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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON PRA IMPLEMENTATION PLAN

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PUBLIC MEETING

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Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland

Wednesday, October 16, 1996

The Commission met in open session, pursuant to notice, at 2:07 p.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission
KENNETH C. ROGERS, Member of the Commission
GRETA J. DICUS, Member of the Commission
NILS J. DIAZ, Member of the Commission
EDWARD McGAFFIGAN, JR., Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

JOHN HOYLE, SECRETARY

KAREN CYR, GENERAL COUNSEL

JAMES TAYLOR, EDO

EDWARD JORDAN, Director, AEOD

CARL PAPERIELLO, Director, NMSS

NORMAN EISENBERG, Senior Advisor, Performance Assessment, NMSS

ASHOK THADANI, Associate Director for Inspection and Technical Assessment, NRR

GARY HOLAHAN, Director, Division of Systems Safety and Analysis, NRR

THOMAS KING, Deputy Director, Division of Systems Technology, RES

JOSEPH MURPHY, Special Assistant, RES

P R O C E E D I N G S

[2:07 p.m.]

CHAIRMAN JACKSON: Good afternoon. I am pleased to welcome members of the Staff to brief the Commission on the status of the PRA Implementation Plan.

The PRA Implementation Plan was first issued in August 1994, and the Staff provides quarterly written updates and briefs to the Commission semiannually.

Previous written updates on the status of activities in the PRA Implementation Plan were provided to the Commission in March and June of this year. The Commission was last briefed on the plan in April of this year. The plan is intended to be a management tool that will help ensure the timely and integrated agency-wide use of PRA methods and technology in the Agency's regulatory activities.

During today's briefing, the Staff will cover its recent accomplishments, policy issue recommendations, key technical and process issues, and its plan for future activities. I am particularly interested in hearing about progress on the PRA regulatory guides and standard review plans, as well as how these activities are being informed by pilot applications. I am also interested in cross-office integration, and my fellow Commissioners and I are looking forward to your briefing today.

I understand that there are copies of the viewgraphs available at the entrances to the room.

If no one has any additional comments, Mr. Taylor, please proceed.

MR. TAYLOR: Good afternoon. With me at the table from several offices is Norm Eisenberg, Carl Paperiello from NMSS, Ed Jordan of AEOD, Ashok Thadani and Gary Holahan from NRR, Tom King, and Joe Murphy from the Office of Research. I think this represents a good cross-section of people who are working on this particular area.

I would like to preface the presentation, and I think Ashok will bring this up again, that in order for licensees to use PRA and regulatory applications, the design basis and configuration management issues at their plants must be resolved. In other words, the plant design bases must be clearly known and maintained. The plant must have been constructed in accordance with the design basis, and the plant must be configured and operated in accordance with our NRC requirements and license commitments.

With those opening thoughts, I will ask Ashok Thadani to continue.

MR. THADANI: Thank you, Jim.

May I have viewgraph No. 1, please?

Good afternoon. We thought it was probably useful to go through fairly quickly some of the background

information, and I will do that, hopefully, quickly.

Then Tom King from the Office of Research will pick up on the recent accomplishments, as well as discussing some of the key technical and process issues and the types of questions that we need to make sure we can address.

Part of these key technical issues are also some policy matters, and then Gary is going to go over the four key policy issues, as well as the next activities that we are going to embark on in the next few months.

May I have the next viewgraph, please?

I know most of you know all of this information, but again, the final policy statement was published over a year ago, and following the policy statement, it was clear that we needed to have a more detailed set of task schedules that needed to be laid out, and with the special focus, as you indicated Chairman Jackson, it was to accelerate development of regulatory guides and standard review plans as part of the activities.

The Staff has been providing quarterly progress reports to the Commission and a semiannual briefing on the progress that we have made as we go forward.

In the March '96 status report, we identified four policy issues, and in the SRM that came out in May of 1996, the Commission asked the Staff to provide its recommendations to the Commission on each of the policy

issues.

Last week, we had the last update report, and that does get into the issue of where we stand on a number of activities in the Implementation Plan, and there is a special discussion of each of the policy issues.

In addition to that, there is an attachment in the last update which does identify the type of technical process issues that we need to make sure to address.

May I have the next viewgraph, please?

We keep having to remind ourselves that the policy statement has certain constraints and boundary conditions that we have to keep in mind as we go forward, and it is hard to capture everything on one chart, but I think this chart does capture some of the important aspects of what is in the policy statement.

The desire, clearly, is to use probabilistic safety assessments or risk assessments, use them in all of our regulatory activities, and the key there was all, but then there are qualifiers, obviously, with those applications.

Certainly, as long as the methods are appropriate, the database is there to support decisions in those areas, and two important elements are that the decisions were not to be based on risk analysis alone; that they had to complement the traditional deterministic considerations as

well. The idea, then, was to integrate the deterministic and probabilistic considerations before making any final decisions on regulatory matters.

An issue that had to be dealt with was the issue of uncertainties, not just the uncertainties that one can quantify and develop distributions, but there are issues that are very difficult to quantify as a matter of fact.

So specific focus had to be given to maintaining defense in depth; that is, preserving the barriers that are there, multiple barriers.

The next element was very important to make sure that when the policy statement went out that the industry did not misunderstand the statement itself; that licensees had to meet all current rules and regulations, even if there were rules and regulations which may have low safety significance, but the idea there was that if there are insights from risk assessments that point out that some other requirements may not be properly in tune in terms of risk significance, that the process would be to first change the requirements and not presume that they didn't have to meet the requirements.

The second part, and this is the one that Mr. Taylor mentioned, is that the risk assessments are not very useful if they don't really represent the plant itself. If the documents don't reflect the plant design and the risk

assessment is based on those documents, then, clearly, the risk assessment doesn't really represent the plant. To what degree depends on the differences between the actual plant configuration design procedures versus what is in the documents. So that is an important element that needs to be recognized, and it is clearly a lesson that we have learned from some of the millstone activities.

The third bullet there refers to in June of 1990, the Commission gave us guidance through an SRM, indicating that we ought not to be using the Commission's safety goals and the subsidiary objectives, which relate to core damage, frequency, and containment performance; that we ought not to be using these on a plant-specific basis, but they should be used in generic matters for things like future rulemaking activities and so on.

One of the policy issues that you will hear about later on is, in fact, should we use these objectives on a plant-specific basis, but we will come back to that issue when Gary gets into those policy issues.

The next viewgraph, please.

This really highlights that the PRA can make a pretty significant role in regulatory activities, and this chart is really representing a reactive program in a very broad scope manner.

As our resources go down, there are budgetary

constraints. With time, it becomes even more and more important to focus our activities in areas that are more important to safety. So the idea here is to show that the scope can be pretty broad in terms of where these techniques can be applied.

The reason for that is if one were to use these techniques in conjunction with our deterministic assessments, the end results are going to be much better decisions, much more effective safety decisions. There would be obviously much more effective use of resources, both in terms of the Agency resources, but also in terms of the industry resources. So, again, this chart supports the major thrust of the policy statement that we should, in fact, go forward and apply these approaches in our regulatory activities.

CHAIRMAN JACKSON: Before you go ahead, can you give us some sense of the status of licensees' implementation of accident management strategies?

MR. THADANI: Yes. I will give you just a general sense.

Many of the licensees, as you know, most of them have completed individual plant examination. As a result of the IPEs, they had identified a number of procedural enhancements that could be made, and by and large, the ones that they identified, they have gone forward, but the broad

scope accident management program that we have been working on with the industry for some time, which really goes into not only in terms of prevention of accidents, but also following core damage events, what are reasonable things to do, and all the way into communication with different groups. That is broadly included under what we call the accident management program.

The industry through the owners group, they have done essentially all of the technical work. There are minor issues that need to be dealt with on the BWR plants, but by and large, much of the technical work is completed, and the utilities now are going to be converted that information, which is generic, a fair amount of good technical assessment, converting them into their plant-specific either emergency operating procedures or guidance for technical support groups, which would be called upon to provide guidance in case of an accident.

The schedule currently calls for all the licensees implementing accident management by December of 1988. Some of the licensees would have implemented accident management early '98, and very few late '97. Most of them in 1998, and the last ones, end of 1998, would have implemented accident management.

Could I have the next viewgraph, please?

As I have said, the policy statement is to

incorporate all activities, which meant that it was very important to capture these activities in detail, and that is where the Implementation Plan comes in.

In the plan, which is very comprehensive and broad scope, there are a number of tasks. I forget the exact number, but certainly over a hundred distinct activities are involved.

From those tasks, some of which we have not met the schedule or we think we won't be able to meet the schedule, there will be some delays, but the highest priority we have given is to regulatory guides and the standard review plans. There, the schedule was to get drafts completed by the end of this year, and that is, in fact, the schedule we're still on.

You will hear about where we are in terms of the pilot applications. There have been some delays in the projected completion dates for pilot plans.

One reason for delays is resources, but I think that is a smaller reason. The larger reason has been trying to do a fairly thorough job, which means a fair amount of information that is needed from individual pilot participants, and in some cases, it has taken longer to get answers to some questions, but nevertheless, the key point is that we are getting sufficient information from these pilots, so that we can, in fact, go ahead, get the reg guide

and the standard review guide out for public comment, and finish up the pilots perhaps even during that comment period.

The scope of the Implementation Plan goes well beyond what NRR does, of course. It includes a number of activities that AEOD is involved in, NMSS, and of course, Office of Research has been working with NRR on some of these activities I have already described.

Now, unless you have other questions, I was going to go to Tom King, so he can get into the real substance of the issues.

MR. KING: Thank you, Ashok.

What I wanted to cover was to briefly summarize the recent accomplishments since the last status report in June, and then to discuss the review process and the key technical and process issues that have come out of developing the reg guides and SRPs to date.

If I could have Slide 6, please.

Slide 6 summarizes the recent accomplishments. The first bullet talks about the draft reg guides and SRPs, but I think what I will do is when we get to Slide 7, we will talk about that in more detail.

We are continuing to review the industry-initiated pilot applications, as Ashok mentioned, the pilot applications in four areas, ISI, IST, QA, and tech specs.

It involves seven or eight plants that are participating in the pilot process. We expect to complete those reviews and send to the Commission a recommended decision over the next two to eight months, starting in December with the tech specs and then through June of next year with ISI and IST.

CHAIRMAN JACKSON: To what extent have those industry-initiated pilots informed the development of the guidance documents that you are talking about?

MR. KING: They have provided input. We have gone through and taken our list of issues that we have developed in drafting the reg guide and SRP and looked at the pilots as to how they were addressing those to get some feedback, and we have actually gotten some feedback that has been incorporated.

CHAIRMAN JACKSON: And it is somewhat of a lag, also, you are saying, relative to when the final outputs of the pilots will be available. Is that a fair statement?

MR. KING: I am not sure.

CHAIRMAN JACKSON: Well, what I am saying is, do you feel you have gotten all out of the industry-initiated pilots that you can relative to how it propagates into the development of the guidance documents?

MR. KING: I suspect we will probably. As they continue to respond to request for additional information, we will continue to learn some more.

CHAIRMAN JACKSON: Okay.

MR. HOLAHAN: I can remind you that I believe at the last Commission meeting, we presented a matrix identifying 10 or a dozen issues and which ones we learned stuff from on the various pilots and a couple of areas where we needed to do more work.

CHAIRMAN JACKSON: And those ones where you have identified that you have learned some things from the pilot, is that what you mean when you say these things have or --

MR. HOLAHAN: Yes, yes.

CHAIRMAN JACKSON: -- what you have learned has been incorporated in these guidance documents?

MR. HOLAHAN: Yes.

MR. KING: Yes.

CHAIRMAN JACKSON: Okay.

MR. KING: The backup viewgraphs to the package you have has some more details on the pilots in terms of the plants and the schedules and so forth. I wasn't going to cover those specifically.

The third bullet talks about the IPE and IPEEE. We are continuing to review in both of those areas. We currently have 19 IPE reviews to go until we are complete. We expect 16 of those 19 to be done by December. Three will probably carry over until next year, probably spring or so. Those are three where we have had problems with the IPE, and

we have requested that parts of it basically be redone. We are waiting for a resubmittal.

CHAIRMAN JACKSON: Let me ask you a question. These IPEs are essentially PRAs; is that correct?

MR. KING: Yes.

CHAIRMAN JACKSON: Will you be coming out of that review with some assessment of how strongly coupled they are to the design basis or how well known the design basis is for those plants relative to what these IPEs, in fact, are showing?

MR. KING: Not through the IPE program. We are not doing that. We are not trying to go back and confirm the design basis through the IPE program. We would expect licensees in doing their IPE actually reflect the as-built and operated plant. We have not checked that.

CHAIRMAN JACKSON: Mr. Thadani, you look like you must say something.

MR. THADANI: No. I think that is the answer.

As you know, we have 50-50 4F letters out now, and depending on what results come out as a follow-up to those letters, there may be an action that we may have to follow.

CHAIRMAN JACKSON: Okay. I've got you.

MR. KING: The IPEEEs, we have 24 of those under review. None have been completed at this point that we would expect early next year that they would start coming

out, the staff evaluation reports on those.

The other thing I want to mention on IPEs is that we have prepared an insights report. A copy was sent to the Commission last week. We have also been going to the regions and briefing them on the insights coming out of the IPEs, both the generic insights and the plant-specific insights, so they can factor them into their inspection programs and other interactions with licensees. So that is continuing to go on.

CHAIRMAN JACKSON: I hate to keep dwelling on the same thing, but let me ask you this question. Based on what you may get out of the 50-50 4F responses, the letter responses, are you going to do some juxtaposition of any sample of the IPEs, what comes out of that to have some sense? In a sense, these insights are based on acceptance as is, right?

MR. THADANI: That is correct.

CHAIRMAN JACKSON: So is there going to be any kind of a sampling?

MR. THADANI: If certain plants are identified which may, in fact, have differences, then I think we would go back to those plants --

CHAIRMAN JACKSON: And review the IPE?

MR. THADANI: -- and ask them --

CHAIRMAN JACKSON: To review.

MR. THADANI: -- to address those.

CHAIRMAN JACKSON: Redo.

MR. THADANI: Yes.

CHAIRMAN JACKSON: I got your point.

MR. THADANI: Yes.

CHAIRMAN JACKSON: Thank you.

MR. KING: The fourth and fifth bullet really address the proposed Reliability Data Rule. AEOD conducted a public workshop in June and received a number of comments. They are continuing to look at those and work on resolution.

In parallel, I understand industry recently submitted some sample data to demonstrate a proposed voluntary alternative to the data rule.

CHAIRMAN JACKSON: Let me ask if I may, Mr. Jordan --

MR. JORDAN: Yes.

CHAIRMAN JACKSON: -- where do things stand with regard to our review of that sample data?

MR. JORDAN: We have a dataset that represents the data elements from the safety system performance indicator that INPO uses, and we are applying those data elements into our reliability data scheme. We are still in the process of assessment to identify what elements might be needed in order to assure that we have training level system reliability.

CHAIRMAN JACKSON: Okay.

MR. KING: And the backup viewgraphs have some additional information on the Reliability Data Rule.

CHAIRMAN JACKSON: Okay.

MR. KING: And finally, AEOD has completed development of PRA training guidance document, NUREG BR0228, and that was issued in July. They have also developed a prototype PRA for a technical managers course, which they had a dry run on several months ago and I understand will be available, be offered to the Staff in the next several months.

If I could have Slide 7.

CHAIRMAN JACKSON: I hate to do this to you, but given that this PRA training guidance document has been completed, how is it being used?

MR. JORDAN: Okay. I can answer that. It is the basis for managers identifying appropriate courses for staff members. So it is a road map in order to provide the right level of qualification for staff members.

CHAIRMAN JACKSON: So it identifies some qualification level and associated training program for a given function in a job that someone has?

MR. JORDAN: Correct. That is correct. So it identifies the various levels of qualification and then the scheme of courses that, of course, can be looked at with

respect to that individual's experience, education, and training to pick the right courses.

MR. KING: Slide 7, please.

Slide 7 gives a little more detail on the regulatory guides and standard review plans that are being developed to support risk-informed regulation. The regulatory guides are really the guidance for licensees in terms of what their submittal should contain, and then the standard review plan is guidance for the staff as to how to review that submittal.

Early in 1996, we had put together inter-office teams to draft the reg guides and standard review plans, and the ones being worked on are listed here. We had also put together an inter-office PRA coordination committee to provide some oversight and direction into that effort. Overall, those activities have been working well.

Currently, there are drafts for all of the reg guides and SRPs. The ISI one has slipped three months, as noted in the SECY paper that came up, primarily because of late start on the pilot programs, but the others are underway. They are under various stages of review. We plan to get them to ACRS.

We have also developed a draft NUREG 1602 which is a key reference document in the general reg guide in terms of the standards for a PRA, in terms of the level of detail

and quality and so forth.

CHAIRMAN JACKSON: So you have laid that out?

MR. KING: That has been sent to ACRS for review. We have had numerous interactions with industry on both the pilots and generic topics, as well as ACRS. We have had a number of meetings with them. We have the next one coming up on October 31st and then another one after that on November 21st where we will be reviewing the reg guides, the SRPs, the draft NUREG, and the issues that are coming out of these things.

If we could move on to Slide 8.

Slide 8 shows the review process around which the reg guides and SRPs are being developed, which we are trying out on the pilot activities. It is a six-step review process that we have defined to try and provide some consistency and structure to the evaluation and review, and we would expect licensee submittals and the Staff review would follow these six steps as much as possible.

The six steps are shown on Slide 8, and the feedback loops are shown. We thought it would be useful to put it in this presentation as background because, as we get into the discussion of the technical and policy issues, this will illustrate the sequence of the logic in the evaluation and I think will help in understanding where the technical and policy issues fit in the evaluation process.

