UNITED STATES
NUCLEAR WASTE TECHNICAL REVIEW BOARD

QUALITY ASSURANCE AND
STRUCTURAL GEOLOGY AND GEOENGINEERING
JOINT PANEL MEETING

The Adolphus
Sam Rayburn Room
1321 Commerce
Dallas, Texas

March 26, 1991

BOARD MEMBERS PRESENT

Dr. Don U. Deere - Chairman, Nuclear Waste Technical Review Board
Dr. Clarence R. Allen, Chair, SG&G Panel, Nuclear Waste Technical Review Board
Dr. John E. Carlton, Chair, QA Panel, Nuclear Waste Technical Review Board
Dr. Melvin W. Carter, Member, Nuclear Waste Technical Review Board

Dr. Roy E. Williams, Consultant
Dr. Sherwood C. Chu, Senior Professional Staff
Mr. Russell K. McFarland, Senior Professional Staff
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DR. DON U. DEERE: Good morning. Welcome to the joint meeting of the Panel on Structural Geology and Geoengineering and the Panel on Quality Assurance. I am Don Deere, Chairman of the Nuclear Waste Technical Review Board, and am also a member of the Panel of Structural Geology and Geoengineering. Dr. Clarence Allen is chairman of that panel. Chairman of the Panel on Quality Assurance is Dr. John Cantlon. You will be hearing shortly from both of those gentlemen.

Why are we all here? I will give two answers as I see it. One, as Chairman of the TRB and one as a panel member, the first reason deals with the makeup and the mode of operation of the Technical Review Board. We operate by means of technical panels, each treating a set of related or scientific or technical issues. This format allows two or three of us to delve deeper into DOE's program, to study and to question it and to report our findings twice a year back to the DOE through the Secretary and to Congress.

The individual panels bring back their findings to the Board and the Board then has a chance to consider these, they question the panel members, but there is one shortcoming in this mode of operation. While this mode of operation does allow us to go deeper into some subjects, and allows us to make our scheduling a little bit easier, it is much easier to
bring together two or three people from our Board than it is
to get a full Board Meeting of the nine people, which
hopefully, shortly will be eleven, the full Board membership.
So there is an efficiency involved, and I think it does
allow us to go into questions considerably deeper than we
would if we were just sitting as a Board.

However, there is one major shortcoming, and that
is the board members that are not here, today we happen to
have four board members of the nine that are representing the
two panels, but the other five board members are missing
something in that they are not going to hear or to see the
main players in the game from DOE, from the National Labs,
the U.S. Geological Survey, the State of Nevada and the
Utility Industry when they appear to brief the Board on
particular subjects. Therefore, by bringing two panels
together in a joint meeting where there is some overlapping
interest, we do achieve a greater board member participation,
and I think a better overall understanding of the DOE
program. And as a Chairman, I feel part of my duty is to try
to foster this cross-fertilization.

The second reason for this meeting, is for the
Panel on Structural Geology and Geoengineering to find out
how DOE is progressing with the ESF design studies, and
specifically how QA is factored into the present plans and
the futures planes. In December I read a note that an audit
of the Yucca Mountain Project had found among the QA deficiencies one related to design. Well, since many of the activities at the moment are related to the layout of the ESF facility, it seemed that this is something that the Board on Structural Geology and Geoengineering would be interested in finding out what these deficiencies were. So I immediately telephoned John Cantlon of the QA, Chairman of the QA Panel and told him about this, and wouldn't it be a good idea for a joint meeting. And he felt that this was a topic that we ought to pursue farther and after additional consultations with panel chairmen, panel members and staff, why we were able to arrange this particular meeting.

I am sure that the Panel on Structural Geology and Geoengineering is going to learn a lot today and tomorrow about QA, and I think this is good. And that the Panel on QA is going to know a lot more about the ESF facility and the design studies and how QA will work into that particular work.

I would like to thank very much the DOE and the related entities that have taken their time to respond to our request to prepare for the briefings that we are going to give today.

I will ask John Cantlon to say a few words on the QA Panel's interest and their meeting tomorrow, and then Clarence Allen to introduce his panel and staff, and then to
I also have been asked to remind us all including panel members to speak into the mike so that we get a good quality of reproduction.

So, John Cantlon, please.

DR. JOHN CANTLON: Well, good morning.

Let me say just a few words about the Quality Assurance interests of the Board. I think that obviously the Board along with the Department of Energy and the Nuclear Regulatory Agency and the Environmental Protection Agency, the public at large in the State of Nevada, because of the nature of a high level waste repository put the quality of the data that go into those decisions at a quality level, a demand for quality level that probably exceeds most of what one does in science and technology today. The level of broad paranoia is not uniquely an American thing. We visited in Germany and Sweden and we know that these kinds of concerns about the nuclear elements of their long life and the nature of those compounds are such that the public has a great deal of concern.

So we are really as scientists and engineers, as research managers, agency managers, politicians, whatever are involved in this, the quality of the data that go into the decision making is probably at a level that we are really
beginning to appreciate as necessary. And I think that what we are looking at is, how has the Department of Energy in deploying its Quality Assurance Program, how has it put it together? We know from our earlier and first meeting on Quality Assurance and also from talking with the scientific community and with the regulatory agencies that the initial deployment of the Quality Assurance program didn't get off to its most illustrious start. What we want to look at in our session tomorrow is the progress that is being made in the reorganization and redesign of the Quality Assurance program and the nature of the progress.

To DOE's credit, they discovered very early on that there were problems in two directions. One, the Regulatory Commission found deficiencies in the Quality Assurance program, but at the other end of the spectrum, the scientific community also found deficiencies in the constraining nature of the Quality Assurance program as one gets out into exploratory research and prototype exploration. So, at the two ends of the spectrum, the system needed some change, some adjustment, and those processes are underway and we'll be listening tomorrow to the progress that is being made in that direction.

Let me introduce now the Panel Members. Dr. Melvin Carter from Georgia Tech University, he is a specialist in the area of health and environment, and, Dr. Clarence Allen
who is also on the Quality Assurance Panel who is a specialist in seismology. Staff member, Dr. Sherwood Chu, who supports us, and we have asked Dr. Roy Williams who is a consultant to the program who has also been supportive. So, I'll turn the chair over to Clarence Allen for his session today.

DR. CLARENCE ALLEN: Thank you, John.

My remarks are very brief, so I think I'll simply do it from here.

Let me welcome you here on behalf of our Panel. The other member of our Panel who is present is Don Deere whom you have already met this morning, but I should also point out that Russ McFarland, Sr. Professional Associate Staff member is here and we are actually indebted to him for spearheading the program that we have today.

Let me just mention that you'll notice on the agenda that at 3:15 this afternoon we have a round table discussion, including most of the people who will have spoken during the day. And after lunch, at the start of the afternoon session, I will detail a list of questions that we hope you people will be considering that we might discuss during the round table discussion. And we will specify this, perhaps we can write them out if it is appropriate so that we can focus the round table discussion on particular issues that are of interest to the Board, and of the other people
In terms of today's proceedings also, let me emphasize what Don said. We do have a court reporter present. It is absolutely essential that people who speak, particularly from the audience who have comments, that they speak in to the mike and also identify themselves so this can be appropriately logged.

So, without further adieu then, I guess, I think I'll turn the meeting over to Don Horton for the introductory comments from the DOE.

MR. DON HORTON: Good morning, I'm Don Horton. I am Acting Director of Office of Quality Assurance for the Department of Energy. What I'd like to do is start out this morning by providing a quick overview of our presentations and then I would like to go into an overview of the QA program for the Department of Energy.

We are going to start out, as I said, by me giving the overview of the Quality Assurance program for ESF design process, and Dwight Shelor from our headquarters office is going to describe the development of the design requirements. Then after that, Ted Petrie from the project office, will give an overview of the ESF design control and then Ted will go into the Quality Assurance criteria applicable to the design process. Then after lunch, Al Stevens from Sandia will go into the control of the development of design inputs.
Subsequent to that, Dr. Bullock from Raytheon will go into the control of the actual design process from the AE standpoint. Then of course, this afternoon we will go into round table discussion questions.

What I am going to briefly cover this morning is the summary of the OCRWM Program, the relation to the overview of participants QA programs and the QA role in the design process.

Now from the project office standpoint, the QA organization is made up of verifications group which includes audits and surveillances not only internal to DOE but also external organizations such as Raytheon, Sandia and the other participants in the program. The program control group which includes the preparation of the procedures, review of the QA program documents of the participant's and also assistance in the development of the overall QA program documents for DOE. And then the site overview group which at the current time is not staffed subsequent to getting on site and starting a site exploratory work, we will staff someone on site for that organization.

Our current documents at the project level consists of the Quality Assurance Requirements Document, the Quality Assurance Program Description which are for OCRWM and then at the project we have APs and QMPs which are the implement procedures to address the requirements of these two
The interaction with OCRWM, the QA organization being one organization now for both headquarters and the project, we perform overviews of the activities of the headquarters organization. Specifically we will be reviewing the preparation of the requirements documents that Mr. Shelor performs, and by doing audits and surveillances of his activities.

Also, the headquarters in the project office QA organizations work together in development of the upper tier QA documents, the QARD and QAPD and also we are working on an effort on combining many of the procedures so we have one procedure for the overall program versus separate procedures.

In relation to the overview of the participant's QA programs, first of all we have to review and approve the QA program documents that are prepared by each of the participants. These documents are reviewed to the requirements of our upper tier QA documents. Once we have reviewed these any comments resolved, we approve these documents and we formally submit a letter through Dwight Shelor to NRC for their acceptance of these documents. To date all of these have been done.

Subsequent to review and approval of their QA documents, we go in and we perform a qualification audit of each of the participants, and this has been done on all of
them. The only one that is currently scheduled is Raytheon and this may be just a small audit to verify transition of the implementation of their program since F&S and Holmes and Narver were combined into Raytheon.

After the qualification audit and all the deficiencies have been resolved they go ahead and implement their program, and then at various times during the year we go in and perform surveillances of specific activities that we feel that are important to the process that they are performing. In this case, the design process. We go in and we perform surveillances on critical areas which we feel we need to assure that the design control process is being implemented. Then in addition, on an annual basis we go in and do another qualification audit to maintain their qualification.

In addition to all of the audits, surveillances and subsequent reviews of the QA programs and any changes, we also have meetings on a bi-monthly basis of all of the QA managers from all the participants on the program. In these meetings, we discuss specific concerns that any of the managers have, not only in their area, but overall program area. It is an open discussion. Any problems or recommendations we have for improving the program are identified at this meeting and we take action on it. In addition to that we give specific presentations from each of
the organizations to see if there are certain things that are
being done that other participants can benefit from.
And as many of you heard in November, we have
several workshops going now which we will discuss further
tomorrow. We have currently the scientific workshop,
Software Quality Assurance. We have scheduled a workshop
starting in April on the trending program, enhancing the
trending program, resolving any concerns there and we are
also contemplating a workshop on data. At our original
meeting in Denver one of the problems identified was the
preparation and submittal of "data". We are trying to define
what the problems are with the scientific personnel, and also
get a firm definition of what "data" is and when it is
required to be submitted.

The QA role in the design process consists of, as I
stated earlier, the audits and surveillances of the design
activities. We also participate in the design review
meetings, which are held throughout the process. We have
close interaction with the responsible design organizations.
I have a QA project engineer which is specifically assigned
the responsibility to interface with the design
organizations, attend all the meetings, get back with me on
any problems. The individual reviews the design documents,
procedures, et cetera. And, in addition, they review the
design requirements documents.
Through this process and the processes that are implemented by the design organization's QA groups, DOE feels we have enough overview of the overall program that we can feel confident that an adequate design program is being implemented.

Dwight Shelor can now go through the development of the design requirements.

Any questions?

DR. ALLEN: Any comments or questions from the Board members?

DR. DEERE: I mentioned a report that was published of a deficiency in the design process. Would that have come in your next to the last slide, the audit and surveillance of activities? Or, was it the first audit that was made? Of course my reference is rather obscure.

MR. HORTON: I have two answers to that. Number one, yes it would have, but I guess the other one is not an answer it is a question. I am not really sure what that deficiency was. I don't recall any being identified in that in December.

DR. DEERE: There were about seven that were listed, and only one said design. It seemed to me like it was a general audit and this was published in the Radioactive Exchange. Is that the name of the magazine?

MR. PETRIE: This is Ted Petrie, DOE. The deficiency in
design control was related to the design inputs to the actual design. In that the NRC reviewers are our design review, and I'm reading the SCP, felt that some of the input information or requirements with respect to waste isolation had not been adequately addressed in the design input requirements on the exploratory studies facility.

DR. DEERE: I see. Thank you.

MR. HORTON: It was an old finding then. I wasn't aware of any recent findings in December, that is why I questioned Dwight if he knew of any finding that was identified in December.

DR. DEERE: It was published in December, but I think the finding was before that.

MR. DWIGHT SHELOR: It was probably last April.

DR. DEERE: Oh, I didn't realize it was that far back.

MR. HORTON: Any other comments or questions?

MR. RUSS MCFARLAND: Yes, one.

You make a comment that you pass judgment with regard to the adequacy of the design process, I think were your words. Is that adequacy—what is the perspective of the term adequacy? Is it technical? Is it from QA? What is the scope of your purview there when you say adequacy?

MR. HORTON: It can be both. If it is from the technical aspects, we take technical personnel along with us on our surveillances, and we try to determine the technical
adequacy of it. Normally the technical adequacy is determined during the design review process by the technical organization, and we go with them or behind them and see if they follow the correct process. Ordinarily QA determines the adequacy of the QA content of the design, not the technical portion. If we do get in technical, we have technical personnel with us.

MR. MCFARLAND: But on occasions you do then a technical evaluation calculations of design processes?

MR. HORTON: Normally that is done in the review process. When we do surveillances and audits, we go in for a quick review and we don't have time to go into in depth review of calculations and all that. We verify that the calculations are there, that they were properly processed in the design control, but we don't go in and do actual calculations. Time doesn't allow it.

DR. DEERE: John Cantlon.

DR. CANTLON: As you have reorganized the QA oversight process now, you've had a fair amount of interplay and interaction with NRC. Do you have a pretty good feeling of confidence that they like the redesign of the DOE QA oversight process now?

MR. HORTON: We feel confident. We will go in during these next several months, we will be doing several surveillances on the design process in the NRC and the State
of Nevada and the counties will probably be participating
with us. And with that participation I feel that they will
gain the confidence that we can control the design process.

DR. CANTLON: Thank you.

MR. SHELOR: It is my pleasure to be here this morning.
I am Dwight Shelor. I am the Acting Associate Director for
the Office of Systems and Compliance in the office of
Civilian Radioactive Waste Management.

I have several things that I want to touch on
today. Before I start, however, I am going to deviate from
what I've planned to say somewhat in response to Dr. Deere's
introductory remarks and also Dr. Allen.

I think we are absolutely correct, this is a first
of a kind endeavor. Nobody has actually designed and built
and licensed and operated a deep geologic repository for high
level waste. And there are elements of this program that do
involve first of a kind scientific investigations. Some very
sophisticated research and analysis particularly in the form
of assessments and design of the waste package and the
engineered barrier. However, our general approach to all of
these is one, recognizing what the objectives are of each of
the scientific investigations and research programs, and
planning and conducting these with some type of a baseline
plan. We can't go into any activity of this type without a
plan. And our plans, we refer to as our baseline. Our
activities are controlled and conducted in accordance with our baseline.

The challenge that we face in this endeavor is to make sure that when we construct the baseline that we have built in it our planning and analysis of the baseline, the flexibility to accommodate changes. This is the key part and it is a key element that we must recognize and have available. A plan is necessary in order for us to establish a cost baseline to go to Congress and request appropriations for a budget to conduct that program. When we see that we have deviated from that baseline, then we must change the baseline in accordance with the needs and request additional funds or reallocate existing funds in order to carry out the program.

Now, I will go into what I originally started out with.

Today, I would like to cover several topics very briefly starting with what I call the regulatory compliance approach with the Quality Assurance spin or requirements that we have. I want to describe again very briefly, the systems engineering process that we are using. Then I will as part of the systems engineering process, touch very briefly on the overall mission statement, the functional analysis approach that we are using to develop system requirements, and the development of the ESF technical requirements and how
1 baseline document evolution, how they evolve. And then I
2 will summarize with the appropriate QA controls that we
3 utilize in these processes of developing requirements. And
4 then I want to finish with an explanation with a graphic of
5 our transition into the new system requirements that we are
6 currently developing. I want to make it very clear what is
7 happening now with the existing documents and how the new
8 documents are developed and then how the program will
9 transition into use of those.
10 To start with, I want to emphasize that OCRWM is
11 fully committed to the Quality Assurance program. There is
12 no--absolutely no doubt, because it is required first of all
13 by NRC, and secondly is required by the Department of Energy
14 of which we are an element. We fully support the
15 implementation and we will describe part of that here today.
16 And the Quality Assurance is there to assure that adequate
17 controls for development of requirements and design
18 activities are in place and documented. This program or the
19 facility that will accept high level nuclear waste and spent
20 nuclear fuel, will be licensed by the NRC. It requires fully
21 documented traceable records, and this is obviously a long-
22 term program. Most of us here now will not be here when the
23 facility is operated. The design, the analysis, the review
24 and the basis for decisions that we make in this program must
25 be documented for future use. We won't be able to come back
and ask us what we meant.

DR. DEERE: Before you remove that particular slide, in the second one down, "assure adequate controls for development of requirements and design activities", it is just the development of the requirements that I guess has to be a predecessor to the design activities?

MR. SHELOR: Certainly. I'll emphasize that again when we get into the design process. It does enhance, obviously, any design that you come up with to first of all decide what the requirements are. And in a systems approach, a systems engineering approach, the very first thing we do is to develop the requirements. Once we have established the requirements, then we go to the scientists and engineers and say okay, now what is the design solution to meet these requirements?

Obviously I've already covered some of them. There are benefits from doing it this way. One of the obvious benefits is if we do it correctly and we are successful, we will obtain a license from the NRC. And it is not as sufficient, the Quality Assurance is certainly a necessary condition to obtain the license.

In the development of the requirements and the design, we can be able to show a logical, defensible, documented process for the characterization and development of the repository design and operation, by a combination of
1 both the system engineering process with Quality Assurance.
2 Obviously, by doing this and having the documentation
3 available which is under continual review by both interested
4 parties, State of Nevada in this case, other states for other
5 activities, and the Technical Review Board, we will enhance
6 our technical credibility, by having this documentation
7 available.
8
9 And it is a systematic approach that doesn't
10 guarantee, but will probably reduce the likelihood of major
11 redesign and or retrofit at some point in time. It is
12 obviously, an extra burden, but I think time will demonstrate
13 that this extra burden and translated to extra cost is a very
14 economical way to manage the program, because, ultimately by
15 eliminating many redesigns and retrofits, we will be light
16 years ahead.
17
18 A system engineering process is depicted
19 generically in this graphic, and this is very generic because
20 there will be slight modifications depending on what the
21 activity is, but in essence as I indicated earlier, the very
22 earliest thing to do is to establish the mission need, the
23 objectives and the requirements. What does the system have
24 to do and how well does it have to do it?
25
26 When you have established that as a starting
27 criteria then you can begin to do a functional analysis which
28 in a simplified version, is simply taking the overall mission
need or the system requirement and breaking that down to successively lower levels and identifying those functions that need to be performed to satisfy the mission. Once you do this then you can establish how well each one of those subfunctions need to be performed, which are the subsystem requirements. And then you can begin to make decisions on the decision architecture. In this case, I recognize that it is confusing sometimes to call it a system architecture, but a system architecture is at each succeeding lower level. In your functional analysis you need to establish what system configuration if you will, is another word, will satisfy that requirement.

For example, Congress did some systems engineering for us. They established the system architecture. They made a decision that the program does not have to make. Congress specified that this will be a deep geologic disposal. We did not have to examine alternatives to deep geologic disposal to make that system architectural decision.

Congress also gave us the option of specifying a monitored retrievable storage. Now we have elected to go with a monitored retrievable storage. Now at some point we have to make a system architectural decision on what kind of storage we will use in the MRS. Will it be wet? A pool? Or, will it be dry? And what kind of dry storage? There are many options. So, in some cases, as we'll see in a moment,
you will have to go down and do system trade studies to
evaluate alternatives to make architectural decisions.
I may be getting slightly ahead of myself, but I
want to emphasize that we continue this process of
subdividing functions that are required to meet the overall
system objective to the lower and lower levels until we have
defined the system.
A lot of people are quite concerned on how far down
do you go in this? You go down to a level where it is
commonly understood. You do not have to make any more
architectural decisions. If you come down to the point where
you can specify commercially available equipment or designs
that have been conducted and proven before, then you stop.
Typically, what we will do in the analysis, is to go down one
level below that and then roll back up and say we've gone far
enough. Now we go to the designers to come up with a design
solution which is basically the next step.
Once you've established the requirements then you
go into a design synthesis. Now, many cases in our program,
that block we refer to as the conceptual design, and then you
go to system definition which is a combination if you will of
Title I and Title II. It is a preliminary design and then
the final design.
Now in many cases we may want to come back here and
look at alternative conceptual designs which meet the system
1 requirements and pick the best, establish the criteria and
2 then evaluate each of the conceptual designs and pick which
3 one you want to go with. You may elect to do that also in
4 the Title I, the preliminary design. There may be more than
5 one preliminary design alternative, or there may be subparts
6 in there that you want to do a study, evaluation and a
7 selection. And eventually, of course, you go to the system
8 build test and demonstrate.
9
10 The other thing I would like to point out is, in
11 this process there may be need to conduct tests and
12 evaluation to provide data to make decisions that are
13 required to make decisions or selections. In this continual
14 process there are feedback loops and down in the lower two
15 boxes are the system trades, the cost effectiveness, risk
16 benefit, system analysis, and particularly important is risk
17 analysis. Risk in this case is technical risk. And risk is
18 also cost and schedule. All of the risk needs to be
19 evaluated. We will develop a programmatic process to allow
20 us to conduct what we refer to as risk management. In the
21 risk management we will analyze risk from all perspectives,
22 but specifically cost, schedule, technical performance. We
23 will analyze the risk. We will normalize if we can that risk
24 to some common value, probably dollars.
25
26 When we can assign dollar values to the risk, then
27 we can design our program to mitigate risk and by mitigating
risk, what I mean is we will allocate our resources to those
areas that have high risk. We will conduct our program but
we may reallocate resources on a risk base to keep the
relative risk fairly constant. That will be a basis for that
process.
To do this you need models. We need to develop
models. We need system simulation models that can be used
for both cost and technical performance, a life cycle cost
logistics report and effectiveness. All of these will be
done.
Go back as I refer back to this graphic as I go
along. But, with respect to the mission need, one thing we
have to start with and we do start with is the mission
statement. What is it we are trying to do? "To permanently
isolate spent nuclear fuel and high-level...", I won't read
that to you, but that is our overall mission. Now we need to
identify all of those necessary functions to accomplish this
mission. And that is what we are about.
One of the things that we will be talking about in
the next few minutes are constraints. What are the
constraints? We have a mission. Congress gave us the
mission in the NWPI and its amendments. Now what are the
constraints? Well, the mission plan that we produced will
have many constraints on how we are going to do it. The 10
CFR 60 is a requirement and also a constraint; 72, 960 191,
this is just a partial list of all of the constraints that we have to meet our mission. In addition there are DOE orders and executive orders of the President that the Department of Energy has to carry out.

