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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON NUCLEAR WASTE

(ACNW)

151st MEETING

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THURSDAY,

JUNE 24, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 11:00 a.m., Michael T. Ryan, Acting Chairman, presiding.

COMMITTEE MEMBERS:

MICHAEL T. RYAN, Acting Chairman

JAMES H. CLARKE, Consultant

ALLEN G. CROFF, Invited Expert

GEORGE M. HORNBERGER, Member

RUTH F. WEINER, Member

ACNW STAFF PRESENT:

JOHN T. LARKINS, Executive Director

NEIL COLEMAN, Designated Federal Official

LATIF HAMDAN

HOWARD J. LARSON

MICHAEL LEE

RICHARD K. MAJOR

ALSO PRESENT:

JOSEPH D. ZIEGLER, U.S. Department of Energy

P-R-O-C-E-E-D-I-N-G-S

11:00 p.m.

CHAIRMAN RYAN: Good morning. I guess we'll go on the record please. This is our last presentation of this meeting. We're going to hear from the Department of Energy's Response to the NRC Independent Evaluation of DOE Documents Supporting the Yucca Mountain License Application. We have a remote location giving the presentation. Good morning.

MR. ZIEGLER: Good morning. I'm Joe Ziegler from Las Vegas. I'm the Director of License Application and Strategy from the Department of Energy.

CHAIRMAN RYAN: Just for your information, we have your slides in front of us and I think we're going to see them on the screen here as well.

MR. ZIEGLER: Okay. Good. I'm going to just briefly walk through the slide package and then I'll take any questions you have. If you want to stop me during the presentation, that would be fine as well. If you could go to page two of the slides, this gives a little outline of what I'm going to what I'm going to go through. I'm going to briefly summarize the NRC's technical evaluation from our perspective. I'm going to use a lot of their own words. I'll speak

of high response, how we evaluated the NRC findings, we have done in response to those findings and in particular, a team effort we have put together we call the regulatory integration team, talk about what changes and improvements we have made over the last year in our corrective action program and then I'll summarize very briefly.

If we go to slide no. 3, just briefly, NRC approached us in the fall of 2003 and basically told us they wanted to do a technical evaluation of our processes leading up to our total system performance assessment (TSPA) and to do that, they wanted to develop teams that would include TA personnel, technical personnel, some of their federal staff, some of their contractor staff to come in and look and evaluate selected, what we call, analysis and model reports (AMR) and those are the direct leads into our total system performance assessment in various technical topical areas.

NRC selected three to look at. The first one was General and Localized Corrosion of the Waste Package and its outer barrier in particular. The second one was Commercial Spent Nuclear Fuel Waste Form Degradation Model and the third one was Drift Degradation Analysis of Rock Mechanics of the drifts

and how they perform.

Those evaluations were conducted in one week segments. NRC sent between eight and twelve people in each week. The first one was in November of 2003, then December of 2003 and in January of 2004. They looked at the controlling processes, our processes, our databases, how we implemented those procedures and they also looked at our corrective action program, how we were doing and the time of identification and effective resolution of issues as we did our work.

NRC's evaluation in a nutshell came up with three basic types of findings. They found some good practices. Some of those were related to how we house the data, how we house the software and the models, our ability to retrieve and access those databases.

Okay. I'm being asked here to ask you to put your speakers on mute except when you're speaking. There's some feedback on this end. I don't know if it's showing on your end or not.

CHAIRMAN RYAN: You might also check your other microphones and those –- They may be on.

MR. ZIEGLER: She's doubling checking that but I think we've done that. Thanks. So in a

nutshell, that's what they were looking for. They found these good practices. They also noted that the Staff's support during the evaluations was excellent. That's so much a technical issue but its's something that we have spent a lot of effort on here because we understand that we need to learn how to be a licensee from a rigorous regulator. That's something that we on this project have not always done well. I think we showed that we know how to do that now and we got a lot of compliments in that area. I appreciate our Staff work in that area.

They also noted some improvements such as the process procedures that we were using, the software development and control procedures, the amount of validation procedures and processes. Those have been evolving over the years and have actually had great improvement in recent months and in the last year or so, part of that due to some long-standing conditions adverse to quality that had been identified through our quality assurance program, but the Staff here has done a lot of good work in that area improving those processes. And thirdly, they identified a lot of concerns and they noted them.

I'll go to the next slide and give you a general feel for what those types of concerns were.

I was a little hesitant to characterize them myself so what's on slide number four are quotes out of the NRC evaluation report that they sent back to us. But basically their concerns and findings were in three areas as far as where we needed to improve.

The first one dealt with the clarity and the technical basis and the sufficiency of technical information to support those technical bases. What they found was that looking at that documents, and they did a lot of document review for they were doing a lot of database review, is that it wasn't clear in many instances what the bases for the technical information and parameter distributions that were used.

What they also found is that as they talked to our analysts, as they interviewed our analysts and authors of those reports, that the information generally did exist and in many cases, it was just providing the right pointers, maybe it existed in a different document, existed in a different database and had not been carried through to the documentation. They noted that reasonably we should been able to catch that during our review and checking processes.

The second area they identified was

deficiencies that I believe they stated they confirmed the deficiencies that we had already identified through our corrective action program and these had to deal with quality assurance deficiencies and the manner in which we controlled and qualified data.

