UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON MEASURES TO ENSURE INTEGRITY OF RESEARCH DATA - PUBLIC MEETING

Location: Rockville, Maryland

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON MEASURES TO ENSURE

INTEGRITY OF RESEARCH DATA

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PUBLIC MEETING

Nuclear Regulatory Commission

Room 1F-16

One White Flint Plaza

11555 Rockville Pike

Rockville, Maryland

Wednesday, November 15, 1995

The Commission met in open session, pursuant to notice, at 1:58 p.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission

KENNETH C. ROGERS, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

ANDREW BATES, ACTING SECRETARY

KAREN D. CYR, OGC/NRC

JAMES TAYLOR, EDO

JOHN CRAIG, DEPUTY DIRECTOR, DIVISION OF ENGINEERING TECHNOLOGY, RES

CHARLES SERPAN, CHIEF, GENERIC SAFETY ISSUES BRANCH, RES

RONALD THOMPSON, DIVISION OF CONTRACTS, OFFICE OF ADMINISTRATION

DAVID MORRISON, DIRECTOR, OFFICE OF NUCLEAR REGULATORY RESEARCH

P R O C E E D I N G S

[1:58 p.m.]

CHAIRMAN JACKSON: Well, good afternoon. Some of you, I recognize from this morning.

Today, the NRC Staff is here to brief us concerning our internal measures to ensure the integrity of research data.

The Commission became interested in this topic after being informed of an investigation by the Office of Inspector General which had substantiated allegations that falsified research test data that had been submitted to the NRC. The data had been provided to the NRC pursuant to a research contract with a national lab.

As a general matter, however, the Commission would like to hear, in the aftermath of this specific incident, how the NRC retains assurance about the integrity of research data. The Commission is looking forward to hearing from you about the management control process that we exert on research contracts and about how the NRC may be assured of management control within contractors organizations.

Commissioner Rogers, do you have anything you would like to say?

COMMISSIONER ROGERS: No, not just yet.

CHAIRMAN JACKSON: You may proceed, Mr. Taylor.

MR. TAYLOR: Good afternoon. As you know,

Chairman, the review at this time of our management controls on research projects was motivated a situation that arose at one of our national labs. The Agency takes seriously the integrity of its research products, since they are an essential input to our licensing and regulatory processes.

While we believe that the situation, we would note, is an isolated occurrence, it is prudent to assure ourselves that this is the case and that our management controls are sufficient.

At the Commission's request, the Office of Research has undertaken a review of our management practices to determine if they are adequate to ensure the quality of our products and to identify any gaps in the process or lapses in its execution before it could impact the integrity and credibility of our research activities.

During the briefing, you will hear that under our memorandum of agreement with the Department of Energy, we place a strong alliance on the management at the national labs, which include quality control and assurance procedures.

The controls and procedures, in effect, at the labs are suitable to assure the integrity of the research products and are comparable to controls and procedures used in other Federal agencies and by industrial research labs.

Responsibility for implementing these procedures

is clearly assigned to several levels of management, so there are checks and balances on the process, as you will hear more about today.

With me at the table are Dave Morrison, Director of the Office of Research, John Craig, Chuck Serpan from Research, and also with us is Ron Thompson from the Division of Contracts.

John Craig will take the lead in the presentation.

John?

MR. CRAIG: Good afternoon.

CHAIRMAN JACKSON: Good afternoon.

MR. CRAIG: Go to slide 2, please.

[Slide.]

MR. CRAIG: As Mr. Taylor mentioned, as a result of the request from the Commission, we visited several of the laboratories, and we took a look and reviewed our internal procedures to define management controls on research projects, and we tried to look at those in the context of the three questions that were contained in the Office Staff Requirements memorandum that basically asked the same kind of question from a couple of different perspectives why we have confidence in the quality, the integrity of the research data, the research products that we get both from the standpoint within the NRC and within contract organizations.

Slide 3, please.

[Slide.]

