS ON PROPOSED REGULATORY GUIDE 1.XXX (RS-704-4) "Applicability of Appendix B" Draft H

At the meeting of the Interoffice QA Task Force in my office on June 6, 1979, you provided copies of the subject proposed regulatory guide for task force review. This guide is intended to resolve the dichotomy that has developed since promulgation of Appendix B to 10 CFR 50 regarding the applicability of the QA criteria in Appendix B to all the structures, systems, and components addressed in the GDC of Appendix A. The QAB has reviewed the guide and offers the following comments:

1. The guide attempts to establish equivalency between the definitions of "important to safety" (see second sentence of first paragraph of the Introduction to Appendix A) and "safety-related" (see third, fourth, and fifth sentences of the first paragraph of the Introduction to Appendix B) as applied to structures, systems, and components of interest to NRC that are included in nuclear power plants. While it may not have been the intent of the writers of these regulations to establish a difference in the meaning of these terms, users of these regulations, namely NRR reviewers and industry personnel, have perceived a difference and have based many decisions regarding the need and extent of QA requirements for specific items in a nuclear power plant on this difference. One major result of this perception is the establishment of a list of specific SSC's (i.e., the Q-list) to which the provisions of Appendix B are applicable. At this point in time, we find it extremely difficult to see how NRC, through the mechanism of a regulatory guide with its inherently lower stature, can obviate these perceived differences in definitions without a corresponding change in the regulations. The proposed regulatory guide does not merely provide guidance on how to implement the regulations, which is its normal function, but rather attempts to modify the meaning of the regulations to be different than they have been perceived to be for several years.

2. The approach proposed for resolving the Appendix A/Appendix B problem in the subject regulatory guide is viewed by the QAB to be excessively simplistic and, consequently, of little use to QAB reviewers and, we think also, to IE inspectors. In discussions we have had with QA representatives of utilities, A-E firms, and reactor vendors on this subject, it is our understanding that presently very little QA is imposed on items derived from Appendix A but not on the Q-list. Their responses to our questions on how much QA is applied generally are like, "We don't know," "Very little," or "Commercial practice" /although the staff would generally agree that, at a minimum, the requirements of GDC #1 (Appendix A) are applicable/. As an example, when we asked a formal question on the QA requirements imposed on the Offsite Power System (i.e., the electrical switchyard located onsite but outside plant buildings) on a particular project, we were far from satisfied with the formal response. Therefore, QAB is concerned that, absent more specific guidance on the QA requirements for non-Q-list items, utilities could, under the proposed regulatory guide, simply add the new items to the Q-list and justify no further QA requirements by citing application of the graded approach (see lines 117 and 118 of the proposed regulatory guide). Conversely, some utilities would escalate the QA requirements to the point where all Appendix B requirements would be imposed (as you state in lines 45 through 47 of the subject guide). What we really believe to be necessary is a QA program with requirements somewhere between these extremes and we believe the quickest and surest way to achieve this is by establishing clear guidance that defines the level of QA requirements necessary. Otherwise, the utilities and their contractors would establish a wide range of QA requirements for a specific item that only after years of jawboning in meetings, discussions, and inspections would converge to the level we believe is appropriate.

3. The proposed regulatory guide gives no guidance regarding the determination of what additional SSC's should be included on the Q-list. We have no specific suggestions to offer at this time, but we believe a set of criteria defining "the SSC's that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public" needs to be developed and included in the guide. The general, nonspecific nature of the wording in the GDC's of Appendix A establishes a clear need for such guidance. Further, the items to be added to the Q-list are not always simply SSC's; we strongly believe that pertinent design data (e.g., "ology" measurements derived during site investigations), consumables, and other such items should be included. This is recognized to some extent in lines 111 through 115 of the proposed guide.

We believe the criteria for determining those "SSC's that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public" are fairly well in hand (Regulatory Guide 1.29), although some may disagree. The criteria presented in proposed Regulatory Guide 1.XYZ are more definitive, however.

4. Other questions that come to mind and appear to require investigation when "safety-related" and "important to safety" are equated are:

   a. Is the scope of the reporting of defects and noncompliances under Part 21 affected?

   b. Is the scope of the deficiencies reporting rule under 10 CFR 50.55(e) affected?

   c. Are the SRP, standard format guide, and other regulatory guides affected?

5. Other comments of a more minor nature have not been identified in this memo. They will be provided when the issues we consider to be more significant, as described above, are resolved.

Alternate Approach

In lieu of the approach to resolving the Appendix A/Appendix B problem presented in the subject regulatory guide, we recommend that an alternate approach be considered that retains the existing definitions for "important to safety" and "safety-related" and provides a clear definition of the QA requirements we believe are appropriate for non-Q-listed Appendix A SSC's to be added to the program. The latter definition would serve as a QA programmatic "umbrella" for the Appendix A SSC's from which the requirements for a specific SSC could depart, as appropriate, using the graded approach in a manner analogous to the current use of the Appendix B "umbrella" for safety-related SSC's. This approach would provide a more definitive target for utilities in establishing QA requirements for these kinds of SSC's and would also assist our IE inspectors in determining whether NRC requirements were being specified and met. The new SSC's from Appendix A could be included within the Appendix B program but subject to the QA programmatic requirements defined by the new "umbrella."

In the past year or so, QAB has developed considerable background and experience in developing graded QA programs for various activities and items for which NRC is responsible. Primary examples are QA for radioactive material transportation containers (for NMSS) and QA for research programs (for RES). In each of these cases, we have utilized the acceptance criteria given in SRP Sections 17.1 and 17.2 as a starting point and, based on the objectives and characteristics of the activity/item under consideration, made judgment decisions regarding the need for each acceptance criterion in the QA program. We believe a similar approach could be applied to developing a QA "umbrella" program for "important to safety" SSC's and, with the agreement of the Interoffice QA Task Force and other NRR management, are prepared to undertake such a development. This QA "umbrella" or checklist could be part of a new regulatory guide that would provide guidance to industry. The new guide would also include criteria for determining the SSC's that should be subject to the requirements of the checklist as noted in comment 3 above.

We are available for additional discussion on our comments. We suggest an early meeting of the Interoffice QA Task Force for this purpose.

Walter P. Haass

Walter P. Haass, Chief
Quality Assurance Branch
Division of Project Management

cc: D. Skovholt
J. Heltemes
W. Reinmuth
M. Peranich
S. Richardson
J. Gilray
W. Belke
J. Conway
F. Liederbach
J. Spraul

Was previously sent out as Subject Matter For reference - Exhibit 1090

FEB 8 1979

MEMORANDUM FOR: Richard C. DeYoung, Director, Division of Site Safety and Environmental Analysis

Roger J. Mattson, Director, Division of Systems Safety

THRU: Roger S. Boyd, Director, Division of Project Management

FROM: Donald J. Skovholt, Assistant Director for Quality Assurance & Operations, Division of Project Management

SUBJECT: REVIEW OF APPLICANT'S Q-LIST FOR ACCEPTABILITY

During our recent efforts to upgrade Chapter 17 of the Standard Review Plan, we identified a need for clarification of assigned branch responsibility to review for completeness and accuracy the list of systems, components, and structures (Q-List) to which the quality assurance program, developed in accordance with Appendix B to 10 CFR 50, is applicable. The need for such a Q-List is a requirement of Appendix B. SRP Sections 17.1 and 17.2 require the QAB reviewer to assure that a Q-List is either included in Chapter 17 of the SAR or appropriately referenced therein. However, the assignment of responsibility to assure that the Q-List is complete and accurate is not well in hand. Under present practices, the QAB developed a Q-List based on past SAR reviews against which each applicant's Q-List is compared. Applicants are then requested to resolve any discrepancies.

We believe that this practice needs revision. Within the staff, the persons best qualified to determine the safety significance of plant items are the technical reviewers that perform the safety evaluations of each plant. Therefore, we believe that these reviewers should be assigned primary responsibility for determining the adequacy of each Q-List, and comparison with a checklist by the QAB reviewer should be a back-up check for apparent inconsistencies or omissions.

Accordingly, we recommend that the SRP be modified to identify the need for review of the Q-List and to assign responsibility for the review. Specifically, we recommend that:

1. Section 3.2.1 of Reg. Guide 1.70 (Rev. 2) be revised to request applicants to provide a Q-List which would be referenced in Chapter 17. Guidance to the applicant should also indicate a suggested tabular format, the criteria for determining whether an item is safety-related, and the level of detail to which an item should be specified.

2. SRP Section 3.2.1 be revised to include the review of the Q-List as an area of review, and to include the [illegible]

OFFICE ➤						
SURNAME ➤						

branch review responsibilities to assure the accuracy and completeness of the items on this list. The latter responsibility should be consistent with the areas of review assigned to the branches through other SRP sections. This change in review responsibility is not meant to infer that the scope of the Q-List should be changed.

3. By memorandum to the QAB, each technical review branch should indicate that the adequacy of the Q-List has been verified within the assigned area of responsibility.

As an interim measure, to accommodate the current projects under review, we have proposed that each cognizant LPM issue a memorandum to the assigned reviewers requesting that the Q-List presented in the SAR be reviewed for completeness and accuracy in the areas for which each reviewer is cognizant.

At the January meeting of the LSRC, this proposal was considered. The Committee considers it to be an improvement to the review process with very nominal staff impact and recommends that the Directors of DSS, DPM and DSE approve the proposal.

Your approval is requested. We are available for further discussion of this matter at your earliest convenience.

Original Signed by.
Donald J. Skovholt

Donald J. Skovholt
Assistant Director for Quality
Assurance and Operations
Division of Project Management

cc: D. B. Vassallo
F. Schroeder, Jr.
D. R. Muller
W. P. Haass
J. W. Gilray
R. L. Baer
O. D. Parr
J. F. Stolz
S. A. Varga

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FLiederbach, PM:QAB

	[illegible]	DJSkovholt	RSBoyd			

GAB Projects
1091

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APR 1 3 1979

MEMORANDUM FOR: Commissioner Kennedy

FROM: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

THRU: Executive Director for Operations (Signed) LVG

SUBJECT: QUALITY ASSURANCE PROGRAMS FOR NUCLEAR POWER PLANTS

In your memorandum of March 28, 1979 to Lee V. Gossick, you requested our views as to whether quality assurance programs for nuclear power plants require additional staff attention as a result of (1) the recent shutdown of five nuclear power plants and (2) the recent chain of events related to North Anna Unit 1. In addition, you requested us to include any recommended action in this area.

It is our present view that sufficient quality assurance programmatic requirements and controls are already imposed on applicants and licensees through their commitments to meet the provisions of Appendix B of 10 CFR Part 50 and the amplifying guidance presented in regulatory guides, endorsed ANSI standards, and other criteria in the Standard Review Plan (Sections 17.1 and 17.2). The concern you have expressed more properly lies in the implementation of these requirements and controls, and the events you have cited in your memorandum, among others cited by I&E as a result of inspection efforts, are examples of improper implementation. Implementation, it should be noted, includes the translation of QA programmatic requirements and controls, specified in the applicant's SAR and approved by NRC, into the specific policies and procedures that comprise the QA Manual, and the proper utilization of these policies and procedures by the QA and QC personnel and other personnel as assigned within the applicant's organization and the organizations of its principal contractors and other suppliers.

Contact:
W. P. Haass, NRR
49-27741

As you know, the volume and variety of activities performed by the nuclear industry are immense and the resources of the Commission available to police these activities are limited. Consequently, the IE inspection program must, of necessity, utilize a sampling system for verifying implementation. Inherently a sampling system cannot cover every detail; thus the program inevitably will not independently identify every problem that arises. Consequently, substantial reliance must also be placed upon the licensee and its agents for identifying problem areas and for conformance to requirements.

To date, the balance between regulatory effort vs industry effort has been considered acceptable by the Commission and the staff. In view of the Three Mile Island incident, however, the acceptability of this balance has clearly been upset and additional high level reviews appear to be imminent. These reviews will undoubtedly address many factors, including not only the general QA requirements and implementation aspects but many specifics as well. The staff concurs in the need for these reviews and expects to participate as necessary. Even though such reviews usually result in recommendations for added and more stringent requirements, more inspection and enforcement, and more regulation in general, it should be noted that no program, government or private, will be absolutely effective in preventing every personnel error or equipment malfunction. Perfection, although a goal that is continually strived for, is not an absolute necessity for the protection of the health and safety of the public. The realization that deficiencies will occur led to the defense-in-depth concept in the design of nuclear facilities. Quality assurance is only one of the several lines of defense provided under this concept.

In a directly related activity we are close to completing, the NRC staff, at the request of Commissioner Gilinsky, has undertaken a study of the acceptability of QA practices in the development and use of computer codes for nuclear power plant design. This study was prompted by the identification of errors found in computer programs, and was initiated even prior to the identification of the discrepancy in computer programs that resulted in the recent shutdown of five nuclear power plants. The findings and recommendations resulting from this investigation will be documented in a separate report due to the Commission approximately June 1, 1979.

In summary, the NRC staff shares your concern regarding the adequacy of quality assurance programs for the design, construction, and operation of nuclear power plants, both in their formulation and in their implementation. We will consider the need for re-evaluation of current QA requirements and inspection practices as a result of recent events and keep you informed of our plans on this matter.

Original Signed By.
Roger S. Boyd

for Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosure:
NRC Review and Inspection
Practices for Quality Assurance

cc w/enclosure:
Chairman Hendrie
Commissioner Gilinsky
Commissioner Bradford
Commissioner Ahearne
Samuel Chilk, SECY
Albert Kenneke, OPE
Leonard Bickwit, OGC

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NRC REVIEW AND INSPECTION PRACTICES FOR QUALITY ASSURANCE

NRC has several specific QA responsibilities. First, it has a responsibility for developing the criteria and guides for judging the acceptability of nuclear power plant QA programs. Second, it has a responsibility for reviewing the descriptions of QA programs of the licensee and its principal contractors to assure that sufficient management and program controls are provided. Finally, NRC inspects selected activities to determine that the QA programs are being implemented effectively. In the detailed review and evaluation of the description of the QA program of the applicant and its principal contractors, including the reactor vendor, the architect-engineer, and the constructor, a determination is made of program acceptability based on defined acceptance criteria. The staf verifies that:

(1) The organizations and persons performing QA functions have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for costs and schedules, and

(2) The QA program descriptions contain requirements and controls which, when properly implemented, comply with the requirements of Appendix B.

The NRC's Office of Inspection and Enforcement (OIE) conducts periodic scheduled and unannounced field inspections of the applicant's QA program implementation as well as those of its contractors and suppliers. These inspections start prior to docketing of the application and continue throughout the construction phase, the preoperational test program, and the operating lifetime of the facility. These field inspections during the construction phase are extensive and cover: (1) a review of the applicant's QA performance, including audits of the applicant's QA records and documentation; (2) a witnessing of the construction practices and an inspection of the facility at various stages of construction; and (3) a review of the qualifications and training of the construction personnel as well as those of the quality assurance and quality control (QA/QC) personnel. The review of the qualifications and training of the QA/QC personnel is conducted for all types of personnel at the site, including the specialized subcontractors and at the manufacturing facilities of the vendors and suppliers.

During the operating license review phase, the staff reviews the description of the operational QA program in much the same manner as the QA program description for construction was reviewed earlier. The NRC maintains its

QA responsibilities throughout the operational lifetime of a nuclear power plant. These responsibilities are discharged through frequent and regular inspections of operations and records for compliance with NRC requirements. Also, the NRC must review and approve any change to licensed operating conditions.

NRC looks to the power plant owners, the utilities themselves, to take the leadership role in assuring the quality of their plants and operations. This requires careful attention to the selection of engineering specifications and QA procedures and practices for each task and their implementation by the workers on the job. And, most importantly, there must be adequate resources of qualified personnel at management, operating, and staff levels. The NRC places the highest emphasis on the active involvement of top management in QA programs. The NRC evaluates those programs, the licensees execute them, and the NRC assesses performance.

The effectiveness of licensee quality assurance programs cannot be directly measured. A qualitative assessment, however, is made by NRC on a plant-by-plant basis by comparing performance against the requirements imposed. NRC's conclusion about the effectiveness of a licensee's ongoing quality assurance program is based principally on NRC inspection findings. The NRC inspection program is an audit or sampling of licensed activities to test the effectiveness of licensees' control programs, including specifically quality assurance, in meeting NRC requirements. Deficiencies in licensee performance may also be identified through the review of events which are required to be reported to NRC.

Licensee quality assurance programs are believed to be effectively implemented for plant construction, testing, operation, maintenance, and repair. From time to time, significant weaknesses have been identified in a particular licensee's quality assurance program. When this has occurred, NRC has required prompt corrective action.

In cases where deficiencies or noncompliances are found, NRC requires the licensee not only to fix the specific deficiency, but also to re-evaluate and to correct the quality assurance program as necessary to preclude further deficiencies. Activities carried out during the period of program weakness are given more thorough checks to determine that they were not adversely affected. The overall trend in items of

noncompliance by a licensee is important to NRC as an indicator of trends in control or quality systems. A trend toward numerous or repetitive items of noncompliance is viewed as a signal that may indicate a deterioration of licensee management control systems. Stronger enforcement actions may be taken if needed to cause licensees to correct deteriorating programs.

The NRC inspection and enforcement program basically is preventive in nature--aimed at achieving implemented licensee control and quality systems to assure proper protection of the public health and safety. The requirements that are included in the approved quality assurance program description as a result of detailed staff review are used as signals to identify deteriorating quality systems so that corrective systematic action can be taken to upgrade control thereby preventing serious situations. Enforcement options available to NRC are such as to provide incentives to correction as well as deterrents to degradation.

None of the licensee programs are absolutely effective in preventing every personnel error or equipment malfunction. Perfection, although the goal continually strived for, is not required for the protection of the health and safety of the public. The realization that deficiencies will occur led the safety design of power reactors to be based on the defense-in-depth concept. Quality assurance is only one of the several lines of defense provided under this concept.

FROM:
Comm. Kennedy

TO:
Gossick

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Suggest Quality Assurance Programs for nuclear power plants may require additional attention

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

OFFICE OF THE
COMMISSIONER

March 28, 1979

Memorandum for Lee V. Gossick
Executive Director for Operations

From: Richard T. Kennedy

Subject: QUALITY ASSURANCE PROGRAMS FOR
NUCLEAR POWER PLANTS

Events related to the recent shutdown of five nuclear power plants for seismic-related concerns and the recent chain of events related to North Anna Unit 1 suggest that the quality assurance programs for nuclear power plants may require additional staff attention. In particular, errors associated with such a simple matter as the weight of a check valve raise doubts regarding the adequacy of such programs.

I would appreciate receiving staff's views on this subject, including any additional actions which staff may recommend.

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Bradford
Commissioner Ahearne
S. Chilk, SECY
A. Kenneke, OPE
L. Bickwit, OGC

Date 3/29/79
1:45

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

Exhibit 1092

May 19, 1976

Honorable Marcus A. Rowden
Chairman
U. S. Nuclear Regulatory Commission
Washington, DC 20555

SUBJECT: REPORT ON NUCLEAR REACTOR INSPECTION

Dear Mr. Rowden:

In response to a request from the Commission in early 1975, the Advisory Committee on Reactor Safeguards established an Inspection and Enforcement Subcommittee to review and comment on the adequacy, scope, and possible redirection of the Nuclear Regulatory Commission's Office of Inspection and Enforcement (NRC-IE). This action was also in response to recognition of a need for greater attention to these matters as a result of the boiling water reactor (BWR) pipe cracking problem. The scope of the Subcommittee's evaluation program was directed primarily to those matters pertaining to portions of commercial nuclear power plants covered by the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Sections III and XI. While an attempt was made to develop some information pertaining to fire inspection practice, the depth of the review was somewhat limited. The Committee also had limited opportunity to review inspection and enforcement aspects of instrumentation and controls, concrete containments, rotating machinery, heat transfer equipment, and preoperational testing.

A review of these matters was completed by the Committee during its 193rd meeting, May 6-8, 1976. The subject was also a matter of discussion with the NRC Staff during the 191st meeting of the Committee, March 4-6, 1976, and at meetings of the Inspection and Enforcement Subcommittee held in Washington, D. C., on August 13, October 1, and November 21, 1975. Members of the Subcommittee and invited experts visited the pressure vessel facilities of Combustion Engineering, Inc., in Chattanooga, Tennessee, on January 23, 1976, and a Subcommittee meeting was held that same day. A Subcommittee meeting was also held on February 20, 1976, in Chicago, Illinois, to discuss inspection procedures with personnel from Commonwealth Edison Company and Region III NRC-IE. During this review, the Subcommittee had the benefit of discussions with representatives from code groups, insurance companies, electric utilities, nondestructive testing organizations, the National Board of Boiler and Pressure Vessel Inspectors, and of the documents listed.

The problem of terminology in the inspection and examination of nuclear components is recognized as relatively complex. Therefore, the Committee is attaching a glossary of terms used, or directly interacting with

terms cited, in this report to minimize confusion concerning the meaning intended for specific terms. Most definitions were derived from the ASME Boiler and Pressure Vessel Code, but are considered applicable to other areas of concern in electrical components, instrumentation, structures, and fire prevention. There should be a clear differentiation between examination and inspection. The Committee will use the terminology indicated in the attached glossary, where the "examiner" conducts the nondestructive or destructive tests whereas the "inspector" is responsible for such items as the validation of test methods and calibration procedures, qualification of examiners, monitoring and/or auditing the tests, and reviewing the records. While terminology such as testing, checking, etc. is used in lieu of examination by other groups, "examination" will be used herein regardless of the components considered.

The Committee recognizes that the National Aeronautics and Space Administration (NASA) and Federal Aviation Administration (FAA), and various other federal agencies use combined examiner-inspector approaches. However, this type of arrangement is ineffective unless the inspection agency can provide its own examination facilities at the point of inspection. In the case of the nuclear industry, this is impractical because of the need to utilize the owner's operating personnel and equipment for the examination program. It is possible for the inspection agency to perform some types of examination, but these should be primarily confirmatory actions to establish that the examination procedures are appropriate to the need.

In evaluating the requirements for inspection and examination of nuclear facilities, the Committee considered the relevance of the practices of NASA, FAA, and other organizations who have rigorous requirements for environmental testing of components, including extensive life testing under environmental conditions, as a part of their inspection requirements. For short-lived space vehicles and high speed aircraft, where there is no latitude to determine performance adequacy prior to use under extreme conditions, stringent performance verification is necessary before operational use. In the case of nuclear power reactors, performance verification is achieved partly by environmental tests, partly by a series of plant preoperational tests, and partly by closely controlled tests during low power operation and the period of gradual increase of power to the operating level. This procedure allows ample opportunity to expose most inadequacies of design or construction.

An examination of various foreign codes relevant to the inspection of pressure boundary components did not reveal substantive differences or potential improvements that could be incorporated into appropriate

United States codes or standards. The fundamental differences between codes are too great to permit a quantification of the pluses in one code versus the minuses in another. Until differences in philosophy can be resolved, there appears to be only limited opportunities for combining the best features of the relevant French, German (Federal Republic of Germany), Japanese, United Kingdom, and United States codes.

An increased effort between the NRC and appropriate code or standards groups to develop better criteria and codes or standards comparable to the ASME Nuclear Codes for fire prevention, for electrical systems, and for other safety-related components, is desirable. Current requirements often are ill-defined and amorphous so the "inspector" lacks adequate criteria to determine acceptability. Until these criteria are better defined, there will continue to be confusion concerning acceptable limits as evaluated by the NRC-IE organization.

A well-defined Quality Assurance (QA) Program developed by all responsible parties for design, construction, and operation is essential if there is to be a coordinated and meaningful inspection program by the Third Party (authorized inspector) and the Fourth Party (NRC-IE). Such a program provides criteria for the evaluation of the relevant components or systems. An inevitable result of a good QA program is the identification of some inadequate quality or erroneous work by an effective inspection and enforcement activity since lack-of-perfection is implicitly indicated by the need for inspection. The adequacy of workmanship should be evaluated on the basis of frequency of occurrence of unacceptable results and repetition of substandard results rather than on the basis of isolated incidents. The principle of in-depth safety protection is predicated on the assumption that even though one or more lines of safety defense may break down, simultaneous failure of all lines of defense has a sufficiently low probability of occurrence to make its consequences an acceptable safety risk. Cooperative efforts leading to an improvement in QA such as the activities of the Coordinating Agency for Supplier Evaluation (CASE) should be encouraged. The Committee recognizes the need to validate QA programs through review of appropriate documentation. However, inspections should represent a balance between direct inspection of equipment and facilities and review of documents since the best way to assess an organization's attitude is through direct observation during construction or operation of a facility.

With regard to the problem of detection of stress corrosion in piping that initiated this report, its ultimate solution will depend to a major degree on better nondestructive examination techniques and on more clearly

defined standards for such examinations. The Committee is aware of the joint efforts by industry, the Electric Power Research Institute, the Nuclear Regulatory Commission, and the Energy Research and Development Administration to improve nondestructive examination procedures on austenitic stainless steel and hopes such efforts will lead to appropriate improvements. With regard to examination procedures, such as those presented in the American Society for Nondestructive Testing document, SNT-TC-1A, modifications are desirable but may need to await the results of experimental programs.

The Committee believes that the NRC Office of Inspection and Enforcement can be more objective if its personnel, while being responsible for inspection, are not responsible for the performance of the examination and testing activities. It is not necessary to perform the work in order to establish that examination practices are appropriate. The Committee believes that if the NRC-IE organization has a suitable staff of experts in inspection and examination practices and monitors the use of these practices at important installations, it will provide the most effective inspection program. Further, conflicts between the NRC Staff and other government-authorized inspectors required by mandatory codes followed in the United States will be avoided. For example, the cases of intergranular stress corrosion cracking (IGSCC) in BWR piping were identified by operating personnel retained by the licensee and used during routine plant operation. It would be totally impractical to obtain comparable timely response under such conditions if the NRC Staff had to perform these examinations and inspections before the safety implications could be evaluated.

It is necessary to recognize that the qualifications of both "inspectors" and "inspection specialists", whether employees of an "authorized inspection agency" or NRC-IE, will vary with the type of inspection. For example, the qualifications of an "authorized inspector" on a construction project, where ASME, Section III, is applied, will differ markedly from the qualifications of an "inspector" on an operating nuclear power plant who is required to audit and evaluate by ASME, Section XI. Because this difference is not generally recognized, some "inspectors" may lack necessary qualifications.

In the inspection of the pressure boundary, where ASME, Sections III and XI are comprehensive codes with well-defined responsibilities for examination and inspection, it should be possible to enhance NRC-IE activities by giving ASME more authority while holding them accountable. A specific suggestion would be to modify Article NA-4000 of ASME, Section III, to conform more closely to 10 CFR 50, Appendix B, and by requiring an upgrading of the qualifications of the "authorized inspector" through rigorous application of the American National Standards Institute, ANSI-626 series on

Quality Assurance. To a degree, the preceding has been accomplished, but further improvements may be possible and should be explored.

A fertile area for improving the reliability and scope of inspections is through improved interactions between Third Party (authorized inspector) and Fourth Party (NRC-IE) inspectors and acceptance by Fourth Party of Third Party inspections, subject to audit. Each of the levels of inspection and each of the inspection parties would have its capabilities strengthened and its duties better delineated. The NRC-IE Staff could concentrate its efforts on making certain that this is the case so that it can use the results of these inspections as a basis for safety evaluation.

"Authorized inspectors" employed by inspection agencies, inspectors employed by the owner or his agent, and NRC-IE personnel have different levels of capabilities and responsibilities. To some degree the responsibilities overlap and this situation has some advantages as well as disadvantages as applied to the ASME codes. The situation is less clear with respect to operational inspection, fire prevention, and instrumentation and controls. The level of expertise available to the several inspection sources is not fully defined and may be inadequate. The responsibilities and capabilities of the various inspection organizations need further review and evaluation.

The enforcement policy of the NRC-IE should be such as to encourage responsible reporting of unsatisfactory conditions of significance to public health and safety. Penalty systems should be directed toward those having responsibility for organizing and implementing inspection and examination functions (e.g., owner-management, architect-engineer (A-E) management when designated under owner-A-E contract, insurance agencies when designated by owner-contract, constructors and suppliers when designated by recognized codes, standards, and regulations or by owner-contract).

A potential limitation pertinent to both Third Party (authorized inspectors) and to Fourth Party (NRC-IE) inspection personnel is the inability of a single person to cope with the tremendous detail in a code such as ASME, Section III, where familiarity with design, construction, materials, and examination is required. A viable solution is a strong cadre of "inspection specialists" in both the "authorized inspection agency" and the NRC-IE organization. Such specialists are essential where problems arise that exceed the capabilities of online "inspectors". Competencies among "authorized inspection agencies" vary with some being stronger than

others. The Committee believes that the NRC-IE organization needs to increase its Staff in this area through direct hires or through increased use of consultants.

The existing level of staffing and capabilities in the NRC-IE organization probably needs to be expanded. The capabilities of NRC-IE could be used more effectively if some of the duties now performed by its personnel were performed by "inspection agencies" not in the employment of the NRC. However, regardless of this, there appears to be a definite need for more expertise in the NRC-IE organization to serve as a cadre of supporting personnel when important safety matters arise requiring resolution. Further, the inspection capabilities need to include fire protection, instrumentation and controls, rotating machinery, and various operational test activities as well as matters covered by the ASME Boiler and Pressure Vessel Code.

The Committee believes that the problems identified above are amenable to solution, and positive programs leading to resolution of these items should produce substantive improvements in the inspection process.

Sincerely yours,

Dade W. Moeller

Dade W. Moeller
Chairman

Attachment:
Glossary of Terms

References:

1. Letter, dated February 17, 1976, E. L. Kemmler, The Hartford Steam Boiler Inspection and Insurance Company, to the Honorable Abraham Ribicoff, concerning the inspection of nuclear plants by insurance companies
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6. Technischer Ueberwachungs-Verein Rheinland (TUV), "Requirements for the Design and Execution of a Quality Assurance Program for Nuclear Installations," Report No. 932/7411, July 17, 1975
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9. Joint Hearing - The Joint Committee on Atomic Energy of the United States and the Committee on Government Operations of the U. S. Senate, Ninety-fourth Congress, Nuclear Regulatory Commission Action Requiring Safety Inspection Which Resulted in Shutdown of Certain Nuclear Power Plants, February 1975
10. ASME Boiler and Pressure Vessel Code, Section III - Nuclear Power Plant Components, 1974 Edition
11. ASME Boiler and Pressure Vessel Code, Section XI - Rules for Inservice Inspection of Nuclear Power Plant Components, 1974 Edition
12. Letter, dated October 27, 1975, Institut Fur Reaktorsicherheit Der Technischen Ueberwachungs - Vereine (IRS-TUV) to Battelle Memorial Institute, Pacific Northwest Laboratory, Richland, Washington (Battelle, Northwest), concerning inspection and enforcement information from Sweden
13. Letter, dated July 11, 1975, IRS-TUV to Battelle, Northwest, concerning inspection and enforcement information from Sweden, ("Wes und Geschichte der Technischen Ueberwachungs - Vereine", G. Wiesenack 1971)
14. Topical Report on Coordinating Agency for Supplier Evaluation, January, 1976

ATTACHMENT

GLOSSARY

The following definitions are those used in ASME, Section III and ASME, Section XI; however, they are considered to be generally applicable to all classes of components, examinations, and inspections. (Note: "NA-____" refers to ASME, Section III, "IWA-____" refers to ASME, Section XI, and "*" refers to usage by the ACRS Inspection and Enforcement Subcommittee)

AUDITS - NA-4900

A comprehensive system of planned and periodic audits shall be carried out by the Certificate of Authorization holder's organization to assure compliance with all aspects of the Quality Assurance Program and to determine the effectiveness of the Program.

AUTHORIZED INSPECTION AGENCY - NA-5111

An Authorized Inspection Agency is one designated as such by the appropriate legal authority of a State or Municipality of the United States or a Province of Canada. The agency employs the Authorized Inspectors who perform inspections required by this Section. The agency may be a State of the United States or a Province of Canada or an insurance company authorized to write boiler and pressure vessel insurance.

CERTIFICATE OF AUTHORIZATION - NA-8112

An Owner, Engineering Organization, Manufacturer, or Installer may apply to the American Society of Mechanical Engineers, upon forms issued by the Society, for a Certificate of Authorization for the scope of work which he intends to perform.

CLASSES - CODE*

Construction rules are specified for items which are designated Code Classes 1, 2, 3, CS and MC. These code classes recognize the different levels of importance associated with the function of each item as related to the safe operation of the nuclear power plant. For example, Class 1 includes, but is not limited to, components making up the primary coolant boundary.

CODE*

Those safety laws, rules, and regulations pertaining to systems or components (e.g., pressure vessels) contained in the laws of States, Municipalities, Federal Government, etc. The ASME Boiler and Pressure Vessel Codes are a specific example. They are mandatory.

CODE - ASME III - NA-1110

The rules of this Section constitute requirements for the construction of nuclear power plant items such as vessels, storage tanks, piping, pumps, valves, and core support structures, and component supports, for use in or containment of, portions of the nuclear power system of any power plant.

CODE - ASME XI - INTRODUCTION/FOREWORD

Section XI, Rules for Inservice Inspection of Nuclear Power Plant Components of the ASME Boiler and Pressure Vessel Code is addressed to provide rules for the examination, testing, and inspection of Class 1, 2, and 3 components and systems in a nuclear power plant. Application of this Section of the Code begins when the requirements of Section III, Rules for Construction of Nuclear Power Plant Components, have been satisfied.