So, what are we going to do? We are going to come through with a systematic approach and decompose this mission into its respective and logically, necessary functions and do the best job we can to identify those functions and come up with design solutions to meet them.

This is referred to as the FRA. Functional analysis specify the requirement or determined functions specify requirements and set the system architecture, FRA. One of the things and it is a very key point to keep in mind here are the legend that we use consistently in our functional analysis. It is very simple. The input is on the left, the output is on the right, resources from the bottom, constraints or controls and requirements come in the top. And then when you look at this, you can see for example there's our mission over here. What comes out is a function hierarchy. We come down to requirements, we have law standard, regulation commitments. We have experts in the programs as resources to specify and allocate those requirements of each function. And then we come down to selecting an architecture. Again we have criteria, we have program management, we have trade studies, and alternative
architectures that we can select from. This is a systematic process that we can carry out to lower and lower levels. And again, just to emphasize we are talking about the next step.

I won't dwell on this, but what we are doing right now is we are looking at both a FRA approach to both the physical system and the programmatic system. What is the difference? The physical system is those real pieces, hardware, items, components, subsystems that you can design, build and operate. The programmatic system are all those functions that we as managers and workers must perform in order for the physical system to be brought into being. What functions do we as people need to perform to provide the physical system that satisfies the mission requirement?

We are analyzing both. We have two teams. We have a programmatic task team that is going through again systematically, identifying programmatic functions such as; one, Quality Assurance; one is system engineering; one is design; construction; operation. We are looking at each one of those major functions decomposing them and developing a process that people then can use to perform that function.

We are doing the same thing obviously, as I have already gone into for the physical system. We are taking functional requirements, developing a function tree, taking the function tree over to a regulatory research team,
identifying the regulations that correspond to that function and feeding it back to the core team. We are also taking the analytical needs from each functions over to a group of program experts for them to come back with their performance requirements for each function, and then developing this tree and taking it down into a relational data base so that we can produce the reports that you all have to sit down and read.

What does the function tree look like? This is an early version. We are in the process of review right now. But on a physical side we can start out saying, our top level function is manage waste disposal and meet the mission requirements. When we come through at the first level what do we have to do? Well, we have to accept waste from the generators and the utilities. There is also defense waste. There is commercial high level waste and other types of bits and pieces that we will take eventually.

We have an interface. We haven't settled this yet, but we recognize that there is an interface between us and the producers and generators of the waste. They have certain things that they need to do in order for us to accept the waste. We do too. Across that interface, the identification, control and execution of that interface is critical to the stakeholders in this program.

The other thing we have to do is transport waste. We'll have to transport waste from the generators to an MRS,
1 from an MRS to a repository, most likely. We'll also have to 2 store waste. We may have to store waste at more than one 3 location. There may be temporary storage requirements at the 4 repository. There will be storage requirements for 5 retrievability in order to meet one of our requirements. We 6 can identify these.

7 And then there is another function, of course, is to 8 dispose waste. And when you come down to it, these four 9 primary functions are, one, necessary and logical. So, they 10 are based on logical necessity in order to satisfy our 11 mission requirements. We take for example, in disposed 12 waste, we can come down to subfunctions like operate the 13 repository, isolate waste, evaluate system performance and 14 conduct exploratory studies. This is temporary right now, 15 but I think it will eventually prevail that these exploratory 16 studies you'll recognize later on as being the exploratory 17 studies facility, commonly known as ESF.

18 DR. MELVIN W. CARTER: Dwight, could I ask you a 19 question about, is there any question at all now regarding 20 the sites or the places at which DOE or OCRWM will accept 21 waste. Now, I'm trying to differentiate if there is any 22 differentiation between commercial waste, the waste say at 23 West Valley versus defense programs waste. Do you accept it 24 always at the site?

25 MR. SHELOR: That is correct. Right now to the best of
1 my knowledge, all our plans include accepting defense waste
2 at their site, for example the DWPF and Savannah River,
3 Hanford, Idaho, where ever it is generated and packaged for
4 receipt. We will also accept canisters at West Valley, which
5 is the commercial high level waste. And we will accept and I
6 believe the Act specifies that we will take title to spent
7 fuel when it leaves the reactor gate. When we pass through
8 their gate we will then take title.
9
10 Now there are conditions for our taking title.
11 One, the fee has to be paid; two, it has to meet all our
12 acceptance requirements. But it is developing and
13 negotiating with the utilities those acceptance requirements
14 that is the real hard part, because, virtually all of them
15 are different in terms of what kind of transport cask are we
16 going to provide them to load. Now, they have to load, they
17 are obligated to load the transport cask under their existing
18 tech specs or modifications if required.
19
20 DR. CARTER: Thank you.
21 DR. DEERE: A question.
22 MR. SHELOR: Yes.
23 DR. DEERE: I think you have just made official, perhaps
24 the ESF definition, is that right? It is now the exploratory
25 studies facilities.
26 MR. SHELOR: That is correct. We elected to retain the
27 acronym, change it from a shaft to studies, because it may
1 not have a shaft.
2 A brief look at system architecture that corresponds with the previous functions. Now it may sound like it is a little silly and redundant, but it is necessary because the system architecture is different than the functional tree. We still have—you know, we have changed verbs in many cases, but when we come down, this is a geologic repository now instead of disposed waste. Our solution, one of our top level solutions to disposed waste is to have a geological repository. And so, there is a logic to this madness and it does make sense when you get down to it.
3 You'll have an operation system, performance evaluation system, multiple barrier system and probably an exploratory studies facilities, for example.

The next step and one that we are doing right now is on a service that is very easy to explain, very difficult to do, but what we have in terms of disposed waste we can do and have done essentially in draft form now, the disposed waste functional analysis for the repository. That is a necessary first step. We have already kind of predetermined that in our architectural system that the exploratory studies facilities will be co-located with the repository. Therefore if there are requirements that the repository must meet that will also be applicable to the exploratory studies facility. So we have done a functional analysis to look at the
1 regulatory requirements and as many performance requirements
2 as we can for the repository before doing the functional
3 analysis for the exploratory studies facility. So, with that
4 as a necessary requirement, then the next step is to
5 determine the site testing requirements which basically
6 establish the need for the exploratory studies facility. Why
7 do you have it if not to determine site suitability and
8 determine site characteristics for a repository.
9
To determine the site testing requirements, we have
10 already and are in the process of defining the performance
11 measures for the repository with describing the methodology
12 or the models that will be used. We will specify the data
13 needs and determine which tests and coalesce all of the tests
14 that we can think of in the common test to eventually specify
15 their required facility capabilities for the exploratory
16 studies facility.
17
When we finish this, this output and the
18 information from the repository functional analysis and
19 requirements, then we can do a functional analysis for the
20 exploratory study facility, and issue technical requirements
21 for it. Then it will be necessary to verify since we have
22 got the cart before the horse a little bit, to verify that
23 the design in fact meets the requirements.
24
Okay, doing this, how do these baseline documents
25 evolve? And here we are talking about the system
1 requirements. In every case we start with a development of a
2 management plan. And this is a plan that basically sets down
3 what is it we want to do, who is going to do it, how long is
4 it going to take and what resources are required. And what
5 Quality Assurance controls are going to be applied during
6 this process. Very important.
7
8 Then we basically go through the FRA process that I
9 just talked about, and then we will conduct a technical
10 review by independent experts of that result to provide a
11 document that will go to our Program Change Control Board,
12 the action of that Board then will be to baseline the
13 document for use in this program. System requirements in
14 general will always have an introduction of functions and
15 requirements, the architecture description and the
16 interfaces. It will describe the interfaces.
17
18 One of the things that the FRA process does for us
19 is when we go through it, we obviously will identify needs
20 for system studies and trades to make architectural
21 decisions. But, we will also identify needs where we have to
22 determine what performance requirements are. For example,
23 what is the throughput rate of this system? It has not been
24 firmly established yet. We need to conduct an analysis. And
25 we need to interface with the utilities to come up with a
26 throughput rate. Is a throughput rate important? It
27 certainly is. It sets the cost of this program. You know
there is a tradeoff between capital investment in facilities for capacity and a long duration of the program. All of those things have to be done. 

Yes?

DR. DEERE: And it also has a technical input on the heat generated.

MR. SHELOR: That's correct. In otherwords, how old does it have to be, and what are the requirements that we place on accepting spent fuel.

DR. DEERE: Let me ask a question here, and that is with respect to how our Board would function. You have there the technical review. Now that technical review I presume will be done by--NRC will be looking at part of it? We certainly will be looking at it. Now, are you referring also to your own experts that you will bring into look at it?

MR. SHELOR: In this case I am referring to specifically a requirement to have our independent experts look at it. And by independent it is somebody that was not involved in the actual conduct of the original work.

DR. DEERE: I see.

MR. SHELOR: And it is a technical check on the adequacy, the logic, the reasoning and the determination of what went into that requirements document.

For example, as I indicated, we have the regulatory research team, and there are procedures that require at least
two of the regulatory research team we call it RAT team, regulatory analysis team. The RAT team, it takes at least two of those members to put a portion of a regulation on a function. After all of that is done, then there is going to be, somebody else on that team is going to come back and review the final report. So it will be an independent check, technical evaluation of how well they did and how they did it.

Now, obviously, the information is available to the TRB, it will be available to the NRC. They will all look at it. If they have comments then those come back and will be addressed.

DR. DEERE: I presume at that time there will be a document or a series of documents that will go for the review so you will have--it will be like a milestone. You will have completed certain things so that they have something to look at if they haven't done the work, then they have to be right up to speed. But, if we have a comment that we feel strongly about and we think should be looked at, wouldn't it be better rather than bringing it in at the technical review level to have it in the slide before? Could you go back one slide?

MR. SHELOR: Sure. Back here?

DR. DEERE: First in the site testing requirements. During the time that you are doing these in preparing your study plans which you have many of them already to go, but,
1 this would be the time--the earlier you could get our input
2 it would be better, wouldn't it?
3 MR. SHELOR: It would be a great time as a matter of fact. Unfortunately there is very little time and I have to
do it in the next couple of months because we will--we plan
to have this completed and this analysis finished by the
middle of June. So it is happening--we are in the process
now and we will complete this by the middle of June.
4 DR. DEERE: In June we will have our, I believe it is
5 our June meeting on testing.
6 MR. SHELOR: It's a great time. It's a great time.
7 DR. DEERE: The third week in June.
8 MR. SHELOR: You know, we will be in our internal
9 review cycle at that point. As a matter of fact if you want
to specifically look at the site testing requirements, I can
get back with you. I don't remember now, but it is going to
have to come up into the April time period. April or early
May because it takes about three weeks to do the ESF
functional analysis after we get this output.
10 Now, we are going to review both of these
11 simultaneously at the same time, because we don't have time
to do them in series. So, we are going to combine them and
12 do a technical review of both parts.
13 DR. DEERE: We have interest in the rock mechanics
14 testing, but I think there is more interest early on in the
geohydrology line in the tests that are being done.

MR. SHELOR: Well, I think that and if you don't mind my suggesting, I think you would be interested in this whole process, what performance measures have we identified, what models, you know how we come up with the data needs. What we really need to come out with in determining or specifying facility capabilities are what measurements do we need and where? That is the answer that we need to go right there.

DR. DEERE: And that is our main interest as well.

MR. SHELOR: Exactly. And you know this brings up all the issues you know, uncertainty, variability and the whole bit. How many--what measurements do I need to make and where to answer all of our questions on site suitability, site characterization and the rest.

Now, that's our baseline. That will then be our baseline plan for a baseline ESF to make those measurements.

DR. DEERE: Okay. I guess we'll have to try to keep in touch to see if--I don't know if we can schedule an earlier meeting or not.

MR. SHELOR: Okay. Now we have started the technical review on three system requirement documents. We have one document that is called the overall system and then we have one subservient to that which is the MRS and the other one is the MGDS. So those three documents are going into our
internal technical review this week. And then this activity is ongoing now and then this will follow very shortly.

Then later on we have to back up to accept waste and transport waste. We are not doing those right now. They have all of our resources committee and then some, and other people's.

Now, back into our context here today. What are the Quality Assurance controls that we implement during this process of developing requirements?

Well we assure that we have qualified personnel. Those personnel have had the appropriate indoctrination and training. Indoctrination on the QA program and training on specific procedures that we use. We have a management plans for the document development. Now all of these are related to our Quality Assurance Administrative Procedures. I could give you the name, but let me assure you each one of these corresponds to a procedure. This is QAAP 3.5, this is 3.6 and this is 3.7. We have to show that we have input control on source documents. We don't to put a constraint in a system requirement document that we have not verified its source and that the source applied the proper QA controls into its development. Now we don't second guess NRC, 10 CFR 60, those we accept. But our internally generated input documents are verified before we place them in the document. Control of interfaces, obviously important. We
1 will have a technical review that is our QAAP 3.1. We have a
2 Program Change Control Board which consists of members from
3 each of the offices in OCRWM that sit on the Board and the
4 Deputy Director of OCRWM is the chairman of that Board.
5 We have requirements of QA records, that's QAAP
6 17.1 and procurement of services, there is also a control
7 under the combination of 4.1, 4.2 and 7.1. So all of those
8 QA controls are implemented and we have Don Horton to come
9 and surveillances to verify that we are doing a good job in
10 implementing these QA controls.

DR. CARTER: Dwight, can I ask you a question about the
11 qualified personnel. You mentioned it in general a bit ago,
12 but I wonder if you would discuss it a little bit in detail?
13 Are these all essentially DOE internal procedures or for
14 example the Quality Assurance Society for example, do they
15 have qualifications that you might use? Do people have to be
16 registered engineers or licensed here and there and this sort
17 of thing?

MR. SHELOR: Well, we don't normally do that, but the
19 qualification in personnel is based on that person's position
20 description. Now, within the Department of Energy, everyone
21 of us has a position description. There are federal
22 standards set by OPM on minimum qualifications for each
23 series and grade that we have. We have general engineers, we
24 have mechanical engineers, electrical and what have you.
There is a series and a grade. OPM has established minimum qualifications in terms of either education or experience or a combination of both, or in most cases they have also established what additional--what experience can substitute for a formal degree. We have used those minimum standards. The participants in the program also have their own company standards. They also have position descriptions on all of the personnel then are evaluated against a minimum qualification for that position.

**DR. CARTER:** Okay. For example if you need an electrical engineer for something, I presume the quality or the position description would cover that. But that engineer would not necessarily have to be registered in the state in which he hoped to practice, for example in Nevada if you were concerned with the repository.

**MR. SHELOR:** Okay. That is correct as far as the federal government is concerned. Yes.

**MR. HORTON:** I'd like to clarify something here for you Mel. These Quality Assurance controls, these are not Quality Assurance organization activities. These are Dwight's organization activities. So it is not QA's people doing this it is his technical line organization. You were talking about QA certifications or whatever it is not.

**MR. SHELOR:** But I also recognize that I happen to be a licensed professional engineer, but I also understand the
dilemma that we are going through today in the fact that the federal government and states do not require licensure and that is being debated now. Personally, I would prefer that that eventually both the federal and state do require and accept professional registration.

DR. ALLEN: Well, particularly in the research areas or the more innovative aspects of the work, I would hope that that would not be required. For example if you were to require that a geologist be registered, I think that would almost guarantee that you would not get innovative kind of approaches.

MR. SHELOR: It probably would. But there are many things when you come to standard designs in meeting codes and standards it is hard to beat.

DR. ALLEN: Well I would emphasize there are many aspects of this program. Some of which are more research oriented, innovative than others that are more engineering oriented.

DR. CARTER: I was really looking, Clarence, for a certified volcanologist.

MR. SHELOR: That's hard to do.

DR. CARTER: Not one that needed certification.

MR. SHELOR: Okay. Now I want to again just go back and indicate that what we have gone through is the establishment of the requirements, the QA controls that we implement
1 internally in the development. Later today you'll have a 
2 description of the design process and the QA controls that 
3 are applied in the development of the design. 
4 And I would like to then conclude with a very 
5 important message, also. This is kind of saying where are we 
6 today and what are we doing? As you know, there has been an 
7 ESF alternative study underway for some time. That ESF 
8 alternative study uses an existing set of requirements and I 
9 believe that has been described to you in prior meetings. 
10 Those requirements are being updated and controlled at the 
11 project level and a design study is not underway based on the 
12 early results of the alternative study. This may lead to a 
13 design that would be preferred based on the alternatives. 
14 The process I just described to you what we call here 
15 are the new requirements for both the overall system, 
16 disposed waste and exploratory studies facility are now under 
17 preparation. They will be baselined, and then there will be 
18 a review of this design study against these requirements 
19 which will then result in hopefully very minor modifications 
20 to the design study to come up with a Title I design summary, 
21 which then forms the basis for a the Title II design of 
22 exploratory study facility. This is what we are doing, 
23 really a rough time line in July. This is the one we are 
24 trying to hold. 
25 **DR. ALLEN:** Comments or questions from the Board?
DR. CANTLON: Yes. Obviously in building a high level nuclear waste repository we are not in the mass production business. We are only going to make two, but it might even only be one. Furthermore, the process of design and construction is going to cover a very long period of time relative to most construction type projects, even big dams won't take the kind of time we are looking at here. As a consequence science doesn't sit still. There is going to be new discoveries, new techniques and so on. And what I would like to get you to address, looking at your generic thing, is do you have a way of incorporating formally a sort of planned innovation? Where will new discoveries be fed into the system, because if you look at the top financial constraints on everything that we do in our society, on one hand there is this yen on the part of the money managers to freeze everything so there is total certainty about time and cost and that sort of thing.

We are looking at a unique event here, a unique engineering challenge, a unique science challenge and a unique political pane of an event with a lot of time. I don't see anywhere in there where you have got sort of planned innovation. How are new discoveries going to be fed into the system and put in in a way that will not keep total turmoil in the system and you can keep the money managers happy and the people building process happy. Where does that
MR. SHELOR: It's very--that is a key part. As I said this is generic. As you can see while we are still on paper changes are relatively inexpensive as long as they are on paper. Once you go to disturbing dirt and building facilities changes are more expensive. Secondly, as you pointed out, planned innovation—you know, I am confident there will be innovation and new understandings that we have. What I don't have on the graphic, but it is part of the QA program, it is also part of the systems engineering process that we are implementing and this graphic doesn't have it. But, out here is where you absolutely have to have the Change Control Board.

Changes can be submitted by any member of this team that leads up to building this. Each one of those changes, once you get to this point, has to be justified, why do I want to change and what are the impacts. And, then somebody, the management then has to make a decision, is it worthwhile? That's the part that is not here. But it is a formal change control process. Now I think we probably get into change control in general, but it is absolutely mandatory on this program.

DR. CANTLON: Well, you can look at change control as a constraining device to make sure that the changes are within fiscal and temporal constraints. I am looking at how do you
ensure that the innovation is going to be harvested and fed into the system. That is the piece I am really raising. Where in the system do you have your planned innovation pressing out there on what we know about science, what we know about engineering, what we know about computation, what we know about risks?

MR. SHELOR: I think it really is--again, I don't have a good graphic on that Dr. Cantlon, but it is down--it is right in here (indicating), particularly with respect to the repository. There is a continuing performance evaluation system. Because, you know, as required by the Act, we will go in and develop techniques to monitor what will eventually be a relatively short-term performance of that repository. But, that will be the entire basis of our knowledge during the period that the repository is opening, is opened, we are emplacing waste and prior to closure, we need to collect the information, demonstrate to the best of our ability that the design is performing as predicted for that period of time before we go back to the NRC for a license amendment to close the repository.

And I think part of this innovation will come in here (indicating). Where would you expect to find this innovation? You may have the innovation in different mining techniques to excavate rooms, those are relatively minor changes that may not impact the regulatory considerations.
But, you may come up with new materials or different materials or a different engineered barrier system and now you are faced with two things. Well, I have an improvement, I may want to go ahead and implement that, and the next thing is do I retrofit? It's a typical problem that we have. But, all of those factors enter in during that preclosure phase.

DR. CANTLON: And the Quality Assurance for that innovation would come through your Change Control Board?

MR. SHELOR: The Change Control Board does require a technical review using Quality Assurance procedures to evaluate both the technical change and the impacts of the change.

DR. CANTLON: Thank you.

DR. ALLEN: Other questions from the Board?

MR. MCFARLAND: Dwight will you put your Physical Engineering Chart up please?

MR. SHELOR: Sure.

MR. MCFARLAND: You made a comment about proceeding from conceptual to Title I to Title II in a rather vague separation. In the Department of Defense and in NASA both, one of the major system engineering principals is that there is a milestone separation between these processes and you never enter one without officially leaving the other. Title I design is not approached until you have a complete
1 consensus that conceptual design has been completed. In the
2 Department of Defense they call it DSARC. It is a major
3 milestone. In NASA the same thing was done.
4 The point being that if you proceed from one phase
5 to the other without having thoroughly established the fact
6 that that phase has been completed, then you are constantly
7 making changes. Conceptual design process usually has a
8 Configuration Control Board also and I don't see the
9 similarity between the established procedures in the military
10 and I think also required by an OMB directive for major
11 systems acquisitions. I don't see that here. Can you
12 comment on that?
13 MR. SHELOR: I'd be happy to. I called it generic
14 because we are doing a couple of things. But you are
15 absolutely correct. The Department of Energy also has what
16 we call an ESAB. That is the Executive Level Change Control
17 Board, and they control all major system acquisitions. The
18 ESF has been for some time designated as a major system
19 acquisition. The MRS will be a major system acquisition.
20 The ESAB group has established milestones. KD-0, this is
21 approval to begin the conceptual design and then K-1 I
22 believe is approval of the Title I design. And then there is
23 another one for Title II. And then there is another approval
24 that you have to go through before you can do site prep.
25 For example, all of these are in our plans I did
1 You have to recognize again here what we are involved in. We
2 already have a Title I. Now we are going back and taking
3 another look—we did an ESF alternative study. We may want
4 to revise Title I. So, for all practical purposes, what we
5 are doing here is a second look at the Title I design with a
6 view to an update of the Title I design summary. At this
7 point I put in all the steps. We have them already
8 identified. We will go to the ESAB, the Executive Level
9 Change Control Board, because there is a change in the Title
10 I. There is a change in the cost and a change in the
11 schedule. And we will go to them and have to justify the
12 changes.

14 MR. MCFARLAND: We have a Title I for what?
15 MR. SHELOR: An ESF, it has two shafts.
16 MR. MCFARLAND: And there is a corresponding Title I for
17 the repository?
18 MR. SHELOR: No. There is only a conceptual design for
19 the repository that was done back in 1985.
20 MR. MCFARLAND: Okay.
21 MR. SHELOR: But there is an official ESF Title I which
22 consists of the two shafts and that is where we are right now
23 today.
24 MR. MCFARLAND: But my point is, you have mentioned
25 these milestones, but it is not for the total program, it is
for pieces of the program. Is that correct?

MR. SHELOR: That is correct. The Executive Secretary has not yet designated this entire program as a major system acquisition because of the way it is being phased in. I'm sure that the repository will be a major system acquisition if the site is found suitable. Now to designate it as a major system acquisition today would be prejudging the suitability of that site.

MR. MCFARLAND: That's an official DOE position?

MR. SHELOR: No, that is my official opinion. I wouldn't even ask them to designate Yucca Mountain as a major system acquisition for the purposes of being a repository because we have not yet determined its suitability. But, it makes eminent sense to have the Exploratory Studies Facilities. It more than meets the criteria for a major system acquisition, which is basically anything that costs over $50 million.

DR. ALLEN: I'm lost. Don do you want to comment?