MR. CRAIG: The structure of the presentation is divided into two parts, an overview of the NRS management control process and one for the laboratories and then finally some conclusions and some actions that we are contemplating.

As we began the review of our own process, we identified some things that we thought may be needed to be reinforced or beefed up. We will talk about those a little bit later.

We had discussions with the Department of Energy authors of the Quality Assurance Criteria that are applicable to the national laboratories, and Chuck Serpan, Ron Thompson, and Owen Gormley visited several of the labs to discuss the management control process that the labs have in place, as well as the quality assurance activities that are applicable to NRC research projects.

Slide Number 4.

[Slide.]

MR. CRAIG: The NRC management control process begins in the planning stage for research projects, and they are described in Office Letter 4.

The key document in our planning process is a program plan development. We have extensive interactions

with the user office at the technical level as we prepare each one of the program plans, and the program plans are pretty extensive. They discuss the broad objectives and then specific objectives for each task, regulatory applications, resources, schedules, regulatory products, specific questions that may need to be asked, as well as closure of the projects and the program plan.

Part of the review that goes on internally in addition to the user office research project manager interaction to develop the plan is extensive discussion at the branch chief level as the plan is developed.

When the plan is prepared, it is reviewed internally within the Office of Research, up through the office director level, and it is sent to the user office for endorsement, and that culminates in a review at the deputy EDO level as we review program plans, changes to the program plans, and that process has been underway for several years.

So we have a pretty elaborate process to ensure that the research projects that are contemplated are focussed. The regulatory uses are clearly identified, and the issue of closure is addressed as part of the planning process.

Then, as the plans are being implemented, Research Office Letter 6 describes the project manager's role in ensuring quality that he is the front line as he interacts

with the principal investigator at the laboratories, and it stresses a fundamental aspect of the review of the research results as peer review.

In the context of --

CHAIRMAN JACKSON: Would you repeat what you just said about peer review?

MR. CRAIG: The peer review process and the requirements for peer review as described in the office letter are rather elaborate, and in each one of the statements of work both for the laboratories and in commercial contracts, the objective of ensuring peer review of the products is discussed specifically.

So it is a fundamental aspect of getting outside experts' input evaluation of the research project, the steps that were undertaken and the results of the data, and these things, as we will see in a couple of slides, it is one of the factors that we think is fundamental in ensuring the integrity of the process and the results.

CHAIRMAN JACKSON: Okay. I don't want to slow you down, but I just want to make sure I understand.

So you are telling me that peer review is, in fact, part of the contractor's quality assurance and control functions?

MR. CRAIG: Yes.

CHAIRMAN JACKSON: And we ensure that that is, in

fact, in place?

MR. CRAIG: Yes, that's right.

DR. MORRISON: Well, that is just one level of peer review. There are several other peer review levels.

CHAIRMAN JACKSON: Right, but I'm saying that that is one level.

DR. MORRISON: That is one, right.

CHAIRMAN JACKSON: Okay, and you're going to talk more broadly about other levels in this presentation.

MR. CRAIG: Yes.

CHAIRMAN JACKSON: Okay, very good.

MR. CRAIG: One of the things that takes place during the implementation phase between the project manager and the principal investigator at the laboratory is sometimes it's daily, but it's a constant interaction with respect to results, evolving work that's going on, equipment issues that may take place, and a monthly letter report that I'll talk about in a minute.

Can we go to slide 5, please?

[Slide.]

MR. CRAIG: Each month for each one of the projects, we get a monthly business letter report, and we also get a summary, and it discusses for each one of the projects two parts, a financial summary and a technical summary.

The technical summary focusses on the issues, the work that's been completed that month, the work that's planned for the next month, trips that may take place, any problem areas, planned activities.

In addition to that monthly letter report that the project manager in RES has to review and annotate that he's reviewed it and discussed it with his management as appropriate, there are management performance review meetings that are held.

These are typically held by the project managers periodically during the year. It depends on what's going on in each one of the projects.