CONSTRUCTION - NA-1110 FOOTNOTE

Construction is an all-inclusive term comprising materials, design, fabrication, examination, testing, inspection, and certification required in the manufacture and installation of items.

ENFORCEMENT AUTHORITY - IWA-2110(e)

Denotes a regional or local governing body such as a State or Municipality of the United States or Canadian Province empowered to enact and enforce boiler code legislation.

EXAMINATION - IWA-2110(a)

Denotes the performance of all visual observation and nondestructive testing such as radiography, ultrasonic, liquid penetrant, and magnetic particle methods.

EXAMINATION TECHNIQUES - IWA-2200

Methods, techniques, and procedures for the inservice inspections are titled visual, surface, and volumetric. Each term describes a general method permitting a selection of different techniques or procedures restricted to that method to accommodate varying degrees of accessibility and radiation levels, and the automation of equipment to perform the examinations.

EXAMINER - IWA-2110(a)

The individual(s) performing all visual observation and nondestructive testing such as radiography, ultrasonic, liquid penetrant, and magnetic particle methods.

EXAMINER - QUALIFICATIONS - IWA-2300

a) Personnel performing nondestructive examination operations shall be qualified with a procedure prepared in accordance with SNT-TC-1A for the applicable examination technique and methods.

b) For nondestructive examination methods not covered by SNT-TC-1A documents, personnel shall be qualified by the Owner or his agent to comparable levels of competency by subjection to comparable examinations on the particular methods involved; for example, leak testing. The practical portion of SNT-TC-1A shall be performed using the Owner's procedure(s) on part(s) representative of the Owner's plant.

FLAW INDICATION -IWA-2110(c)

Denotes the evidence or signal obtained by application of a nondestructive examination that may reveal the presence of a flaw. Flaw indications include cracks, slag inclusions or segregates, aligned or clustered porosity, lack of weld penetration, lack of weld fusion, and laminations or combinations thereof.

INSPECTION - IWA-2110(b)

Denotes verifying the performance of examinations by an Inspector representing a State, or Municipality of the United States, Canadian Province, Authorized Inspection Agency, or other enforcement authorities having jurisdiction over the nuclear power components at the plant site.

INSPECTION AGENCIES - NA-3520

Organizations having agreements with Owners, Engineering Organizations, Manufacturers or Installers to provide inspection of nuclear power plant items or their installation.

OFFICE OF INSPECTION AND ENFORCEMENT*

The office under the Nuclear Regulatory Commission responsible for inspection of nuclear facilities (see Regulatory authority).

INSPECTION - FIRST PARTY (OWNERS)*

Denotes verifying the performance of examinations by an inspector who represents, and is employed by, the owner of the facility.

INSPECTION - SECOND PARTY (MANUFACTURERS)*

Denotes verifying the performance of examinations by an inspector who represents, and is employed by, the manufacturer.

INSPECTION - THIRD PARTY*

Denotes verifying the performance of examinations by an inspector as defined in IWA-2130.

INSPECTION - FOURTH PARTY (NRC-IE)*

Denotes verifying the performance of examinations by an employee of the Nuclear Regulatory Commission's Office of Inspection and Enforcement as distinguished from an Authorized Inspector.

INSPECTION SPECIALISTS - NA-5113

Any Inspection Agency which has contracted to perform inspections required by this Section shall, in addition to Inspectors, maintain a staff of Inspection Specialists, each of whom has demonstrated his qualification by passing an examination acceptable to the Society in one or more methods of nondestructive examination and, in addition, the tests for Inspection Specialists given by the National Board of Boiler and Pressure Vessel Inspectors for knowledge of and familiarity with this Section.

INSPECTOR - IWA-2110(d)

Denotes an "Authorized Inspector" as defined in IWA-2130.

INSPECTOR - DUTIES (INSERVICE) - IWA-2120

a) It is the duty of the Inspector to witness or otherwise verify all the examinations and pressure tests required by this Division for Class 1, and for Class 2 components where required. The Inspector shall also make any additional investigations necessary to verify that all applicable requirements have been met.

b) It is the duty of the Inspector to assure himself that the nondestructive examination methods used follow the techniques specified in this Division. The Inspector shall also assure himself that the examinations are performed in accordance with written qualified procedures and by personnel employed by the Owner or his agent and qualified in accordance with SNT-TC-1A and IWA-2300. The duties of the Inspector include checking with his Inspection Specialists for the technical content and requirements of the examination procedures and the qualification procedures of nondestructive examination personnel.

c) It is the duty of the Inspector to assure himself that the inservice tests required on pumps and valves (IWP and IWV) have been completed and the results recorded.

d) It is the duty of the Inspector to assure himself that the examinations and tests required for Class 3 components and systems (IWD-1000) have been conducted and the results recorded.

e) The Inspector has the right at any time to require requalification of any procedure or operator when the Inspector has reason to believe the requirements are not being met.

f) The examination records shall be certified by the Inspector only after he has satisfied himself that all the requirements have been met and that the records are correct.

g) The Inspector shall review the repair program to determine compliance with the requirements of this Division.

h) It is the duty of the Inspector to assure himself that the welding procedures employed during the repair and the welding operators are qualified in accordance with IWA-4000 and that all nondestructive examination methods used comply with requirements in IWA-2200 and IWA-2300.

INSPECTOR - DUTIES (CONSTRUCTION) NA-5210

a) The Inspector who performs the detailed inspections in compliance with this Section shall witness or otherwise verify all examinations and make all inspections required by this Section. He shall also make any other inspections and witness or verify (including making measurements) any other examinations and additional investigations which, in his judgment, are necessary to ascertain whether the item being inspected has been constructed (NA-1110, Footnote 1) in compliance with the rules of this Section. Parts and piping subassemblies shall be in accordance with the accepted design drawings.

b) The duties of the Inspector shall not be interpreted by virtue of these rules to extend to any construction requirements beyond those of this Section which may be set forth in the Design Specification or on drawings. However, such requirements shall not result in construction which fails to conform with the requirements of this Section (NA-3252).

INSPECTOR - THIRD PARTY (AUTHORIZED) - IWA-2110(d)

Denotes an "Authorized Inspector" as defined in IWA-2130.

INSPECTOR - QUALIFICATIONS - IWA-2130(b)

Any Inspector who performs inspections required by this Division shall have first been qualified by written examination pursuant to the legislation or rules of a State of the United States, the legislation of a

Canadian Province, or the rules of another authority having jurisdiction over a nuclear power plant at the installation location and that has adopted thi Division. The Inspector shall not be an employee of the Owner or his agent.

JURISDICTIONAL AUTHORITY*

That body in the State empowered by its legislature to enforce the laws of the State with respect to boilers, pressure vessels, and nuclear reactors. The title of the Chief Enforcement Officer is usually Chief Inspector.

MANUFACTURER - NA-3310

The organization or combination of organizations which constructs (NA-1110) any item to meet the Design Specifications and the requirements of the Code.

OPERATION*

Denotes status of a nuclear power system during the power generation (and ascent to power) stages.

OWNER - IWA-1400 FOOTNOTE

The organization responsible for the operation, maintenance, safety, and power generation of the nuclear power system.

QUALITY ASSURANCE - NA-4121

All those planned and systematic actions necessary to provide adequate confidence that all items manufactured or installed are in accordance with the rules of this Section.

Quality Assurance includes:

1) Quality Control Examination (NA-4122), which comprises the examinations of the physical characteristics of a material, components, part, or appurtenance and the acceptance standards associated with those examinations;

2) Quality Control Administration (NA-4123), which is the management and documentation which assures that the specified Quality Control examination is carried out.

REGULATORY AUTHORITY - IWA-2110(f)

Denotes a Federal Government agency, such as the United States Nuclear Regulatory Commission, empowered to issue and enforce regulations concerning the design, construction, and operation of nuclear power plants.

STANDARDS*

Those test methods, definitions, recommended practices, classifications, specifications, and other related material representing a common viewpoint to those parties concerned (producers, users, general interest groups). Unlike codes, standards are voluntary.

1093

DEC 15 1976

MEMORANDUM FOR: Roger S. Boyd, Director, Division of Project Management

THRU: Donald J. Skovholt, Assistant Director for Quality Assurance & Operations, Division of Project Management

FROM: Walter P. Haass, Chief, Quality Assurance Branch, Division of Project Management

SUBJECT: ASSIGNMENT AND DOCUMENTATION OF REVIEW RESPONSIBILITY FOR TECHNICAL QUALIFICATIONS

Findings relative to technical qualifications are made for all CP and OL applicants in accordance with 10 CFR Sections 50.34 (a) (9) and (b) (7). Appendices M, N, and O to Part 50 also require the Commission to make a finding relative to technical qualifications of applicants involved in standardization. However, hearing testimony, questions from OELD, and intervenors' contentions on this subject have identified the necessity to clarify the information needed and to clarify the assignment of responsibility for determining such findings.

The staff's findings regarding technical qualifications of the applicant are normally prepared by the LPM and presented in Chapter 21 of the SER. The basis for the findings, however, as presented in other sections of the SER, has been rather minimal for some of the areas of review considered in evaluating technical qualifications. The QAB proposed procedural modifications to correct this situation in early 1973 that received agreement in principle within DPM. One relevant task, the modification of SRP Section 13.1, has been completed. A second task, the instituting of a procedure for I&E input, is well underway. One major task that remains, among others, is the clarification and documentation of the LPM's responsibilities.

The QAB has prepared the attached table as a summary of the specific areas of review identified as pertinent to the determination of an applicant's technical qualifications. Those areas for which QAB is responsible are already documented, or will be shortly, in SRP Sections 13.1 and 17.1. We suggest that the areas for which the LPM is responsible be documented either in the LPM's Handbook or in a new SRP Section 13.7 to be created. Note that for items 10 and 11, we recommend that the I&E and DOR inputs be sent to the LPM with copies to the QAB reviewer for use in developing the QAB portion of the findings as necessary. This is analogous to the present method for handling the I&E input for item 7.

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DATE ▶						

In summary, QAB will provice its conclusions to the LPM regarding the technical qualifications of the applicant for the areas so identified in the attached table. Utilizing the QAB conclusions as well as I&E and DOR inputs, the LPM can develop his findings, including the basis, for presentation in the SER. It is suggested that the LPM's review responsibility be documented either in the LPM's Handbook or in a new SRP Section 13.7. We will continue our present effort to work with I&E in developing the procedural and informational needs to satisfy NRR requirements for items 10 and 11. We expect the LWR Group to initiate efforts along similar lines with DOR for item 11 input.

We would be happy to participate in further discussions of this matter as necessary.

Original signed by
Walter P. Haass

Walter P. Haass, Chief
Quality Assurance Branch
Division of Project Management

Enclosure:
Table: Determination of
Technical Qualifications

cc w/enclosure:
D. Ross
D. Vassallo
W. Gammill
D. Beckham
L. Crocker
F. Williams
H. Berkow

DISTRIBUTION:
Central File
~~QAB Projects~~
QAB Chron. File
NRR Reading File
DJSkovholt, DPM
~~RReiss, DPM~~
FAllenspach, QAB
RMcDermott, QAB

OFFICE ▶	DPM:QAB	DPM:QAB	DPM:QAB	DPM:QA&O		
SURNAME ▶	FAllenspach:cb	RMcDermott	WHaass	DJSkovholt		
DATE ▶	12/14/78	12/15/78	12/15/78	12/12/78		

NRC FORM 318 (9-76) NRCM 0240 ★ U.S. GOVERNMENT PRINTING OFFICE: 1978 - 261 - 769

Determination of Technical Qualifications

	Area of Review	Responsibility	Reference Document	Comments
1.	The completeness, adequacy, and basis of the technical design and related information described in the SAR.	LPM, DPM	None	This is an implicit part of the review process done by the LPM.
2.	The organizational structure of the applicant.	QAB	SRP Section 13.1	
3.	The applicant's technical staff including the breadth and level of experience and available manpower.	QAB	SRP Section 13,1	
4.	The utility's past experience in the design and construction of projects of similar scope including nuclear power plants.	QAB	SRP Section 13.1	This area of review will be included in the revision to SRP 13.1, has been approved by the R^{3}C, but has not yet been published.
5.	The experience level of the applicant's principal contractors, including the NSSS vendor, and A-E and in some cases the constructor.	QAB	SRP Section 13.1	Same as 4 above.
6.	The scope and content of the applicant's quality assurance program.	QAB	SRP Section 17.1 or 17.2 as applicable	
7.	The implementation of the applicant's quality assurance program as determined by the Office of Inspection and Enforcement.	I&E	SRP Section 17	The conclusions of I&E are incorporated into the SER input for Section 17 by Q/8.
8.	The applicant's competence in technical discussions with the staff.	LPM, DPM	None	This is an implicit finding by the LPM based on his daily interface with the applicant.
9.	The applicant's responsiveness and resources in the resolution of technical issues that come up during the licensing review process.	LPM, DPM	None	Same as 8 above.
10.	The implementation of the FSAR organizational and administrative commitments.	I&E	None	We intend to revise SRP Section 13.1 to include this item; no R^{3}C review needed.
11.	The applicant's past history with operating nuclear plants (where applicable)	I&E, DOR	None	This input should be provided to the LPM to be used in his evaluation of technical qualifications.

Startup services and training activitives during 1977.

W. H. Spangler
Manager, Plant Startup Services
Nuclear Power Generation Division
Lynchburg, Virginia

During 1977 B&W's Startup Services organization assisted in the startup of three plants, Crystal River-3, Davis-Besse-1, and Three Mile Island-2. This paper provides a brief recap of the completion of the CR-3 startup and discusses the progress of startup activities at DB-1 and TMI-2, along with generic conclusions that can be made regarding plant startups. Also included is a description of what B&W is doing to qualify its personnel to meet new regulatory requirements made effective in 1977. In addition, new developments in simulator training are presented.

CRYSTAL RIVER-3 STARTUP

Major milestones of the CR-3 startup are shown in Figure 1. The Reactor Coolant System Hydrostatic Test was completed on November 23, 1975. Fuel loading was completed on December 4, 1976, and criticality was achieved on January 14, 1977. With successful completion of the Unit Acceptance Test, power escalation testing was completed on April 26, 1977.

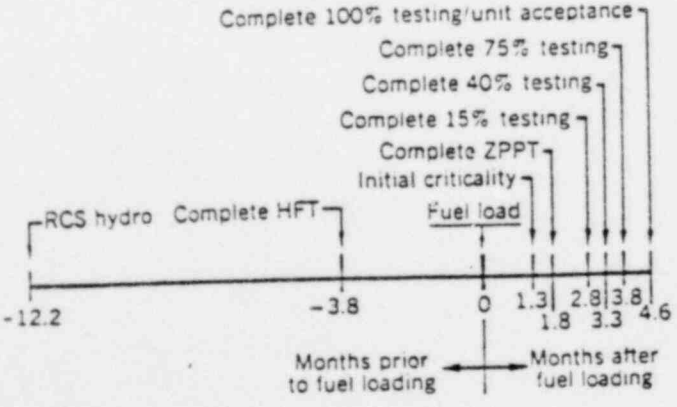


Figure 1 Crystal River - 3 plant startup milestones.

DAVIS-BESSE-1 STARTUP

Major milestones of the DB-1 startup are shown in Figure 2. As points of reference, the hydrostatic test of the Reactor Coolant System was completed on September 9, 1976, and the unit acceptance test was scheduled for March 1, 1978.

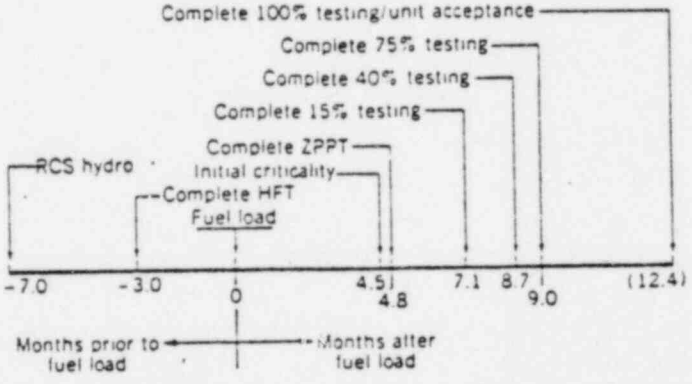


Figure 2 Davis-Besse - 1 plant startup milestones.

Figure 3 shows the makeup of the overall startup task force overlayed on the major milestones of startup. Note that personnel reductions began just after fuel loading, however, the major reduction in manpower did not occur until three months following fuel loading. The dotted line in Toledo Edison Company (TECO) statistics shows the anticipated staffing for normal operation. Thus, those in excess of 194 are considered to be dedicated solely to plant startup and then only because of startup.

The breakdown of responsibilities for the startup is shown in Table 1. TECO retained overall responsibility for the startup, for those activities associated with normal plant operation, and the

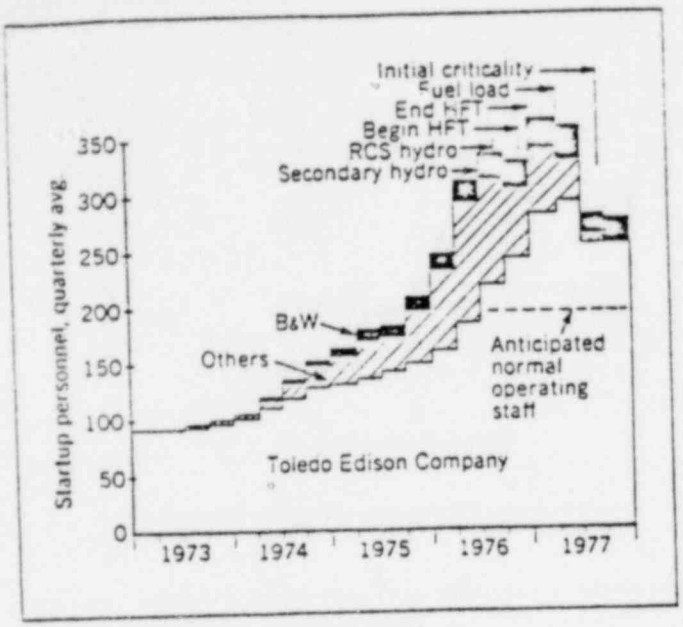


Figure 3 Davis-Besse-1 startup personnel.

Table 1 Davis-Besse-1 plant startup responsibilities

TECO
- Overall plant startup
- Administer QA/QC program
- Administer safety tagging and clearance program
- Operate and maintain permanent plant equipment
- Calibrate all instruments
- Develop startup procedures
- Perform startup testing

B&W
- Test program manager
- Schedule startup and test programs
- Provide technical advice, consultation, and direction on all NSS systems
- Provide technical direction and assistance in plant startup
- Assist in individual component and system checkout, testing, and turnover
- Guidance on instrumentation and controls calibration and tuning
- Develop startup procedures
- Perform startup testing

Others
- Provide technical direction and overall coordination of construction testing and plant startup
- Perform construction testing
- Assist in individual component and system checkout, testing, and turnover
- Assist in conduct and documentation of plant system flushing and cleaning

conduct of startup testing. TECO contracted B&W personnel for tasks associated with startup planning and startup test management, for technical advice and consultation on the NSS systems, and overall plant startup. TECO contracted the assistance of others for those tasks associated with construction acceptance checkout, cleanup, and testing.

Figure 4 shows a breakdown of the types of startup activities and the assistance of B&W and others to TECO in those activities. (The percentages for each type of activity add up to greater than 100% because of the combined involvement in many activities.)

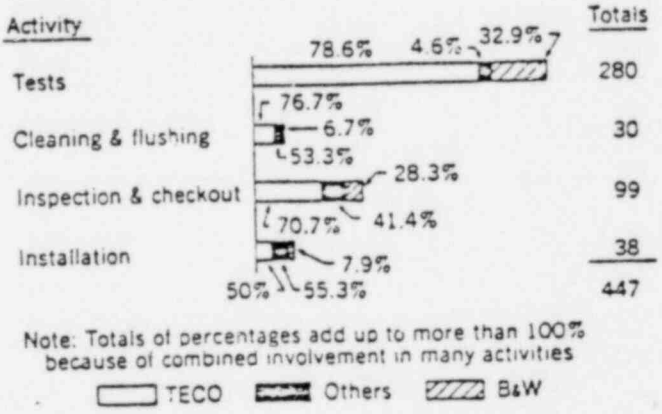
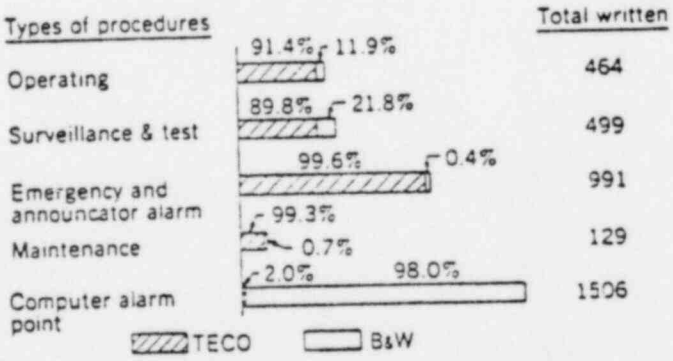


Figure 4 Davis-Besse-1 plant startup activities.

Figure 5 shows the participation of TECO and B&W in the preparation of procedures.



Note: Totals of percentages add up to more than 100% because of combined involvement

Figure 5 Davis-Besse-1 startup procedures.

Table 2 identifies the major difficulties encountered while completing each startup milestone. These difficulties did not have equal delaying effects and it is not practical to assign a delay period associated with each. They do, however, aid in explaining particularly long phases in the startup.

Table 2 Davis-Besse-1 problems during startup

Milestone	Problems in completing milestone
RCS hydro	• Turnover of incomplete systems
HFT	• HPI pump lube oil system • Plant construction not complete
Fuel loading	• Surveillance specimen holder tubes • Internals guide blocks • Auxiliary feedwater system • Reactor vessel head O-rings • Auxiliary building penetration sealant • Fuel handling equipment • Startup source handling tool • Station grounding • Nuclear instrumentation • Radiation monitoring system • Extremely cold weather – lost time
Initial criticality	• Incore detector guide tubes • Plant construction not complete • Hot weather – lack of system power • Design of pressurizer relief valve loop seals
Unit acceptance	• Steam-feedwater rupture control system • Main feedwater pumps and controls • Auxiliary feedwater pumps and controls • Turbine stop valves and controls • Condenser tube leak (drain impingement) • Cold weather – need for power from DB-1 • Electromatic relief valve • Main steam code safety valves • Piping and valve vibrations • Turbine bypass valves • Feedwater system piping • Interface between custom designed secondary plant and ICS tuning • On-line computer

Figure 6 shows a comparison of the startup of DB-1 to previous B&W NSS startups. This startup was particularly long in the phases between hot functional testing and initial criticality (7.5 months); and between the completion of zero power physics testing and the completion of the 15% power testing plateau (2.3 months). The remaining phases look very similar to previous startups. The primary reason for lengthy delays identified were construction problems. The difficulties in completing the 15% plateau testing were primarily with the Steam/Feedwater Rupture Control System and the Auxiliary Feedwater System, which are both first-of-a-kind systems.

THREE MILE ISLAND-2 STARTUP

Startup of TMI-2 has progressed as shown by the major milestones presented in Figure 7 The RCS Hydrostatic Test was completed on June 6, 1977, and fuel loading was scheduled for February 1, 1978.

Figure 8 shows the numbers of personnel involved solely with plant startup from General Public Utilities (GPU), B&W, and other support organizations.

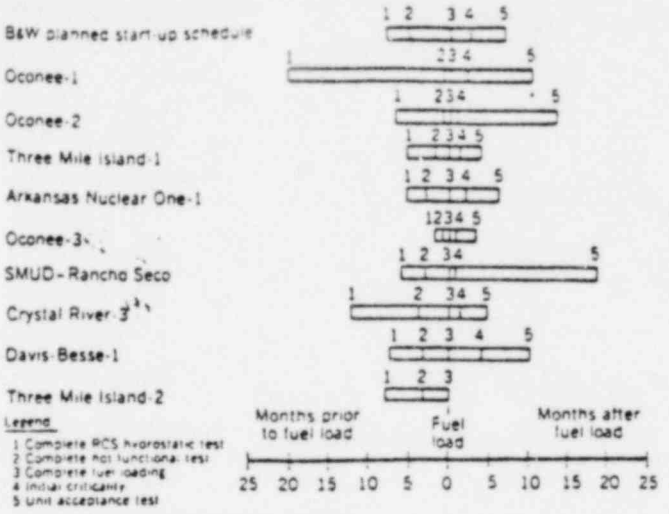


Figure 6 B&W NSS startup history.

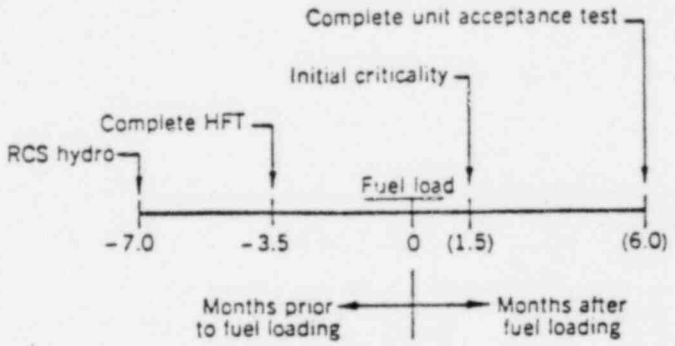


Figure 7 Three Mile Island 2 plant startup milestones.

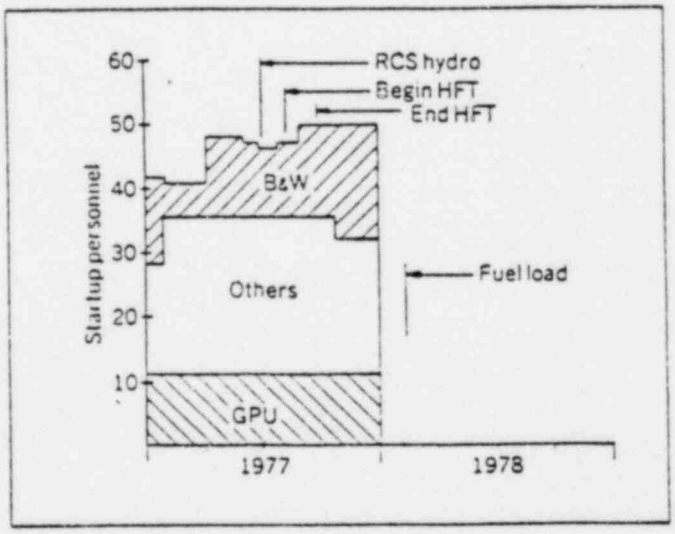


Figure 8 Three Mile Island-2 startup personnel.

The breakdown of responsibilities for the startup program is shown in Table 3. GPU retained overall responsibility for the planning, management, and direction of startup testing. Metropolitan Edison Company (Met. Ed.) will be operating the plant and was therefore given the responsibility to operate all equipment during

Table 3 Three Mile Island
—unit 2 plant startup responsibilities

GPU/MET ED
- Overall plant startup
- Test program manager
- Administer QA/QC program
- Administer safety tagging and clearance program
- Operate and maintain permanent plant equipment
- Calibrate all instruments after turnover
- Perform startup testing
- Schedule startup and test programs
- Calibrate and tune instrumentation and controls
- Coordinate startup procedure development

B&W
- Provide technical advice, consultation, and direction on all NSS systems
- Provide technical direction and assistance in plant startup
- Assist in individual component and system checkout, testing, and turnover
- Develop startup procedures

Others
- Provide technical direction and overall coordination of construction testing and plant startup
- Perform construction testing
- Assist in individual component and system checkout, testing, and turnover
- Assist in conduct and documentation of plant system flushing and cleaning
- Perform pre-operational calibration of all instruments
- Develop startup procedures

startup. GPU has contracted the assistance of B&W in the preparation of a large portion of the NSS related procedures and surveillance related procedures necessary to meet requirements of the Standard Technical Specifications, in addition to providing advice and consultation on the NSS systems. GPU contracted the assistance of other support organizations for those tasks associated with construction acceptance checkout, cleanup, and testing.

Figure 9 shows the assistance B&W and others provided to GPU in preparation of the various types of startup procedures.

Table 4 identifies the major difficulties encountered in completing each startup milestone. The plant startup at TMI-2 is not far enough along that many conclusions can be drawn or that effective comparisons with previous startups can be made.

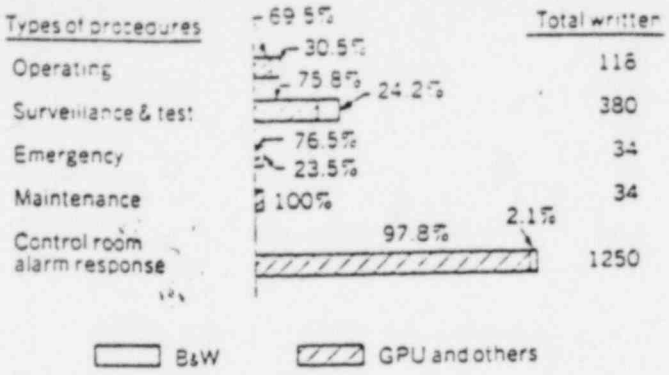


Figure 9 Three Mile Island 2 startup procedures.

Table 4 Three Mile Island—unit 2 problems during startup

Milestone	Problems in completing milestone
RCS hydro	• Pressurizer heater closure O-rings • Control rod drive closures • Surveillance specimen holder tubes • Internals guide blocks
HFT	• Plant construction not complete • Reactor vessel head O-rings • Phosphate contamination of OTSG's • Inadequate supply of demineralized water • RC pump seal damage • Demineralizer resin recovery • RC pump casing gaskets • Auxiliary steam system shared with unit 1 • Change in prime construction contractor
Fuel loading	• Reactor coolant pump casing gaskets • Plant cleanup and painting delayed until busy post-HFT period • Fuel handling equipment

GENERIC CONCLUSIONS

Based on experiences in 1977, two conclusions generic to the startup of a nuclear steam system can be drawn:

- The need for additional manpower at the job sites during the startup period is continuing to grow because of expanding documentation requirements and the more extensive testing programs now being required. B&W is continuing to meet utility needs in these areas by making available increased numbers of personnel with broadened scope of capability. Table 5 shows B&W startup assistance personnel assigned for the three most recent plant startups at various periods.
- Utilities continue to become committed to startup schedules prepared early in the project that later prove to be unrealistic because of construction constraints. Loading fuel in the core prior

to the time the plant is ready for criticality severely limits access to complete construction. In addition, pressure on startup personnel to achieve unrealistic schedules often results in serious mistakes being made that ultimately cause additional delays. Two recent examples of this type of mistake are: flushing a demineralizer resin bed into the cooling water system, and contamination of the reactor vessel, internals and transfer canal while shot blasting containment concrete surfaces. There needs to be an industry-wide effort to establish and maintain realism in project scheduling.

Table 5 B&W startup assistance personnal

Discipline	Plant CR-3	DB-1	TMI-2
Startup test program manager	1	1	
Reactor performance engineer	3		5
Senior startup consultant			2
Test coordinator	2	4	
Test engineer		8	
Shift augmenter	4		
Scheduler	2	2	
Chemo nuclear engineer	1	1	1
Reactimeter operator		2	
Instrumentation and controls engineer	1	1	
Procedure writers		3	3

PERSONNEL QUALIFICATIONS

New personnel qualifications are continuing to be imposed upon the industry. Some of the more recent are:

- Security Requirements NUREG 0220 ANSI N18.17 Reg. Guide 1.17

  Operating Plant Personnel Qualifications ANSI 18.1 1.8

  Qualifications of Inspection, Examination, and Testing Personnel for Construction Phase ANSI N45.2.6 Reg. Guide 1.58

  Requirements for Special Physical Examinations for Those People Who Are Expected to Work While Wearing Face Masks (NUREG 0041) (Reg. Guide 8.15)

The following actions are being taken by B&W to train and qualify personnel so as to be of maximum assistance to utilities during start-up, refueling, or maintenance outages.

A formal screening program to assure the reliability of all B&W personnel permitted unescorted access to nuclear power plants. The program is managed by the B&W Security Department and meets the requirements of ANSI N18.17. All B&W personnel subject to field assignment are given thorough physical examinations to assure their suitability to work in the nuclear power plant environment, including medical certification to work in environments where face masks are required. The examinations meet the requirements of NUREG 0041 and are documented as shown in Figure 10.

Figure 10 Medical certification record.

A program has been instituted to certify B&W personnel to the highest possible ANSI qualifications commensurate with educational background and experience. Each individual will have a summary of his/her history readily available along with documentation certifying the expertise and level to which he or she is qualified.

Formal training programs are being instituted to qualify people for the various levels of Non-Destructive Testing work to meet the requirements of ANSI N45.2.6.

TRAINING SIMULATOR IMPROVEMENTS

Training on the B&W Simulator is in heavy demand. The facility is essentially booked for the first two shifts during 1978. To maintain and improve the quality of training available with the B&W Simulator, we are currently in the process of making major changes to improve the accuracy of representation of the Rancho Seco core during Cycle 2. These revisions will enhance the ability to demonstate axial power imbalance control, core quadrant power tilts from asymmetrical control rod conditions, the different reactivity effects resulting from a single control rod movement as compared to a group of control rods and the reactivity differences reflected from a dropped control rod versus an ejected control rod.