The steps we believe are consistent with the PRA policy statement, they are set up such that risk assessment complements the deterministic evaluation and defense in depth.

There is a step that specifically was put in on performance monitoring, which is related to one of the policy issues we are going to talk about, and even though there is not a feedback loop shown, if you go through this process, you could end up coming back to step one and redefining the scope of your proposed change, depending on how the outcome of the evaluations were.

If we could go to Slide 9.

Pages 9 through 13 contain a list of what we call the key technical and process issues. These are things that we are addressing as part of the reg guide and standard review plan development, and they were identified as part of drafting the reg guide, standard review plan and interaction with the pilot projects.

I don't plan to discuss all 27 of them, but what I wanted to do is highlight the ones that are related to the policy issues that are going to come up later on in the briefing, as well as any others that are of particular importance.

We thought it would be useful to present these in this briefing because they do provide some key background

regarding the six-step review process, as well as the background for understanding the policy issues.

CHAIRMAN JACKSON: Let me ask you, before you go through them, can you say to what extent these questions will be addressed in the guidance documents being developed, and if not, are they dependent upon the Commission addressing the policy issues, and if they are not dependent upon that, how are you working on answers? So it is a three-part question.

MR. KING: All of them will be addressed in some fashion in developing the reg guides and standard review plants.

CHAIRMAN JACKSON: Okay.

MR. KING: We are proceeding on the ones that are related to the policy issues. The path we are proceeding down is consistent with what we are recommending on the position on the policy issues. If the Commission decides otherwise, we will have to revisit those.

CHAIRMAN JACKSON: Okay.

MR. KING: Before I get into some of the example issues, I did want to say a couple of things about how we are using this list.

We put it together for several reasons; one, to help focus attention on the more important items, both Staff and management intention. Two, it is a good way to track

progress as to how close we are to getting these things resolved, and three, it does provide, as I mentioned earlier, a systematic way to go through and get some feedback from the pilot plants, ask what the pilot activities -- find out what they are doing and to address each of these things. So it is being used in several different ways.

Also, I want to mention that some of these issues have sub-elements. We didn't list all of the sub-elements because it would get too complicated.

Also, some of these issues, the answers may have -- there may be several options in the way to deal with some of these issues, and in some cases, we will probably recommend -- go to ACRS with some options, and we may want to go for public comment on some options and make a final decision after we get feedback from the public comment process.

So we are not planning at this point to pick just one option for each one. Where it makes sense to list several options, we would plan to do that.

Our next meeting with ACRS is going to focus on these issues as part of reviewing the reg guide and standard review plant.

Let me start with page 9. These are laid out in accordance with the six steps. Roman Numeral I is step one

on the flow diagram, and I-(a), what information does the licensee need to submit to characterize the change, this addresses right up front the point that Mr. Thadani brought up. Unless a plant knows its current licensing basis and has the plant built and operated in accordance with the risk evaluation and the deterministic evaluation, it may not be very useful. So we want to establish right up front that a licensee has confirmed its current licensing basis and that the plant is built and operated in accordance with it, so that the rest of the analysis is consistent with that.

Issue II-(b), what are the acceptance guidelines for the deterministic evaluation, this is one we have been struggling with quite a bit. Again, the PRA policy statement says PRA is to be used to complement the deterministic evaluation. Deterministic terms like "defense in depth" and "design margins" and so forth are used quite a bit, but when you go to write the standard review plan and a regulatory guide to find exactly what is meant by those things and what are the acceptance criteria, it gets a little tougher. So we have been struggling with this. I am not here to say we have an answer yet, but it is going to be one item that is going to involve a lot of discussion over the next several months.

CHAIRMAN JACKSON: Well, one could argue that that is an interesting statement, but one could also say that

maybe this exercise, then, in developing a PRA framework helps us focus on what we mean --

MR. KING: Yes.

CHAIRMAN JACKSON: -- by defense in depth and design margin.

MR. KING: Yes.

MR. HOLAHAN: As a matter of fact, on that subject, we have an interoffice meeting this afternoon at 4 o'clock to see if we can come a little closer to figuring out exactly what this ought to be.

MR. KING: Slide 10, please.

Item III-(g) and (i) are directly related to two of the policy issues, the policy issues associated with plant-specific application of the safety goals and the risk neutral versus risk increase. (g) is how should the acceptance guidelines be structured, and that gets into issues like what metrics should be used, should it be core damage frequency, condition of containment failure probability, large early release frequency, some other aspect, how do we pick the values to be consistent with the safety goal, considering the fact that we are talking plant-specific application, how do you account for less than full scope PRA.

The safety goal policy statement was fairly clear that the risk that it was talking about was from all aspects

of plant operation, and a lot of the risk analysis that is out there, including the IPEs, are focusing on full power operation only.

CHAIRMAN JACKSON: I have to play the devil's advocate here again. If we look at issue (a), what determines the extent to which risk analysis can be used, did the Commission's policy statement itself address that question?

MR. HOLAHAN: It has.

MR. THADANI: Yes. I think, in fact, that was the very first bullet when I went through.

CHAIRMAN JACKSON: Right.

MR. THADANI: To that extent, it is supported by methods and data and to be used as complement.

CHAIRMAN JACKSON: So what you are trying to do is pin down in some more quantitative way what that is?

MR. THADANI: More details and what does it really mean, supported by methods and data, what does that mean.

CHAIRMAN JACKSON: I just want to go through a couple of them, not all of them.

MR. KING: Sure.

CHAIRMAN JACKSON: With (b), where you say what determines the required quality of the risk analysis, will the guidance documents answer that question?

MR. KING: Yes.

CHAIRMAN JACKSON: Then, my favorite topic is (d), how is uncertainty to be addressed. There are two questions. One is, how has uncertainty been treated in the past, in past uses of PRA insights in the regulatory process. So, if you could give me an answer to that, and then the other one, which is that I note that in your SECY 96-218, the Staff indicates that it intends to use the mean value for comparison with numerical guidelines associated with absolute measures, such as core damage frequency, and this is my favorite topic.

So the question becomes answering how an uncertainty to be addressed, referencing it to how it has been addressed in the past. Does this imply that if you have equal mean values -- this is where the rubber meets the road -- with big differences in uncertainty, would that lead to the same regulatory decision?

MR. KING: Not necessarily.

CHAIRMAN JACKSON: Okay. So can you maybe illuminate or amplify on that a little bit?

MR. KING: We haven't settled exactly on how we are going to treat uncertainty at this point either.

CHAIRMAN JACKSON: Okay.

MR. KING: The Commission safety goal policy said use mean values in assessing against the goals.

CHAIRMAN JACKSON: Do you feel that is enough?

MR. KING: In some cases, it is enough, but it does require a full uncertainty analysis be part of the analysis and evaluation by the licensee and by the review by the staff.

MR. THADANI: I think that this is obviously a very tough issue. Mean values relate to where you are able to quantify a number of things and you are able to actually draw some sort of distribution and so on, but there are many elements where the uncertainties are really not quantified, organizational cultural issues, some other things, for example, millstone issues, some of the millstone issues.

So there are areas where uncertainties are not quantified, programmatic weaknesses or problems. So what it really boils down to is when you get an issue where let's say a licensee wants to use these techniques, it seems to me we are going to have to look at that specific issue and try to use some judgment on what are some of those so-called unquantified uncertainties and should we, in fact, use a mean value, then. Maybe not.

So it seems to me that there has to be some balance brought into this process to recognize that we cannot answer all the questions up front, I don't think, but the process should allow those considerations whenever there is an application to be made. So I am hoping that is how we can move forward.

CHAIRMAN JACKSON: If you look through this list of A through I, have you identified which ones minimally have to be answered at some level in order to develop realistic guidance documents? Have you answered that?

MR. KING: I think it is all of them. Our intent is all of them.

CHAIRMAN JACKSON: To have some answer?

MR. KING: To have some answer, yes.

CHAIRMAN JACKSON: For all of them?

MR. KING: Yes.

MR. HOLAHAN: Yes.

MR. THADANI: Yes.

CHAIRMAN JACKSON: So, when you say, then, that these draft documents are available, that means that you have some answers to all of them relative to development of those guidance documents?

MR. KING: The drafts have some answers. Whether there is consensus on the Staff regarding those answers is another question. They are under review.

CHAIRMAN JACKSON: That is what you mean when you say under Staff review?

MR. KING: Yes.

CHAIRMAN JACKSON: I see. Okay. Now I understand.

COMMISSIONER ROGERS: Well, before we leave this,

I'd like to just pursue one little aspect of it, and you touched on it a bit, the question of quantitative measures or lack of quantitative measures.

It is kind of my intention that some areas of risk analysis that are being used, particularly in the fuel cycle facilities, are not really being carried out using probabilistic analysis, but they are risk analyses, and it seems to me that we are going to have to deal with that issue of risk analyses which are not really based upon a strictly probabilistic calculation, and nevertheless, do the job in some way.

This may or may not fit into the reactor area. It probably does to some extent, but it may be very important in the nonreactor area.

MR. THADANI: Yes, yes.

COMMISSIONER ROGERS: So I do think that while I am very high on numbers, I do think we have to recognize that there are other ways of analyzing risk that are not strictly based on probabilistic calculations, but nevertheless are something closer or a little bit to the usual traditional deterministic, but nevertheless are a risk analysis rather than a straight engineering calculation of some sort.

I hope somehow we keep that in mind here for those situations where that is the only way to go.

MR. THADANI: Yes, indeed. In fact, I was going to say some people don't like to hear this, but I think when you go through the process of risk analysis, the first parts are probably the most robust in the sense of logic models. The event trees and fault trees, by and large, I think, are the most robust.

When you get into quantification is where one has to be cautious, and no matter what application, one needs to look hard, I think.

MR. HOLAHAN: I think in many cases, this is not a go and no-go sort of decision. There are stages, as in the policy statement suggestion is, first, does the state-of-the-art support the kind of issue you are trying to deal with, and I think after that, if the issue is amenable to a probabilistic risk assessment, you still want to choose the proper-sized tool for the job. So, if it is a relatively easy question or, in fact, a qualitative risk assessment, it would convince you that this is a net improvement, and why go through an elaborate uncertainty analysis to figure out how sure are you or how big is that.

CHAIRMAN JACKSON: It strikes me, though, that there is kind of a baseline question that in doing everything that you have just described, you have to address, which is kind of -- let me see if I can articulate it. It is essentially saying how much do I have to know and

be bale to quantify to make a judgment here, and if I want to make a judgment somewhere else at some other level, that it requires that much more, and if I can't get that, then the decision-making has to be done a different way.

Now, will the kind of guidance that you are working your way up on allow those kinds of assessments to be made?j

MR. HOLAHAN: Clearly, that is our goal. It is early on in this process to identify what is the proper tool for the given issue. Can you make a certain type of decision with a qualitative analysis? Does it take a quantitative analysis, but not necessarily an elaborate uncertainty analysis, or in some cases, are we making sufficiently complicated decisions that a full scope, full uncertainty analysis is needed?

I think, in each case, what you are trying to do is to say do I have confidence in the decision that I am making.

CHAIRMAN JACKSON: I appreciate what you are saying, and I guess all I am really asking is will the guidance documents be such that one proceeds along a path and comes to come bifurcation point that says I can go further down this PRA path or I can't, and if I can't, then it kicks over into something else. I mean, that is presumably where you are trying to go.

MR. HOLAHAN: We are working on that very subject. As recently as yesterday's meeting, we were going to divide up regions in which more details on certainty analysis was appropriate and where less is needed. That is the kind of thing that belongs in a guidance document.

CHAIRMAN JACKSON: Okay.

MR. THADANI: We had identified in an earlier paper, actually, that generally we were looking at three categories of applications. One was what we called prioritization which is, by and large, NRC activity, and that one could go with something fairly simplified. You don't want to spend a lot of resources to see how to prioritize things, but that you can use better understanding of risk importance to make those kinds of decisions. That was probably the simplest type of application in terms of the quality of analysis.

The next one was where the decision was not really eliminating a requirement, so to speak, but that you are just shifting importance, so to speak, high safety significance and medium safety significance and low safety significance. That would require a certain type of analysis.

Whereas, if you are really completely walking away from what today's requirement might be, then one has to do a very thorough analysis before saying that that makes sense.

So those are the categories that we have been looking at, and then, of course, the toughest issue, I think, is the issue of how to deal with uncertainties in all of this.

CHAIRMAN JACKSON: Okay, thanks.

MR. KING: Just to quickly highlight item (i) at the bottom of page 10, should the acceptance guidelines apply to proposed changes individually or as a package, the topic there is when someone comes in with a proposed change, can they group changes together, look at risk changes due to changes, proposed changes in tech specs versus ISI versus graded QA and add them all up and get a net reduction or net increase, whatever it turns out to be, or do we want to limit it to just a single topic. So that is the issue that is being talked about there.

On page 11, issues associated with implementation and monitoring, this is tied to one of the policy issues. This step was explicitly added in the process so that we would use performance monitoring as much as practical to check the assumptions and provide feedback into the evaluation and the changes that were being made.

If assumptions are made regarding equipment reliability or so forth, this is a step that would hopefully check to see whether those assumptions are becoming true, and if not, provide the appropriate feedback into the process.

CHAIRMAN JACKSON: Now, a natural question that arises is this. Now we have a maintenance rule that just became effective. Presumably, each one of these questions have to be addressed in implementing that rule for the SSCs that we mean for it to cover. What are the answers to those questions within the context of the maintenance rule, and then how does that flow into this and vice versa?

MR. KING: It may very well be the maintenance rule is accomplishing this for whatever proposed change they are making.

CHAIRMAN JACKSON: Well, I guess what I am trying to say is that it strikes me that that is something you have to come and tell us; namely, how are these four questions being answered within the context of the maintenance rule, and how, then, does that tie back into what you are doing and how is what you are doing affect how these questions are answered.

MR. THADANI: I think that there are two parts that we need to be sure about.

The first part would be depending on what performance criteria one sets up. If those are really related to reliability analyses, so to speak, then, clearly, one has to have some guidance document on how to assess and interpret what has been done.

As far as the maintenance rule is concerned, some

licensees may have used some reliability guidelines that may have come out of the PRAs. Some may not have. That was not strictly necessary under the maintenance rule.

We have initiated our inspections, what we call baseline inspections, under the maintenance rule. As I had indicated to you in the past, I am hoping that by February time frame we will have done enough inspections, 10 or 12 or some number like that, that we can probably draw some inferences and some potentially generic insights.

Our intention is to then step back. What we learn from those inspections would be considered, if it is appropriate for these guides, but that I don't have the answer today as to what we are going to find.

CHAIRMAN JACKSON: Let me, then, say this. I am going to be explicitly asking you this. Since you would be coming back in the March-April time frame to briefing the Commission again, that you come back as part of that brief with answers to these four questions in the context of the maintenance rule --

MR. THADANI: Yes.

CHAIRMAN JACKSON: -- and how that ties into the answers to these questions --

MR. THADANI: Yes.

CHAIRMAN JACKSON: -- within the context of what you are doing --

MR. THADANI: Yes.

CHAIRMAN JACKSON: -- because it is very important, okay? Because first of all, we shouldn't be going down a path relative to the maintenance rule that is somehow different than the path we are going down in the overall PRA Implementation Plan.

Two, we say that the maintenance rule is our first example of a risk-informed performance-based rule, and if it is, then it better tie into the PRA framework that we are developing.

MR. THADANI: Yes.

CHAIRMAN JACKSON: And I understand your point about doing these baseline inspections, but since you indicated that sometime after the first of the year --

MR. THADANI: Yes.

CHAIRMAN JACKSON: -- you will have more data, then along around March-April, you should be able to put it together, and you will be further along in these reviews of your reg guides because I think this is very important.

MR. THADANI: It is critical, I agree, and we will do that.

MR. HOLAHAN: I think it serves the same role as some of the pilot applications, but there are differences in the scope and the intent of the maintenance rule versus the general --

CHAIRMAN JACKSON: No, I appreciate that, and that is, in fact, what you have to come back and tell us because, in fact, we need to understand how the scope differs.

MR. HOLAHAN: Right.

CHAIRMAN JACKSON: We have talked about this before within the context of the reliability data rule or putative reliability data rule, but it is very important because it is important in terms of consistency in how we do things.

MR. HOLAHAN: Yes.

CHAIRMAN JACKSON: Okay, thanks.

MR. KING: Let me move on to Slide 12, issues associated with integrated decision-making. This is where the deterministic and the probabilistic evaluations come together and a decision has to be made. Again, it relates to what we talked about earlier, what are the deterministic decision criteria. A number of these items are directed toward that.

Let me just mention item (g) at the bottom of the page, the role of 50.109. This actually came out of one of the pilot programs. If the Staff has conducted the review and feels that something else needs to be done over and above what the licensee has volunteers to do, do we have to follow 50.109 to get that in place.

Counter to that or the reverse of that, we have

also discussed, and that is a licensee comes in and proposes a change that causes some increase in risk, why shouldn't we apply the backfit rule in a reverse way. Is the cost savings associated with that sufficient to justify the increase in risk? So that is what we have been talking about. I am not here to give you an answer, but that is what that item means.

CHAIRMAN JACKSON: Let me just make one other comments. Aren't B, C, and D on here linked? That is, if one really had a process for addressing uncertainty, then this issue of the extent to which the existing degree of defense in depth should be maintained is more addressable, as well as the issue of the margin of safety.