On an annual basis, typically, it will involve the branch chief and/or, at a separate time with the branch chief, a division-level manager to review the status of the project, the findings, and any issues. Frequently, the ones that I have attended, we discuss communications issues between the principal investigator, the project manager, or managers in the chain, any issues that are broader than a request for another piece of equipment, a computer, an extension of three months to write a report, but any of the broader issues that may come up are discussed at those meetings.

Can we go to Slide 6, please?

[Slide.]

MR. CRAIG: What we tried to do in this slide is show from a different perspective the layers or the tiers of activities that contribute to the management control process for projects.

I am not going to read all of them, but the research data for any project such as reactor pressure vessels is a body of work, so that the research is being conducted today builds on a lot of work that has taken place in the past, so that there are multiple sources for data and information. So that helps provide a level of confidence for the overall conclusion since we don't rely on single pieces of data.

The program reviews that I just discussed and the progress reviews that take place throughout the planning and the implementation phase, the view groups, the technical review groups and bench mark exercises that may be part of a research project involve other experts, other than the people at the labs doing the work, and so that's another source of review and comment on the data and the project.

Peer review of publications is specifically identified in the contracting paperwork, the laboratories and commercial contracts, and for those new regs that we publish, we publish them from public comment.

The peer review can include both experts at that laboratory and different laboratories in the commercial,

from the industry, as well as international experts and people from universities.

There are numerous technical meetings that take place where contractors, researchers present the work that they have been working on, the water reactor safety meetings as an example, American Nuclear Society meetings, ASME meetings, or various technical meetings that take place.

In addition to that, the codes and standards participation for the various IEEE AMSE codes and standards where the researchers, in fact, go and present the data to the people that participate in the codes and standards body, typically. Their representation includes various companies, utilities, and also international experts that are interested, whether it's a Section 3 or Section 11 issue, an inspection issue, materials issue, and there's some pretty vigorous discussion of specific findings with respect to whatever the technical issue is at the codes and standards.

I mentioned the frequent interaction between the RES project management and the principal investigator at the lab, as well as the close and frequent interaction with the user office.

When the project managers go to the laboratories, when I go to the laboratory for a review meeting, it is frequent that somebody from the user office will also attend the meeting to get a better understanding of the status of

the project, where it is, and the types of issues that are being identified.

This provides an overview of the NRC control process that we have, a couple of aspects of it.

The subsequent slides will provide an overview of the Department of Energy process and the management controls at the laboratories that we rely upon them to implement.

Slide 7, please.

[Slide.]

MR. CRAIG: I have divided somewhat artificially the management control process at the laboratories into two broad groups, the normal procedures and practices that define operations at the laboratories and then the quality assurance programs as a layer of defense and depth, a second check, recognizing that the review process and the quality assurance activities that take place are interwoven with normal procedures and practices.

I should note that while the labs are not identical, they are pretty similar in the procedures and practices and the quality assurance programs that they have in place.

If we go to slide 8.

[Slide.]

MR. CRAIG: The fundamental or the primary portion of the laboratories that contributes to the integrity of the

research projects and the data is derived from the normal procedures and practices. It starts with a management review and oversight of the conduct of operation, including the planning of the project within the laboratories, assignment of people, use of controlled and approved procedures, uses of various engineering standards, such as ASTM standards that account for equipment, IEEE standards, those types of activities.

The peer review that takes place within the laboratories both in the context of the senior scientist and engineers to the laboratories reviewing the work of other people at the laboratories and the internal peer review process that takes place, as well as the external peer review, we are depending on the complexity of the project or results. They frequently get external experts to review the project and the data.

CHAIRMAN JACKSON: How often do the results end up being published in refereed journals?

MR. CRAIG: Every year, we provide a report, and so I have to answer the question in that context. We prepared a summary of the peer review research project for '94, this past August, and we gave it a quick count. It includes refereed journals, as well as other professional publications, so that for that year, it was between 250 and 260 in that year.

CHAIRMAN JACKSON: Out of what size universe? You can tell me later. Why don't you do that.