Using an auxiliary computer in the Simulator, we will implement a back-track capability which will allow the Simulator to be restarted at those conditions that existed during the time from 1 to 30 minutes prior to reset. This reset function will allow students to repeat operations with different actions or to repeat the same actions with a different operator. The auxiliary computer will implement expanded plant computer capability including the plotting of eight selected variables on a strip chart recorder, color CRT display of plant status and alarms, and new alarms and event recorders. The simulator program will be further revised during a summer outage to implement a more complete representation of the Rancho Seco secondary plant and to replace the current Integrated Control System and its analog equations with digital equations in an on-line computer.

TRAINING VIA VIDEO TAPES

We have developed nine video tapes under the sponsorship of the Operator Licensing Branch of the Nuclear Regulatory Commission. These tapes represent the B&W plant response to various methods of control and to certain casualty conditions. Specifically, they include the plant response to automatic Integrated Control System action plus the three major manual modes of operation. The casualty tapes cover loss of a single feedwater pump, loss of all reactor coolant pumps, and steam generator tube leak. Each is approximately twenty minutes long and is provided with an instruction manual for assistance to the student. The tapes are fast moving and will maintain the student's interest while they are in use. We are continuing with this series on control and casualty tapes, and are beginning a maintenance series starting with reactor coolant pump seals and control rod drives.

Acknowledgements

The author gratefully acknowledges the contribution and support of Mr. Jack Evans, Davis-Besse-1 Station Superintendent, in the preparation of this paper.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAY 22 1979

Exhibit 1095

MEMORANDUM FOR: Walter P. Haass, Chief, Quality Assurance Branch, DPM

FROM: Robert J. McDermott, Quality Assurance Branch, DPM

SUBJECT: RECOMMENDATIONS FOR IMPROVEMENTS TO INITIAL TEST PROGRAM REVIEW IN LIGHT OF THE THREE MILE ISLAND 2 INCIDENT

1. Require all applicants whose SER is not issued to address Regulatory Guide 1.68, Revision 2.

2. Require all PWR's not yet licensed to conduct natural circulation tests. Include in the next revision to Regulatory Guide 1.68. Justification: (1) Regulatory Guide 1.68 allows credit for tests conducted on prototype plants. However, few plants are truly identical and plants referenced as prototypes may differ in many ways from the plant being reviewed (e.g., core size, reactor internals geometry, coolant loop pipe diameters); (2) performing a natural circulation test on each plant would be a check on the procedures used to start and maintain natural circulation; (3) the test would familiarize plant operators and supervisors with these procedures; (4) the test would require a delay of only a few hours in the plant startup.

3. Review auxiliary feedwater test descriptions for all PWR's not yet licensed to verify that full flow tests and low flow/high head (or shutoff head) tests have been performed. Require applicants to perform these tests, if not already planned or conducted. Justification: Regulatory Guide 1.68 does not state specifically what tests should be performed for auxiliary feedwater. Further justification for low flow testing: pumps are generally not designed to run for long periods under low flow/high head conditions; they may be required to operate under these conditions following some accidents and transients. Modify Regulatory Guide 1.68 at the next revision to include specific statements of auxiliary feedwater system tests.

4. Review ECCS test descriptions for all plants not yet licensed to verify that tests include demonstration of pump capability to operate at low flow/high head (or shutoff head) conditions. Require applicant to do so, if necessary. Justification: pumps are generally not designed to operate for long periods under these conditions but would be required to do so for some accidents (e.g., small break LOCA). Modify Regulatory Guides 1.68 and 1.79 at their next revision to specifiy these tests.

5. Require all plants not yet licensed to conduct tests to demonstrate the capability of all systems (which are designed to do so) to automatically

to DSS that they consider requiring this in design of all systems which are assumed to mitigate the consequences of accidents (this would include such systems as emergency core cooling, residual heat removal, fuel building ventilation, and emergency service water) and getting surveillance requirements for these features in the technical specifications (including plants which now have these features).

6. Require all plants not yet licensed to perform leak tests of the following systems (or portions of systems) if they are located outside containment:

   a. hydrogen recombiners

   b. decay heat removal systems

   c. ECCS

   d. reactor coolant purification system

   e. closed cooling water systems that have interfaces with reactor coolant

   f. other systems unique to plant design

   Require these plants to establish acceptance criteria, or review existing criteria, in light of the problems with leakage from systems outside containment at Three Mile Island 2. Recommend to DSS and DSE that they re-evaluate design criteria and accident analysis assumptions for leakage from these systems and for the ventilation systems for buildings which house these systems, in light of the TMI-2 incident. QAB should recommend that technical specifications be established to require surveillance tests for leakage from these systems. Modify Regulatory Guide 1.68 at the next revision to include leak tests from these systems.

7. Review test program descriptions for all plants not yet licensed to see if adequate tests are performed for "non-safety" systems (e.g., auxiliary feedwater systems, turbine bypass system, pressurizer power operated relief valves).

8. Recommend QAB & DSE clarify testing required for environmental monitoring systems. (See Regulatory Guides 4.1 and 4.15 for existing requirements.)

9. QAB should recommend that DOR consider items 1 through 8 for applicability to operating reactors.

10. Because modifying regulatory guides requires a fairly long time, we should consider other short-term measures (e.g., Branch Technical Positions) for getting these changes into the regulatory process.

11. We recommend that these improvements be given high priority in the Initial Test Program and Conduct of Operations section. All plants whose OL reviews have been started, but whose SER will not be issued before fuel load, should be reviewed based on their proximity to fuel load date (as estimated by NRR). Plants whose OL reviews have not yet started can be handled during the course of the normal review.

12. Estimated manpower requirements (after management approval).

a. Submitting recommended changes to Regulatory Guides 1.68 and 1.79 to OSD. 3 man-days

b. Submitting recommendations to DSS, DOR, and DSE. 2 man-days

c. Performing re-review of plants whose OL reviews are already started (Q-1's already issued):

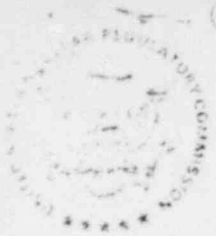
Bellefonte	12 man-days
Byron/Braidwood	5 man-days
Comanche Peak	12 man-days
Diablo Canyon	12 man-days
Farley-2	12 man-days
Fermi-2	7 man-days
Grand Gulf	4 man-days
LaSalle	7 man-days
McGuire	12 man-days
Midland	12 man-days
North Anna-2	12 man-days
Salem	12 man-days
San Onofre 2,3	12 man-days
Sequoyah	12 man-days
Shoreham	7 man-days
Summer	12 man-days
Susquehanna	4 man-days
WPPSS-2	7 man-days
Watts Bar	12 man-days
Zimmer	7 man-days
Total	192 man-days

Incorporating these changes in reviews which have not started would take no more than one man-day each.

These concerns/considerations were raised in a meeting of the Initial Test Program and Conduct of Operations section on May 10, 1979.

Brent Clayton

for Robert J. McDermott
Quality Assurance Branch
Division of Project Management



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAY 24 1979

Exhibit 1096.

MEMORANDUM FOR: Donald J. Skovholt, Assistant Director for Quality Assurance & Operations, Division of Project Management

FROM: Walter P. Haass, Chief, Quality Assurance Branch, Division of Project Management

SUBJECT: RECOMMENDED CHANGES TO QAB REVIEW OF INITIAL TEST PROGRAMS RESULTING FROM THE TMI-2 ACCIDENT

As indicated in the enclosed memorandum, the Initial Test Program/Conduct of Operations Group within QAB has developed a set of recommendations to supplement the normal review of test programs described in FSAR's. The recommendations are based on our present knowledge of the TMI-2 accident. With your approval, I recommend that the following course of actions be adopted:

a. For those items that affect the QAB review only, develop a technical position that has QA Branch and your approval, at a minimum, and is documented as either a BTP and/or a modification to a regulatory guide. This would apply to items 1, 2, 3, 4, 5 (first sentence), 6 (initial portion), and 7.

b. Transmit new technical positions as they are developed and approved to OSD for formal codification, and to the "Lessons Learned" task force.

c. Prepare specific recommendations for transmittal to other NRR divisions, as appropriate. This would apply to items 5 (second sentence), 6 (latter portion), 8, and 9. Again, the "Lessons Learned" task force would be kept informed.

d. Implement new technical positions resulting from a above in OL reviews as outlined in item 12c.

We are prepared to discuss the above recommended course of actions and the recommended changes to the QAB review process with you at your earliest convenience.

Walter P. Haass

Walter P. Haass, Chief
Quality Assurance Branch
Division of Project Management

Enclosure:
Memo, R. McDermott to W. Haass
dated May 22, 1979

cc: R. McDermott
D. Gilray
D. Clayton

Exhibit 1097

U.S. DEPARTMENT OF COMMERCE
National Technical Information Service
PB-272 040

A Study of the Nuclear Regulatory Commission Quality Assurance Program

Sandia Labs, Albuquerque, N Mex

Prepared for

Nuclear Regulatory Commission, Washington, D C

Aug 77

PB 272 040

NUREG-0321

A STUDY OF THE NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE PROGRAM

Sandia Laboratories

for

U. S. Nuclear Regulatory Commission

Available from
National Technical Information Service
Springfield, Virginia 22161
Price: Printed Copy $5.50; Microfiche $3.00

The price of this document for requesters outside of the North American Continent can be obtained from the National Technical Information Service.

NRC FORM 335 (7.77)

U.S. NUCLEAR REGULATORY COMMISSION

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This report contains recommendations from a three month study of quality assurance in nuclear power plants as it is practiced in industry and regulated by the NRC. Requested by the NRC, the study was accomplished through on-site visits by Sandia personel at NRC offices and industry locations and through discussion with relevant technical society groups and interested individuals. The study group recommended changes to improve QA regulation by the NRC, to improve industry application of 10CFR50, Appendix B criteria, and to extend and expand the scope of QA activities by both industry and NRC.

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A STUDY OF THE NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE PROGRAM

F. W. Muller and others

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Sandia Laboratories
P. O. Box 5800
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A STUDY OF THE NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE PROGRAM

ABSTRACT

This report contains recommendations from a three month study of quality assurance in nuclear power plants as it is practiced in industry and regulated by the NRC. Requested by the NRC, the study was accomplished through on-site visits by Sandia personnel at NRC offices and industry locations and through discussion with relevant technical society groups and interested individuals. The study group recommended changes to improve QA regulation by the NRC, to improve industry application of 10CFR50, Appendix B criteria, and to extend and expand the scope of QA activities by both industry and NRC.

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

SUMMARY

At the request of the Nuclear Regulatory Commission (NRC), a Sandia Laboratories study group has investigated the Commission's regulatory activities pertaining to quality assurance for nuclear power plants. The study analyzed representative aspects of the NRC quality assurance (QA) program, evaluated the program's philosophy and practices, and identified potential program improvements. The study group evaluated the quality assurance activities of both the NRC and the nuclear power plant industry, for consonance with NRC's definition of quality assurance as "all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service." The study did not evaluate the safety of nuclear power reactors.

The group gathered information through: (1) discussions with representatives of NRC and industry organizations, professional societies, and industry standards development groups, and also with selected individuals; (2) observations of industry and NRC activities; and (3) reviews of documentation and literature pertaining to nuclear power and its regulation.

The addition of Appendix B to Title 10 of the Code of Federal Regulations, Part 50 (10 CFR 50, Appendix B) has established requirements for administrative systems pertinent to quality assurance, and thereby has ensured consistent recognition and application of quality assurance practices in the nuclear industry. In our examination of quality assurance activities we observed that assurance measures have been applied to the design, construction and operation of all nuclear power plants, and that the NRC continuously strives to improve and expand these measures.

The beneficial impact of existing NRC quality assurance activities is apparent. However, based on the results of our survey and the stringent demands for reactor safety (and, therefore, on quality assurance), we conclude that further improvements are warranted in both industry quality assurance programs and NRC regulation of these programs. For the NRC program these improvements involve (1) the communication of regulations and guidance, (2) the definition and communication

of responsibilities and authorities of offices and other organizations, and (3) the capability for inspection and enforcement. For industry, these improvements include more intensive application of measures required by 10 CFR 50, Appendix B, particularly by strengthening planning activities and by increasing emphasis on certain aspects of testing and auditing.

We note that the NRC has not required the use of certain techniques which have been found valuable in other quality assurance programs. These techniques include the application of reliability models and analysis of unreliability modes and rates. The use of these techniques can provide a systematic structuring of the quality assurance program, and thus strengthen the program. Additional benefits, such as the provision of bases for utilizing test and operating experience for determining quality assurance effectiveness, can also result from the use of these techniques.

In accordance with these conclusions, we recommend that:

- The NRC strengthen, through its communications to industry, recognition of the Standard Review Plan as the basic source of guidance on quality assurance requirements.

- 10 CFR 50, Appendix B be used in the regulation of all areas of power reactor design, construction, and operation which are judged to have sufficient importance to safety to fall under other NRC regulation. The selective application of QA elements now applied to safety-significant items not interpreted as falling under Appendix B should be replaced by an approach in which the degree to which the 18 criteria of Appendix B are applied would reflect the safety significance of the item.

- The Transfer of Lead Responsibility Memo be revised (or that some supplemental means be established) to provide a schedule for completion of activities and a status reporting mechanism, for problems requiring action by both the Office of Inspection and Enforcement and the Office of Nuclear Reactor Regulation.

- The NRC take steps to assure that each vendor inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) is aware of the continuing

responsibility and authority of the licensee with respect to vendor quality assurance.

- IE headquarters clarify responsibility for inspection of quality assurance activities of utility-run architect-engineers as belonging either to the regular inspection and enforcement program or to the Licensee Contractor and Vendor Inspection Program (LCVIP).

- Vendors to be inspected under the Licensee Contractor and Vendor Inspeetion Program (LCVIP) be selected on a basis which ensures that every vendor has some likelihood of being inspected.

- IE inspection of material produced under the ASME Code provisions be eliminated, but only if the ASME requirements are expanded to include operation. Since efforts in this direction are under way, this recommendation is intended to encourage such efforts.

- The Inspection and Enforcement staff strengthen its review of the inspectability and enforceability of Technical Specification requirements.

- Routine direct NRC inspection and testing of hardware be increased, and that data pertinent to quality decisions made in the construction and operation of a plant be evaluated by the NRC on a routine basis. (This includes the evaluation, for example, of radiographic and ultrasonic test data.)

- IE inspections for QA program implementation during construction (Modules 35700B through 35736B of the IE Manual) be conducted more frequently during the period of personnel turnover prior to operation.

- Qualification testing be required for design verification when practicable.

- IE inspections "QA Program (Receipt, Storage and Handling of Equipment and Materials)" (Module 35720B of the IE Manual) and "QA Program (Test and Measurement Equipment)" (Module 35736B) be conducted more frequently during construction.

- The NRC establish requirements and guidance for comprehensive qualification and proof test programs, similar in detail to the requirements and guidance for preoperational and startup testing programs. The guidance should include criteria for practicability.

- The NRC actively continue support of cooperative audit programs in the industry, especially programs for the sharing of audit data among licensees and contractors, and for the conduct of joint audits.

- The NRC adopt, for nuclear power plants, a more systematic, yet simple method of representing hardware and human performance characteristics that are significant to safety. This method should address the importance to safety of these characteristics and should also consider their unreliability modes and rates, in order that a more comprehensive quality assurance program can be applied. Toward this end, we recommend the use of simplified event models and equations within the industry and the NRC.

- The quality assurance planning and evaluation function in the NRC be assigned to a separate group. This function would include:

  1) Performing continuing reviews of all assurance measures in standards, Regulatory Guides and Standard Review Plans for consistency and adequacy,

  2) Evaluating overall QA effectiveness (ultimately by comparing assessments of the reliability of reactor safety features from all plants with established goals) and recommending programmatic improvements when indicated, and

  3) Developing and implementing improved quality assurance techniques.

The study group previously had only minor contact with commercial nuclear power plants and, as a result, had few preconceptions concerning either the status or form of quality assurance in the nuclear industry. However, members of the group have had a substantial background in quality assurance as applied to nuclear ordnance systems. A brief description of Sandia Laboratories quality assurance activities and resumes of the major contributors to the study are contained in Appendix D.

Nuclear power plants and the nuclear weapon ordnance system hardware which Sandia Laboratories is concerned with differ significantly in important attributes such as complexity and size. However, nuclear weapon system reliability can be compared to the reliability of safety features in nuclear power plants. Some power plant systems operate continuously, but many of the systems of interest, in each case, are called upon to function after long periods of inactivity. This leads to correspondence, in concept, between safety features of reactors and reliability features of nuclear ordnance. Evaluation techniques and insights gained from one program are relevant to the other. Because of the similarity in requirements and concepts noted above, it was considered that the practices of quality assurance for nuclear ordnance would (with modifications to accommodate the differences in the character and context of the two industries) provide a reasonable base for the evaluation of nuclear power quality assurance. Consequently, in evaluating NRC and industry activities and developing recommendations for potential improvements, we have attempted to apply some of the techniques that have been found useful in our nuclear ordnance quality assurance program experience.

In the course of the study, the study group developed a general understanding of the nuclear power industry and the regulatory activities of the NRC. Within this general context we addressed those regulatory activities -- principally in the Offices of Nuclear Reactor Regulation (NRR), Inspection and Enforcement (IE), and Standards Development (SD) -- which are related to quality assurance for the design, construction, and operation of nuclear power reactors. By agreement with NRC, the study has not addressed the following areas:

- An evaluation of the safety of nuclear power plants.

- Quality assurance for other parts of the nuclear fuel cycle, such as the regulation of enrichment or reprocessing facilities or the transportation of new or spent fuel.

- Quality assurance for activities having to do with the physical protection of facilities or with the control of special materials.

Because of the limited resources and time to perform the study, we did not learn enough of the technical details of nuclear power plant design, construction, and operation to address all specific technical aspects that were considered to fall into the province of quality assurance. In such areas the study group examined the pertinent regulations and practices to determine emphasis and direction.

Quality Assurance Defined

The definition of quality assurance given in the introduction to 10 CFR 50, Appendix B, is that it "comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service." This broad definition of quality assurance is compatible with Juran's discussion of quality in terms of "fitness for use" (see Juran, section 2, pps. 2-1 through 2-12). "Quality of conformance" (to specifications) is one parameter of fitness for use, and an equally important parameter is the "quality of design" which considers the adequacy of specifications and any implied requirements necessary for the product to do what it is intended to do. NRC has dealt with both of these parameters in its regulation of quality assurance, but quality of conformance is addressed primarily by 10 CFR 50, Appendix B and quality of design is addressed primarily in other parts of the regulations.

There are a number of aspects of nuclear reactor facilities — safety, reliability, availability, capacity, cost, etc. — which affect fitness for use.

Most of these aspects are of principal interest to the industry and are not addressed in this study, except where attention given them may affect reliability of safety systems. Quality assurance activities provide industry's assurances that safety, availability, capacity, and cost objectives will be met, but we have concerned ourselves only with quality assurance related to safety features, since safety is the primary concern of the NRC.

The study group used the definition of quality assurance given in 10 CFR 50, Appendix B as the referent for evaluating the QA program for nuclear power plants. Although this broad definition increased the scope of the study, it permitted an evaluation of activities in terms of the overall goal of assuring the reliability of the safety features of nuclear power plants. Such a scope for the study was felt to be more meaningful than a narrower scope using a definition of QA as conformance to specifications. Appendix B of this report amplifies on the definition of QA, and identifies the functions necessary to achieve this broad assurance.

Nuclear reactor safety depends upon features of nuclear plants which prevent or mitigate the consequences of accidents. It is to assure the desired performance of those features that activities pertinent to quality of design and quality of conformance are required. Thus a restatement of the definition of quality assurance which was used for the study would be, "all those planned and systematic actions necessary to provide adequate confidence that the features of nuclear power plants which prevent or mitigate the consequences of accidents will perform reliably in use."

Conduct of the Study

The first effort of the study was to learn how the NRC conducts its operations, and how the various organizations in the NRC contribute to the assurance of quality. Three two-man teams spent two or more weeks at NRC headquarters interviewing personnel in all NRC organizations that appeared to be directly involved in assurance activities. Most of this time was spent in the Offices of Standards Development, Nuclear Reactor Regulation, and Inspection and Enforcement. The Office of Nuclear Regulatory Research (RES) was not visited

because some members of the study group had become familiar with RFS programs during review of the Reactor Safety Study (WASH 1400).

Other offices and organizations visited included:

- Office of Inspector and Auditor
- Office of Planning and Analysis
- Office of Management Information and Program Control
- Office of Policy Evaluation
- Statistical Staff for the Technical Adviser to the Executive Director

Some discussion with legal and public affairs personnel also was included in our NRC contacts to identify the particular problems NRC faces in these areas.

A considerable amount of documentation was collected at NRC headquarters for later study. These included regulations, Regulatory Guides and associated standards, internal NRC guidance and procedures, examples of Preliminary and Final Safety Analysis Reports (PSARs/FSARs or SARs), Standard Review Plans, status documents, etc.

With the background provided by the NRC visits and the material obtained from the NRC, representative organizations within the nuclear industry were selected for visits to determine the manner and extent to which QA was practiced in the industry, and to judge the effectiveness of that effort. Meetings were also held with industrial groups, concerned individuals, technical and industrial societies engaged in standards activities, and four NRC Regional Offices. A list of facilities visited and persons interviewed is given in Table 1-1.

The visits were arranged by the NRC, but no NRC personnel accompanied us to the places visited. It was felt that more candor was possible if only the study group members were present, and if it was agreed that anonymity would be preserved to the fullest extent possible. Unless a serious safety problem was observed (none

TABLE I-1

Contacts Made During Study

UTILITIES	
North East Utilities	Hartford, CT
Duke Power	Charlotte, NC
Philadelphia Electric Co.	Philadelphia, PA
Indiana & Michigan Power Co.	Benton Harbor, MI
Florida Power Co.	St. Petersburg, FL
PLA's	
Millstone 1,2 and 3	New London, CT
McGuire 1,2	Terrell, NC
D. C. Cook 1,2	Benton Harbor, MI
Crystal River 3	Crystal River, FL
A-Es	
Stone & Webster	Boston, MA
Duke Power	Charlotte, NC
United Engineers & Constructors	Philadelphia, PA
NSSS	
Babcock & Wilcox	Lynchburg, VA
Combustion Engineering	Windsor, CT
General Electric	San Jose, CA

TABLE I-1 (Cont'd)

VENDORS	
Atwood & Morrill (valves)	Salem, MA
Westinghouse EMD (Pumps)	Pittsburgh, PA
Combustion Eng. (pressure vessels)	Chattanooga, TN
Allegheny Ludlum Steel	Pittsburgh, PA
Babcock & Wilcox (fuel)	Lynchburg, VA
General Electric (instrumentation)	San Jose, CA
Southwest Research (vendor services, Nuclear Plant Reliability Data System)	San Antonio, TX
REGIONAL OFFICES	
Regions I, II, IV, and V	
INDUSTRY GROUPS & ASSOCIATIONS	
Edison Electric Institute (EEI), QA Mgrs.	
Atomic Industrial Forum (AIF)	
American Society for Quality Control (ASQC) Nuclear Division Conference	
American Nuclear Society (ANS) Executive Conference	
SELECTED INDIVIDUALS	
Dan Ford (Union of Concerned Scientists)	
Edward A. Reynolds (QA Consultant)	
STANDARDS ORGANIZATIONS	
American Society of Mechanical Engineers (ASME)	
American National Standards Institute (ANSI)	
Institute of Electrical and Electronics Engineers (IEEE)	

was), remarks or observations were only to be used in support of general findings and recommendations addressed towards improvements in the NRC regulatory process.

These visits, varying in length from a few hours to a week at each place, occupied the study group for about three months. Two-man teams, generally consisting of one QA engineer versed in audit or survey practice, and another representing a background in QA program evaluation and advanced planning, visited each site. An effort was made to expose each team member to all types of organization in the nuclear industry, i.e., utility, plant, architect-engineer (A-E), nuclear steam system supplier (NSSS), and vendor.

While the visits involved only a small percentage of the overall nuclear power industry, the combination of discussions and observations at the places visited and the additional study of documents and literature provided a reasonable grasp of the industry in general and the activities pertinent to quality assurance in particular. A description of those characteristics of the nuclear industry and the NRC which we believe are pertinent to quality assurance is presented in Appendix A of this report. Readers not familiar with the processes by which nuclear power plants are designed, constructed, operated and regulated are referred to Appendix A.

It is important to recognize that the nuclear power industry is broad and diverse. Not all of the observations in this report which prompted recommendations are uniformly characteristic of the industry, but they indicate the need for additional NRC control. In this report, we have focused our recommendations on those areas where, to us, the need for further improvement was apparent and likely to be significant. We neither stressed in the study, nor reported in detail, areas where the NRC and industry quality assurance activities are strong and effective.

In general, our recommendations are directed to achieving QA goals; thus, recommendations have been placed in the context of identifying what is needed, rather than offering specific details for accomplishment. Examples of how recommendations might be implemented are given, but we have attempted to avoid encroachment on NRC options, especially in the area of organizational adjustments.

The ideas presented in this report reflect the study group's independent judgment, but are not necessarily novel or original. We have examined some earlier evaluations of the NRC QA program, and have noted similar ideas for potential improvements. We are aware that at least part of what we present here has been anticipated by others. The bibliography lists some studies and reports dealing with regulation and quality assurance.

We wish to acknowledge here the assistance of both NRC staff and others who participated in this study. Their assistance was freely given, and the cooperation which we received was invaluable in achieving the study goals.

CHAPTER II

GENERAL ASPECTS OF ASSURANCE REGULATION

The scope and complexity of The Nuclear Regulatory Commision's activities pertinent to quality assurance have grown rapidly over the past several years. This growth has resulted in increasing demands for initiating and communicating quality assurance requirements, and also in inspecting and enforcing compliance. Although the NRC has taken positive steps to accommodate these demands, there are additional steps that the NRC can take to improve the general characteristics of quality assurance regulation. Recommendations for improvements to those characteristics are described below.

Provision of Guidance

The NRC quality assurance program depends on licensees meeting requirements which have been established by regulation. Thus, clear and understandable communications of requirements from the NRC to licensees are vital to QA program success. The regulations themselves -- 10 CFR 50.34 and 10 CFR 50, Appendix B -- are broad and are oriented toward results rather than methods. Eleven of the eighteen Appendix B criteria begin, "Measures shall be established to ...." The choice of specific measures to be employed is left to the licensee, subject to approval by the NRC staff.

The NRC has implemented several channels of guidance defining acceptable methods. More than 100 Regulatory Guides covering specific topics have been issued by the Office of Standards Development, following review and concurrence by the other affected NRC Offices. These guides often endorse industry standards documents, with or without modifications and/or exceptions. Branch Technical Position papers are published by individual technical review branches in the Office of Nuclear Reactor Regulation (NRR). Three documents (WASH-1283, WASH-1284, and WASH-1309) were published in 1973 and 1974 to provide guidance on quality assurance requirements. These books collected various sources of guidance together. Although they are now out of date, they are still referred to because of their usefulness as a single source of QA guidance.

The Office of Nuclear Reactor Regulation (NRR) has prepared a series of Standard Review Plans (SRPs) for the guidance of its staff in reviewing SARs. These SRPs spell out guidance directly in addition to referencing Regulatory Guides, industry standards, Branch Technical Positions, and, occasionally, other sources. The various SRPs are keyed to sections in the SAR format standardized by Regulatory Guide 1.70. Thus, the set of SRPs covers all guidance pertinent to the SAR and is indexed to the SAR table of contents.

NRC guidance documents, in general, bear more weight than the word "guidance" would normally imply. The following quotation from the Introduction to the Standard Review Plans reflects a significant impediment to approaches other than those contained in NRC guidance. "Like Regulatory Guides, the Branch Technical Positions and Appendices represent solutions and approaches that are acceptable to the staff, but they are not required as the only possible solutions and approaches. However, applicants should recognize that, as in the case of Regulatory Guides, substantial time and effort on the part of the staff have gone into the development of the Branch Technical Positions and Appendices and that a corresponding amount of time and effort will probably be required to review and accept new or different solutions and approaches". Discussions with a number of industry representatives led to the observation that, in view of this unavoidable increase in review effort, utilities often conclude that proposing alternatives to solutions and approaches identified in NRC guidance would be too costly. In these cases the NRC guidance serves as de facto regulation.

To evaluate what licensee activities fall under the individual criteria of 10 CFR 50, Appendix B, the study group reviewed the NRC guidance documentation relating to each criterion. Tables II-1 and II-2 illustrate the difficulty in identifying various sources of guidance for two of the Criteria: X (Inspection) and XI (Test Control).

Table II-1 begins with Criteria X and XI of 10 CFR 50, Appendix B in the center and follows two separate routes toward more specific guidance. To the right of the criteria, we have listed those Regulatory Guides which we identified (through review of all Regulatory Guides) as pertaining to inspection and/or testing. Several of the listed Regulatory Guides refer in turn to industry

TABLE II-1

Guidance for Inspection and Test Control

Determined From Review of Standard Review Plans		Determined From Review of Regulatory Guides	
STANDARD REVIEW PLANS	APPENDIX B CRITERIA	REGULATORY GUIDES	INDUSTRY STANDARDS
See Table II-2 For References From These Standard Review Plans: 3.8.1, 3.8.2, 3.8.3, 3.8.4, 3.8.5, 3.9.4, 3.11.2, 4.2, 6.3, 6.6, 7, 8., 14.1, 14.2, 16, 17.1, 17.2	X, XI	1.10	
		1.15	
		1.18	
		1.19	ASME Code III & VIII
		1.20	
		1.28	ANS N45.2
		1.30	ANSI N45.2.4 (IEEE 336)
		1.33	ANSI N45.2
		1.34	ASME Code
		1.41	
		1.52	
		1.56	
		1.63	
		1.68	
		1.68.1	
		1.70	
		1.79	
		1.80	
		1.89	IEEE 323
		1.90	
		1.94	ANSI N45.2.

TABLE II-2

References From Selected Portions of the Standard Review Plan

STANDARD REVIEW PLAN	INDUSTRY AND GOVERNMENT STANDARDS	REGULATORY GUIDES	10 CFR 50 REFERENCES
3.8.1	ACI 359 (ASME Boiler & Pressure Vessel Code, Section III, Division 2)	1.10 1.15 1.18 1.19 1.35 1.55 1.70 1.90	Appendix A Criteria 2, 4, 16,50
3.8.2	ASME Boiler & Pressure Vessel Code, Section III, Division 1, Subsection NE	1.57 1.70	Appendix A Criteria 2, 4, 16, 50
3.8.3	ACI 318 ACI 359 ASME Boiler & Pressure Vessel Code, Section III, Division 2 (ACI 359) & Subsections NE, NF AISC "Specification for the Design, Fabrication, and... of Structural Steel..." ANSI N45.2.5	1.10 1.15 1.55 1.57 1.70	Appendix A Criteria 2, 4
3.8.4	ACI 318 AISC "Specification for the Design, Fabrication, and... of Structural Steel..."	1.70	Appendix A Criteria 2, 4
3.8.5	ACI 318 AISC "Specification for the Design, Fabrication, and... of Structural Steel..." ASME Boiler & Pressure Vessel Code, Section III, Division 2 (ACI 359)	1.70	Appendix A Criteria 2, 4

ACI - American Concrete Institute
AISC - American Institute of Steel Construction

standards; some of this guidance is also shown in the table. To the left, we have listed the Standard Review Plans which a review of Regulatory Guide 1.70 (Standard Format and Content of SAR's) identified as pertaining to inspection and/or testing. In the case of Standard Review Plans, the references to standards, Regulatory Guides, and portions of 10 CFR 50 are too extensive to permit their tabulation in Table II-1. Therefore, Table II-2 lists, for some of the Standard Review Plans in Table II-1, the references to standards, Regulatory Guides, and portions of 10 CFR 50. It should be noted that the listings of guidance provided in these tables are not complete in the sense that standards often reference other standards and we have not pursued these references.

The volume and variety of guidance place a burden on the industry. Extensive research is required, on the part of each applicant, first to find all of the guidance, and then to determine what is pertinent to his situation. Also, since different forms of guidance on a given topic usually emphasize different aspects of the topic, the guidance sometimes appears confusing or even contradictory. These characteristics of the guidance system limit the efficient control of industry quality assurance activities by the NRC.

For the efficient communication of guidance, we believe that there should be one basic source for all guidance. This basic source should contain, or reference other sources which contain, optional methods of compliance, pertinent standards, clear definition of all terms, information on how the particular topic will be reviewed by NRR, and the criteria the NRC will use in judging acceptability. Since the SRP has these characteristics, and is available to the public, the NRC treats it as the basic source of guidance on quality assurance requirements. We recommend that the NRC strengthen, through its communications to industry, recognition of the Standard Review Plan as the basic source of guidance on quality assurance requirements.

Although such increased emphasis on the SRP as the basic guidance source would reduce the difficulty in understanding the guidance, an increased effort within the NRC in reviewing all forms of guidance for consistency and adequacy is also desirable. Such a review effort could be obtained through the assignment of a planning and evaluation function, which is discussed in a later section.

Applicability of QA to Other Plant Systems

Appendix B of 10 CFR 50 is not used in the regulation of several areas whose importance to safety has been acknowledged by the NRC by issuing specific regulations and prescribing inspections. These areas include the handling of spent fuel and radioactive waste at reactor facilities, occupational exposures, and on-site radiation monitoring and meteorological instrumentation. In these cases, which the NRC has found to be of less significance to safety than some other reactor features, only selected elements of a QA program are applied. For example, the calibration of meteorological instrumentation is covered in Regulatory Guide 1.23 and section 2.3.3 of the Standard Review Plan, both of which treat meteorological instrumentation. IE personnel provided examples relating to radiation monitoring instrumentation to illustrate the difficulty with this approach. Specifically, enforcement actions considered necessary by IE to solve instrument problems at several plants could not be taken since the Appendix B criteria were not considered applicable and since alternate requirements do not address all areas normally addressed by the Appendix B criteria.