MR. HORTON: Yes, I'd like to identify one change in our schedule this afternoon. Al Stevens had a minor fender-bender, so he won't be here and Bob Richards who is the QA manager for Sandia will be presenting his information.

DR. ALLEN: Thank you.

Okay, we'll take a 15 minute coffee break starting now.
(Whereupon, a recess was had off the record.)

DR. ALLEN: Okay let's reconvene and Don wishes to make a further statement here.

MR. HORTON: The additional workshop that I described in my presentation, I was told that I was quoted as saying trending, it is grading process. Enhancement to the grading process not trending.

DR. ALLEN: Well, Don do you wish to proceed without Ted, or--well I guess we will stall until the speaker shows up.

(Off the record.)

DR. ALLEN: We will go back onto the record if we may. Ted, you are on. Max volunteered to give your talk, but we refused to let him.

MR. EDGAR H. PETRIE: Okay. My name is Ted Petrie. I am the Acting Director of the Engineering and Development Division for the Yucca Mountain Site Characteristic Project. I am going to talk to you first about the overview of the ESF design control. Let me first state that our Quality Assurance program, while the design control process is based upon QA program which is based upon our QA documents that Don discussed a little bit earlier. The definition of design control, I'm not going to read to you, but that's what we consider to be the design control.

Our major design activities are the preparation of
1 design input and those are external and internal and by that
2 we mean external to the AE and internal to the AE. The
3 design process which includes QA grading, engineering plan,
4 interface control, design analyses, reviews, design
5 verification and design change control, and design outputs
6 which are the products developed by the AE and all that goes
7 into our QA records.
8
9 External design inputs are those requirements
10 imposed on the design organization by the project office.
11 ESF system requirements, Dwight talked about a little bit
12 earlier, the designs which are currently being developed.
13 But, in the meantime the design study is currently being
14 performed using existing controlled requirements documents.
15
16 These are the waste management system requirements
17 which is the top level one. Volume I is the top level one
18 and Volume IV is the one associated with the MGDS. The
19 system requirements which takes the higher level ones and
20 turns into a project specific requirements. A system
21 description which is also specific to the project. Site
22 characterization program baseline which provides the testing
23 needs required. The repository design requirements which
24 provides those requirements to the repository necessary to
25 develop those interface requirements imposed on the ESF by
26 the repository. The exploratory studies facility design
27 requirements document which includes those requirements
specifically placed on the ESF. And as a Reference
Information Base which provides specific technical data about
the site which is required for the design.
The internal design input is all that design input
used by the design organization whether received from others
or developed internally and that includes as a minimum,
assumptions necessary to implement external design
requirements, and here by others we are talking about other
participants, as opposed to a project office, supplementary
regulations, design codes and standards, design models and
methods to be used. So he has two sets of things to work
about. He looks at the design requirements, the requirements
imposed by the project, which are the things which we as a
project say he must meet. And then he in turn looks into
design codes such as sanitary system codes, electrical codes,
defines what those are for his designers and that is another
set of what we call internally developed requirements.
The design organization reviews and improves design
input according to its procedures and formally notifies the
project that approves all applicable external design input.
So in other words I give him a set of requirements, he
reviews it and he approves it. He says, yes I can provide
your product consistent with your requirements. That is what
he says to me. Now if he finds something that is
inconsistent or a concern where he cannot provide that
1 product consistent with my requirements, it is his obligation
2 to tell me that so that we can resolve that issue.
3
4 All internal design input must be under design
5 organization change control and the all design input must be
6 formally controlled. In this case the internal design input
7 is controlled by the designer; external design input is
8 controlled by the project.
9
10 QA grading, and you are going to have a bigger
11 picture on this tomorrow, so I won't spend too much time on
12 it, is the process for determining the QA measures necessary
13 to develop and maintain confidence in the quality of an item
14 or activity. It is performed for all work, even if not
15 related to nuclear safety or waste isolation. And for the
16 ESF design, the preparer of the process is the design
17 organization, or the AE. The design work will not commence
18 until QA grading for the design process has been approved by
19 the project quality review board.
20
21 DR. ALLEN: What do you mean by the kind of work that is
22 not related to waste isolation? What is an example of that?
23
24 MR. PETRIE: Parking lots. A design for a parking lot
25 or a subsidiary warehousing. Generally there are auxiliary
26 facilities that are not generally a part of the exploratory
27 shaft but are necessary for the operation of the exploratory
28 shaft.
29
30 DR. ALLEN: Okay. It is related to waste isolation but
only in a peripheral sense, I guess. Not anything with a safety consideration.

MR. PETRIE: That is certainly true, yes.

DR. SHERWOOD CHU: But they are subject to Quality Assurance?

MR. PETRIE: Definitely. Yes.

DR. CHU: A parking lot?

MR. PETRIE: Well, yes, sure. All DOE programs are subject to Quality Assurance.

MR. HORTON: Not necessarily the regulatory QA program, but there are quality requirements with everything associated with DOE programs.

DR. CHU: But now in your language would a parking lot be a part of that QAL?

MR. HORTON: Not the regulatory QA program.

DR. CHU: Thank you.

DR. ROY E. WILLIAMS: It wouldn't be part of the list of 20 criteria on the grading sheet.

MR. PETRIE: Well, the criteria are those criteria--it includes the 18 criteria that you find in NQA1 or in 10 CFR 50, Appendix B, plus two more.

MR. MAX BLANCHARD: Ted, let me help with Roy.

MR. PETRIE: Okay.

MR. BLANCHARD: When you look at structures that are built underground in the mountain, even during the
exploratory phase, there is a chance that some adverse impact could occur to the mountain. It would have a negative impact on the potential for waste isolation. Those kind of things using the procedures we have in place, one way or another get into an identification process for an item or activity important to safety or waste isolation, or an activity related to a quality affecting activity related to an item or an activity that affects waste isolation. Those are on so to speak "the Q list", both activities and items are.

DR. ALLEN: You mean a parking lot could affect the drainage.

MR. BLANCHARD: Now, ordinarily you would think a road, a parking lot or a power line or a power pole wouldn't fit there, but there are some conditions under which you would want, in order to be conservative that you would consider them from a waste isolation impact.

Let me give you a "for instance". If you were off the block way outside the potential perimeter of the repository building the road, what you could do with that road, how much water you'd put on that road could have no impact on waste isolation. On the other hand, if you are working on a road or clearing away the side of a mountain for a portal and you are putting millions of gallons of water for dust control, then it is possible that a certain amount of that water could migrate down and cause a negative affect on
1 some in-situ tests in the unsaturated zone.
2 So we go through these things methodically looking
3 for what could have an adverse impact on waste isolation and
4 we do a calculations to determine how much is acceptable and
5 what controls we want to place. And so when Ted answered
6 that question about everything is subject to quality control,
7 he really meant for those things that are not quality
8 affecting items, we go through and do an analysis to find out
9 whether or not we need a management control. If we do, we
10 place that control based on some analysis, quantitative or
11 qualitative that establishes some limit somewhere in the
12 system. Usually a limit that is effectively created by a
13 management control using the same procedures that we use in
14 our quality program.
15 Whereas, for those things that we know there is not
16 a remote chance of having an adverse impact on waste
17 isolation, they are treated in another side of the program.
18 But they still are subject to some aspect of management
19 controls. But not as Don says, part of the NRC Quality
20 Program.
21 Don, is that fair? I don't know if I helped, but
22 it is not the grading that does that, it is where it fits in
23 potential for adverse impacts. But everything is subject for
24 grading. It fits into that concept, whether it is part of
25 the Q program or not part of the Q program.
MR. PETRIE: Okay. The Engineering Plan is prepared by the design organization to describe the work to be performed in detail. It is approved by the project office and contains as a minimum these items: purpose, scope and description of the work to be performed, design methods and procedures to be used, interface controls needed, internal reviews planned, list of deliverables, applicable portions of QA program, schedule and budget and an acceptance criteria. Then, as I said this is approved by the project office.

In effect, we send a letter to the AE that says provide me with design studies for the exploratory studies facility and that is nice, but it really doesn't tell him or me very specifically what he is going to do. So we tell him also to prepare a plan which describes what you are going to do. This plan is then what he prepares, submits it to me and then I say either yes this is what I had in mind, or no, you need some modifications to it to reflect what I have in my field to do as part of this program.

Interface control involves identifying, documenting and tracking the status of all interfaces. Responsibility of the interface control working group, the ICWG which is in a project office chaired organization.

There are two sides of interfaces. There is physical interfaces which is the place where two or more
systems or structures or components intersect, or
organizational interfaces, the relationship between two or
more organizations working on impacting physical item.

Let's say an example of this, as you are probably
aware, we have a half a dozen different participants working
on this project. Each one has certain areas of expertise.
The AE will come up with a design which says I have to--I am
going to put water to control the dust. The AE as a
participant is not responsible for determining how much water
he could put onto the system before he affects waste
isolation. That is a responsibility of one of our other
participants as far as waste isolation is concerned. So the
AE then has to--gets the participant to review his designs,
see what he is doing as his architecture and get the
responsible participant then to tell him you can put this
much water on with no impact. So when we talk with
interfaces, this is in effect an agreement which says you can
put this much water on the site and it will not affect waste
isolation by the responsible participant.

Interface may occur solely within the D.O. like a
piece of equipment into our building or something like that,
or it may occur with another participant, as I just
mentioned.

DR. DEERE: Excuse me. Before you remove that slide,
you say the responsibility for this interface control is a
1 working group, and this includes Yucca Mountain Project
2 Office, Headquarters, the A&E, the different laboratories?
3 MR. PETRIE: In this case, the interface control working
4 group is a project office function. And we are controlling
5 the interfaces between participants. Now we are not smart
6 enough to recognize all those interfaces and we expect the
7 participants to do that. It is their responsibility to
8 recognize where an interface exists, the prepare a
9 documentation of that interface, in effect constraints on the
10 design, and they go into the baseline documentation, those
11 interface control documents.
12 Design analysis, that is a documented record of how
13 design input is translated into design. It is a documented
14 record of the process used in making engineering decisions.
15 It consists of calculations, trade studies and general
16 studies performed under the participants procedures.
17 A little bit about reviews, we have progress
18 reviews of the ESF design are conducted on a weekly basis.
19 the management reviews will be performed by the D.O. prior to
20 the completion of each design package. And in effect, this
21 is where the responsible participants and the AE review the
22 design at that point and say, yes it is ready to go into the
23 design review. In otherwords, all the participants who have
24 contributed to the design, look at what the AE has come up
25 with and say yes, this is now ready to go into a design
Design reviews are performed by the D.O. upon completion of each design package. A little bit about design verification. This is a design control measure which are applied to verify the adequacy of the design. If we have a design that is completed, how do we know it is any good? So there are four acceptable for performing that function. A design review which is accomplished by an independent set of reviewers, competent in the technical areas of expertise which is being reviewed. It is generally the proposed method of verification. Very seldom will we on the ESF be using these alternate techniques, but the alternate techniques are included here for completion.

Qualification tests, we could take the item and physically test it to see if complied with all its requirements under all of its environmental conditions. Alternate calculations and analyses, we could go through some other technique for calculations. Or a peer review, it is used when independent expert judgment is needed or to validate technical adequacy or when data or conclusions go beyond existing state of the art. I generally go by the latter part of that, because I do use independent expert evaluations.

DR. CANTLON: By independent, you don't necessarily mean outside of DOE and your providers?
MR. PETRIE: No. The independent people can be in the same design organization, but cannot have contributed to the design.

Design change control, changes to design related documents are processed using the same methods applied to preparation of original documents. Same organizations do the same activities. Changes reviewed and approved by organizations that reviewed the original document. Field changes will be handled by a Field Change Control Board. This is an expeditious Board handled in the field, but all the same participants must be represented on the Field Change Board.

Design outputs, main output documents are construction drawings and specs. After verification and internal D.O. approval, they are transmitted to P.O. for acceptance and following acceptance by the P.O., they are placed under project change control.

And finally, a little bit about QA records. As Dwight mentioned this is a long-term project and we need to keep records, good records of virtually everything we do. And this is not, I suspect, there are a few things that would have to be added here like training qualifications, I don't see that on there, but all design inputs and relevant correspondence, drawings including as-builts, specifications, approved changes to design input analyses, drawings and
specs, evidence of design verifications, records confirming
interface control and documentation of design reviews. The
major part of things go in here, but not necessarily all.
Okay. That is all I have for this part of the
presentation.

DR. DEERE: Could you back up there?
MR. PETRIE: Sure.

DR. DEERE: Design Process at the top and then the dot
is at design change control.
I'm looking down at the second one, the changes
reviewed and approved by organizations that reviewed original
document. Now how about the original designer? Where does
he come in to take a look at that change?
MR. PETRIE: He--in general, he will initiate, well the
original designer did review the document. The organization
did review the document. Okay. It is that AE's
responsibility then to review the change. That doesn't mean
it has to go back to the same individual who did the original
design, organizationally, it has to go back to the same
organization.

DR. DEERE: I think it is very important and I certainly
agree that that should be a requirement.
MR. PETRIE: Absolutely.

DR. DEERE: Because in a lot of the difficulties that
have occurred, it is when there has been a design change made
1 in the field without the proper check back to the designer.
2 And the reason this is true, so many of the agencies are now
3 not giving the construction management and the inspection to
4 the design firm. In the old days you know the corp of
5 engineers would design it and the corp of engineers
6 inspectors would inspect it and they had a pretty good
7 relationship working with the designers. It's the same way
8 with one of the private firms. They did the design and they
9 did the construction management, but back in those days they
10 didn't call it that. They used to call it just the
11 inspection.
12 But, as time went along, it seemed to be, a lot of
13 people felt it was better, a lot of organizations if you were
14 an owner, to have the design done by one firm and then to
15 have the inspection and the construction management done by a
16 second firm. So you lost then some of the input from the
17 designer because he was no longer on the project. Maybe he
18 would have one man there and maybe he would have none. And
19 when the changes are made, often the design intent was lost.
20 MR. PETRIE: That has happened.
21 DR. DEERE: It has happened. And in the hydro projects
22 when this has happened, it has often led to a rather costly
23 failure of the project or partial failure of the project.
24 MR. PETRIE: Within the Department, we have talked about
25 Title I and Title II and we also have what we call a Title
III which is the inspection activity of the constructed product. Now within the DOE that Title III cannot be done by the constructor. We have to hire a separate agency for that. Now in general it is the AE that does that inspection. So that alleviates some of your concern. And on this field--we have to agree I think that in the field you need to handle those changes expeditiously. There has to be some technique that is a little bit faster than going 200 miles away or 2,000 or 3,000 miles away to get a change approved. But, the design organization is represented on that Change Board. Then the person there must be in contact with his organization to get an, I won't say an approval, but an acceptance of the change at essentially the same time he is approving it. The same way with any other participant that has worked on the original document.

DR. DEERE: I think that is very good.

DR. ALLEN: Any other comments or questions before we move ahead? Russ?

MR. MCFARLAND: Ted, were these controls or controls similar to this applied to the conceptual design of the repository?

MR. PETRIE: Before my time, but--

MR. MCFARLAND: Well perhaps I should direct the question to Don.

MR. PETRIE: I think it was before his time too.
MR. MCFARLAND: Do we have an accepted conceptual design of the repository?

MR. HORTON: I think at this time I'd have to say we may have one, but we are going back and reverify that conceptual design.

MR. PETRIE: Let me try to put it this way for you, okay? I said a little bit ago that we had a repository design requirements document. In that requirements document are those requirements which are necessary to define from the DOE's viewpoint the constraints to be placed on the ESF based upon a repository design. Over the next six months and prior to the completion of Title II, we will re-evaluate those interface requirements between a conceptual repository and the ESF to assure ourselves that the conceptual repository is consistent with those requirements. And that will be done in accordance with our QA program.

MR. MCFARLAND: Then the driving factor will be the ESF design not the conceptual repository?

MR. PETRIE: No, I didn't say that. No. Remember I said the repository requirements document will include those requirements on the repository which could lead to constraints from a repository onto the ESF. The repository designer then has to come up with the interface documents or requirements to place them on the ESF consistent with those repository requirements. In effect, it will be a partial
conceptual design to the extent necessary to define exploratory studies facility interfaces. We will not do a complete conceptual design though.

DR. DEERE: I think that one reason for the question and we bring it up in the current report that is our third report to the Secretary and the Congress, and that is it did appear that in the 17 alternatives and in the early access of the Calico Hills the other 17 alternatives, only four used a different two-level layout of the repository instead of one level. And one or those or two of those had very high rankings. And it wasn't quite clear to us if it was the access that gave it the higher rankings or is it the fact that we had the repository at two levels. In otherwords maybe the outcome was that it was the repository at two levels. Because, in the other studies we didn't have a repository at two levels so we really couldn't back out that influence. It is just a question that we raise in the report.

MR. PETRIE: It's true, that the repository, the potential--every place I say repository, put potential in front of it. It is true that the potential repository concepts as indicated by that two-level was considered better because of the distance from the water table. We will not be able to confirm whether or not that is an appropriate thing until we have done some borehole testing. That will be done,
1 God willing and the flood don't rise, but that will be done
2 early before we have gotten that far into the construction of
3 the ESF. And at that point, we would expect to make a
4 decision as to what really would be our conceptual design
5 with regard to the levels of the repository.
6 MR. BLANCHARD: Ted, I think what you've said in another
7 way, stated another way is that by carrying on these ESF
8 design studies which are an enhanced version of Option 30, we
9 in no way believe we are precluding the possibility of a
10 repository configuration that would be different than what we
11 now have in the CRD, Conceptual Design Report. In
12 otherwords, we still have the possibility of considering more
13 than one level and different layout configurations and even
14 changing the repository horizon.
15 DR. DEERE: Well, I think the flexibility that this
16 alternative contains is one of its strengths that you can do
17 that. We can even put an internal shaft in or winds are
18 raised for a short distance if one needs it. It doesn't
19 necessarily have to come from the surface. So there is
20 flexibility I think.
21 MR. PETRIE: You know, eventually we are going to come
22 to a place of no return, but we want to make sure that we get
23 these kind of testings done before we get to that point.
24 DR. DEERE: And I was prepared for this in case the
25 questions at the Senate Hearing last week got more detailed,
1 such as is the DOE ready to start shaft construction? And I
2 was prepared to say that you need borings first—in
3 otherwords it is a progression of tests. And you really
4 won't define where you want the exploratory units to go
5 exactly until you get some of the first test results in.
6 MR. PETRIE: That's right.
7 MR. MCFARLAND: Ted, one other question and to follow-up
8 one of Dr. Deere's comments about the sensitivity of knowing
9 that the original designer, that the input from the design is
10 understood in field changes. I think a key element of this
11 risk or one way of addressing this risk is the development of
12 an acquisition strategy for construction. Where does that
13 fit in the sequence of events?
14 MR. PETRIE: We are in the process of developing that
15 acquisition strategy. And that's all I can say about that
16 now. We have not completed our acquisition strategy yet. We
17 are still working on it.
18 MR. MCFARLAND: Thank you.
19 MR. PETRIE: Anything else? Did I see somebody over
21 Now I want to talk a little bit about the Quality
22 Assurance criteria applicable to the design process.
23 And I will say a little bit more about the grading
24 process to begin with and what the grading process does for
25 us. First we provide an activity identification and
definition. We define this thing we are looking at a parking lot? If it is a parking lot, where is it? Is it in a place where it could impact waste isolation? Whatever this thing is that we are putting into the design process we identify what it is so that the grading is done generally for a high level and then lower levels as necessary. But the first thing you do is identify what it is that you are going to be looking at.

We determine if the activity is on a quality activities list or project requirements list. Those are things that have been predetermined to be either important to safety or waste isolation or important to project requirements. And again Ram will talk a little bit more about that tomorrow.

Then we state the importance of the project. Is it worker radiological safety, operational concerns, reliability, or whatever. And then we identify the applicable QA criteria and provide justification if we say the criteria is not applicable. And then the performer then obtains quality review board acceptance.

As I said a little earlier, the AE was responsible for preparing the QA grading package for exploratory studies, and the following criteria were identified by the AE through his QA grading process and are applicable to ESF design activities. And this is the set of criteria that has been
identified by the AE and approved our Quality Review Board as those things which apply to the higher level to the exploratory staff facility. And I'll go through each one of these--well, I don't know the names of all the things I am missing but you see it is really criteria 8 through 15. Some of those things are like instrumentation, where in a design process, there is not calibration of instrumentation required. Now that doesn't mean obtaining data, obtaining data that is used in the design would be subject to that, but the designer is not obtaining the data, the data is provided to him. And so some of the criteria as you can see were determined not to be applicable, because work on them was not being included in this design activity.

And some of the things then we have to do if Criterion 1 - Organization applies, we need to establish document lines of authority, define functional responsibilities and again document them, define lines of communication for guidance, direction and control, and to have full documentation of organizational actions. So we in the Project Office then need to make sure that each of the participant's activities are well defined so that we can have a definition of the functional responsibilities. And again, that has to be all well documented. We can't say, "Hey, Joe, you take care of this, Bill you take care of that, and by the way talk to each other when you get a chance." Now, that is
Our Quality Assurance program requires the establishment of the QA program, it requires QA organizational independence, that is, Don's organization has to be independent of the line organizations performing the function. Identification of quality effective items or activities and we've just talked a little about that. Identification of applicable QA criteria, again we've discussed that a little bit. Identification of QA controls and these are the procedures then that implement those QA criteria we just discussed. Each one of the organizations has as you are probably aware, a gamut of procedures for implementing those QA criteria.

We have to have documented personnel qualification, again, Dwight talked about that a little bit about how in the federal government how this is accomplished. Training of personnel and training records and training of personnel means that if a person is responsible for an activity associated with a specific procedure, he needs to be trained on that procedure. And we demand verbatim compliance. If the procedure says dot an "i", he has to dot the "i". If it says cross a "t", he better cross a "t". If an engineer is not comfortable with verbatim compliance, he really doesn't belong on this program.

I think we find that most engineers or many of them
any how are accustomed to defense work, NASA work, they have been acclimatized to this kind of activity. Engineers from other areas are not quite as accustomed to it.

Quality Assurance criteria applicable to the design process, design controls requires definition of the design control process and again that has to be documented. Control of design inputs, we discussed that a little bit, design verification is required, establishment of change control measures, archiving of design documentation. That all has to be put in the formal record system. And it has to be of course legible. No pencil written notes generally don't make it. You have to go back and do them over again.

Procurement document control, requires that the applicable design bases/requirements necessary to assure quality be included or referenced in procurement documents. If you write a purchase order, it has got to have reference to a technical requirement that is being imposed on the vendor. Procurement documents need to specify that suppliers have an adequate Quality Assurance Program. One other thing that these are also under change control. If you change a procurement document you have to have record of the changes.

Now one would think, heck, that is automatic. I've worked in one or two places where it wasn't. And as you are probably aware you can get into some substantial difficulty.

MR. SHELOR: Excuse me, Ted.
MR. PETRIE: Sure, go ahead.

MR. SHELOR: I would just like to add two points. The first one is that these requirements are not unusual and these would apply to any nuclear facility design. You know it is the normal standard operating procedure for nuclear facility design. And a second point I'd like to make is that it is entirely conceivable in the grading process and when you come down to a procurement of an item that it can be graded down to commercial grade, but there will be documentation that justify the acceptance of a commercial grade item into the system. So we are not talking about unusual specifications or items or components just because it is part of a nuclear facility.

DR. ALLEN: You mean like the quality of the asphalt in the parking lot.