MR. CRAIG: We will get back to you with that number.

CHAIRMAN JACKSON: I just wanted to get some sense of really how often these things end up being published in refereed journals. That's all.

DR. MORRISON: That is out of approximately a $60 million research budget that would relate to those laboratories.

CHAIRMAN JACKSON: So about 250.

DR. MORRISON: So 250 every quarter of a million dollars results in publication or something like that.

CHAIRMAN JACKSON: Well, that compares with loaded salaries of some scientists I know.

DR. MORRISON: Right, yes. It is about a 1-person-a-year work.

CHAIRMAN JACKSON: Right.

MR. CRAIG: Of note also are the special procedures that the laboratories have if it involves environmental safety or health considerations, and finally, the management review and approval process that they undergo to make sure that it meets the criteria, they have to say it is good enough to put the lab's name on it.

Can we go to Slide 9, please?

[Slide.]

MR. CRAIG: As we try to prepare a slide to describe the quality assurance process and controls that are applicable to the laboratories, it became apparent that it was going to be a difficult thing to do because it is a little bit confusing because the Order 5700.6C, which is equivalent to our 10 CFR Appendix B and the Implementation Guide, was supplemented with a third bullet, the DOE-ER Standard 6001-92, which was developed specifically for quality assurance and research programs. Those documents have been superseded by 10 CFR 830.120.

Having said all that, the quality assurance criteria in the documents are essentially the same. They are very similar, and the newer -- the incorporation into the Code of Federal Requirements changes some of the options that the Department of Energy has for people that don't, in fact, implement the programs, but the basic criteria are that the laboratories have to have quality assurance programs that are reviewed and approved by the Department of Energy, and they cover such things as personnel training, qualification of personnel, procurement, inspection, testing, working to approved procedures, management controls, those types of things.

One of the central things that struck me as I reviewed the documents were the two critical criteria, and

that's a quote. The critical criteria are hiring the most qualified personnel and peer review, and the peer review process makes great emphasis in the quality assurance programs on those two aspects of ensuring quality research programs.

Slide 10, please.

[Slide.]

MR. CRAIG: So the Department of Energy's Quality Assurance Requirements get interpreted into the labs typically at the Department-level Quality Assurance Programs, and at the Department level, there is a Quality Assurance Specialist who works with the principal investigator at the lab as programs are developed and implemented to determine what additional quality assurance activity should be applied to that research project.

Some of the activities include audits. They include peer review, indoctrination of new employees. The internal review and controls for products and data, such things as traceable standards, these activities supplement the normal -- to some extent, the normal procedures and practices within the laboratories. So it provides a second layer to ensure that they get high-quality results in data.

Slide 11, please.

[Slide.]

MR. CRAIG: In parallel with the planning and

implementation phase that we talked about in the NRC management control process, as we looked at the control process in the laboratories in the planning phase, there is the review with the normal procedures and controls, and they may supplement it by additional controls or criteria, whether it be qualified instruments, special testing considerations, as well as quality assurance criteria.

Then, in the implementation phase, we discussed the review of the NRC project manager, the performance review meetings, and the laboratory procedures and controls, normal review of the paperwork that goes on at the laboratories and the review process that takes place there.

Let's go to Slide 12.

[Slide.]

MR. CRAIG: With that overview and as a result of our review, there are a number of conclusions. As Mr. Taylor noted, we think there is reasonable assurance that we have confidence in the integrity of the data and research projects, the controls that are in place both within the NRC and that the laboratories provide reasonable assurance. We have high-quality projects.

We rely on DOE and the laboratories to implement their procedures and practices, but we note that during our reviews, if there are issues with schedules or there are significant comments as a result of peer review, we

frequently get involved in discussions with the laboratories of those.

We note that the process did identify the falsified data, and in a sense, that is a mixed blessing. It is good news that we see that the process worked. It is bad news that it also showed that the process broke in a couple of places.

CHAIRMAN JACKSON: Multi barriers.

MR. CRAIG: Yes.