We recommend that 10 CFR 50, Appendix B be used in the regulation of all areas of power reactor design, construction, and operation which are judged to have sufficient importance to safety to fall under other NRC regulation. The selective application of QA elements now applied to safety-significant items not interpreted as falling under Appendix B should be replaced by an approach in which the degree to which the 18 criteria of Appendix B are applied would reflect the safety significance of the item. Adoption of this recommendation would change decisions from "whether" a criteria should be applied to "how much" it should be applied.

Problem Response System

Efforts to improve the overall quality assurance program are evident in the manner in which NRC responds to problems which occur in the field. A review of NRC responses to nuclear power plant problems such as those revealed by the Browns Ferry fire (See, for example, NUREG 0050), and the set point drift problem (See USAEC publication OOE-ES-003) shows that the responses brought improvement both in the NRC QA program and in the implementation of that program.

Although the response that some problems require may be only an enforcement action, program improvement comes about through an investigation/action type of response. The NRC uses several types of responses including: investigations in the field by IE teams, bulletins distributed to the industry, staff reviews of problems, assignment of special study groups, data analysis, and hearings conducted by NRC boards.

The actions resulting from investigations, at least from the examples reviewed, tend to concentrate on improvement in the implementation of the NRC quality assurance program (for example, the improvement in coverage of instrumentation resulting from the set point drift study). In addition, instances were also noted of changes to the program itself as part of the response (for example, the establishment of an Incident Management Center as a result of the Browns Ferry experience).

One difficulty observed in the NRC problem response mechanism is determining which problems need response. Although a large number of problems are brought to light each month, few of them require more than routine reaction by the NRC. Some are reported by licensees in required Licensee Event Reports or Construction Deficiency Reports. Others are found and reported by IE inspectors. Still other problems are identified in reports from a variety of sources. The implementation of some means of sorting reported problems according to their potential significance to safety (such as described in Chapter IV) is important.

Some of the problems require cooperative action by more than one group or individual. In recognition of this situation, some NRC offices have developed systems for ensuring appropriate response. The Action Item Tracking System (AITS) in the Office of Inspection and Enforcement, for example, assigns responsibility for action, establishes a schedule for completion, and requires periodic status reports. These systems have been effective in improving the response to routine problems within the organizations where they are applied.

For problems which entail cooperative or coordinated actions between the Office of Nuclear Reactor Regulation and the Office of Inspection and Enforcement,

system has been developed for identifying responsibilities for action by means of a Transfer of Lead Responsibility Memo. This memo includes a description of the problem requiring investigation and resolution and the proposed actions to be taken by each office. Comments by NRC personnel indicate that the proposed actions are occasionally not completed in a timely fashion or that NRC personnel are not aware of the status of the actions. Our experience and IE's experience with the AITS indicate that cooperation and coordination are improved if a schedule of activities and a status reporting mechanism is established. We recommend that the Transfer of Lead Responsibility Memo be revised (or that some supplemental means be established) to provide a schedule for completion of activities and a status reporting mechanism, for problems requiring action by both the Office of Inspection and Enforcement and the Office of Nuclear Reactor Regulation.

LCVIP/Licensee Relationship

At the present time, 10 CFR 50.34 and 10 CFR 50, Appendix B hold licensees accountable for the quality assurance of all activities pertinent to the design, construction and operation of nuclear plants. The licensees are, therefore, responsible for requiring and auditing quality assurance activities of applicable contractors and vendors. In addition, the Office of Inspection and Enforcement has instituted the Licensee Contractor and Vendor Inspection Program (LCVIP) to check further on the adequacy of the quality assurance programs of those involved in design and construction of nuclear power plant components. (See Appendix A of this report for further details of the LCVIP).

Since the LCVIP is a relatively new program, its relationship to the IE licensee inspections and the required licensee auditing of vendors is still not well understood by some industrial organizations. For example, we were advised of two cases in which a company, after being inspected under the LCVIP, concluded that it was exempt from both licensee audits and compliance with licensee requests for corrective action. We recommend that the NRC take steps to assure that each vendor inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) is aware of the continuing responsibility and authority of the licensee with respect to vendor quality assurance.

It was also observed that the LCVIP activities cover all active independent

architect-engineering companies, but that, in at least one case, the quality assurance program of the architect-engineering organization within a utility had not been inspected by either the LCVIP or the local IE Region. We understand that the intent of the LCVIP is to address quality assurance for all architect-engineering work, but the responsibilities of the LCVIP and the routine IE inspection program are not clear in the case mentioned. We recommend that IE headquarters clarify responsibility for inspection of quality assurance activities of utility-run architect-engineers as belonging either to the regular inspection and enforcement program or to the Licensee Contractor and Vendor Inspection Program (LCVIP).

The function intended for the LCVIP (to supplement the licensee audits in verifying the proper implementation of quality assurance programs in NSSS, A-E, and vendor plants) would be ideally served by inspecting all vendors of all safety-related items. In the practical performance of this function, however, IE must use a more restricted approach. Generally, all NSSSs and A-Es are inspected, but vendors are selected for inspection on the basis of production volume, importance of product to reactor safety, and quality history. This vendor selection system is intended to utilize the available IE resources in areas where they would be most productive. Although all vendors are theoretically subject to inspection under this selection system, vendors of product with lesser importance to safety or vendors with low production volume do not expect to be inspected.

Frequent inspections at any location tend to reach a point of diminishing returns. After a few inspections, the most significant improvements have been effected, and subsequent inspections tend to concentrate on less important aspects of the quality program. It is usual to extend the interval between inspections when this occurs, thereby reducing the inspection load at those locations. On the other hand, when a group of contractors or vendors is never inspected, serious quality problems can remain undetected, even though a minimal amount of inspection would find the problems. Also, it is not necessary to inspect all vendors in a given grouping, as long as they are all aware that there is a possibility that any of them may be inspected. This possibility supplies a motivation for self evaluation. A vendor selection system which makes every vendor obviously subject to inspection, then, should provide a greater overall effectiveness for the inspection program, but need not require significant additional inspection

resources. We recommend that vendors to be inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) be selected on a basis which ensures that every vendor has some likelihood of being inspected.

A selection system which would provide such inspection possibilities is one which uses random sampling. Since it seems desirable to have a greater probability of selecting those vendors which, for one reason or another, are most important to nuclear plant safety, a stratified or weighted sampling plan might prove effective. For such a plan, all of the NSSSs, A-Es, and vendors might be placed in "strata," or classes, in accordance with: (1) the importance of the product or service to safety, (2) the quality history of the product or service, (3) the relation of the product or service to the total quality assurance program (i.e., will it be tested or inspected later, etc.), (4) the time since last inspection, etc. Each stratum might then be assigned a sampling rate, as necessary to provide a desired probability of selection (e.g., if it is desirable to inspect all NSSSs and A-Es, these organizations could be placed in a stratum which is completely inspected -- 100% inspection).

Quality Assurance of Code Material

There is a partial duplication of effort for material covered by both 10 CFR 50, Appendix B and the ASME Boiler and Pressure Vessel Code, which appears to be detrimental to the industry quality assurance program. Some industry organizations are inspected by NRC to assure compliance with Appendix B, and also by ASME authorized inspectors for compliance with the Code. These two documents have quality assurance requirements which are different in some important respects -- e.g., operation of hardware is not covered by the Code. In addition to the obvious waste of resources this dual inspection causes, the confusion due to partially overlapping responsibilities can lead to omission of important parts of the QA program provisions.

We recommend that IE inspection of material produced under the ASME Code provisions be eliminated, but only if the ASME requirements are expanded to include operation. Since efforts in this direction are under way, this recommendation is intended to encourage such efforts.

Inspectability of Technical Specification Requirements

Industry and NRC personnel commented on situations in which design requirements in SARs had not included provisions for inspection and testing, although such inspection and testing was required. A Technical Specification that prohibits operation of a polar crane over the reactor vessel while the vessel was pressurized furnishes an example. In this case, no interlock arrangement was required to assure this prohibition, and no documented evidence was required to provide the basis for inspection and enforcement. To minimize the possibility of such unenforceable requirements, we recommend that the Inspection and Enforcement staff strengthen its review of the inspectability and enforceability of Technical Specification requirements.

Direct Inspection and Testing by NRC

Evaluation of the control of an operation (e.g., a manufacturing process) involves two essential elements: to verify that a control system is being implemented (auditing), and to verify that the output of the operation is correct (inspection of product). Since a function of the NRC Office of Inspection and Enforcement is to evaluate the control of reactor construction and operation, the IE inspections should include both of these elements. That is, IE should both evaluate implementation of the quality assurance program and directly inspect the "product" produced under that program.

We noted that limited direct inspection and testing is presently conducted by the Office of Inspection and Enforcement. Large-scale direct testing actions by the NRC present cost (and perhaps legal) problems. However, an increase in direct testing or inspection of the "product" in the IE inspection program could be expected to increase confidence in the total evaluation. Also, in a related area, increased use of direct examination of test data to verify evaluations (such as radiographic or ultrasonic test data interpretations) by the IE inspectors would encourage increased attention, on the part of industry, to the test data. Therefore: we recommend that routine direct NRC inspection and testing of hardware be increased, and that data pertinent to quality decisions made in the construction and operation of a plant be evaluated by the NRC on a routine basis. (This includes the evaluation, for example, of radiographic and ultrasonic test data.)

Summary

The recommendations included in this chapter have dealt with the general aspects of the NRC's regulation of nuclear power plant quality assurance. The aim of the recommendations is both to improve the effectiveness of regulation and to increase the efficiency of NRC's operations.

CHAPTER III

THE CRITERIA OF 10 CFR 50, APPENDIX B

This chapter is concerned with the eighteen criteria of 10 CFR 50, Appendix B (individually or in related groups) and the NRC and industry activities pertinent to each criterion. The recommendations are for potential improvements in the industry application of specific Appendix B criteria. Recommendations concerning the general characteristics of the current industry and NRC quality assurance activities and potential additions to these activities are contained in Chapters II and IV.

The addition of Appendix B to 10 CFR 50 illustrates the continuing effort by the NRC to achieve greater assurance of the reliability of nuclear reactor safety features. The development and implementation of this regulation has reduced the variations in emphasis and application of administrative systems for assurance activities in the nuclear industry. Through Appendix B, the importance of administrative systems and the need for specific policies and organizations to address them have been identified. As a result, a substantial consistency in administrative controls has been achieved.

Industry reaction to the requirements established by 10 CFR 50, Appendix B seems to be largely positive. Although we noted a variety of complaints about specific provisions or interpretations, the utilities and their major contractors appear to recognize the need for these requirements. Where the requirements need additional definition, there is substantial industry cooperation in the development of standards.

Since the requirements of 10 CFR 50, Appendix B are policy statements rather than detailed specifications, the study group's evaluation of Appendix B criteria included the NRC guidance and the related industry standards which have been developed to elaborate and clarify the requirements.

Organization and Program

riteria I and II of 10 CFR 50, Appendix B include requirements which have to do
th administration and definition of the QA program. Criterion I (Organization):
1) places responsibility for establishment and execution of the program with the
icensee (applicant), (2) distinguishes between those functions which achieve
uality objectives through their correct performance and those functions which
erify that the quality objectives have been achieved (the quality assurance
unctions), and (3) requires independence for those performing QA functions.
riterion II (Program) requires a documented program for quality assurance,
overing all quality assurance activities and providing for the conduct of these
ctivities under controlled conditions by qualified personnel. Further emphasis on
lanning is contained in the introduction to Appendix B which identifies quality
ssurance as planned and systematic actions.

Observations of a limited number of QA programs in the nuclear industry showed that they comply with the requirements of Criteria I and II. Programs are documented, ensure the independence of QA personnel, and cover all activities included in 10 CFR 50, Appendix B. However, problems in the continuity of the program were observed during the changeover from construction to operation.

One implementation problem observed during the turnover period involved two completely independent warehousing operations going on in two different buildings. The contractor-run warehouse was an efficient operation with an experienced staff. In contrast, the operating warehouse staff were new to the job and were still setting up their procedures, although they had been responsible for material for several months. They had established a recall procedure for periodic preventive maintenance only a week before our visit and had just begun preventive maintenance on material which had been in their warehouse for a period much longer than its required maintenance interval. Another example of confusion resulting from the turnover to operating personnel was found in a standards calibration laboratory where a new recall system was being introduced; a number of instruments were found whose calibration status was unknown to any of the staff, all of whom were new to the plant.

Inquiry at other utilities revealed that the change of personnel which had contributed to the observed problems is the rule rather than the exception. It is common practice in the commercial power industry for plants to be operated by an organization within the utility which is different from the organization which is responsible for building the plant. Even when construction activities are performed by the utility itself, functions generally are transferred to a different utility organization when the plant becomes operational and, therefore, most of the personnel are changed. Control of quality-related activities during the phasing out of design and construction and during preoperational testing and plant turnover is a specific Criterion for QA program acceptability given in Standard Review Plans 17.1 and 17.2. Implementation is verified by IE inspections which determine that activities are under control at the time of inspection. To reduce transition problems, we recommend that IE inspections for QA program implementation during construction (Modules 35700B through 35736B of the IE Manual) be conducted more frequently during the period of personnel turnover prior to operation. We anticipate that licensees would respond to the recommended increase in NRC inspections by increasing their own efforts to smooth the transition from construction to operating personnel. In any event, confidence in industry QA would be increased by the lessened opportunity for problems to go undetected.

Design Control

Criterion III of 10 CFR 50, Appendix B deals with the administrative controls to be applied to the design process, but does not explicitly consider design strategies or design criteria (design input requirements). These design criteria are presented in other portions of 10 CFR 50 (50.34a, 50.55a, Appendix A, etc.) and amplified in other documents, such as ANSI N18.2 and the ASME Boiler and Pressure Vessel Code. Quality assurance pertinent to the process of translating these criteria into a final design is addressed in Criterion III.

ANSI N45.2.11, Quality Assurance Requirements for the Design of Nuclear Power Plants, is endorsed by Regulatory Guide 1.64 as being descriptive of a design control program acceptable to the NRC for complying with Criterion III. The requirements of Criterion III (proper translation of regulations and design bases into definition documents, identification and control of design interfaces, design verification, and control of design changes) are all covered in N45.2.11.

The design philosophy applied to all reactors has been to anticipate potential problems and to both prevent their occurrence and mitigate their consequences. The designs have been characterized by substantial redundancy and large design margins to accommodate potential problems.

Design control is an interdisciplinary function in that control procedures are established and implemented by a design engineering group, while the quality assurance organization's function is to insure that the proper controls are implemented. The overall goal of design control is avoidance of errors in the design process which might affect fitness for use of the product. There is a dual quality assurance function in this area -- first to insure that the controls are proper, and second to insure that the controls are implemented.

Appendix B of 10 CFR 50 allows three optional methods of design verification (design review, alternate calculations, and qualification testing). Criterion III, Regulatory Guide 1.64, and ANSI N45.2.11 all indicate that there is no preferred method. On the other hand, Regulatory Guide 1.89 (Qualification of Class IE Equipment for Nuclear Power Plants) endorses IEEE Standard 323 as an "adequate basis for complying with the design verification requirements of Criterion III." The IEEE Standard 323 indicates that qualification testing under simulated service conditions is a preferred method of design verification. Since testing is a well-established method of developing objective and pertinent QA data (see Appendix B of this report), it should be considered an important component of design verification (particularly for components required to function under accident conditions) and should be required wherever practicable.

The industry programs we examined all contained systems for design verification. However, among the methods used to verify design in accordance with criterion III, there was not an emphasis on qualification testing.

We recommend that qualification testing be required for design verification when practicable. Some discussion of practicability is given in a following section on Inspection and Test Control.

The three approaches to design verification identified in Criterion III are not direct substitutes for one another, but rather complement one another. Each is

capable of providing verification of some aspects of design that the others do not provide. For example, qualification testing will normally provide little information regarding an item's ability to survive or be maintained in a state of readiness for the forty year life now anticipated for nuclear power plants; clearly design review or alternate calculations must address this aspect of design verification. The need for design reviews and alternate calculations, therefore, should be determined by the unique contribution to design verification that they can provide over and above the contribution which may be available through qualification testing.

Documentation Controls

The requirement for documentation is either expressed or implied in all of the 10 CFR 50, Appendix B criteria. Criteria IV (Procurement Document Control), V (Instructions, Procedures, and Drawings), VI (Document Control) and XVII (Quality Assurance Records) contain specific requirements for the use and control of documentation. Guidance with respect to these requirements is contained in Standard Review Plans and Regulatory Guides, and in the industry standards which they reference. The principal standard for Criteria IV, V and VI is ANSI N45.2 (endorsed by Regulatory Guide 1.28). For Criterion XVII, extensive guidance is contained in ANSI N45.2.9 (endorsed by Regulatory Guide 1.88). A number of other Regulatory Guides and standards address documentation requirements for specific types of activities related to quality assurance.

The establishment and communication of measures pertinent to quality assurance require documentation. The procedures required to implement these measures, the evidence that procedures have been carried out, and the results of the activities involved, if they have more than transitory significance, must be recorded. As a consequence, the volume of documentation required for quality assurance is necessarily large, and it is important that the quality assurance program include provisions for the proper initiation, use and control of documentation.

The effort of Inspection and Enforcement focuses strongly on the presence and adequacy of documentation. The written description of quality assurance plans and programs, the implementing procedures, and the records of assurance activities and resulting data are all examined to a substantial degree in the inspection program.

The quality assurance program provisions for document control, procurement control, and records are specifically addressed in IE inspections. In the construction phase, inspections are designed to determine the adequacy of procedures and quality assurance records, as well as the work performed.

Comments received from industry representatives indicate a frequent concern that there is an overemphasis by the NRC on paperwork. However, since the documentation involved in quality assurance is necessarily extensive, it appears reasonable that a substantial regulatory effort would be devoted to it.

The documentation of industry quality assurance programs and program activities appears to be satisfactory. Programs and procedures are generally well defined, and records of activities are complete and available. There seems to be a general understanding of the requirements for documentation, even where there is disagreement with the need. We conclude that NRC regulation has been effective in this area.

Hardware Processing Control

The quality controls applied to the manufacturing/construction process (i.e., process control) include those which maintain identification of all materials and parts used in the process, and assure that actions performed on these materials and parts are done by qualified people using proper equipment and following approved procedures. Appendix B of 10 CFR 50 requires these controls through Criteria VII (Control of Purchased Material, Equipment, and Services), VIII (Identification and Control of Materials, Parts, and Components), IX (Control of Special Processes), XII (Control of Measuring and Test Equipment), XIII (Handling, Storage, and Shipping), XIV (Inspection, Test and Operating Status), and XV (Nonconforming Material, Parts, or Components). Some of the controls developed in the ASME Boiler and Pressure Vessel Code are also required through 10 CFR 50.55a. The requirements and guidance given in 10 CFR 50 and the supporting standards are quite comparable to those in other industries, as is illustrated in the ASQC "Matrix of Nuclear Quality Assurance Program Requirements."

The nuclear industry, as we observed it, has some general characteristics which affect the manner in which these process controls may be applied. The

installations are large, complex and costly, but the quantities of most components are quite small. The size of some of the components also increases the difficulties of maintaining control. However, in an overall sense, the uses of process controls in the nuclear industry are quite typical of those in other industries. Problem areas noted (not necessarily unique to the nuclear industry) are as follows:

A. Material Control. Maintaining control of material at a large construction site is typically a problem because of the large quantities, temporary storage locations, and the non-uniform flow of the material. We observed a number of instances of lack of control in this area. Observations included lost identification, safety-related and non-safety-related material in close proximity in violation of company QA procedures, cut-off ends of material in stock without identification, pipes not capped, unidentified nonconforming material, and personnel responsible for an environmentally controlled storage area who were unfamiliar with the environment controls. Based on the number of problems observed in just a small sample, it appears that material control needs improvement.

B. Calibration control. There are many areas in the nuclear industry which require a calibration program for tools, instruments and gages. Even if only a small number of instruments and standards are needed, the basic elements of a calibration program are required. We observed some instances of lack of control, including discontinuous control between the construction and operation phases, inadequate calibration stickers on equipment, inadequate environment controls for standards labs, and the use of "dual" programs (one set of equipment under strict control and another under no control, with the possibility of interchanging equipment between the two sets). These observations indicate that calibration controls need improvement.

We conclude that increased effort should be applied in the areas of material control and calibration control by the IE inspection program. We recommend that IE inspections "QA Program (Receipt, Storage and Handling of Equipment and Materials)" (Module 35720B of the IE Manual) and "QA Program (Test and Measurement Equipment)" (Module 35736B) be conducted more frequently during construction.

Inspection and Test Control

Criteria X and XI of 10 CFR 50, Appendix B set forth requirements for inspection and test control. These criteria establish two types of requirements. First they require that administrative systems be adopted to assure that the necessary tests and inspections are adequately accomplished. Second, they indicate in general terms what tests and inspections should be performed. The associated guidance provides additional detail for both types of requirements.

One source of guidance is the Standard Review Plans (SRPs). The general characteristics desired in the administrative systems for testing and inspection are included in SRPs 17.1 and 17.2 (Quality Assurance). A second group of SRPs provide general information on the testing and inspection to be performed. These include 3.11.2 (Qualification Testing), 6.6 (Inservice Inspection), 14.1 and 14.2 (Preoperational Testing), and 16 (Surveillance). We have attempted to illustrate the relationship of the various sources of guidance for criteria X and XI in Tables II-1 and II-2.

The regulations establishing the first type of requirement have resulted in the development of industry administrative systems for inspection and testing which seem to be uniform and consistent. In all cases observed they (1) are based on the Appendix B Criteria, (2) require that testing and inspection be done in accordance with established procedures, and (3) identify the responsibility for assuring that procedures are developed and followed. So far as we observed, the implementation of these administrative systems also appears satisfactory.

The second type of requirement established by Criterion XI, the requirement for adequate application of testing, has not been sufficiently detailed, for some types of tests, to assure a consistent industry response.

The importance of inspection and testing to quality assurance has been generally recognized (for example, Juran). The primary advantage of testing and inspection over other methods of verifying design and production is provision of direct evidence that assumptions involved in the design and production process are valid, and that all recognized considerations significant to safety have been adequately addressed. These advantages suggest that testing and inspection

should be emphasized in the nuclear industry quality assurance program. Further, since the safety of operating facilities depends upon the ability of components and systems to survive and operate in rigorous environments, environmental testing should be employed wherever practicable.

Of the five major types of testing considered in NRC regulations and guidance (qualification testing, proof testing, preoperational and startup testing, inservice inspection, and surveillance), the last three are well defined and well regulated. Common features of these three types of testing are that the activities to be performed are established clearly and in detail, either by regulation or by licensee commitments, and that inspection and enforcement effort is extensive. The industry definition and implementation of preoperational and startup testing, inservice inspection, and surveillance activities have been very effective. The NRC inspection program is naturally most effective where the licensee requirements and commitments are clearly set forth, and that is generally the case with respect to these test categories.

Requirements are not as detailed for qualification tests (tests to verify adequacy of design) and proof tests (tests to verify adequacy of production) as they are for other types of testing. Criterion XI requires that testing be employed "as appropriate." However, the definition of appropriate qualification and proof testing is not given in regulations or guidance. Further, for practical reasons, detailed description of these tests is not required in the SAR, and, therefore, not subject to review for adequacy. As a consequence, neither regulations nor licensee commitments provide a satisfactory basis for inspection and enforcement.

Thus, the determination of "as appropriate," as applied to testing, becomes a significant factor. For example, in the case of most types of nuclear hardware, preoperational and startup testing, inservice inspection, and surveillance provide the needed assurance that design and production activities have been satisfactory. Specifically, these are the types of components and systems which must survive and function under normal operating environments. However, for hardware which must function under accident conditions, we conclude that qualification testing and/or proof testing can contribute strongly to the assurance of safety. The Office of Nuclear Regulatory Research is currently conducting studies of methods for

qualification testing.

Since the cost of testing is high, indiscriminate application of qualification and proof testing should not be required. Instead, the criteria for application should be carefully and clearly developed, as they have been for preoperational and startup testing, inservice inspection and surveillance, so that testing will be applied where it is practicable and avoided where it is not.

Considerations of practicability must address such aspects as the availability of suitable test facilities, the cost of the test, both in terms of time and money, and the ability to instrument the tests well enough to obtain meaningful test information. On the other hand, the safety significance of the item and test or operating experience with similar items under service conditions should be major factors in deciding whether a given qualification test is practicable.

Based on the above, we recommend that the NRC establish requirements and guidance for comprehensive qualification and proof test programs similar in detail to the requirements and guidance for preoperational and startup testing programs. The guidance should include criteria for practicability.

Corrective Action

Criterion XVI (Corrective Action) requires that conditions adverse to quality be promptly identified and corrected, and that the causes of significant conditions adverse to quality be determined so that they can be eliminated. The pertinent guidance (N45.2, endorsed by Regulatory Guides 1.28 and 1.33; and the Standard Review Plans for SAR Chapter 17) restate the requirement without elaboration.

The observations made in this study suggest that situations requiring improvement in corrective actions still exist, but that regulation has focused considerable attention on this area. Inspection and enforcement efforts emphasize corrective action responses to problems in the industry. The IE program places considerable emphasis on the timeliness and adequacy of these responses, and involves licensees in problems occurring at suppliers. This emphasis is an important and beneficial aspect of the NRC effort, and is elevating the status of quality assurance throughout the industry.

Audits

The requirement for audits is contained in Criterion XVIII of 10 CFR 50, Appendix B. A need for external audits is also implied in Criterion VII as part of the requirement for assessing the control of quality by contractors and subcontractors. Standard Review Plans 17.1 and 17.2 identify the scope and features required in applicant audit programs, and reference ANSI N45.2 (endorsed by Regulatory Guides 1.28 and 1.33) and N45.2.12. Some additional standards such as N45.2.9 (endorsed by Regulatory Guide 1.88), N45.2.11 (Regulatory Guide 1.64) and N45.2.13 (Regulatory Guide 1.123), contain information on auditing of specific quality assurance activities.

Audits are a useful and necessary part of quality assurance programs. They have inherent limitations, however, in their ability to evaluate either the implementation or effectiveness of quality assurance programs. One limitation of audits is that the body of evidence with regard to program implementation is often quite large, involving many thousands of individual actions and similar numbers of documents. As a practical matter, an audit can examine only a small percentage of the total program, and significant information pertinent to implementation can be missed. A second limitation is the variation in effectiveness among auditors, even those with substantial background and training. Notwithstanding these limitations, audits do find problems in quality assurance programs and cause corrective actions to be taken. Another positive result of audits is the psychological impact on organizations or individuals who know that they will, or may be, audited. While audits are necessary for nuclear industry quality assurance, we believe that they should be regarded as a means of supplementing more positive assurance measures such as testing.

The Standard Review Plans, Regulatory Guides and industry standards provide sufficient guidance regarding the type of administrative system required and a general description of the mechanics of audits. Inspection and enforcement activities include examining the adequacy of administrative systems for audits and reviewing audit documentation to ascertain whether the systems are being implemented.

The structure of the nuclear industry creates a chain in which lower-tier suppliers are contractually obligated to higher-tier suppliers, who, in turn, are contracted to constructors, architect-engineers and/or steam system suppliers, who are contracted to applicants or licensees. These contractual obligations include quality assurance programs. The regulatory process imposes on applicants/licensees a requirement to assure that all applicable quality assurance activities are satisfactorily conducted. Generally, the applicant attempts to discharge part of this requirement by auditing both his own quality assurance program and, where appropriate, the programs of his major contractors. The total number of industries involved in the design and construction of nuclear plants is so large, however, that it is impractical for a single auditing organization to monitor all of the quality assurance programs of subcontractors and suppliers. As a result, applicants are forced to rely, at least to some extent, on the auditing activities of quality assurance programs distributed through the contractual chain.

A single nuclear-industry supplier may have, at one time, contracts to supply many different customers. Each of these contracts will involve quality assurance commitments. As a consequence, a supplier may be subjected to a large number of audits in a short period of time. We were advised of cases where major suppliers were audited over 200 times in one year. This proliferation constitutes a significant burden on both those audited and the auditors without providing a significant improvement in quality assurance.

In recognition of the audit proliferation problem, the NRC and the industry are examining cooperative auditing methods for reducing the amount of duplicate auditing. One method being studied is the use of industry-based audit data sharing programs, such as CASE (Coordinating Agency for Supplier Evaluation). The NRC has accepted the CASE QA Topical Report for review. Another method, which has been used on a trial basis, is the joint audit of one supplier by a group of customers.

We recommend that the NRC actively continue support of cooperative audit programs in the industry, especially programs for the sharing of audit data among licensees and contractors, and for the conduct of joint audits.

Summary

The recommendations given in this chapter have been based on observations of the NRC and industry activities pertinent to the eighteen criteria of Appendix B and the associated guidance. Adoption of these recommendations should improve the industry application of Appendix B.

CHAPTER IV

ASSURANCE PROVISIONS NOT COVERED BY 10 CFR 50, APPENDIX B

Chapters II and III of this report discuss current industry and NRC quality assurance activities and make recommendations for adjustments or modifications to those activities. In this chapter, we recommend additions to the NRC quality assurance program. The purpose of these recommendations is to make the planning and implementation of quality assurance functions more comprehensive, and to provide a more objective basis for evaluating the effectiveness of assurance activities. While the scope of the recommended additions is extensive, their incorporation would permit the quality assurance program to deal more effectively with the complex and stringent quality requirements of nuclear power plants. We believe that the initiation of measures to implement them is the most important step toward improvement of quality assurance which NRC could take at this time.

Use of Reliability* Techniques

The introduction and Appendix B of this report note that 10 CFR 50, Appendix B provides a broad definition of quality assurance that "comprises all those planned and systematic actions necessary to provide adequate confidence...." The recommendation presented in this section is intended to extend the programmatic coverage of quality assurance by adding recognized reliability analysis techniques which the study group considers best able to improve the structure of the quality assurance program under this broad QA definition.

Nuclear power plant design has incorporated many safety features. To a substantial degree, safety is achieved by active, operating devices rather than by devices which rely on passive resistance to potentially unsafe conditions.

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* As used in this report, reliability relates to the probability that a device will operate properly upon demand, and therefore includes considerations of availability. Thus, causes of unreliability include both failures and other conditions which make an item unavailable for use, such as being off line because of inspection or maintenance.

Consequently, we note that while the reliability of a nuclear power plant from the standpoint of power availability, capacity, etc., may not be of primary concern to NRC, the reliability of safety features is a legitimate and primary concern. Reliability technology, including the use of reliability data, can be applied directly to the NRC task of structuring industry QA programs and should be a part of quality programs relating to components of the engineered safety systems.

Some of these modeling techniques are discussed in Appendix C of this report, and examples of their use in a simple application are shown. Their essential element is the formal modeling method used to represent the reliability of subsystems in terms of single components. In this manner, quantitative estimates can be made of the reliability of safety features based on their component reliabilities or requirements for component reliabilities can be derived from the requirements for operation of safety features. In either case, the modeling technique fosters a methodical, detailed consideration of the interaction of components which allows incorporation of important modes of unreliability of subsystem components. It is this rigorous examination of unreliability modes which provides the structure for a stronger and more comprehensive QA program.

Therefore, we recommend that the NRC adopt, for nuclear power plants, a more systematic, yet simple method of representing hardware and human performance characteristics that are significant to safety. This method should address the importance to safety of these characteristics and should also consider their unreliability modes and rates, in order that a more comprehensive quality assurance program can be applied. Toward this end, we recommend the use of simplified event models and equations within the industry and the NRC.

Benefits

It is expected that the adoption of this recommendation will have a positive impact on nuclear power plant QA programs and on confidence in the performance of quality assurance in the industry. This positive impact will be achieved by:

A. Inclusive identification of the hardware and human performance characteristics significant to reliability of safety features.

B. Identification of the importance of performance characteristics to safety.

C. Provision of a comprehensive planning basis for QA activities.

D. Provision of a basis for utilizing test and operating experience.

E. Provision of additional bases for design review.

F. Provision of additional bases for making or reviewing decisions.

G. Provision of a basis for NRC determination of QA effectiveness.

H. Improvement of communication within the industry.

Detailed discussion of each of these benefits is provided in the following sections, in order to establish the basis for the recommendation and to indicate the overall desirability of this proposed addition to the NRC QA program.

A. Inclusive Identification of the Hardware and Human Performance Characteristics Significant to Reliability of Safety Features - Many design, production, and operating activities affect the reliability of safety features in nuclear power plants. The basic role of quality assurance is to assure that these activities needed for the required reliability are adequately implemented. In order to assure the adequacy of the quality function it is necessary to determine that it is comprehensive, i.e., that all of the hardware and activities which may significantly affect reliability of safety features have been addressed.

The need for comprehensive treatment of these safety-significant items of a nuclear power plant is acknowledged by the NRC and is explicit in the NRC regulations and guidance. Because the quantity and variety of nuclear plant components and their variation in function are so great, the distinction between those that do and do not have safety significance may not be readily accomplished by general definitions. Currently, 10 CFR 50, Appendix A is considered applicable to a list of safety-related systems whose identification is based, in part, upon analysis of accident sequences required to demonstrate that the design of safety systems is adequate to cope with events which have the potential of causing

accidents affecting the public health and safety. The SRP for Chapter 15 of the SAR takes 154 pages to cover 39 different potential accident sequences.