We have a lot of data that goes back many, many years, decades in some cases. It wasn't collected under an NRC regulated quality assurance program at the time. So we had to a lot of data, reconstruction is not the right word, but validation of that data to make sure that it was suitable for its intended purposes and had met all the traceability requirements. So there's been some long-standing, what we call now, condition reports on data qualification, software development and controls and model validation in general.

NRC Staff confirmed the deficiency that we had identified that we were working actively in our quality assurance program and corrective action programs to correct those conditions, where indeed we had identified the right things and we were indeed making progress in working those things out. We were not, in the documents they reviewed, where we needed to be yet at that point, but we made a lot of progress and I'll tell about some of the additional progress we

made since the technical evaluation in a few minutes.

The third area was one of the general implementation. If you look at the quote, and we clarified this at the exit meeting that was held here in Las Vegas a couple months ago, is that if we continue to use the policies, procedures, methods and practices at the same level of implementation of rigor, it would basically lead to extensions of the review of our license application and its supporting documents because of the ease of traceability and transparency.

The clarification point was because they had been very complimentary during the evaluation of the procedures, of the methodologies, of the recent improvements that had been made, but the criticism here was of the implementation. The rigor of implementation was not what it needed to be of those documents that they reviewed. Now those documents typically were prepared over a year, year and a half, ago. So we have had some on-going problems in that area and again we made great strides in improvement and I'll talk about that a little bit later.

If you go to page five, slide no. five, once we got the written evaluation report, we analyzed it in several different ways. We analyzed it with a

technical staff. We also went over and did a broad evaluation so that we could try to characterize the findings. I guess the second bullet on slide five gives a very brief summary of that.

Forty-five percent in our view were dealing with transparency and traceability issues or ease of traceability issues. I think once we pulled the string, we were able to show that traceability existed, but the ease of traceability such that the regulator could go in and pull the string and find everything they needed without recourse back to our personnel was not what it should have been.

Thirty percent were technical issues. When I say technical issues, there may be one or two exceptions. They weren't really issues where we had broad disagreements with technical approach. They were more with the clarity of the explanation of technical basis which is what I talked about previously.

Twenty-five percent were actually positive observations of everything they found. There were about 100 or so. I don't remember the exact number of these total findings. They didn't number them, but we went through and counted.

We generally agree with NRC's conclusion.

I think there were two technical points they made dealing with emplacement drift degradation that we basically have a differing view on the approach and maybe some of the technical bases. Some of the modeling used by NRC's contractor in that area, we think, maybe the physics aren't exactly correct. So some issues come up in those areas. But other than two things, I think we're in agreement with the findings that the NRC technical staff made.

Slide no. 6. Again our post evaluation review then went more in-depth into the technical and the substance of portions of the evaluation. Transparency and traceability, we had identified previously. I guess we had known for some time. I had talked about it and other DOE management had talked about it in several NRC management meetings over the last year, we did those quarterly, that we knew the way our technical bases were developed.

We managed it in a broad program out of our facilities and the staff in Las Vegas, but we've gone out to several national labs, Las Alamos, Livermore, Sandia, Berkeley and others actually. So the work is being done at multiple locations around the country and by different staff even within some of those locations. So there's somewhat over 100 of

these analysis and model reports and there's some other technical feeds as well.

But when the work was out, even though we're requiring everybody to work with the same procedures and have been for the past few years, it wasn't that way probably before about 1999. But consistency and procedural implementation has been issue that's been an on-going issue. Also we knew that there were going to be integration issues when we have staff again spread out geographically to where there is communications, but it's not as good as if the staff all is one place.

So we knew there was going to be an integration task that we would have to do before we actually submitted the license application. When I talk about that, that's things like there are certain parameter values and parameter sets that have to be used in various parts of the analysis, for instances, water and infiltration and seepage.

I'm a nuclear engineering so I don't want to pretend to be an expert in those areas, but those parameter values have to used in many different parts of the evaluation. As those parameter sets are being developed, sometimes they were being developed at multiple places. So we use different datasets in

establishing those parameters.

Now we've now gone back and much of the integration and identified any issues with it. It's not that we found inconsistencies. It just they're different sets. So what we tried to do was do a better job in the correction of these things of integration. That's something that you and me would have to do, but we really hadn't started that in earnest and I think these technical evaluations gave us the incentive to get that process started.

The way we did that is we developed a regulatory integration team. I'm going to talk about that more in a couple slides, but basically we pulled about 140 or 150 people together here at one place in Las Vegas. We divided them up into their technical areas of expertise.

We also put in staff that was very experienced in regulatory processes and communication processes and dealing with the regulators. We also integrated a quality assurance staff into these teams and subteams. By doing that, we were addressing the traceability, transparency and these other issues. I'll go more into specifics in a minute.

We also paid better attention to our corrective action program. We had a lot of actions

already in progress, but we tried to basically accelerate those actions and to make sure that we had dealt with the long-standing issues. Since the technical evaluations, those three areas that I mentioned, data qualification, software development and the retrieveability and documentation and model validation, I think two of those condition reports had been open for nearly three years. The other one had been open for nearly two years.

Two of those are now closed, the one on software development and documentation and retrieveability, the one on data qualification. So that means our process is not just for what we're doing today, but going back into the past to make sure that everything is suitable for its intended purpose and the safety analysis going forward is adequate and serves that need.