As a result of that review and as a result of the changes that are taking place in the laboratories, the reductions in staffing and budgets, loss of expertise, a change in climate, we believe it is appropriate to send a letter to the laboratories from Mr. Taylor that will raise their level of awareness with respect to the importance of management controls at the laboratory, specifically with some of the circumstances where work may be contracted outside the laboratory. Before we send that letter to the labs, we will send it to the Commission for review.

We also note that we believe that we need to be more proactive in the implantation of the controls that are applicable to our research projects. We need to be more aggressive in the review, both in the planning phases and the implementation phases, and we intend to use the management performance review meetings and our program

reviews to determine what specific additional action is appropriate.

Slide 13, please.

[Slide.]

MR. CRAIG: The potential actions that we are considering, and we haven't identified specific ones yet, are revision of the memorandum of understanding with the Department of Energy, the potential revision of Management Directive 11.7, or the RES office letters.

The last bullet is intended to give you an example of the kind of thing we are thinking about where we would review the audits of evaluations that are conducted by labs, potentially if they conducted an audit and the conclusions reflected something that may be of interest to us or could impact the conduct of one of our research programs, that maybe we should take a stronger look at that. So that those are the types of things that we are considering.

I will conclude the presentation with that. I have a couple of backup slides, but I think they are pretty much self-explanatory. I open it up for your questions.

CHAIRMAN JACKSON: I only have one.

You mentioned that sometimes you have fully independent peer reviews. What conditions trigger that kind of review? Are there any particular -- or is it just a judgment in a particular area?

MR. CRAIG: The answer is a combination. The judgment of the RES project manager -- and in part, that is tied with some guidance from his management, the significance of the project, the significance of the findings, the regulatory application, certainly, is used in that decision.

Additionally, within the laboratories, depending upon the technical complexity and some other factors, they also have some guidelines that trigger more independent -- other than an internal review, an external review, an independent review that would trigger that, also. It is a combination.

DR. MORRISON: I think I would add to that list, John, that if there is a particularly contentious issue that is on the table, we have used external advisers to come in or had a special team of people look at this particular subject area, and that has been, I think, quite useful in the several times that I am aware that it has been used. It has brought at least clarity to the issue, and I think as a result of the clarity, then the steps were taken to move to resolve it.

CHAIRMAN JACKSON: You mentioned these potential actions on Slide 13. Are these under active consideration, or are you going to wait and see what comes out of the last three steps on page 12 before you make a decision?

MR. CRAIG: We are going to wait until we have had some interactions with the labs before we make a final decision, but it is also fair to say that, as we have prepared for this briefing and reviewed the slides and reviewed criteria that EPA uses for peer review processes and other things, we are defining the alternatives and discussing them. So they are actively being reviewed and discussed as we move. We are not waiting necessarily for some point in time. It is both.

CHAIRMAN JACKSON: Okay.

Commissioner Rogers?

COMMISSIONER ROGERS: Well, this is a very important area, and it is one that has several different facets to it. I am not sure I am going to say anything that is very useful or helpful, but just give you some observations.

One is that, of course, we want the very best quality product in the end that we can get, and it is very clear that sometimes there are disagreements among experts and that we may be dealing with some difficult areas where everyone doesn't agree and we need -- certainly need peer review and we need as much input as we can get to get the best possible product under the circumstances, whatever those circumstances are, and peer review certainly plays a very important role in that. There is no question it is

fundamentally important in dealing with the basic quality of research.

I guess what I have tried to say is it seems to me there are a couple of different issues here. One is quality of research and integrity of results, and they are not necessarily completely congruent. They relate to each other, but they are not completely congruent.

You can have results which have basic integrity, but are still not terribly high quality. There are lots of people who think about things very hard and do their very best, and they don't do a very good job even when they do. So there is where peer review is terribly important because you want the very best lines and the best expertise to be brought in to criticize whatever it is we do, so that we come out with the best that can be achieved.

