

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

OFFICE OF INVESTIGATIONS

- - - - -X

In the Matter of: :

INVESTIGATIVE INTERVIEW :

David E. Cunningham, M. D. :

(CLOSED) :

- - - - -X

Oncology Services Corporation

755 Arlington Avenue

Harrisburg, Pennsylvania

Thursday, December 17, 1992

The above-entitled matter commenced at 10:04

o'clock a.m., when were present:

CASE NO. 1-02-0602

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EXHIBIT 50

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1 APPEARANCES:

2

3 DR. CARL PAPERIELLO, IIT - TEAM LEADER

4

5 DR. MOHAMED SHANBAKY, IIT MEMBER

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7 ALAN MADISON, IIT MEMBER

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

[9:04 a.m.]

DR. SHANBAKY: Good morning, Dr. Cunningham.

THE INTERVIEWEE: Good morning.

DR. SHANBAKY: Today is December 17, 1992. We are at Oncology Services Corporation office in Harrisburg, Pennsylvania. I would like everyone to introduce himself, please.

DR. PAPERIELLO: I am Carl Paperiello. I am the IIT Team Leader.

DR. SHANBAKY: My name is Mohamed Shanbaky, Assistant IIT Team Leader.

MR. MADISON: I am Alan Madison, with the NRC in Washington, D. C.

THE INTERVIEWEE: I am David Cunningham, Director of Radiation Safety for Oncology Services Corporation.

DR. SHANBAKY: Before we start discussing the event of November 16, I would like to turn the discussion over to Mr. Madison to give you an overview of the transcripts and the process of the IIT.

MR. MADISON: First of all, the purpose of an IIT, and we may have explained this to you during the entrance meeting a couple of weeks ago -- It is the highest form of response to events or incidents that the NRC has.

The purpose of the IIT is to gather as much

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1 information, as much fact as possible to make a  
2 determination of what can be done better, either by the  
3 licensees from the industry's point of view, or from the  
4 NRC's point of view; what the NRC can do better, what the  
5 licensee can do better to prevent these type of events from  
6 happening in the future.

7 The purpose of the interview is, again, to gather  
8 facts from those people that were directly involved, or  
9 because of their position in the corporation or the  
10 structure, they have direct authority or direct  
11 responsibility for this type of event.

12 We are transcribing the interview and, again, the  
13 purpose of that is to get as much clear information as  
14 possible so there is no misunderstanding about what was  
15 said. It also helps as a convenience factor not to take  
16 notes. We don't have to interrupt your dialogue by asking  
17 you to repeat something so that we can get it in our notes.

18 Later on, we can all review the transcript and see  
19 exactly what was said. You will have a chance to review the  
20 transcript when they are completed -- once it is typed up.

21 We will make arrangements probably to mail that  
22 transcript to you for you to review it. There are some  
23 guidelines when you do the review.

24 We ask you not to mark on the transcript at all.  
25 We provide an addenda sheet and you will have an opportunity

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1 on the addenda sheet to make any corrections -- if you think  
2 there was an error made in the transcript, to say that; make  
3 any clarifications if you think something didn't come out  
4 clear -- make a clarification on the addenda sheet.

5 That also becomes part of the record, your addenda  
6 sheet. The transcript and the addenda sheets, at the close  
7 of the investigation, when the report is issued, go into the  
8 public document room in Washington, D. C., and also in the  
9 local public document room.

10 At that time, you can request a copy for your own  
11 use. What I am going to give you now is Exhibit 3.1.  
12 Basically, in a written form, it describes what I have just  
13 said.

14 [Handing document to Interviewee.]

15 MR. MADISON: Do you have any questions about the  
16 transcripts?

17 THE INTERVIEWEE: Yes, I do. In reviewing the  
18 transcript, the recorded transcript -- and I assume you  
19 review them also --

20 MR. MADISON: Yes.

21 THE INTERVIEWEE: And sign off on them. And if  
22 there is an uncertainty in your mind as to what you said, do  
23 you have access to the tape?

24 MR. MADISON: I guess I don't understand the  
25 question.

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1 THE INTERVIEWEE: If there was an area -- a  
2 critical area in the discussion and the recorded record is  
3 different from what is in your mind, and you want to be sure  
4 that the correction you made is exactly the way it was in  
5 discussion, do you have, as an NRC official, access to the  
6 tape?

7 MR. MADISON: We have not used the tapes in the  
8 past. What we would generally do is ask for a clarification  
9 from you in written form. If there is something that is not  
10 understood, we ask for a clarification. We normally do not  
11 have access to the tapes.

12 THE INTERVIEWEE: I am not sure you answered the  
13 question.

14 MR. MADISON: We don't have access to the tapes.

15 THE INTERVIEWEE: You cannot review the tape?

16 MR. MADISON: No. We have the written transcript.

17 THE INTERVIEWEE: You are not allowed to review  
18 the tape?

19 MR. MADISON: I really can't answer whether we are  
20 prohibited from listening to the tape. I can't answer that  
21 question. I can check for you and get back to you.

22 We have never used them in the past. We have  
23 always relied upon the written transcript and if there is  
24 any clarification --

25 THE INTERVIEWEE: I mean, this is a practical

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1 question because I am an elected official and all of our  
2 meetings are recorded and then we get minutes from the  
3 meetings. There are times when we go back to listen to the  
4 tapes to make sure that it is correct.

5 MR. MADISON: We do not as a practice go back and  
6 listen. We have never done it in the past.

7 DR. SHANBAKY: You will have the opportunity to go  
8 over the transcripts, Dr. Cunningham. Anything in the  
9 transcript that you feel is not exactly what you intended to  
10 say or that is what was your understanding -- you believe it  
11 is an error or it is mischaracterized, or it is not exactly  
12 accurate, you have to put it in the errata. You disagree  
13 with this statement or this statement.

14 MR. MADISON: We might do the same thing. If  
15 there is a misunderstanding, we would like to get it cleared  
16 up. That formal method would be to ask you a written  
17 question and then have you respond in writing to that.