The only reason I keep bringing this up, you say it to me and I am saying it back to you. Somehow we have got to really get our hand around where we can get our hand around. I will put it that way, get our hands around where we can get our hands around the uncertainty issue, because if we don't somehow get that bullet bit and at least know where we can and cannot do something. I understand we cannot do it everywhere. I don't see how we are going to answer (c) and (d).

MR. KING: Slide 13 has to do with what actually has to be part of the submittal. The documentation needs to be submitted. Do we need the full PRA or just some summary

of what was done that describes in enough detail?

Regardless of whether the full PRA comes in or just some summary information, item C is a process issue. Will our explicit use of risk information and plant-specific decisions now require PRAs to be put on the docket and litigated? It is an item that just remains to be seen at this point.

With that, Gary Holahan is going to talk about the four policy issues.

MR. HOLAHAN: Could I have Slide No. 14, please? The four policy issues that we identified are shown here, the role of performance-based regulations, the use of the safety goals or guidance, the decision process derived from the safety goals on the plant-specific basis, whether increases in risk should be allowed at all or under what circumstances increases are appropriate, and then something of a process question on how should changes in the ISI and IST program be --

CHAIRMAN JACKSON: Mr. Holahan, you know I can't let you slide. How clearly do you feel the Staff knows what performance-based regulation means, how clearly do you feel you know, and what degree of concurrence is there on a definition? If not, how do you go about -- what are you doing to clarify that?

MR. HOLAHAN: Well, I think there is not a

unanimity of understanding as to what the definition of performance-based regulation is.

I have seen lots of different definitions. I think we understand common features that performance-based regulations have.

I remember that we were told that performance-based fire protection requirements are being put in place around the world. So a number of the staff met with the National Institute for Standards and Technologies. They were involved with those things, and I guess they confirmed our view that each country, each application has a slightly different definition, but with some common elements.

So I think we are starting out with maybe buzz words, but we are developing guidance documents which I hope will clarify the situation.

CHAIRMAN JACKSON: Is there a utility, too, and have you been able to garner any input from other types of industries or regulatory bodies that have gone at this? Are we on the cutting edge?

MR. HOLAHAN: Well, I think there are some other areas. We have had some input from the industry. There is an industry white paper on the subject.

A number of recent PRA conferences have identified this as an issue, and so it has been discussed. We

discussed it with the ACRS.

CHAIRMAN JACKSON: But is it all the nuclear people talking to each other as opposed to --

MR. HOLAHAN: I would say, largely, it is. In the fire protection area, obviously, it goes well beyond the nuclear area, but there are probably numerous other industries that we haven't fully tapped.

CHAIRMAN JACKSON: Okay.

MR. HOLAHAN: Can I have Slide 15, please?

The issue on Slide 15 being the role of a performance-based regulation in the PRA Implementation Plan, the Staff identified three options. I guess it is also important to note that as a result of the strategic assessment, there is, in fact, a paper on the subject which also identifies three, I would say, similar, not identical options.

So the Staff's moving ahead on these options, I think, is also tied to the decision in the strategic assessment arena.

The first option we identified basically is to continue our current practice, and our current practice being what Tom King showed, which, in fact, is to have developed what we called step four, which is as part of risk-informed regulation, actually searching out opportunities for monitoring in a plant application

information that would validate the assumptions that went into a risk analysis or the assumptions that went into a deterministic engineering analysis. So the first option is to continue with that process.

The second option is a bit more aggressive in that it would within the context of the PRA Implementation Plan solicit additional areas in which the industry was interested in pursuing examples.

The third option would, in effect, be to create something akin to the PRA Implementation Plan, which you could name the performance-based regulation implementation plan and collect together all those related topics and sort of give it a life of its own.

Staff has recommended option one, but I think it is fair to say that option one with a leaning towards option two because there is some receptiveness to additional initiatives, and the Staff did send a letter earlier this year to NEI suggesting that at least some additional options as a learning or pilot-type experience would be appropriate.

We have discussed this issue with the ACRS. At the bottom of the page, you will see a quote from their August letter. I think they were definitely very supportive of doing at least what the Staff had recommended; that is, to find a constructive place in each risk-informed decision for a performance-based strategy to be included as a

verification or validation step, but I think the important thing at this stage is that we are going ahead at least with option one, and we need to do that for the development of the regulation guides and the SRPs. If the strategic assessment process should have the Staff to do more, I think it is highly unlikely that it will be asked to do less.

So I think in the context of the reg guide and the SRP, it is fairly clear what we should be doing. What is not entirely clear and is a policy issue for the Commission to decide is how much more should we do.

COMMISSIONER McGAFFIGAN: What was the response from NEI to your letter? Did they have initiatives that they would like to --

MR. HOLAHAN: I don't recall them coming back with a specific example. It seemed to me that it was between the time when they send us a draft of their white paper on performance-based regulation and when they finalized it. So I might say they were at least encouraged enough to go forward and finalize their views. I don't think they have identified specific examples to follow up since then.

MR. THADANI: I think it is important to make a point. The PRA Implementation Plan is really focused on risk-informed activities, and in some cases, where some reliability guidelines are developed or to be used, then the Implementation Plan can give guidance on how one would

assess that.

Frankly, for many systems where you establish very high reliability, steam-generated tubes, reactor and pressure boundary, pressure vessel itself, many of the complements, the expected reliability is very high, and so the performance criterion one establishes cannot be first failure. It cannot be that. It has to be something else. It has to be some engineering consideration that goes in, how much thickness of a pipe, how much thickness can you afford to lose.

PIA can tell you how important that component is, and that is an important part. That is the risk-informed part, but the performance-based part is non-numerical because of what confidence one is trying to ascertain reliability of a component.

That is why I think we need to be very clear on what is it that we mean by performance-based because, in many cases, going forward in the risk analysis approach cannot answer some of the concerns that we might have. It is that element of performance-based aspect. That would be very difficult for this plan to address. It requires a lot of thoughtful experience and understanding.

Really, that is why we said in our letter to NEI that we need to learn from experience and we need to move a little slower in this area is basically what we said. It is

not to say that we shouldn't go in this direction, but let's make sure where are we going, learn from whatever experience we have as we go forward.

MR. HOLAHAN: I think, as also pointed out in the Commission paper, resources are an important element here. We are trying to maintain an aggressive schedule on the reg guide and the SRP development, and there is a concern of diverting resources from that activity if we take on a little bit more than we can manage all at once.

Can I have Slide No. 16, please?

The second issue relates back to, as Mr. Thadani mentioned, the June 15, 1990 SRM in which the Commission instructed the staff not to use the safety goals for plant-specific purposes, but to use them in a generic decision-making, and that policy was, I would say, restated in the PRA policy statement, but I think it was restated in the context that the Staff needs to come back to the Commission if it proposes to do otherwise than the 1990 directions. I think we have read it not to be an absolute prohibition, but if we develop this to be a worthwhile idea, we need to bring it back to the Commission for Commission's approval to go forward.

COMMISSIONER ROGERS: Well, if I could just say anything?

MR. HOLAHAN: Yes.

COMMISSIONER ROGERS: It seems to me, as I recall, when the Commission first took that position back in 1990, PRA was not a very attractive method of making regulatory decisions around here, and there was considerable resistance to it up until later than that, I believe. So, at that time, the Commission felt that we weren't on very solid grounds in going beyond a kind of generic approach to using the safety goals, but in the meantime, the kind of development of PRA for nuclear applications and the data that have developed have given us a great deal more confidence that you can begin to think about the possibility of using the safety goals themselves in some way for plant-specific applications.

I can't speak for the whole Commission, but it certainly seemed to me that what we were saying there was to open the door to that possibility cautiously and not just say that it is still locked.

MR. HOLAHAN: Okay. In fact, we developed two options. One option would be to develop guidelines for plant-specific decisions and to have those guidelines derived from safety goals and the subsidiary objectives. The second would be to derive plant-specific guidelines, but to try to preserve the generic national average nature of the safety goals by coming up with a scheme for relating an individual plant regulatory decision, the effect it would

have on the nationwide risk.

What we found is that the second approach is in addition to being rather complicated, since one would have to have a full understanding of the risk assessment at all plants to make a decision on any plant, and I think it also raises a number of rather complicated social and policy issues about decisions, about is it appropriate to make a risk decision at one plant where you are averaging out that local effect nationwide.

CHAIRMAN JACKSON: Right. It is a lot harder to raise an industry average than an individual number.

MR. HOLAHAN: Yes. So I think it is fair to say we found the second option untenable.

The first option is very much desirable in the sense that if we are going to use risk assessment in the decision-making process, certainly the output from the individual calculation seems to be a natural part of the calculation to use in that decision process.

CHAIRMAN JACKSON: Mindful of addressing all the issues we have been talking about all afternoon.

MR. HOLAHAN: Absolutely, yes. Yes.

CHAIRMAN JACKSON: Okay.

MR. HOLAHAN: With a full understanding of scope and uncertainties, et cetera, but as we say, without having a locked door.

So the Staff is recommending option one which would be a change in Commission policy.

MR. THADANI: If I might, I think it is important to note this is, in a way, one of the difficulties in pilots because the Staff is pushing to get a lot of information, and in some cases, that means a fair amount of additional work on the part of those volunteer pilot licensees, and that has caused some delays, trying to generate that information or the need, the discussion back and forth as to why is it really needed to generate this information. We will wait and see how it all works out, but currently, we have a number of outstanding questions to those licensees.

MR. HOLAHAN: I think there is also a related aspect to it, and that is, in some sense, the genie is out of the bottle already.

We know that the maintenance rule is being implemented in many cases with licensees using plant-specific risk assessment.

CHAIRMAN JACKSON: That is why I asked you about the implementation and the monitoring part.

MR. HOLAHAN: Yes.

CHAIRMAN JACKSON: That is exactly why you have to have that issue addressed.

MR. HOLAHAN: Yes. And it is clear that licensees are making other day-to-day prioritization and other

decisions based on the results of risk analysis.

So, to confine the Staff to not use a similar approach in plant-specific decision-making, it seems -- I think, as Commissioner Rogers suggested, perhaps that had a basis at the time, but I think that time has gone.

CHAIRMAN JACKSON: We heard you, Mr. Holahan.

MR. HOLAHAN: And the ACRS appears not only to agree with us, but I think they were considerably ahead of us on this issue, encouraging this view for several years, I think.

Can I have the seventh slide?

The seventh slide is really contingent upon the answer to the sixth, and that is, if you are going to use the results of a risk analysis in plant-specific decisions, should those results, in effect, be a proof that no risk change has occurred or only an improvement has occurred, or should increases be made under some circumstances.

I think what is fair to say is this is a policy matter to the extent that explicit changes in risk would be identified and approved because, in an unquantified way, I think it is clear that Staff does through the normal license amendment process, under some circumstances where we feel it is appropriate and the Commission's regulations are met, that we do allow small risk increases.

This would say that in the risk-informed

regulatory context, we would consciously, knowingly, and with some numerical analysis make such a decision. So, basically, the two options that we have identified as to allow small increases under certain circumstances and the regulatory guidance and the review plan would be the guidance document to identify how small is small and what are those circumstances, or we could say no, it is not appropriate, you should use your risk analysis to hold the plant risk at some value where you think they currently are.

We looked at the pros and cons of these options. The Staff has recommended the first to allow increases under certain circumstances. We think that is appropriate. We think we can identify how small is small and what is appropriate. The reg guides will help to balance any small changes with deterministic engineering margins to give us additional confidence that the decision we are making really makes sense.

The ACRS spent some time also reviewing this topic and also agreed with the staff. I would say, as a matter of principle, we haven't brought an example to the ACRS yet as to how those guidelines would be developed.

COMMISSIONER DICUS: I want to ask you a question about this. I don't necessarily disagree at least on the surface with the recommendation, but if you were to, for example, allow a small risk increase on one circumstance and

later there is another circumstance and then later another one, the way to follow these small risks that accumulated, to have a point in time, you say --

MR. HOLAHAN: Yes.

COMMISSIONER DICUS: -- and you track this and you know this.

MR. HOLAHAN: We will certainly address that issue.

One of the techniques we have considered for that -- and in fact, it is fair to say that the industry in its PSA application guide, I think, has addressed it to a certain extent in saying that a plant would develop a baseline risk analysis and then any changes that it made, either risk increases or decreases, at either a certain time interval or when a next major change would be anticipated, the analysis would be updated, in effect, if they had moved closer to some ultimate goal, that that would be reflected and understood before the next change would be made.

CHAIRMAN JACKSON: At the risk of preaching to the choir, let me just reference Mr. Taylor's beginning comments and Dr. Thadani's comments; that it still tracks back to the licensing/design basis issues because if you don't know what you are building the PRA on and if changes aren't appropriately captured and documented as of now, then it is very difficult to talk about moving forward in terms of

looking at how a risk profile of an individual plant may change; that these are inextricably linked issues. Do you disagree?

MR. THADANI: No, not at all.

MR. TAYLOR: We agree 100 percent.

MR. THADANI: Totally.

In addition to that, I would note that you tasked us, the Staff. The Staff should track cumulative changes for those individual plants. So in the Implementation Plan, we have an activity. Not only do we have expectation that the PRA should reflect the plant design and operation; that the plant should track if they are going to be using that tool -- they need to keep track of cumulative effects, but that the Staff will also be tracking that information.

MR. KING: Commissioner Dicus, in our list of 27 issues, it was item III-(e) on page 10, the issue you brought up. We didn't miss it.

[Laughter.]

COMMISSIONER DICUS: You are on top of it.

MR. HOLAHAN: Let the record show the choir says amen.

Could I have Slide 18, please?

The fourth policy issue was a little different from the first three in that it is more of a procedure and process question than a technical or real technical type

policy matter, and that is where we are considering risk-informed changes in the in-service inspection and in-service testing programs, how should those be treated in the context of the current regulations.

We identified three options. One would be to consider them exemptions to the current requirements in 10 CFR 50.55a. If we were to review these as being quite different from previous changes and the kind of alternatives the Staff has allowed to change in the past, then it would be most appropriate to treat those as exemptions.

The second option would recognize the fact that the regulation currently allows for authorized alternatives in Section 50.55a(a)(3)(i), and the third option would be to defer any such changes until the national consensus standards, the ASME standard process had actually adopted those changes.

We have looked at these options, and we have considered whether the risk information and the kind of decision we would be making would be consistent and appropriate, similar to decisions we have made before, and our recommendation is to treat the code alternatives, to treat the ISI and IST alternatives to the normal code requirements as authorized alternatives under that element of the regulations.

However, we think that carrying those for a long

period of time as authorized alternatives is probably not the clearest and the best approach. So, in parallel with that, we would be working with the ASME to move these alternative approaches into the national codes and make them a part of the -- that would draw them into the normal coverage of the regulations.

MR. THADANI: I might just note again, on that one, the Staff is looking. For example, in ISD, there are two approaches that are being looked at. One approach to sponsor is ASME is the sponsor.

MR. HOLAHAN: I think in that context, if we were to approve both options, then, perhaps, the ASME part would be taken care of because the regulations refer to the ASME code, but perhaps a role change would be appropriate to reference the other methodology.

CHAIRMAN JACKSON: Is this a technical recommendation or a legal?

MR. HOLAHAN: This is really a legal and procedural matter.

CHAIRMAN JACKSON: I mean, this is including the legal staff analysis of this?

MS. CYR: We concluded that, in our understanding of where they have looked at alternatives in the past, that it is an alternative under the 50.55a(a)(3).

MR. THADANI: Correct. Otherwise, we couldn't

proceed under that.

CHAIRMAN JACKSON: But greater clarification would come from this dual path.

MS. CYR: Ultimately to adopt that. Now there will be an approved alternative that the ASME adopted as a consensus standard. Then you would want to reflect that essentially as your main part of your --

MR. THADANI: That is right.

MR. HOLAHAN: And largely, because this was a legal and procedural matter, we did not ask the ACRS to comment on it.

I will cover the last two slides quickly. We have a number of activities over the next six months. We have meetings with the ACRS, October, November, and December. Those are largely focused on the regulatory guide and the standard review plans.

We are still striving to issue the reg guides and the SRPs by December 31st. We have a couple of major activities to go in order to achieve that. I think both the ACRS views and the CRGR in November will be challenges to the Staff to get those out on the current schedule.

We will be continuing our review over the pilot applications, with the IST pilot in March of '97 and the technical specification pilot at the end of this year.

We will be moving over the next six months, as Tom

King mentioned, to complete the IPE reviews. The draft IPE insights report is, in fact, to the Commission, and I guess it will be sent out for public comment shortly.

MR. KING: Yes.

MR. HOLAHAN: I think we already covered the reliability data rule as an ongoing activity.

CHAIRMAN JACKSON: When is that evaluation expected to be completed? When are you going to be completed?

MR. JORDAN: I will ask Pat Baranowsky to give me advice.

MR. BARANOWSKY: I believe we are going to try to have something to the Commission giving the status of that evaluation either late February or early March.

CHAIRMAN JACKSON: So March of '97?

MR. BARANOWSKY: '97, yes.

CHAIRMAN JACKSON: Okay.

MR. HOLAHAN: Of course, having developed the number of new training programs, we will be continuing to use those.

May I have the twentieth slide, please?

This is just a summary of our next commitments to the Commission, with a December update and a briefing plan for next April. I think by the time we prepare the December update, we will have a much clearer view of where we stand

with respect to the regulatory guide and the standard review plan because we will have been through the ACRS and CRGR and we will know how close we are to having a version available for public comment.

CHAIRMAN JACKSON: Okay, thank you.

Commissioner Rogers?

COMMISSIONER ROGERS: Just in the December briefing, do you have essentially a topics list for that yet as to what you think you will be discussing?

MR. HOLAHAN: I think the current plan is we would have briefing -- you mean the Commission briefing?

COMMISSIONER ROGERS: Yes.