The incident which prompted this work was not of that nature. The incident that prompted this effort, in my opinion, was really one of integrity of research data, not quality of research data in the sense that it was the highest quality. It just didn't have any quality at all.

So there, that is a different kind of problem, and peer review in a number of these actions and so on and so forth would perhaps eventually turn up something like that, but it might take some time.

However, the basic integrity of research data

seems to me has to be explored or dealt with in a little different way, and that is by holding individual managers accountable for supervision of the work. I am not talking here now about NRC managers because they are not directly involved. I am talking about the contract managers, the people who have responsibility as principal investigators, let's say, of a project. They should have such an intimate knowledge of that research that it wouldn't take them more than a day or two to find out that somebody wasn't actually collecting data when they said they were collecting data.

You'd stand them up to a blackboard and you start asking them some questions about it, and within five minutes, you know that they don't know beans about what they were doing. That is the responsibility of the principal investigator under a contract to us.

It seems to me that while I have no quarrel with the controls and so on and so forth that are being put on here, they seem to be more of the nature of adding requirements on that still could be subverted by somebody who wants to cheat in a way. They would eventually turn it up, but, you know, in this particular case, I think it took about a year to find out that somebody wasn't doing what they were doing, when it probably could have been found out by the principal investigator that somebody wasn't actually taking the data they said they were taking within minutes in

a searching oral examination.

So I guess what I am coming to here is it seems to me that I don't see in the approach that we are taking here enough of an effort to hold accountable, personally accountable, let's say the principal investigator in a case like this, and through the laboratory itself.

When the laboratory has a principal investigator operating under them that has been asleep on the job, I think it is just as serious and maybe even more serious than when we find a reactor operator licensee that has somebody asleep on the job in the control room, and let me tell you, we have held the highest level of the corporations accountable in cases like that.

So what I am saying here is I see an approach here which is probably important and necessary. It is a kind of procedural control approach, and what I would like to see that buttressed by is some kind of an effort to hold personally accountable the people who are running the laboratories, and they ought to make sure that they have people that they can trust on their staffs, and those folks ought to know that the people who are doing the work on the lab bench or in connection with the lab bench are actually doing it.

There is a personal involvement there, a factor that is absolutely essential in research. This is what I

don't see necessarily coming out of this. I think that the controls that we are putting on here are all procedural controls that would eventually turn up a problem, but I think the element of accountability, personal accountability and collective accountability of the lab and the people who are working in the lab, I don't quite see coming through here.

I wonder if you want to comment on that.

DR. MORRISON: Let me comment briefly on it, Commissioner Rogers, because I think you put your finger on the key to the problem or the key to the issue at least for integrity of research results, and that is the individual that is doing the work.

In part, that would be addressed under this letter that we are talking about for Mr. Taylor to send to the laboratories to increase the awareness of the situation and make sure that they are following through on it.

Certainly, the laboratories, as you read their procedures, do start with the hiring of the best qualified individuals, and that in itself is a difficult process, as we all know, to determine across the table in an interview if that person is going to be one that will have high-integrity standards. I suspect Daiwa Bank did that when they hired the individual that got into trouble there, and that was, again, the same sort of problem that you are

dealing with.

If someone is out to defeat the system and they are bright individuals and we assume that the laboratory hires bright individuals, they will find a way to get around the system.

I think you are right that the only way we can do that is to make sure that the various levels of the laboratory are held accountable for that.

COMMISSIONER ROGERS: Yes, that is what I am saying.

DR. MORRISON: I think that we do need to continue the peer review process at all the various levels that was talked about --

COMMISSIONER ROGERS: Oh, absolutely, yes.

DR. MORRISON: -- to be sure that there is a check and balance on that approach.

I would resist saying that we at NRC should get more involved in the audit process because that is very expensive and very time-consuming.

I sort of relate it to a situation while I was at IIT Research Institute where we had contracts from the National Cancer Institute, and they generally were chronic studies that ran over a three- to five-year period, and every year, NCI would send in a group of quality assurance people, like 10 people who were there for a week, and they,

indeed, went through all of the files and all of the information with regard to the calibration of equipment, following an individual mouse from when it was received in the laboratory until it was finally disposed of.