The model validation condition report is still open because as we go through this regulatory integration process, we want to make sure there's an output of that process to make sure that we will not close that condition prematurely. But we are well on our way to closing that and we expect that one to be closed in late summer as well.

If you go to slide 7, the initial

evaluation looked at the apparent cause of the problems that had been identified and we initiated a lot of condition reports within our corrective action program that basically we agree with the NRC Staff with the findings, narrow interpretations of what the regulatory requirements were. We can go in there and if you look at our reports, we met the specifics of the regulatory requirements. Our technical staff did a pretty job.

We didn't communicate that very well though. So we didn't put ourselves in the place of the regulator staff such that they need to look our products, they need to understand them. If they want to pull the string and fully trace them back to all the bases, the technical bases, the modeling bases, the data validation and verification bases, that needs to be easy for our regulator staff because we don't want just adequate technical products.

We want to facilitate a timely and efficient NRC review of these products because our ultimate goal is not to submit the license application. Our ultimate goal is to get a construction authorization, construct the repository and to operate it and to be able to do that in a timely way and have any chance of 2010. We have to

basically facilitate NRC review process. So we want to do that.

We also had insufficient focus on the transparency and traceability. It's kind of the same issue. It's that we did not really put ourselves in the regulatory shoes and we try to do that more now. That's basically about bringing a regulatory perspective, a licensing perspective, to these documents and to entire body of work.

The recommended corrective actions were to emphasize the transparency, the completeness, the traceability, use the experienced regulatory reviewers - I have covered some of this - establish accountability. So we put these teams together in one location in Las Vegas. These subteams have gone through, identified any issues and problem areas, not just similar to the ones NRC identified, but we have a complete checklist that they went through that includes all of the types of things that were identified by NRC. Identified those, bring in a more senior team to look for common elements of problems to make sure if one technical area was finding types of problems then we looked for those types of problems in the other areas as well.

So we just went through a comprehensive

process where one team wasn't finding something and we went back to make sure they were accountable and they understood what they needed to be looking for.

In those cases, we did some retraining there. We tried to institutionalize our license because we had to tweak our procedures a bit to make sure that these types of problems that had been coming that there are warnings and notations and procedural staffs that we will specifically look for those types of problems.

On the next slide, I go into a little bit more detail on the regulatory integration team. It's basically a one-time effort to do an extensive evaluation and analysis of all of the analysis and model reports that we're going to need to support our license application. It's regulatory focused. We're looking at the requirements, but we're also looking at the focus of a perspective of the regulators. That's what we're trying to do.

We divided this effort up into two phases. The first phase which has just been completed is the evaluation phase where we have gone through and identified a number of actions in these 100 plus AMRs. I think we're up to about 2700 actions. Phase two then will be to take these actions and implement what

we need to implement to make the improvements we need in our analysis and model reports. So we've identified and documented the issues and we're revising where it's necessary. We're in the revision mode of the Phase two mode now.

Our objective is to refine the analysis and model reports, to improve the integration, the consistency, the transparency and traceability and we're also double-checking if there's any additional technical issues that need to be resolved. We're not really finding a lot of technical issues. So we're confirming NRC's evaluation and our previous evaluations and self-assessments and we're really focusing on that regulatory perspective.

On slide 9, the primary task out of the regulatory integration team, and again this summarizes the bases, the checklist that we are using that the team needs to get through and identify actions that were necessary. We looked at the TSPA architecture. In other words, we looked at the way the analysis and model reports and other inputs and fed the total system performance assessment. So we go through the entire process starting with the technical bases, parameters, data.

We looked at the risk significance. We

actually tried to focus on the AMRs and give priority to those and run those through the system first that might have the most risk significance or most effect on the performance of the repository. Now we did the model, but we did them in risk-rank order. We looked at data confirmation, data qualification, to make sure that the data we were using to support validation of the model was adequate.

We looked at parameter evaluation to make sure the traceability and technical parameters we were using were developed and the handout from AMR to AMR, but again many AMRs use the same parameters. We wanted to make sure there was consistency in this parameter used across the evaluation and adequate technical basis.

We looked at our evaluation of features, events and processes to make sure that where we had screened certain processes and features out is not being risk significant to our modeling. We did accurate basis for that. We looked for the ones that were screened in that we had developed bases adequately and modeled them correctly. And we looked at the analysis and model evaluation to traceability of inputs and outputs, the appropriate and consistency of data. We actually specifically went back and

looked that NRC's Yucca Mountain review plan to make sure we were addressing the elements that we knew the regulator would be looking for. We looked at the transparency of our discussions and we looked at again the technical bases.

So what did we find? What we found was many of the same things NRC had found. I guess a brief summary, and it's not on a slide, is that it looks like we have about 3,000 open items, about six percent, with some sort of technical problem, a traceability problem with some sort of technical input. About 35 percent were dealing with the transparency of clarity of our model support or justification that we put in writing the documents. We had 16 percent procedural or quality errors and 26 percent were dealing with just a document problem, the clarity in the document, did we follow the right steps to make it very easy and retrievable.

So that's kind of the nature of what we found under the regulatory integration team and we are actively now implementing the corrective action for that. We expect all of that work to be done by September.