An accident analysis addresses system level considerations, and the identification of safety-related items is reviewed at that level. The industry develops more detailed lists at the component level. They do not, however, have a uniform and consistent method of identifying the safety-related components. For example, we were informed of instances where safety-related lists developed by A-Es were modified by utilities without discussion with the A-E. While this would not be prevented by adoption of the recommendations given above, modeling is likely to minimize the uncertainties regarding which items are safety-related.

Additionally, as mentioned in Chapter II, a number of items are not included in the list of safety-related items, but are deemed significant to safety. Modeling of all such items would provide a basis for ensuring the appropriate application of quality assurance to all items significant to safety.

B. Identification of the Importance of Performance Characteristics to Safety - Simplified event equations, described in Appendix C of this report, can provide a general indication of a component's or subsystem's importance to safety. In a reduced form, the equations can be presented as the sum of a number of multiplicative terms. In this form, each multiplicative term describes the lines of defense which are involved. The number of factors (events) in the term corresponds to the number of lines of defense. Terms consisting of a single event (called "first order" terms) are most significant to the reliability of the safety feature involved; terms consisting of two or three events (second or third order terms) normally identify events relatively less important to safety.

The allocation of unreliabilities to the various events and the consideration of common-mode potentials provides a precise indication of an event's importance to safety. In fact, they may indicate occasions where events in a higher order term are more important than those in a lower order term by virtue of the unreliability rates or common-mode potentials involved. Generally, however, the "order" of a term provides adequate definition of importance for purposes of QA.

The importance of an item may be used to identify the degree to which quality assurance measures should be applied. For example, it may be used in connection with the planning matrices discussed in C below, to verify that hardware containing first order unreliability events or expected high rates of unreliability are accorded extra emphasis in establishing requirements for qualification and proof testing, frequency of tests and inspections during operation, and maintanence policies.

C. Provision of a Comprehensive Planning Basis for QA Activities - One important aspect of quality assurance for large complex programs is that the planning of the assurance program must itself be done in a systematic way. For nuclear plants some systematic approach must be taken to make sure that all safety-related components and activities are addressed and that all appropriate assurance measures are applied.

The key to such comprehensive assurance planning is the identification of all of the QA measures which are required or applicable. Failure to properly identify and plan for a certain type of concern can have a major impact on assurance. The need to eliminate this possibility constitutes the strongest argument for systematic and thorough assurance planning. For example, if the need for testing under worst-case environments is not recognized and addressed in the planning process, the assurance for those components and systems which must function under accident conditions will be diminished. The systematic identification of tests to be conducted in relation to each failure event provides a basis for determining (1) whether the associated items have a demonstrated capability to operate or survive under all service conditions, (2) whether opportunities have been provided for observing interactions between the various parts of the system which might affect a given event (common-mode consideration), and (3) whether the hardware tested is representative of the hardware to be used in the plant.

Assurance planning also should address the degree to which inspection and maintenance considerations are built into the operating QA program, since this will influence the need for preventive measures to be taken during design and production. To illustrate, if the individual failures of redundant items can be quickly detected and corrected on a continuing basis, a somewhat higher failure rate (and less restrictive QA measures in design and production) for these items

will provide a network which is as available as one containing items with a lower failure rate (and a more stringent QA program), but a longer "down time."

One approach to comprehensive QA planning, used successfully by ERDA and DOD, is to use planning matrices. The basic intent of the matrix approach is the identification of the appropriate assurance activities for each mode of unreliability associated with a component. In the following hypothetical example (Figure IV-1) two safety-related components of an accummulator subsystem shown in Figure C-2 of Appendix C are listed in the left-hand column of a matrix, and the pertinent environments are listed at the top. Columns are provided in which to identify the item's unreliability modes and allocated rates as discussed in the following section. In this simplified illustration, the Accumulator Tank 1A and Motor Operated Valve MOV6808A are shown. In practice, all of the concerns in the Figure C-2 model would be listed. In addition to the matrix itself, Figure IV-1 lists the kinds of assurance activities which could be specified in the plan.

The matrix is filled by determining, for each block in the matrix, what activities (if any) are planned to assure that design and production activities have adequately addressed each concern for each of the pertinent environments. These planning decisions are identified in the matrix by symbols corresponding to the tests, audits, etc., selected. The completed matrix should provide evidence that, to the extent practicable, all concerns have been addressed by QA activities.

D. Provision of a Basis for Utilizing Test and Operating Experience - It is necessary to accumulate data relative to component reliability from all nuclear power plants to establish a meaningful data base to support the application of reliability techniques for assessing unreliability modes and rates for all safety-related features, and for evaluating whether unreliability events are correlated. The NRC currently supports the operation of the Nuclear Plant Reliability Data System (NPRDS), an industry-wide data collection effort to accumulate test and operating experience with reactors. While industry participation in NPRDS is presently voluntary, the NRC is strongly supporting full industry participation. The NPRDS effort is a start and, with more involvement by the NRC and the industry, could be developed into the necessary data base. Close interaction between the data collection effort and the proposed reliability

Component	Unreliability Mode	Unreliability Allocation	Worst Case Environments			Normal Operating Environments
			Pressure	Temperature	Vibration	
Accumulator Tank 1A	1. Ruptures	0.0001	Q,P,A	PO	Q	PO,I,S
	2. Water low	0.0002				I,A
Motor Operated Valve MOV8808A	1. Plugged	0.005				PO,I,S
	2. Ruptures	0.0001	Q,P,A	PO	Q	PO,I,S
	3. Closed inadvertently faulty signal	0.0001				PO,S
	4. Closed for maintenance	0.0014				A
. . .	. . .	. . .	. . .	. . .	. . .	. . .

Assurance Activities

Q - Design qualification test
P - Proof test
S - Surveillance test
PO - Preoperational system test
I - Inspection
A - Audit

Figure IV-1. Illustrative Example of Comprehensive Planning Matrix

modeling effort would result in maximum benefits from each. In particular, descriptions of unreliability events should influence the manner in which data are collected and the kind of data available from the industry should limit the degree of detail incorporated into modeling efforts.

E. Provision of Additional Bases for Design Review - The establishment of simplified reliability models and rate allocations for reactor safety features provides a desirable basis for QA participation in design reviews. During the study we found that design measures for accommodating errors (i.e., use of redundancy, design margins, etc.) in reactors are based on (1) deterministic criteria whose blanket application does not consider, for the hardware involved, factors which might affect either the failure rates or common-mode failure potentials (such as complexity or difficulty of fabrication), or (2) a qualitative approach to reliability.

One example of the deterministic criteria approach is the "single failure criterion" (10 CFR 50, Appendix A) used for establishing redundancy requirements. In implementing the single failure criterion, the accident analysis required for Chapter 15 of the SAR examines the effect of a single active component failure in conjunction with an initiating event. All other components are assumed to work. This imposes an amount of redundancy that, depending upon the various factors mentioned above, might be inappropriate. For example, three or more devices should be used if two could not be made to perform reliably enough or if the failures tended to correlate. Design review based on unreliability rate analysis can generally identify such situations, even when there is only generic data to assess failure rates.

Another related example is the "defense in depth" concept often cited as the basis of reactor safety. We found that it is sometimes interpreted as meaning that a design should be such that a number of different things must occur before an accident will result. This is a qualitative interpretation of the probabilistic notion that by providing a design in which a number of improbable, uncorrelated events must occur to produce an accident the probability of an accident can be made very small. A design review based on the results of reliability analysis can help in assuring that unreliability events are both improbable and uncorrelated.

F. Provision of Additional Bases for Making or Reviewing Decisions - Many decisions by both the industry and the NRC are based on qualitative evaluations of importance to plant safety, without explicit identification and consideration of the reliability factors involved. It is our judgment that both NRC reviews of industry decisions and NRC decision making would benefit from the quantification of contributions to reliability of reactor safety features. This includes decisions regarding the acceptability of SARs, judgments regarding appropriateness of corrective actions, requirements for backfitting plants, and the significance of failure to comply with specifications in particular instances.

G. Provision of a Basis for NRC Determination of QA Effectiveness - A most significant function of quality assurance as defined by 10 CFR 50, Appendix B, Juran, et. al., is to determine that the many activities which affect quality and its assurance are accomplished effectively. Juran defines quality assurance in precisely this way, stating that quality assurance is the management responsibility to determine that the quality function is adequately performed. The NRC has recognized the need to address the question of QA program effectiveness, as is evidenced by numerous ad hoc studies by various NRC groups and by the solicitation of this study.

Reliability modeling and assessment of unreliability rates, which are based on the use of test and operating data, should be used to evaluate the effectiveness of assurance activities. Unless this is done, it is necessary to utilize conservative approaches to the implementation of quality practices. That is, quality practices are often utilized, not because it is known that they are needed, but rather because there is no convincing way to show that they are not. The application of experience data in reliability modeling may provide a rational basis for the relaxation of quality requirements.

Further, without appealing to experience data, the effectiveness of a QA program can only be judged in relation to substitute criteria which are often only indirectly related to the goal of assuring the reliability of safety features. Such substitute criteria as "good quality practice," and the numbers of noncompliances, findings, and corrective actions, become the "yardsticks" for gaging whether more or less effort should be expended in a given area. While the use of such substitute criteria may be warranted, these criteria should be

calibrated frequently against the degree to which the overall objective of quality assurance is being achieved. Formalizing the assessment of reliabilities of safety features of nuclear power plants would facilitate this calibration.

The study group was asked to assess the effectiveness of the NRC QA program. However, without direct measures of reliability attained we could only apply some additional substitute criteria in attempting to answer this question. We made comparisons of the assurance activities in the nuclear industry with other quality assurance programs, but with the recognition that this is not automatically a valid basis for recommendations. For example, it is not obvious that the activities in widely different industries should be alike, or that being alike (in those characteristics we have been able to observe in this brief study) they will necessarily be similar in effectiveness. In previous chapters we have offered a number of recommendations in areas where we believe the translation from one industry to another to be valid, but we are unable to make any claim of comprehensiveness. Consequently, we believe that the major recommendations of this study are those which will enable the NRC to evaluate assurance activities routinely, objectively, and comprehensively, based upon analysis of test and operating experience.

H. Improvment of Communication Within the Industry - The clear communication of quality assurance requirements, and their importance, to all those in the industry and the NRC whose actions can affect the reliability of safety-related hardware provides the opportunity for each person to perform his QA function knowledgeably and responsibly. This is particularly important since the effect of individual activities on the performance of reactor safety features is often difficult to discern. Consequently, event equations, the definitions of the events, their allocated reliability goals, and their assessments should be widely distributed and used. These serve as identification of items significant to safety (thereby requiring QA), the extent of their significance, and their quality status.

Implementation of Reliability Analysis Techniques

The foregoing expression of need to use the techniques of reliability analysis and the benefits to be derived from such analysis by the quality assurance program

provides little insight of the program's scope and the resources to be committed should NRC act to implement this recommendation. To a large extent these features depend upon the philosophy of the program instituted. Given the internal structure of NRC and its interface with the nuclear power industry, the study group cannot fully anticipate the program that might be adopted or evaluate the full program costs. However, we can offer our visualization of a program and evaluate the resources necessary for its execution.

The basic philosophy of the program visualized by the working group is that it should be the responsibility of the nuclear power industry to develop and use the reliability analysis techniques in support of their QA programs. The scope of the analysis should include plant-specific items up to the subsystem level at each reactor. The corresponding NRC responsibility should be to specify, in general, the techniques and applications to be used and to examine the industry QA programs to assure compliance. Thus the NRC through its SD, NRR, and IE Offices must become sufficiently familiar with reliability techniques to be able to formulate appropriate Regulatory Guides, sections of the SRP and Inspection Manuals.

The reliability techniques required to achieve the above are within the grasp of the technical people already within the NRC and the industry. In fact, these techniques merely represent a formalized way of structuring the concerns that the industry now addresses in power plant design. While we visualize the need to utilize plant specific models, we are not suggesting an effort comparable to the Reactor Safety Study for each plant. The reliability techniques advocated here are simpler and apply only to subsystem levels and below. The intent of the modeling effort is not to provide for risk assessment, but to consider only the reliability of hardware and human performance which is properly addressed by QA programs. For this purpose, simplification of the analysis can be achieved with conservative models which, for example, would not acknowledge improbable or uncertain ways system operation might be achieved. Only in those exceptional cases where the conservatism itself appears to be responsible for excessive costs would it be necessary to resort to more detailed representation.

Applicants can, we believe, prepare the necessary models in conjunction with the accident analysis now required in Chapter 15 of the SAR with some additional effort. We also believe the NRC can review whatever modeling it might deem

appropriate for the SAR with the addition of one or two specialists to the staff. The development of detailed models within the industry, and their use in QA program planning, can be inspected within the present IE framework. Although the appropriateness of the models might be verified with little addition to the inspection effort, it is expected that an increase in inspection effort would be required to verify that QA planning and implementation address appropriate measures for safety significant items identified through the modeling process.

We visualize phasing-in the program by successive implementation of three distinct levels of reliability analysis. The simplest, or lowest, level would entail the development and use of formal models to describe relationships among the causes of system unreliability. In particular, symbolic expressions would be developed which identify the significant aspects of hardware (or human) performance, and of test, inspection, and maintenance policies; and describe their logical relationships to the reliability of the safety features. Many of the benefits to the QA program discussed above can be obtained by implementing only the first level (benefit A can be realized completely; and benefits B, C, E, F, and H partially). The remaining benefits require that the second or third level be implemented.

The second level would add:

- The collection and analysis of data reflecting test and operating experience with failure modes, test and maintenance downtimes, etc., which are associated with the elements of the reliability models,

- Assessments of the reliabilities of the various safety features and their components, and finally,

- The continuing evaluation of the QA activities in light of the need to maintain a balanced overall QA effort.

Adopting the second level appears feasible for the industry, since they are already largely committed to support of NPRDS and possess the necessary expertise for performing data analysis. The major impact will be the additional data collection, particularly at lower contractor levels, and dedicating some additional

effort to data analysis.

Within NRC, additional effort will be required to verify that suitable programs are being implemented to achieve the long term objectives of this activity, to perform the necessary analysis of results to measure QA program performance in the industry, and to develop recommendations for adjustments to the regulatory process. The first activity could be achieved within the IE structure with, again, some increase in inspection effort and with some support from data analysts, while the remaining activities could be achieved effectively by a small branch or subbranch as recommended in the following section.

The third level involves an NRC provision of explicit goals for the reliability of the various reactor safety features. From a quality assurance viewpoint, the primary use of numeric probabilistic goals is to establish feedback loops which will provide continuing, objective indications of the adequacy of the QA programs throughout the industry. These goals should permit identification of attainable component reliability requirements, yet result in system reliabilities appropriate to the task of protecting the public health and safety.

We believe that, initially, goals should be established for current safety systems that are compatible with NRC assessments of the unreliability of systems fulfilling a similar role in the prevention or mitigation of accidents in licensed nuclear plants. To make these assessments, it would be necessary for NRC to use their own models or those obtained from industry together with test and operating data representing industry experience. This would seem an appropriate first task for part of the new group recommended in the next section, en route to the longer term objectives of evaluating QA performance in the industry and recommending indicated adjustments in the regulatory approaches to QA. Guidance to applicants might consist of the levels of reliability which are considered by the NRC to have been achieved in operating plants.

NRC Quality Assurance Planning and Evaluation Function

We have noted, in the section of Chapter III titled Organization and Program, the importance of systematic planning to industry quality assurance activities.

Planning is also important for the regulatory aspects of the QA program. The number and diversity of assurance activities involved in regulation is large, and the nature of the activities is such that they must be well coordinated to achieve effective regulation. For example, many quality assurance requirements are addressed by Standards Development, by Nuclear Reactor Regulation, and by Inspection and Enforcement. For effective regulation, these requirements should be treated in a consistent manner within, and among, the various NRC organizations.

Program planning and evaluation are so closely related that neither is effective if it exists in isolation. Planning cannot result in logical choices for changing program direction unless accurate assessments of present conditions are available. Complete and accurate data, collected and analysed in timely fashion, is therefore the foundation upon which effective planning rests. A group of staff specialists would be extremely useful for this planning and evaluation function, since they would possess the time and the skills required to collect information, analyse it, draft proposals for improvement, and present these proposals to line management.

In view of the above, there appears to be a need to create a separate staff assignment to perform the planning and evaluation function. The staff performing this function would be protected from the pressures of routine regulatory operations, yet be dedicated to the continuing review of all aspects of the quality assurance effort, and to making recommendations regarding program improvements. The successful performance of this function would ensure a responsive, adaptable quality assurance program. We recommend that the quality assurance planning and evaluation function in the NRC be assigned to a separate group. This function would include:

1) Performing continuing reviews of all assurance measures in standards, Regulatory Guides and Standard Review Plans for consistency and adequacy,

2) Evaluating overall QA effectiveness (ultimately by comparing assessments of the reliability of reactor safety features from all plants with established goals) and recommending programmatic improvements when indicated, and

3) Developing and implementing improved quality assurance techniques.

Summary

In this chapter, we have recommended additions to the NRC quality assurance program to improve the planning and implementation of quality assurance functions, and to provide a more objective basis for evaluating the effectiveness of quality assurance activities. While the scope of the recommended additions is extensive, we believe that their initiation is the most important step toward improvement of quality assurance which the NRC could take at this time.

CHAPTER V

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The earlier chapters of this report have presented conclusions and comments regarding specific aspects of quality assurance programs in the commercial nuclear power industry and NRC regulation of those programs. This chapter presents an overall evaluation of the regulation and implementation of quality assurance and brings together all recommendations for potential program improvements.

The NRC has exerted a continuing effort toward the improvement of quality assurance. The design and production activities in the nuclear industry (and the organizations involved in these activities) became so numerous and widely dispersed that large variations in the emphasis on, and application of, administrative systems for assurance activities tended to exist. The development and implementation of 10 CFR 50, Appendix B by the NRC has reduced this variation and established minimum requirements for administrative systems. Through Appendix B, the importance of administrative systems and the need for specific policies and organizations to address them have been identified. The administrative systems commonly considered necessary have been defined and implemented for the control of nuclear reactor design, procurement, production, and operation. The result has been the achievement of a substantial consistency in administrative controls used in the industry. Moreover, despite the gains already made, the NRC has continued to further improve and enforce the application of administrative systems. Industry reaction to the requirements established by Appendix B seems to be largely positive. Although a variety of complaints about specific provisions or interpretations were noted, there appears to be a general recognition by utilities and their major contractors of the need for these requirements. Where the requirements need additional definition, there is substantial industry cooperation in the development of standards.

The beneficial impact of NRC assurance activities is apparent from the foregoing discussion. However, given the nature of the demands on safety and

uality assurance, and the observations made in this study, the study group concluded that further improvements are warranted in both the industry quality assurance programs and the NRC regulation of those programs. The areas in which improvements would be desirable are detailed in Chapters II, III, and IV of this report and are summarized below.

The rapid growth of regulatory activities pertinent to quality assurance and the consequent increase in the demands on the processes by which regulations are administered have given rise to some problems. Improvements are warranted in the communication of regulations and guidance, in the definition and communication of responsibilities and authorities of offices and other organizations, and in the capability for inspection and enforcement.

Improvements could also be made in the industry application of assurance measures required by 10 CFR 50, Appendix B. The recommended changes are primarily directed to the strengthening of planning activities and to increasing emphasis on, and effectiveness of, testing and auditing. Testing, particularly at system and subsystem levels, is among the most important of the quality assurance measures required. Preoperational and startup testing provide assurance that nuclear facilities are capable of functioning successfully under normal conditions at the time they begin operation. The overall surveillance test and inspection program provides a substantial capability for detection of problems during the operating phase. Preservice and inservice inspections focus on pressure boundary components, which are particularly significant for safe facility operation. It was found, however, that qualification and proof testing are not utilized to full advantage. Therefore, it was concluded that more detailed requirements by the NRC are needed to increase the use of qualification and proof testing.

The NRC has not required the use of certain techniques, which have been found valuable in other quality assurance programs, into the industry or regulatory programs. These include the application of reliability models, and analysis of unreliability modes and rates. The use of these techniques would provide a systematic structuring of the quality assurance program, and thus strengthen the program. Additional benefits, such as the provision of bases for utilizing test and operating experience and for determining quality assurance effectiveness, would derive from the use of these techniques.

Recommendations

It is useful to categorize the recommendations in the previous chapters into those which we believe can be implemented in a relatively short time, and those which may take more time to implement. In the following list, those recommendations which can be implemented in a relatively short time are marked with an asterisk. The position of each recommendation in the report is also given to aid reference to the supporting material. We recommend that:

*1. The NRC strengthen, through its communications to industry, recognition of the Standard Review Plan as the basic source of guidance on quality assurance requirements. (Page 25)

2. 10 CFR 50, Appendix B be used in the regulation of all areas of power reactor design, construction, and operation which are judged to have sufficient importance to safety to fall under other NRC regulation. The selective application of QA elements now applied to safety-significant items not interpreted as falling under Appendix B should be replaced by an approach in which the degree to which the 18 criteria of Appendix B are applied would reflect the safety significance of the item. (Page 26)

*3. The Transfer of Lead Responsibility Memo be revised (or that some supplemental means be established) to provide a schedule for completion of activities and a status reporting mechanism, for problems requiring action by both the Office of Inspection and Enforcement and the Office of Nuclear Reactor Regulation. (Page 28)

*4. The NRC take steps to assure that each vendor inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) is aware of the continuing responsibility and authority of the licensee with respect to vendor quality assurance. (Page 28)

*5. IE headquarters clarify responsibility for inspection of quality assurance activities of utility-run architect-engineers as belonging either to the regular inspection and enforcement program or to the Licensee Contractor and

Vendor Inspection Program (LCVIP). (Page 29)

5. Vendors to be inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) be selected on a basis which ensures that every vendor has some likelihood of being inspected. (Page 30)

7. IE inspection of material produced under the ASME Code provisions be eliminated, but only if the ASME requirements are expanded to include operation. Since efforts in this direction are under way, this recommendation is intended to encourage such efforts. (Page 30)

8. The Inspection and Enforcement staff strengthen its review of the inspectability and enforceability of Technical Specification requirements. (Page 31)

9. Routine direct NRC inspection and testing of hardware be increased, and that data pertinent to quality decisions made in the construction and operation of a plant be evaluated by the NRC on a routine basis. (This includes the evaluation, for example, of radiographic and ultrasonic test data.) (Page 31)

*10. IE inspections for QA program implementation during construction (Modules 35700B through 357[illegible]B of the IE Manual) be conducted more frequently during the period of personnel turnover prior to operation. (Page 35)

11. Qualification testing be required for design verification when practicable. (Page 36)

*12. IE inspections "QA Program (Receipt, Storage and Handling of Equipment and Materials)" (Module 35720B of the IE Manual) and "QA Program (Test and Measurement Equipment)" (Module 35736B) be conducted more frequently during construction. (Page 39)

13. The NRC establish requirements and guidance for comprehensive qualification and proof test programs, similar in detail to the requirements and guidance for preoperational and startup testing programs. The guidance should include

criteria for practicability. (Page 42)

*14. The NRC actively continue support of cooperative audit programs in the industry, especially programs for the sharing of audit data among licensees and contractors, and for the conduct of joint audits. (Page 44)

15. The NRC adopt, for nuclear power plants, a more systematic, yet simple method of representing hardware and human performance characteristics that are significant to safety. This method should address the importance to safety of these characteristics and should also consider their unreliability modes and rates, in order that a more comprehensive quality assurance program can be applied. Toward this end, we recommend the use of simplified event models and equations within the industry and the NRC. (Page 48)

16. The quality assurance planning and evaluation function in the NRC be assigned to a separate group. (Page 60-61) This function would include:

    1) Performing continuing reviews of all assurance measures in standards, Regulatory Guides and Standard Review Plans for consistency and adequacy,

    2) Evaluating overall QA effectiveness (ultimately by comparing assessments of the reliability of reactor safety features from all plants with established goals) and recommending programmatic improvements when indicated, and

    3) Developing and implementing improved quality assurance techniques.

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APPENDIX A

Overview of NRC Program for Regulating QA

Introduction

This Appendix describes the nuclear power industry, the Nuclear Regulatory Commission, and the regulatory process. The description is based on information developed during the study and establishes the general context for evaluation of nuclear power quality assurance activities. It should be useful to those not familiar with the processes involved in the design, construction, operation and regulation of nuclear power plants.

The design, construction, and operation of nuclear power plants is the responsibility of the utilities which own the facilities. The mandate of the Nuclear Regulatory Commission (NRC), under the Energy Reorganization Act of 1974 is to protect the health and safety of the public, i.e., to assure that the nuclear power plants can be, and are, operated without undue risk to public health and safety. In its regulatory capacity the NRC has established standards for industry activities and facility characteristics. Inspections and evaluations are conducted to determine whether these standards are being met. To enforce adherence to the standards, when required, the Commission has the authority to grant, suspend, modify or withdraw Construction Permits; assess monetary penalties; grant, suspend, modify, or withdraw Operating Licenses; and deny applications for Construction Permits or Operating Licenses.

Description of Nuclear Power Program

The basic process by which a nuclear power reactor facility is designed, constructed, and operated involves several major steps. Some of these steps are completed by the utility (applicant) who wishes to construct and operate the facility. Others are the responsibility of the NRC. A brief description of this

overall process is provided to establish a frame of reference for the discussion of quality assurance and its regulation.

Siting Study--The first step taken by a utility is to conduct a siting study. The study considers the intended design and operation of the reactor facility; population density and use characteristics of the site and surroundings; and physical characteristics of the site, including seismological, meteorological, geological, and hydrological features. Based on these considerations a site is selected for the proposed facility.

Application for Construction Permit (CP)--The utility's application for a Construction Permit includes an Applicant's Environmental Report (AER), antitrust data, and Preliminary Safety Analysis Report (PSAR). The PSAR covers comprehensive data on the selected site; a facility description (especially a description of features affecting safety); an analysis of "design basis" accidents and consequences; preliminary personnel and operations plans; and emergency planning.

Application Review--After confirming that there is sufficient information in the PSAR to review, the NRC substantively reviews the document. This is primarily a detailed assessment of those characteristics of the plant design (at the system level) that the NRC believes affect safety. The intent is to determine whether there are any aspects of design, construction and operation of the facility that will result in undue risk to the public. This process usually entails additional questions to the applicant, and requests for changes or additions to the PSAR. It also entails inspections of the applicant and major contractors to verify implementation of the programs described in the PSAR. The result of the review process is a Safety Evaluation Report (SER). The NRC staff also studies the AER and issues a Final Environmental Statement. Following the NRC staff review, an independent review of safety considerations is accomplished by the Commission's Advisory Committee on Reactor Safeguards (ACRS) — first by a subcommittee and then by the full ACRS. The findings of the ACRS review are reported to the Chairman of the NRC.

Public Hearings--After completion of the Final Environmental Statement, the Safety Evaluation Report and the ACRS Report, public hearings are held by the

Atomic Safety and Licensing Board (ASLB), usually in the vicinity of the proposed facility location. These may be "uncontested hearings," consisting only of testimony and documentation of the applicant and the NRC, or they may be "contested hearings," at which intervenors become a party to the process. A favorable finding of the ASLB, barring subsequent appeals, results in issuance of a Construction Permit by the NRC.

Facility Design--Conceptual design plus a small part of the detail design, or engineering, is normally completed at the time of application for the Construction Permit. Detail design work continues, essentially throughout the construction phase. By the time the CP is issued, perhaps 20 to 30 percent of the detail design has been completed. Procurement activity is conducted over the same general time frame. The bulk of these activities is usually accomplished by a nuclear steam system supplier (NSSS) and an architect-engineering (A-E) firm under contract to the utility.

Facility Construction--Construction for a single-unit facility typically extends over a five or six year period following issuance of the CP. Most often the basic construction task is handled by a construction firm under contract to the utility. The construction is frequently done by the same organization that provides the architect-engineering service.

Preoperational and Startup Testing--As systems and subsystems are completed, a series of checkout and functional test operations is conducted to assure that each system will perform its intended function. This preoperational testing increases in scope and complexity as the facility nears operational status. After an Operating License is issued, and the fuel is loaded in the reactor, startup testing is performed, culminating in power ascension tests.

Application for Operating License (OL)--During the construction phase, amendments are made to the original application as work progresses. Approximately 24 months before the target date for loading fuel in the reactor, a Final Safety Analysis Report (FSAR) and an updated AER are submitted to the NRC. These reports cover the same general areas as the PSAR and the AER submitted at the time of the

application for CP, and represent the "as built" plant. Coverage is in substantially greater detail, however, particularly in areas pertinent to the safety of facility operation.

Review of Application for OL--In its review of the application for an Operating License, the NRC staff considers all new information bearing on public safety and its environmental impact. In addition to review of the final design, including the planned facility operation and organization, it considers site inspection reports reflecting the status of construction. The intent of the review is to assure that the facility was designed and constructed and will be operated in conformance with NRC rules and regulations, and without undue danger to public health and safety or damage to the environment.

An independent review of the application for an OL is again conducted by the ACRS, whose findings are reported to the Commission. The general pattern of review and hearings by the ASLB for a Construction Permit may be repeated in the case of application for an Operating License.

Operation--The Operating License normally authorizes a utility to load fuel in the reactor, conduct low power level tests, and operate the facility at increasing power levels until full-power operation is reached. It is expected that facilities will be operated for about 30 or 40 years before becoming obsolete (although no reactors have been in operation long enough to validate this expectation). At the end of operating life the facilities will be decommissioned.

The foregoing is a very general description of the nuclear power program features which relate to the regulatory program for nuclear power stations. Many details such as docketing of applications, appeal processes, topical reports, etc., are omitted. The role of quality assurance activities in the overall program and the NRC regulation of those activities is addressed elsewhere in this report.

NRC Organization

We now describe the NRC organizational structure as it pertains to the safety

aspects of commercial power reactor licensing and to quality assurance associated with those plants. The description is therefore incomplete, ignoring the many other activities in which the NRC is engaged.

The NRC carries out its responsibilities primarily through an Executive Director for Operations under whom are five major Offices. The major Offices involved directly in quality assurance for nuclear power plants and its regulation are Standards Development, Nuclear Reactor Regulation, and Inspection and Enforcement. By statute, the director of the Office of Nuclear Reactor Regulation (like the directors of the Offices of Nuclear Material Safety and Safeguards, and Nuclear Regulatory Research) also reports directly to the Commission on matters affecting public health and safety.

The Commission is also assisted by supportive organizations, including the Advisory Committee on Reactor Safeguards (ACRS), the Atomic Safety and Licensing Board Panel (ASLBP) and the Atomic Safety and Licensing Appeal Panel (ASLAP).

The ACRS consists of technical experts, principally from National Laboratories and universities, and a small permanent staff. It reviews safety studies and applications for construction permits and facility operating licenses, as well as other matters referred to it by the Commission. It reports on the reviews to the Commission, and advises the Commission with regard to hazards associated with facilities and with regard to the adequacy of regulations.

The ASLBP develops policies and procedures applicable to the various hearing boards and makes recommendations to the Committee relating to the regulatory process. The boards under this panel conduct hearings and make decisions to grant, suspend, revoke, or amend licenses.

The ASLAP provides the Appeal Boards which exercise the authority and perform the review functions which would otherwise be exercised and performed by the Commission in licensing matters.

Office of Nuclear Reactor Regulation (NRR)--The Office of Nuclear Reactor Regulation is the principal contact with the nuclear power industry involving licensing of reactors. It administers regulations, policies and procedures governing licensing; and performs safety reviews of PSAR's, FSAR's, SAR amendments, topical reports, etc. It also determines the necessity of backfitting operating plants when new regulations or requirements are adopted.

A project manager is assigned to represent NRR licensing in dealing with an applicant for a CP or OL, and coordinates the review activities within the office. The review activity itself is disseminated among a number of separate branches where technical or administrative specialists review those aspects of the SARs that fall within their area of specialty. For example, a Quality Assurance Branch reviews parts of the SARs considered to be pertinent to QA. After an OL is granted, licensing considerations -- e.g., amendments to the FSAR, -- are transferred to the Division of Operating Reactors. This division possesses, in somewhat less depth, all of the areas of expertise present in the other divisions. Consequently, QA considerations with operating reactors would normally be handled by a staff member in this division, rather than by the QA Branch.

In addition to SAR review, NRR reviews topical reports which address specific technical or administrative proposals by utilities or their major contractors. The topical report concept was initiated so that new or alternate proposals could be reviewed without delaying the SAR review, greatly helping reduce licensing time. Topicals on QA programs at utilities or major contractors have also been allowed, to eliminate the need for review each time the company is involved with a new plant.

The procedures used by NRR to review SARs are published in a Standard Review Plan (SRP), which is available to the public. For the most part, the SRP references Regulatory Guides and industry standards, but it also goes beyond this guidance where it is deemed necessary to address additional topics.

Office of Inspection and Enforcement (IE)--The primary responsibility of the Office of Inspection and Enforcement is to develop and conduct programs for the inspection and investigation of activities of applicants and licensees. These inspections and investigations (and enforcement actions as appropriate) are not only for the purpose of assuring compliance with license provisions and Commission rules, regulations, and orders relating to health and safety, but also for the general assurance of safety.

The basic functions of IE are the development of the inspection and enforcement program, and the implementation of that program. The policies and practices of the Office are detailed in the Inspection and Enforcement Manual, which describes the administrative policies and practices and the programmatic and functional aspects of the IE activities.