18 THE INTERVIEWEE: Okay. Another question I have  
19 related to this: Because we are going to cover a lot of  
20 material and if there is -- when I read the transcription  
21 and you ask me a question and I give you recollection, you  
22 know, as I sit here of all the aspects of our program  
23 related to that question, and then I read the transcript and  
24 I say -- oh, I forgot to even mention that we do this, this,  
25 this and this -- Will I be allowed to supplement that?

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1 MR. MADISON: On the addenda sheet, yes.

2 THE INTERVIEWEE: And say that, it did not occur  
3 to me because I am not going to take time, an hour, to go  
4 back and go through every particular aspect of all these  
5 procedures, which as you know, are quite elaborate.

6 MR. MADISON: We will also offer you the  
7 opportunity if you want to refer to a procedure, or even  
8 written notes --

9 THE INTERVIEWEE: Well, I will be, but even doing  
10 that --

11 MR. MADISON: No, that is fine.

12 THE INTERVIEWEE: I think we will be doing quite a  
13 bit of that, but even doing that, I can assure that there  
14 are going to be things that I am going to forget to say to  
15 you that I think are very important for you to know.

16 MR. MADISON: That is the purpose of the addenda  
17 sheet.

18 THE INTERVIEWEE: That will occur to me after you  
19 leave.

20 DR. SHANBAKY: That is a very important remark,  
21 Dr. Cunningham, because, please, when we ask you a question,  
22 please try to answer it not in a narrow sense but in a  
23 rather global manner. Anything associated with that  
24 question. We will not be able to ask every question that  
25 will clarify things.

1           If you have any more clarification, or things  
2 related -- programmatically related to that question we were  
3 asking, you can address it. Try to interpret our questions  
4 in a rather wide manner rather than very narrow.

5           MR. MADISON: We will also allow for an  
6 opportunity, if there is any further statement you want to  
7 make, before we quit, to get that on the record, too.

8           If you think there is something that hasn't been  
9 asked that should have been asked.

10          There are certain things that happen in a  
11 transcript, because of her taking a recording, for clarity's  
12 purpose, we would appreciate it if, instead of saying things  
13 like "here" or "there" --

14          THE INTERVIEWEE: I understand.

15          MR. MADISON: -- if you would actually be more  
16 specific in what you are saying.

17          THE INTERVIEWEE: I understand.

18          MR. MADISON: I don't know exactly what questions  
19 Dr. Shanbaky is going to ask, but times are important, and  
20 if you can remember times, we would appreciate your giving  
21 the times to those type of questions.

22          THE INTERVIEWEE: Okay. To the extent that is  
23 possible.

24          I have one more question. Will it be possible  
25 during this, because this is recorded, to go off the record?

1 MR. MADISON: It depends upon the situation. As I  
2 said, the purpose of the transcript -- the purpose of the  
3 IIT is to gather as many facts as possible. We can take  
4 pauses but as far as --

5 If things are necessary to develop the facts of  
6 the investigation, we need to have a documented form either  
7 in writing from you or in the form of this transcript for  
8 those -- to collect those facts.

9 THE INTERVIEWEE: I understand that. And anything  
10 related to that -- that is not really what I had in mind.  
11 For example, when you talked in Indiana, there might have  
12 been some proprietary information that we could go the  
13 record, discuss, and then you could make a decision whether  
14 it has to be on the record or not.

15 MR. MADISON: Certainly. That is not a problem.  
16 Also, any time if there is anything that you think -- any  
17 document that you have that you think is proprietary, we  
18 would like that identified.

19 THE INTERVIEWEE: Can we go off the record for a  
20 second?

21 MR. MADISON: We can pause for a moment.

22 [Pause.]

23 MR. MADISON: Back on the record. I will it over  
24 to Dr. Shanbaky.

25 THE INTERVIEWEE: May I make an opening statement?

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1 MR. MADISON: Certainly.

2 DR. SHANBAKY: Please do.

3 THE INTERVIEWEE: I am not sure how we are going  
4 to proceed. I am not even sure what the exact intent of  
5 this conference is, other than to provide information that  
6 you need to evaluate the incident that occurred.

7 I assume in doing that, you want to have specifics  
8 related to the incident and you want to have a thorough  
9 understanding of the overall program. That is my  
10 assumption. Is that correct?

11 DR. SHANBAKY: That is correct.

12 THE INTERVIEWEE: So, in that context, anything  
13 that I have to say -- I emphasize -- is not intended to  
14 ameliorate in any way the seriousness of what happened in  
15 Indiana.

16 However, I feel that it is essential for you to  
17 understand the level of sophistication we have in our  
18 program and overall program. So I am going to say many  
19 things that I believe will emphasize the strengths that we  
20 have in our program.

21 It is, again, not to do that -- to in any way  
22 justify what happened. I can't explain what happened. But  
23 I intend to give you what I feel is an overview of this  
24 program. Okay?

25 DR. SHANBAKY: All right. Dr. Cunningham, would

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1 you please describe your affiliation with Oncology Services?

2 THE INTERVIEWEE: I would like to start by giving  
3 my credentials, as an individual. My position is director  
4 of physics, bioengineering, engineering.

5 We have a physics department and an engineering  
6 department. I think you would describe it as an  
7 administrative or managerial position in that, as we have  
8 grown over the past few years and the staff has grown, I  
9 have less and less time for direct clinical work and more  
10 managerial responsibilities.

11 I stress that that is an evolution, an evolution  
12 not just in our corporation -- as we know, we have an  
13 evolution in the delivery of medical care in this country.

14 So I am Board Certified by the American Board of  
15 Radiology. I am Board Certified by the American Board of  
16 Medical Physics and I am a Certified Health Physicists.

17 I am also an Examiner for the American Board of  
18 Radiology in physics. We have a physics staff in our  
19 department, the physics department. We have 18 physicists  
20 and two dosimetrists.