I always could find something that was wrong. There was no way in which the system caught all of those errors, but in the aggregate, I am not sure that they really improved the quality of the work because it was really the principal investigator that was on top of it all the time, and he or she knew whether things were being done.

COMMISSIONER ROGERS: They could probably catch it if somebody was painting the mice.

DR. MORRISON: Oh, absolutely. That, you can find.

CHAIRMAN JACKSON: That has been known to happen.

Well, I think that within what you are proposing lies a methodology for getting at Commissioner Rogers' concerns. I think heightening the awareness relative to accountability and letting it be known that that then becomes part of an evaluation process which can effect further placement of research, I think, is a message worth propagating.

COMMISSIONER ROGERS: Yes. I think that is really the point that the whole lab is on trial when something happens that destroys the basic integrity of their research.

We can forgive them for perhaps doing their very best and not winning a Nobel Prize, but we can't forgive them for not even checking to see whether somebody actually graduated from a college when they claim they did.

I mean, you know, that is so fundamental, and that ought to be found out very quickly and whether they were actually doing, carrying out tests, when they claim they were doing them.

So it seems to me, Mr. Taylor, that if we saw something like this happen in a power reactor, we would conclude automatically that there was a breakdown of management control.

MR. TAYLOR: Yes.

COMMISSIONER ROGERS: Without a doubt.

MR. TAYLOR: That is true.

COMMISSIONER ROGERS: And it is just as important that the quality of the research be up to what we expect its safety use will be.

So that, folks doing research, I am sure they are dedicated and want to do the right job, but they have to recognize when they are working for NRC, the quality of what they do is just as important, and they are going to be held just as accountable as we would hold somebody who is actually running a powerplant that is somehow or another fundamentally dependent upon the integrity of the research

for its operations.

MR. TAYLOR: Yes, I agree.

CHAIRMAN JACKSON: Well, having said that, thank you very much. We will be looking to see how it evolves and that we close these gaps.

MR. TAYLOR: We will give you further follow-up, too.

CHAIRMAN JACKSON: Thanks.

MR. CRAIG: Thank you.

[Whereupon, at 2:40 p.m., the meeting was concluded.]

CERTIFICATE

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

TITLE OF MEETING: BRIEFING ON MEASURES TO ENSURE INTEGRITY OF RESEARCH DATA - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, November 15, 1995

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

Transcriber: Jennie Malloy

Reporter: Mark Mahoney

MANAGEMENT CONTROLS ON RESEARCH PROJECTS

November 15, 1995

Office of Nuclear Regulatory Research
Division of Engineering Technology

John W. Craig, Deputy Director

Charles Z. Serpan, Chief
Generic Safety Issues Branch

Ronald D. Thompson
Division of Contracts

August 8, 1995 SRM

- NRC confidence in other data supplied by that contractor.

- NRC management control process on this and other contracts.

- NRC assurance of adequate management controls within contractor organizations.

PRESENTATION

Overview of:

- NRC Management Control Process
- Laboratory Management Control Process
  - Procedures and Practices
  - QA Program
- Conclusions

NRC MANAGEMENT CONTROL PROCESS

Planning - RES Office Letter No. 4, Revision 1 - November 1993 "Planning Research Programs"

- Quality in Performance of Research - "high quality results"
- Program Plan Development/Implementation

Implementation - RES Office Letter No. 6, Revision 1 - November 1993 - "Implementing Research Projects"

- "Published reports must contain sufficient information to permit an independent evaluation of the quality of the work."
- "...front line in ensuring quality, it is also the project manager's responsibility to ensure that the contractor's quality assurance and control functions are in place and functioning well."

NRC MANAGEMENT CONTROL PROCESS (Con't.)

(RES Office Letter No. 6 Con't.)

Review - Management Performance Review Meetings

- PM
- Branch
- Division

"...improve program effectiveness by jointly focusing on quality, timeliness, cost, effectiveness of research..."