MR. SHELOR: Or the toilet in a trailer. Those can be commercial grade components and equipment, but you arrive at that through the grading process at the designer documents.

MR. PETRIE: Excellent point. Go ahead.

DR. DEERE: And of course a lot of the commercial, I'm not sure a toilet, but the commercial goods that you are using have to meet some code anyway. They have to the ASTM or ASME or--

MR. SHELOR: That's right. But, the spec may in fact take a brochure from a manufacturer and say that is a spec
1 that we want. Now you probably most likely would have a
2 quality control inspection to make sure that you did get that
3 commercial grade equipment. That is only common sense in the
4 construction of quality control.
5
6 There is another thing. Excuse me for
7 interrupting.
8
9 MR. PETRIE: Go ahead.
10
11 MR. SHELOR: You have to be very careful in the grading
12 process and in a nuclear facility. I refer you back to NUREG
13 1055, the Ford Report that was kind of the lessons learned
14 from nuclear facilities. One of the things that I think is
15 amongst a lot of others is very important. If you have only
16 one item important to safety then it may be conceivable that
17 you can isolate that one item and all the others not have a
18 QA program at all. I think you run into problems and yet in
19 the planning and the conduct of the construction and building
20 of this facility is mixing and matching. If you have to have
21 separate warehouse areas for QA material and separate them
22 from material and equipment that is commercial grade, you
23 have to be very, very careful in the whole management of this
24 construction so that you don't mix these components up.
25 And sometimes you may be better off designating the
26 entire thing as under QA control.
27
28 MR. PETRIE: Okay. Criterion 5 - Plans, Procedures,
29 Instructions and Drawings, requires design activities to be
conducted in accordance with approved plans and procedures. You just can't go to work. You have got to have a plan on what you are going to do. And you have to procedures which describe what you are going to do. Identification of acceptance criteria for design products, you can't just say, "Hey, Joe, go see if what we built is what you want?" It has to be a documented criteria for acceptance. Controlled changes to those plans and procedures. If you want to change them you've got to have a new revision, you have to have a record of it, you have to retrain all the personnel who were using that procedure.

DR. CANTLON: As you go out from a construction item, more and more in the direction of a research need, how do you get the flexibility put into that first bullet there?

MR. PETRIE: Well, that's not my bag. Larry Hayes will be discussing that tomorrow afternoon.

DR. CANTLON: Okay, thank you.

MR. PETRIE: We are here to talk about design.

DR. ALLEN: I do recall I was out in the field with a group including Jerry Szymanski who had made some claims about certain geological phenomena and I asked one of the survey people there, can you go out on a Sunday afternoon and look at this? And he said, no, it is not in the study plan. And some lack of flexibility was frustrating the system.

MR. PETRIE: Larry will be talking to you tomorrow
afternoon.

Criterion 6 - Document Control, that is control of design generated documents. Establishment of criteria from control of design inputs. We have talked about that. Status of design generated documents is to be maintained. That is if a document has been revised, you have to have a record that it was revised, and of course not only that, you have got to make sure that the users of that document do have the revised document, and the documentation of design changes. Most of these as Dwight says are standard for nuclear industry. Many of them are standard in the defense industry or NASA.

Criterion 7 - Control of Purchased Items and Services, control of procurement of items and services to assure conformance with specified requirements. This includes source evaluation and selection, objective evidence of quality by the supplier, source inspections and audits, examination of items/services upon delivery. That's pretty straight forward.

Criterion 16 - Corrective Actions, requires prompt identification and correction of conditions adverse to quality. It requires remedial action, that is you need to correct the problem as soon as you recognize you have a problem. If you have a drawing that is incorrect, fix the drawing. Identify the root cause of the condition. You look
1 into the drawing and say why did that mistake get into the 2 drawing. Are there 15 more drawings with the same mistake on 3 it. Can it be traced back to an individual? Can it be 4 traced back to a calculational standard that has been imposed 5 by the AE which may be incorrect? Look for the root cause. 6 Investigate it. And, then you take corrective action to 7 assure yourself to the extent you can that it will never 8 happen again. And then you take and document, of course, all 9 these actions that you have taken.

Criterion 17 - QA Records, documentation of 11 evidence of compliance to QA requirements. Now many 12 commercial industries if you provide a product, that is 13 evidence of compliance. You built it. Not us. All the 14 documentation has got to be in the files, legible and 15 identifiable records, provisions for supplementing or 16 amending the records, submittal of records to approved 17 records facility. And in fact I send a records package to 18 the records facility, there is somebody there who looks at 19 every single page to make sure that every single page is 20 legible and identifiable. If they find something that is 21 not, back it comes.

Criterion 18 - Audits, Don spoke about those a 23 little bit. But from a line organization standpoint, we are 24 required to be auditable. We have to have the records such 25 that when the QA organization comes to us and says have you
been meeting this requirement, we need to be able to
demonstrate with documentation. Yes, we were meeting that
procedural requirement. We must be auditable. To not be
auditable is a cause for a finding.

DR. CARTER: What is the frequency of audit? Is this an
annual audit?

MR. PETRIE: It is really—well Don, do you want to talk
about that a little bit?

MR. HORTON: Currently our audits are conducted on an
annual basis. The real meat of our program is the actual
surveillances now where we go in on a short-term basis on
specific areas that we want to take a quick look at to see if
things are under control.

DR. CARTER: Again these audits, I presume these are
external audits, again, external by DOE definition?

MR. HORTON: They are both external and internal. Our
own operation plus the design organization.

MR. PETRIE: They are all external to the line
organization that is responsible for the activity being
audited.

DR. CANTLON: Are the external audits announced or
unannounced?

MR. HORTON: They are announced.

DR. CANTLON: With what kind of lead time?

MR. HORTON: It varies. We put out an annual audit
1 schedule, but due to other circumstances those have to
2 change, but it is announced annually.
3       DR. CANTLON: Sure.
4       MR. SHELOR: I might just add to that on the annual
5 audit schedule, in general the state does come as observers,
6 the NRC generally comes as observers on the audits and in
7 addition, the NRC they believe is the latest information--
8 they have budgeted for conduct of three or four audits that
9 they perform on DOE. Normally they observe our audits, but
10 they can come in and audit at anytime.
11       MR. PETRIE: Criterion 19 - Computer Software, and this
12 is such a sensitive subject that we decided at this point to
13 have our own criteria for it, at least for the moment. That
14 may change. But it requires the development of computer
15 software development and control program and development of a
16 computer software QA plan. I don't know if any of you have
17 any software, you probably have and if you are running your
18 own computer you probably change your software and as soon as
19 you saw something wrong you went in there and fixed it. And
20 then you fixed it again and you fixed it again and you fixed
21 it again, and a month later you say, what did I do a month
22 ago and you say, "Oh, shucks".
23       That's not allowed. In this development of
24 computer software development control program is to make sure
25 that our software preparing people are under control, operate
by procedures. They know what they've got in their software
program at all times in effect. Then there is a validation
and a verification of validation program that goes with this
and it is really a whole--it is worth an hour's discussion
just by itself. But, let me just say, we require that all
software get the same or more rigorous controls as what we
have for any other part of the design program.

DR. ALLEN: Then this too is subject to grading.

MR. PETRIE: Pardon?

DR. ALLEN: This too is subject to grading depending on
the implication of that particular software.

MR. PETRIE: Yes.

Okay, are there any questions? That's the end of
my prepared talk.

DR. CANTLON: Where to the TIGER teams fit into the
audit system?

MR. HORTON: They don't.

DR. CANTLON: They don't?

MR. HORTON: No. That's something that is controlled by
the Secretary.

DR. CANTLON: So it is a tier of audits internal to DOE
above the level of the QA system itself?

MR. HORTON: Yes, along with GAO, IG and everyone else.

DR. CANTLON: Right. Okay.

MR. SHELOR: I might add another one to that. Within
the Department of Energy, the Office of Environment and Safety has the responsibility on behalf of the Secretary to ensure that in fact QA programs, safety and health requirements are being met. OCRWM by virtue of the fact that we are regulated by NRC, we have an agreement with that office that we would not have dual regulatory oversight. So they look at what we are doing, but they don't come in and perform audits.

However, if there is an essence of a problem, the Secretary can have them come in and audit at anytime and he would probably form a TIGER team to do that. But we have so far been reasonably successful in avoiding dual regulatory compliance within the Department, but however we are not subject to the new requirements being developed by the Department within the Office of Nuclear Safety. We are required now through departmental regulations to conduct a nuclear safety self-assessment every year and to have the staff and the capability to do that assessment, which is basically how well are we implementing the nuclear safety rules.

DR. CANTLON: Now how would that be scheduled relative to the scheduled QA oversight, typically beforehand, I would presume?

MR. SHELOR: No, unfortunately, they just lay it in on top of us. The Office of Nuclear Safety, they ask us to
1 update our self-assessment every quarter.
2 DR. CARTER: Let me ask you--this may not be the time, I
3 was going to bring it up tomorrow, but since it looks like we
4 have got a little bit of time, I just wondered if you had any
5 concerns so far of trying to avoid in the QA area or we are
6 talking a little broadly about audits no, a "policeman role".
7 In other words in auditing our Quality Assurance or
8 scientific and technical matters, do you run into any
9 problems of trying to separate these from the discovery of
10 fraudulent procedures and that sort of thing? I know a
11 number of groups that have been in this business awhile have
12 run into this problem and they try to separate these two, EPA
13 being a good example of this. I just wondered if you had
14 encountered this?
15 MR. HORTON: To date, we haven't. You know, generally
16 we already know what the program is and what we want to do is
17 go in and verify satisfactory implementation of that program.
18 So it is--from our respect it is not a police action.
19 DR. CARTER: Well, you know, they have encountered and I
20 guess most of the programs in this area, they have
21 encountered things like people falsifying data and a number
22 of other things. People that obviously have an axe to grind
23 in terms of some financial reward if they pass muster and
24 this kind of thing. This is the area that I am talking
25 about.
MR. HORTON: I think, Mel, that there has to be a sense of pride by the line organization in doing their work and the implementation of the QA program. We can't as a QA organization inspect the quality and the product. They have to build it in and if they want to hide something from QA, they can do it anytime they want. So, we try to promote a feeling of their own program. It is not QA's program.

DR. CARTER: Well I think the QA in going about its activities, might indeed either find or stumble on something of this sort, so this is the question.

MR. HORTON: That's correct.

DR. CARTER: I know in EPA's case, they even give it a different name. They call it data authenticity or something of that sort to distinguish it from QA.

MR. SHELOR: I think the other part of this that Don was alluding to is we have an IG in DOE to report waste, fraud and abuse and we should do that. But the other part of Don's activities in terms of independent QA is the whole concept of not only compliance but effectiveness. Are the procedures effective in getting the design resolved. And I think that is why we now see technical experts as part of the audit team come in and give some evaluation of the effectiveness of how it is working.

MR. BLANCHARD: Mel, I have some information that may be of use to your question. The operations office is following
a DOE order to conduct annual vulnerability assessments which address what Dwight just mentioned as waste, fraud and abuse. These are done by non-quality assurance people. They are done by management people who are trained or experienced in conducting waste, fraud and abuse studies. That information is then viewed by the IG or whoever is doing that oversight.

This program is annually, or this project anyway is annually subjected to a vulnerability assessment and there are documents on file that represents what those results are. Basically they are looking for misuse of federal funds of the misapplication of funds on things that are not of real direct benefit to the actual project. That goes on independent of the Quality Assurance Program and it is driven by prudence of management. And so far as I can remember, ever since I've been in this project, there has always been one of those every year.

With respect to looking at the data and trying to decide, is data being falsified, I think that is a part of the Quality Assurance Program, but it is also a part of the management to ensure that that doesn't happen and to set up management controls to preclude that. Some of the things that we do from the management of data standpoint to try to preclude that is to require data be prepared in some sort of a data form and to go into the local record center. We also
1 require sweeps, periodic sweeps of data in the central
2 records facility.
3 We have data systems which use that data that are
4 data bases and are accessible to everyone, all the
5 disciplines on the project that need it. Some of these data
6 systems computerize the information from a particular test
7 and calculate mean and standard deviation and variance.
8 Others of these data systems actually sort through what we
9 have and compare those test measurements with measurements
10 obtained by other people on the same subject that are outside
11 the program. This gets compiled and is available for use by
12 the design and the performance assessment people in the RIB.
13 So the people that are doing design work, their performance
14 calculations are not limited just to the test data that comes
15 from a test that we sponsor, but anything that has been
16 published or documented is also perused.
17 We have technical data advisory groups that sort
18 through all the data in different disciplines like thermal
19 conductivity and periodically decide how much more to put
20 into the RIB. All of this is available to anyone outside the
21 program that requests copies of it. We publish quarterly
22 data catalogs that tells what data we have and where it is
23 at. That is available to be distributed. We prepare rather
24 routinely big packages of data or data tapes and turn it over
25 to anyone outside the program that is asking for it. For
instance, the state from time to time makes a request for
seismic data, everything that has come out of the 51 station
seismic network. Or they request information for the past
five years on water level monitoring in the various soils or
meteorological data. So I think there are data groups, there
are record centers, there are other people manipulating the
data in data bases and then there is a process of getting
official data into the RIB for use by design and performance.
And then there is the distribution of that data in an
orderly fashion to people outside the program.

I think the likelihood is low that there will be
anything that would seriously affect designer performance in
the area of errors that creep into the data accumulation
process by such a multi-faceted method of acquiring, sorting
through, examining, perusing the data, and then making it
available.

DR. CARTER: Well that is informative as far as I'm
concerned. I guess what I am hearing in essence is that you
have the both programs and they are essentially dual programs
and I presume then that there is something maybe reading
between the lines, I presume if the QA program did encounter
this sort of thing, fraudulent behavior or whatever, then it
would turn it over to the IG or someone like this.

MR. BLANCHARD: Yes.

DR. ALLEN: Whether we like it or not, you know public
and Congressional concern on this issue is very high. Just this morning the New York Times had an editorial of the Baltimore alleged fraudulent data in medical research. I guess our challenge is to assure the public and Congress that we are worried about this and constructively worried about it without over-reacting and that is a difficult task.

DR. WILLIAMS: Ted, could you put your last slide back on there for a second?

MR. PETRIE: Sure.

DR. WILLIAMS: This is a source of a lot of discussion and I'm sure you have heard in various places.

MR. PETRIE: I haven't really been involved in it but I've heard plenty, sure.

DR. WILLIAMS: Well, I'm glad to see you split it into two parts, but I want to ask you what do you do in the second part, especially when it comes to verification and validation, which is the only place where it can be addressed?

MR. PETRIE: Maybe I don't really understand your question, but that is what the computer software quality assurance plan of what is in the requirement for validation and verification.

DR. WILLIAMS: Well, actually, I don't see how that can be done ever.

MR. PETRIE: Which? Both? One?
DR. WILLIAMS: The creation of the quality assurance plan that demonstrates verification and validation. I think you could spend years doing that and never get to first base. That is why I want you to tell me what you do.

MR. PETRIE: It does not demonstrate, the quality assurance plans don't demonstrate anything. The quality assurance plans tell you want to do so what you've done can be demonstrated.

DR. WILLIAMS: Well let's get to what you've done. I think developing a QA plan for computer software that includes QA for verification and validation which is on a slide that--I've forgotten which one you presented, is very difficult. I don't understand what the QA plan would consist of that is required by the second item.

MR. PETRIE: Well, I'm not the local expert.

DR. WILLIAMS: You are not the guy to ask, huh?

MR. PETRIE: No. But, I've done it. I can tell you my experience in the area, but I don't know what the project office has put in. Don, shall I go ahead or do you want to try to answer?

MR. HORTON: Go right ahead.

MR PETRIE: Okay. Well I've had problems in this nature and first I had to do a verification and then I do a validation. In the verification we define very similarly what we do in the design process. It is where the designer
of the software performs his activity, gets his software all
designed, all in shape, all well documented, and then he has
a review by independent reviewers of that software to see if
it does what his requirements were. I left out the step,
first he's got a set of requirements, and then he prepares
the software to meet that requirement, and then he has a
verification to make sure from an independent reviewer
standpoint that he is in fact going to meet those
requirements with that software.

The validation part is the more difficult one
generally because that means what you do is you are required
to take input information for which you know what the output
is. Put that input information into quantitative input
information into your software and validate that your output
is identical to what you have obtained from an experiment or
some other method.

Now the software, the QA plan can only tell you to
perform those activities. It can't tell you you are going to
be successful. Okay?

MR. SHELOR: Let me add a little bit. We don't have the
software QA experts here, but there is a couple of twists in
addition to that. Really what you are talking about when
they come down to a software QA play, they talk about life
cycle control of the software program from the very inception
in terms of documenting what your approaches are and what
your QA controls are going to be, a review of all of the model that you developed and the documentation all the way through to the verification and then the validation then comes in in demonstrating that the models do what you intended to do.

Now validation of a performance assessment software program for 10,000 years is going to be very difficult. We have to take a different approach. What we can do is to validate that it does give us the results in the time frame that we know about.

DR. WILLIAMS: Well there is some actual differences between what verification is interpreted to mean and what validation is interpreted to mean between you and some of your contractors.

MR. SHELOR: I'm sure there is, but each one, you know we have got to iron that out, but it is different. If I was going to validate a shielding code, I could do that. I could run an experiment and validate a shielding code to demonstrate that I get the right thickness depending on what the source is. I might also have more difficulty now validating a seismic response code, because now I am going to have to go in with some experts and probably end up with a peer review to validate.

DR. ALLEN: They are two different things. One is what if the software gives you the right answer. And the other is
whether it gives the answer that the programmer wanted.

MR. SHELOR: Exactly. That's the difference basically between a verification and validation.

DR. ALLEN: No one can predict what is going to happen 10,000 years from now, but maybe the program does exactly what the programmer was trying to do.

MR. SHELOR: Right.

MR. PETRIE: Is it tenderloin steak in, tenderloin steak out, is that the way it goes?

DR. ALLEN: What?

MR. PETRIE: You put in tenderloin steak, you get out tenderloin steak.

DR. ALLEN: Are there other questions from the Board? How about questions and comments from the audience?

MR. HORTON: I would like to clarify something.

DR. ALLEN: Please do.

MR. HORTON: Unless you are going to do it, Ted.

On the previous presentation he talked about the design verification, one or more of four methods which included the design review which is normally referred to the independent design review, qualification tests, alternative calculations and analysis and the peer review. The lead in states it is accomplished by one or more of the four acceptable methods. The peer review cannot substitute for any one of the foregoing three. The peer review has to be in
addition to one of the others.

DR. ALLEN: Thank you.

Okay, let's break for lunch. Do you want to reconvene at the scheduled time or 15 minutes earlier?

Okay, the scheduled time is 1:15, and we'll reconvene at that time.

(Whereupon, a lunch recess was taken off the record.)
AFTERNOON SESSION

1:15 p.m.

DR. ALLEN: May we reconvene, please?

I said this morning we'd say a few words right now about the roundtable discussion. We have posed a few questions here. Actually, Russ McFarland put these together and I'll read these off, although I think we should keep in mind that to some extent many of these questions will have already been addressed by some of the speakers, but you might jot down anything, any of you who will be members of the roundtable, of items you might wish to comment on.

The first four questions have to do with the conceptual design. One of these is from a QA perspective is the conceptual design phase of system development quality affecting? If it is, how is assurance provided that QA has been met?

Is there specific reference to the conceptual design phase in 10 CFR 50, Appendix B? A key element of the conceptual phase of design and conventional engineering practice is the evaluation of alternative concepts and the development of the rationale leading to a preferred concept. Is this activity contained in DOE 4700.1, the definition of conceptual design, and, if so, is this activity quality
1 affecting?
2 Some mention has been made from time to time to exempt prototype or scoping research activities from being classified as quality affecting. If this were to be done, would it logically follow that conceptual could be viewed as synonymous with prototype?
3 Another two or three questions. At a recent TRB panel meeting, the following comment was presented. Total Yucca Mountain Project QA program does not explicitly address the matter of staff from on participant working on activities controlled by another participant. Question, are there sufficient differences in the QA training between the various YMP organizations that will support this observation?
4 Finally, in response to Question #63 of the NRC review of the SCA, the DOE stated that the final decision regarding standards for conflict of interest and the dependence of DOE QA reviewers must remain the prerogative of the DOE and that different standards may be appropriate for different types of review topics. Question, is this still the position of the DOE? If so, what would be the different standards and topics that would warrant these differences?
5 Well, you might just keep these questions in mind. We're certainly not limited to those, but that, at least I think, might be a jumping off point for our discussion later
DR. DEERE: Perhaps we can get some xeroxes of this and hand them out and also they can be glanced through.

DR. ALLEN: Okay. So, this afternoon, I guess our first talk is by--do you wish to introduce the speakers? Are you still in charge or--

MR. HORTON: Mr. Richards.

DR. ALLEN: Okay.

MR. RICHARDS: Let me start with our first slide here. I am not Al Stevens. Some of you may recognize that. I'm Bob Richards. Rather than the title that's given up there, I'm the Division Supervisor for the Quality Assurance Division of the Department at Sandia Laboratories that handles our work in this project. I guess, I ought to extend my apologies for Al not being here. I'm sure he would probably rather be here in these pleasant surroundings rather than dealing with the auto repair and insurance and travel change that he's having to deal with today.

In any case, I'd also like to comment a little bit about the title of this particular talk. It says control of design input. That's somewhat of a larger topic than what Al or I really intend to discuss here. What we really want to talk about, what the scope of my presentation will be, is the actions that we take at Sandia and among the other partici-
pants who worked with us on this to control the process of
preparing information that may be used as design inputs by the
design organization. There are also other responsibilities
for control of design inputs that the design organization has
and those will be covered, I'm sure, by Mr. Bullock later on.

Let me first refresh you with a little bit of
history. I think most of the Board has probably seen this
slide before when you've had discussions that have talked
about that particular topic. And, Al Stevens or Tom Hunter or
Tom Blejwas has probably tracked through the process of going
from the various things that initiated the ESF Alternative
Study through the process that led to the ESF Alternative
Study Report, itself. Not mentioned too many times in those
presentations was the fact that another -- a byproduct, almost
of that activity is the production of the exploratory shaft
design requirements and, to go along with it, the
part of the repository design requirements that is related to
the exploratory studies facility. The exploratory studies
design requirements document is one of the two major
pieces of information that I'd like to talk about. The other
one that will be available to the design organization and is
available is the reference information base for the project.

What I'll do is take you a little bit through what
we have done to work on the exploratory studies facility
design requirements document, where the information that's in it comes from--many of you are already familiar with that, I'm sure--what the information consists of and then we'll talk about the controls that were applied to that process. Many of those controls are in common with the process for maintaining the reference information base. So, the discussion I have about reference information base will be somewhat shorter than that on the exploratory studies facility design requirements. Where the ESFDR basically flows down from starts with the waste management systems requirement, Volume IV. Volume IV, as I understand, has to do with the repository, the mine geologic disposal system, whereas the other three--the preceding three volumes--have to do with things such as the transportation system, monitored retrievable storage system, and waste generation. That document, Revision 1 of which is very recent--January, as a matter of fact--is basically decomposed down for the things that have to do with the mine geologic disposal system into a systems requirements document and a system description document. Sandia worked primarily on that.