21 We have 11 full time physicists and we have -- the  
22 remaining physicists are contract physicists. In those 11  
23 full time I include two contracted physicists that are  
24 exclusively under my contract so that I own 100 percent of  
25 their services.

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1           The other individuals are contracted in  
2   less-than-full-time capacity.

3           I think all these things are important.

4           Nine of our physicists are Board Certified; four  
5   are Board eligible. We have two dosimetrists, one who is a  
6   certified or registered dosimetrist.

7           Of the 18 physicists, 9 are Ph.D.'s. I don't know  
8   if you need their names or not. If you need them, they are  
9   available for your records.

10          Then the question was regarding my position. I am  
11   directly responsible for hiring and supervising the physics  
12   staff and the engineering staff.

13          DR. SHANBAKY: Are you working for Oncology  
14   Services on contractual basis, or are you a full-time  
15   employee of the company?

16          THE INTERVIEWEE: I am not contracted. I am an  
17   employee, as are all of these physicists with the exception  
18   of the two that I indicated previously.

19          That is an important question. Because when this  
20   program started out, before I came with the program, the  
21   standard procedure was to have physics contract.

22          When I started with this program, I began to  
23   immediately alter the physics services from one where we had  
24   a physicist coming in one day a week, where we had full-  
25   time employees.

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1           So if you look at the personnel history over the  
2 past three years, we have gone from essentially having one  
3 or two physicists that are employees, to the description  
4 that I just gave you in which we are predominantly employees  
5 and predominantly responsible to the corporation.

6           MR. MADISON: How long have you been with Oncology  
7 Services?

8           THE INTERVIEWEE: Four years and three months.

9           DR. SHANBAKY: Are you a partner in the company?

10          THE INTERVIEWEE: No, I am not.

11          DR. SHANBAKY: Are you a major shareholder?

12          THE INTERVIEWEE: No, I am not. I have no  
13 financial interest, other than as a salaried employee.

14          DR. SHANBAKY: Who are the owners of the company?

15          THE INTERVIEWEE: The owners of the company are  
16 Douglas Colkitt.

17          DR. SHANBAKY: One owner?

18          THE INTERVIEWEE: He is the -- he is the owner to  
19 the extent that I don't believe the other participation is  
20 significant. I mean, I think that --

21          DR. SHANBAKY: Who do you report to, Dr.  
22 Cunningham? Do you report directly to Colkitt?

23          THE INTERVIEWEE: That is correct.

24          DR. SHANBAKY: Can you give us an overview of the  
25 organization? You said you are the head of the physics

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1 department and report directly to Dr. Colkitt.

2 You have said you have 11 physicists.

3 THE INTERVIEWEE: I have 18 physicists -- 18; 11  
4 are full time. They are employees. The others would fall  
5 into classification like Greg Haig, where they are  
6 contracted. So we have 11 full time and we have 7 that are  
7 still contracted, but the evolution, as I indicated, is to  
8 go to employees.

9 DR. SHANBAKY: Full-time employees?

10 THE INTERVIEWEE: Full-time employees.

11 DR. SHANBAKY: Speak of Mr. Hay, can you describe  
12 to us what Mr. Hay is responsible for?

13 THE INTERVIEWEE: Mr. Haig is responsible for all  
14 the technical support at the Indiana Cancer Center.

15 DR. SHANBAKY: What is he required by contract to  
16 perform?

17 THE INTERVIEWEE: He is responsible for all the  
18 technical services at the Indiana Cancer Center.

19 MR. MADISON: What would that include?

20 THE INTERVIEWEE: That would include comprehensive  
21 physics support.

22 MR. MADISON: Would that include training of  
23 personnel?

24 THE INTERVIEWEE: That would include comprehensive  
25 physics support, including training a person to the extent

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1 -- to the extent that that training is not covered by  
2 another entity which is aware of.

3 For example, Omnitron may provide training.  
4 Omnitron is recognized by the NRC as being an approved  
5 provider of training. It is my understanding that they are.

6 Are they?

7 MR. MADISON: I don't know if we actually approve  
8 training.

9 THE INTERVIEWEE: I think you have to approve  
10 their program.

11 DR. SHANBAKY: Whose program?

12 DR. PAPERIELLO: Omnitron has no license from us.

13 MR. MADISON: They are licensed by an Agreement  
14 State.

15 DR. PAPERIELLO: The Food and Drug Administration  
16 reviews the product. The State of Louisiana certifies the  
17 source.

18 THE INTERVIEWEE: So that when a licensee sends in  
19 for an NRC license and they indicate that they are going to  
20 purchase an Omnitron, and the question of training comes up,  
21 and the --

22 DR. PAPERIELLO: They accept the fact that  
23 Omnitron will provide training on the use of the device,  
24 yes.

25 THE INTERVIEWEE: And the syllabus is sent in as

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1 part of the license application and I am told it is  
2 reviewed.

3 DR. PAPERIELLO: It probably has been reviewed.

4 THE INTERVIEWEE: Let me say that that is my  
5 understanding. That that is a program that has regulatory  
6 review. Maybe it is an Agreement State, but I think we all  
7 would accept the fact that Agreement States do not operate  
8 outside the purview of the same statute that we all deal  
9 with.

10 DR. SHANBAKY: Understand. Let us get back to Mr.  
11 Hay. Who wrote the contract for Mr. Hay, Dr. Cunningham?

12 THE INTERVIEWEE: Mr. Haig did.

13 DR. SHANBAKY: He wrote his own contract?

14 THE INTERVIEWEE: Mr. Haig was an employee -- a  
15 contracted employee prior to the time that I came with  
16 Oncology Services. Mr. Haig was in a corporate partnership  
17 with another physicist from Johnstown, Pennsylvania. You  
18 may have seen his name on the records, also, up to last  
19 year.

20 As a partnership, they collectively provided  
21 physics support and they have a name for their corporation.  
22 You may have that in your testimony from him.