The other set of findings the NRC had were dealing with the corrective action program

effectiveness. We have already implemented a lot of actions. We had already through these long-standing condition reports and other timeliness of effective corrective action had made some great strides in the last year and a half in our corrective action program.

We have done a fairly large rewrite of our corrective action program processes. We have installed new software to be able to help manipulate and manage data within our corrective action program. I guess the greatest benefit of that is hugely increased ability to trend data as far as corrective action goes and define, seek and be aware of adverse trends and then pay attention to those adverse trends across the board, not just in the AMR areas, but across the board in all of our quality effective work.

So we had made a lot of those improvements. The NRC did confirm that those improvements were necessary. Our performance recently has been much, much better. As I mentioned some of these long-standing condition reports or what we used to call CARs or corrective action reports have been closed and the remaining long-standing condition report that has not been closed which we expect to be closed within the next couple months.

The rates for creating action plans once

a condition adverse to quality has been identified, we were taking then, in a sense, three or four months just to create a corrective action plan. We got those numbers down below 100 days in almost all cases and in most cases for the less significant ones, we're down below 60 days in creating and having an approved corrective action plan.

We also have brought down the number of days it takes to actually fully implement the corrective actions. We're down at around 100 days average on what we call "Level A" and "B" and that's the more significant condition reports. Our average time to complete corrective actions has been improved by a matter of about 30 days on average.

We are on-going with our corrective action program improvements. The software that we've developed is good. It provides increased training capability, but it also provides an additional burden on our staff. There are some efficiencies that can be developed to make it more efficient for our staff so they don't have to spend as much time just using the system. We want them to spend their time on actually identifying and correcting conditions. So I guess all and all in corrective action we did all these individual, but what it really comes down to and I

think what makes by far the biggest difference is a hugely increased management attention to corrective action to make sure they are identified properly and once identified, to make that they are corrected promptly and effectively.

One area that came through and it came out of the training program, we have training ability in our corrective action, is that a lot of our conditions adverse to quality really deal with one element and that's human performance. So our trend analysis really brought this to our attention in a much great stead.

We've done a lot of things and just some of the things we've done to deal with this -- It's also in the design area. It's in the pre-closure safety analysis area. It's across the board on our quality effecting activities and actually some non-quality effecting activities because it's just good work practice. We've increased our pre-job rates.

When assignments were made, we briefed the assignees with the types of errors and problems that have occurred in similar work in other instances. We identified problems within process work. We've done something we call "Timeout for Quality" where we take that lesson of that work and we just don't correct it

on the spot there which we do, but we also do a Timeout for Quality and try to communicate that lesson across the product areas so that the error and the lessons learned from that error aren't just benefitted by the individual who made it, but it's identified across the project.

We've integrated an awareness of error-likely situations. In some of our procedures and work plans and pre-job briefs, we know where errors are being made in many cases and we just haven't communicated that well going into to the work. So we're doing a better job of communicating where errors are likely to occur before the work is done such that the staff doing the work can pay particular attention to those areas and avoid the problem.

We put some of that same stuff in procedure critical steps. So we have done some procedure modification in certain key procedures where we're having on-going error. We put warnings or notifications within those procedural steps. We've clarified expectations and values. We've made it clear to our staff and we continue to communicate that periodically both at an upper senior management level, but we're forcing that down into the direct supervisory level that we expect our staff when

there's a problem to identify it, to stop work, to write a condition report, get it corrected and get it communicated such that we can communicate it across the project and that our values are for getting quality work down. Where there's a problem, correct the problem in an effective and efficient way.

We issued a management directive that basically supports this. We've communicated it in many different ways. We continue to periodically put it in our newsletters. One of the most effective things I think is in some of our newsletters we basically identify a quality issue of the week. This is where a particular issue has been identified and that brings reality back to it because if it's not a problem you have to deal with personally or a particular staff member has to deal with personally, sometimes it doesn't seem real. So we put that back into the process and that seems to be paying dividends as well. All in all, we're well on our way to making the system work and work very well.

In summary on the last slide, basically the NRC technical evaluation confirmed many of our own findings. We appreciate they did find some things that we had not found, but the types of the things they found we were aware of and I think their

evaluation brought it to a head and let us know that we needed to take some immediate action. We have, I believe, been responsive to their technical evaluation.

Some of the things we had already started. Some of the things we basically probably accelerated some to make sure that we dealt with it, but it really was eyeopener and I think it's been somewhat helpful to us. Actually getting these corrective actions in place has been a very good thing. We have demonstrated some progress in our preparation for licensing and I think that's a very important point.

We are dedicated to providing a high quality license application and applying the insights from the NRC's review as well as our own QA evaluations and self-assessments. As of right now, we're still on target to get all this work completed, to get the corrective actions completed from not just the technical evaluation but our long-standing corrective action program problems and get the license application submitted to the NRC in December of `04.

So all in all, it has been a somewhat trying exercise, but it's been very useful to go through this process. I think a lot of improvements have been made. If you have any questions, I would be

more than happy to entertain them now.

CHAIRMAN RYAN: Thank you very much, Joe. I'll start to my left. George.

MEMBER HORNBERGER: Joe, first of all.

MR. ZIEGLER: I think you're on mute. I can't hear here.

MEMBER HORNBERGER: Are we set now?

MR. ZIEGLER: Yes, that's good.