And then, from that information into a document that is specific for the exploratory studies facility design, the information is compiled again into the ESFDR. Most of the information in the ESF design requirements document comes from
1 this source through these two pathways; however, not all of
2 it. As you can see, there's other information. For example,
3 the exploratory studies facility is intended or the concept
4 now is that it will become part of the repository. Those
5 things that have to do with its performance later on as part
6 of the repository are requirements for the design of the
7 exploratory studies facility, itself. And, so there's
8 information from this document, the repository design
9 requirements document, that must be brought into the ESFDR.
10 The main reason for the ESF to exist is to conduct
11 studies in that facility, to find out whether or not the site
12 might possibly be suitable as a place for a repository. A lot
13 of testing will go on in the ESF and so there are a lot of
14 testing requirements that come out of the site characteri-
15 zation plan baseline that must be incorporated into the DR.
16 There are also a number of environmental regulations and so
17 the environmental regulation compliance plan also provides
18 information that must be brought into the ESFDR.
19 Let's look briefly at what the document consists of,
20 itself. The first volume of the exploratory studies facility
21 design requirements document is as shown. Basically, all this
22 is, once you get past the initial general introductory
23 information is a breakdown of the individual physical
24 subsystems and functional subsystems that have to do something
in order for the ESF to function as a whole. This is the main body of the report, general content-wise. And, that is backed up by the second volume of the report or the document which provides a lot of background information. For example, I mentioned earlier the information from the repository design requirements that impact the exploratory studies facility right there in what is--they're not numbered here or named here--but is the first appendix, Appendix A, of the ESFDR. Just essentially a direct carryover of requirements that the repository must meet that have to do with the exploratory studies facility itself that must be addressed in the design. The second two appendices are those that primarily flow out of the site characterization plan, the testing requirements, the requirements for underground tests and drilling requirements that are related to the ESF. I mentioned earlier the environmental regulations that must be met. They're listed here as Appendix, I believe it's J. I'm not sure.

In the middle of this set of appendices is some information that's very important to us as a project because of the need to show linkage between a design, the design requirements, back to the basic requirements that that design is intended to meet. And, here, you have a set of appendices that serves to tie in with higher level reference documents and provide a cross reference, individual requirement by
individual requirement, concerning where they appear in the ESFDR and where they appear in these two higher level documents, the waste management systems requirement and 10 CFR 60.

I've told you now what's in it and how we got there, as far as flow data from higher level requirements. Another obvious question is, well, how did we control that process? What did we do to insure that it came out right? Well, that's one of the basic philosophies that we have at Sandia for control of any of the work we do that's quality related and that's that we want the work to be such that whatever you use as inputs to the process, they will be capable through the process of producing the desired result. In the process itself, we take actions to insure that it's sound and in control, so that we can count on the result being good.

We've --not so much as an afterthought, but because it's a good idea--also checked the result to make sure that the result is, in fact, adequate, that our process controls did work. Here, you see some examples of the things and these are essentially reiterations of what you saw earlier this morning in, I think, two different presentations. Some of the things that go into the process of producing the ESFDR are people and information. We apply controls to those; qualified people trained, familiarized, indoctrinated as you saw this
morning, and information that we know has come from a current correct, valid source. This particular aspect provided us some interesting times during February in that the time frame. From the time that the waste management systems requirement, Volume IV, Rev 1, was finalized and then to the time that we had to essentially flow-down that information into the ESFDR was relatively short and we had to do some interesting things to make sure that we were, in fact, using the correct current information rather than one revision old of any of those documents that I mentioned earlier.

We use plans and instructions and documents which establish agreements between ourselves and other organizations about what we're going to do to help control the process itself. In that, there are some reviews that occur and at the end of the process, before the final product is turned over to the DOE, we also do a final review. And, across the whole thing, we do task focused QA surveillances.

I was asked to describe specifically what the quality assurance organization does in this effort. It was really two things that we do. We do general activities which are not so much focused on a particular work activity, as much as things like establishing an environment in which that basic philosophy I mentioned a while ago will be achieved, will be adhered to. The philosophy that we start with good inputs, we
control the process to come out with a good product, a good result. And then, of course, we're still involved in detailed day-to-day activities. Some examples of those are as you can see here; reviews of those various plans and instructions and interface documents that I mentioned before, the surveillances that I mentioned are focused on the specific task at hand and the important aspects of that test, and then using this, as well as possibly results of auditing efforts if the auditing effort occurs in a time frame that covers the work we're concerned with. We use that information to provide feedback to management and technical staff to help them make decisions to keep the process on track.

Now that I've generally gone through the process that we utilized in dealing with the exploratory studies facility design requirements document, let me talk about the reference information base. That's the other major item of information that may be used by the designers and selected as design input. It also is essentially a process described here.

What we want to be able to provide is information that is usable by designers or scientists for their needs in doing the work on the project. Generally, the process is that by means of the work breakdown structure, the site characterization plan, and other vehicles, individual
participants know what kind of information they're responsible for generating. They do that. They go out and collect data, they then pass that data—not totally raw data, but to some extent, processed—to the Yucca Mountain Project technical database, also known as the site and engineering properties database. It's a database of numbers, of large amounts of numbers from individual experimental efforts.

DR. DEERE: Question?

MR. RICHARDS: Yes, sir?

DR. DEERE: For instance, if you had a--let's say, we had one of the new borings coming in. Where does that information go, the boring log?

MR. RICHARDS: Okay.

DR. DEERE: Would that get into it or does it have to be tested before information goes in? Let's say that you hit a zone that the field geologist called fault zone at a given depth. Does that get into--

MR. RICHARDS: The way I describe that, sir, is that the geologist here working for the participant organization would develop his information from his bore log that is quantifiable and would be able to put quantifiable data into the site and engineering properties database, all the data he wants to, as many data points as he cares to. The site and engineering properties database is a computer database. So, it's not very
well set up to handle qualitative or narrative information.
That information can be gotten via this--these are actions and
this is a process--into the reference information base itself
if it's analyzed to be the kind of information that can be
representative of the information that's needed by the project
users. Did I help?

DR. DEERE: Well, you may have. Well, I mean, the most
important thing in a given boring may well be the presence of
a fault and a fault that's not going to be crossed, let's say,
or particularly looked for in the underground drifting
program. And, how does that information stay up front and
doesn't get lost?

MR. RICHARDS: Okay. There's another pathway not shown
here. That investigator will, most likely, write some kind of
technical report in words--maybe with a lot of date with it--
but in words that explains his findings. Those technical
reports, then, for one thing, are distributed into the public
domain and also into the project's record system, so that they
are available, referenceable by other people at the project or
other people outside the project to be able to use.

MR. BLANCHARD: Don, I might help a little bit. Maybe it
would help if we took an example. Let's say, are you thinking
of a logging report where a field geologist is looking at core
that comes out of a drill hole or are you looking at a field
geologist's map having walked down a drift and started mapping fractures and rock characteristics?

DR. DEERE: Let's say one of the borings. You're going to have several 500 foot borings made early in the program, once we get site access on Yucca Mountain. Let's say that, boy, he found a zone there, poor recovery and fragmented material that to him shows it's a fault zone. Okay. In that case there, how does that really get jiggled into the--

MR. BLANCHARD: Well, we have a straight forward process, I think, that's probably similar to what you're accustomed to seeing and then we have another route which is an unusual occurrence route. In the first case, whoever the PI is that's doing that would be preparing his report, acquiring data, and then writing interpretations in that report. Every 45 days, some piece of information from that goes through a sweep and it goes into the local record center, and then when the report is finished, along with his interpretation, that is then delivered to the project to go through final review and release. Along with that, the raw data comes in, the actual logs and things like that. That goes into the central records facility. But, in the meantime, he's already put that into the local records facility and the central records facility. Then, that information is drawn from if there's numerical information by the people that run databases like the SEPDB
where they want to calculate mean or standard deviation, variance, things like that. If it's not, if it's more like a map, then it's used by those people in the RIB who want qualitative data. Now, there's general characteristics of the rock units from a stratigraphic standpoint or other features of discontinuities between one rock unit that weren't expected. That kind of information, maps that are made based on an interpretation, whether it's photo interpretation or core logs, those come out in our daily catalogs which occurs periodically and through this data committee, technical data management group. This kind of information is periodically reviewed and determined to be desirable attribute for the RIB because designers or PA people want it. So, it formally goes into the RIB.

Then, we have a procedure that we call unusual occurrences and that one, any time something significant that wasn't expected in the field is encountered, we follow what's in that procedure and that generally says, hey, if this is something that the principal investigator didn't anticipate and there's some reason to believe it could have an adverse impact on design or waste isolation or something of that sort, then let's raise a flag. Let's call in some review team. Let's take a look at what's going on. Let's try to decide whether we need to continue with what we're doing. Let's
decide whether we need to notify NRC of this occurrence. So, a course of action is developed based on a plan that's written, more or less, within 24 hours, you might say. I can't remember the time frame, but in a relatively short interval.

DR. DEERE: Is that up here amongst the letters?

MR. BLANCHARD: The unusual occurrence AP isn't AP-30 or AP-5.2. It's a different one. It's another route in case--

MR. RICHARDS: A way to think of that is that this other information change coming in here might serve to represent--that would be one example of other information. Other information also might not be unusual, at all. But, although it's somewhat obscure, that's a way to think about that.

MR. BLANCHARD: I don't know if we're helping answer your question as directly as we can.

DR. DEERE: No, you are. I just want to make sure that in such a very large program that we have and so much data being collected, so many different organizations going, that the effort in trying to make sure that we're going through the correct steps has one in it that does exactly what you've just described. You hit a fault, immediately it's an unusual occurrence or, I would say, it's certainly a significant occurrence for somebody to look at and decide what it's going to do and that information must get out, like you say, if it's
24 hours, great, or one week. But, that's the kind of stuff, what we're really, really interested in because that's the way the program is going to evolve. As soon as one finds one of those occurrences, what do you do next? Well, you review your plans up to that moment and say, well, we're not going to make the boring over there. We've got to come in now and come across here and see what attitude we have on that because maybe the first boring wasn't able to get enough information to determine its orientation and the people in hydrology are going to be very interested in what's the permeability characteristics of that and these are questions that want to be raised real fast, I think.

MR. BLANCHARD: Yeah, the creative and difficult part of that, I think, is trying to decide when is something you've seen an unusual occurrence.

MR. SHELOR: Can I offer some insight? It seems to me that by definition it's an unusual occurrence if it was not considered in the analysis that formed the basis for the design. In other words, if you run into a situation where your physical properties data exceeds the bounds that you used as the basis of your design, you have to stop and reassess that design and impacts on it.

DR. CARTER: Well, is this spelled out specifically? I'm somewhat familiar with DOE orders that relate to unusual
occurrences in the health and safety area. And, they're rather specific. You know, if exposures either do or are suspected, the amount is such-and-such an exposure, then you have to--

MR. BLANCHARD: Yes, it's not identical to that, but it's fashioned in a similar vein. And, if there's something in the RIB that doesn't provide enough information for the designer, I would think the first thing the designer would do or the performance assessment person would be to go back to the record and, when he looks in the records package, he's going to find probably a photograph of these features. He's going to find an actual drawing made by the individual that did the work. He's going to find a drill hole completion report or a core analysis report prepared by either that individual or some people that work for him. He's going to find a QA records package that shows what surveillances and what QA procedures were followed in the course of doing that work. And, he's going to find whether there was an unusual occurrence report filed as a consequence of that activity, too. All of that should be in the records package for that particular item, if it was a drill hole or if it was mapping along a face of a drift.

DR. DEERE: I was a little worried about your answer, Dwight, when you said that if it had been anticipated in the
design, then it wouldn't be called an unusual occurrence. To me, it's not a question of unusual occurrence, it's whether it's a significant occurrence. Because, usually, the designer doesn't expect a given fault at a given location of a given thickness. Now, he might when you drill for one that's been mapped on the surface, but still when he finds it, it's information that is so important that I think it's a significant occurrence, maybe not an unexpected occurrence.

MR. SHELOR: Right. Right. Well, rather than them to drill—for example, you have done your drilling. You have an estimate of what you expect to find and you start your tunnel boring machine and then you find something different. That's really unusual and you may want to go back and check your analysis that formed a basis for your design to make sure that you're still okay on the physical properties and the tunnel is not going to collapse on you or you have the right reinforcement on it. It's that kind of thing that you need to do. However, if in the analysis of the original design for the tunnel support, the assumptions were broad enough and whatever you find falls within that range, you may not have to change your design.

DR. CANTLON: We've been talking kind of at the show-stopper side of the continuum. So, let's go at the other extreme. What sort of process do you have to sort of look at
a economic component of the QA oversight? In other word, the
cost effectiveness of the program? Where do you hit that
diminishing return on accuracy? Is there some kind of a
screen of how much is enough? Anything--

MR. RICHARDS: I will take a stab at that, although I
welcome Don Horton's additional comments. To some extent, the
grading process addresses that. Although there is not a real
heavy-handed cost benefit, economic consideration in the
grading process, the grading process does consider the degree
of importance of some particular piece of work to the project
as a whole and applies controls, hopefully, commensurate to
that. Cost and delays are one of the numerous considerations
in there. But, as I said, it's not a real high profile
consideration.

Don?

MR. HORTON: The QA costs are so minimal, we don't even
worry about it.

MR. RICHARDS: Of course, another consideration is that
by maintaining an effective quality assurance program that's
going to insure that this program is, whatever the outcome is,
successful as opposed to unsuccessful when we come to
licensing. It would be a big problem if we came to licensing
and could not--if we submitted the licensing, could not defend
it. There would be a lot larger cost than whatever the QA
1 program consists of.
2 MR. SHELOR: I think that's a very important point and, 3 you know, in that context, not as far as Don would go, but QA 4 is a cost of doing business. It's a cost of doing this 5 business.
6 DR. CANTLON: But, it's like auditing. You can audit 7 every transaction that ever takes place except that it now 8 requires a total GNP to do it.
9 MR. SHELOR: Well, that's correct. But, at the risk of 10 getting NRC mad at me, let me relate to you my understanding 11 of their philosophy in overseeing our QA activities and also 12 at nuclear power plants. If they come in and observe an audit 13 and there is a problem, they're going to look at the 14 corrective action and they're going to see if timely action 15 was taken in correcting the problem. If it was, then they'll 16 probably drop it. If it wasn't, then they're going to look 17 more often in that area and they'll look for systemic problems 18 across the board and they will continue to audit problem areas 19 until they're no longer problem areas. Because you simply 20 don't have, anybody, sufficient resources to just audit 21 everything all the time. But, you do through the process--and 22 I think it's a very good approach that NRC has. They have 23 insufficient personnel to audit everything that we do, but by 24 looking at how well we're implementing our own internal
audits, they can get a good feel for where they need to concentrate.

DR. CANTLON: I take it there's no formal cost effectiveness study component yet in the QA oversight system? Am I correct on that?

MR. HORTON: Not really, that's correct.

DR. CANTLON: Okay. Thank you.

MR. HORTON: I wasn't being entirely facetious when I said that QA cost was so minimal. In reality, to the overall cost, it is minimal and it's come down significantly in the past year. There are areas that we can improve in and we're doing it.

I would like to address Dr. Deere's comment. I think it was about the plan or what happens if we don't get the right results. You know, each time someone performs some activity, they have this plan. They follow that plan on whatever work they're going to do. They have an expected results from that and what happens if you don't get those results. To me, it's just a continual feedback loop in everything we do. It feeds back in to what the end produce is that we're trying to get. So, if it comes out with the results different than what he had anticipated, it feeds right back into the overall system.

MR. RICHARDS: Another aspect about the cost effective-
ness, I mentioned earlier task focused surveillances. Both in surveillances and audits, we are careful to focus our activities on things that are apparently important to the project as opposed to everything, so that we're being effective in looking at things that are important to management so we can provide them that feedback for them to make decisions about things that are important.

DR. CANTLON: It was the absence of that in your diagrams that triggered my question. I didn't see that that was explicitly in your plan.

MR. RICHARDS: One comment to wrap up on this, somewhat explicitly here, some of the QA controls that are in here is, as indicated by these little parenthetical alpha-numeric designations, those are procedure designaters. The people who work on the experiments and collect the data have plans and procedures to do that. We have a work plan and a set of procedures for maintaining the technical database. This process, although it may vary from time-to-time, will have some kind of definition document about how the approach will be and the reference information base has its own set of procedures. So, there's a structure there.

So, to wrap up, the two main components that we, the project, are providing to the design organization as information that they can use as design input is the reference
information base and the ESF design requirements document.
And, I hope I've given you an idea of what's in them and how
we've controlled the work preceding what the design organiza-
tion will do.

Do you have any other questions?

DR. DEERE: Well, I think the thing that probably
triggered my question of a few minutes ago is in the technical
database, as you pointed out, if you have a numerical value,
why you can put it in. And, I think we have all of the
strength data of all of the samples that have been tested, we
have permeability data, et cetera, et cetera. But, it's much
more difficult, it seems to me, to be able to catalog in that
you have a fault so that's it kept up in front of people's
mind. And, I will cite DOE as an example of presenting us
several cross sections that we've talked about two years ago
when we were getting into the program and then we had another
talk on the Ghost Dance Fault and they showed the nice fault
and the offset of the formations and really triggered some
questions, obviously. And then, the next few presentations,
we got the fault was gone and it got lost someplace. And, the
designers and other people in the program were working as if
we had a perfectly known and unfaulted zone within the Yucca
Mountain block, not during certain ends in the boundaries.
But, that one disappeared. Well, I think they've been very
careful in the last year that they never show us a cross section that doesn't have a Ghost Dance Fault offset a little bit when they're presenting to this group and I presume to others. Because it's the qualitative data that isn't all that easy to get a finger on until you make the test if you do do a permeability test, although I guess if you put in core recovery or fracture frequency at the core, you would have a numerical value which would stand up as being considerably different than the rock above it and below it. And, that could be an indication, certainly.

DR. ALLEN: Other questions?
MR. RICHARDS: Well, I'm done with my information and--
DR. ALLEN: Well, I thought this was as if Al was talking.
MR. RICHARDS: I'm presenting the information for both Al Stevens and myself.
DR. ALLEN: Okay, all right. I thought there were two presentations.

This is also just one presentation, but two authors. Is that--
DR. DICK BULLOCK: It's one presentation and, if you want to hear more about QA and our shop, then Mike Regenda is here to give you more. So, I'll cover some of it and you be the judge how much more you want to hear.
I'm Dick Bullock from Raytheon Services Nevada and I'll be giving you the A/E's aspects of some of the same things you've heard earlier. And, I'm sorry to repeat the things, but it's from the A/E's perspective and it's what we do with the rules and the regulations or the requirements that are put down to us. In the first place, I will cover a flow chart. Ted has kind of stole my thunder in tabulating everything. So, I wanted to be different. I put a flow chart to show you the design process and it's a little complicated, but I'll try to show you how we apply our design procedures to control each portion of our activities in the design process. And then, I want to talk about the A/E's considerations in design and how they do apply as they would at a nuclear plant, but maybe differently than a normal A/E designing a mine or some industrial plant. This, we'll be covering here.

At the top of the chart, these two boxes pretty well represent—or maybe the top three there represent—what you've heard from the Sandia and what you've heard about the requirements documents that flow down to the A/E. As Ted said this morning, these various documents flow to us and we have a right to—in fact, we have an obligation—to read them, be sure that we can design through them, be sure there's nothing in it that will create a problem for our design, and we finally then accept them. If there's something that we feel
that we can't design to or we have a little problem with it, we'll work through the--resolve the consideration and it will come back to us and then we'll finally accept it.

Now, we do have this iterative process described in one of our procedures. I know these numbers mean nothing to you, but it just shows that they are numbers of our design procedures. Design methodology describes how we take care of that. Also, once we accept all those design inputs--and they come in volumes and we literally turn them into another volume--but, in the process, it goes through our--we baseline these and put them into a tracking mechanism, so that every design input that we use is tracked all the way through the design process to the design output. And, it may splinter and go into many design outputs, but we have to track it because that's a part of our requirements. So, that is why it is controlled by configuration management. That's our internal--ours and the configuration control board.

So, the information comes down to us in various documents as was described, the RIB or the ESF design requirements document. It flows into us and we prepare what we call a basis for design. On some companies in industry, they have something like this. We called it design memorandum at the company I worked for before. But, it's one document that all the engineers can come to. They don't have to
interpret from 10 CFR 60 or from anything else. It's all right there in front of them and it's already been interpreted for them and everybody knows to use this piece of data for that type of work. And, furthermore, it shows that the A/E has done his homework and can respond back in paper for his engineers to actually have something to work with.

So, the basis for design is learning an internal document for the A/E's and you also bring in other design inputs. MSHA regulations, we have to follow them. OSHA regulations for the surface, we have to follow. They're in there. Many of the ASTM standards or whatever IEEE standards we may be using, it will be in there. So, whatever we want the engineer to follow, it will be in the basis for design. And, by the way, there's a procedure which controls how we prepare this document.

The other document that Ted mentioned earlier was the engineering plan and he's gone through some detail describing to you what the engineering plan is. So, I'll not do it. But, we also have a procedure which tells us how to prepare the engineering plan. So, every time we prepare one of these for whatever design purpose, it's always done the same way and the records are kept on it.

At the same time we're doing our engineering plan, we're also working on grading packages for this activity or
these activities that we're going to be carrying on. And, you also heard what the quality assurance grading is and you'll hear more about it tomorrow. But, these packages that are turned into the project office, just as the engineering plan is, we can't proceed with our design until we get approval on both aspects, the QA grading, as well as the engineering plan.

And, finally, when we do reach the approval, we can proceed with our design process and really begin our design. And, these boxes down here represent the design process.

Whether you're doing analysis which would lead into a tradeoff study which leads into making drawings or specifications, whatever it is, we have procedures that tell you how to do it and how to document it. And, our engineers must follow these things. First of all, we have a configuration management procedure so when something reaches a certain point, it's baseline. Design analysis, design interdiscipline review, and intradiscipline reviews are spelled out in our procedures, processing the documents, the record keeping, and so on.

We also have procedures talking about interfaces. They're sub-tier to the APs that were spoke of earlier, but they are in our shop. We handle the interfaces with other participants. And, we also have a software quality assurance plan because we do use software to design quality affecting items. So, we have a software quality assurance plan that was
approved. And, we have some six implementing procedures that
we follow in verifying and eventually validating our software.
Now, we have a considerable advantage over the PIs. The PIs
are normally developing software from scratch. We're using
software off of the shelf. Nevertheless, we still have to
document the life cycle of that software, even though it was
developed by someone else in industry and maybe used many,
many times, like FLAK used all over the country. We still
have to go through the process of documenting it for our
record keeping.

DR. DEERE: Where does the PP-03-13 or 03-10 come from?
What's the origin of those?

DR. BULLOCK: We had to sit down and write procedures
based on the upper tier documents. I was not here when the
originals for Fenix & Scisson were written, but they're
simply--they're basic procedures that you would follow in an
engineering design shop except the documentation many times is
different. I mean, you're following the upper tier document
--I was trying to think of an example. Well, for example,
someone brought up about the engineers' notes. An engineer
may be going through calculations that we've all done. If you
sit there and you scribble your notes and you work in a hurry,
you come up with an answer. Well, another engineer can sit
down beside you and check those notes and you're sitting right
there with him and he can probably follow through it and check
your work, but that's not good enough. That's got to be
microfilmable in order to preserve the record. And, so it's
little things like that that are in the procedures. They're
part of the flow-down requirements. That's just an example.
I mean, there's lots of other ones there.

MR. HORTON: The requirements come from their QA program
description document and these are the implementing procedures
which describe the exact process for design review, everything
else that they have.