23 MR. MADISON: I want to clear up something for the  
24 record. You are saying "Haig". It is our understanding  
25 that his last name is Hay -- H A Y.

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1 THE INTERVIEWEE: Hay; yes.

2 DR. SHANBAKY: Physics support, it includes  
3 multi-facet areas. In my mind, it is rather ambiguous.  
4 What I am trying to understand, Dr. Cunningham, is what his  
5 contractual agreement with Oncology Services entails, and  
6 the second part of this, what is the expectation of the  
7 performance there?

8 I am trying to see what exactly he is doing, how  
9 much time he has there -- how much time he is required to be  
10 there. We need your cooperation.

11 THE INTERVIEWEE: It is my understanding and has  
12 been told me on several occasions over the course of the  
13 last few years that Greg Hay is a very competent physicist.  
14 He provides complete coverage and he is available any time  
15 that he has been needed at the Indiana Cancer Center.

16 This has been told to me by Dr. Bauer, who is the  
17 medical director of the Cancer Center. He has been very  
18 pleased with the physics support that he has received from  
19 Mr. Hay.

20 He has repeatedly told me that he is a very  
21 well-qualified physicist and that he goes out of his way to  
22 provide not just the minimum, but to provide whatever is  
23 required to ensure that they have a good program.

24 MR. MADISON: I think, again, to clear the issue;  
25 I think what we are asking is, for instance, who is

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1 responsible for general radiation safety training at the  
2 facility in Indiana?

3 THE INTERVIEWEE: The responsibility lies with the  
4 medical director and the physicist on site.

5 MR. MADISON: Who would then be responsible for  
6 developing all treatment plans?

7 THE INTERVIEWEE: Be more specific. What do you  
8 mean by treatment plan?

9 MR. MADISON: Is there a split in the  
10 responsibility for the development of the treatment plan, or  
11 does that lie on one person's shoulders?

12 THE INTERVIEWEE: I don't know what you mean by  
13 the treatment plan.

14 MR. MADISON: The treatment plan that is developed  
15 for the HDR unit for treating patients.

16 THE INTERVIEWEE: You are talking about the  
17 prescription -- the iso-dose distribution?

18 MR. MADISON: Yes.

19 THE INTERVIEWEE: In medical practice, the  
20 treatment plan is not what the physicist does. The  
21 treatment plan is done by the physician. And that involves  
22 review of the patient, to consultation, and writing the  
23 prescription.

24 MR. MADISON: Who is responsible for directing the  
25 technologist in the operation of the HDR unit?

1 THE INTERVIEWEE: The technologist that we have -  
2 -first of all, the physicians that we have as our authorized  
3 users -- as you know, the statement of responsibility says  
4 that authorized users are responsible for the procedures and  
5 are responsible for the personnel that act under their  
6 supervision.

7 So by your own statement, that question is clearly  
8 defined. Our technologists are registered technologists.  
9 Our physicians are Board Certified physicians.

10 These are not people that are untrained. These  
11 are trained people and they are not -- these are not  
12 low-level positions. The technologist today has a  
13 sophisticated amount of training.

14 I don't know if you have ever been involved with  
15 the training. They get rather high salaries.

16 MR. MADISON: What is your understanding of the  
17 training, for instance, on the use of radiation survey meter  
18 at the facility in Indiana?

19 THE INTERVIEWEE: My understanding is, as I have  
20 been told, that they have been trained on at least three  
21 occasions on the use of it and when it is appropriate to use  
22 it.

23 MR. MADISON: Do you have any documentation of  
24 this?

25 THE INTERVIEWEE: No, I have no documentation.



1 Other than the testimony, the assurance that I have  
2 received.

3 MR. MADISON: From whom?

4 THE INTERVIEWEE: From Greg Hay.

5 DR. SHANBAKY: We are going to get back to  
6 training in a little bit. I am trying to understand what is  
7 the set up at the Indiana clinic.

8 What is your view of the responsibilities of Dr.  
9 Bauer? What is he responsible for there?

10 THE INTERVIEWEE: At every cancer center, we have  
11 each day anywhere between 20-40 patients that receive  
12 treatment. Some of this treatment is external beam  
13 treatment.

14 A physician writes the prescription, oversees the  
15 treatment and by Pennsylvania law is there supervising the  
16 treatment.

17 This is law in Pennsylvania.

18 DR. SHANBAKY: When you say he is there, it means  
19 where?

20 THE INTERVIEWEE: In the building.

21 DR. SHANBAKY: Not necessarily at the location of  
22 the treatment?

23 THE INTERVIEWEE: Absolutely not. That is not  
24 required by law nor by practice.

25 You have trained personnel and the physician

1 administering treatment, whether it be brachytherapy or  
2 external beam, the physician is not going to stand every  
3 time behind a technologist and -- over their shoulder --  
4 ever time they turn on the linear accelerator.

5 That is why they are trained.

6 DR. SHANBAKY: Who in the corporation has the  
7 oversight responsibility of making sure that Mr. Hay, as a  
8 contractor, is performing all the duties up to the  
9 expectation of the corporation? As contracted.

10 THE INTERVIEWEE: Who has responsibility for--

11 DR. SHANBAKY: Oversight over the contractor. He  
12 is a consultant.

13 THE INTERVIEWEE: That is a shared responsibility  
14 between myself and the medical directors. Myself because of  
15 my position in the corporation, but recognizing with 25  
16 cancer centers, it is impossible to do direct surveillance  
17 on a routine basis of the physicists.

18 So it is a shared responsibility in that I do site  
19 visits and I rely on the feedback from the medical directors  
20 as to the capabilities and the functioning of the  
21 physicists.

22 DR. SHANBAKY: So if you did not do personnel,  
23 through oversight -- you said you visited the facilities --  
24 How often did you visit the facilities?

25 THE INTERVIEWEE: It is more today -- more today,

1 communications are done via telephone and fax. Actual site  
2 visits in Indiana, I believe I have only been there once to  
3 do a complete site visit.