MEMBER HORNBERGER: Joe, first, can you give me a little more information on the 140 person team? Where do these 140 people come from? Are they DOE people? Are they Yucca Mountain project people?

MR. ZIEGLER: Yes. Most of them were project people that I'd say about one-third of them were already in Las Vegas, about not quite two-thirds of them mostly come from the national labs. So they either came from Berkeley or Livermore or Sandia or Las Alamos and some other locations. We basically hand selected from the groups that had been working on these technical areas the right technical expertise, the people that we thought were the best of the people working on the project. The best of the best. We brought them to Las Vegas.

We added to that QA support staff and we actually went outside and brought in some additional

people with regulatory expertise where we brought very experienced people in in regulatory proceedings, licensing staff and other NRC regulated activities and we integrated them within the team. Some of them were in the management of the overall project. So I'd say probably 95 percent of them came within the project from one place or another, but they were a hand selected group from within the projects.

MEMBER HORNBERGER: And is this team still functioning or was this a task force that came together and disbanded?

MR. ZIEGLER: Okay. They are still functioning and we're expecting them to continue to function through September. The Phase 1, the action identification phase, has just completed and we're in the corrective action phase right now where we're modifying.

I think nearly every AMR is going to require some degree of modification. So it's the same team that's come together to identify the actions and the problems and they are actually going to correct the problems. So they would be here through September and as the work is completed - the whole 150 won't be through September - then they will go back into their other jobs. The most immediate thing that they are

going to be moving back into right now is LA, license application, Chapter preparation because we want to take these same lessons learned and our technical documents and make sure that those lessons are applied to the license application itself.

MEMBER HORNBERGER: Okay. And also just to make sure that I did get this clear from your presentation, on your fifth slide, you mentioned that 30 percent of what NRC identified were technical issues and then you went on to say that essentially all of them, the technical information was there and it was more traceability. Then if I heard correctly on the presentation part that you made that we didn't have a slide of the 3,000 issues or something, I think I heard you say that about three percent were technical and some 35 percent were traceability. That is I thought I heard you distinguish between technical issues and traceability issues later. I was wondering what the three percent of technical issues how you categorize them.

MR. ZIEGLER: Okay. Two different sets of information. On slide five, that's NRC's report and what they reported back to us.

MEMBER HORNBERGER: I know that.

MR. ZIEGLER: The other information, I

think it's six percent. I may have said three percent. But a relatively low percentage and our categorization is a little bit different. I don't have examples of those technical errors or problems, but I can tell you that none of them were show-stoppers. None of them made us go out and collect additional data. None of them made us go out.

I think in one instance we did go out and did some reanalysis, maybe a couple of instances. So in those instances, we were looking at the technical bases, not just how we portrayed the technical bases but was the documentation, was the backup and supporting information adequate to support those technical bases? In some cases, we actually had to go back and do some modification to either the analyses or make sure that the datasets that we were using actually supported the information that the on-going analysis that we did and the conclusions that were drawn.

There were a couple of instances where we had to go back and actually apply additional datasets or different datasets because the datasets that were used had not been through the data qualification process yet. So that six percent was a little more technical than just clarity of explanation.

Now there still wasn't anything identified where the information ultimately didn't exist or we weren't able through additional analysis to correct the problem, but they were more, I think, technically oriented in a sense of actually having to do additional technical work versus just clarify the work that had already been done.

MEMBER HORNBERGER: Thank you.

CHAIRMAN RYAN: Ruth.

MEMBER WEINER: Joe, could you describe to me what happens when you find a mistake or a traceability error? What happens? What do you do then? Suppose you have a document and you see that the wrong table has been put in or there is a number in the table which you question. What happens?

MR. ZIEGLER: Okay. Within the regulatory integration -- If it happened outside of this regulatory integration team, what would immediately happen would be a condition report would be issued. It would go into our corrective action program. We would identify an action plan, document that. The corrective action would be taken and it would work its way through the program and we would close the action once the corrective action was complete.

Within the regulatory integration team

since basically the entire regulatory integration team, if you will, is a corrective action process, is we have gone through every AMR and actively sought to find those kinds of problems with teams that were experts in the particular technical area. We've identified about 3,000 actions and most of the actions were of the type that you just mentioned, either that or just a clarity traceability, you know, the wording could have explained this better based on what we did.

Those actions have been compiled into a database and distributed out. Then they compared the actions in various subgroups to see that if one subgroup identified actions whether those actions needed to take place across the board or whether they were limited to a more focused area. Once we determined the extent of the conditions, then these actions are being grouped.

The technical subgroups are in the process of implementing the corrective action. So we are in the process of modifying the AMRs to correct those conditions that were found. That process is a very proceduralized, strict, compliant process. As we go through those modifications, then there will be additional checks. So we make the change we're required. The qualified reviewers that did not do the

work check the changes in another check step to make sure once all those technical areas and changes were identified that there's another double check.

Then it goes through and is signed off by appropriate technical staff and management. Each of those steps is signed off by appropriate technical staff and management. What comes out the other end is an AMR in this case that have had all the corrective actions made, that has had all the checks on the changes within the framework of those corrective actions made and then is signed off by management. Then it is used as the bases for the TSPA that will ultimately feed the license application.

MEMBER WEINER: So it sounds like a good program in its structure. How do you deal with the individual or individuals who were responsible for the mistakes? Let me be very specific. Do you encourage people to find their own mistakes and correct them or do you land on them like a ton of bricks when they make one?