MR. HOLAHAN: I think the Commission briefings have been set on six-month intervals.

So, although we would produce an update of the report, right now there is not a --

CHAIRMAN JACKSON: The report comes in three-month intervals. The briefings are six months.

COMMISSIONER ROGERS: Right, but just what will be the emphasis of that?

MR. HOLAHAN: Just looking at the topics that are ongoing, I would say the regulatory guide and the standard review plans would be the dominant issues.

COMMISSIONER ROGERS: When will you be able to talk to us a little bit about how we expect to use PRA in

inspections?

MR. HOLAHAN: I think we could do that at almost any stage since it is sort of in the process. We have heard some progress.

COMMISSIONER ROGERS: Well, I would be very interested in hearing that because the standard review plan is important, but how do we expect to actually employ the use of PRA out in the field, particularly, for instance, with resident inspectors?

MR. THADANI: Actually, we have started to move slowly in that direction.

CHAIRMAN JACKSON: Why don't you speak to it specifically in your briefing to the Commission.

MR. THADANI: We will do that. WE will do that.

MR. HOLAHAN: And there are two or three examples, at least two, in the current Commission paper.

The one thing that I would say, the thing that I am most optimistic about is the senior reactor analyst program where we have taken about 10 of the experienced senior inspectors largely from the field offices and put them in two-year training programs for PRA, and that looks like it is working very effectively. That is a mechanism for getting experienced inspectors with risk insights, putting them back into the regional offices to be the local experts.

COMMISSIONER McGAFFIGAN: I got stuck back on page 13. I kept going back to it. If the answer to VI-(c) is yes, that the licensee's PRA would be put on the docket and subject to litigation, what are the implications of that for this whole effort?

MR. HOLAHAN: Well, at first, it might make the licensees a little bit reluctant to submit those, but I think, in practice, what is likely to happen is not that the whole PRA is subject to litigation any more than every code analysis and every code run shows up in the litigation, but the information that is extracted from it and summarized and is actually in the licensing decision process. Frankly, if that element of the analysis is really what is at least in part convincing the Staff that this is a good regulatory decision to make, then I think it ought to be subject to public scrutiny.

CHAIRMAN JACKSON: Commissioner Dicus, any questions?

COMMISSIONER DICUS: No.

CHAIRMAN JACKSON: Commissioner Diaz?

COMMISSIONER DIAZ: Yes. I just have a comment. When I read these documents, I was sure I was confused. Now your pages 10 to 13 assure me that I have good cause to be confused because there are a lot of good questions in there.

However, looking back a little bit over the

history, to be able to make an informed risk decision, I think we already realize we have got to take a risk, and I think we took a risk with the maintenance rule. Is that correct? Was it something we did that we weren't sure how it was going to come out and we took a risk? And I think that's great.

In all these studies, sometime soon we are going to have to come with another risk. We are going to have to take a risk, and that is going to be an informed risk to implement risk-informed performance-based decision.

Has the Staff identified any particular area where we are closer to a definite answer to say we are going to be able to do this at a definite time? I mean, is any of the multiple series of issues resolved to a point that we can say in a year we can do that or whatever?

MR. HOLAHAN: I think it is fair to say that the pilot activities are the areas that we are getting the most experienced, and I would say I think we are pretty optimistic in each of those.

Certainly, perhaps with the ICI, in-service inspection area, it requires a bit more technological development than the others, but I think the Staff is optimistic about using these approaches and coming to agreement with the industry on the in-service testing. I think there is very good reason to think that, certainly,

within a year we will be ready to deal with technical specification changes, and I think in the graded QA area, we will come to an understanding of the appropriate uses.

One of the difficulties in that area is it is hard to quantify the value of doing quality assurance, but certainly, the use of risk input in deciding what is more or less important equipment in the plant, I am very optimistic that all of those will be successes.

COMMISSIONER DIAZ: Is the critical path dependent on the database that you have established on how to track that database?

MR. HOLAHAN: I guess I don't see the data role as absolutely essential in the sense that nothing can be done without it.

COMMISSIONER DIAZ: I see.

MR. HOLAHAN: I think it is a very important element. I think it would reduce the uncertainties. It would make it much more practical to be making decisions.

Perhaps you can't make as good and maybe, therefore, you can't make as certain a decision or maybe you need to put in a little extra margin if you don't have as much data, but I am still optimistic that improved decisions can be made.

COMMISSIONER DIAZ: Certainly, if the rule is imposed, we will be able to track it.

MR. HOLAHAN: Yes.

MR. THADANI: Yes.

If I may expand on what Gary has said, Commissioner Diaz, actually we at the Agency are using these techniques today in many of our decisions. In fact, we have a regulation that is called the backfit rule that calls for us to make two determinations before we can impose any new generic requirement.

The first one is that it should lead to substantial improvement and safety, and then we do use the Commission's subsidiary objectives derived from the safety goals and do, do risk analysis to see how the issue might relate to risk before we would go back and do cost benefit analysis, which is the second element of the backfit rule.

As far as we go forward, we are even today using what I would call risk insights to complement our deterministic evaluations and some of the changes that the licensees come in and propose in terms of technical specification changes.

What we do not do today, we do not have fixed numerical criteria or what I would call the infrastructure, the regulatory guide standard review plans, but we do use risk insights in these decisions as we go forward. In fact, it is an important element that we need to consider.

So I want to be sure that you know that we are

actually using these concepts and these decisions, but we just don't have the fixed criteria and we don't have guidance on how far to review these things called quality methods and so on. It is sort of ad hoc today, I would say.

COMMISSIONER DIAZ: I understand.

CHAIRMAN JACKSON: I would like to thank the Staff for what has been actually a very informative briefing on the Agency's PRA activities. Thank you.

We commend you, in fact, for the progress you have made to date in this sometimes difficult area. I know some of you have lost a few hairs along the way, but at the same time, we encourage you to continue to improve the process and to provide appropriate review mechanisms to ensure that PRA is used appropriately in our regulatory processes. Clearly, PRA has become an important tool of the regulatory process, and therefore, we have to strive to enhance the process, when necessary, but to ensure its consistent use where appropriate, and that is where the development of what you call, Dr. Thadani, the infrastructure is very important.

MR. THADANI: Yes.

CHAIRMAN JACKSON: It is also the reason for the fact that I am explicitly asking you to address the implementation and monitoring issues within the context of the maintenance rule and so forth in the next briefing.

We, the Commission, owe you decisions on the

policy issues as soon as possible; for example, the one we have been discussing, the use of the Commission safety goals for plant-specific applications.

Then, as long as we understand what is really needed or how far one can go in the use of these methodologies for a given decision, then I think we will start out on more solid ground.

So, unless my fellow Commissioners have any further comments, we are adjourned.

[Whereupon, at 3:42 p.m., the briefing concluded.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON PRA IMPLEMENTATION PLAN - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, October 16, 1996

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Jennie Malloy

Reporter: Mark Mahoney

United States
Nuclear Regulatory Commission

STATUS UPDATE OF PROBABILISTIC RISK ASSESSMENT (PRA) IMPLEMENTATION PLAN

Ashok C. Thadani
Gary M. Holahan, Thomas L. King

October 16, 1996

OVERVIEW

- Background
- Recent Accomplishments
- Summary of Key Technical and Process Issues
- Policy Issues Recommendations
- Future Activities

BACKGROUND

- Final PRA Policy Statement published on August 16, 1995
- January 3, 1996, staff submitted action plans for pilot applications and the development of RGs and SRPs
- Staff provides quarterly written updates on the progress of the PRA Implementation Plan and briefs the Commission semi-annually
- May 15, 1996, SRM requesting staff recommendations on policy issues
- In early October, 1996, staff submitted status update for the PRA Implementation Plan and policy issue recommendations

KEY ELEMENTS OF THE PRA POLICY STATEMENT

- Increase PRA applications in all regulatory decisions
  - supported by methods and data
  - complements deterministic approach
  - supports defense-in-depth philosophy

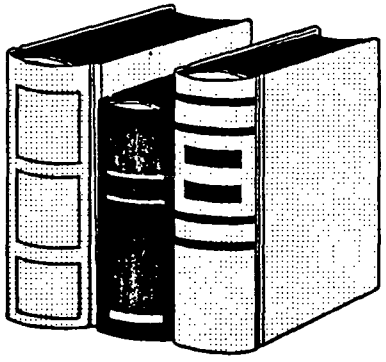
- PRAs are not substitutes for meeting current rules, regulations and requirements. Current rules and regulations shall be complied with unless these rules and regulations are revised

- Safety Goals and subsidiary numerical objectives are to be used for generic requirements

INTEGRATION OF PRA INTO REGULATORY ACTIVITIES

PRA

- Research
  - Prioritize Safety Issues
  - Severe Accident Assessment



- Current Rules and Requirements
  - Tech Specs
  - Inservice Testing

- Regulatory Oversight
  - Licensing
  - Inspection
  - Analysis of Experience
  - SALP

Enhance Safety Decisions (e.g., Configuration Control, Accident Management)

Efficient Use of NRC Resources (e.g., IPE Insights, Risk-Based Inspection)

Reduce Industry Burden (e.g., Graded QA, Risk-Based IST)

PRA IMPLEMENTATION PLAN

- Inter-office activities - comprehensive, broad scope, ongoing activities
- Develop risk-informed Regulatory Guides and Standard Review Plans
- Industry pilot applications (e.g., inservice inspection and testing, graded quality assurance)
- Analysis of operational data including accident sequence precursors
- Staff PRA training
- Nuclear waste management

RECENT ACCOMPLISHMENTS

- Draft RGs and SRPs for internal staff review
- Review of industry-initiated pilot applications
- Review of Individual Plant Examination (IPE) and Individual Plant Examination-External Events (IPEEE) submittals
- Public workshop to discuss the proposed Reliability Data Rule and Draft Regulatory Guide
- In parallel, industry is providing sample data to demonstrate a proposed voluntary alternative to the Reliability Data Rule
- Completed PRA training guidance document and "PRA for Technical Managers" course

RGs AND SRPs DEVELOPMENT

- Inter-office teams established to develop

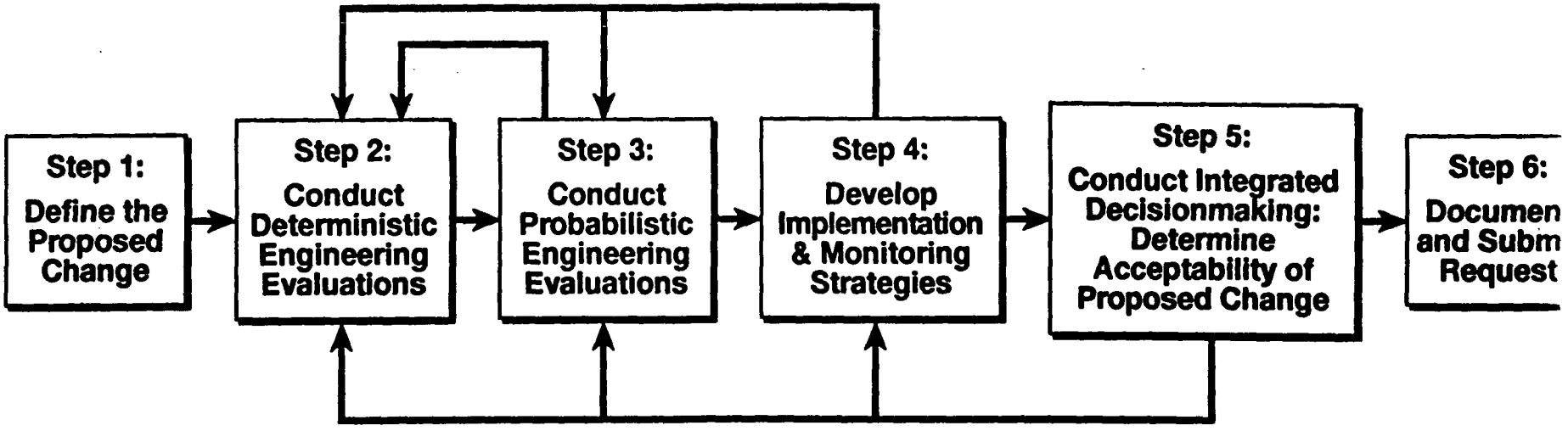
  General RG and SRP
  Application-specific RGs and SRPs
  - Inservice testing (IST)
  - Inservice inspection (ISI)
  - Graded Quality Assurance (GQA)
  - Technical Specifications (TS)

- Interactions with the industry and the ACRS

- Draft General RG and IST, GQA, TS RGs are currently under staff review

- Draft General SRP and IST, ISI SRPs are currently under staff review

Principal Licensee Steps in Risk-Informed, Plant-Specific Regulatory Process



Summary of Key Technical and Process Issues

I) Issues Associated with Definition of Proposed Change:

a) What information does the licensee need to submit to characterize the change?

b) Should the proposed change be required to meet at least one of the three goals of the PRA Policy Statement?

II) Issues Associated with Deterministic Evaluation:

a) What deterministic evaluations are required?

b) What are the acceptance guidelines for the deterministic evaluation?

III) Issues Associated with Risk Evaluation:

a) What determines the extent to which risk analysis can be used?

b) What determines the required quality of the risk analysis?

c) How is the appropriate quality assured?

d) How is uncertainty to be addressed?

e) How are cumulative changes in risk accounted for?

f) Should the acceptance guidelines be based upon total plant risk?

g) How should the acceptance guidelines be structured?

h) What is the role of importance analysis?

i) Should the acceptance guidelines apply to proposed changes individually or as a package?

IV) Issues Associated with Implementation and Monitoring:

a) What are the appropriate performance characteristics to monitor?

b) How should the SSCs to be monitored be selected?

c) How should the SSC performance be monitored?

d) How will feedback from the monitoring be used to make adjustments in implementation?

V) Issues Associated with Integrated Decision Making:

a) What are the important factors in integrating deterministic and probabilistic considerations?

b) How are uncertainties to be treated?

c) To what extent should the existing degree of defense-in-depth be maintained?

d) To what extent should the existing margins of safety be maintained?

e) What should defense-in-depth be based on?

f) What is the role of an expert panel?

g) What is the role of 10CFR50.109?

VI) Issues Associated with Documentation and Submittal:

a) What documentation is to be submitted?

b) What level of detail of risk information should be submitted?

c) Will explicit use of risk information in plant specific regulatory decisions require the licensee's PRA to be put on the docket and subject to litigation?

POLICY ISSUES

- Role of "performance-based regulation" in the PRA Implementation Plan
- Plant-specific application of Safety Goals
- Risk neutral vs. increases in risk
- Changes in risk-informed IST and ISI requirements

- **Issue: The role of performance-based regulation in the PRA Implementation Plan**
- **Options:**

  1) **Implement performance-based regulation in the context of the current PRA Implementation Plan through the current process**

  2) **Implement performance-based regulation as an explicit element of the PRA implementation Plan by actively soliciting industry initiatives**

  3) **Implement performance-based regulation outside the context of the PRA Implementation Plan**

- **Staff Recommendation: Option 1**

- **ACRS letter dated 8/15/96: "We agree with the staff that, where practical, performance-based strategies should be included in the implementation and monitoring step of the risk-informed decision-making process."**

- **Issue:** Should the Commission's Safety Goals and subsidiary objectives be referenced or used to derive guidelines for plant-specific applications and, if so, how?
- **Options:**

  1) Develop guidelines for plant-specific decisions that are derived from the Commission's current Safety Goals and subsidiary objectives

  2) Relate plant-specific risk changes to industry average population goals

- **Staff Recommendation:**

  Option 1

- ACRS letter dated 8/15/96: "We believe the safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications."