4 MR. MADISON: During what time period?

5 THE INTERVIEWEE: Three years.

6 DR. SHANBAKY: Dr. Cunningham, can you describe to  
7 us your affiliation with other companies, medical  
8 institutions, scientific organizations, professional  
9 societies?

10 THE INTERVIEWEE: Let's go down the list.  
11 Professional societies?

12 DR. SHANBAKY: Let's start with other companies,  
13 medical institutions.

14 THE INTERVIEWEE: I am an associate professor of  
15 radiology at Pennsylvania State University, College of  
16 Medicine. I served there on the full-time faculty for 13  
17 years and I received academic tenure.

18 Four years ago, when I took this position, I  
19 retained an appointment as associate professor for the  
20 purpose of training the residents in the Department of  
21 Radiology, a position I still hold.

22 I am a part owner and consultant with Pennsylvania  
23 Radiation Physics Associates.

24 DR. SHANBAKY: While you are giving these, can you  
25 just give us an idea about percent of your time spent at the

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1 University and other?

2 THE INTERVIEWEE: I would be happy to. I need to  
3 understand, in order to properly answer your question, I  
4 need to understand what we are trying to discover.

5 DR. SHANBAKY: I am trying to understand what is  
6 your workload; how much of your effort is here at Oncology  
7 Services, how much of your effort you put in the clinics, et  
8 cetera.

9 THE INTERVIEWEE: Okay. I spend, outside, on a  
10 regular week, outside of this position, four hours or less,  
11 with the exception of four times during the year when I run  
12 a one-week training program for the residents at Hershey  
13 Medical Center.

14 That class runs from four to six o'clock every  
15 day, five days a week for those four weeks. So during those  
16 weeks, I would say probably 20 hours is spent here. Okay?

17 DR. SHANBAKY: Okay. How about the consulting  
18 company?

19 THE INTERVIEWEE: Less than four hours a week, and  
20 frequently that is outside the normal working hours.

21 DR. SHANBAKY: How about scientific organizations?

22 THE INTERVIEWEE: I am a member of the American  
23 Association of Physicists in Medicine, American College of  
24 Radiology. I serve on a committee for the American College  
25 of Radiology; Board Examiner for the American Board of

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1 Radiology.

2 I am a member of the Health Physics Society and  
3 various other scientific associations which don't have too  
4 much relevance -- Radiation Research Society, Susquehanna  
5 Valley Chapter of Health Physics.

6 I can give you a CV which would list all of those.

7 DR. SHANBAKY: I would appreciate getting a copy  
8 of this when we are concluded.

9 How about your membership on standard committees?  
10 Are you a member of committees to develop documents like  
11 NCRPs, ICRPs?

12 THE INTERVIEWEE: I have been a member of an NCRP  
13 and developed Handbook -- I believe it is 48. Radiation  
14 Safety Procedures for Allied Health Personnel.

15 That I served on I think two years before we  
16 completed that task. Ken Miller was the chairman of that.

17 Currently?

18 DR. SHANBAKY: Yes, sir.

19 THE INTERVIEWEE: I am on an ACR committee,  
20 American College of Radiology, now, and also a Board  
21 Examiner. That is primarily right now the committee work I  
22 do. Not significant, no.

23 As you know, Boards are given once a year. This  
24 is strictly for the oral boards and they are given once a  
25 year in Louisville. So that is three days -- maybe four

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1 days at the most, in June.

2 DR. SHANBAKY: We talked a little bit about your  
3 responsibility in Oncology Services. You said that you are  
4 really in a managerial position.

5 But I would appreciate it if you would expand a  
6 little bit on what you actually do in terms of overseeing  
7 and supporting the physics of the company at your satellite  
8 locations.

9 THE INTERVIEWEE: Okay. As I indicated, this has  
10 been an evolution in this position. First of all, when I  
11 came to the company this position did not exist, so I  
12 functioned as a physicist who was in charge of this cancer  
13 center and one other.

14 As the company had additional cancer facilities, I  
15 recognized a need to alter the way in which the physics was  
16 being done which, at that time, was primarily contracted to  
17 individuals who had usually 80 percent of their salary  
18 coming from another source.

19 So at that time, over a period of a few months,  
20 several months, in discussions with Dr. Colkitt, we decided  
21 to change the way in which physics services were being  
22 provided to the corporation.

23 MR. MADISON: Do you have a time frame?

24 THE INTERVIEWEE: I would -- I really don't  
25 remember for sure, but I can say that it has been probably

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1 somewhere around a year and a half to two years. Somewhere  
2 in that -- we began the process.

3 MR. MADISON: When did you become the RSO on the  
4 license for the various facilities?

5 THE INTERVIEWEE: The license was originally  
6 written for the Harrisburg Cancer Center.

7 MR. MADISON: And you were the RSO?

8 THE INTERVIEWEE: I was the RSO.

9 DR. SHANBAKY: Let's try to understand this.  
10 Let's ask the question first, who is the radiation safety  
11 officer for Oncology Services, including all the satellite  
12 locations?

13 THE INTERVIEWEE: The radiation safety officer  
14 that is listed on the license is my name.

15 DR. SHANBAKY: What are the responsibilities of  
16 the radiation safety officer, to your understanding?

17 THE INTERVIEWEE: They are to ensure that all  
18 aspects of regulatory compliance are fully followed.

19 DR. SHANBAKY: All right. We will go now to how  
20 do you ensure that training was given?

21 THE INTERVIEWEE: How do I ensure?

22 DR. SHANBAKY: Yes, sir.

23 THE INTERVIEWEE: First of all, by being aware of  
24 all the regulatory requirements, by hiring qualified people  
25 and making them aware of what is required and then

1 communicating with them on any problems or difficulties to  
2 make sure that we are following them.