Program development activities are carried out by the Division of Reactor Inspection Programs and the Division of Materials Inspection Programs. These divisions develop the portions of the Inspection and Enforcement Manual which specify the inspections to be performed and the frequency and manner of those inspections. Programmatic chapters of the manual describe the programs of inspection to be conducted by IE in fulfillment of its responsibilities. Functional chapters identify specific requirements which IE inspectors must meet during inspections of licensee and contractor activities.

Program implementation is the basic activity of five Regional Offices with the guidance and support of the Division of Field Operations (DFO). Regional Offices conduct the actual inspection of activities and report findings regarding compliance, safety-related problems, and the inspection program itself, to DFO. They also make recommendations to DFO for enforcement action (in excess of a letter of citation) and for bulletins or inquiries. The DFO is responsible for coordination and support of the Regional Office inspection and enforcement activities. Routine matters are handled by the Field Coordination and Enforcement Branch. Investigations and major problems which may require outside assistance are coordinated by the Field Operation Support Branch.

The above two paragraphs describe the organization of IE as of the time of the study. A 1977 reorganization of the Headquarters staff has redistributed responsibilities, but the overall IE effort has not been changed.

A large percentage of IE efforts concern quality assurance. Meetings and inspections, prior to issuance of the Construction Permit, are designed to assure that a quality assurance program plan has been satisfactorily developed, and implemented where applicable. During the construction phase, many of the inspections are directed to evaluation of QA procedures and records. Preoperational and startup activities are closely monitored by inspectors. During plant operation, nearly all licensee activities fall within the scope of 10 CFR 50, Appendix B, and are inspected throughout the life of the plant.

Licensee Contractor and Vendor Inspection Program (LCVIP)--To monitor the licensee's, contractor's, and vendor's QA programs, the NRC's IE Headquarters has established an LCVIP which is implemented by the Vendor Inspection Branch at Region IV. Inspections are made by this branch at firms designing nuclear steam systems, at architect-engineering firms doing design work on nuclear power plants, and at certain selected vendors on a regular basis. Inspection procedures for the LCVIP are issued by the IE Division of Reactor Inspection Programs. The Vendor Inspection Branch inspects the implementation of quality assurance programs which have been approved by NRR in the form of Topical Reports (reports of standardized quality assurance programs from NSSSs and A-Es).

When IE inspections confirm satisfactory implementation of the QA program described in a Topical Report, a confirming letter is sent by IE to the NSSS or A-E inspected. Licensees may use this confirming letter to fulfill their obligation under Criterion VII of 10 CFR 50, Appendix B to establish that their contractor who has been issued such a confirming letter is effectively implementing his QA program as described in his Topical Report or standardized program. The NRC expression of satisfaction confirms only that the programmatic aspects of the NRC approved QA program have been implemented, and does not assure that any unique programmatic requirements imposed by a licensee are being implemented or that a specific product

or service provided to the licensee is of acceptable quality. Should subsequent IE inspections determine that a contractor's QA program implementation is unacceptable, the licensee(s) will be notified by letter. From the date of such a letter the licensee(s) must provide the necessary assurance required under Criterion VII, Appendix B.

Another significant part of the LCVI program is the Region IV component inspection activity of vendors supplying safety-related components. The production volume and the performance history of an item is used as a basis for determining which suppliers will be inspected. Cables, instruments, and other electrical items are normally inspected at the vendor per applicable 10 CFR 50, Appendix B requirements. Safety-related pressure items are inspected according to an ASME accepted QA manual.

Office of Standards Development—The function of the Office of Standards Development (SD), as given in the NRC organization chart, includes developing and recommending nuclear safety standards, criteria, guides and regulations for location, design, construction, operation and performance of reactors. The Office also coordinates Commission participation in ANSI and International Atomic Energy Agency (IAEA) standards-related activities.

SD is composed of two divisions: The Division of Engineering Standards and the Division of Siting, Health and Safeguards Standards. Efforts related to the NRC QA program are primarily concentrated in the the Division of Engineering Standards. Of the several functions performed by SD, the production of Regulatory Guides and Regulations, and participation in committee work are of primary importance to the NRC QA program.

Regulatory Guides are offered to the industry as acceptable ways of meeting regulatory requirements. Licensees have found that commitments to Regulatory Guides greatly expedite the review process, eliminating the need for a detailed review of alternate approaches during the SAR review. Wherever possible, the Regulatory Guides approve the use of consensus standards prepared by national societies (ASME, ANSI, IEEE, etc.), thereby providing industry with some sense of

involvement in the regulatory process while availing the NRC of the support of the extensive industry standards effort. SD staff members work on the industrial standards committees to help assure efficient application of the standards effort.

Following the development of a suitable industry standard -- a lengthy process itself -- the incorporation of a standard into a Regulatory Guide is a consensus operation within the NRC. The concurrence of other Offices that will use the Regulatory Guide is sought, and comments from these sources are resolved through staff reviews, often resulting in the Regulatory Guide departing in some particulars from the standards upon which it was based. After review by other NRC groups, the Regulatory Requirements Review Committee (RRRC), and the ACRS, the draft guide is published for a 60-day comment period, allowing industry and other public comment. The internal NRC review process is normally repeated after comments are received, so the total time for production of a Guide can approach two years from the time the standard was completed. However, use of the Guide may begin when it is issued for comment, approximately one year after the standard is completed.

Other NRC Organizations--Many organizations within the NRC have functions which are peripherally or occasionally related to the regulation of quality assurance. A discussion of the structure and function of all of these organizations would contribute nothing significant here. There are two organizations, however, performing functions which have actual or potential contributions to the NRC quality assurance program. These are the Office of Nuclear Regulatory Research and the Office of Management Information and Program Control.

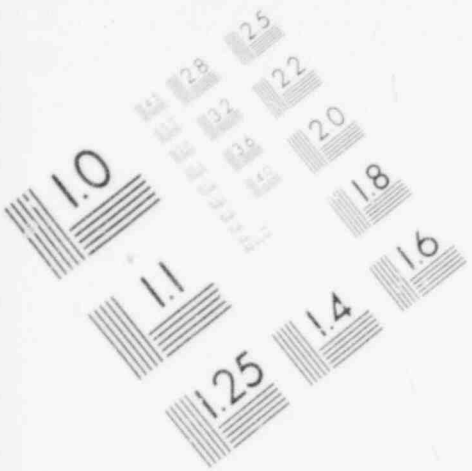
The Office of Nuclear Regulatory Research administers those research efforts which are deemed necessary for the performance of the NRC regulatory functions. These efforts account for about half of the total NRC budget. Major divisions of the Office are the Division of Reactor Safety Research (RSR) and the Division of Safeguards, Fuel Cycle, and Environmental Research. The RSR is further divided into two major functional areas -- water reactor safety research and advanced reactor safety research. A major effort in the water reactor safety research area which relates to quality assurance is the Loss of Fluid Test (LOFT) program which

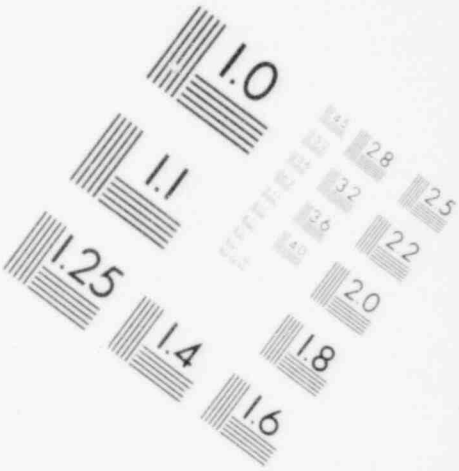
is being conducted to evaluate the effectiveness of light water reactor emergency core cooling systems. Also of importance to quality assurance is a Probabilistic Analysis Branch which reports to the RSR Director. This branch is involved in developing the application of risk analysis techniques for the regulatory process.

The Office of Management Information and Program Control (MIPC) administers management information systems by which information on the performance of reactor construction and operation and various regulatory functions is collected, analyzed, and reported. Reports include routine computer listings of information, such as inspection and enforcement findings and licensee event reports and reactor operating experience, sorted as appropriate. A series of status reports is prepared and issued under the LORDS (Licensing On-line Retrieval Data System). In addition to various other routine reports, MIPC responds to special requests for information and maintains certain data files.

NRC Interfaces—The overall regulatory functions with respect to quality assurance are, in general, divided along organizational lines. That is, the staff review of license applications and supporting data is done almost entirely within NRR, and inspection and enforcement actions are the province of IE. A significant exception exists with respect to the development of "standards" for regulation. Much of this is the responsibility of, and is administered within, SD. The result is mainly the issuance of Regulatory Guides. Standard Review Plans and Branch Technical Positions, however, also have the character of "standards," and these are developed by NRR. To some extent, IE also generates "standards" in the guidance section of Inspection Modules.

To the extent that the regulatory functions are separated by organization, interfaces between the organizations are important. Overall philosophy and policy with regard to regulation should be consistent across organizations. The NRR staff needs information and evaluations developed by IE. IE should be aware of changes which NRR makes to Construction Permits and Licenses and understand the rationale for them. SD personnel should be privy to licensing, inspection, and enforcement actions and the impact of standards on these actions. Mechanisms for communication and cooperation are, therefore, a necessity.





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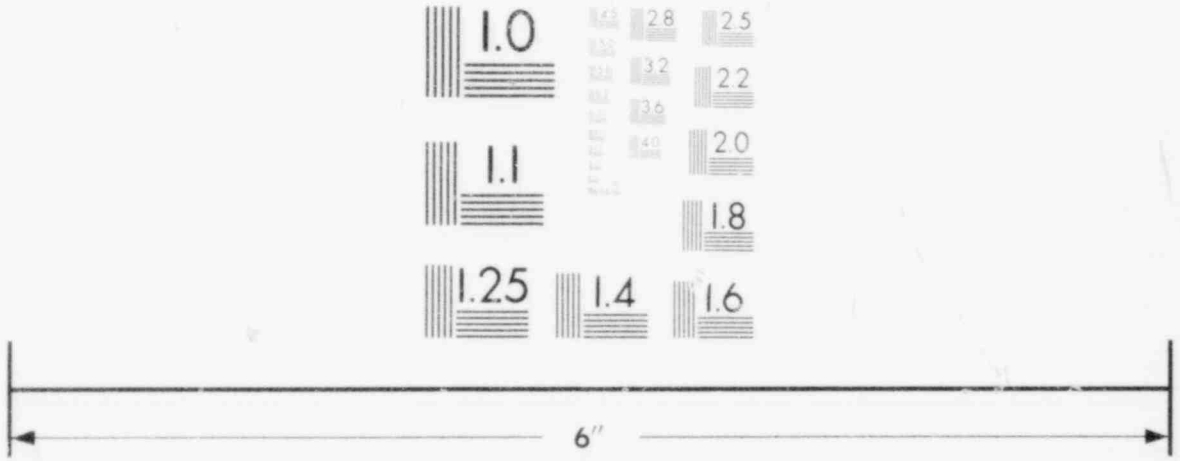

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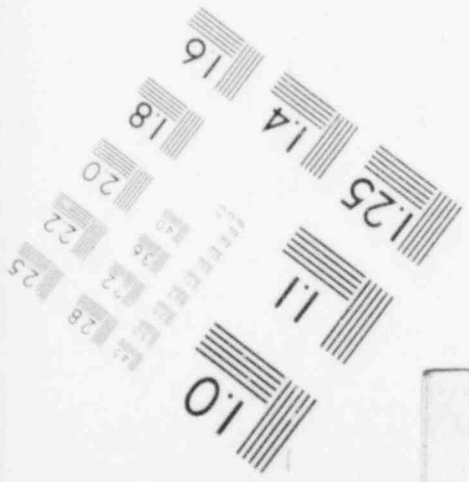

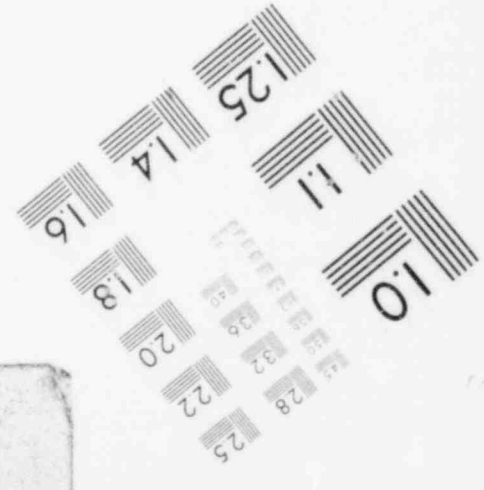

There is a variety of such mechanisms within the NRC. Among these are the normal organizational channels through which information can flow upward through one organization structure and down through another. Informal exchanges (usually unwritten) take place between organizations at all levels. Written communication is also accomplished by the circulation of draft guides and standards (and the comments on these drafts) and by hearings on proposed guides and regulations. Information is also disseminated across organizational lines by publications issued by NRC.

Coordination of policies and practices can be achieved through staff meetings at the policy level which are conducted as the need is perceived. Ad hoc groups of representatives from various offices are formed to deal with special problems. Perhaps most pertinent to the subject of this study is the Interoffice Quality Assurance Task Force — a standing group which meets on a regularly scheduled basis to address quality assurance problems.

Nuclear Industry

The design and contruction activities for commercial nuclear power facilities are applied to structural, mechanical, electrical, chemical, and hydraulic systems and components, and involve a hierarchy of industrial organizations. The utility must assure that not only its own quality assurance program, but the quality assurance program of each involved organization is adequate and appropriate to the design or construction activities being performed. To appreciate the significance of the utility's responsibility and the implications for quality assurance regulation, it is necessary to understand the working of the overall industrial process. A brief discussion of the process follows.

Utilities--Most utility companies provide overall project management for design and construction of the reactor facilities, but do not participate directly in the design/construction process. There are numerous exceptions wherein the utilities do participate to some degree, and a few cases where they design, procure and construct all of the facility (except the nuclear steam supply system). In the

majority of cases, however, the responsibility for these activities, including the quality assurance programs associated with them, is contracted to nuclear steam system suppliers, architect-engineering firms and construction contractors.

Nuclear Steam System Suppliers--There are currently four active NSSSs involved in the fabrication of light water reactors in the United States. They function as the design and procurement organizations for that portion of the reactor facility required to produce steam to drive turbine generators. For a pressurized water reactor this includes items such as the reactor, the steam generators, the main coolant pumps, and the pressurizer. For a boiling water reactor the steam supply system includes items such as the reactor, the recirculation pumps, and the primary containment.

Generally speaking, an NSSS designs at the system level. A result of this activity is the generation of component design specifications which identify the required component characteristics. The system supplier then incorporates the design requirements into a procurement document (or package) which is used for procurement from component manufacturers. Included in the procurement document are the QA requirements pertinent to the component. Since the steam supply system is pressure containing and safety related, the requirements of 10 CFR 50, Appendix B, and the ASME Boiler and Pressure Vessel Code, Section III, apply.

Architect-Engineers--Approximately twenty architect-engineering firms provide design services for complete nuclear power plants, except for the portion comprising the nuclear steam supply system. The general pattern of design and procurement is the same as that described above for the nuclear steam system suppliers. Since parts of the facilities are safety related and parts are not, QA provisions required by the NRC will apply to only part of the A-E activities. The determination of applicability is one of the significant judgment areas for both the utility and the A-E.

Constructors--Actual on-site construction of nuclear plants is usually contracted to an organization specializing in this type of activity. The constructor receives the components and materials, designed and procured by the

NSSS and A-E, at the site and assembles them into a complete facility. Some A-E organizations also function as constructors. The constructor functions under the direction of project management, which may be the utility, the A-E, or another organization with project management responsibility. QA requirements are included in this direction.

Component Manufacturers--Thousands of component manufacturers (both US and foreign) supply components of reactor facilities. These manufacturers provide components to satisfy the design specifications, either by selection of an existing design which they have developed for some prior purpose or by developing a new design. Note that actual design is done by the component manufacturer, in response to a set of design requirements established by others. The component manufacturer's QA requirements are transmitted to him in the procurement process and, for safety-related components, should include the quality requirements to be imposed on suppliers of parts and materials.

Material Manufacturers, Material Suppliers--The suppliers of basic materials and of such materials processed to achieve required characteristics and dimensions represent the end of the overall procurement process. Their product goes to the component manufacturer and to the constructor for use in fabricating the systems and structures of the facility. Again, these products are designed and produced to meet requirements specified in procurement documents, and QA requirements are received in the same way. With respect to regulatory requirements, they are at the end of a communications chain as well as the end of the procurement chain.

Suppliers of Services--There are many organizations which provide specific services other than design or procurement, and the utility company or its major contractors may elect to use such organizations rather than perform these tasks directly. Examples are firms which provide inservice inspection, QA program definition, and siting studies. Some QA provisions can be applicable to suppliers of services as well as to suppliers of design or hardware.

NRC External Interfaces

Since NRC has the responsibility for protecting the health and safety of the public, by assuring that nuclear power plants are designed, constructed and operated in a controlled manner, the basic external interface is obviously with the licensees. Some details of this interface have been given above, in describing the functions of NRC organizations, but it is also useful to consider this interface in more general terms.

Outgoing transmissions through the NRC/licensee interface consist of requirements, guidance, and decisions. Requirements are in the form of Federal Regulations and have the force of law. Guidance takes many forms including Regulatory Guides, Standard Review Plans, Branch Technical Positions, standards and standard formats endorsed or provided by the Regulatory Guides, letters, and study reports. Decisions involve Construction Permits, Operating Licenses, and inspection reports.

Requirements, by their very nature, are stated in broad, general terms. Federal Regulations, like other laws, must not only be enduring but must also allow for options in the methods of satisfying them. Decisions, on the other hand, are generally "yes" or "no" decisions and are hence quite specific.

Despite the multitude of rules, regulations, requirements, and guidance documents, the two most significant communications are those related to the SAR review process and those resulting from the IE activities.

The SAR review (for a CP or OL) is conducted in accordance with a Standard Review Plan (SRP) and Branch Technical Positions (which are considered part of the SRP). These documents -- which are available to the public -- tell the licensee and his contractors precisely what NRR will look for in the SAR, and how they will determine its acceptability. The SRP is a document prepared unilaterally by NRR, although other offices of NRC do have the opportunity to comment on it.

The SRP approach was developed as an aid for NRR reviewers in order to "improve the quality and uniformity of staff reviews." Through the SRP, information on the review process is also made available to industry. The

significance, therefore, of this communication is considerable, representing NRR's interpretation of all the other guidance.

The other significant communication to the industry is that resulting from the IE inspections of utilities and plant sites by all the regional offices, and of contractors and vendors by Region IV as part of the LCVIP. Each finding or noncompliance represents an interpretation by IE of how the regulations and commitments by the utility must be measured, and constitutes a guiding influence as important as that of the review process.

Incoming transmissions through the NRC/Licensee interface include a multitude of submissions, but may be grouped into those required for license or permit judgments and those required for evaluating implementation of commitments. Except for some ambiguity with regard to applicability (due to unclear definition of "safety related"), the submissions required are quite well defined.

Problem Response--An important obligation of the NRC in assuring safety of nuclear plants is the evaluation of accidents, incidents, or other safety-related problems that occur in the field. Such evaluation provides a major basis for the orderly evolution of the nuclear technology and of the regulatory processes intended to control it. The NRC has provided channels for handling problems observed in the field. The cognizant Regional Office is notified of certain events by the utility in accordance with the technical specifications which are part of the Operating License. Depending upon the seriousness of the event, the IE inspector or an IE team consisting of regional office personnel, will provide a front line investigation. Information collected is transmitted to IE Headquarters for immediate determination of action and consideration throughout the NRC. From this point, the necessary additional NRC participation (including ACRS or ASLB hearings) is called into play for whatever action the particular incident might warrant. The entire NRC organization is on call as the needs of the problem dictate.

After the plant has been restored to a satisfactory condition, and any necessary enforcement action taken, follow-up activities are conducted. Bulletins

are often distributed to all licensees that may have a similar problem, asking for information on plant design or ordering specific actions or reviews. All incident reports are disseminated among the NRC staff for their review and recommendations for corrective action. Modifications to the Regulatory Guides, the SRP, or other regulatory processes are often made to prevent repetitions of the problems in other plants.

Interfaces with States--Since the elements of the nuclear industry in the United States also exist within state boundaries, they are subject to both federal and state jurisdictions. Where these jurisdictions overlap, as in the regulation of by-product material, the industry is accountable to both authorities. This dual control is modified in some states (agreement states) in which the NRC has agreed to allow the state to exercise regulatory authority in certain specific areas.

The interface between the NRC and state authorities may take several forms, such as different degrees of coordination on emergency plans with the various levels of state and local government.

Another relation between the NRC and the states comes into play in those states requiring inspection by an Authorized Inspection Agency for items which fall under the ASME Boiler and Pressure Vessel Code. This will be discussed further in the next section.

The NRC/ASME Interface--Standards and codes approved by NRC as acceptable means of satisfying regulatory requirements are produced primarily by national professional societies. In the QA area, ASME is responsible for two of the basic documents: the Boiler and Pressure Vessel Code and ANSI Standard N45.2 (Quality Assurance Program Requirements for Nuclear Power Plants). To implement the Code, ASME also provides a certification program for suppliers of Code items and an Authorized Inspection program as noted above.

The Code, and hence the Authorized Inspection, is concerned only with the pressure integrity of Code items and not their operability or reliability. This

means that two inspections are required on Code items, the Authorized Inspection and another inspection by the procuring agency.

Other External Interfaces--The NRC has many external interfaces. In addition to those noted above, this section discusses others which impact to some degree on the overall QA program.

The standards producing organizations, such as IEEE, interface with the NRC in two ways. NRC personnel participate in the committee work which produces the standards, and thus have a direct input to those standards. Secondly, in the endorsement of standards in Regulatory Guides, etc., there is a continuing dialogue between the NRC and the standards organization (including the coordinating body, the American National Standards Institute). Draft Regulatory Guides are issued for comments from the standards organizations, the industry, and the public before being finalized. Industry organizations, such as AIF and EEI, also interface with the NRC.

Organizations and individuals who either object to the use of nuclear power or the present methods of regulating the production of nuclear power are another important interface with the NRC. Such groups are collectively titled intervenors, since the chief form of interface available to them is that of "intervening" in NRC hearings and court cases. The interface, in this instance, is usually quite formal, following legal practice, although there is much informal communication either directly or through the news media.

APPENDIX B

Quality Assurance Principles

Introduction

This Appendix discusses the more general aspects of quality assurance which the study group considers necessary to actually provide assurance as defined in 10 CFR 50, Appendix B. Further elaboration of these aspects is provided in relation to specific areas discussed in the main text.

The study of the NRC QA program consisted primarily of comparisons of the information collected from the NRC and the industry (including the regulations and guidance provided by the NRC) with a formulation of basic quality assurance tenets. The tenets relate to those functions, activities, and principles which generally address "fitness for use," in accordance with the broad definition of quality assurance given in the introduction of 10 CFR 50, Appendix B. The evaluation of the NRC QA program reflects the results of this comparison between the NRC QA Program and the tenets. Thus, the understanding and acceptance of the tenets is critical to the value of this study.

By way of qualification, the tenets are the development of a study group whose members have a background in quality assurance for nuclear ordnance. Further, they are based on the views of outstanding experts in the field of quality assurance (e.g., Juran) and the approaches used by other industries familiar with stringent safety requirements (i.e., DOD and NASA).

The Nature of Quality Assurance

The introduction to 10 CFR 50, Appendix B states that QA "comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in use." Taken literally, this definition implies that QA applies to all activities involved in the design, production, construction and operation of nuclear power stations, including NRC regulatory and evaluative activities.

This is true to the same extent and in the same way that fiscal control applies to all activities which affect budget and produce earnings. In pursuit of either quality assurance or fiscal control an isolated organization cannot achieve the desired result. Each demands some sort of organization to guide those whose activities affect the particular goal desired and to integrate the results of the numerous activities.

In addition to the development of quality assurance, specialized sciences or methods have been introduced which supplement and interact with traditional activities to achieve and maintain product fitness for use. They include reliability, safety, quality control, maintainability, human factors, logistics, and other specialties. In this report we refer to these disciplines as the "quality sciences."

The quality sciences applied to the traditional design, production, and operation activities perform what Juran calls the "quality function" necessary to achieve "fitness for use". Quality assurance is the response to management concern with whether the quality function is performed adequately, and uses information from the quality sciences in addressing that concern.

Quality requirements are imposed when the behavior of systems in use may have undesired outcomes. The outcomes may be in the form of direct costs (e.g., the system is damaged or destroyed) or indirect costs (e.g., the services provided by the system are faulty or not available). The outcome of concern to the NRC is that nuclear power stations may behave in such a way as to endanger public health and safety.

For the following discussion, we consider that any misbehavior of a system or component is the result of an "error" made during design, production, construction, or operation of the component or system. An error may arise from limitations of technical knowledge or from human failure. In these terms, the objective of the quality function is to deal successfully with these errors and their outcomes, so that system misbehavior will not occur too frequently.

Fundamentally, there are three ways of dealing with errors:

- Accommodation.
- Prevention.
- Detection and correction.

Accommodation is an attempt to live with occasional errors by circumventing their effect. Prevention is an "a priori" effort to anticipate opportunities for error and eliminate them. Finally, detection and correction is an "a posteriori" effort to determine whether the present technological endeavor is free of error, and to provide after-the-fact correction of any errors found. More than one of these approaches may be combined in a single activity.

These three approaches are normally considered separately; taken together, however, they provide a defense in depth against the misbehavior of systems. In a practical situation, none is capable of dealing with all errors, however, so that a combination of approaches is necessary to achieve the desired control. These approaches to the control of error are important enough to warrant discussion in some detail.

Accommodation of Error--In the design, production and operation of complex systems, prevention of many errors is not practical. It is necessary to detect and correct each error made unless accommodation of such errors is possible. Accommodation, therefore, has been a traditional part of design. Conservative design practice, such as use of adequate design margins and derating of equipment, allows for some uncertainty or range in both the stress levels which a design might experience in use and the strength actually attained in the finished hardware.

With the emergence of quality sciences -- notably reliability, maintainability, and safety analysis -- accommodation techniques have become a subject of serious scientific inquiry, resulting in a variety of methods for applying redundancy in useful forms. First, the design margins and derating techniques -- both of which represent a redundancy of material -- have been made more precise by the application of probabilistic and statistical techniques to estimate variations and uncertainties involved in the building and use of equipment. To this have been added techniques of applying discrete redundancy in terms of components and systems in ways to enhance reliability, maintainability, or safety, again using probabilistic and statistical techniques to provide measures of "how much is enough."

A guiding principal in the application of discrete redundancy is that the probability of an undesired behavior of a system can be made as small as desired by designing the system in such a way that a number of distinct events must occur before the system misbehavior can result.

The number of distinct events required to reduce the probability of an undesired system behavior to a given level will depend upon the probabilities of occurrence of each of the distinct events and the amount of statistical correlation which exists between their occurrences. For example, if the events are positively correlated (i.e., they occur together more frequently than would be expected due to chance), it will take more distinct events (of the same probability) than it would if the events were not correlated, or were negatively correlated. In fact, if the positive correlation approaches its maximum value of 1.0 (where the occurrence of one event is always accompanied by the occurrence of other events), additional events beyond the first provide no improvement.

Prevention of Errors—The most common type of preventive measure involves administrative or management systems which impose the use of formalized procedures as a means of improving the reliability of human performance. The 10 CFR 50, Appendix B criteria require the adoption of administrative systems and the documentation necessary to verify conformance. These measures can eliminate undue reliance on human memory by prescribing, step by step if necessary, the performance of a task. They can also greatly improve communication between those personnel whose activities interface with one another. However, while administrative systems do address human performance directly, they can represent only a broad barrage against errors, if no consideration is given to how each error might affect safety. There are so many opportunities for error that attempts to control all of them through procedures would completely overtax the available resources. As a result, preventive measures such as administrative systems should be used sparingly, to address "the vital few" situations where their application will produce the greatest benefit. They should not be expected to prevent all errors.

Detection and Correction of Errors--A significant part of coping with errors in technological processes is the detection and correction of errors before they

produce undesired consequences. In general, it is necessary to consider one approach prior to the time the system is put into operation and another after the system is in operation. Prior to system operation, detection of errors is best accomplished by the use of models (physical and mathematical) and design reviews. By resorting to the use of models, designs can evolve without the risks which would result if the system were put into operation prematurely. In this approach, the first models are usually mathematical models. Each design discipline may model different aspects of a system. Of particular interest to quality or safety are models which describe the ways in which component misbehaviors occur and combine to produce system misbehaviors.

There are numerous ways of detecting errors during the design and construction phases, besides modeling. Design reviews, inspections and tests, material analyses, audits, and examinations of records are all examples of ways to detect errors. Ideally, mathematical models are followed by physical models which are tested to detect errors that might have occurred. Successively closer approximation of the model hardware to actual hardware and of test conditions to actual use conditions continues, expanding the opportunities for new types of errors to display themselves. Finally, if nearly complete systems are tested under extremes of actual use conditions, there will be little opportunity for new types of errors to appear when the system is put into use. Nearly all types of errors will have been given an opportunity to display themselves so they may be corrected.

Modeling full scale systems and testing them under extremes of use conditions can become expensive and difficult. This is particularly true in programs addressing safety, because of the severe accident conditions in which hardware must operate or survive. However, if the last steps of the modeling and testing process are omitted, the errors which only those steps could detect will manifest themselves during actual use of the system. No number or variety of tests of less than complete models can provide opportunity for those types of errors which involve the synergistic or interactive effects among the system elements and the combined environments in which they must operate or survive.

Industrial experience indicates that errors will occur when a system is placed in operation without completing the modeling and testing process. The current

emphasis on system testing by DOD, NASA, ERDA and others grew from experiences which showed that limited testing failed to detect many errors.

After a system has been placed in operation, it is necessary to consider degradation due to age, misuse, wearout, and other factors, which might increase the chance of misbehavior. It is therefore necessary to monitor or test the critical characteristics of the system throughout its life. Degradation can be detected prior to the time that it has progressed to a dangerous point, if the appropriate characteristics to monitor are identified and provision is made to monitor them. The development of the surveillance program should closely parallel the development of the design itself.

Organizational Aspects of Assurance

In technological endeavors involving large and geographically dispersed industries, organizations usually have been established to assure that the quality function is properly addressed (e.g., DOD and NASA). These assurance organizations are the counterpart of the comptroller organization, and represent quality issues at high levels of management. This provides a check and balance system in which design and production is the responsibility of the traditional engineering organizations, and the assurance that the design will meet requirements is the responsibility of the assurance organizations. Inasmuch as production and assurance considerations are sometimes in opposition, this arrangement fosters a healthy conflict situation that gives balanced representation to these considerations.

In arrangements where assurance does not have access to the highest levels of management, it may be expected that most decisions will favor production, resulting generally in a less expensive product with a higher risk of failure to meet requirements. This follows because the production and sale of product is the primary reason a company exists, a fact that automatically gives production considerations highest priority. In other words, even though most companies today recognize the value of attending to consumer desires, they would not be inclined to treat them at the same level of priority as they would matters judged to affect company survival directly.

Regulatory agencies, of course, tend to even up or reverse the imbalance that can result between product (producer) and requirement (customer or consumer) interests, particularly if they make full use of the quality sciences in identifying and enforcing requirements. In the arrangement with a regulatory agency, the representation of product and requirement interests are not brought together at a high company level for trade-off decisions, but rather are brought together at a political level. This, of course, effectively gives a voice to the voting public in establishing the proper trade-off. The regulatory agency represents the requirement interests, leaving product interests to the companies involved.

In addition to the difference in viewpoint between the engineering and the quality sciences (product versus requirement), there are other differences that stem from the nature of the sciences involved; i.e, the engineering activities which support product interests and the quality activities which support requirement interests. These differences tend to further enhance the check and balance arrangement between these interests, with the different activities providing independent and objective views of common problems. These complementary, but distinct, orientations are illustrated in Table B-1.

TABLE B-1

Product Orientation	Requirements Orientation
Product	Results or Requirements
Deterministic	Probabilistic
Achieving Success	Avoiding Failure
Avoiding High Costs	Avoiding High Risk
Microscopic	Macroscopic

These differences reflect the training of staff and the complexity of product. The engineering disciplines applied in reactor design are highly technical and specialized. Such complex entities must be compartmentalized so that specialists can perform design or analysis within their own sphere of expertise (microscopic approach). The quality sciences, on the other hand, focus on aspects that run across all the disciplines (macroscopic approach).

The engineering activities concentrate on how to get something good to happen (achieving success) while the quality activities concentrate on keeping something bad from happening (avoiding failure).

Another significant difference lies in the fact that the engineering disciplines are predominantly deterministic, while the quality activities reflect a probabilistic view.

The individual quality sciences -- reliability, safety, quality control, etc. -- tend to relate to parts of the overall quality function, just as do the individual activities within the engineering fields. Further, the part of the overall quality function addressed by a given quality science is usually shared with one or more of the engineering activities, e.g., design, or production. Consequently, it is usual that organizational arrangements provide for strong interaction between these closely coupled activities, yet still preserve for the quality sciences the desired objectivity and independence from pressures of production interests. The assurance organization provides the administrative chain to assure that quality interests are given proper representation, i.e., that quality interests cannot be negated at lower management levels.