MR. ZIEGLER: We don't land on them like a ton of bricks. I guess what we found is that it is true that certain groups probably have had less of this kind of problem than others. But what we try to do is encourage people to identify the errors

themselves because the first line of defense is the individual doing the work. We want to encourage the individuals to do the work. So we're trying to take a broader look and not place personal blame on the individuals.

But what we are doing though is where there's more of a problem in one area than the other, we are providing some remedial training in those areas. We are emphasizing to the management in those areas that they need to pay more attention. So we're trying to put additional focus and management attention where the errors occur, but we're trying not to punish our employees because we want our employees to bring forth problems when they come up.

MEMBER WEINER: Thank you. I have just a couple more questions. When NRC Staff discussed this with us, they gave us a couple of examples because I work best from examples. The best people to answer the transparency questions as in why did you make this measurement at temperature X instead of temperature Y, the best person to answer that question is the person who did the work. So I would like to know. To what extent do you actually call on the technical people who did the actual work that went into the AMRs when there is an NRC review like this?

MR. ZIEGLER: Actually, extensively, when the NRC came in and did the evaluations, we set up interview schedules so that the authors were the actual ones that interviewed with NRC and I think that's where the nature of the NRC findings came. They were largely able when they talked to the authors to know that the adequate information existed. But just from reading the documents, it wasn't as apparent as it needed to be.

So I absolutely agree with you. And when we pulled the teams into Las Vegas, we pulled either the individuals that did the work or if there were multiple individuals doing the work, we hand selected the ones that we thought could best represented that work when we pulled the teams to Las Vegas.

MEMBER WEINER: The final question. What kind of internal review do you have for an AMR? In other words, what is the review procedure that the AMR goes through before it sees the light of any kind of day?

MR. ZIEGLER: Okay.

MEMBER WEINER: When somebody prepares a draft, what happens to it?

MR. ZIEGLER: The way it works, first there has to be a technical work plan and that

technical work plan has to go through an approval process not just management approval, but a secondary technical reviewer has to review the technical work plan and our QA organization that currently works the technical work plan to make sure that all the QA program requirements are within the work plan. We have to rigorous follow the work plan. If we need to vary from the work plan, then we go back and modify the work plan. So we go through that same type of review to modify it.

The work plan requires the author to do the technical work. It requires them to use data sources that are qualified data sources. It requires them to use software that has been developed and qualified according to the quality assurance procedures for software that may be associated with the model. The models that are developed have to be validated according to some very strict model validation requirements that are in Supplement 3 to our quality assurance program.

Once the work is completed a technically-qualified reviewer that did not participate in the work, is independent of the work itself, has to review the work and check it and make sure that it is adequate and meets all the requirements technically

and the other process requirements. Once that step is complete because we have had some outstanding issues, we have a mandatory step that's under our procedure, I think, AP 2.14Q that says we do a second technical review to make sure that the work is done and adequately and meets all the requirements, it adequately uses data, model validation software, and other elements that are required.

Then after that –- Well actually during that review, typically this work is done by contractors. Simultaneously with that review for the key products such as AMRs, the key primary inputs to our licensing and safety analysis, my DOE staff actually does a review of the work in concert with that secondary technical review. Once that is all complete, all comments have been resolved and documented and resolved, then there's a final management sign-off and the work is complete. In addition to that, all this work, the quality assurance audit and surveillance at least on sampling basis, that's done across the board.

MEMBER WEINER: So you should expect no further findings of deficiencies such as were found with these three particular AMRs. You got your program under –

MR. ZIEGLER: We certainly don't expect any broad findings across the board. There may be isolated instances that may result in from just differences of opinion. Sometimes we get a quality assurance auditor or self-assessor or regulator that has an opinion about, especially, on these clarity traceability issues. So I would expect it to be much less but occasionally that type of thing is there should be no technical errors.

MEMBER WEINER: Thank you.

CHAIRMAN RYAN: Allen.

MEMBER CROFF: Thank you, Mike. We talked a lot here about the AMRs and trying to fix those. As I understood what you said before, you've tried to apply the same lessons learned, of let me call it, upward in the document hierarchy toward the license application. To what extent are the relevant lessons learned being applied downward in the document hierarchy?

MR. ZIEGLER: Downward. I guess the primary inputs of these AMRs would be the data that's collected, the software that's developed. You know a model is developed and that's kind of the AMR, but software has to be developed and controlled and that software has to match the model that's were developed

to separate those two steps. We have applied these same controls to those processes as well and again the lessons are in there. That's the starting point. It's to decide which data needs to be collected. Again there has to be technical work plans to do that work. The data has to be collected. It has to be verified. It has to meet all the measurement and test equipment. So we have applied it downward as well, but the technical leads tend to start at the AMR level. So the same technical leads that define the data needs that define the software needs that define those other input needs.

MEMBER CROFF: Okay. My second question. Can I assume that these AMRs are a part of this large block of documents that's coming into the NRC?

MR. ZIEGLER: The AMRs will be referenced in the license application and they will be made available to the NRC. They are actually not part of the application. They are analytical inputs to the license application and they will be made available to the NRC.

MEMBER CROFF: I wasn't clear in my question. There's this large block of documents that's supposed to be here at the NRC any day now, I guess, I'll call it. Are the AMRs part of that block?