3 MR. MADISON: How do you accomplish that?

4 THE INTERVIEWEE: Either by direct supervision  
5 with the people that are located here, that I interact with.

6 MR. MADISON: Here meaning the Harrisburg  
7 facility?

8 THE INTERVIEWEE: We try to, as much as possible,  
9 we try to have everybody operate out of here. We have  
10 another building, not too far from here, and as much as  
11 possible we try to make this the hub of activity.

12 But, understanding that we have distributed  
13 services, so to the extent that it is possible we do it by  
14 coming together here; to the extent that it is not, we  
15 converse.

16 MR. MADISON: By coming here -- how often do you  
17 call in, say, your technologists or your physicists into the  
18 Harrisburg office for in-service training or briefings?

19 THE INTERVIEWEE: The technologists? The  
20 technologists would not be called in here for training.

21 MR. MADISON: I guess I don't understand. You say  
22 that you try to operate from here as a base and have  
23 everybody work out of here. How do your technologists in  
24 Indiana fit into that organization?

25 THE INTERVIEWEE: Technologists in Indiana would

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1 -- I have already indicated how they are trained and how  
2 they are supervised.

3 DR. SHANBAKY: Is there any lesson plan or  
4 material to be covered in the training that you -- You said  
5 that you required Mr. Hay to provide that training. Am I  
6 correct in saying that?

7 THE INTERVIEWEE: What I said is that Mr. Hay  
8 provides comprehensive physic services for the Indiana  
9 Cancer Center and part of that is training.

10 DR. SHANBAKY: Training --

11 THE INTERVIEWEE: Training, or -- or if the  
12 training is provided elsewhere and he is aware of that, and  
13 he has talked with the people that has provided the training  
14 and he knows -- he has personal assurance that the training  
15 has been carried out.

16 I recognize Omnitron as being adequate and by  
17 regulatory review in the ability to train the technologists  
18 in the use of their equipment.

19 I recognize it as being -- my understanding from  
20 the regulators, the best way to ensure that they are  
21 trained.

22 DR. SHANBAKY: I am getting back, again, to the  
23 responsibility of the radiation safety officer. Under  
24 regulation, there are requirements, like 10 CFR Part 19,  
25 that people be trained on radiation, what is radiation,

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1 radiation hazard, risks associated with radiation,  
2 radiological conditions in the areas they are working,  
3 understanding the radiation alarm systems, monitoring  
4 systems; understanding the basic stuff -- dose rates, times,  
5 distance and shielding.

6 That is exactly what we are talking about, Dr.  
7 Cunningham. You keep talking about physics support. I want  
8 to get a little bit away from physics support and talk about  
9 radiation safety training of personnel.

10 THE INTERVIEWEE: There are two aspects to  
11 radiation safety. There is an understanding of the  
12 principles and the basic concepts involved in all aspects of  
13 radiation safety. This is some of the things you asked.  
14 Distance, time and shielding. Basic elements of radiation  
15 safety. Basic elements of instrumentation.

16 So, these are underlying concepts. We have  
17 different levels of delivery of this training; physicist's  
18 level of understanding of these concepts is different from  
19 the technologists.

20 We all go through training programs. These  
21 training programs and these certification procedures -- the  
22 intent of these is to establish that these individuals have  
23 the necessary understanding conceptually of all of these  
24 aspects.

25 The intent is not to train a technologist in the

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1 field of aspects of radiation safety. If so, then our  
2 training programs are a complete and total failure.

3 If we have Board registered technologists, Board  
4 certified physicists and they don't have any comprehension  
5 of distance, time and shielding, then our complete system -  
6 -educational system is a failure.

7 That is one aspect of training. There is another  
8 aspect that has to do with the uniqueness of the delivery  
9 systems at an individual center, such as the survey -- the  
10 particular survey meter you use. Not survey meters in  
11 general, but the particular one you use; the particular  
12 prime alert you use; the particular linear accelerator you  
13 use; the particular brachytherapy HDR unit that you use.

14 So there are certain aspects of radiation safety  
15 to be reviewed with respect to those instruments. That is  
16 the kind of training that I expect to be done on site.

17 I do not expect to be training the inverse square  
18 law to somebody who is certified as a Board Certified  
19 physicist or a registered technologist. It is ludicrous.

20 MR. MADISON: How would you verify that they are  
21 capable, for instance, of using the survey instrument that  
22 is provided on site?

23 THE INTERVIEWEE: Verification right now is  
24 provided by the integrity of the individuals that are  
25 overseeing the training.

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1           So that right now --

2           DR. SHANBAKY: Who is that?

3           THE INTERVIEWEE: Right now, verification would be  
4           the integrity of the training company and medical director  
5           and the physicist. That is the current way that we have of  
6           verifying.

7           MR. MADISON: Am I understanding you correctly;  
8           you do not directly verify that yourself?

9           THE INTERVIEWEE: At what level?

10          MR. MADISON: At the technologist's level.

11          THE INTERVIEWEE: No.

12          MR. MADISON: At the physicist's level?

13          THE INTERVIEWEE: Let me comment. I give an  
14          annual in-service to the technologists, all of them,  
15          collectively, at a meeting that we held last summer.

16          MR. MADISON: Do you have any records, for  
17          instance, a syllabus of what was discussed during that  
18          meeting?

19          THE INTERVIEWEE: I believe that meeting was  
20          recorded, although I am not sure. We have and I believe --  
21          did you go to State College?

22          MR. MADISON: I did not.

23          DR. SHANBAKY: I went to State College.

24          THE INTERVIEWEE: I believe that -- We have  
25          different ways in which to collectively review aspects of

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1 clinical radiation medicine with our physicians and with our  
2 technical staff.

3 The physicians, we have bi-annual meetings and we  
4 have records and minutes from those. We also have this  
5 meeting with the technologists, and these matters were  
6 discussed with them.

7 I can assure you that I went over the quality  
8 management program and all the aspects of the quality  
9 management program with all of the technologists.