In an arrangement involving a regulatory agency, it seems clear that the regulatory agency assumes the burden of assurance. In fact, it is easily argued that the regulatory agency is the assurance organization whose responsibility it is to assure that the quality function is properly accomplished.

Beyond that, there are any number of arrangements possible for the conduct of the quality function. In particular, the regulatory agency may choose to do some of the quality activities itself, or it may require that they be performed by those being regulated. In the latter case, the regulatory agency is still responsible to assure that the activity is properly conducted, and it must undertake those actions necessary to determine that this is the case. That is, the agency (organization) doesn't have to do everything itself if (and only if) it can satisfy itself objectively that the tasks are being done properly by someone else. The techniques of quality assurance, per se, therefore include those fundamental techniques for determining whether activities conducted by others are being done properly. Audits,

inspections, requirements for reporting, review of reports and documentation, and independent test and verification activities, are among the techniques used. The form an assurance organization will take depends upon which techniques must be utilized, and how.

These techniques must be effectively applied in measuring overall results of the performance of the quality function. As indicated earlier, this is most easily accomplished when it is possible to test the full-scale system functionally under use conditions, both prior to initial operation and periodically throughout the operational life of the system. This essentially constitutes a direct measure of fitness for use, and circumvents the need for detailed evaluation of the total quality function; if the product is fit for use, then the quality function was accomplished sufficiently well. Consequently, the assurance organization would in this case be formed to provide the expertise needed to develop and conduct suitable tests of fitness for use (or to evaluate the tests developed by someone else).

If it is not possible to measure all aspects of fitness for use by direct test, then it becomes necessary to evaluate the "upstream" efforts regarding errors that will not be visible in the testing. The assurance organization must now include the expertise needed to determine what quality concerns are not covered by test, how the quality function addresses such concerns, and how to measure the effectiveness of these activities directly.

In any event, the assurance organization must include sufficient expertise in the quality and engineering sciences to identify what constitutes fitness for use, what characteristic aspects of the system affect fitness for use, under what conditions fitness for use is needed, and how best to determine whether fitness for use has been achieved. The further "upstream" one must go to find results pertinent to determining fitness for use, the larger an assurance organization tends to be because of the need to evaluate individual activities. Also, there is greater dependence upon preventive and accommodative measures taken in the activities, both of which are inherently limited by the level of knowledge available for anticipating errors and the state of the quality sciences in knowing how to deal with them.

Relationships Between the Assurance and the Quality Functions

The quality function has been identified as the task of achieving product fitness for use, while the assurance function is the task of determining that the quality function is properly accomplished. In other words, a distinction is made between quality and assurance of quality. The importance of achieving quality in the nuclear power industry is obvious. However, we also need the ability to determine that this goal has been attained. While it is possible to have quality without having assurance of it, such uncertainty is unacceptable. Consequently, we insist on assurance of quality too.

Unfortunately, it is possible to believe (i.e., have assurance) that quality exists when, in fact, it does not. This is possible because of the subjectivity involved in determining whether a given collection of programs, activities, facts and information justifies assurance. It is inevitable that there will be subjectivity involved in assurance, because our knowledge, our theories, and our ability to test are necessarily imperfect and incomplete. The aim is to limit the subjectivity to a degree commensurate with the difficulty and importance of achieving fitness for use.

The reduction of subjectivity in assurance depends upon the utilization of the quality sciences and the adoption of systematic, methodical, painstaking approaches to identifying and treating as many of the potential error situations as is practical, and then verifying that the treatments are effective. To ignore such methods is to invite the risk that knowable, treatable problems will not be identified before consequences are suffered. The imposition of systematic approaches to the conduct of the quality function is a major aspect of the assurance function.

While it is not difficult to identify the quality function with the attainment of quality and the assurance function with determining that quality has been attained, it is not so easy to identify where the various quality and engineering sciences and activities fit into the structure. In point of fact, they usually support both the quality function and the assurance function.

Consequently, the assurance organization or regulatory agency must draw heavily on the quality and engineering sciences in determining whether or not

fitness for use has been achieved, making use of analytical or other tools developed by these sciences. The unique contributions by the assurance organization are the coordination of all activities in terms of both planning and evaluation, and the assurance that quality matters receive proper attention. The basic functions necessary for an effective assurance program for complex devices with stringent requirements are:

- Analysis of assurance requirements
- Assurance planning
- Program implementation
- Measurement of program effectiveness and use of this measurement to influence program management.

These are accomplished by the assurance organization, and are in addition to the similar steps being taken by the individual participants in the quality function; they relate to the unique contribution of the assurance role.

Analysis of Assurance Requirements

An essential feature of an effective assurance program is that it be directed to a clearly defined and meaningful goal. Such goals are typically expressed in terms of probabilities or allowable defect or failure rates, a fact which brings us to the first of several reasons for the probabilistic view reflected by the quality sciences.

The quality sciences do not exclude treatment of cause and effect, but they have found probability to be useful in describing the behavior of systems and components. A deliberate choice is made to treat things as chance (probabilistic) phenomena when the cause and effect relationships are unknown or are too complex to treat individually. Reliability and safety requirements are identified in terms of probabilities to permit a description of system behavior which may not identify all the cause and effect phenomena involved, but which adequately reflects customer requirements. For instance, it would be totally impractical, if not impossible, to try, through deterministic methods, to determine precisely which items in a population might fail, or at what instant in time a given item might fail. "Statistical laws," however, are practical, and will do the next best thing.

They can describe about what fraction of the items might fail, or about how many times during a year an item might fail.

A probabilistic requirement also is an explicit way of acknowledging that failures or other misbehaviors will occasionally occur, and provides a way of identifying what is necessary to accommodate them. That is, while the misbehaviors of systems can't be completely eliminated, their probabilities of occurrence can be controlled. The quality sciences address the problems of quality in precisely these terms.

Given an overall goal for the assurance program, the next steps in developing an assurance program would be to identify which hardware has quality requirements, what those requirements are, and under what conditions of use they must be satisfied. The best method for identifying the pertinent hardware is through the use of logic models. Appendix C of this report describes the use of these models, which show the logical relationships between component misbehaviors and those system misbehaviors which can affect public health and safety.

It is in connection with this modeling that another reason for the probabilistic view emerges. There are endless combinations possible when all possibilities are considered (the "what if" game), many of which affect safety only through obscure combinations of numerous peculiar component behaviors and external influences. A complete logic model, therefore, would assume proportions which put it completely beyond practical bounds.

However, through the introduction of probability consideration into the modeling process, it is possible to truncate the logic models when it becomes evident that the probabilities that would be associated with various combinations of component behaviors are negligible. However, this question is not so trivial as to simply make comparisons between one of these low probability combinations and one of the higher probability combinations. The number of low probability combinations may be great enough that these combinations cannot be ignored, or there may be common-mode problems that affect correlations, but with proper attention to these possibilities, the logic models can be sensibly truncated to practical proportions.

The events depicting failure or other misbehavior of components in the logic models identify the hardware which is of importance to public health and safety, and to which assurance activities should be directed. The model itself (plus the definitions of the events in it) serves as a means of communicating this information to all those involved in the quality function, as it is relatively easy to interpret and understand. Hardware not involved in any of the events in the model is, at most, of secondary interest in the assurance program, only requiring enough attention to determine that probabilities which may have been assumed to justify truncation of the model are indeed low enough to warrant that action.

It is fortuitous that the introduction of probability into the modeling process is direct and straightforward. As discussed in Appendix C of this report, unreliability models — reduced to symbolic form — may be interpreted as approximate unreliability equations. This allows one to assign values to the individual events in the model in such a way that if each assigned value is met the overall subsystem unreliability (computed directly in the equation as a function of event probabilities) is maintained at a desired level. If the assigned values for the individual events appear sensible in terms of what can be reasonably expected as probabilities of loss of the involved components, they may be taken directly as component reliability requirements. As the modeling is expanded to include lower levels of components, this allocation process identifies the importance of each item of hardware to performance of the system, and provides goals for those activities associated with each item.

It is also necessary to establish for each item in the model the conditions under which the item must operate or survive. Based on this information, the assurance program can be established in a deliberate, methodical way that will assure attention to each item in proportion to its importance to safety, and minimize the possibility of something being missed.

Assurance Planning

An overall quality assurance program should address each of the components involved in the model. For each component a quality assurance plan should be developed, based upon its operating requirements and environments, experience with similar components, and the failure rate allocation for events related to the

component. The three approaches to dealing with errors (accommodation, prevention, and detection and correction) should be reflected in the quality assurance plan. Figure B-1 illustrates where the various approaches would normally come into play throughout the design, production, construction, and operating life of the plant. Also identified are the engineering and quality groups involved in the various phases.

For example, the major accommodation effort is associated with design of the system, where both the design and safety analysis groups would interact to produce a design with the ability to accommodate probabilities of component failure or other misbehavior reasonably expected to result from the existing technology. Similarly, the design and safety analysis groups should design to prevent errors, including those which may occur in manufacture and operation. Here, conservative design margins, redundancy (with a minimum potential for common-mode failures), and utilization of compatible materials should be applied as necessary. Selection of manufacturing and installation processes and process controls which have a demonstrated capability to produce what has been designed in a consistent and controllable manner should be included. For operations, those operational features which provide safety assurance, such as redundancy and competence of operators, and effective surveillance and maintenance processes should be incorporated.

Detection activities (test and inspections) are scattered throughout the effort. These activities form the backbone of an assurance effort, since it is almost exclusively through this approach that unknown and unsuspected errors will be identified. Also, a strong program of detection (and the forcing of subsequent correction) serves as a powerful impetus to provide similarly strong efforts for prevention, accommodation and even preemptive detection and correction, since these measures reduce the costly corrections that occur if the error awaits detection in later testing.

As implied above, the detection activities are of little or no value unless the errors are corrected or it is objectively determined that their effect on safety is insignificant. The correction of deficiencies found is normally not the responsibility of those conducting the detection activity which disclosed the deficiency. (Figure B-1 shows that feedback to design, manufacturing, or operational groups is necessary to achieve the correction.) However, we believe it

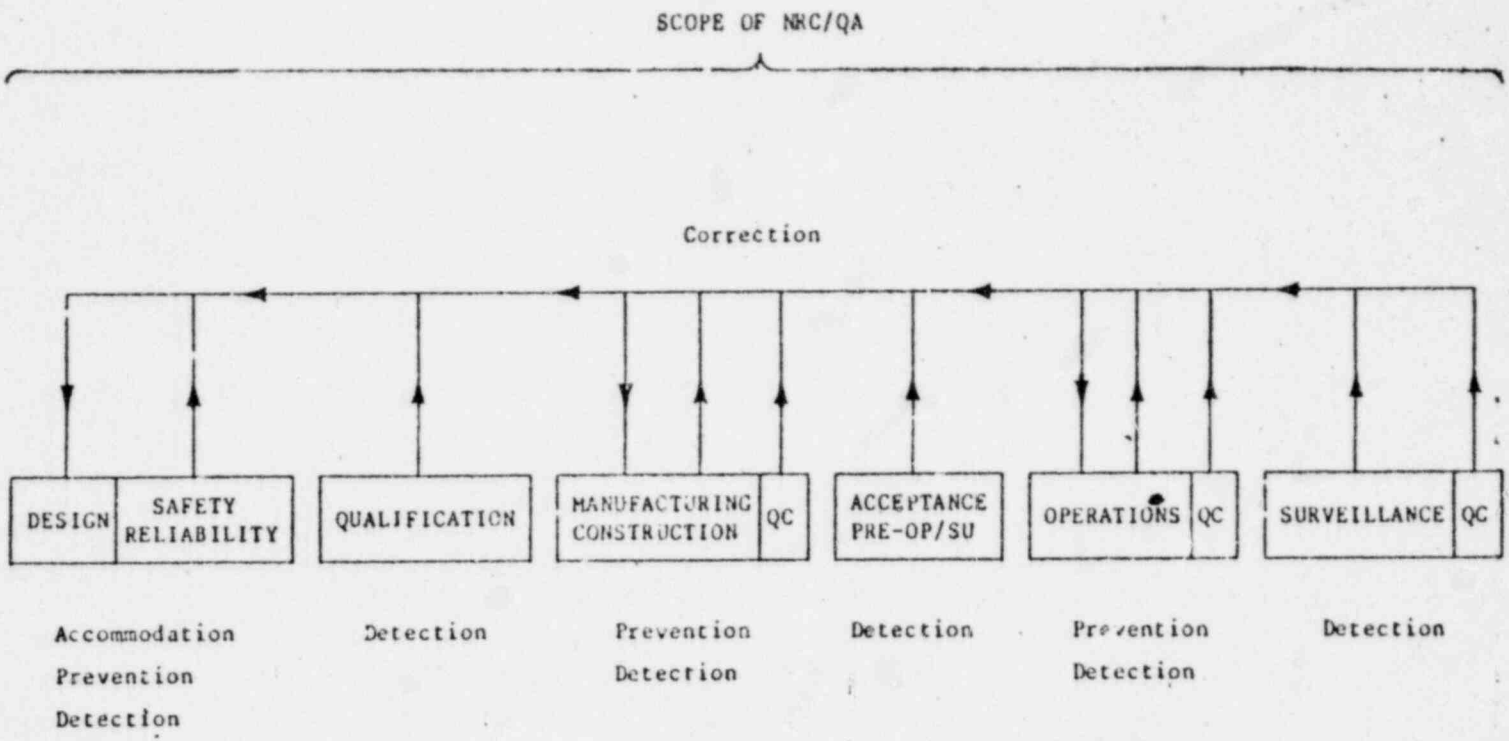

Figure B-1 Scope of NRC Quality Assurance

should fall within the purview of the assurance organization to assure that errors disclosed are pursued and brought to an appropriate conclusion, whether that be a correction to design, manufacturing, etc., or an objective determination that the error does not have significant import to safety. In the nuclear ordnance field, the assurance organization normally chairs such investigations, and reports status periodically until the investigation is concluded and appropriate actions have been assigned and accepted. The expertise for the investigation is drawn from design, reliability, safety, and materials groups, as the needs of the investigation dictate.

The degree of assurance achieved by testing depends on the extent to which it provides information on function under the conditions experienced in use. The optimum information, for example, derives from functional testing of a complete system under conditions which equal, or exceed, end use conditions. For nuclear reactors this would be a full-scale test of a reactor, including tests similar to LOFT, which is being conducted under the auspices of the Office of Nuclear Regulatory Research.

Full scale, complete system testing as described above is not feasible for nuclear power facilities, for a variety of reasons. This applies also to nuclear ordnance with which the study group is experienced. In these cases, assurance must be sought through alternative tests which may involve less than the full system, or may approximate the use environments, or both. For example, qualification testing of components is probably the most practical way to demonstrate capability of these items under destructive accident conditions. The assurance value of these tests is less than that achieved through tests of a full scale system, but is none the less appreciable.

Because of the significant assurance value of testing and inspection in detecting errors, a well conceived and well executed comprehensive test program is an essential element in assurance planning. The systematic identification of testing conducted on each safety-related item will provide a basis for determining: whether an item has demonstrated a capability to operate or survive under all use conditions; whether opportunities for observing interactions between it and other parts of the system have been provided; whether hardware tested is representative of hardware to be used in the plant; etc.

Shortcomings in the test plan can then be eliminated wherever feasible, or failing that, they can be identified as areas where other approaches to assurance must be relied upon to prevent or accommodate possible errors. In these areas, more extensive effort in analysis, use of administrative systems, design reviews, etc., is warranted, and can be planned.

The preventive approach is reflected largely in the use of administrative or management systems in the conduct of all actions whose incorrect performance may have a significant effect on safety. Administrative systems comprise those organizational arrangements and formal procedures which are instituted to define the measures necessary for assurance, and to assign the responsibilty for them. The appropriate measures (such as design control, document control, control of nonconforming material, etc.) have been defined in many quality assurance documents. For the nuclear reactor industry, they have been embodied in the 18 criteria of 10 CFR 50, Appendix B.

Program Implementation

Implementation of the assurance program also implies implementation of the activities which perform the quality function. It is considered that the assurance organization (regulatory agency) has the responsibility, the authority, and the necessary expertise to direct that the necessary quality activities be implemented, and, to some extent, by whom. For example, the organization may decide to implement certain parts of the quality function itself. However, it is normal that the assurance organization would subsume only those activities it considers will not be properly accomplished elsewhere, (even with inspection and enforcement), thereby taking the fullest advantage of existing organizational structures and activities.

This now creates an obligation on the part of the assurance organization (the regulatory agency) to verify program implementation. That is, the assurance organization must verify that the responsibilities for each of the necessary activities are accepted and understood, that the necessary authority and expertise for its successful execution exist, and that implementation is scheduled so that the full benefits of the activities may be realized.

Measurement of Effectiveness of the Quality Function

Since quality assurance is concerned with whether the quality function is properly accomplished, the measurement of effectiveness of the quality function is vital to the achievement of that objective. Effectiveness of the quality function is of interest at several distinct levels.

At the first level, the effectiveness of individual actions is of interest whenever it appears that [illegible] may be in jeopardy. Either direct involvement in such cases, or close attention to the handling of these situations, is necessary to assure their effectiveness. In these individual cases, each is judged to have been handled effectively or not.

At a more statistical level, the assurance organization must be concerned with the effectiveness of individual programs, activities, and organizations involved in performance of the quality function. Effectiveness of an activity is determined fundamentally by how well the activity deals with the types of errors it was intended to deal with. In the context of nuclear power stations, the errors of interest would be those that affect safety of the power stations. Consequently, an activity intended to prevent safety-related errors would be effective if the frequency with which such errors occurred or escaped detection was sufficiently low.

Finally, the effectiveness of the performance of the total quality function determines the real assurance of quality. Again, this is a statistical measure related to the frequency with which all safety-related errors result in misbehavior of systems or components in operation.

Whether the total program (taken in relation to either the total system or to individual hardware items) is effective depends upon the comparison between the observed and allowed rates of errors. In this regard, it should be noted that, because of the desire for extremely high safety for the total system, an immense number of years of reactor operation would be necessary to provide a suitable statistical base to make useful conclusions about assurance observed if there have been no system misbehaviors. While it may be true that this is the only

irrefutable measure of assurance, it is not available to us.

Fortunately, there are other methods of measuring assurance. For example, it has been acknowledged that errors will occur that affect the performance of hardware. Further, these error rates are noticeable and measurable, at least at hardware levels below those where accommodative measures such as redundancy have been applied. By measuring or estimating these rates, and by using the mathematical model to depict the effect of the accommodation measures used in the design of the system, an estimate of system level performance can be computed for comparison with an allowable failure rate.

Of the three levels at which effectiveness is of concern, the second level -- effectiveness of individual activities -- is probably the most difficult to deal with. For example, there is difficulty in relating administrative procedures to safety. In these activities the relationship between the actions taken and the types of errors they treat are variable and difficult to trace. Consequently, it is usual to attempt to measure effectiveness of such activities against substitute criteria such as errors, error rates, the number of noncompliances, etc. These are examples of measurements of pseudo-effectiveness. These measurements probably correlate with effects on safety, but may not in all cases. For this reason, the study group would minimize dependence on measures of pseudo-effectiveness.

APPENDIX C

Modeling Illustration

The purpose of this appendix is to illustrate some of the methods which may be used to construct the models discussed in Chapter IV. These models will be used to approximate the relationship between the reliability* of components and subsystems, and the reliability of the systems they comprise. This process will provide a basis for the systematic structuring of the quality assurance program. The impact of these models on the quality assurance program is obtained through analysis of the models in order to define pertinent modes and rates of component unreliability. The models are also used to assist in identifying appropriate test and surveillance procedures, and to assure that the quality function is satisfactorily accomplished.

These quality assurance benefits are best obtained by the application of simplified modeling which includes failure mode and effects analysis, maintenance considerations, and unreliability rate allocation, and which can be adapted to utilize data that can be made available routinely. The modeling illustrated in this appendix considers only lower-level systems and below, e.g., as shown for the accumulators system in Figures C-1 and C-2. The major prerequisite for such modeling is a technical understanding comparable to that required to perform the accident analyses now required in Chapter 15 of the SAR. This appendix addresses the few additional specialized techniques required.

Event Diagrams

Event diagrams show the logical relationships which exist among various contributory (component or subsystem) events and a given system event. There are

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* As used in this report, reliability relates to the probability that a device will operate properly upon demand, and therefore includes considerations of availability. Thus, causes of unreliability include both failures and other conditions which make an item unavailable for use, such as being off line because of inspection or maintenance.

ACCUMULATORS SYSTEM -- 3 of 4 Required

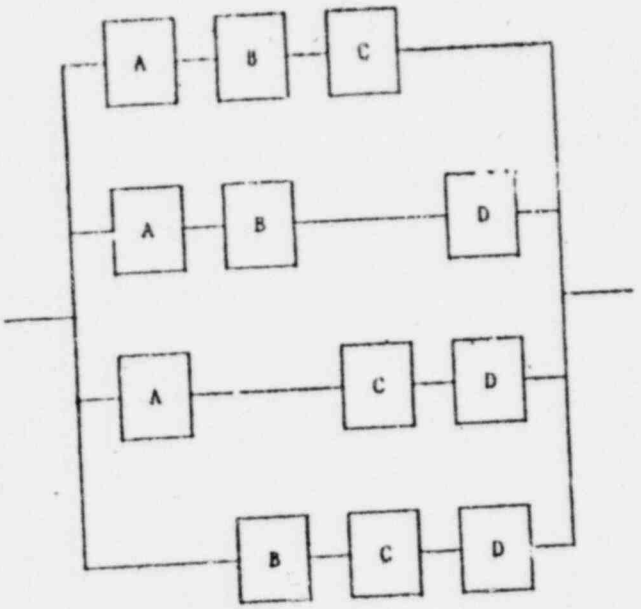


Figure C-1

System/Subsystem Level

A = Accumulator Subsystem A
B = Accumulator Subsystem B
C = Accumulator Subsystem C
D = Accumulator Subsystem D

$$U = A \cdot (B + C + D) + B \cdot (C + D) + C \cdot D$$

In the equation, the symbols A, B, C, and D are taken to mean unreliability of the respective subsystem, and U to mean unreliability of the accumulators system.

Explanation

This model describes the logical relationship between the various subsystems of the accumulators system when there has been no cold leg pipe break. It is assumed that output from 3 of the 4 accumulators is required. The branches represent the four different ways of achieving system success using the minimum number of components. A fifth parallel branch including all four subsystems has been omitted from the diagram. This branch would be superfluous and would not change the equation. (A cold leg pipe break could cause the loss of one accumulator output. In this event, failure of any of the remaining accumulator subsystems would constitute failure of the accumulators system.)

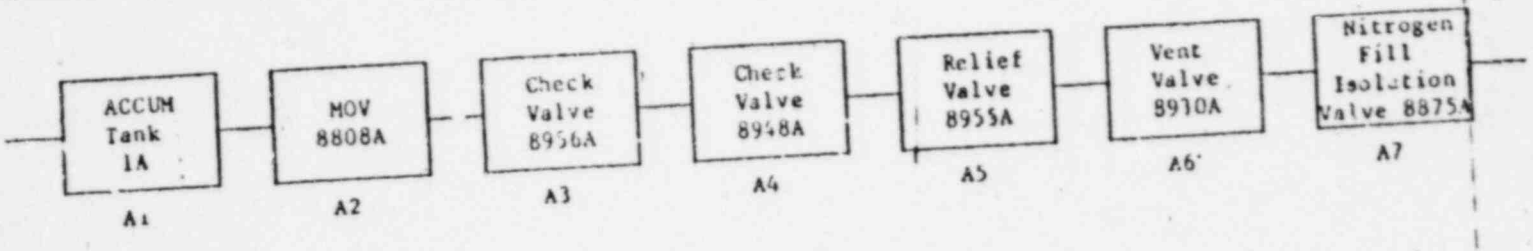
ACCUMULATOR SUBSYSTEM

Subsystem/Component Level

Explanation

This model describes the logical relationship between the individual accumulator components.

= A1 + A2 + A3 + A4 + A5 + A6 + A7



Specific Component Unreliability Events

A1	A2	A3	A4	A5	A6	A7
1. Ruptures	1. Plugged	1. Fails to open	1. Fails to open	1. Leaks	1. Leaks	1. Leaks
2. Water low	2. Ruptures	2. Ruptures	2. Ruptures	2. Ruptures	2. Ruptures	2. Ruptures
	3. Closed inadvertently faulty signal					
	4. Closed for maintenance					

Figure C-2

DERIVATION OF SIMPLIFIED EVENT EQUATION FROM EVENT DIAGRAM OF FIGURE C-1

From the event diagram we write directly,

$$U = (A + B + C) \cdot (A + B + D) \cdot (A + C + D) \cdot (B + C + D).$$

Multiplying the first two terms and the last two terms,

$$U = (A \cdot A + A \cdot B + A \cdot D + A \cdot B + B \cdot B + B \cdot D + A \cdot C + B \cdot C + C \cdot D) \cdot (A \cdot B + A \cdot C + A \cdot D + B \cdot C + C \cdot C + C \cdot D + B \cdot D + C \cdot D + D \cdot D).$$

Utilizing the relations $X \cdot X = X$, $X + X = X$, and $X + X \cdot Y = X$ to simplify by eliminating redundant terms,

$$U = (A + B + C \cdot D) \cdot (C + D + A \cdot B).$$

Multiplying the two terms,

$$U = A \cdot C + A \cdot D + A \cdot A \cdot B + B \cdot C + B \cdot D + A \cdot B \cdot B + C \cdot C \cdot D + C \cdot D \cdot D + A \cdot B \cdot C \cdot D.$$

Again using the relations $X \cdot X = X$, $X + X = X$, and $X + X \cdot Y = X$ to eliminate redundant terms,

$$U = A \cdot C + A \cdot D + A \cdot B + B \cdot C + B \cdot D + C \cdot D.$$

Factoring,

$$U = A \cdot (B + C + D) + B \cdot (C + D) + C \cdot D.$$

Figure C-3

numerous ways such diagrams may be prepared, but they all require some convention for depicting the necessary logical relationships which can occur between the events.

Event diagrams can often be derived directly from functional flow diagrams. Component unreliability is visualized as an open switch within the box representing that component, and system unreliability is considered to occur whenever there are sufficient "open switches" to interrupt the continuity from one end of the diagram to the other. Thus, events in components connected in series describe logical situations in which loss of any single component will cause loss of the system portrayed by the diagram. Similarly, components connected in parallel describe logical situations in which loss of all components is required to produce system loss. (Figure C-1 depicts a more complicated parallel arrangement in which loss of two of the four accumulator subsystems is necessary to cause system loss.)

Simplifications to such diagrams can be achieved in several ways. These include:

- Assuming that unreliability of a device would always lead to a given system fault when, depending upon a number of outside considerations, the failure of the device might sometimes be compensated for.

- Truncating the model to exclude relatively remote or obscure ways in which a system event might be realized.

- Not carrying the model to additional levels of detail, once a level has been reached for which appropriate failure rate data can be obtained.

Of these simplifications, only the second exposes the modeler to the danger of omitting significant influences on the unreliability of safety features, thereby causing later probability assessments to be unduly optimistic. The techniques or guidelines used in truncating the modeling effort require continuing scrutiny to protect against this eventuality.

Figure C-1 shows a lower-level system and represents the highest level for which simplified modeling is proposed. Figure C-2 presents a model of one

accumulator subsystem at the component level. At this level, it is appropriate to list the specific co[illegible] events which would result in unreliability of the subsystem. These are, in fact, the basic concerns which must be addressed by the designer, fabricator, and operator of a reactor facility. They identify areas appropriate for testing and for data collection and analysis, and provide a definition of safety-related components which is sufficiently specific to allow concentration of quality assurance on the pertinent facility hardware. This is as far as the modeling need proceed to satisfy normal quality assurance responsibilities.

Event Equations

Information displayed graphically in any of the various forms of event diagrams can also be written in equation form by providing symbols for the various events and adopting a convention for symbolizing the necessary logical relationships. A convention that will produce equations which may also be interpreted as numerical unreliability rate equations is to represent the logical "and" (intersection, shown graphically by parallel arrangements) by a multiplication symbol and the logical "or" (union, shown graphically by series arrangements) by an addition symbol. If each fault is given a different symbol, these event equations are essentially set theoretic expressions, or Boolean algebra expressions, and are simplified by the use of basic set theory or Boolean algebra relationships. (E.g., $A + A = A$, $A + AB = A$, $A \times A = A$, etc.) Figures C-1 and C-2 provide the simplified event equations for the event diagrams, where completeness of the diagrams is assumed. Figure C-3 illustrates derivation of a simplified event equation directly from the event diagram of Figure C-1. Certainly, experience leads to the use of shortcuts which can speed the derivation in more complicated situations such as this. However, the illustrated procedure is practicable and the resulting equations will be equivalent regardless of the methods used.

The simplified event equations can, to an excellent approximation, be interpreted directly as numerical unreliability rate equations. (The event equations must be simplified for this interpretation to be valid.) Having developed the equations with the use of set theory considerations, one may ignore those considerations entirely and treat each equation as a normal mathematical relationship between the unreliability rates of the events symbolized in the

equation. For example, if each of the four unreliability rates in the equation given in Figure C-1 were 0.01 per demand, the unreliability rate computed for the accumulators system would be 0.0006 per demand.

These equations assume independence among component and subsystem events modeled in parallel arrangements, and provide excellent approximations to the actual failure rates in the absence of unanticipated common-mode influences among these parallel component or subsystem events. Common-mode influences result in positively correlated, multiple events of concern in parallel components or subsystems; such influences can result from a single initiating cause, where "cause" is used in its broadest context. The presence of unanticipated common-mode influences could result in the calculated unreliability rate being far too low. Consequently, to preserve the desired accuracy, it is necessary to examine components and subsystems arranged in parallel for the presence of common-mode potentials. For example, Figure C-1 illustrates a parallel arrangement in which an examination of the accumulator subsystems for common-mode potential is prompted by the fact that the accumulator subsystem events are multiplied together in the equation (i.e., the subsystems are arranged in parallel).

The unreliability rate equations have another important use. Given that an acceptable unreliability rate for the system fault is stated, it is possible to allocate unreliability rates to the contributory events. These allocations then become goals to be achieved in the design, production, and operation of the pertinent systems.

Conclusion

The modeling process described in this appendix is relatively simple and straightforward, given sufficient technical understanding of systems comprising a facility. The end result is:

- An analysis of the reliability of the safety-related features to the extent necessary to support a quality assurance program.
- Identification of data required for assessment of QA program effectiveness.

- A means for relating component or subsystem unreliability rates to system unreliability.

- A means for specifying acceptable unreliability rates for component failures, given a reliability goal.

APPENDIX D

Background of the Study Group

Quality Assurance at Sandia Laboratories

Sandia Laboratories' Quality Assurance organization establishes and manages continuing evaluation programs to assure that Sandia-designed weapon material possesses the high reliability and safety required of it throughout its stockpile life. A Memorandum of Understanding between Sandia Laboratories and the Energy Research and Development Administration (ERDA) delegates the Quality Assurance function to Sandia Laboratories. It states that Sandia Laboratories shall:

1. Develop, maintain and conduct continuing Quality Assurance engineering and test programs throughout production and stockpile life to assure that [ERDA]-accepted material conforms to design and quality requirements, both expressed and implied.

2. Periodically issue a report of the reliability of stockpiled weapons.

3. Conduct a continuing review of current quality methods and advanced techniques.

4. Make recommendations to [ERDA] as necessary to maintain a properly balanced Quality Assurance function.

To enhance objectivity, Quality Assurance has been assigned to a Sandia Laboratories organization that is independent of project groups responsible for design, development, and production engineering.

In addition to the activities described in the foregoing paragraph, the quality assurance techniques developed for nuclear weapons have been applied to various projects outside the nuclear ordnance field. These include radioisotopic thermoelectric generators for use in space, sensor systems for nuclear burst detection satellites, and conventional ordnance items.

of Study Participants

rief description of pertinent background and experience for members of the aboratories staff who participated in the study is presented in this

ller, Principal Investigator

n Texas A&M. Completed company sponsored Masters Level program in al Engineering and substantial graduate work in Mathematical Statistics, ty of New Mexico. Has been a member of the Sandia Laboratories staff since rior to 1965, was a member of the Reliability Department as a system ity engineer, and supervisor of a training and methodology development where he developed improved reliability techniques. Authored monographs bility technology and numerous methodological papers. Since 1965, has been or of Quality Assurance Advanced Planning Division, with a responsibility: rm a continuing review of all aspects of Sandia's QA Program; to make conduct research, formulate plans and develop improved QA philosophies and es.

ent with NRC has included management of study group proposing statistical procedure for IE, review of the methodology applied in WASH 1400, ation in cost benefit analysis of NRC research program, and review of NRC Evaluation Group study of IE.

isbin

l BA Journalism, Washington State University. Recent study includes courses ear engineering, radiation effects, and consequences of radioactive releases clear accidents. Employed by Boeing Airplane Company from 1951 through d has been a member of the Sandia Laboratories Quality Assurance staff 956. Most of the latter period was spent in development and implementation programs for nuclear ordnance. Lesser periods were spent in analysis of nonconformance, reliability analysis and planning of quality assurance s. Was project leader for a study to develop a statistically based sampling ion program for commercial nuclear reactors under Sandia Laboratories

contract with NRC Office of Inspection and Enforcement.