DR. BULLOCK: Going back to the original bullet here, in
other words, all this process flows down from the QARD which
is their document, which flows to our document, the QAPD, the
quality assurance project design description, and then it
flows into our procedures. We implement what's in the QARD
and the QAPD into our procedures. But, there are many other
things that get into them also that are not necessarily in
there. Good engineering practice, we would put in there also
if we want something done a certain way.

DR. DEERE: I think these design reports are similar to
what are used quite often in some of the hydroelectric
projects. In making the proposals for the projects, some
engineering firms have as part of their proposal a certain
amount of money and time assigned to prepare the design
reports, a design on the spillway, a design on the dam, a
design of the turbines, et cetera, et cetera. Others do not.
So, they have a lower price and the owners often go with a
lower price. And, being on the board of consultants that
looks at these things over a period of years on many different
projects, what you find is that the owner is shorting himself
considerably if he doesn't require the design report which
document the alternative studies they have made, their reason
for selecting this, the calculations showing it, two or three
drawings on the back that document it. And, as you say, you
have a baseline document there and it stands forever.

DR. BULLOCK: And, also in the engineering plan, we are
bidding a job, but in a sense, we're telling DOE, okay, you're
giving us a general scope of work, now we're coming back and
giving you our interpretation of what deliverables there will
be in this scope of work, and they'll spell it out in the
engineering plan, then we'll estimate the man-hours for each
deliverable. In the case of the studies right now, there's
190 of them. We'll estimate the man-hours and we'll cost out
and we'll budget that and that's what in the engineering plan.
They see from our point of view what it's going to cost them
to do this piece of work. So, we do go through this.

DR. CANTLON: Before you take that off, looking at your
quality assurance grading there, could you give us some kind
1 of a feeling, rough ball parks, of what percent of the process
goes into one of the grades versus another? Is that a
significant sorting action that takes place or is it
predominately going one way with a rare exception getting into
one of the other grades?

DR. BULLOCK: I say we tend to err to be conservative.
We tend to err to--we sure don't want to slight something if
there's a chance that someone may construe it or twist it
around to be something that you might get away with it. And,
someone mentioned earlier that if you're going through a
design process, it's a little bit difficult to work the two
sets of procedures, one that isn't QA and one that is. And,
your training engineers--and these engineers get a mindset. I
mean, engineers are regimented and they'll follow a set of
regulations that you want them to follow in doing their work
and you're better off to let them go ahead and do it at the
conservative standard. And, that's my opinion.

MR. SHELOR: I think it's also important to point out
that the grading process that's being implemented now doesn't
result in a grade like 1, 2, or 3 or A, B, and C. The
controls are selected from the entire suite of QA controls
that need to be applied to that particular work activity based
on its intended use. So, there's not one that's called QA
work or QA level 1, 2, or 3, being different QA controls. The
grading process assigns a QA that holds to the work based on what its eventual use will be.

DR. DEERE: Like this would be 3, 6, and 14--

DR. SHELOR: In terms of criteria. For design, you know, you can go through the suite of 20 criteria which they've done and identify half of them as being applicable to the design effort itself.

DR. BULLOCK: If you were in Title III where you were constructing an inspection, it would be another set for inspection and corrective action and things of this sort.

MR. BLANCHARD: All right. I might be able to give you an example of QA and a non-QA graded event. Suppose someone was going to prepare an analysis of some mapping along a drift and provide that as an input to the design team. And, in order to get that mapping product finished, they call out our process. Our Q process calls out the review must be multi-disciplined and it must follow an AP that we have called 6.04. That requires a multi-disciplined team of people who didn't author the report to review and comment on that report. It requires that those people show evidence in the record that they were adequately trained, educated, had appropriate experience, and if there's any special procedures that they were trained in that before they reviewed the report. And, that all comments on that report were documented on a special
1 form and that the comments went back to the author, that the
2 author worked off every one of those comments by either
3 talking to the commenter and getting an amenable resolution in
4 his written report or by making a change or by saying we can't
5 reach an agreement, let's go to our boss and get our boss to
6 get in the picture to see if we can resolve that comment.
7 And, that could go all the way up the chain. In the end, when
8 that report is finished, along with a data package, it comes
9 in to the designer through these record keeping processes and
10 databases and things like that. But, the actual report comes
11 in for project approval with the records package with it.
12
13 Now, that's a very structured, very documented
14 process and it allows you 10 years hence, when all the people
15 will have left the project that are involved in that
16 particular activity, as Dwight mentioned this morning, to go
17 back into the record package, pull it out, and see who did
18 what, what their training was, what they said, what the debate
19 was, whether they were all resolved or not.
20
21 If, on the other hand, you were off the site and all
22 you were trying to do was to decide whether to run a road
23 around the right or the left, the north or the south side of a
24 mountain, and you were going to cut part of a slope off, and
25 it was outside the control zone even, couldn't possibly
26 conceivably have anything to do with the design effort on the
repository or waste isolation, then you might not want to
spend the time and money to go through this regimented 06.04
review. What you might have is the guy that was doing the
grading and the geologist that was helping do the routing on
that get together and talk about it, the geologist write a
report. It would be reviewed by a supervisor and it would be
a letter report to go to the road construction group and the
designer of the road siting and that would go in their package
and it would be in the system, but not in Q, the formal record
system that's there. If you want to retrieve it from the
letter files, you know about the subject and you do a sort on
subject or you know that the letter is XYZ #227 dated such-
and-such. You could go back into the administrative records
and pull that out, out of either the design team or the
originating organization. But, that would be all that would
be there unless you actually asked for something other than
that.

And, so from one side, what I've given you is a
spectrum of, one, a full QA applied program to the other one
which is let's don't go through this heavy regimented Q
system, let's just use, more or less, administrative protocol
for getting the input to the designer for whatever he's going
to do because it doesn't matter in terms of safety and health
with respect to the NRC licensing process.
MR. SHELOR: That's correct and that would be pointed out in the grading report for that activity.

DR. DEERE: It would be rated how?

MR. SHELOR: It would be called out in the grading report.

MR. BLANCHARD: The grading report would explain whether you were going to use AP-6.04 or whether you were just going to write a--have the siting geologist write a letter to the designer of the routing and the construction crew for how to cut that slope.

MR. SHELOR: Yeah. Part of the philosophy there is that on every activity, there is a conscious decision made and recorded on how you're going to do it.

MR. HORTON: I would like to make one final comment about this grading. There's one step that's involved prior to grading that is very significant. That's an evaluation to determine what type an activity this is, whether it's on the Q list or whatever. The grading comes in after that. If it's determined to be important to waste isolation, et cetera, then the grading is quite important. If it comes out of that, then it's management controls in many cases then, what management decides they want to put on it.

DR. BULLOCK: Okay. And, you're going to get more on grading tomorrow. I was down here where we had produced our
design output documents and they're ready to move on. One thing, the A/E has a responsibility for the verification that Ted also described this morning and we have a PP which describes basically the four processes. We intend to use design review on everything we can see in sight right now. There might be some computer work that must be verified or at least validated by peer review, but I think primarily design review will suffice in every case.

Once it's gone through design reviews or verification, then we submit it to the project office for their acceptance. They, in turn, are ready to do their management or technical review. In which case, there undoubtedly will be people who will find things that they--well, back up in verification, let me go back there for just a minute. One of the things that the outside independent people will be looking at is does it meet the requirements? Along with that, from the way I see it, any performance assessment which you have started in the design process, you hope to involve the people doing performance assessment before you get there, so that by the time they get down to verification, they can finalize on performance assessment and the verification, also. That's what we would hope for. And then, as there are changes in the design review process--maybe they missed something back up there and there is a requirement that we've
1 missed and we must go back through, resolve the comments on
2 that that were made, adjust the drawing or the calculation,
3 what it was, work the interfaces if there's interfaces to be
4 worked, go right back through the same process, and come back
5 through and correct the design. Go back to verification and
6 bring it back further. So, it's an iterative process, but you
7 must go back and use the same process for design that you used
8 originally.

Finally, you have an acceptable design which is
9 accepted by DOE, and at this point, the design, as I
10 understand it, is accepted and then it will go into the
11 configuration control board for baseline. And, these are all
12 spelled out by various procedures we have in place.

Now, I'd like to talk a moment about how we are like
15 the nuclear industry in that we're working from upper tier
16 regulatory system requirements. In our case, we, of course,
17 can't do anything that would preclude the potential repository
18 from meeting the system regulatory requirements from 10 CFR 60
19 or 10 CFR 960, anything in the ESF that would mess up the
20 potential repository. I think that's pretty obvious we have
21 to do that. And, in particular, must design the ESF so as to
22 limit impact on waste isolation capabilities of the site. A
23 case in point might be in a mining situation. If we were to
24 drive tunnels as long as we're proposing to drive them and
coming across on the level to meet them, no doubt, we would want to put down some ventilation raises if this were normal industry to get some ventilation. We wouldn't even consider doing it in this case because of the potential messing up the site from waste isolation.

DR. DEERE: Working on the Channel Tunnel, I can say we don't ventilate--

DR. BULLOCK: Well, that was another unique problem. No, but a lot of times in mining, at least, when we've driven two and three miles out, every 4,000 or 5,000 people put out ventilation rigs and this helps your ventilation. It lowers your power cost and that's the way to do it. We certainly wouldn't consider doing it here nor the Channel.

The ESF will function primarily for site characterization activities and, as such, we can't allow testing to testing interference or construction testing interference. And, it's the A/E's job to lay out those testing alcoves so that one test can be going on while another test is going on without interfering between the two. Or, if the constructor is still constructing and he's constructing the next alcove, that he's not interfering. And, that's our responsibility to lay these things out and that is spelled out under one of the requirements. So, this is things that make it different than laying out a normal mine.
The ESF will be designed, as will the potential repository, to meet structural stability criteria with superimposed thermal loading. I don’t know of any mine anywhere that’s ever been designed to have thermal loading come on in the future. Some of them do due to the oxidizing ore bodies, but they usually aren’t designed that way. So, that makes it different than normal industry, but again it’s something that’s given to us by the requirements.

This last one here is a Catch 22. The ESF will be designed for very limited data. The design must not preclude the capability of potential repository to meet the system requirements for waste isolation. In other words, we have to design the ESF to withstand the loads as if it were the repository. Yet, we don’t have the information from the ESF on the heat loads that will be generated and how the rock would react so we can use that information in the design. So, what we must do is design it so that the ESF can be hardened or can be strengthened at a later time once you learn more about it. We can’t do anything to that structure that will preclude future stiffening or hardening or reinforcing of the ESF as they learn more about it. So, it’s different.

Major ESF design considerations from a quality assurance point of view, again the same things you heard this morning. Certification of qualified personnel performing
work, this is required, I'm sure, throughout the nuclear industry. The degree to which we do it is far more than what would be industry practice, but it's--and, by the way, all these things are good and we do them, but they are different than industry practice. Detailed precise records required, we do keep a lot of detailed records and we must to make a traceable record for everyone to see throughout eternity.

And, the QA grading process where I talked about design verification. In industry, you normally have the client's people in your shop and they verify as you go along and then finally you come up to the end of the design and the upper management usually examines your work and says it's okay if all the other people have said it's okay. You don't really bring in--sometimes, you do, but not often, you bring in outside people to re-verify to see if it meets those special requirements.

Tracking of all design inputs and design outputs is an excellent idea. Unfortunately, a lot of industry does not do this. In the nuclear industry, I'm sure they do all these things consistently. Verification and validation of computer software codes, we do an exhaustive effort, I think, of verifying our computer codes and I was made to realize it. For the IDS, we will do our own code development, we meaning Raytheon. We have two different groups in Raytheon that are
specialists in data acquisition known as Seis Corps and the
other one is the missile systems division for Raytheon. These
people are very accustomed to developing software and
verifying it. In fact, I think they helped write the book in
some cases because we wait for them to see what they thought
about doing the software coding work for the data acquisition
system and they said, well, sure, there's nothing to it. You
know, they're very accustomed to it. And, they're the same
people that programmed the Patriot Missiles. So, I guess they
know what they're talking about. Apparently, this is a very
common practice in the missile industry to use software
verification and validation and they've been doing it for
years.

Training, record keeping, and compliance monitoring
is very detailed and it's more than you would find in all
industry, but certainly nothing more than you would find in
nuclear industry. Finally, the interfaces, cost, and special
design considerations, as far as the ESF to mesh with the
potential repository, that's the point that was raised this
morning. The ESF people, the A/E must be in contact with the
thinking of the conceptual design people. In our case, we
work with Parsons-Brinkerhoff who did the conceptual design at
least for the underground portion and we work with them very
closely. We talk to them every week. We know what they're
1 thinking. They will work through a process while we're
2 working through design study and come up with interface
3 drawings for us, and I assume that in Title II there will be a
4 similar type of interplay or reaction interfacing with them to
5 carry us on through the Title II design. So, they will be
6 right along with us.

7 The ESF design to meeting the needs of the research
8 community, we have to remain flexible. This was also brought
9 up this morning, that the PI is looking for new technology all
10 the time, new instrumentation, new methods of dig, gathering
11 data and transmitting data. And, ESF designers have to stay
12 alert to this and we do this through our interface LANL and
13 they actually interface through the PIs, but we stay in touch
14 with them weekly to make sure that we have the latest
15 information that they have from the PIs about what they want
16 to see in the ESF.

17 As to quality assurance, what they do for us, they
18 review/approval of the following types of documents: analysis
19 and studies; drawings; technical specs; and computer software.
20 I want to point out when we're in a design mode there are two
21 or three QA people. They don't work for me, but they're on
22 the design floor and I expect them to be on the design floor
23 every day. And, they're working with those engineers to make
24 sure that they're not missing any t's that need to be crossed
and they are signing the right document. They're using the right form where they should use the right form. And, these people, you could call them surveillances, but they're not really formal surveillances, at all. They're out there working with the engineers because that's where quality is generated, on the design floor. And, these people are out here to make sure that nothing gets started wrong. It is hard to go back and correct. So, we expect to have Mike Regenda's people working with us every day and then, of course, he has a different group of people that come in and do audits and surveillances on us. Now, if you want to hear more about this process, Mike's prepared to talk about the quality assurance program and I assure you it's a good one. And, we don't mind working through it. It's just a part of the job.

Any questions or would you like to hear more about the quality assurance?

MR. MCFARLAND: I think you mentioned one task would be to design the test alcoves.

DR. BULLOCK: Yes.

MR. MCFARLAND: Now, in recalling previous discussions, particularly from Dr. Cording, one of our--

DR. BULLOCK: Dr. Cording?

MR. MCFARLAND: Yes, one of our consultants.

DR. BULLOCK: Yes, I know him.
1 MR. MCFARLAND: Made the point that one of the great
2 advantages of the ramp was to be able to build alcoves at
3 points in the excavation that would offer conditions that
4 would make you want to stop at that point and go in and do
5 tests. That you would have the degree of flexibility in
6 testing that the ramp would offer. If you design those ahead
7 of--I don't understand how you can design them. How do you
8 take account of that flexibility?
9 DR. BULLOCK: Okay. Well, what I was really referring
10 to, there's tests that will be going on in the ramps
11 themselves and I was not referring to those. I was referring
12 to the alcoves in the main test level area. And, there are
13 predetermined tests that are going to be run and we have to be
14 sure those tests are far enough apart and out of the way of
15 construction interference and that's what I was talking about.
16 DR. DEERE: You do have the flexibility, I presume, that
17 if you want to take off and go over 500 feet and put an alcove
18 there for some particular reasons which was not in the study
19 plan, but something that you saw or something that was brought
20 up in a meeting, this is what--you know, when we get so
21 prescribed that we have everything down and this is what we're
22 going to go toward, but yet there may well be where you say,
23 oh, but if we could do this, we could gain this additional
24 information. Now, that's going to cost a little bit more
money, but it may well be very, very worthwhile.

DR. BULLOCK: If something like that—and, I'm sure that LANL would be the first ones that would be going to DOE and saying, hey, we just discovered there's no other way we can get this information. The PIs say we have to have it. We've got to test this area which is 500 feet away. And, we'd like for you to direct the A/E to do that. That's kind of a special case. It would have to come through DOE, but we certainly would be glad to lay it out for them.

MR. SHELOR: But, all of that would be part of our change controlled process.

DR. BULLOCK: Yes.

MR. SHELOR: It would be a change and the important part there is that the change would be identified, be technically reviewed, and the impacts and cost and schedule evaluated.

MR. BULLOCK: See, you remember when Richards was talking about his appendices on the ESFDR, Appendix B and C, I believe. B is the one. Well, these test requirements are all spelled out. Well, this one you cited probably wasn't in there because they just realized there's something down there that happened that caused them to have to do it. Therefore, they would need to go through the change control process and give us some direction in writing through the change control board that the project office wants to go ahead and do that.
MR. DEERE: Because you can't possibly lay out a perfect exploration program on the base of the information we have now, it has to be one that has the flexibility that we can make another boring that hadn't been counted on or another branch-off or something that hadn't been counted on.

DR. BULLOCK: Well, now, in that aspect, we are trying to lay it out so that we have equal amount of room to lay out future tests. We don't know what those tests are going to be, but they're spaced there in the layout we're making at this time. They're spaced to do at least 100% duplication of the test that you are laying out. At least, in this configuration, we have room to do that. In some of the other configurations in the earlier iterations of Title I, this was not done. There really wasn't that flexibility to do these things as you might want to do them.

DR. DEERE: Thank you.

DR. ALLEN: Other questions or comments?

(No response.)

DR. ALLEN: Okay. Mike, you're up.

MR. MIKE REGENDA: My name is Mike Regenda. I'm the Manager of Quality Assurance for the Yucca Mountain Project for Raytheon Services Nevada. I've been on this program now for about six or seven years. So, I'm not exactly a virgin on it.
What I'd like to cover—you've heard so much about it. Just about everybody has covered everything about the overall QA program. So, I want to try to limit mine to a certain area of, okay, where are we directly involved because we're a little different in the overall QA organization in that a lot of organizations are doing a lot of overview by surveillances and audits. We're different. We are very intimately involved with the actual project people which Dick has mentioned. So, what I'd like to cover basically is the organization chart, the criteria for QA, the QA design review process that we are intimately involved with, our QA computer software, and then our audits and surveillances. That particular area.

First of all, I'd like to give you an overall view of Raytheon Services. As you've heard, Raytheon Services took over Fenix & Scisson, which I was originally with Fenix & Scisson and the H&N organization and it became Raytheon Services of Nevada. This particular thing, we have a general manager and coming down—I just want to try to cover some areas—coming from general manager, we have the technical project officer which is Dick Bullock. And, he has support from the program support people which are basically our actual human resources and money people and what have you. And, here, we have also a separate group for environmental safety
1 and health that support him when he needs some additional
2 help. Underneath Dick, we have the actual facilities design
3 manager, systems engineering, field operations, and a project
4 administrator. These are the people we work with. Going over
5 further here, he has an IDS, integrated data system, project
6 manager who actually has been involved with the computer work
7 and he reports to Dick with a dotted line to the general
8 manager. Over further here, we have the quality assurance
9 manager and that's a new man that just came in from Raytheon
10 Services who has all of the actual Raytheon organization which
11 is Johnson Island, Nevada Test Site, Tonopah, and the Yucca
12 Mountain Project. Underneath him is myself as a quality
13 assurance manager. I have full control of the quality
14 assurance program with very little interference except when I
15 need further support which I have had great support and I have
16 no troubles with Dick in actually working with him.
17 This is basically the organization as we have it for
18 reiterating a little bit showing where general manager,
19 technical project officer, field operations. It basically
20 shows the organization here. I have a manager of software and
21 he's stationed right now at the missiles system division in
22 Massachusetts and he will be coming on board when we start
23 getting heavily into the ideas or he will be working with us
24 from that particular thing. But, he does report to me. I
1 have a manager of quality assurance engineering that works
2 directly with our people, Dick's people. You heard him say I
3 have people assigned directly working with him intimately. I
4 have a manager of audits and a manager of quality control.
5 This is once we get in there and start building it.
6
7 The next thing is criteria for QA. Okay. How are
8 we set up here in our program? First of all, we have the DOE
9 QARD which is our guiding Bible here. From that, we had to
10 come up with a program description of how we would meet all
11 these requirements and establish a QA program. This we did
12 and the program has been approved now. Our QAPD covers all 20
13 criteria now. It used to be 18. But, it covers all the
14 criteria and we, in turn, have to submit that to our customer
15 here, the DOE, who has approved it.
16
17 Now, some of you asked where did the project
18 procedures come from. This is where it comes from. In other
19 words, Dick has to have project procedures to meet our
20 program. On top of that, I have to have procedures that's
21 going to implement it. These two procedures implement this
22 thing and over here we have a software. These three
23 particular types of documents implement our QA program.
24
25 DR. CANTLON: You commented your QA program had been
26 approved.
27
28 MR. REGENDA: Yes.
DR. CANTLON: Approved internally with Raytheon by DOE, by NRC--

MR. REGENDA: Oh, no. By DOE completely. Before that, we had two approved programs. F&S, we had our approved program and H&N had an approved. Then we had a transition period. The transition period, we worked out time factors and we went into a transition period and changed our procedures into RSN which we're still working on, but our program has been changed and they've approved that.

When does quality assurance get in here on design review? These are three areas we cover. Let me point out one thing. These are not the only areas we get in. We are intimately involved in all design control processes. In other words, all those procedures you saw Dick list, I'm limiting mine only to these three. We review every one of those procedures and basically approve. In other words, we have an agreement here that I review each one or my people review them. So, in the case, we are intimately involved with everything that goes on in the actual project.

Okay. Here is an example of design analyses and studies. Again, we're just showing--this basically is the project procedure that tells how to do an analysis and how to do the studies and what have you. We, in turn, have a procedure how we verify this. Now, this particular one covers
all three of the areas, but we use checklists. In other words, a man has to go in there and he checks each one. On top of working with the individual, once they start doing it, then we come down with a checklist and verify that everything has been done. The checklists become quality records.

The next area that we cover in design review are specifications. Here again, he has a procedure for development of specifications and again how we do it. We review and live with them on actually preparing specifications and make sure that all quality requirements are incorporated and they're passed down either in the input documents or whatever is required for that particular area.

The same thing goes for the drawings. I might point out also, as I said, on the drawings, here we go through this preparation control and verification. QA signs off on all drawings. We don't just review them, we approve them. Until we have signed them and approved them, they don't go out. So, that's why I say we are intimately involved in an actual project.

Now, this one, somebody keeps asking, software. Dick went into this thing, but in our software review, these are basically the five items that we look at, that we will look at; in other words, the software requirements package, the verification and validation plan, hardware certification,
software, and the use. We will have people that will be following through again utilizing checklists. And, as an example, here's some of the actual procedures that are involved in this particular thing. The requirements are basically spelled out in those various project procedures and our verification again is done by our 19.1.

Finally, as a part of the overall verification and what do we do in a design process, we have audits and surveillance. Somebody says how often do you do audits? We try to—not try, we do it. We do a manual audit of every criteria in the various areas. We do at least one annual. On top of that, we do many actual surveillances. Our surveillances cover all the actual actions being done by the engineers on those various PPs. We may decide, okay, this week we'll go in and pick three PPs and we'll go in detail. Again, these are basically verifying that they are working to the QA program. And, again, as I say, we may do something in the neighborhood of 20, 30 surveillances, but we'll do one full one—now, this one audit may involve two or three mini-audits. On top of that, we also have a management assessment that Dick is required to have annually. He brings in an outside consulting firm or if we can use somebody else from Raytheon that does a management assessment of the QA program to see that we are actually living up to it. Of course, then
we have our friendly DOE here that's there quite often. Every
time we turn around, they're either doing a surveillance or an
audit and I think our friendly NRC also joins us.