10 Yes, I gave them direct, personal training.

11 MR. MADISON: Is there a copy of the quality  
12 management program at the various facilities?

13 THE INTERVIEWEE: It is part of the license  
14 application.

15 MR. MADISON: Is there a copy at the facility?

16 THE INTERVIEWEE: Yes.

17 DR. PAPERIELLO: Can I summarize I guess what you  
18 see your responsibilities as, as radiation safety officer,  
19 in terms of meeting your obligations under the regulations  
20 and your license?

21 If you satisfy yourself that the individuals that  
22 you employ as occupational workers have some certification,  
23 either by -- either the physicians or the technologists --  
24 by the appropriate professional organizations, you feel that  
25 meets any requirements we might have for fundamental

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1 radiation safety training, and supplement that by training  
2 that might be provided by vendors of equipment, would be the  
3 equipment-specific training.

4 I guess you are telling me, you feel that the  
5 medical directors and/or the physicists provide any other  
6 training that the technologists might require on specific  
7 items of equipment, such as the survey instruments that  
8 might be present at the facility?

9 THE INTERVIEWEE: Yes. The NRC -- we had a site  
10 visit here, to review the HDR Program. Part of that was  
11 training, a discussion of training.

12 The training -- the unit that was installed then  
13 was a Gamma Med unit. The training that I was required to  
14 have was to come from the manufacturer.

15 It was my understanding from the NRC that there  
16 was a syllabus supplied and that is what they required  
17 regarding training; that it be provided by the manufacturer.

18 MR. MADISON: On the operation of the unit?

19 THE INTERVIEWEE: On the items that are listed in  
20 the syllabus.

21 MR. MADISON: Does that include anything outside  
22 the operation of the unit?

23 THE INTERVIEWEE: Yes.

24 MR. MADISON: What?

25 THE INTERVIEWEE: The syllabus is in the -- Here

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1 is the one from Omnitron [indicating]. Here are the records  
2 from the other manufacturers [indicating].

3 There is a comprehensive syllabus of training.

4 MR. MADISON: Do we have a copy of the syllabus  
5 from Omnitron? Have we requested that?

6 DR. PAPERIELLO: I don't know.

7 MR. MADISON: I will make a note of that.

8 DR. SHANBAKY: Any record, Dr. Cunningham, that  
9 you feel would be useful in clarifying certain points,  
10 especially related to radiological safety training, would be  
11 appreciated -- that you would give us a copy of so that we  
12 know that there is something here on record; we can say that  
13 there is a training program, or whatever.

14 It is really -- it is very important, Dr.  
15 Cunningham.

16 THE INTERVIEWEE: But I want to stress, when we  
17 set this program up -- From the NRC, the direction I got is  
18 that we should be trained by the manufacturer.

19 DR. SHANBAKY: That is my understanding, too, but  
20 we are talking, again, there are regulatory requirements for  
21 the licensee under 19.12 for radiological safety training.

22 There are peculiarities about the machine or the  
23 equipment, and that is expected that the manufacturer is the  
24 best individual who would be familiar with the equipment to  
25 give the training on that equipment.

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1 But that does not really preclude the training on  
2 the general radiological safety, either survey equipment,  
3 radiation area, monitor, alarm systems, response to alarms.  
4 We are talking about training and training.

5 THE INTERVIEWEE: And I never indicated that the  
6 responsibility for the training was completely with the  
7 manufacturer. I indicated that the manufacturer plays a  
8 role in this training and that specific training was given  
9 in addition to that from the physicist and in the operation  
10 of the survey meter, as I indicated to you before, I have  
11 been assured by Greg Hay that he had reviewed with them the  
12 operation of the survey meter and the appropriate times when  
13 it must be used.

14 DR. SHANBAKY: Dr. Paperiello, do you have an  
15 understanding now -- To be clear on this, I am not sure,  
16 again, exactly how the training is given, who is giving the  
17 training?

18 When I went to State College office, the clinical  
19 training came a little bit clearer in my mind -- who is  
20 giving the clinical training. Dr. Rogers explained how he  
21 provided the clinical training. But I did not really get an  
22 understanding of the radiation safety training and I am  
23 still struggling with how the radiation safety training is  
24 given.

25 THE INTERVIEWEE: Part of the requirement -- and



1 this, again, is my understanding from the Nuclear Regulatory  
2 Commission, for the training, that it is specific to the  
3 delivery system itself, is emergency procedure.

4 Now the physicist who is getting an Omnitron  
5 delivered to him is not going to be involved on training the  
6 technologists on emergency procedures. He is learning it  
7 himself for the first time. He is not the appropriate  
8 trainee for that.

9 The appropriate trainee is the manufacturer who  
10 has been reviewed by regulatory agencies and, as a user, I  
11 believe we have the assurance that they are recognized  
12 capable trainees. Okay?

13 The survey meters and the prime alert, that is the  
14 responsibility of the physicist. That is not part of the  
15 Omnitron unit. The physicist must be sure that the  
16 technologists understand the operation of the prime alert  
17 and I can assure you they do.

18 DR. PAPERIELLO: The question comes down to who  
19 assures the corporation that holds the license that, in  
20 fact, that is done? How do you know it is done?

21 THE INTERVIEWEE: How do I know it is done? This  
22 is the same question that you asked earlier. I have the  
23 same answer.

24 MR. MADISON: I think I can cut to the quick here.

25 DR. PAPERIELLO: My problem is this: You are the

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1 radiation safety officer on the license. What you see your  
2 responsibilities as and what I see your responsibilities as  
3 -- I am trying to come to closure. If we don't have a  
4 common understanding of that, that means -- one of the  
5 purposes of this investigation is to find out whether or not  
6 we have to change the way we do business.

7 It may be that we have written an inadequate  
8 license in this case and we are going to have to change the  
9 license.

10 Now the question is, my understanding of the  
11 duties of the radiation safety officer is to ensure that  
12 everything gets done.

