

**UNITED STATES OF AMERICA**  
**NUCLEAR REGULATORY COMMISSION**

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

**Location:            Rockville, Maryland**

**Date:                Wednesday, November 15, 1995**

**Pages:              1 - 30**

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1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

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4 BRIEFING ON MEASURES TO ENSURE  
5 INTEGRITY OF RESEARCH DATA

6 \*\*\*

7 PUBLIC MEETING  
8  
9

10 Nuclear Regulatory Commission  
11 Room 1F-16  
12 One White Flint Plaza  
13 11555 Rockville Pike  
14 Rockville, Maryland  
15

16 Wednesday, November 15, 1995  
17

18 The Commission met in open session, pursuant to  
19 notice, at 1:58 p.m., the Honorable SHIRLEY A. JACKSON,  
20 Chairman of the Commission, presiding.  
21

22 COMMISSIONERS PRESENT:

23 SHIRLEY A. JACKSON, Chairman of the Commission  
24 KENNETH C. ROGERS, Member of the Commission  
25

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1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:  
2 ANDREW BATES, ACTING SECRETARY  
3 KAREN D. CYR, OGC/NRC  
4 JAMES TAYLOR, EDO  
5 JOHN CRAIG, DEPUTY DIRECTOR, DIVISION OF  
6 ENGINEERING TECHNOLOGY, RES  
7 CHARLES SERPAN, CHIEF, GENERIC SAFETY ISSUES  
8 BRANCH, RES  
9 RONALD THOMPSON, DIVISION OF CONTRACTS, OFFICE OF  
10 ADMINISTRATION  
11 DAVID MORRISON, DIRECTOR, OFFICE OF NUCLEAR  
12 REGULATORY RESEARCH  
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## 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,

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

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

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

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

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

25 Responsibility for implementing these procedures

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

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

8 John Craig will take the lead in the presentation.  
9 John?

10 MR. CRAIG: Good afternoon.

11 CHAIRMAN JACKSON: Good afternoon.

12 MR. CRAIG: Go to slide 2, please.

13 [Slide.]

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

1 Slide 3, please.

2 [Slide.]

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

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

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

19 Slide Number 4.

20 [Slide.]

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

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



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

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

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

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

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

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

4 In the context of --

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

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

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

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

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

24 MR. CRAIG: Yes.

25 CHAIRMAN JACKSON: And we ensure that that is, in

1 fact, in place?

2 MR. CRAIG: Yes, that's right.

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

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

7 DR. MORRISON: That is one, right.

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

10 MR. CRAIG: Yes.

11 CHAIRMAN JACKSON: Okay, very good.

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

19 Can we go to slide 5, please?

20 [Slide.]

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

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

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

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

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

24           Can we go to Slide 6, please?

25           [Slide.]

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

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

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

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

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

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

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

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

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

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

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

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

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

8 Slide 7, please.

9 [Slide.]

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

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

22 If we go to slide 8.

23 [Slide.]

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

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

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

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

19           MR. CRAIG: Every year, we provide a report, and  
20 so I have to answer the question in that context. We  
21 prepared a summary of the peer review research project for  
22 '94, this past August, and we gave it a quick count. It  
23 includes refereed journals, as well as other professional  
24 publications, so that for that year, it was between 250 and  
25 260 in that year.



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

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

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

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

11 CHAIRMAN JACKSON: So about 250.

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

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

16 DR. MORRISON: Right, yes. It is about a  
17 1-person-a-year work.

18 CHAIRMAN JACKSON: Right.

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

25 Can we go to Slide 9, please?

1 [Slide.]

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

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

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

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

6 Slide 10, please.

7 [Slide.]

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

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

23 Slide 11, please.

24 [Slide.]

25 MR. CRAIG: In parallel with the planning and

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

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

13 Let's go to Slide 12.

14 [Slide.]

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

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

1 frequently get involved in discussions with the laboratories  
2 of those.

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

8 CHAIRMAN JACKSON: Multi barriers.

9 MR. CRAIG: Yes.

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

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

1 reviews to determine what specific additional action is  
2 appropriate.

3 Slide 13, please.

4 [Slide.]

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

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

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

21 CHAIRMAN JACKSON: I only have one.

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

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

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

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

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

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

10           CHAIRMAN JACKSON: Okay.

11           Commissioner Rogers?

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

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



1 fundamentally important in dealing with the basic quality of  
2 research.

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

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

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

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

25 However, the basic integrity of research data

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

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

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

1 a searching oral examination.

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

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

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

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

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

8 I wonder if you want to comment on that.

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

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

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

1 dealing with.

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

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

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

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

14 COMMISSIONER ROGERS: Oh, absolutely, yes.

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

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

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

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

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

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

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

15 CHAIRMAN JACKSON: That has been known to happen.

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

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

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

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

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

13           MR. TAYLOR: Yes.

14           COMMISSIONER ROGERS: Without a doubt.

15           MR. TAYLOR: That is true.

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

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

1 for its operations.

2 MR. TAYLOR: Yes, I agree.

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

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

8 CHAIRMAN JACKSON: Thanks.

9 MR. CRAIG: Thank you.

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

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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.**