So, gentlemen, that's basically how we overview the
overall design process at Raytheon. Are there any questions?

DR. DEERE: Would it be possible to get a set of those?

MR. REGENDA: I offered them to them.

UNIDENTIFIED SPEAKER: We're having that made right now.

MR. REGENDA: You're having that made? Good.

DR. DEERE: Fine. And, now the second question.

MR. REGENDA: Yes, sir?

DR. DEERE: Is it possible to get a set of all your
procedures, your PPs this, and PPs that?

MR. REGENDA: I think--well, let me say one thing. A lot
of these procedures are still in draft form because up to the
transition phase--we're in two phases. We need a certain
number of procedures by October--no, April 1. That's for the
general arrangement type things. Now, we do not need the
others for Title II design until October 1. So, we're in a
two phase process. But, I'm sure that through DOE we can get
you the actual procedures you need.

MR. BLANCHARD: Don, are you interested in just the
Raytheon procedures or--

DR. DEERE: Well, at the moment. Since the shaft is--or
DR. ALLEN: Since we're getting the shaft.

DR. DEERE: The study facilities--

MR. BLANCHARD: To have a complete set, you'd want the hierarchy plans that called for certain procedures.

DR. DEERE: Yes.

MR. BLANCHARD: Then, the enabling top level procedures which have been referred to here as APs and things like that. And then, next level procedures which would be PPs or whatever.

DR. DEERE: Right. We'd like to have a set of those, I think--John, wouldn't you agree--in our library back in our office. So, let's say we're going to take a visit to your design shop in a couple of months. We'd like to be able to go through before we come out these listings--not only the listings, but actually read.

MR. BLANCHARD: Are you asking to be put on the control document list so that you have an update--

DR. DEERE: No, no, no. I think we are. I think we are.

DR. CANTLON: The central office.

DR. DEERE: The central office, I think--

DR. CANTLON: Not us, individually.

MR. BLANCHARD: Just for the Raytheon?

DR. DEERE: Well, that--
MR. HORTON: You know, we've been looking for an
opportunity to include you in our audit program.

DR. DEERE: I'm afraid I'm on it already in my house and
I'm still looking for something. So, that's why I want to
make sure that it goes to our library. So, it's readily
available to our staff, as well as to the board members when
they come in. I don't know how extensive the thing is, but I
would rather imagine that we do need it all.

MR. HORTON: I think that we can discuss that with you,
Dr. Deere, and whatever control procedures that you would
like, we'll work out something for you. But, keep in mind
there is a responsibility to go along with that and we might
have to come in and check on you once in a while.

DR. DEERE: That's fine. That's fine.

MR. HORTON: And, you know, NRC, Bob Bernaro would like
an opportunity to come in and look at you, too.

DR. DEERE: We'll talk about this in executive session.

MR. HORTON: And, Susan Zimmerman from the state.

MR. REGENDA: Of course, it's up to--let's see if you
keep these things up to date.

DR. ALLEN: Could I ask a question to get your general
feelings on this and I think the DOE people might also wish to
respond. Outfits like yours seem to find it possible to live
with QA without great trauma. Now, I've talked to many
1 people, scientists working with individual companies, many of
2 whom don't like QA and many of whom help support it. They
3 still say it's no big deal. Somehow, we manage to work with
4 it. The Government seems to have a different experience, in
5 general. It's traumatic. Why is this different? Or is my
6 perception wrong?
7 MR. REGENDA: One of the reasons it's different is
8 because a lot of people still have the idea QA is nothing but
9 a policeman. And, here they are, they say gotcha. And, so
10 they resent that. A lot of resent being regimentized saying
11 you've got to have records. If you hit some of the long-
12 haired scientists that have been working all these years and
13 doing everything by a book, you know, you say, well, good,
14 your book, you haven't been able to produce. Oh, I can't do
15 that. I'm not going to give you that book. That's my private
16 book. But, there are more demands on the actual people to
17 have a documented program. The biggest part of it is that
18 they resented this idea of being told you have to have
19 something and you're a policeman. Here he comes. Here comes
20 that QA guy with that white hat he has on. He's out to get
21 me. And, that's what happens with audits. Unfortunately, a
22 lot of auditors still think they have to find something or
23 they haven't justified their existence. Where instead of
24 going in there and saying, hey, you have a good program, but
you do have--I can go into any place and find something wrong, but how bad is it?

So, to try and answer your question--and maybe they can give us some more--it's the idea of being a policeman, I think, is the greatest resentment.

DR. CANTLON: Don't you think also there's an element that Government has regulated the private sector for many, many years. Government is not used to being regulated itself.

MR. REGENDA: Very possible. And, I've been on NASA programs, as well as I spent 10 years with DOD, the chief of inspection for Army Signal Corps. So, I've lived on both sides.

DR. ALLEN: Do you have any thoughts on this, Don?

MR. HORTON: Well, I'm relatively new within--

DR. ALLEN: Well, maybe that's one of the reasons. Maybe, it was just as traumatic 10 years ago for you as it is now for the DOE. It's just--

MR. REGENDA: I've been 30 years in QA.

MR. HORTON: I think that it is a new way for DOE. Within DOE itself, OCRWM has a much broader program than many other facets of DOE. They're starting to come around, you know. For a long time at the Nevada Test Site, they didn't want anything to do with our QA program because it was too rigid for them and they were afraid that the NRC might get
involved, et cetera. But, you know, slowly, they are seeing that possibly in the future they're going to be regulated much like we are and they're turning their program around and it's meeting many of the requirements that we have. And, the same way with the other facets of Department of Energy. But, I think, as you stated, it's very hard for the regulator to be regulated.

DR. ALLEN: Well, also, it's certainly true that the DOE activities include a much greater part of sort of research, basic research, than does anything being done by most of the contractors. That, itself, is quite a difference in the kinds of people that are being subjected to QA procedures.

MR. BLANCHARD: Clarence, I'm sure there's no one answer to a question as resounding as this. But, some agencies, some Federal agencies, carry out technical work themselves, as well as asking contractors to do work. For instance, the years I spent with NASA, there were some field centers that had groups of engineers and scientists on unmanned missions that they wrote their quality assurance program that abided by the NASA hierarchy of QA documents, they wrote their own procedures, they had their own audits, and they had to demonstrate the same kind of things that the aerospace contractors had to demonstrate to show that their booster or their payload package was okay. The Department for many years because of
the way it was formed from ERDA and then AEC before has had in
the past a general operating philosophy where it was just a
few, more or less, administrative contract managers overseeing
a large facility that was managed and operated by something
called a management and operating contractor, like a Union
Carbide or whoever the organization was, but they were a
complete entity that was operating the facility, whether it
was Nevada Test Site or Rocky Flats or Fernel or wherever,
like Savannah River, Union Carbide down there. Well, they had
the engineering culture, the administrative, the technical
accountability, and what they were doing was carrying out
management instructions and fulfilling a contract requirement.
And, the Department group was not doing anything that people
would call quality affecting. They were basically providing
management oversight and dollars so that the facility could
operate. When the Nuclear Waste Policy Act was passed, this
particular program moved to the forefront of the DOE programs
where it had a measure of accountability in becoming a
licensed applicant to the NRC. This called for significantly
different perspective of the way the DOE civil service
engineers and scientists and management interacts with the
body that's going to issue the license and calls for a
different role for the Government than just asking many
different contractors to come in and do their thing. And, so
1 I think that shift in culture has been necessary as a
2 consequence of the passage of the Nuclear Waste Policy Act and
3 there's been growing pains in recognizing how to do that.
4 And, even now, I think we're still learning how to do that.
5 Don, would you say that's fair?
6 (No response.)
7 DR. ALLEN: Any other questions or comments?
8 (No response.)
9 DR. ALLEN: We're exactly on schedule. We'll take a 15
10 minute break.
11 (Whereupon, a brief recess was taken.)
12 ROUNDTABLE DISCUSSION
13 DR. ALLEN: Okay. May we reconvene? I hope the
14 alignment here doesn't indicate it's us against you. May I
15 also ask that since we have a smaller number of microphones
16 than we do people at the tables that those of you who are
17 speaking lean over to a nearby microphone and announce
18 yourself for the help of the court reporter here.
19 Let's start off by diverting a little bit away from
20 the sheet here that we just passed out and let me ask Don to
21 introduce a question here.
22 DR. DEERE: A question was raised at the Senate hearing
23 last week, essentially to Bob Bernaro, as well as to me. Is
24 the DOE ready to start work at the facility at Yucca Mountain?
And, are there any known disqualifying features on the basis of the current information? That question also was asked to the Admiral and the Secretary of Energy and I think some of the Nevada delegation also had some comments about it.

Both Mr. Bernaro and I answered that we felt that DOE was ready to start work at the site in a progressive fashion, meaning that there are bits of information they could start collecting immediately and, although I didn't have a chance to go into it in greater detail, had I been asked for further discussion, I probably would have said the shaft work as far as construction really cannot begin until additional information is collected ahead of time, such as some of the stratigraphy studies with the deep borings and the continuation with the trenching and the mapping. I wasn't asked this, but that's--I said in a progressive way and Mr. Bernaro had something similar, not exactly the same words.

He said there were questions. This is Mr. Bernaro. If he had been asked that question two years ago, he would have answered no because he did not think that all of the procedures and all of the comments that they had made on the site characterization plan had been answered at that time. But, to date, he feels that these have been answered on a number of the first activities, such as the trenching at Midway Valley and some of the other work and he would say,
1 yes, they are ready to start work.
2 Now, I guess the question is how far along can this
3 work go or are the QA processes getting in the way of any of
4 these other activities or are they all falling in line,
5 particularly the design and the beginning of construction of
6 the underground facilities? Now, from the QA point of view,
7 first.
8 MR. HORTON: From the QA standpoint, I feel that we
9 currently have adequate procedures in place to proceed with
10 this work. Some of the things that we have to do in the
11 interim, prior to starting some of this, is verify
12 implementation of these. Since there has been essentially no
13 design going on for the past many months now, what QA has to
14 do is go in and verify during the implementation process of
15 the design that these procedures are being implemented and
16 that there are adequate controls in place to assure the
17 quality of the design. So, as I say, we're in the process of
18 doing this. We have a specific schedule laid out over the
19 next several, many months, in which case QA has inserted in
20 there specific points where we're going in to do surveillance
21 to verify the process.
22 DR. DEERE: Thank you. And, Dwight, I guess that there
23 is a lead time necessary for these studies that you've
24 mentioned this morning to go ahead and take their progression?
MR. SHELOR: Yes, that's correct. I think--let me answer specifically. I think Max has part of the answer to your overall question. But, I think in terms of the development of the system requirements from the overall system, for the transportation, MRS--all of those specific activities, we have three of them, the overall system, the MRS, and the mine geologic disposal system, nearly finished and we're starting in on our technical review procedure on those now and, as I indicated, we're working now on developing the test facility requirements for the ESF and then we'll complete the functional analysis for the ESF. I personally believe that the QA controls that we have on that are adequate and also necessary.

DR. DEERE: Max, you had something to add, perhaps?

MR. BLANCHARD: Well, from a technical management viewpoint, there's only a couple of things that stand out. One is like Dwight has mentioned, we want to make sure that we have the right set of requirements to work to, that we've developed a design and test process which follows those requirements and has procedures which implement the requirements. We're not there yet, but we're not too far from being there. We got some things under control that have been in the program for quite a while and Dwight is finishing more classical systems engineering approaches, as I mentioned, to
get the requirement documents more refined. Some time this summer, we'll have that and we will then be modifying the procedures that we've got in place to adapt to that.

The other thing we have to have is a graded QA program for all those activities that affect the design work. That is essentially complete now. Sometimes, you go back and grade things at a lower level of detail, but that kind of effort, going back and going to lower and lower level of detail, is iterative. And, that's the kind of thing that you continue on as you evolve your design and performance and site suitability assessments.

So, I think all the elements that are critical to answering that question affirmative are there. They're in place. They're in different stages of maturation. Each stage gets more comprehensive and better and we feel better about it and the people that are overseeing it, like our quality assurance department and people that come with that from the NRC, gives us confidence that we're on the right track and we're very close to being able to move out.

Ted?

MR. PETRIE: Okay. I think we have everything in place. As Don pointed out, what they're looking for now is a demonstration that we can implement these procedures properly. I feel confident that for the most part, we will, and we will
probably have a few findings here and there, but I don't see anything that would be show-stopping at this point. And, in fact, so what we're really saying is, yes, we're ready to proceed. We need to implement these things we've already developed and demonstrate during the implementation process that we know how to perform the task.

DR. DEERE: I wonder if NRC would like to add any comments about this? Maybe, you'd give a better interpretation of Bob Bernaro's answer than I did?

MR. CONWAY: I'm Jim Conway with NRC, the Office of High Level Waste. Our initial exposure with QA with regards to the ESF Alternative Studies has been that we participated as observers on an audit that DOE did of Sandia, I believe, back in October of last year and they followed it up with a surveillance in September. The bottom line being that we felt that again, as Don said, controls were in place to go on with new work, but also that we didn't have a chance, as DOE did, as to look at implementation and this is what currently has to be looked at with the observances done by the state and the NRC.

DR. CANTLON: Before you leave, in your judgment is it unlikely that NRC would find anything at this stage that would hold up the ESF from proceeding on a QA basis?

MR. CONWAY: I don't think so. I don't think on the
number of observations and surveillances we've been on that we see anything that's been commented, to date, anything that would be called show-stoppers. I think you're going to find if you've got a good surveillance team, a good auditing team out there in the QA arena, they're certainly going to pick up some things. But, again, if these things are corrected, corrective action is taken, preventive action to prevent recurrence, you're going to strut through your programs. And, again, as I think a lot of people have commented on here earlier in the session today, DOE has certainly come a long way, at least in the two years that I've been on the project and since they've started this QA program, we've all gone through a learning. QA is certainly not a static issue. It's a dynamic sort of thing and it's changing every day. And, again, I feel and the staff, I believe, feels that DOE has come a long way. There's no show-stoppers on the horizon that we can see. We've approved again, as people have said today, the QAP, the QARD, the recent revisions to those, feel that the participants have programs in place with controls to proceed on with the calcite-silica Midway Valley investigations and any future site characterization activities in the future.

DR. CARTER: I'd like to ask a related question, I guess, to DOE, but perhaps others. I'd be interested if someone
would sort of summarize for us the DOE interactive process in the QA area, as far as OCRWM is concerned, with not only the NRC and their site representative in Nevada, but also the State of Nevada and any of the other principal players in the drama.

MR. HORTON: You would like to clarify the interactions with them?

DR. CARTER: Well, not clarify necessarily. I'd like to hear a summary of it. How do you interact? What's the process on a day-to-day basis, if you will, between, for example, your office, the NRC, the State of Nevada, and so forth?

MR. HORTON: Well, currently, we have two project people located in Nevada from the NRC. These two interface on a day-to-day basis with specific activities that are ongoing at the project level.

DR. CARTER: These cover the entire project, I presume?

MR. HORTON: That's correct.

DR. CARTER: Okay.

MR. HORTON: They often come in, interface with me, in addition to the line organization itself. We also have bimonthly meetings formally announced by monthly meetings with the NRC, in which case we have not only DOE QA, but if there are specific presentations to be made during this meeting that
would require support from one of the participants, the
participants accompany us on these meetings, specific Clark
County, Nye County, and any others that are directly involved
attend these meetings. EEI attends these meetings and all
interested parties are allowed to attend them. These occur
approximately on a bimonthly basis. Sometimes, they occur
monthly depending on the activities of the overall program at
that time. We have various correspondence, of course, with
the NRC and all these are directed to the NRC through Dwight
Shelor's organization, but we do communicate on a daily basis.
Susan Zimmerman comes by and discusses the overall program
with me on an occasional basis when she can make it down to
Las Vegas. In addition to that, you know, several of the
counties come in and talk to me when they have an opportunity.
So, there's constant interaction between all the parties
involved here.

DR. CARTER: Okay. The other thing, I guess—and, maybe,
Dwight would want to comment on it—but, I presume there's an
ongoing working day-to-day relationship from what you've said,
Don, and I presume also from what you've said is that in terms
of policy matters that involve QA, then this is through
Dwight's office if it relates to the NRC. Is that correct?

MR. HORTON: Yes, that's correct. Not only QA, but the
entire program. The official NRC interface is through my
office. Right now, they have a new director for the division of regulatory compliance from NRC, John Roberts. He's been on board now--this is his second week. Between John Roberts and previously, of course, Linda Desell, we establish through a quarterly meeting with NRC a management meeting on meetings. We formally set up technical exchanges and we arrange for the QA meetings. And, the reason we have these is because our procedural agreement requires 10 days notice for every meeting that we have to give the state and the counties and other affected parties an opportunity to attend. Every meeting is noticed by the NRC 10 days before with an agenda. And, that becomes, then, the official record. Any official correspondence going through the NRC goes through my office.

DR. ALLEN: Any other comments or any other closely related questions?

(No response.)

DR. ALLEN: Well, maybe, Russ, since you posed some of these questions, let's talk about the conceptual design problem for the moment and maybe if you could focus in on things perhaps you thought were not adequately responded to this morning. Some of these were already treated.

MR. MCFARLAND: Be glad to, Clarence. As you can well imagine, trying to write questions before the presentations is a bit of fishing. But, I think some of the questions here
that we listed perhaps were directly addressed. In particular, as you can see, I did concentrate on the question of conceptual design. The very first phase is design in which you're trying to understand your parameters, your variations of parameters, and the direction to go, and, particularly, curious about the QA perspective of the conceptual design phase. And, you can see that the first question is that from the QA perspective, is this a quality affecting phase of the program? Don, perhaps you could offer me some clarification on that?

MR. HORTON: Well, first of all, we've come up with answers to all these questions. It's yes, no, yes, yes, and NA.

(Laughter.)

MR. HORTON: On the first question, from a QA perspective is the conceptual design phase of the system development quality affecting? If it is, how is assurance provided that QA has been met? The answer to that is, yes, it is. Conceptual design is quality affecting. It's so specified in our QA program documents. And, that through our evaluation and grading process and implementation of our control processes which includes surveillances and audits, we verified the QA requirements are implemented.

MR. RICHARDS: Don, I might be able to add a little to
that also from the historical point of view. If you think of the conceptual design that was completed to accompany the site characterization report as being something that ended a while ago--and, if it's revisited, that's another aspect--in that particular time frame, the conceptual design activity was not considered to be what would correspond to the term quality affecting. It was considered to be essentially similar to what is down here further on the page, to be preliminary and scoping. At that time, the organizations involved--I must say the reason I'm responding to this is that Sandia had a lead role in the conceptual design report. At that time, the quality assurance programs for Sandia, as well as the project, were not sufficiently mature nor accepted by the NRC for us to make the case that whether we applied them or not, which we did, to that activity that it would later be all blessed and everything because we were still in a process of getting our QA program's feet on the ground.

Now, having said all that, I would say that the kinds of things that would be applied to a quality affecting activity now, all the things you saw in these slides this morning about qualified personnel and plans and procedures and that sort of thing, were in place and were, in fact, applicable to the preparation of the conceptual design and the report that summarized it. It would probably, however, be
very difficult to make that case from the documentation that exists from that time frame. In any case, we treated it. Because we didn't feel we had the fundamentals for the QA program in place, we treated it as—what at that time was called a quality level 3 activity. IN terms of, you know, if somebody asked what is this? Well, this is a quality level 3 activity. However, if you asked, well, are you using qualified people to do the work, the answer is yes. Do you have a plan for it? Yes. Are you going to review the results? Yes, thoroughly. And, all that was done. So, there's certainly a two-tier answer to that question.

MR. PETRIE: Let me just add a little bit to that. Ted Petrie. This is one of the reasons why we went through and did the alternative studies, was to provide the equivalent of a conceptual design on a solid basis of a quality assurance program.

MR. MCFARLAND: Excuse me, Ted, the alternate study?

MR. PETRIE: For the ESF, yes. That program we've just gone through when we looked at something like 54 different concepts for the--

MR. MCFARLAND: Repository to ESF real quick.

MR. PETRIE: Yeah.

MR. SHELOR: Let me, Russ, if I can--this is Dwight Shelor. Let me switch you again to another area entirely...
1 different. Let's talk about the MRS, for example. There has
2 been a lot of work done in the past, but for all intents and
3 purposes, we're about to start over again dependent upon the
4 success of the negotiator and the volunteer host sites. There
5 is a good probability that we will modify the system approach
6 to the development of the MRS design and that here we have an
7 opportunity to establish our requirements up front and then to
8 do the thing that we'd really like to do and that's to develop
9 several alternative conceptual designs. And then, evaluate
10 each one of them to determine if it meets the requirements,
11 identify all of those that meet the system requirements, and
12 then involve the host state or the host, imparting to as their
13 value judgments, as to which of the technically acceptable
14 alternatives they would prefer. So, the selection process
15 may, in fact, have a major involvement of the host in the case
16 of the MRS.
17    MR. MCFARLAND: You've clarified a question I had
18 considerably. Let me postulate in that further analysis would
19 say that we should not have a hot repository, we should go to
20 a cold repository and that we would still like to hold 70,000
21 metric tons. This would have immense impact on an MRS
22 conceptual design. Will that be one of the alternative
23 scenarios that you're--
24    MR. SHELOR: Okay. Well, this is very interesting. Next
1 week, there's a meeting in Denver on the Strategic Principles Workshop and these are issues that will come up. But, for example, in answering that question, it would be difficult to argue that these issues are not related and they are systems issues to be resolved because, clearly, the strategy for the repository design, if the site is found suitable, will have an impact on the MRS. That impact is--some people have claimed that it's further downstream, but in fact, it's not. It has to be upstream. A licensing strategy for the MRS may, in fact, take us through a conceptual design or several alternative conceptual designs and selection up through Title I, but then in Title II, only select a phase. Take off a first portion of it where we have store only. It may be just a simple handling facility and then the second phase would be of much larger capacities, in order to try to accelerate that date when we can begin accepting spent fuel. But, in order to license this and not segment the licensing in the conceptual design and in the Title I design, we will have to address the full-up facility, the Phase II, if you will, and then take off part of Phase I. And, we have to do that in the EA and in the EIS. They will have to be submitted with the license application. So, I think that the time that we'll have available to do the analysis and make decisions is very, very short. I hope it doesn't result in having to make a decision
1 to proceed on one or the other and have it then become a
2 constraint on the rest of it. But, right now, those are of
3 major issue on our point.
4 MR. MCFARLAND: Thank you. That was most helpful to me.
5 DR. ALLEN: Any other comments here? Do you want to
6 proceed with the second one? You said the answer was yes?
7 MR. HORTON: No, the second one is no.
8 DR. ALLEN: I'm sorry, I got the order wrong.
9 MR. MCFARLAND: The second question was a comment made
10 at, I believe, it was our Denver meeting and, going back and
11 re-reading the handouts and the transcript, I was hard pressed
12 to understand the implications of this question or this
13 comment that was made and I thought, gee, I'll just take this
14 opportunity and let Don answer at our roundtable.
15 DR. ALLEN: Wait a minute, Russ. Are you referring to
16 Question 2 at the bottom of the page?
17 MR. MCFARLAND: Question #2 at the bottom.
18 DR. ALLEN: Okay. What about the other three at the top?
19 MR. MCFARLAND: I think he has addressed them. I think
20 Dwight addressed them quite nicely in discussing the
21 alternatives.
22 DR. ALLEN: Okay, fine. I just wanted to make sure where
23 we are.
24 MR. MCFARLAND: Between Don and Dwight, I think we put to
bed the question that prototype could be synonymous to conceptual.