NRC MANAGEMENT CONTROL PROCESS (Con't.)

- Integrated Approach To Achieve High Quality
  - Multiple Sources of Data and Information
  - Program Reviews, Progress Reports
  - Review Groups - Benchmark Exercises
  - Peer Review of Publications
  - Public Comment on Documents
  - Technical Meetings, National and International
  - Codes and Standards Participation
  - Close and Frequent Interaction Between PM and PI
  - Close and Frequent Interaction With User Office

LABORATORY MANAGEMENT CONTROL PROCESS

- Procedures and Practices that Define Operations
- Quality Assurance Programs
  - DOE
  - Laboratory

LABORATORY (Con't.)

Procedures and Practices

- Management Oversight and Control of the Conduct of the Project
- Approved Project Work Plans
- Select/Assign Qualified and Experienced Staff
- Engineering Standard Practices (Calibration, Configuration, Model Development)
- Peer and Mentor Interaction
- Peer Reviews of Products
- Special Procedures and Documentation for Complex Activities
- Special Procedures and Documentation for Environmental Safety and Health Considerations
- Training
- Emphasis on Technical Excellence
- Management Review and Approval of Products

LABORATORY (Con't.)

- DOE Quality Assurance Criteria
  - DOE Order 5700.6C - Establishes QA Requirements for DOE
  - 10 CFR 830.120 - QA Requirements for DOE Contractors
  - DOE-ER-STD-6001-92 - Implementation Guide for QA Programs for Research

LABORATORY (Con't.)

LABORATORY QA PROGRAMS

- QA Specialists at Department Level
- Lab PI Consults with QA Staff to Define QA Plan for Programs
- Audits
- Peer Review
- QA Indoctrination for New Employees and General Training
- Products/Data Review
- Traceable Standards

LABORATORY (Con't.)

Project Criteria

Planning Phase

- Review of Procedures and Controls

  Supplemented by:
  - PM identification of specific additional criteria
  - PI assignment of additional controls

Implementation Phase

- PM Review
- Performance Review Meetings
- Laboratory Procedures & Controls

CONCLUSIONS

- The Staff has reasonable confidence in the integrity of data and research products.
- NRC relies on DOE Laboratory procedures and practices.
- Process identified falsified data.
- A letter from EDO to Laboratories will be sent to raise their level of awareness following Commission review.
- The Staff has reasonable assurance that the current process is adequate to define and implement necessary controls. However, RES should be more proactive to ensure implementation of controls applicable to our research projects.
- Management Performance Review Meetings and RES Program Reviews will be used to determine if additional action is appropriate.

CONCLUSIONS (Cont't.)

Potential actions include, but are not limited to:

- Revision of NRC/DOE MOU
- Revision of MD 11.7
- Revision of RES Office Letters
- Discuss NRC review of audits or evaluations of laboratory activities with DOE.

PROGRAM PLAN

- Background
- Objectives
- Rationale
- Constraints and Assumptions
- Significant Accomplishments
- Funding
- Approach
- Uncertainties
- Regulatory Focus
- Significant Milestones
- Closure
- Appendix

PEER REVIEW

OFFICE LETTER 6 - ENCLOSURE C

Peer Review

- Independence
- Expert Knowledge in the Field
- Broad Knowledge of Science and Engineering
- Balance among Description, Institution, Point of View

Publication of Research Results

COMMERCIAL CONTRACTS

- Federal Acquisition Regulation (FAR), Subpart 46.2, "Contract Quality Requirements" states:

  - The Contracting Officer shall include appropriate quality requirements in solicitations and contracts.
  - The type and extent of quality requirements range from inspection at time of acceptance to a requirement for the contractor's implementation of a comprehensive program for controlling quality.

- CFR Inspection Clauses:

  - Require the contractor to provide and maintain an inspection system;
  - Require the contractor to maintain complete records of inspections; and
  - Give the government the right to inspect and test all contract work.