DR. HAMDAN: THE LSN.

MEMBER CROFF: As part of the LSN. Thank you for the nomenclature.

MR. ZIEGLER: Oh, the LSN. Absolutely. The AMRs, yes, absolutely. Those are the primary inputs.

MEMBER CROFF: And so can we expect modifications to be submitted through the next several months to these as you guys revise the AMRs at your end?

MR. ZIEGLER: Yes, absolutely.

MEMBER CROFF: So we'll see changes in these things as they go along.

MR. ZIEGLER: Yes, sir.

MEMBER CROFF: Okay. Thank you.

CHAIRMAN RYAN: Jim Clarke.

MEMBER CLARKE: Joe, this is a follow-up to Ruth's last question and perhaps where Allen was going. I don't know if you are continuing to generate AMRs or if you're pretty much done with that exercise. But my question is if you were to generate a bunch of AMRs over the next few months, what would you do differently compared to what you had done to generate the ones that required the corrective action? I hope it's not too academic, but I just wonder what came out

of this process that you would really change how you would develop any future documents.

MR. ZIEGLER: I think the biggest lesson learned here is that I think where we are today and what we're doing today if we had started there we would have been in better shape. But I think we would have done a better job of integrating all the different pieces. We have these 100 and some odd AMRs out here and they were done by groups across the country. I think we'd do a better job of integrating and planning the work before the work started.

Now that may be a little over simplified because the work we're talking about has gone on over the last 20 years in many cases so the groups didn't exist as they exist today, but doing a better job of integrating and making sure we knew how the pieces of the puzzle fit together in a systematic way before we get so far into the work that we start getting these inconsistency in integration issues. I'll give you an example.

Five years ago, we didn't really didn't have one software development and control procedure that we were using across the entire project. We didn't have one model development procedure that we used across the entire project. We didn't have one

data collection procedure that we used across the entire project. So I think the biggest lesson learned is that we should have practices and procedures and processes in place, one practice for every type of work and then we should have forced all of our contractors and laboratories and participants to use that one set of processes.

To me, that's the biggest lesson learned because trying to control it by equivalent processes by groups that in my opinion are not used to working in such a rigorous regulatory environment actually caused us to go back and have to redo a lot of work or at least redocument a lot of work. I think that's the biggest lesson. It's to consistent processes and practices across the project, sharing of lessons learned when there are problems and just sticking to that consistency.

Even if the work could have been spread out, I think having a centralized group so if there's any problems, then there's one place to go to get that problem resolved so that the problems were resolved and communicated once you have the problem across the board is the way to go. That's what we've instituted now. So I think from this point forward, I think we can manage this project and these problems very well.

I've always known for the most part that had we done a better job of that cross integration and consistency in our processes, I think we could have avoided a lot of this.

MEMBER CLARKE: Thank you.

CHAIRMAN RYAN: Okay. Thanks, Jim. Joe, I want to turn your attention to the bottom of page four in your slides. When the NRC gave its presentation to us last month, the last sentence of your third quote there is what caught my attention. "This could as a consequence prevent NRC from making a timely decision regarding the issuance of a construction authorization." I do appreciate what you've gone through today in some detail about how you've addressed the specifics of the quality improvements efforts over all and you've done a nice job of outlining what you're done.

I'm curious to hear your opinion on two points and I think I know the answer to the first one. Do you view that the things that you have done are going to help avoid that kind of delay? I'm assuming the answer is yes based on all the practices and policies and improvements that you've outlined to us today. But the $64,000 question to me is have you had additional interaction with NRC Staff on getting

either their concurrence or agreement that you're on the right track and what I'm really looking to do is to get you to talk about how have you brought closure to this whole exercise with NRC and do you have what you can characterize as a joint view moving forward or are you waiting for that secondary assessment and so forth? Does that make sense to you?

MR. ZIEGLER: Yes, it does. I do think it will largely address the issues raised by the NRC Staff. I don't think that means we're not going to get any requests for additional information on our license application. I still expect a lot of requests, but I think this will probably alleviate some of the larger number. We probably won't get as many as we would have gotten and it probably won't take as long for them to review it to be able to determine what additional needs they have.

As far as feedback, I guess I got two types of feedback. I think you had a couple presentations on KTIs and KTI agreements by my staff. We instituted a process about, I guess, a year ago where we created technical basis documents and while the issues weren't exactly the same, they probably weren't articulated as well, we recognized based on KTI agreement responses from NRC that although we

responded to the questions, maybe we didn't do a good enough job of putting that response into the framework of the way that the physics of the repository would work.

And we created this concept of technical basis documents which basically put the context and technical groupings together of the physics of how to repository would work. In those instances, we did what I think is a much better job of communications of transparency and traceability. I heard the NRC Staff say that in public forums and when we took the context of the agreement and the response to that agreement and put it into that context.

So we started this kind of lessons learned back then. I think part of what we're doing here in the more formal process is applying some of those lessons learned and we've had very positive response from the NRC Staff about that. They were hesitant at first. I think they were saying we were making this big change and it's not really going to do anything, but I really think it did put things in a perspective and light that facilitated their review of KTI agreements. So I have that data point that basically says "Okay, we're doing similar things here into the licensing products. I would expect that this will

help facilitate the review as well.