- **Issue: Should requested changes to the current licensing basis be risk-neutral or should risk increases be permitted?**

- **Options:**

  1) Small increases in risk be allowed under certain conditions

  2) Only risk neutral changes are permitted

- **Staff Recommendation:**

  Option 1

- **ACRS letter dated 8/15/96: "We agree with the staff and industry that increases in risk should be permitted in some situations."**

- **Issue:** Implementation of changes to risk-informed ISI and IST requirements

- **Options:**

  1) Approve requested changes to risk-informed ISI and IST requirements as exemptions to current regulations

  2) Approve requested changes to risk-informed ISI and IST requirements as authorized alternatives under 50.55a (a)(3)(i)

  3) Defer approval of requested changes to risk-informed ISI and IST requirements until after completion of ASME consensus process and modification of 10 CFR 50.55a

- **Staff Recommendation:**

  Option 2

- ACRS did not offer a view on this issue

FUTURE ACTIVITIES (NEXT 6 MONTHS)

- ACRS full and subcommittee meetings
- Issue draft for general and application-specific RGs and SRPs for public comment
- Continue review of the pilot applications (staff recommendation to the Commission regarding IST and technical specification pilots)
- Complete IPE reviews and issue draft IPE insights report for public comment
- Complete evaluation of industry's proposed voluntary approach to reliability data submittal
- Continue staff PRA training

FUTURE ACTIVITIES (NEXT 6 MONTHS, Continued)

- PRA Implementation Plan updates to the Commission in December 1996
- PRA Implementation Plan briefing for the Commission in April 1997

BACKUP SLIDES

PILOT APPLICATIONS

- **Inservice testing (IST)**

  - Reviewed Palo Verde and Commanche Peak's responses to Request for Additional Information (RAI)
  - Additional information from licensees needed to complete staff evaluation
  - Staff recommendation to the Commission delayed until 3/97

- **Inservice inspection (ISI)**

  - Reviewed initial submittal from Surry
  - ANO-2 and Fitzpatrick submittals delayed until 10/96
  - Reviewed risk-informed ISI guidance from industry

PILOT APPLICATIONS (Continued)

- **Graded QA**
  - Evaluated graded QA programs from South Texas, Palo Verde and Grand Gulf
  - Incorporated elements of the pilot methodology in the risk-informed graded QA RG and SRP
  - Slower progress than planned due to staff's higher priority on RG/SRP development and licensee's higher priority on other plant tasks
  - Staff recommendation to the Commission delayed until 6/97

PILOT APPLICATIONS (Continued)

- **Technical Specifications**

  - Reviewed Combustion Engineering Owners' Group (CEOG) request to extend allowed outage time (AOT) for LPSI and SITs
  - Staff awaits response to third RAI from lead plant
  - Staff recommendation to the Commission delayed until 12/96

IPE/IPEEE REVIEWS AND INSIGHTS

- Draft NUREG-1560 to the Commission in 9/96 providing perspectives from reviewing 75 IPEs
- Briefing regions on plant-specific IPE results and insights
- IPEEE review is continuing

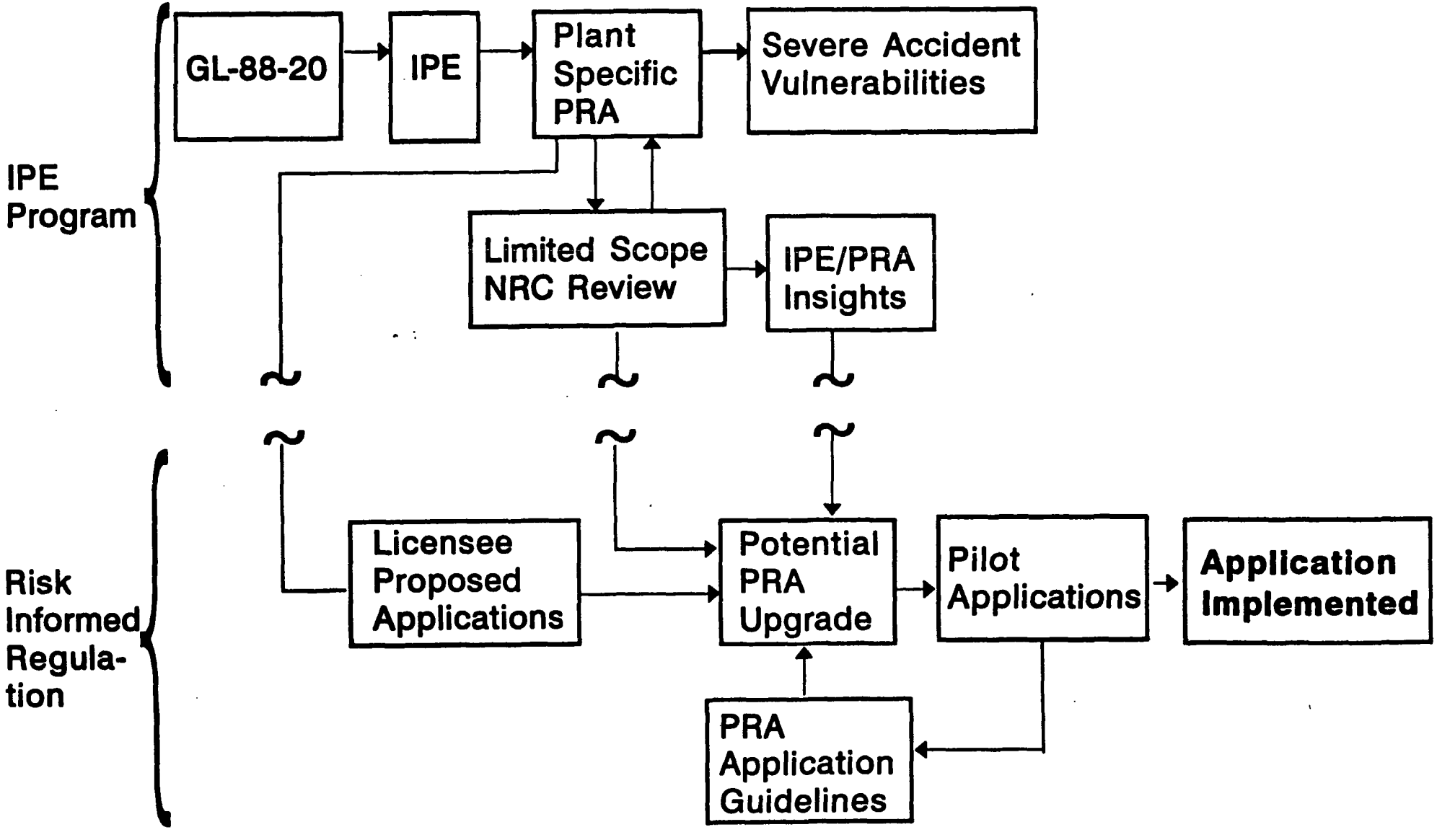
IPE VS RISK-INFORMED REGULATION

- Current IPE results do not by themselves always provide a complete basis for supporting risk-informed regulatory decisions

- NRC will require PRA quality commensurate with the proposed application

- NRC is working with the industry to develop standards for using PRAs in regulatory applications

RISK INFORMED REGULATION



RELIABILITY DATA RULE

- Staff is resolving comments for the proposed rule and the draft Regulatory Guide
- Conducted a public workshop in June 1996
- Parallel effort to obtain necessary data:
  through an industry voluntary program as well as
  through rule making
- Expect to complete an evaluation of industry's voluntary proposal in about 6 months
- Once a decision is made on the voluntary approach, issuance of the final rule would proceed if appropriate

PRA STAFF TRAINING

- Issued NUREG/BR-0228, "Guidance for Professional Development of NRC staff in Regulatory Risk Analysis"
- Staff has completed the "PRA for Technical Managers" course development and conducted a successful dry run
- Turnover in the Senior Reactor Analyst program due to promotions; training and rotational assignments near completion

REVISIONS TO PRA IMPLEMENTATION PLAN

- Pilot application target dates delayed due to
  - licensee's delay in responding to RAIs
  - staff effort focused on RGs and SRPs development

- Tasks to incorporate risk insights into inspection programs delayed due to resource diversion to other critical short term activities

- Implementation of the revised operator licensing examination standards incorporating risk insights contingent upon Commission approval

- Task 1.10 added to use IPE insights to identify appropriate staff and industry followup actions and to track regulatory use of IPE/IPEEE results

POLICY ISSUE
(Notation Vote)

October 11, 1996 SECY-96-218

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: QUARTERLY STATUS UPDATE FOR THE PROBABILISTIC RISK ASSESSMENT (PRA) IMPLEMENTATION PLAN, INCLUDING A DISCUSSION OF FOUR EMERGING POLICY ISSUES ASSOCIATED WITH RISK-INFORMED PERFORMANCE-BASED REGULATION

PURPOSE:

To provide a quarterly update on the progress of activities in the PRA Implementation Plan, including the development of risk-informed standards and guidance, and to provide the supplemental information requested in the May 15, 1996, Staff Requirements Memorandum (SRM), including a discussion of the four emerging policy issues associated with risk-informed, performance-based regulation.

BACKGROUND:

In a memorandum dated January 3, 1996, from the Executive Director for Operations to Chairman Jackson, the staff stated that it would provide quarterly updates on the status of developing risk-informed standards and guidance. Previous updates on the status of activities in the PRA Implementation Plan, including the status of developing risk-informed standards and guidance, were provided to the Commission on March 26 and June 20, 1996.

CONTACT:
A. Thadani, NRR
415-1274

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

In its SRM dated May 15, 1996, the Commission requested that the staff develop a policy paper, with recommendations, addressing the resolution of the four emerging policy issues identified in the March 26, 1996, quarterly status update. In the May 15, 1996, SRM, the Commission also requested that the staff provide an update on the implementation and use of subsidiary safety goal objectives and clarify how the staff intends to address uncertainty in the implementation of risk-informed and performance-based regulation.

The May 15 SRM also encouraged the staff to consider the use of expert judgement such as being applied in the high level waste area, as a guide for implementing the expert panel process being used for some risk-informed licensee applications. The Office of Nuclear Regulatory Research (RES) and Office of Nuclear Reactor Regulation (NRR) staffs have been following this work and are continuing to keep track of the NMSS development effort in high level waste management. All applicable information will be considered as a source of guidance in the development of Regulatory Guides and the Standard Review Plan sections for risk-informed applications.

DISCUSSION:

This Commission paper forwards: (1) the quarterly status update to the agency's PRA Implementation Plan; (2) the staff's recommendations concerning the four emerging policy issues identified in the March 26, 1996, PRA Implementation Plan status update; and (3) a list of technical issues that the staff is continuing to resolve during the development of risk-informed Standard Review Plans and Regulatory Guides.

The staff has updated the status of activities in the agency's PRA Implementation Plan in Attachment 1. The update includes a new activity that will address the Commission request in its May 21, 1996, SRM, that the staff track the regulatory uses of the IPE/IPEEE results and consider linking IPE/IPEEE databases together in a single, integrated, coherent program.

The staff recommendations concerning the four policy issues are contained in Attachment 2. Attachment 2 also contains the supplemental information requested by the Commission in its May 15, 1996, SRM concerning (1) implementation and use of subsidiary safety goal objectives and (2) uncertainty in the implementation of risk-informed and performance-based regulation. To meet the aggressive schedule for completing risk-informed standards and guidance, the staff continues to review pilot licensee risk-informed programs and develop Regulatory Guides and Standard Review Plans consistent with the staff's proposed recommendations on the policy issues.

Attachment 3 contains a summary list of key technical and process issues identified to date in the development of the Regulatory Guides (RGs) and Standard Review Plans (SRPs) and through the risk-informed pilot applications. The staff is working to resolve these issues and will propose its resolutions of these issues in the draft RGs and SRPs. A related issue in developing these Regulatory Guides and Standard Review Plans is the importance of the plant's current licensing basis. To proceed efficiently toward more risk-informed regulatory approaches, licensees and the staff must ensure that the plant's

current licensing basis and actual operating condition and practices continue to be properly reflected in the risk estimates using the plant PRA model. Otherwise, the risk assessment may provide inaccurate or misleading information that will need careful scrutiny before use in any regulatory decision-making process.

COORDINATION:

This paper was developed jointly by the Offices of Nuclear Reactor Regulation (NRR), Nuclear Regulatory Research (RES), Analysis and Evaluation of Operational Data (AEOD), and Nuclear Material Safety and Safeguards (NMSS).

The staff has briefed the Advisory Committee on Reactor Safeguards (ACRS) and its PRA subcommittee on the risk-informed policy issues, technical issues, and pilot applications. In its August 15, 1996, letter to the Chairman, the ACRS provided its views on selected issues related to risk-informed, performance-based regulation.

OGC has no legal objection.

RECOMMENDATIONS:

The staff recommends that the Commission:

(1) Agree to the staff's use of the recommended options on the four policy issues (as discussed in Attachment 2) in the continuing development of the Regulatory Guides and Standard Review Plans.

(2) Solicit comment on the staff's recommendations as part of the public comment process on the Regulatory Guides and Standard Review Plans (this is planned for January 1997).

(3) Note that the staff is working on the list of technical and process issues (Attachment 3) and will propose resolutions to these issues in the draft Regulatory Guides and Standard Review Plans.

(4) Note that the staff will continue to interact with risk-informed pilot licensees, industry representatives, ACRS, and the public regarding the increased use of risk insights in our regulatory processes.

James M. Taylor
Executive Director
for Operations

Attachments:
As stated

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Monday, October 28, 1996.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT October 21, 1996, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ATTACHMENT 1

STATUS UPDATE OF THE AGENCY-WIDE IMPLEMENTATION PLAN
FOR PROBABILISTIC RISK ASSESSMENT (PRA)
(FROM JUNE 1, 1996 TO AUGUST 31, 1996)

SUMMARY OF SIGNIFICANT PROGRESS

(1) Regulatory Guide (RG) and Standard Review Plan (SRP) Development (Tasks 1.1 and 2.1)

The draft broad-scope general RG and the draft application-specific RGs for Inservice Testing (IST), Graded Quality Assurance(GQA), and Technical Specifications (TS) are currently under inter-office review. The development of the draft RG for Inservice Inspection (ISI) is continuing. The staff has completed its review of the draft Nuclear Energy Institute (NEI) "Industry Guideline for Risk-Based Inservice Inspection" including the Westinghouse Owners Group methodology and is preparing to issue its comments and request for additional information to the industry.

The initial draft broad-scope general SRP and the initial application-specific draft SRP for ISI are under staff review. The draft SRP for IST has had several revisions and is still undergoing staff review. The development of the draft SRPs for GQA and TS is continuing. The significant amount of effort required by key staff members associated with the development of RGs and SRPs and the delays from some pilot licensees have contributed to some delays in the progress on pilot applications.

During the development of the RGs and SRPs, and through the risk-informed pilot applications, the staff identified a number of key technical and process issues related to risk-informed regulation. The PRA Coordination Committee (representatives from NRR, RES, AEOD, and NMSS at the Branch Chief level) has met with each of the RG/SRP development and pilot teams to discuss and review the list of key technical and process issues generated by the staff (Attachment 3). The staff is focusing its attention on these key issues during the pilot applications and the RG/SRP development. Resolution to these issues will be included in the final version of the risk-informed RGs and SRPs, as appropriate.

The staff has benefited from meetings with the ACRS and its PRA subcommittee to discuss technical and policy issues related to risk-informed, performance-based regulation. This dialog will continue during the RG and SRP development.

(2) Pilot Applications (Task 1.2)

The licensees' submittals for the risk-informed IST pilots (Comanche Peak and Palo Verde) have been very useful in assisting the staff to identify key technical and process issues to be included in the RG and SRP development. However, additional information from the licensees is needed for the staff to complete its evaluation of the proposed risk-informed

IST program and make recommendations to the Commission. Accordingly, the scheduled target date for the staff recommendation to the Commission on implementing the risk-informed IST pilot has been postponed to March 1997.

For the risk-informed ISI pilots (ANO-2, Fitzpatrick and Surry), an initial submittal from Surry was received in June. The submittals from ANO-2 and Fitzpatrick are delayed until October, 1996. The staff has had several meetings with representatives from Surry, Westinghouse Owners Group and the American Society of Mechanical Engineers (ASME) to identify and discuss key technical and process issues.

The graded QA volunteer pilot licensees (South Texas, Palo Verde, and Grand Gulf) have articulated a number of criteria for evaluating relative safety significance of structures, systems, and components (SSCs), particularly for those that are not modeled in the PRA. The staff has observed portions of the pilot licensees' graded QA process and incorporated elements of the pilot methodologies having merit in the development of the risk-informed RG and SRP.

The staff received the technical specifications pilot licensees' [Combustion Engineering Owners Group (CEOG)] response to the second request for additional information (RAI) for the Low Pressure Safety Injection System (LPSI) and the safety injection tanks (SITs) on June 19, 1996. The staff is awaiting response to the third RAI from the lead pilot licensee (Arkansas Nuclear One, Unit 2). The staff's contractor has reviewed the responses received to date and drafted a technical evaluation report. This report will serve as the basis for the staff's safety evaluations for the LPSI and SIT changes.

The staff met with the CEOG on August 15, 1996, to discuss the status of the technical specifications pilot activities and additional risk-informed technical specifications improvements that the CEOG is planning to submit in the future. The staff informed the CEOG that it may decide to visit a third pilot site before finalizing its review of the LPSI and SIT changes.

(3) Training for Inspectors (Task 1.3)

The staff has identified inspector functions and the areas where PRA methods can be applied to inspection activities. A draft course outline and task objectives were developed and forwarded to the Technical Training Division requesting training course development for NRC inspectors, project managers and technical reviewers. This new course is intended to combine applicable portions of several existing PRA training courses and present the material in an applications-oriented training environment.

Although there is a Senior Reactor Analyst (SRA) turnover issue due to selection of several individuals to supervisory positions, the PRA course training and rotational assignments for the remaining SRAs are on schedule and the SRAs are expected to be certified early next year.

(4) IPE and IPEEE Reviews (Task 2.5)

The internal NRC review of the draft NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," is on schedule and will be transmitted to the Commission for information in October 1996, and issued for public comment in October, 1996. This NUREG provides perspectives gained from reviewing 75 IPE submittals covering 108 nuclear power plant units.

As documented in SECY-96-088, "Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research," the staff could not conclude, based on the licensees' submittals, that all the licensees met the intent of Generic Letter 88-20. In that Commission paper, the staff indicated that IPE reviews will be completed by December 1996. Due to delays in responses from several licensees to staff questions, the completion of approximately three IPE SERs may slip beyond December 1996.

(5) Trending and Statistical Analysis Procedures (Task 3.1)

During this period, the seventh and last report in a series of trending and statistical analysis methods reports was completed. These reports addressed several topics for trending and analysis of different types of data. This completes the milestone "Develop standard trending and statistical analysis procedures for identified areas for reliability and statistical applications" under Task 3.1.

(6) Reliability Data Rule (Task 3.5)

Following the June public meeting on the proposed rule for collecting reliability and availability data, comments were received on the rule and the proposed regulatory guide. Work continues on modifications to the regulatory guide, the regulatory analysis supporting the rule, and the response to comments on the rule and regulatory guide. Efforts to obtain the necessary data through a voluntary program are continuing in parallel with the rule making activities. The Institute for Nuclear Power Operation (INPO) has indicated a willingness to allow the staff access to the Safety System Performance Indicator (SSPI) raw data in order to evaluate its usefulness and determine whether any deficiencies noted by such an evaluation can be remedied in the context of a voluntary program. INPO has declined to provide such data on a continuing basis unless the NRC adopts the voluntary approach to obtaining data as opposed to the approach in the proposed rule and regulatory guide.