A. C. Ellingson

BA degree with major in Mathematics, Augustana College, and post-graduate work, University of Wyoming. Recent studies include physics of interaction of radiation with materials, radiation effects, basic radiation chemistry, nuclear engineering, reactor theory and radiation transport, and consequences of radioactive releases from nuclear accidents. Was an instructor in mathematics, science, and electronics in public and DOD schools for about twenty years. Employed as a design engineer at Consolidated Vultee for one year. Has been a member of the Sandia Laboratories staff since 1952. Experience at Sandia Laboratories includes design and supervision of design and development for test equipment and automated data systems through 1963, and quality assurance activities since 1964. Was chairman of working group preparing ANSI Standard N402, "Quality Assurance Requirements for Research Reactors." Participated in study to develop a statistically-based sampling inspection program for NRC Office of Inspection and Enforcement. Recently established a quality assurance program for SPR III, research reactor.

M.A. Griesel

BA Mathematics, UCLA; MA, PhD Mathematics UCR; MBA, Claremont Graduate School. Major fields were numerical analysis, probability, mathematical applications in organizational studies, and business economics. Joined the Sandia Laboratories Quality Assurance staff in 1974. Activities include development of a new program for quality assurance of products built for ERDA acceptance, cost-benefit analysis of alternative corrective actions, development of evaluation methods for quality assurance programs, and a critique of economic analysis in the Draft Environmental Statement for the WESCO Coal Gasification Project. NRC related work includes participation in a critique of the methodology of the WASH 1400 Reactor Safety Study and a cost-benefit study of reactor safety research.

R. L. Hannigan

BSEE, University of Kentucky. Recent studies include physics of interaction of radiation with materials, materials analysis, developing a total quality program,

and statistical design and analysis of experiments. Has been a member of the Sandia Laboratories staff since 1955; in Quality Assurance since 1959. Experience includes quality survey and support activities, quality assurance advanced planning, testing and evaluation of electrical and electronic devices, and product acceptance programs. During the past ten years has been project engineer for several quality assurance programs associated with the ERDA Space Nuclear Systems Division.

J. Kirby, Jr.

Was Chief Inspector for Superior Electric Company where he established and directed the quality control program. Was responsible for product acceptance activities at 30 plants producing mechanical, electrical and electronic components for USAF during World War II. Was production supervisor in clock and watch industry. Has been a member of the Sandia Laboratories Quality Assurance staff since 1949. Has been a major contributor in the establishment and maintenance of quality assurance survey activities in the nuclear weapons field. Has provided consultant and program development services for programs of the US Navy, ERDA Space Nuclear Systems Division, and Lawrence Livermore Laboratory.

G. J. Lynch

BSEE Villanova. US Army Signal Corp. 1949 to 1955. Performed resident inspection for quality assurance, analysis of corrective action for QA problems, and development of quality assurance inspection programs and procedures. Has been a member of the Sandia Laboratories Quality Assurance staff since 1955. Experience includes preparation of quality assurance procedures for AEC manual. Current activity includes planning and development of ERDA acceptance programs (inspections, surveys, and data analysis) for weapon systems and test equipment, and technical consultation to ERDA on corrective action. Also provides technical direction for hardware evaluation, process surveys, and data analysis -- identifying critical product characteristics and establishing allowable levels of defectiveness.

R. C. Mueller

BA in Physics, Colorado College; MA in Physics, Dartmouth; substantial graduate work in statistics and computer sciences at University of New Mexico. Joined Sandia Laboratories in 1962. Involved in component development work for three years and in support of Joint Task Force Two in design and analysis of large-scale test programs investigating the capabilities of military aircraft and crews in low-altitude flight for three years. Worked in analysis of safety risks of SNAP applications for AEC Space Nuclear Systems Division, as a member of the Sandia Laboratories Aerospace-Nuclear Safety Group during 1968 and 1969. Publications include several papers on radiation release risks and consequences pertinent to space nuclear systems. Has been a member of the Sandia Laboratories Quality Assurance staff since 1969, primarily in advanced planning and program improvement. Participated in critique of the methodology of WASH 1400 Reactor Safety Study.

J. D. Wright

Employed in the Sandia Laboratories Quality Assurance organization since 1948. Most of this period was spent in developing and coordinating the performance of evaluation programs for electronic and electromechanical nuclear weapon components and subsystems. Was supervisor of component test and analysis group for approximately fourteen years. Activities have also included the performance of audits for supplier manufacturing and quality related operations. Is currently engaged in the development and implementation of nuclear ordnance system test programs.

W. Hamm
Exhibit 1097

FEB 1 1978

For: The Commissioners

From: Edson G. Case, Acting Director, Office of Nuclear Reactor Regulation

Thru: Executive Director for Operations

Subject: PLANNED STAFF ACTIONS WITH RESPECT TO THE SANDIA STUDY OF THE NRC QUALITY ASSURANCE PROGRAM

Purpose: To inform the Commission of planned staff actions regarding the recommendations of subject program.

Discussion: On May 4, 1976 in SECY-76-254, we informed the Commission of our plans to procure an independent study of the NRC quality assurance activities regarding nuclear power stations. Authorization to conduct the study was issued to the Sandia Laboratories. The study has been completed and a final report thereof entitled, "A Study of the Nuclear Regulatory Commission Quality Assurance Program," was provided to us in August 1977 and has been published as NUREG-0321.

The report of the study contains 16 recommendations that the study team believes will enhance the quality assurance activities of the NRC and the nuclear power industry. The staff has considered these 16 recommendations and has developed a planned course of action. A condensed status report of the planned action regarding each recommendation is contained in Enclosure 1 and a more detailed discussion of the recommendations and planned action is contained in Enclosure 2.

With respect to 12 of the 16 recommendations, the staff has in progress, or has completed, actions that are consistent with each study recommendation; in almost all cases, these actions were underway prior to receipt of the Sandia report. For three of the study recommendations, the staff has concluded that further study is necessary in order to determine the appropriate action and has initiated such study. For the remaining study recommendation, no staff action is planned.

Contact:
D. J. Skovholt, NRR
49-27492

Although the staff actions discussed herein are responsive to the study recommendations, the need for these actions had already been determined by the staff and they were underway. The results of the study are considered confirmatory in this regard. Usually, the need for a certain action is determined and confirmed by staff review of the experience within the industry. For example, both Sandia's Recommendation No. 13 and the recent experience with failures of electrical cable connectors provide independent confirmation of the need for the current staff activities to further define requirements and guidance regarding qualification testing.

Coordination: This has been concurred in by the Offices of Inspection and Enforcement and Standards Development. The Office of the Executive Legal Director has no legal objection.

Original signed by
EGCase

Edson G. Case, Acting Director
Office of Nuclear Reactor Regulation

Enclosures:
1. Status Report
2. Detailed Discussion

DISTRIBUTION:
Central Files
NRR Reading File
QAO Reading File
DJSkovholt, PM:ADQAO
RCDeYoung, PM:DD
RSBoyd, PM:D
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JLLochte, PM:QAO
HSBassett, PLA
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SLevine, RES

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EVolgenau
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*SD
RMinogue
1/26/78

*See previous yellow for concurrences

OFFICE ➔	PM:AD[illegible]	*OELD	*PM:D	NRR Signed	EDO	
	DJSkovholt	JSelote	RSBoyd	EGCase	LVGossick	
DATE ➔	2/ /78	1/17/78	1/19/78	2/ /78	2/ /78	

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Edson G. Case, Acting Director
Office of Nuclear Reactor Regulation

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EHughes, PM
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See Note to DJS
1/17/78

for JE Norman
EVolgenau
1/20/78

SD
RMinogue
1/26/78

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SURNAME ➤	DJSkovholt:jh		RSBoyd	EGCase	LVGossick	
DATE ➤	1/ /78	1/ /78	1/ /78	1/ /78	1/ /78	

Enclosure 1

STATUS REPORT

PLANNED STAFF ACTIONS

Recommendation		Action Completed	Action is a Continuing Effort	Action In Progress	Action to be Determined by Further Study	No Action Planned
NSIR/SO	1			X		
SO/NRR	2			X		
NRR/IE	3	X				
IE	4	X				
	5	X				
	6				X	
NRR	7		X			
	8					X
	9			X		
	10			X		
SO/NRR	11			X		
IE	12			X		
SO/NRR	13			X		
NRR	14		X			
NRR/SO	15				X	
NRR	16				X	

Enclosure 2

Discussion of
Planned Staff Actions

Recommendation #1

"The NRC strengthen, through its communications to industry, recognition of the Standard Review Plan as the basic source of guidance on quality assurance requirements."

Status: Action in Progress

Discussion:

It has been the objective of NRR to assure that Chapter 17 of the Standard Review Plan (SRP) identifies all guidance relevant to licensing activities concerning quality assurance requirements, either through inclusion or reference, and that industry thoroughly understands the purpose of the SRP in the licensing process. While this objective has been largely accomplished, the fact that some elements of the SRP are no longer up-to-date has resulted in some limitation of its usefulness as a basic source of guidance. However, a number of actions have been initiated which have strengthened this activity since discussions with Sandia personnel during the summer of 1976.

The SRP identifies: (a) what will be reviewed by NRR, (b) who will perform the review, (c) what acceptance criteria will be employed, and (d) what finding will be made by the staff. Thus, the SRP will either contain specific control and acceptance criteria or will reference pertinent documents, such as regulatory guides and industry standards, which must be considered and addressed in the applications. The SRP, in conjunction with its sister document, the Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, are the mechanisms by which documents produced by the Office of Standards Development and actions identified by the Office of Inspection and Enforcement are appropriately identified and incorporated into the licensing process. In this manner, a controlled, consistent, and documented review process is assured.

Over the past year, the following actions have been initiated with regard to the QA section of the SRP (Chapter 17).

(a) The industry and other NRC offices were asked to comment on the SRP QA guidance. As a result, extensive comments were received from AIF, IE and Standards.

(b) The role and importance of the SRP continue to be highlighted in speeches and meetings with industry. For example, this subject was discussed in formal presentations at: the Third and Fourth Annual Conferences of the ASQC Nuclear Division in San Francisco in October 1976 and in Washington, D. C. in October 1977, the ASME Conference on Quality Assurance in Miami in September 1976, and the AIF Workshops in Atlanta in December 1976 and in Boston in October 1977.

(c) NRR has initiated a program for the updating of the SRP on a consistent basis. Chapter 17 on QA has been extensively revised and updated and is now undergoing management review.

(d) Actions have been initiated to assure that Regulatory Guide 1.70 covering the Format and Content of Safety Analysis Reports and the SRP are consistent.

Based upon the above, the thrust of the Sandia recommendation has been and is being carried out. NRR certainly concurs in the objective of the recommdation and will continue to seek additional vehicles to strengthen the communication with industry on the SRP.

Recommendation #2

"10 CFR, Appendix B, be used in the regulation of all areas of power reactor design, construction, and operation which are judged to have sufficient importance to safety to fall under other NRC regulation. The selective application of QA elements now applied to safety-signficant items not interpreted as falling under Appendix B should be replaced by an approach in which the degree to which the 18 criteria of Appendix B are applied would reflect the safety-significance of the item."

Status: Action in Progress

Discussion:

We agree that there is need for additional guidance in determining what structures, systems, and component , important to safety fall within the requirement of Appendix B to 10 CFR Part 50. We also agree that Appendix B requires a graded approach to implementing quality assurance practices such that the degree to which the 18 criteria of Appendix B are applied

should reflect the safety-signficance of the item. The Office of Standards Development has a regulatory guide (RS Task 704-4) presently under development concerning the applicability of the quality assurance criteria of Appendix B to 10 CFR Part 50 to structures, systems, and components of nuclear power plants. It is expected the guide will be issued for public comment in mid calendar 1978.

Recommendation #3

"The Transfer of Lead Responsibility Memo be revised (or that some supplemental means be established) to provide a schedule for completion of activities and a status reporting mechanism, for problems requiring action by both the Office of Inspection and Enforcement and the Office of Nuclear Reactor Regulation."

Status: Action Completed

Discussion:

At the time of the discussions with Sandia personnel in the summer of 1976, it was indicated that the formal guidelines covering lead responsibilities and interfaces between NRR and IE were out of date and, as a result, there were some uncertainties. The previous formal procedures on this subject were established via a December 29, 1972 memo from L. Manning Muntzing to J. F. O'Leary and F. E. Kruesi.

A revised agreement between NRR and IE was documented in a memorandum to Lee V. Gossick from Ben C. Rusche and Ernst Volgenau dated March 21, 1977, subject: Agreement on NRR/IE Interface and Division of Responsibility. This memorandum recorded the general areas of responsibilities of each office and specific agreement on the division of responsibility between the Offices in those areas where interfaces or overlaps existed in the functions assigned to each organization.

A schedular and status-reporting mechanism for items involving both NRR and IE was established via a memorandum for Lee V. Gossick from Edson G. Case, Ernst Volgenau and William G. McDonald dated July 1, 1977, subject: Plan for Tracking of IE-Oriented Items Impacting NRR Licensing Activities. This memorandum discussed the Interoffice Action Items and the suggested improvements in the present NRR procedures and management information tracking system, particularly the Blue and Pink Books, to identify for management attention, each such item, the date of transfer or action

request, the responsible branch and individual, the completion date and the current status. This memorandum also noted that procedures had been developed to track the IE-originated items (Interoffice Action Items) and to clarify the internal NRR interface between DPM and DOR on items affecting CPs, OLs and ORs.

In addition, monthly NRR/IE interface meetings continue to be held to resolve any questions regarding implementation of the policies and procedures regarding NRR/IE interfaces.

In sum, the need for action on this recommendation was recognized and implemented prior to submittal of the Sandia report. The actions noted above responded to each aspect of the Sandia recommendation, and thus, this item has been classified as completed. Further improvements in these procedures will be made as the need and our experience dictate.

Recommendation #4

"The NRC take steps to assure that each vendor inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) is aware of the continuing responsibility and authority of the licensee with respect to vendor quality assurance."

Status: Action Completed

Discussion:

Substance of recommendation is published in the White Book, Licensee Contractor and Vendor Inspection Status Report (Forward and Sample Confirming Letter). The White Book is updated quarterly and distributed to all vendors listed in the document.

To further emphasize vendor notification of licensee responsibility, the IE cover letter to each vendor inspection report has been modified to include a standard paragraph with the recommended information.

Recommendation #5

"IE headquarters clarify responsibility for inspection of quality assurance activities of utility-run architect-engineers as belonging either to the regular inspection and enforcement program or to the Licensee Contractor and Vendor Inspection Program (LCVIP)."

Status: Action Completed

Discussion:

Responsibility assignment for the inspection of independent architect engineering firms (LCVIP) and the utility who performs its own inhouse architect engineering (Region) was stated in the early draft MC-2720, Architect Engineer Inspection Program. A subsequent redraft, reidentified as MC-2710, includes the responsibility assignment. It is currently also designated in MC-2500 of the IE Manual, pages 2500-4 and 5, dated January 1, 1977.

Recommendation #6

"Vendors to be inspected under the Licensee Contractor and Vendor Inspection Program (LCVIP) be selected on a basis which ensures that every vendor has some likelihood of being inspected."

Status: Receiving further study.

Discussion:

The criteria used for selecting vendors for inspection must continue to be based primarily upon safety considerations. Since vendor work volume is constantly changing proportionate to overall nuclear industry activity, the vendor population is not fixed at any given time. Further, the majority of vendors are small, single item suppliers, or suppliers of equipment which may or may not be used in a safety important system. It is, therefore, not practical to ensure that every vendor is inspected at some point in time nor is the expenditure of limited NRC resources for inspection of vendors justified under any circumstances if the vendor is not supplying safety-related products or services.

IE will review implementation of present criteria applied for the selection of vendors for inspection to assure as broad a coverage as possible.

Recommendation #7

"IE inspection of material produced under the ASME Code provisions be eliminated, but only if the ASME requirements are expanded to include operation. Since efforts in this direction are underway, this recommendation is intended to encourage such efforts."

Status: Action is a Continuing Effort

Discussion:

Use of the word "material" in the recommendation is unclear since the ASME Code covers the design, manufacture, assembly of parts and components as well as providing rules specific to materials. From the text preceding the recommendation, we assume that material is meant to mean all "products and services" provided a nuclear facility in accordance with ASME Code rules.

In response to the recommendation, as stated, efforts are underway to utilize the ASME vendor certification and inspection system to supplement direct NRC inspections. NRC recognition and utilization of the ASME certification and inspection system is contingent upon two things: (1) development and application of ASME standards that are equivalent to NRC requirements and (2) extension of ASME rules to include all parts of dynamic-type components (e.g., pumps, valves) rather than simply their pressure boundary. Assuming that these conditions are satisfied, the NRC will have a basis for reducing direct NRC inspection of ASME certified vendors. Part of current NRC resources used to inspect ASME vendors will be redirected to the auditing of the ASME certification and inspection system.

A two-year trial program for evaluating the ASME certification and inspection system for supplementing NRC inspections is currently underway. This program will continue to receive priority attention.

Recommendation #8

"The Inspection and Enforcement staff strengthen its review of the inspectability and enforceablity of Technical Specification requirements."

Status: No Action Planned

Discussion:

In accordance with existing procedures, all Standardized Technical Specifications were reviewed for inspectability and enforceability by both IE Headquarters and the Regional Offices. All facility Technical Specifications are reviewed for inspectability and enforceability by the appropriate Regional Offices.

Isolated examples may occasionally be identified where requirements are unclear causing some difficulty in inspection. However, if these oversights have significant safety impact, internal procedures are available for achieving clarification and correction.

In IE's view, sufficient effort is currently allocated to this subject area. No further action is deemed necessary.

Recommendation #9

"Routine direct NRC inspection and testing of hardware be increased, and that data pertinent to quality decisions made in the construction and operation of a plant be evaluated by the NRC on a routine basis. (This includes the evaluation, for example, of radiographic and ultrasonic test data.)"

Status: Action in Progress

Discussion:

The principle of direct inspection and testing of hardware and work activities has been recognized as a valid technique for not only measuring the effectiveness of quality assurance programs but for confirming the adequacy of designs. One of the major offices (Office of Nuclear Regulatory Research) authorized by the Reorganization Act of 1974 was specifically established to provide the NRC with a capability for performing confirmatory research and product qualification.

IE currently has two major efforts underway, utilizing private contractors, for the prime purpose of identifying and evaluating specific activities where direct NRC inspection and/or testing could be applied. Also, IE inspectors routinely examine and evaluate test data (radiographs,

ultrasonic results) on a sample basis covering product quality. These examinations are not performed to provide "product acceptance" for the licensee but are performed as a technique for evaluating QA program effectiveness.

A third initiative underway which will provide further implementation of this recommendation is the Resident Inspection Program. This program will provide additional IE capability for the surveillance of all licensee activities including the direct inspection and testing of hardware and fabrication-construction.

We plan to carry out to completion the contracts for evaluating possible techniques for independent test and measurement by IE and to implement proposals as practical. We shall also continue and expand inspector activities relating to direct observation of hardware and examination of test data.

Recommendation #10

"IE inspections for QA program implementation during construction (Modules 35700B through 35736B of the IE Manual) be conducted more frequently during the period of personnel turnover prior to operation."

Status: Action in Progress

Discussion:

The major portion of the Construction Inspection Program is focused on implementation of the QA program and fully reflects the content of modules 35700B - 35736B. It should be noted that the referenced modules were specifically designed for operational readiness determination. Frequency of conduct is not germane to assuring readiness for operation. It appears inappropriate to recommend actions by module number. In this specific case, modules 35700B - 35736B were superseded by other inspection procedures on 10/1/76.

Initiation of the Resident Inspection Program will provide additional IE surveillance capability of all licensee activities, including the transition period between construction and operation. This program, in conjunction with the current inspection programs, is designed to permit additional observation and surveillance of licensee activities and will meet the intent

of the specific recommendation. The Resident Inspection Program is expected to start in early 1978 with the assignment of inspectors to eight selected sites. Full implementation is scheduled for FY 1982. Revisions to the inspection modules for the Resident Inspection Program have been prepared.

Recommendation #11

"Qualification testing be required for design verification when practicable."

Status: Action in Progress

Discussion:

As noted in the report, Appendix B to 10 CFR Part 50, and Regulatory Guide 1.64 which endorses ANSI N45.2.11, indicates that qualification testing is one method of performing design verification, but not the only method. Other methods are by means of design reviews and alternate calculations. NRC has established and is continuing to establish guidelines for qualification test programs (see discussion for Recommendation #13). These guidelines indicate qualification testing methods which NRC considers to be an acceptable method of performing design verification. Other methods of design verification may be used where specifically justified.

It appears that Recommendation #11 on qualification testing has been somewhat amplified and clarified in Recommendation #13 wherein they recommended NRC establish requirements and guidelines for a comprehensive qualification and proof test program. The report notes in connection with Recommendation #13 on page 4 that, "Since the cost of testing is high, indiscriminate application of qualification and proof testing should not be required. Instead, the criteria for application should be carefully and clearly developed, as they have been for pre-operation and startup testing, inservice inspection, and surveillance, so that testing will be applied where it is practical and avoided where it is not." We agree with this recommendation and have developed and are continuing to develop guidelines for qualification testing as noted in the response to Recommendation #13.

Recommendation #12

"IE inspections "QA Program (Receipt, Storage and Handling of Equipment and Materials)" (Module 25720B of the IE Manual) and "QA Program (Test and Measurement Equipment)" (Module 35736B) be conducted more frequently during construction."

Status: Action in Progress

Discussion:

The referenced modules are operational preparedness modules and do not relate to construction activities. The subject matter covered by the reference modules is fully covered by the construction inspection program in many modules, each related to the functional construction activities in progress.

Our plans are that more extensive observation of the activities described by the recommendation will be performed upon initiation of the Resident Inspection Program. (See Recommendation #10.)

Recommendation #13

"The NRC establish requirements and guidance for comprehensive qualification and proof test programs similar in detail to the requirements and guidance for preoperational and startup testing programs. The guidance should include criteria for practicability."

Status: Action in Progess

Discussion:

We agree with the recommendation that "the NRC establish requirements and guidance for comprehensive qualification and proof test programs similar in detail to the requirements and guidance for preoperational and startup testing programs." We have been and are continuing to implement this recommendation.

For the past several years, NRC has been establishing requirements and guidelines for comprehensive qualification test programs for equipment, starting with the basic criteria of IEEE 279-1968, "Proposed IEEE

Criteria for Nuclear Plant Protection Systems," which was incorporated by reference into the Commission's regulations. This standard, and its successor, IEEE Std 279-1971, require that type test data or reasonable engineering extrapolation based on test data be available to verify that equipment that must operate to provide protection system action will meet, on a continuing basis, the performance requirements determined to be necessary for achieving system requirements.

Regulatory guides delineating acceptable methods for qualifying specific kinds of equipment for LOCA, seismic, and normal ambient environments have already been developed and issued as follows:

1. Regulatory Guide 1.40, "Qualification Tests of Continuous-Duty Motors Installed Inside the Containment of Water-Cooled Nuclear Power Plants"

2. Regulatory Guide 1.63, "Electric Penetration Assemblies in Containment Structures of Light-Water-Cooled Nuclear Power Plants"

3. Regulatory Guide 1.73, "Qualification Tests of Electric Valve Operators Installed Inside the Containment of Nuclear Power Plants"

4. Regulatory Guide 1.100, "Seismic Qualification of Electric Equipment for Nuclear Power Plants"

5. Regulatory Guide 1.131, "Qualification Tests of Electric Cables, Field Splices, and Connections for Light-Water-Cooled Nuclear Power Plants"

As part of NRC's continuing and comprehensive efforts in the area of qualification testing, the preparation of regulatory guidance is also planned for those vital electric equipments not subject to LOCA environments, such as cable fire stops, fire breaks, switchgear, batteries, motor control centers, modules (including sensors), battery chargers, inverters, transformers, and diesel generators. In the development of such guidance, the NRC will take into account all available empirical information and shall apply experience gained in prior activities, such as the recent qualification of electrical connectors. In addition, a general standard for qualifying mechanical, as well as electric, equipment is being prepared by IEEE. This standard, when published in acceptable form, will be endorsed by a regulatory guide.

Specific mechanical equipment qualification guides are also being developed including guides on snubbers, valve assemblies, and pumps.

Recommendation #14

"The NRC actively continue support of cooperative audit programs in the industry, especially programs for the sharing of audit data among licensees and contractors, and for the conduct of joint audits."

Status: Action is a Continuing Effort

Discussion:

Redundant audits are a problem area which was identified and discussed by QAB with Sandia personnel in the summer of 1976. Accordingly, the Sandia recommendation is endorsed, and actions continue to be implemented along the lines suggested by Sandia.

The principal thrust of the Sandia recommendation is to encourage various approaches, such as cooperative audits, which offer the potential of reducing the audit burden without reducing the confidence that work is proceeding satisfactorily. Over the past year, the following actions have been initiated towards this objective:

(a) The CASE (Coordinating Agency for Supplier Evaluation) concept which allows for sharing of audit findings for supplier evaluation through publication of a quarterly register has been endorsed by NRR (letter dated July 1977). The detailed topical report requires only minor revision before it will be accepted as an adequate basis for implementing and inspecting the CASE system. With NRC endorsement of this system, redundant pre-award audits by purchasers should be minimal or non-existent.

(b) The NRC and the ASME have had a number of discussions over the past year on the possibility of the NRC endorsing the AMSE certification and inspection program as a "third party." If successful, the attainment of this objective should further reduce the need for pre-award audits and for yearly programmatic audits by purchasers. It should also greatly reduce the number of audits/inspections by NRC personnel. The initiation of a two-year trial program with the ASME was approved by the Commission in May 1977, and staff discussions are continuing. The ASME anticipates the submittal of a topical report to the NRC this year which would be a major milestone in this activity.

(c) The IE Licensee Contractor and Vendor Inspection Program (LCVIP) also has the potential of reducing the number of audits purchasers must perform on their subcontractors. The LCVIP is continuing to evolve, and greater benefit towards reducing audits may result from future program directions. A major milestone in this regard was the approval by the Commission of the LCVIP concept and program in May 1977.

The actions noted above reflect a continuing effort by NRC to eliminate redundant and unnecessary auditing. Actions already completed and those in progress should greatly aid in this regard. Additional actions will be initiated by NRR, working with IE and Standards, as the need is identified.

Recommendation #15

"The NRC adopt, for nuclear power plants, a more systematic, yet simple method of representing hardware and human performance characteristics that are signficant to safety. This method should address the importance to safety of these characteristics and should also consider their unreliability modes and rates, in order that a more comprehensive quality assurance program can be applied. Toward this end, we recommend the use of simplified event models and equations within the industry and the NRC."

Status: Receiving further study.

Discussion:

Sandia strongly believes that the use of statistical reliability modeling, i.e., mathematical determinations of hardware and human performance reliablity, will provide an improved basis for defining, assessing and balancing quality assurance programs on a component and sub-systems level.

It is suggested by Sandia (pages 56-59) that reliability models and related operating and test data should be included by applicants in the SARs (prepared in conjunction with the Chapter 15 accident analysis), and reviewed by NRC in the context of predetermined numeric probabilistic goals based upon "... system reliabilities appropriate to the task of protecting the public health and safety."

Sandia recognized that there would be impacts associated with this approach on the industry and the NRC, although Sandia believed the NRC SAR reviews could be performed with a staff increase of from one to two specialists. Sandia identified this recommendation as one of a longer-term nature.

Although the importance to safety and unreliability modes and rates are factors in determining quality assurance requirements for a particular item, these factors are not sufficient by themselves to allow such determinations. Other factors include the complexity and uniqueness of the item, the quality history of the item, the degree of standardization, and the degree to which functional compliance can be demonstrated by inspection and test. Simplified event models and equations as recommended by Sandia must be used in conjunction with other factors, and thus, engineering judgment must be used in structuring and assessing QA programs.

However, the overall usefulness of the reliability modeling methodology has been recognized and continues to be seriously investigated by the NRC. Starting with the initiation of the Reactor Safety Study (WASH 1400) in 1972 by the AEC, the methodology and results of this approach have been used by the AEC/NRC to assess the relative safety and critical failure modes of commercial reactors. As a result of this work, the NRC has continued to expand inhouse expertise on the applications and limitations of the pertinent assessment methodologies, and has initiated activities directed at: (1) expanding the application of these techniques from those currently being accomplished in the normal NRR review process, (2) expanding staff capability through intensive training courses, and (3) pursuing outside expert advice and recommendations on the application of these methodologies. The focus of these activities, however, has been broader in nature than just the potential quality assurance advantages. Rather, these efforts are part of a coordinated effort directed at defining how the NRC can best take advantage of these techniques.

Although our plans have not been finalized, we believe that Sandia may have seriously underestimated both the difficulty and the resources required to conduct the recommended activities. For example, such mathematical determinations will require an extensive data base. This data base, presently being built from the Nuclear Plant Reliability Data System and associated Licensee Event Reports, is still in an early stage of development; many years of growth will be necessary before useful data are forthcoming. Therefore, while we believe that these techniques may give added insight and assistance in developing regulatory positions and assessing generic design features having critical safety signficance, we do not believe that application of this methodology along the lines of the Sandia recommendations to specific plant SARs is currently practical.

We recognize that these techniques should provide additional insight into such items as relative safety signficance of components and subsystems, the importance of human performance in achieving satisfactory system function and the need for testing under worse-case environments. These aspects were discussed with Sandia personnel in the summer of 1976, and subsequent steps have been initiated to develop some inhouse capability along these lines. We plan to focus more specifically on such considerations in future reliability modeling investigations. The specific scope of this work will be defined in conjunction with the development of the NRC Probabilistic Safety Analysis Plan now targeted for approval by the end of the second quarter of FY 78. If appropriate, the assistance of the Office of Nuclear Regulatory Research may be requested through a specific research request.

In sum, we do not believe that the full scope of this recommendation should or can be adopted by the NRC without further work. We propose to initiate more focused efforts towards determining the usefulness of risk methodologies, but we see problems in application and in obtaining the necessary staff capability.

Recommendation #16

"The quality assurance planning and evaluation function in the NRC be assigned to a separate group. This function would include:

(1) Performing continuing reviews of all assurance measures in standards, Regulatory Guides and Standard Review Plans for consistency and adequacy,

(2) Evaluating overall QA effectiveness (ultimately by comparing assessments of the reliability of reactor safety features from all plants with established goals) and recommending programmatic improvements when indicated, and

(3) Developing and implementing quality assurance techniques."

Status: Receiving further study.

Discussion:

Sandia observed the potential for inconsistencies to develop among the various NRC organizations (NRR-SD-IE) involved with QA for commercial reactors. Additionally, they believed an advantage would exist from an independent assessment and overview of QA activities from a separate group focusing on QA uniquely across the NRC. This group would have a broader perspective and charter than the rather specific QA responsibilities of the individual offices and would have the ability to balance QA measures, analyze results and problems, and recommend changes without regard to the office where improvements are needed.

The report is silent, however, on any specific examples or other bases which support the need for this recommendation. It makes no mention of existing coordinating and concurrence mechanisms established to assure consistency, such as regulatory guide review process, Interoffice QA Task Force, NRR-IE interface agreements and meetings, formal coordination on the development and interpretation of standards or the extensive discussion and coordination that occurs among the offices. Additionally, it fails to note that a number of independent organizations, such as the ACRS, individual licensing boards and the GAO have looked at QA activities from an overview perspective.

Further, it recommends that improved QA techniques be developed and implemented without specifying what these techniques should be or why they are needed (other than those proposed in part 2 of the recommendation). We are not aware that improved techniques are in fact needed or that if a need is identified, a separate group should be responsible for their development and implementation.

The present organizational arrangement involving QA responsibilities has proven to be practical and workable. Of course, improvements may be possible and the Sandia recommended organizational change warrants consideration, but the overall need for an additional "review" group

without specific responsibilities for defining, applying or assuring QA activities in terms of CPs and OLs is not readily apparent. In fact, IE also notes that the present organization arrangement has proven to be satisfactory, and in view of no identifiable deficiencies by Sandia, believes that this recommendation should not be adopted.

On the other hand, we are aware that inconsistencies in QA provisions can and have developed among the various offices. For the most part, these have been or are being resolved through existing mechanisms. Additionally, the Sandia recommendation is largely based upon having the capability to evaluate QA effectiveness through reliability studies and, as noted in our response to Recommendation 15, the need for this capability remains to be fully evaluated. Thus, the information will not exist in the foreseeable future to fully evaluate the worth of an organization change in terms of this important aspect of the recommendation. Thus, we propose to defer action on this recommendation until the results of work associated with Recommendation 15 (dealing with mathematical reliability modeling) are available.

A STUDY OF THE NUCLEAR REGULATORY COMMISSION QUALITY ASSURANCE PROGRAM

CHAPTER I

INTRODUCTION

At the request of the Nuclear Regulatory Commission (NRC), Sandia Laboratories has conducted a study of the Commission's regulatory activities with respect to quality assurance for nuclear power plants. The study encompassed a detailed analysis of representative aspects of the NRC quality assurance (QA) program, an evaluation of the program's philosophy and practices, and the identification of potential program improvements. Information was gathered through: (1) discussions with individuals and with representatives of the NRC, industry organizations, professional societies, and industry standards development groups; (2) observations of industry and NRC activities; and (3) reviews of documentation and literature pertaining to nuclear power and its regulation.

The study group's report is presented in five chapters, with more detailed discussion of some topics given in the appendices. This chapter provides the definition of quality assurance used in determining the scope of the study and describes how the study was conducted. Chapters II and III deal with observations relating to the current program and methods for improving it; Chapter II addresses general aspects of the program and Chapter III addresses the implementation of the 10 CFR 50, Appendix B criteria. Chapter IV discusses recommended additions to the program. Chapter V presents the overall conclusions of the study and summarizes the recommendations.