We sent a letter. We were required to give a response within 30 days of the exit meeting that the NRC had and their exit meeting, publicly here in Las Vegas, was on May 5th. We responded on May 28th and what we outlined, much what I outlined to you today, is to what we were doing and had done to address these issues. I'm not sure whether NRC plans to respond to that formally, but we have gotten some indication that they believe we understand the issues and what we're doing sounds like it will address the issues.

Of course, NRC always tells us and rightfully so that the proof is in the pudding. Once we implement and once we're complete, have we done an adequate job? So they are not going to commit to this is adequate until they get the produce and I don't blame them for that.

CHAIRMAN RYAN: I fully understand that you're not going to get that commitment up front, of course. So I guess the answer is you haven't really received a formal response on the implementation nor a final follow-up audit of other AMRs or other similar activities. Is that right?

MR. ZIEGLER: That's correct.

CHAIRMAN RYAN: Okay. I appreciate that. And again, I'm just trying to be real clear that there hasn't been a formal test of all the things that you talked about and that are quite clear and sound correct and appropriate given the context, but as you pointed out, the proof is in the pudding. So we'll see how it goes. Again to me, the key was raised as an issue that could have an impact on schedule and making a timely decision. Well, I guess we'll learn more as time goes on.

MR. ZIEGLER: Right. We plan to be extremely responsive to the NRC Staff and doing everything we can do to facilitate a timely license application review.

CHAIRMAN RYAN: And you sure made that clear in your summary which we all appreciate. Thanks very much.

MR. ZIEGLER: Thank you.

CHAIRMAN RYAN: Any other questions? Mike Lee has a question, NRC Staff.

MR. LEE: Yeah, Joe. You made reference in your presentation that there was still one outstanding corrective action that DOE was addressing. Could you just elaborate on that briefly?

MR. ZIEGLER: Yeah. There were basically

three outstanding condition reports significant conditions adverse to quality over the last two or three years. There were others but they were dealt with in a more timely fashion. The one that's outstanding is the one that was written against the model validation process. The subject of what we were talking about here today is basically developed in the AMRs and validated in the models that were already in those ARMS.

We have made a conscious decision even though we believe we have taken the right actions to identify all the problems. We have a work plan in place that we're following, but because we're revising the AMRs and those revised AMRs through this process I described are not going to start coming out of the pipeline.

I think that some of them start next month, but we wanted to see actual product, substance of numbers of these products coming through the final approval before we close that condition. So the actions that were taken to close the conditions are indeed the actions that I described today. But we're not comfortable closing that until we actually see internally product coming through the process and we've identified which of those products that it will

be so we have every confidence that we'll be able to close the condition, the actions that were taken were adequate.

Much like I said, the NRC Staff says the proof is in the pudding. The RTA approach and line management approach are going to be the same way. We're not going to close that condition adverse to quality prematurely.

MR. LEE: Thanks.

CHAIRMAN RYAN: Any other questions? Yes.

DR. HAMDAN: Thank you. Joe, this is Latif Hamdan and I have just a follow-up on our chairman's question about the license application verification schedule. I wonder if you can comment on this work has impacted or how it was impacted by the work that you have done –

MR. ZIEGLER: In our schedule?

DR. HAMDAN: Right.

MR. ZIEGLER: It's had some internal -- It's provided some intermediate scheduling challenges. I don't see it changing the end point schedule at all. We knew that we were going to have to do additional integration work. So as the AMRs were being completed, the first revision of them were being completed, we knew that we were going to have to bring

a group of people together to do some integration and cross-checks.

I guess we didn't know we were going to call it regulatory integration team. We probably didn't feel the extent of what the team needed to be so that we needed to give 100 percent through all of the AMRs, but we did that. I guess the biggest impact is a resource challenge in that I have a lot of KTI agreements and responses to KTI agreements that are due. Actually, I have about 50 more due to NRC between now and August.

I have this AMR process that's going to be going on between now and September and I am in the process of preparing license application sections that all deal with the same technical expertise, the same topics. So I guess the biggest challenge is one of keeping that consistent and making sure that the technical expertise that's being applied has been consistently applied across those three basic products lines. So it's a scheduling challenge.

I guess I often say a compliment to the technical staff and the general staff on this project is they are taking that challenge. So I'm keeping the adequate technical expertise plugged in all three of those product lines, making them consistent and making

these improvements as we go.

I won't tell you that it's not a challenge, but this is where we wanted to be two years ago. We wanted to be in a position to be able to head in towards a high quality license application that met all these technical challenges and I think we're here. While I don't want to downplay the challenge, our staff is up to it and they think what they're doing is important.

Management knows it's important for various reasons and so we're going to get it done. So I don't see it affecting the overall schedule in the end at all. I see a high quality license application in December.

CHAIRMAN RYAN: Anything else? Joe, thank you very much for your time. We appreciate you being with us this morning.

MR. ZIEGLER: All right. Thank you very much.

CHAIRMAN RYAN: Thanks. I think at this point this ends our information gathering part of the meeting and we can go off the record. So I suggest that we just take a couple minute break and then reconvene and pick up any action items to close out and we'll be finished. We have just a few of your

graphs to finish. We'll just take a couple minute breaks in place and go from there. Off the record.

(Whereupon, at 12:07 p.m., the meeting of the Advisory Committee on Nuclear Waste was concluded.)