(7) Staff Training (Task 3.6)

The staff has completed development of a guidance document for agency managers to assist them in developing training and development programs for their staff in the PRA area. The document, NUREG/BR-0228, "Guidance for Professional Development of NRC Staff in Regulatory Risk Analysis," was issued to all agency mangers and contains recommended PRA training guidelines for use by NRC staff.

The staff has developed and completed a dry run for the "PRA for Technical Managers" course. This course has been designed to provide all levels of staff managers a basic understanding of PRA methods, strengths and limitations. Feedback from the dry run was favorable and is being used to finalize the training module.

A new PRA Level 2 course, "Accident Progression Analysis," has been developed. This three-day course addresses accident phenomenology under post-core damage conditions and discusses the PRA modeling technique for this severe accident regime. The staff is developing a new PRA Level 3 course, "Accident Consequence Analysis." This three-day course will address environmental transport of radionuclides and estimation of offsite consequences from core damage accidents.

REVISIONS TO THE EXISTING PRA IMPLEMENTATION PLAN

Key staff members are on the team to develop risk-informed RGs and SRPs, as well as the review of work on pilot applications. Since their effort has been heavily committed to the development of RGs and SRPs, combined with delays for some pilot licensees, the progress on the pilot application has been hampered and the schedules for completion of the pilot SERs have been extended as discussed in the following paragraphs.

Both risk-informed IST pilots' (Comanche Peak and Palo Verde) responses to staff questions were too general and did not provide a sufficient basis for the staff to reach a conclusion regarding the "acceptable level of quality and safety" afforded by the proposed risk-informed IST programs. Consequently, the staff does not anticipate having enough information on which to make a decision relative to the acceptability of the RI-IST programs proposed by the pilot plant licensees until early next year. Accordingly, the scheduled target date for staff recommendation on the risk-informed IST pilot application (Task 1.2) has been postponed to March 1997.

The staff's recommendation to the Commission regarding the risk-informed technical specification pilot (Task 1.2) has been delayed 3 months from the original schedule due to the delay in the response to the third RAI from the lead pilot licensee. The staff expects to have its recommendation to the Commission in December 1996.

The graded QA pilot (Task 1.2) has proceeded at a slower pace than originally anticipated due to several factors, namely: licensee resolution of staff comments are outstanding; licensee resources for implementation of risk-informed graded QA have not received high priority due to other plant needs; staff review efforts have taken longer than expected due to workload impacts and difficult technical issue resolution; and the licensees' linkage of graded QA risk ranking with other risk-informed application results. Consequently, the graded QA volunteer pilot effort completion date has been postponed 6 months to June 1997. The staff anticipates that lessons learned from the volunteer efforts will continue to be assimilated by the staff after draft regulatory guidance documents (SRP and RG) have been generated and incorporated in the final draft after the public comment period ends.

Although the pilot applications have experienced delays as summarized above, the staff still intends to meet the aggressive schedule for the development and issuance of draft risk-informed RGs and SRPs. The staff plans to issue draft RGs and SRPs for public comment. These draft RGs and SRPs will contain a number of policy and technical issues that need to be resolved following the public comment period.

Inspection Manual Chapter 9900 revisions which provide high level guidance on incorporation of risk insights into the reactor inspection program have been drafted and are currently under staff review (Task 1.3). The progress on providing more detailed PRA insights to the reactor inspection program has been delayed because of diversion of resources to other critical short term activities such as the Millstone Task Force and the Maintenance Rule baseline inspections.

Regarding applying risk insights in operator licensing (Task 1.4), the staff recommended in SECY-96-123, "Proposed Changes to the NRC Operator Licensing Program," that the revised operator licensing process be implemented on a voluntary basis with the issuance of Revision 8 of NUREG-1021 and that the Commission approve the staff's pursuit of rulemaking to require power reactor facility licensees to prepare the operator licensing examinations in accordance with NUREG-1021. In an SRM dated July 23, 1996, the Commission requested the staff to develop a detailed rulemaking plan to justify changes that may be necessary to 10 CFR Part 55 and directed the staff to address a number of issues regarding the proposed examination process. The Commission deferred making a decision on implementation of the revised examination process on an industry-wide basis until the rulemaking plan and the responses to the additional items are reviewed. Although, the staff has made the appropriate revisions to NUREG-1021, the NUREG will not be implemented until after the Commission approves the proposed new examination methodology.

In its Staff Requirements Memorandum of May 21, 1996, the Commission requested that the staff track the regulatory uses of the individual plant examination/individual plant examination, external events (IPE/IPEEE) results. The Commission also stated that consideration should be given to linking resulting IPE/IPEEE databases together in a single, integrated and coherent program. Task 1.10 has been expanded to monitor and track the regulatory use of the results from the IPE/IPEEE. An important aspect of this activity will be the tracking of cumulative risk changes from licensees' use of IPE/IPEEE results in regulatory applications.

AEOD has completed an initial draft report on performance of risk-important components (Task 3.1). Peer review comments (including concerns about the completeness of the Nuclear Power Reliability Data System [NPRDS] and assumptions used for estimating demands, especially for plant-specific evaluations) have resulted in a delay of this work while they are being resolved. AEOD has set a new target date of February 1997 to complete the report. The risk-important initiating event study was delayed due to resource limitations.

For the Accident Sequence Precursor (ASP) program (Task 3.2), the initial ASP models for low power and shutdown conditions have been received. However, due to other higher priority tasks, the staff is not expected to complete the review of these models until November 1996.

REVISED TASK TABLES

The attached task tables have been updated to reflect the progress and revisions to the PRA Implementation Plan from June 1 to August 31, 1996.

REVISED PRA IMPLEMENTATION PLAN
TASK TABLE (SEPTEMBER 1996)

1.0 REACTOR REGULATION

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.1 DEVELOP STANDARD REVIEW PLANS FOR RISK-INFORMED REGULATION	Standard review plans for NRC staff to use in risk-informed regulatory decision-making.	* Evaluate available industry guidance. * Develop a broad scope standard review plan (SRP) and a series of application specific standard review plan chapters that correspond to industry initiatives. * These SRPs will be consistent with the Regulatory Guides developed for the industry. * Issue draft SRP for public comment General IST ISI GQA TS * Issue final SRP General IST ISI GQA TS	 12/96 12/96 3/97 12/96 12/96 12/97 12/97 12/97 12/97 12/97	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.2 PILOT APPLICATION FOR RISK-INFORMED REGULATORY INITIATIVES	* Evaluate the PRA methodology and develop staff positions on emerging, risk-informed initiatives, including those associated with: 1. Motor operated valves. 2. IST requirements. 3. ISI requirements. 4. Graded quality assurance. 5. Maintenance Rule. 6. Technical specifications. 7. Other applications to be identified later.	* Interface with industry groups. * Evaluation of appropriate documentation (e.g., 10 CFR, SRP, Reg Guides, inspection procedures, and industry codes) to identify elements critical to achieving the intent of existing requirements. * Evaluation of industry proposals. * Evaluation of industry pilot program implementation. * As appropriate, complete pilot reviews and issue staff findings on regulatory requests.	1. 2/96C* 2. 3/97 3. 6/97 4. 6/97 5. 9/95C 6. 12/96	NRR
1.3 INSPECTIONS	* Provide guidance on the use of plant-specific and generic information from IPEs and other plant-specific PRAs.	* Develop IMC 9900 technical guidance on the use of PRAs in the power reactor inspection program. * Revise IMC 2515 Appendix C on the use of PRAs in the power reactor inspection program. * Propose guidance options for inspection procedures related to 50.59 evaluations and regular maintenance observations. * Review core inspection procedures and propose PRA guidance where needed.	12/96 6/97 10/96 6/97	NRR
	* Provide PRA training for inspectors. *Provide PRA training for Senior Reactor Analysts (SRA)	* Identify inspector functions which should utilize PRA methods, as input to AEOD/TTD for their development and refinement of PRA training for inspectors. * Develop consolidated/comprehensive2-3 week PRA for regulatory applications training course. * First course offering. * Conduct training for Maintenance Rule baseline inspections * Conduct training courses according to SRA training programs * Rotational assignments for SRAs to gain working experience	7/96C 12/96 12/96 8/96C 3/97 3/97	NRR NRR/ AEOD NRR/ AEOD NRR NRR/RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Continue to provide expertise in risk assessment to support regional inspection activities and to communicate inspection program guidance and examples of its implementation.	* Monitor the use of risk in inspection reports. * Develop new methodologies and communicate appropriate uses of risk insights to regional offices. * Update inspection procedures as needed. * Assist regional offices as needed. * Conduct Maintenance Rule baseline inspections	Ongoing 7/98	NRR
1.4 OPERATOR LICENSING	Monitor insights from HRAs and PRAs (including IPEs and IPEEEs) and operating experience to identify possible enhancements for inclusion in planned revisions to guidance for operator licensing activities (initial and requalification)	* Revise the Knowledge and Abilities (K/A) Catalogs (NUREGs 1122 and 1123) to incorporate operating experience and risk insights. * Revise the Examiner Standards (NUREG-1021), as needed, to reflect PRA insights.	8/95C 12/96	NRR NRR
1.5 EVENT ASSESSMENT	* Continue to conduct quantitative event assessments of reactor events while at-power and during low power and shutdown conditions.	* Continue to evaluate 50.72 events using ASP models.	Ongoing	NRR
	* Assess the desirability and feasibility of conducting quantitative risk assessments on non-power reactor events.	* Define the current use of risk analysis methods and insights in current event assessments. * Assess the feasibility of developing appropriate risk assessment models. * Develop recommendations on the feasibility and desirability of conducting quantitative risk assessments.	TBD	NRR
1.6 EVALUATE USE OF PRA IN RESOLUTION OF GENERIC ISSUES	* Audit the adequacy of licensee analyses in IPEs and IPEEEs to identify plant-specific applicability of generic issues closed out based on IPE and IPEEE programs.	* Identify generic safety issues to be audited. * Select plants to be audited for each issue. * Describe and discuss licensees' analyses supporting issue resolution. * Evaluate results to determine regulatory response; i.e., no action, additional audits, or regulatory action.	6/97	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.7 REGULATORY EFFECTIVENESS EVALUATION	* Assess the effectiveness of two major safety issue resolution efforts (i.e., SBO and ATWS rules) for reducing risk to public health and safety.	* Develop process/guidance for assessing regulatory effectiveness. * Apply method to assess reduction in risk. * Evaluate result, effectiveness of rules. * Propose modifications to resolution approaches, as needed. * Identify other issues for assessment if appropriate.	9/97	NRR & RES
1.8 ADVANCED REACTOR REVIEWS	* Continue staff reviews of PRAs for design certification applications.	* Continue to apply current staff review process.	Ongoing	NRR
	* Develop SRP to support review of PRAs for design certification reviews of evolutionary reactors (ABWR and System 80+).	* Develop draft SRP to tech staff for review and concurrence. * Finalize SRP.	6/98 12/99	NRR
	* Develop independent technical analyses and criteria for evaluating industry initiatives and petitions regarding simplification of Emergency Preparedness (EP) regulations.	* Reevaluate risk-based aspects of the technical bases for EP (NUREG-0396) using insights from NUREG-1150, the new source term information from NUREG-1465, and available plant design and PRA information for the passive and evolutionary reactor designs.	12/96	NRR & RES
1.9 ACCIDENT MANAGEMENT	* Develop generic and plant specific risk insights to support staff audits of utility accidents management (A/M) programs at selected plants.	* Perform an assessment of A/M-related information contained in IPE databases to develop generic insights into A/M strategies and capabilities and document it in IPE Insights Report. * Develop plant-specific A/M insights/information for selected plants to serve as a basis for assessing completeness of utility A/M program elements (e.g., severe accident training)	6/97 TBD	NRR & RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.10 EVALUATING IPE INSIGHTS TO DETERMINE NECESSARY FOLLOW-UP ACTIVITIES	* Use insights from the staff review of IPEs to identify potential safety, policy, and technical issues, to determine an appropriate course of action to resolve these potential issues, and to identify possible safety enhancements.	* Review the report "IPE Program: Perspectives on Reactor Safety and Plant Performance" and identify required staff and industry actions (if any).	12/97	NRR & RES
		* Audit licensee improvements that were credited in the IPEs to determine effectiveness of licensee actions to reduce risk.	TBD	
	* Determine appropriate approach for tracking the regulatory uses of IPE/IPEEE results.	* Define use for information, clarify "regulatory use", and assess the most effective methods for data collection.	12/97	NRR
		* If appropriate, develop approach for linking IPE/IPEEE data bases.	12/98	

*C=Complete

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.1 DEVELOP REGULATORY GUIDES	Regulatory Guides for industry to use in risk-informed regulation.	* Issue draft PRA Regulatory Guides for public comment. General IST ISI GQA TS * Issue final PRA Regulatory Guides. General IST ISI GQA TS	 12/96 12/96 3/97 12/96 12/96 12/97 12/97 12/97 12/97 12/97	RES
2.2 TECHNICAL SUPPORT	* Provide technical support to agency users of risk assessment in the form of support for risk-based regulation activities, technical reviews, issue risk assessments, statistical analyses, and develop guidance for agency uses of risk assessment.	* Continue to provide *ad hoc* technical support to agency PRA users. * Expand the database of PRA models available for staff use, expand the scope of available models to include external event and low power and shutdown accidents, and refine the tools needed to use these models, and continue maintenance and user support for SAPHIRE and MACCS computer codes. * Support agency efforts in reactor safety improvements in former Soviet Union countries.	Continuing Continuing Continuing	RES RES RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.3 SUPPORT FOR NRR STANDARD REACTOR PRA REVIEWS	* Modify 10 CFR 52 and develop guidance on the use of updated PRAs beyond design certification (as described in SECY 93-087).	* Develop draft guidance and rule. * Solicit public comment. * Finalize staff guidance and rule.	5/98 11/98 12/99	RES RES RES
2.4 METHODS DEVELOPMENT AND DEMONSTRATION	* Develop, demonstrate, maintain, and ensure the quality of methods for performing, reviewing, and using PRAs and related techniques for existing reactor designs.	* Develop and demonstrate methods for including aging effects in PRAs. * Develop and demonstrate methods for including human errors of commission in PRAs. * Develop and demonstrate methods to incorporate organizational performance into PRAs. * Develop and demonstrate risk assessment methods appropriate for application to medical and industrial licensee activities.	9/97 6/97 9/97 6/97	RES RES RES RES & NMSS
2.5 IPE AND IPEEE REVIEWS	* To evaluate IPE/IPEE submittals to obtain reasonable assurance that the licensee has adequately analyzed the plant design and operations to discover vulnerabilities; and to document the significant safety insights resulting from IPE/IPEEEs.	* Complete reviews of IPE submittals. * Complete reviews of IPEEE submittals. * Continue regional IPE presentations. * Issue IPE insights report for public comment. * Final IPE insights report * Issue interim IPEEE insights report * Issue draft final IPEEE insights report	12/96* 12/98 Ongoing 10/96 6/97 9/97 9/98	RES RES RES RES RES RES RES
2.6 GENERIC ISSUES PROGRAM	* To conduct generic safety issue management activities, including prioritization, resolution, and documentation, for issues relating to currently operating reactors, for advanced reactors as appropriate, and for development or revision of associated regulatory and standards instruments.	* Continue to prioritize and resolve generic issues.	Continuing	RES

* Approximately 3 SERs may slip beyond 12/96; staff is awaiting additional information from licensees

3.0 ANALYSIS AND EVALUATION OF OPERATING EXPERIENCE, AND TRAINING

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office
3.1 RISK-BASED TRENDS AND PATTERNS ANALYSIS	* Use reactor operating experience data to assess the trends and patterns in equipment, systems, initiating events, human performance, and important accident sequence.	* Trend performance of risk-important components. * Trend performance of risk-important systems. * Trend frequency of risk-important initiating events. * Trend human performance for reliability characteristics.	2/97 Annual rpt-9/97 12/96 TBD	AEOD
	* Evaluate the effectiveness of licensee actions taken to resolve risk significant safety issues.	* Trend reactor operating experience associated with specific safety issues and assess risk implications as a measure of safety performance.	As needed	AEOD
	* Develop trending methods and special databases for use in AEOD trending activities and for PRA applications in other NRC offices.	* Develop standard trending and statistical analysis procedures for identified areas for reliability and statistical applications. * Develop special software and databases (e.g. common cause failure) for use in trending analyses and PRA studies.	Complete CCF-Complete Periodic updates	AEOD
3.2 ACCIDENT SEQUENCE PRECURSOR (ASP) PROGRAM	* Identify and rank risk significance of operational events.	* Screen and analyze LERs, AITs, IITs, and events identified from other sources to obtain ASP events. * Perform independent review of each ASP analyses. Licensees and NRC staff peer review of each analysis. * Complete quality assurance of Rev. 2 simplified plant specific models. * Complete feasibility study for low power and shutdown models. * Complete initial containment performance and consequence models.	Ongoing Annual report, Ongoing 3/97 11/96 Complete	AEOD AEOD RES RES RES
	* Provide supplemental information on plant specific performance.	* Share ASP analyses and insights with other NRC offices and Regions.	Annual rpt	AEOD