DR. DEERE: So, we didn't get an answer to Question 2 at the bottom of the page?

MR. MCFARLAND: No.

DR. DEERE: No, you're answering the--

MR. MCFARLAND: Excuse me, Clarence, for jumping ahead here.

DR. ALLEN: I was trying to make sure I know where we are.

MR. HORTON: The answer to Question 2, are there sufficient differences in the QA training between the various YMP organizations that would support this observation? I would say that this was the subject of a recent QA managers' meeting that we had on which we had discussed were there agreements between participants to perform supporting activities for the other participant and them requiring copies of certifications, training documents, et cetera, to be furnished to the requesting participant in this case. This something that we're going to check into further, but it's my position that, since all of us have approved quality assurance programs that meet the upper tier requirements from DOE, that the training requirements should be consistent across the project. There may be a different form that are possibly used
by each participant, things of that nature, but the basic
training requirements should be the same, except in some cases
where one participant might be required to implement all 18
criteria, for example, including design control and they are
requesting support from another participant, in which case
they might not be doing design; so, therefore, they would have
to be trained to specific procedural requirements of that
requesting organization. But, in general, most of the
participants should be trained to the same requirements across
the board and they shouldn't have to have a copy of the
documentation from the other participant.

DR. DEERE: Raytheon is helping with this by gobbling up
two companies, right?

MR. HORTON: Right. Again, I hate to keep adding all the
time. It's possibly an aside, but it's a very important one.
As you know, the M&O contract was awarded recently and TRW
has begun to bring people in on their team. At this point, I
can tell you, quite frankly, that I anticipate that some
members of that M&O team will be assisting us in the review of
the functional analysis reports prior to the time that the M&O
contract QA plan is approved. And, you say, well, how can you
do that? Good question. They are working to our procedures.
We have given them documentation so they can verify the
qualifications of their personnel. We have taken them through
our QA indoctrination program and we are training them on our QA procedures, the same as if it were one of our people going through that.

DR. CHU: Can I ask a question relating to that?

DR. ALLEN: Please?

DR. CHU: Your QA requirements are kind of tiered in the sense of different management levels have different kinds of requirements. Headquarters and OCRWM has one set and the project office and the requirements down at the laboratory then are derived from the more top-tiered kind. The M&O contractor has many responsibilities, both responsibilities resembling those that are at headquarters and also something that's farther down. Could you give us some flavor as to what kind of QA requirements they might have?

MR. HORTON: Well, first of all, I'd like to make the comment that we don't have tiered requirements. All the requirements are the same. It's just that not all the requirements are applicable to every participant.

DR. CHU: I expressed myself poorly. I meant in the sense of the level of--

MR. HORTON: Twenty criteria versus six?

DR. CHU: Yeah. Also, the type of detail.

MR. HORTON: In the case of the M&O contractor, they will have all of them. All 20 criteria or whatever number of
1 criteria that we have at that time will be applicable to the
2 M&O contractor. Specifically, as Dwight described, in the
3 initial stages, they're going to be responsible for the design
4 for the MRS facility. So, therefore, they have to have a
5 design program.

6 DR. ALLEN: Russ, do you want to pursue the third
7 question?

8 MR. MCFARLAND: I think we declined on the third one.
9 DR. DEERE: Maybe you should read it, Russ, for the
10 audience. They don't have a copy out there.

11 MR. MCFARLAND: The third question, in response to
12 Question #63 of the NRC review of the SCA, the DOE stated that
13 the final decision regarding standards for conflict of
14 interest and independence of DOE QA reviewers must remain the
15 prerogative of the DOE and that different standards may be
16 appropriate for different types of review topics. The
17 question is, is this still the position of DOE and, if so,
18 what would be the different standards and topics that would
19 warrant these differences?

20 MR. HORTON: I guess, you know, if that's posed to me, I
21 would need clarification on what you're really asking there.

22 MR. MCFARLAND: You put me in a bad situation. Let me
23 run to the phone. Max, do you recall this particular question
24 on the SCA that came from NRC?
MR. BLANCHARD: No. I'd have to get somebody to call
and--

MR. MCFARLAND: Is there anyone in the room that could
offer some insight into this that remembers those particular
discussions?

DR. ALLEN: Russ, it's not hard to imagine different
kinds of topics that require different kinds of review.
Different kinds of group that--

MR. MCFARLAND: What triggered me was that we're talking
of standards for conflict of interest and independence of
reviewers and that we would have different standards to
determine a conflict of interest for different types of
reviews.

MR. SHELOR: Again, I don't know what the Question #63
really was. We can only surmise. I can only surmise. There
were too many questions in the SCA to remember all of them.

MR. MCFARLAND: Yeah.

MR. SHELOR: But, for example, the one context that that
could have been in was the independence of a technical
reviewer. And, when you come back down, though, to our QA
requirements for the independence of a reviewer, if I remember
correctly--I don't know if I do--the requirement is that if
the--a technical review can be conducted by an individual
supervisor providing he has not directed a specific method to
be used by the individual who conducted the work. Or, it could be review by somebody totally independent of that organization doing a separate set of calculations. And, I believe that is still our position and it's been accepted by the NRC. If that is the context of Question 63.

MR. MCFARLAND: That makes sense to what I read into this question.

MR. SHELOR: Because you may come down to a situation where you have insufficient number of reviewers. So, you don't want to tie your hands, you know, and have to go out all the time.

MR. BLANCHARD: A question somewhat similar to this, I think, was raised by the NRC technical staff when they reviewed the DAA. And, if my recollection is on target, it was something like when you look at this multi-disciplined effort on the DAA, there were some people that were reviewers and, if you look at the list of references, you also find their name in the list of references that were being reviewed in this very comprehensive document. A big thick thing, multi-discipline, science, engineering, QA, performance assessment.

Our response to that was that we continue to meet the requirement that a person doesn't provide an independent technical review by reviewing part of his own work. But, it
1 may well be that a person in performance assessment is very
2 well suited to review an analytical part or some design
3 tradeoff study in engineering or some model of a site process.
4 And, so in the process of putting that team together, a team
5 together to prepare the DAA, we selected people that we
6 thought had the most appropriate background who did not have
7 this conflict. Well, as it turned out, we had someone like a
8 person who had the right qualifications who had done some PA
9 work. He didn't review his own authored PA work, but he did
10 review something in the earth science or the engineering area.
11 And, so that question was raised by the NRC. I don't know
12 how well they are satisfied with the answer, but our view was
13 that we adhered to the requirements adapted in the QA program
14 stated to us and that was people don't review their own work.
15 But, that it's perfectly okay to have a person who has
16 appropriate background and training to review another part of
17 a multi-discipline effort. And, that is the context within
18 which we had some people who were on the DAA preparation team
19 whose names also occurred in the technical reference list of
20 documents that were there that were being reviewed.
21 MR. HORTON: If you would like, I could read you the
22 specific words in NQA-1 on design reviews and what it says.
23 MR. MCFARLAND: Please?
24 MR. HORTON: It says, "Design verification shall be
performed by any competent individuals or groups other than those who performed the original design, but who may be from the same organization. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisor reviews do not satisfy the intent of this standard."

And, I think that that rule was originally included in there for small design organizations because the Regulatory Commission didn't want to limit those small organizations and require them to go outside to get support.

MR. MCFARLAND: I understand.

DR. CANTLON: This is a good question to pursue a chronic question we've been asking you and that is the matter of what percent of the total project do you think now is going into the cost of the QA system? Because, here, you have a matter of review. If you wanted to really take a Caesar's wife approach to it, you'd make sure that no DOE person made the review to satisfy the sharpest critic of DOE's activity. That increases costs. You've got a whole bunch of quality judgments and so on. So, you're making both a quality
determination on the type of review. You're also making an internal cost and time calculation when you choose the reviewer. So, these are ingredients in a management decision of making a judgment between a total Caesar's wife approach versus a no really outside review. To what extent is that part of the rationale for where you came out in specifying your review procedures?

MR. HORTON: Let me add to your question. In some instances, you may elect, for example, to do a peer review if it is beyond the state-of-the-art. And, in many cases, that election may not be because you don't know what you're doing, but it adds to the perceived credibility of the final product. And, it may be a straight management decision that you need the added credibility of one or more peer reviews to do that. Now, that's a management call. I don't think it's in there. I helped Don a little bit. I believe that in many of these we have to meet—if it is through the grading process, if the activity has been determined to be quality affecting in terms of safety and/or waste isolation, then clearly we have to meet the minimum requirements for a technical or peer review. Then, there may be others that you elect to do in addition. But, that is a management call. But, you have to meet the minimum requirements. And, there are similar ones, but they may have different review requirements depending on what the
activity is.

MR. CLARK: If I can add something to that. I'm Bob Clark, DOE. One of the requirements that we have to meet in every review that we do is that we have to cover all the disciplines involved. So, in an attempt to quantify, if that's what you're looking for, the amount of reviewers, that's one thing we would consider. What is the document that we're reviewing? And, if it takes a multi-discipline approach, then we need somebody that can cover all those disciplines.

DR. ALLEN: Russ?

MR. MCFARLAND: Dwight, may I ask you a question? On the peer review, is there a documented process by which you identify and select peers, experts?

MR. SHELOR: Okay. There are two aspects. Let me answer--because there are right now still two procedures on peer review. One that we have in the Forrestal Building and the other one in the project. I really can't speak to the project, but Bob and Don and I can speak to the one in the Forrestal Building. I believe the answer is quite clear. There are only the requirements that we have to meet if--we have to cover all disciplines. There are criteria for determining if a peer review is appropriate and I believe that the basic criteria is, is the subject matter beyond the
accepted state-of-the-art? If it is, then it requires a peer review and that you cover all the disciplines. As far as selecting the individual, there is none other than that they be qualified in that area.

MR. RICHARDS: Dwight, could I ask maybe for some clarification? I know at Sandia we have a real terminology problem because most of the folks who work there use the term peer review to basically mean getting one of their technical reports checked by somebody who is technically competent that works down the hall, but not on that report, as opposed to a peer review board, as it's used in the project documentation.

MR. SHELOR: Absolutely. It's not only confusing to you, but to the rest of the world and, hopefully, through Don's efforts in standardizing some of our procedures and particularly the terminology, we need to settle down on one very clearly. Now, the ones that we have right now, I believe, is consistent with NQA-1 and standard accepted. The technical review is also done by peers, people of equal competence and have done that kind of work. But, the difference is that it's within the accepted state-of-the-art or state of knowledge in that particular area. A peer review then is, as I indicated before, when you're reviewing something that is new and different and beyond an accepted state of knowledge. For example, the hydrology model or
models that you're reviewing may, in fact, require a peer review if it is beyond the accepted state-of-the-art.

DR. ALLEN: Of course, much of a criticism of peer review recently, Congressional members having to do with allocation of research funds and whatnot, is that, yes, you get someone who is not associated with that project, but still a parishioner and member of the same old boys' club, and therefore, the whole process of generating itself and there's no opportunity for really new ideas or something to come into them.

MR. SHELOR: Well, one is just a practical consideration, obviously. If somebody had elected to use somebody's model and then go and ask that person to peer review it, you know, it might be a little self-serving maybe.

MR. BLANCHARD: Dwight, you described the headquarters' procedure. Let me just share with the panel the project procedure. We have one that governs peer review and it focuses--it has words in it like if it's beyond the state-of-the-art, peer review is called for, but it doesn't limit there. It says any time a branch chief, a division chief, or the project manager feels that something is sufficiently controversial in nature, he may call for a peer review. And, it spells out the process for documentation, process for identifying the chairman, and the process for identifying the
1 peers. And, in that definition, it requires each member of a multi-discipline team be selected and be selected from outside the project, someone who has not been funded on this particular subject in the project, in the funding area, as well as in the technical discipline area. And, we have carried out these peer reviews and have written reports, published them. Three that come to mind was one last year we conducted on geophysics and the use of prototype seismic profiling in welded tuffs to determine whether or not the method that's been proposed by the geophysicists from the USGS was one that was worth going forward for doing further geophysics in welded tuff in the vicinity of Yucca Mountain. That report was finished and it used all outside universities and outside consultants who do that work for a living.

We also finished one a couple of years ago where we brought the team of hydrologists, isotope specialists, and mineralogists together to propose a study that they wanted to conduct to determine the origin of the calcite-silica deposits in Trench 14. Again, we went outside and got some outside university people, some outside USGS people, and other consultants to review that plan, write an analysis to us, and make recommendations to the project whether to move forward and fund that plan and carry it out.

A third one, we just finished this year where Alan
1 Freeze, a hydrologist, assembled an independent group of
2 university and outside consultants to peer review our state of
3 knowledge of the unsaturated zone. They also in a similar
4 vein went through the process of being debriefed by all the
5 PIs, reading their reports, asking for briefings, looking at
6 what the data was, and then independently decided whether or
7 not our state of knowledge was adequate for the unsaturated
8 zone to have a meaningful plan to characterize the unsaturated
9 zone and to reach a basis for calculating groundwater travel
10 time. That report is also available.
11 I don't think from an engineering standpoint the use
12 of peer review in the science area is quite the same when you
13 say is it beyond the state-of-the-art. There's two ways you
14 can look at it. You can say, well, studying hydrology is not
15 beyond the state-of-the-art. So, it never fits into that
16 category. On the other hand, you could say making
17 predictions, whether they're mineral stability or groundwater
18 travel time over a 1,000 year or a 10,000 year period, is well
19 beyond what most people would conceive reliably as within the
20 state-of-the-art for predicting and, therefore, just about
21 everything you do is interpreting site characteristics that
22 lead you to conclude an impact on waste isolation over a
23 10,000 year period. Just about everything might fall into is
24 that within the state-of-the-art? The answer might be no.
1 So, we need to do it better. So, we've elected to use from a
2 science standpoint more like what your degree of sensitivity?
3 Is this a big issue? Is it in the area of disqualifying the
4 site or is it in the area which is obviously going to be a
5 heavy licensing issue? If it is or if it's receiving a lot of
6 outside notoriety and debate, then we elect at the supervisory
7 level to immediately go for a peer review and we always have
8 selected people who are not in the project, who are not
9 affiliated with the project, and who are not funded or have
10 been funded by the project.
11 DR. DEERE: It appears that there should be a difference
12 between a peer review and external peer review. You're saying
13 you're essentially using external--
14 MR. BLANCHARD: All external people.
15 DR. DEERE: And, you are not using external peer reviews
16 necessarily?
17 MS. SHELOR: Not necessarily, but it could be. And, you
18 would have to find, you know, obviously, someone who was not
19 directly involved to be a member of the peer review team.
20 DR. CANTLON: Independent review is different from
21 outside review. Theoretically, you could have a DOE internal
22 person who could be a perfectly excellent independent
23 reviewer. But, he would not be necessarily--or she--an
24 outsider.
MR. SHELOR: That's correct. And, it depends on whether you talk about the DOE as the entire DOE or OCRWM as part of DOE.

DR. DEERE: When you read the Congressional record of some of the statements by the House of Representatives during the formation of our particular Technical Review Board, you find that one of the things they had in mind was to create a peer review group that could report to them. That's essentially what they wanted. And, John Bartlett has told us that much. He said you keep asking for a peer review group. Well, that's what you are. We don't need any more.

MR. SHELOR: Right. You fit the definition.

DR. DEERE: It's interesting. They said we want a peer review group, a group similar to the National Academy of Science, but one that has power. Then, in the next statement that got into the final Act, it says the Technical Review Board has no authority. However, they should report their findings to the Secretary and to the Congress.

DR. CANTLON: Well, I must say comparing with where we were when we first met with you and where you are now, there seems to have been a great deal of crystallization, formalization, details put together. You gave us some crude numbers on the general cost of QA when you talked to us in November, but what's your new numbers?
MR. HORTON: I'm not going to tell you.

DR. CANTLON: What do you predict?

MR. HORTON: They're less now.

(Laughter.)

MR. HORTON: I just had a recent discussion with some of the people concerning the QA cost and I think that right now we're down around the 10 or 11% area in most of the organizations and even lower than that in some of them.

DR. ALLEN: Even lower than the overhead at Stanford?

MR. HORTON: I beg your pardon?

DR. ALLEN: Even lower than the overhead of Stanford?

MR. HORTON: Right.

MR. SHELOR: If I can make another comment and an invitation, not on the cost. But, as I indicated, recently with the M&O coming on board and getting some of the people indoctrinated in QA as we did very recently, it occurs to me that one thing that I'd certainly like to do is to invite any member of the Board or their staff who could spare the time to come over and sit through the six hour QA indoctrination. I think you would be impressed. I think you would be very pleased in sitting in to this indoctrination that every single OCRWM employee goes through. And, it would be quite informative to put everything in context.

DR. DEERE: Thank you very much. We'll take advantage of
that, right, Woody?

DR. ALLEN: But, let me ask then, in addition, say, for a specialty, say, for a physicist or some specialty, that person then undergoes an additional indoctrination in his or her particular field?

MR. SHELOR: No. Well, not as far as the QA is concerned. I mean, it's the same QA indoctrination for everybody. Secretaries, everybody that works in OCRWM goes through the general indoctrination and then, depending upon their job function, then there are--there can be additional procedures that they need to be trained in to perform for that function.

DR. CARTER: You know, some of you also were at the QA meeting in Las Vegas last week. So, now, I presume the Board is going to have a designated QA trainee. Last week, the lawyers were talking and they were talking about designated felons.

DR. ALLEN: Are there other questions from anybody at the table here? Roy, you've been very quiet.

DR. WILLIAMS: I think it's safer that way.

DR. ALLEN: Any other comments you people would like to make in response to any of ours?

(No response.)

DR. ALLEN: I have one question. The public image,
1 rightly or wrongly, within the State of Nevada of DOE or at least the waste management part of it seems to be at a rather low ebb among at least many Nevada citizens. At the same time, the Raytheon Corporation seems to come in flying high. Is there some way we can get these two together to get a public image that somewhat combines those two?

MR. HORTON: After listening to the hearings and everything, you know, I don't think that there's anything that we can do to change the attitude of Government officials there. It's politically motivated. But, you know, as far as the interface between Susan Zimmerman from the state, the counties, and everything, from a QA perspective I don't think that we have any differences, you know. We may have some minor conflicts on various things, but communication, I feel, is quite good. But, we're not going to resolve the political issues.

DR. ALLEN: Okay. Anything further?

(No response.)

DR. ALLEN: The remainder of the program has to do with final remarks from the DOE and the Technical Review Board. Let's not change our format here or the arrangement. Would John or Dwight or Ted or any of you wish to make some final statements?

MR. HORTON: Well, since no matter what I would say,
Dwight would have a comment about it--

MR. HORTON: Okay, Don, as a matter of fact--no, I would just like to conclude by saying, one, that we're very pleased to have been here today. I hope that some of the information that we presented and answers to your questions were helpful to you and that we want to continue in that mode and focus and use our time wisely on those areas which are of most interest to you and of some concern.

DR. ALLEN: Thank you. I think we've appreciated the opportunity to learn more about the program. Certainly, I've learned a great deal and I'd also say your invitation to attend the sessions, I think we'll take seriously. I think that's something that--the kind of thing we should become more familiar with.

MR. SHELOR: I'll go ahead on Don's behalf. Many times, it's more convenient for you to have a location and the individual to come to you if you have a few people that can spare the time.

DR. ALLEN: Okay. John, as Chairman of the QA panel, do you--

DR. CANTLON: Well, we will continue our session tomorrow, but today we focused on the QA aspects of design which is very different from things that we're going to be looking at tomorrow which look more into the research side of
things. I think this has been very helpful because, while there are obviously research dimensions that go into good design, nevertheless you're really dealing much more closely with things that are going to make a great deal of difference on the risk elements that the repository or MRS or whatever will be generating. And, so I think it was useful. At least, I come away with a feeling that the QA process is alive and well and developing and maybe even--maybe fully developed is a little too pat an answer, but at least it's in a more mature state than when we talked to you in November. From our comments that we've received from NRC, they don't see any show-stoppers at this point. That's gratifying to hear. Since there have been a lot of other kinds of show-stoppers, it would be great not to have a major QA show-stopper as the exploratory studies facility now begins to mature and to take off. Because until we can begin to see what lies under the repository site, a lot of the ideas of the design of the facility are going to still be in rather limbo, I think. So, for my part, I think I am very pleased to have heard this element on the design and we look forward to tomorrow's activity where we look a little bit more closely at the continuing relationship to your researchers who are a little bit more difficult to get in the barn than perhaps the engineers.
MR. HORTON: We have them in our hip pocket now.

MR. SHELOR: Just a personal note, I do not plan to be here tomorrow morning. I have to go back on vacation. So, tomorrow, I'll leave it in Don's hands and I won't have to second guess.

DR. ALLEN: Okay. Don, the final word is yours?

DR. DEERE: Right. Well, I think I would like to use the 36 minutes we have left here. First, are there any comments from any of the observers, be it Edison Institute or EPRI or Nevada or one of the affected counties? We'd be pleased to take any.

MR. TOM CALANDREA: I'm Tom Calandrea from Edison Electric Institute. I have just a quick comment on the progress of DOE through the years. I've been associated with the project for Edison Electric Institute for a little over four years now and have been observing through various means the progress that DOE has been making from a QA standpoint. And, one of the things that sticks in my mind as one of the milestones along the way that I use for comparison is a meeting held in July of '88 in which the subject of ESF was brought before the NRC and presentations were given. And, the bottom line of that meeting was that the NRC had some questions about the competence that they could place in DOE's approach to QA for the ESF. And, since that time, I've
noticed considerable improvement and I've seen several other milestones that particularly trigger in my mind significant jump shifts or step increases in the rate of improvement. And, I think one of them is bringing Don Horton on board in, I think it was, October of '89, and from that point forward, the rate of increase in DOE's improvement was significantly greater than prior to that point in time.

Other things, though, that were also in my mind step increases were the workshops. There were workshops on the QA flexibility which we discussed in November. They occurred in October. And, they represented a significant closing of the gap in terms of the concerns that the scientists had and the QA's ability to respond to those. So, to me, that was a significant step forward. The workshops held in January and February on software QA were also steps along those lines.

So, from my perception and, I guess, more of personal observation than a statement from EEI, I'm very pleased with the increase in the rate of progress noted by DOE from a QA standpoint and I encourage them to keep that up.

DR. DEERE: Thank you very much, Tom. Now, aren't you glad you stayed around for this?

(No response.)

DR. DEERE: Are there other comments?

(No response.)
DR. DEERE: Well, I think that we, as well, are favorably impressed with what we have heard today and the real progress or the real effort that's being exerted to apply QA to the design. We thank you very much for obvious time that you took in preparing this information to give to us and I think it's been most helpful.

Thank you.

DR. CHU: I have an announcement. The public part of the meeting tomorrow is at 10:30, as it's so noted on the program. So, this is just a reminder.

(Whereupon, the meeting was adjourned.)
CERTIFICATE

This is to certify that the attached proceedings before:
UNITED STATES NUCLEAR WASTE TECHNICAL REVIEW BOARD
In the Matter of:

QUALITY ASSURANCE

and

STRUCTURAL GEOLOGY & GEOENGINEERING

JOINT PANEL MEETING

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was held as herein appears, and that this is the original
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