Regulatory Actvity	Objectives	Methods	Target Schedule	Lead Office
3.3 INDUSTRY RISK TRENDS	* Provide a measure of industry risk that is as complete as possible to determine whether risk is increasing, decreasing, or remaining constant over time.	* Develop program plan which integrates NRR, RES, and AEOD activities which use design and operating experience to assess the implied level of risk and how it is changing. * Implement program plan elements which will include plant-specific models and insights from IPEs, component and system reliability data, and other risk-important design and operational data in an integrated frame work to periodically evaluate industry trends.	Complete 8/97	AEOD
3.4 RISK-BASED PERFORMANCE INDICATORS	* Establish a comprehensive set of performance indicators and supplementary performance measures which are more closely related to risk and provide both early indication and confirmation of plant performance problems.	* Identify new or improved risk-based PIs which use component and system reliability models & human and organizational performance evaluation methods. * Develop and test candidate PIs/performance measures. * Implement risk-based PIs with Commission approval.	Complete 3/98 9/98	AEOD
3.5 COMPILE OPERATING EXPERIENCE DATA	* Compile operating experience information in database systems suitable for quantitative reliability and risk analysis applications. Information should be scrutable to the source at the event level to the extent practical and be sufficient for estimating reliability and availability parameters for NRC applications.	* Manage and maintain SCSS and the PI data base, provide oversight and access to NPRDS, obtain INPO's SSPI, compile IPE failure data, collect plant-specific reliability and availability data. * Develop, manage, and maintain agency databases for reliability/availability data (equipment performance, initiating events, CCF, ASP, and human performance data). * Revise reporting rules to better capture equipment reliability information. * Determine need to revise LER rule to eliminate unnecessary and less safety-significant reporting. * Determine need to revise reporting rules and to better capture ASP, CCF, and human performance events.	Ongoing Ongoing Proposed-Compl.-2/96 Final-10/97 4/97 6/98	AEOD

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
3.6 STAFF TRAINING	* Present PRA curriculum as presently scheduled for FY 1996	* Continue current contracts to present courses as scheduled. * Maintain current reactor technology courses that include PRA insights and applications. * Improve courses via feedback. * Review current PRA course material to ensure consistency with Appendix C.	Ongoing Ongoing Ongoing Complete	AEOD
	* Develop and present Appendix C training courses.	* Prepare course material based on Appendix C. * Present courses on Appendix C.	Complete Complete	RES and AEOD
	* Determine staff requirements for training, including analysis of knowledge and skills, needed by the NRC staff.	* Review JTAs performed to date. * Perform representative JTAs for staff positions (JTA Pilot Program). * Evaluate staff training requirements as identified in the PRA Implementation Plan and the Technical Training Needs Survey (Phase 2) and incorporate them into the training requirements analysis. * Analyze the results of the JTA Pilot Program and determine requirements for additional JTAs. * Complete JTAs for other staff positions as needed. * Solicit a review of the proposed training requirements. * Finalize the requirements.	Complete Complete Complete Ongoing Ongoing Ongoing Ongoing	AEOD
	* Revise current PRA curriculum and develop new training program to fulfill identified staff needs.	* Prepare new courses to meet identified needs. * Revise current PRA courses to meet identified needs. * Revise current reactor technology courses as necessary to include additional PRA insights and applications.	12/97 12/97 Complete 3/96	AEOD
	* Present revised PRA training curriculum.	* Establish contracts for presentation of new PRA curriculum. * Present revised reactor technology courses. * Improve courses based on feedback.	Ongoing Ongoing Ongoing	AEOD

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
4.1 Validate risk analysis methodology developed to assess most likely failure modes and human performance in the use of industrial and medical radiation devices.	* Validate risk analysis methodology developed to assess the relative profile of most likely contributors to misadministrations for the gamma stereotactic device (gamma knife).	* Hold a workshop consisting of experts in PRA and HRA to examine existing work and to provide recommendations for further methodological development. * Examine the use of Monte Carlo simulation and its application to relative risk profiling. * Examine the use of expert judgement in developing error rates and consequence measures.	8/94 Completed 9/95 Completed 9/95 Completed	NMSS
	* Continue the development of the relative risk methodology, with the addition of event tree modeling of the brachytherapy remote afterloader.	* Develop functionally based generic event trees.	TBD	RES/ NMSS
	* Extend the application of the methodology and its further development into additional devices, including teletherapy and the pulsed high dose rate afterloader.	*Develop generic risk approaches.	TBD	RES/ NMSS
4.2 Continue use of risk assessment of allowable radiation releases and doses associated with low-level radioactive waste and residual activity.	* Develop decision criteria to support regulatory decision making that incorporates both deterministic and risk-based engineering judgement.	* Conduct enhanced participatory rulemaking to establish radiological criteria for decommissioning nuclear sites; technical support for rulemaking including comprehensive risk based assessment of residual contamination. * Work with DOE and EPA to the extent practicable to develop common approaches, assumptions, and models for evaluating risks and alternative remediation methodologies. (Risk harmonization).	8/94 PR Complete Final Rule 6/96- 3/97 (Dependent on EPA) Ongoing	RES & NMSS
4.3 Develop guidance for the review of risk associated with waste repositories.	* Develop a Branch Technical Position on conducting a Performance Assessment of a LLW disposal facility.	* Solicit public comments * Publish final Branch Technical Position	1/97 8/97	NMSS & RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
5.1 REGULATION OF HIGH-LEVEL NUCLEAR WASTE	* Develop guidance for the NRC and CNWRA staffs in the use of PA to evaluate the safety of HLW programs.	* Assist the staff in pre-licensing activities and in license application reviews. * Develop a technical assessment capability in total-system and subsystem PA for use in licensing and pre-licensing reviews. * Combine specialized technical disciplines (earth sciences and engineering) with those of system modelers to improve methodology.	Ongoing	NMSS
	* Identify significant events, processes, and parameters affecting total system performance.	* Perform sensitivity studies of key technical issues using iterative performance assessment (IPA).	Ongoing	NMSS
	* Use PA and PSA methods, results and insights to evaluate proposed changes to regulations governing the potential repository at Yucca Mountain.	* Assist the staff to maintain and to refine the regulatory structure in 10 CFR Part 60 that pertains to PA. * Apply IPA analyses to advise EPA in its development of a Yucca Mountain regulation * Apply IPA analyses to conform 10 CFR 60 to EPA's regulations	Ongoing	NMSS
	* Continue PA activities during interactions with DOE during the pre-licensing phase of repository development, site characterization, and repository design.	* Provide guidance to the DOE on site characterization requirements, ongoing design work, and licensing issues important to the DOE's development of a complete and high-quality license application. * Compare results of NRC's iterative performance assessment to DOE's TSPA-95 to identify major differences/issues.	Ongoing	NMSS

ATTACHMENT 2

This attachment contains the supplemental information requested by the Commission in its Staff Requirements Memorandum dated May 15, 1996. This supplemental information includes 1) a discussion of the four emerging policy issues identified in the March 26, 1996, memorandum from the Executive Director for Operations to the Commission providing an update on the agency's Probabilistic Risk Assessment (PRA) Implementation Plan, 2) a discussion of the implementation and use of subsidiary safety goal objectives, and 3) a discussion of the staff's plans to address uncertainty in the implementation of risk-informed and performance-based regulation.

I. EMERGING POLICY ISSUES

In a memorandum dated March 26, 1996 from the EDO to the Commission, the staff identified the following four emerging policy issues:

- The role of performance-based regulation in the PRA Implementation Plan
- Plant-specific application of safety goals
- Risk neutral vs. increases in risk
- Implementation of changes to risk-informed IST and ISI requirements.

As requested by the Commission, each emerging policy issue is discussed below. The discussions briefly describe the issue, the alternatives, including the pros and cons, and provide the staff's recommendation. The staff has also considered the comments contained in the Advisory Committee on Reactor Safeguards letter of August 15, 1996, concerning risk-informed and performance-based regulation.

A. THE ROLE OF PERFORMANCE-BASED REGULATION IN THE PRA IMPLEMENTATION PLAN

In its Policy Statement "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622, August 16, 1995), the Commission affirmed that the use of PRA should be encouraged and that the scope of PRA applications in all nuclear regulatory matters should be expanded to the extent supported by the state-of-the-art in methods and data. The Commission's PRA Policy Statement and the PRA Implementation Plan continue to provide a necessary focus for the staff and industry to proceed toward more risk-informed regulatory approaches that enhance safety decision-making, improve staff efficiency, and/or reduce industry burden.

"Risk-informed" and "performance-based" are not necessarily synonymous terms, and the Commission's PRA Policy Statement does not explicitly discuss performance-based regulation. It is important for the staff and the industry to explore this regulatory concept with careful and deliberate thought. Most of the staff's experience with performance-based regulation has been gained through PRA pilot applications, implementation of the Maintenance Rule (10 CFR 50.65), and other rulemaking. For example, the recent rulemaking on 10 CFR Part 50, Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors" (60 FR 49495), implemented a performance-based option for leakage-rate testing for containments. In addition, several proposed and

ongoing rule changes (as described in the "Proposed Rulemaking Activity Plan," SECY-96-176) take a performance-based approach. The PRA Implementation Plan pilot applications for inservice testing of pumps and valves and inservice inspection are also partly performance-based, focussing on component and system performance. The staff continues to explore approaches that utilize performance assessment.[1]

After reviewing lessons-learned to date with risk-informed regulatory initiatives and after reviewing the performance-based elements proposed by the Nuclear Energy Institute (NEI), the staff has concluded that a risk-informed, performance-based regulatory approach should have at least four key elements: (1) there are measurable or calculable parameters to monitor plant and licensee performance, (2) objective criteria are established to assess performance based on a combination of risk insights, deterministic analysis, and performance history, (3) the licensee has flexibility to determine how to meet established performance criteria, and (4) failure to meet a performance criterion will not have an intolerable outcome.[2]

In some cases, performance-based regulatory approaches can be incorporated into risk-informed regulatory approaches. In other cases, performance-based regulatory approaches can be implemented without the explicit use of risk insights. The latter type of performance-based approach would involve objective performance criteria based on deterministic analysis, engineering judgment, and performance history.

The staff has identified three alternatives for addressing the issue of how performance-based regulation should be implemented.

Alternative 1: Implement performance-based regulation in the context of the current PRA Implementation Plan through the current process. That is, where practical, include performance-based strategies in the implementation of the risk-informed regulatory decision-making process.

PROS

This alternative has several advantages. First, it would allow staff to continue the current process, under the PRA Implementation Plan, for considering risk-informed, performance-based approaches on their own merits on a case-by-case basis. The PRA Implementation Plan is periodically updated to reflect the progress of planned activities, or to add new areas where the staff is pursuing risk-informed approaches.

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[1] These assessments of performance are not identical to and do not have the same regulatory roles as "performance assessments" of waste management facilities.

[2] For waste disposal, performance criteria are inherent in defining the acceptability of the overall system for disposal. For low-level waste, and perhaps high-level waste, dose (and thus risk) criteria are elements of the governing regulations. Thus, for waste disposal, the regulatory approach is both risk-based and performance-based and failure to meet the criteria would be noncompliance.

Second, the current process is responsive to numerous risk-informed industry initiatives in the power reactor area, where the potential benefits for reducing unnecessary industry burden, enhancing safety decision-making, and improving staff efficiency are readily apparent.

Third, under this alternative, risk-informed modification of rules and regulations to move toward increased performance-based regulation would be complementary to the PRA Implementation Plan activities. This complementary approach would promote regulatory coherence and help ensure that the legal and technical issues associated with performance-based approaches are resolved in the context of (and, where appropriate, integrated with) risk-informed regulatory approaches. Currently, performance-based strategies are considered in the implementation and monitoring step of the risk-informed decision-making process the staff is developing for reactor-related activities.

Finally, since this alternative is the current process, a significant change in resource allocation is not necessary to implement it. The resource and programmatic consequences are gradual and incremental.

CONS

The current process could be perceived as moving too slowly toward more performance-based regulatory approaches.

Alternative 2: Implement performance-based regulation as an explicit element of the PRA Implementation Plan by actively soliciting from industry a limited number of additional performance-based initiatives which are also suitable for risk-informed changes.

PROS

This alternative has two advantages. First, it would allow the staff and industry to gain additional experience on performance-based industry initiatives that may not necessarily be part of risk-informed initiatives.

Second, this approach would be responsive to industry initiatives for pursuing performance-based approaches. The transition to performance-based regulatory approaches would focus on areas supported by the industry.

CONS

Additional performance-based pilot reviews would divert staff resources from other regulatory activities and could cause delays in schedules or require additional resources.

Alternative 3: Implement performance-based regulation outside the context of the PRA Implementation Plan.

PROS

Under this alternative, the agency could move aggressively toward performance-based regulatory approaches by establishing a separate oversight program outside the oversight provided by the PRA Implementation Plan. This alternative would be parallel to, and perhaps independent of, risk-informed efforts. The agency could pursue performance-based approaches that are not explicitly risk-informed avoiding many of the risk-related technical issues.

CONS

Significant staff resources would be needed to support a concentrated effort to pursue performance-based approaches, to separately review the regulations and regulatory decision-making processes, and implement rulemaking or procedural changes. It is likely that these resources would have to be diverted from other ongoing or planned regulatory activities. This parallel approach might make it more difficult to integrate activities in areas where risk-informed and performance-based approaches are complementary.

Also, because it would be resource intensive, this alternative could also be the most costly to licensees, at least in the short term. Their participation in and support for such activities could depend on the extent to which they perceived near-term benefits.

STAFF RECOMMENDATION

The staff recommends Alternative 1.

With this approach, the staff plans to include performance-based strategies in the implementation of risk-informed regulatory decision-making processes to the extent that they relate to the activities in the PRA Implementation Plan. Because the staff is aware of a recent OIG audit focusing on peformance-based regulation, the staff will review the findings and recommendations contained in the audit report, after issuance, and inform the Commisison of any changes to the staff's recommendation.

In its letter of August 15, 1996, the ACRS stated that it "agree[d] with the staff that, where practical, performance-based strategies should be included in the implementation and monitoring step of the risk-informed decision-making process. The pilot programs may provide an opportunity for a more concrete definition and development of performance-based strategies."

B. PLANT-SPECIFIC APPLICATION OF SAFETY GOALS

The Safety Goal Policy Statement, issued by the Commission in 1986, established two qualitative safety goals to help assure that nuclear power plant operations do not significantly increase risk to individuals or to society. The policy statement also defined

two quantitative objectives for use "in determining achievement of the qualitative goals." These quantitative health objectives (QHOs) were defined in terms of a percentage (0.1%) of the total accidental and cancer death rates experienced by the public.

Since the policy statement was issued, the staff has developed subsidiary objectives to the QHOs. These subsidiary objectives have been formulated in terms of the frequency of core damage accidents and the performance of containment structures under accident conditions. These subsidiary objectives were established for a number of reasons, including that they introduced a clearer characterization of the desirable performance of some of the critical engineered barriers which protect public health (e.g., containment performance).

Consistent with the Commission's guidance in its June 15, 1990, SRM, the QHOs and subsidiary objectives have been pursued only in the context of generic regulatory decisions, such as generic backfit decision-making.

The Commission's PRA Policy Statement endorsed the expanded use of PRA in regulatory activities. This expansion, specifically in the area of changes to an individual plant's current licensing basis (CLB), has led the staff to consider the need for guidelines to support regulatory decision-making in plant-specific circumstances, recognizing that the use of risk information remains complementary to deterministic engineering analysis and judgment. Specifically, the staff is considering how to develop guidelines for plant-specific applications. The staff has identified two alternative approaches.

Alternative 1: Develop guidelines for plant-specific decisions that are derived from the Commission's current Safety Goals and/or subsidiary objectives.

This alternative involves the development of acceptance guidelines for risk-informed plant-specific CLB change requests, based on the current safety goals and/or subsidiary objectives. The staff and the nuclear power industry have experience in developing such acceptance guidelines. The NRC's Regulatory Analysis Guidelines, which are used in backfit determinations, include guidance on the acceptable levels of risk for a class of plants. In addition, EPRI's PSA Applications Guide contains proposed guidelines for judging the acceptability of plant-specific changes based upon their impact on plant risk.

The derived PRA-related acceptance guidelines would likely be in the form of core damage frequency and measures of containment performance, that are developed to be compatible with the Safety Goals and/or subsidiary objectives. The actual derivation could take different forms, for example:

- plant level guidelines related to plant design such as core damage frequency, conditional containment failure probability and early containment failure probability
- guidelines related to changes in risk such as change in CDF and that also limit cumulative increases from all changes
- guidelines that factor in actual site characteristics

PROS:

This alternative has the advantage of establishing acceptance guidelines which are closely related to criteria associated with the Safety Goals and/or subsidiary objectives. That is, plant-specific regulatory actions (i.e., changes to a plant's CLB) would be compared with acceptance guidelines that are derived from the Commission's Safety Goals to support plant-specific decisions.

The acceptance guidelines could be a combination of the above. The level of detail and scope of the risk information required would depend on the requested change and the acceptance guidelines. The technical content of the acceptance guidelines would be addressed as the Regulatory Guides and Standard Review Plans are developed. This alternative uses an integrated deterministic/probabilistic approach and would consider factors, such as defense-in-depth and compensatory measures, that may be difficult to quantify for impact on risk but that do provide qualitative or deterministic assurance that the risk impact is acceptable.

CONS:

The principal drawback of this approach is that it departs from previous Commission guidance on the use of safety goals. Plant-specific PRAs thus become a more prominent aspect of the decision-making process. Recognizing, however, that such increased prominence is a goal of the PRA Policy Statement, this drawback is not considered to be a fatal flaw in this alternative.

Explicit numerical guidelines could lead to litigation of regulatory decisions that use the guidelines. The use of numerical guidelines could increase the possibility of and difficulty inherent in litigation that would involve PRA. There are significant questions as to the ability of NRC to devote the resources needed to sustain PRA derived conclusions in the event there are numerous contested proceedings. In addition, to the extent that the safety goals or subsidiary objectives are relied upon for staff decisions, the goals or objectives would themselves be open to challenge.

Alternative 2: Relate plant-specific risk changes to industry population goals, i.e., calculate the risk at a plant after a proposed change and then assess this new plant risk against QHOs and subsidiary objectives (average) for the complete population of operating plants.

This alternative would maintain the generic nature of the Commission's Safety Goals while permitting their use in plant-specific regulatory actions. Plant-specific change requests would be compared with goals defined for the total population of plants.

PROS:

This alternative would maintain consistency with the underlying intent of the Commission's Safety Goals that the average risk of all operating plants be the numerical goal under consideration.

CONS:

A practical problem is that the impact of each plant-specific request would be compared with the distribution of plant risk estimates which would be essentially insensitive to all but quite large changes in risk in most plants. Therefore, many proposed changes could end up being acceptable from a risk perspective; thus in effect, making the deterministic factors the sole decision criteria. In addition, this alternative would not exclude trade-offs between large risk increases at some plants, and decreases at others. Complete risk estimates for all plants would likely be required, making this a very resource-intensive option.

STAFF RECOMMENDATION:

The staff recommends Alternative 1.

In its August 15, 1996 letter, the ACRS stated its belief that the safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications. The ACRS further stated that it is "impractical to rely exclusively on the Quantitative Health Objectives (QHOs) for routine use on an individual plant basis. Criteria based on core damage frequency (CDF) and large, early release frequency (LERF) focus more sharply on safety issues and can provide assurance that the QHOs are met. They should be used in developing detailed guidelines."

C. RISK NEUTRAL VS. INCREASES IN RISK

The resolution of this policy issue concerning whether to allow small increases in plant risk is closely linked with the previous policy issue associated with the development of guidelines for plant-specific risk-informed decisions.

Our current regulatory processes allow a qualitative consideration of risk or relative risk increases as part of our regulatory oversight. Accordingly, in certain instances, the Commission may approve license amendments or changes in a licensed facility when the probability or consequences of an accident may increase. Although plant modification under 10 CFR 50.59, cannot involve changes, tests, or experiments that increase the probability or consequences of an accident, the Commission has established a process for approving changes under 10 CFR 50.90 which reduce safety margin (i.e., increase risk). The approval process under 10 CFR 50.90 and 50.91 allows the staff to approve risk increases, but not significant risk increases without an opportunity for public hearing. Changes in Allowable Outage Times for equipment covered by Technical Specifications may be examples of this type of change.

The Commission, in its PRA Policy Statement, indicated that the use of risk insights should be increased and continue to complement and support the defense-in-depth philosophy. The staff will continue to use PRA techniques as an adjunct to the traditional engineering approach in order to better understand the risk significance of proposed CLB changes that impact the defense-in-depth attributes of plant design and operation. Guidance to support decision-making that integrates the results of both deterministic defense-in-depth

evaluations and risk evaluations is under development. This guidance will provide greater consistency in the staff review process and permit more structured consideration of the cumulative impact of risk increases.

Alternative 1: Allow small increases in risk under certain conditions, for proposed changes to a plant's licensing basis.

PROS

Current PRAs indicate that operating plants are generally below the NRC Safety Goal's quantitative health objectives. The QHOs already represent a small increase of the public risk (a factor of 1000 below existing accidental death or cancer risks). Additionally, subsidiary objectives for such parameters as core damage frequency and containment performance have been established to ensure the low likelihood of high consequence accidents. These subsidiary objectives have been shown to be even more restrictive than the overlying QHOs. For these reasons, increases that are a small portion of existing nuclear power plant risk are expected to produce a minimal change in public risk.

Additionally, some proposed changes may well represent small calculated risk impacts that are well within the bounds of uncertainties expected from the methods and available data. Therefore, very small calculated increases in plant risk may, in actuality, have no perceivable impact on public risk, even though in a calculational sense they are not precisely risk neutral.

As part of the development of risk-informed Regulatory Guides and Standard Review Plans, the staff is developing risk-informed acceptance guidelines based on subsidiary objectives such as CDF and large early release frequency and on the underlying risk profile of the plant. If this option is endorsed, the Regulatory Guides and SRPs will provide explicit guidance on what level of risk increase is acceptable. This approach will ensure the existence of more rigorous numerical guidelines for the NRC to utilize in an integrated decision process for assessing licensee initiatives.

CONS

A policy that allows the risk of plants to increase, even by an imperceptibly small amount, may be opposed by the public, regardless of whether there is a strong technical basis and it will result in other benefits (e.g., reduction in unnecessary burden). In addition, subsidiary objectives may become de-facto requirements.

Alternative 2: Require risk neutrality or risk reduction for proposed changes to a plant's licensing basis.

PROS

This approach would require that proposed changes to a plant's licensing basis either be risk-neutral (i.e., the increase in risk associated with a proposed change be compensated for by a compensatory action that will result in an equivalent decrease in plant risk) or result in a reduction in plant risk.

This type of approach would help assure that the plant risk will remain approximately constant or improve for those areas where staff approval is required.

CONS

The staff believes that this alternative is not compatible with the intent of the PRA Policy Statement objective of removing unnecessary conservatism from the regulatory process. Such an approach might also tend to restrict risk-informed applications where quantification limitations make it difficult or impossible to demonstrate with assurance that risk neutrality exists, even though the impact is insignificantly small.

Another disadvantage of this alternative is that it does not consider the actual observed variation in plant risk. Therefore, a licensee that manages risk and strives to keep plant risk low (e.g., a plant whose risk is 1 to 2 orders of magnitude better than some other plant) would be treated the same as licensees whose plants' risk profiles indicate a greater plant risk.

STAFF RECOMMENDATION

The staff recommends Alternative 1, which would permit increases in risk in some circumstances. The staff believes that this position is consistent with the Commission's Safety Goals. Increases in risk would only be considered when the staff determines that the proposed change will not result in an undue risk to the public, and that adequate protection to public health and safety will still be assured.

Additionally, the staff believes that the PRA Policy Statement was not intended to allow only risk-neutral changes. In its August 15, 1996, letter, the ACRS agreed with the staff that increases in risk should be permitted in some situations.

D. IMPLEMENTATION OF CHANGES TO RISK-INFORMED IST AND ISI REQUIREMENTS

Since 1992, the NRC has been working with the Nuclear Energy Institute (NEI) and other industry entities (e.g., ASME Research and industry owners groups) to develop guidelines for using probabilistic techniques to help better define inservice inspection (ISI) and inservice testing (IST) requirements. In late 1994, the staff began to encourage pilot applications of risk-informed methods to improve ISI and IST programs for nuclear systems and components. In late November 1995, the staff received requests from the Comanche Peak Steam Electric Station Units 1 and 2 and Palo Verde Nuclear Generating Station Units 1, 2, and 3 licensees to implement risk-informed IST programs in lieu of the ASME code-based IST program required by 10 CFR 50.55a.

Staff interaction with the industry and pilot licensees is continuing. The staff plans to proceed promptly on rulemaking, once the final Regulatory Guides and Standard Review Plans are in place. The staff's rulemaking effort will consider the appropriate guidelines and Code changes if the industry's consensus-based standards are available.
The staff identified three alternatives for implementing risk-informed inservice inspection and testing programs until rulemaking can be completed.

Alternative 1: Approve risk-informed ISI and risk-informed IST as exemptions to the current regulations

PROS

This alternative would (1) focus staff and industry resources on the more safety-significant components as well as provide early relief to the pilot plant licensees (i.e., cost savings and dose reductions) and (2) allow the staff to gain experience with risk-informed programs as risk-informed ISI and IST Regulatory Guides and Standard Review Plan sections are being developed and before rulemaking to modify 10 CFR 50.55a is initiated. This alternative would also provide the staff and industry with the flexibility they need to progress on risk-informed initiatives as staff review resources permit.

CONS

First, it would require more staff and licensee effort than Alternative 2 to address special circumstances as part of approving changes to pilot licensee IST and ISI programs. That is, the Commission would need to make a finding pursuant to 10 CFR 50.12, that "special circumstances" exist (i.e., that the proposed action would result in benefit to the public health and safety that compensates for any decrease in safety). This finding could be made if, for example, pilot plant licensees identified any non-Code components that should be categorized as high-safety-significant and focused on more testing for the high-safety-significant components while relaxing the inspection and test requirements for a selection of the low-safety-significant components.

Second, the NRC staff and industry will need to evaluate and possibly implement revised ISI/IST strategies, currently being developed by the industry (EPRI and owner's groups) and ASME, after initial approval of the risk-informed ISI/IST programs at the pilot plant sites. The staff has traditionally worked with ASME and the Code consensus process to define inservice inspection and testing requirements. Thus, implementing this option may bypass the traditional code consensus process and result in larger differences between licensee programs. If the staff proceeds with this alternative, pilot licensees with approved or exempted programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans.

Finally, under this alternative, the procedural aspects of granting exemptions (e.g., public notice) could require a substantial amount of staff resources. This alternative may be the least efficient alternative for the staff. The staff and the applicants would have more administrative burden for exemptions than with the other alternatives.

Alternative 2: Approve risk-informed ISI and IST changes approved as authorized alternatives under 10 CFR 50.55a (a)(3)(i)

The Director of NRR may authorize changes to licensee ISI and IST programs under 10 CFR 50.55a (a)(3)(i), and these changes would not be considered exemptions to the rule. Consequently, the Commission would not be required to make a finding pursuant to 10 CFR 50.12 that "special circumstances" exist. The staff is developing uniform criteria to further specify what constitutes "an acceptable level of quality and safety." These criteria could then be used to evaluate risk-informed ISI/IST program changes proposed by licensees.

Alternatives to the Code requirements have been authorized in the past when the proposed alternative provided an acceptable level of quality and safety or when compliance with the specified requirements would have resulted in a hardship or unusual difficulty without a compensating increase in the level of quality and safety. The staff has approved licensee requests made pursuant to 10 CFR 50.55a(a)(3) to accommodate situations such as the inability to conduct a quarterly component test without a plant shutdown.

PROS

Like Alternative 1, this alternative would (1) focus staff and industry resources on the more safety-significant components as well as provide early relief to the pilot plant licensees (i.e., cost savings and dose reductions) and (2) allow the staff to gain experience with risk-informed programs as risk-informed ISI and IST regulatory guides and standard review plan sections are being developed and before rulemaking to modify 10 CFR 50.55a is initiated. This alternative would also provide the staff and industry with the flexibility to continue making progress on risk-informed initiatives as staff review resources permit.

CONS

First, the staff would need to complete the development of the uniform criteria to specify "an acceptable level of quality and safety" using its own resources rather than utilizing industry-developed codes and standards.

Second, the staff has traditionally worked with ASME and the Code consensus process to define inservice inspection and testing requirements. Implementing this alternative for pilot licensees may be viewed as bypassing the ASME Code consensus process.

Finally, pilot licensees with approved programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans. If modifications were necessary, it would create an additional burden for pilot licensees.

Alternative 3: Defer approval of pilot plant risk informed ISI and IST programs until 10 CFR 50.55a has been modified

PROS

This alternative would allow the staff to complete the risk-informed ISI and IST Regulatory Guides and the Standard Review Plan sections before issuing safety evaluations for the pilot plant risk-informed ISI and IST programs. This alternative would also allow greater consideration of revised ISI and IST strategies, currently being developed by the industry and ASME.

CONS

First, this option would delay focusing NRC staff and industry resources on the more-safety significant components and delay potential cost savings and radiation exposure reductions associated with reducing ISI and IST requirements for low-safety-significant components. Second, a delay in considering risk-informed approaches, without a technical basis, or justifiable resource limitation, could be perceived as inconsistent with the Commission's own Policy Statement.

If the Commission chooses this alternative and directs the staff to withdraw, defer, or limit its participation in the risk-informed ISI and IST pilot programs, the risk-informed ISI and IST Regulatory Guides and Standard Review Plan sections, as well as proposed modifications to 10 CFR 50.55a, may not have the benefit of lessons learned from the development and implementation of pilot plant risk-informed ISI and IST programs.

STAFF RECOMMENDATION

The staff recommends Alternative 2, allowing the staff to further use the acceptable-alternative provision of 10 CFR 50.55a (a)(3)(i) to approve the pilot plants' applications. This alternative would provide the staff and industry the flexibility they need to progress on risk-informed initiatives as staff review resources permit.

The staff will continue to interact with ASME, industry owners groups, and licensees as the risk-informed ISI and IST programs evolve. It should be noted that, if the staff proceeds with this alternative, pilot licensees with approved programs will be expected to modify their programs as necessary to reflect experience gained and to conform to the final versions of the Regulatory Guides and Standard Review Plans.

The staff plans to proceed promptly on rulemaking, once the final Regulatory Guides and Standard Review Plans are in place. If the development of industry guidelines and consensus-based standards keep pace, the staff's rulemaking effort will consider the appropriate guidelines and Code changes.

II. IMPLEMENTATION AND USE OF SUBSIDIARY SAFETY GOAL OBJECTIVES

As discussed in Section I, the staff recommends that acceptance guidelines for plant-specific CLB change requests be developed, based on the Commission Safety Goals and subsidiary objectives. The staff will continue to define such guidelines as part of developing SRPs and Regulatory Guides.

The staff is currently considering a decision-making logic that defines regions where the plant-specific guidelines can be used to characterize proposed changes in plant risk. This is conceptually similar to the Electric Power Research Institute's Probabilistic Safety Analysis Applications Guide. The staff is evaluating the appropriate number of regions, boundaries of the regions, and actions associated with those boundaries.

The development of the guidelines that can be applied on a plant-specific basis has resulted in the identification of a number of technical issues. These issues are included in Attachment 3 to the Commission paper and will be resolved during the development of the risk-informed Regulatory Guides and Standard Review Plans.

III. UNCERTAINTY IN THE IMPLEMENTATION OF RISK-INFORMED AND PERFORMANCE-BASED REGULATION

The implementation and use of subsidiary safety goal objectives in establishing acceptance guidelines for decision-making in risk-informed regulation is discussed above. The staff has identified technical issues that will be resolved as we move toward more risk-informed regulatory decision-making. The staff recognizes that this decision-making process must take account of the uncertainty associated with the PRA results.

Uncertainties arise from different sources. There are uncertainties in the values of the parameters of the PRA model (failure rates, initiating event frequencies, operator recovery rates, etc.), uncertainties related to the choice of models for elements of the PRA, and uncertainties due to the incompleteness of the PRA models. For example, in many PRAs, some modes of operation (low power and shutdown) and/or several initiating events (external events) are unanalyzed. The uncertainties of the first two types can be treated explicitly in PRAs to generate a characterization of the uncertainty on the PRA results, although it is not usual in Level I PRAs to include many modeling uncertainties, such as those associated with the choice of success criteria. Thus there are two classes of uncertainty associated with a PRA: those for which the impact is quantified, and those for which the impact is not quantified.

The staff intends, whenever possible, to use the mean value of the results of the PRA, evaluated from a formal uncertainty analysis, for comparison with the numerical guidelines associated with absolute risk measures such as core damage frequency. The guidelines, however, are not intended as "speed limits," so the comparison process has to allow some leeway to accommodate the analysis uncertainty. Thus the issue of the treatment of uncertainty is closely associated with how the subsidiary goal objectives will be used to set acceptance guidelines.

With respect to unanalyzed uncertainties such as those caused by incompleteness in the model, the staff is exploring several different approaches, such as establishing margins in the guidelines, compensating for the incompleteness by placing more emphasis on defense in depth, estimating the impact of the missing pieces in a conservative manner, or restricting the scope of the application.

These issues were discussed with the ACRS PRA Subcommittee on July 18 and August 7, 1996, and with the full ACRS on August 8, 1996. In its August 15, 1996, letter to Chairman Jackson, the ACRS noted that accounting for uncertainties is a difficult issue. The ACRS also noted that the staff's proposal to explore other options seems appropriate. The options include considering margins in acceptance criteria, placing more importance on defense-in-depth and others. Both the staff and the ACRS recognize that additional work remains to be done in this area.

ATTACHMENT 3

Summary of Key Technical and Process Issues

I) Issues Associated with Definition of Proposed change:

a) What information does the licensee need to submit to characterize the change?

b) Should the proposed change be required to meet at least one of the three goals of the PRA Policy Statement?

II) Issues Associated with Deterministic Evaluation:

a) What deterministic evaluations are required?

b) What are the acceptance guidelines for the deterministic evaluation?

III) Issues Associated with Risk Evaluation:

a) What determines the extent to which risk analysis can be used?

b) What determines the required quality of the risk analysis?

c) How is the appropriate quality assured?

d) How is uncertainty to be addressed?

e) How are cumulative changes in risk accounted for?

f) Should the acceptance guidelines be based upon total plant risk?

g) How should the acceptance guidelines be structured?

h) What is the role of importance analysis?

i) Should the acceptance guidelines apply to proposed changes individually or as a package?

IV) Issues Associated with Implementation and Monitoring:

a) What are the appropriate performance characteristics to monitor?

b) How should the SSCs to be monitored be selected?

c) How should the SSC performance be monitored?

d) How will feedback from the monitoring be used to make adjustments in implementation?

V) Issues Associated with Integrated Decision Making:

a) What are the important factors in integrating deterministic and probabilistic considerations?

b) How are uncertainties to be treated?

c) To what extent should the existing degree of defense-in-depth be maintained?

d) To what extent should the existing margins of safety be maintained?

e) What should defense-in-depth be based on?

f) What is the role of an expert panel?

g) What is the role of 10CFR50.109?

VI) Issues Associated with Documentation and Submittal:

a) What documentation is to be submitted?

b) What level of detail of risk information should be submitted?

c) Will explicit use of risk information in plant specific regulatory decisions require the licensee's PRA to be put on the docket and subject to litigation?