13 THE INTERVIEWEE: I agree.

14 DR. PAPERIELLO: And what I am asking is, you are  
15 telling me the physicists are responsible for training the  
16 technicians on how to respond to the prime alert, what they  
17 should do.

18 I am asking, how do you know that that is being  
19 done?

20 THE INTERVIEWEE: Okay.

21 DR. PAPERIELLO: I am trying to understand that.

22 THE INTERVIEWEE: And I am going to give you the  
23 same answer I gave earlier. I believe that in this complex,  
24 overall delivery system that if we had a license for the  
25 Harrisburg Cancer Center, and every treatment was performed

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1 down the hallway there, then I could personally assure you  
2 that every aspect of radiation safety was being followed.

3 That doesn't mean I am going to go and watch every  
4 procedure that is done. We have a system in this country  
5 where we train people and we test them.

6 We train them and we test them and we believe that  
7 they are able to perform certain functions. For somebody  
8 who is in charge of an organization with several hundred  
9 people, to test every individual all the way down to the  
10 level of a technician, I believe is impossible any more than  
11 it is possible at a large nuclear energy facility, for a  
12 person in top management to test somebody who is walking  
13 around with a survey meter on the periphery of the facility.

14 There is a level -- there is a chain of command,  
15 there is a level of assurance that we have by hiring  
16 registered and certified people.

17 MR. MADISON: I can assure you, sir, anybody who  
18 operates a survey meter has been tested on the site by the  
19 site and that certification is documented. That also goes  
20 with any radiation technician on the site, or any operations  
21 personnel on the site, including maintenance personnel.

22 DR. SHANBAKY: The RPM, which is the radiation  
23 safety officer -- in your case, we are talking about -- the  
24 RPM, the radiation protection manager, has also a very large  
25 organization. When we are asking the question, Dr.

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1 Cunningham, it does not mean that you are personally doing  
2 it; you are not actually, you personally, testing the  
3 technologist on how to use a meter.

4 You have the responsibility of getting it done and  
5 verified that it got done.

6 Same thing with an individual RPM; he has a very  
7 big organization working for him. He does not personally go  
8 out and do it. He has methods, systems, procedures to  
9 ensure that all the required functions are actually done.

10 MR. MADISON: Excuse me. We will pause for a  
11 moment.

12 [Pause.]

13 MR. MADISON: Back on the record. As I was saying  
14 during the break, I wanted to make it clear that we are not  
15 just looking at what went wrong at Oncology Services, or the  
16 Indiana Cancer Center, but what is possibly at fault in not  
17 just the industry, but possibly there is something that the  
18 NRC is not doing that we should have been doing, so that we  
19 can correct it and make sure that the problem doesn't occur,  
20 again.

21 If the NRC is at fault, we want to find that out  
22 and correct that problem.

23 Does that make it --

24 THE INTERVIEWEE: Yes. Just maybe a brief  
25 comment, if I could make on that?

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1 MR. MADISON: Sure.

2 THE INTERVIEWEE: I have always been -- and I  
3 still feel strongly that as far as these aspects go -- and  
4 we can argue back and forth, but I believe we are all in  
5 this together and ultimately, whether you are a physicist in  
6 the private sector or a physicist in a regulatory position,  
7 we all have the same intentions. We would like to deliver  
8 safe treatment.

9 We don't want to put up such an impediment to the  
10 treatment that people cease giving treatments. We want to  
11 find suitable and appropriate measures to ensure radiation  
12 safety.

13 That is what I believe, and I believe the NRC has  
14 been somewhat remiss in the HDR area.

15 MR. MADISON: Can you expand on that?

16 THE INTERVIEWEE: I think there is an absence of  
17 guidance for the users, an absence of regulations for the  
18 users.

19 Several months ago, there was an announcement in  
20 one of the NRC bulletins of a committee that was being  
21 formed for the purpose of reviewing HDR utilization.

22 After I read that -- and at the suggestion of  
23 Region 1, they suggested perhaps that I would like to  
24 contact Washington because, quite frankly, we believe -- I  
25 believe at that time that we had the most experience in the

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1 country in delivering HDR and done collectively more cases  
2 and had some rather unique experiences.

3 Initially, our program involved us doing source  
4 changes. Initially, our program involved transporting the  
5 HDR unit.

6 We had very unique information and we had an  
7 excellent record of problems and dealing with problems, I  
8 believe. And I still believe that we have the best program.

9 But in any case, I called Washington. I can't  
10 remember the lady's name. It was published in the record,  
11 with a phone number.

12 I called that for four weeks and I left my name  
13 every time and no one called me back. Then I finally called  
14 and -- I called another number and I insisted to be put  
15 through to that person. And I had to insist on it.

16 They put me through and I told her that I thought  
17 that I should have some discussions and input to that  
18 committee. She said she would check with Mr. Glenn and get  
19 back to me; she never did.

20 DR. PAPERIELLO: I would like to make a remark for  
21 the purpose of the record. The NRC people involved in this  
22 situation have been interviewed -- have been and are being  
23 interviewed the same as you. Those transcripts will also be  
24 in the public domain.

25 DR. SHANBAKY: We were talking about training and

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1 the reason we are not really getting an understanding is it  
2 seemed that your belief -- and correct me if I am wrong --  
3 is that the training was given to the technologists up to  
4 the expectation of Oncology Services. Am I correct in  
5 saying that?

6 You believed that they were adequately trained in  
7 radiation safety? That is really the bottom line.

8 THE INTERVIEWEE: I believed that -- yes.

9 DR. SHANBAKY: Now.

10 THE INTERVIEWEE: And I also agree that there was  
11 no -- there was no on-site evaluation to assure that they  
12 had that training. The reliance was on the integrity of the  
13 individuals providing the training.

14 Knowing those people and knowing their credentials  
15 and knowing that their credentials had been reviewed by  
16 regulatory agencies.

17 There are two or three changes that I am going to  
18 be making to our radiation safety program as a result of  
19 this. They aren't new procedures because I believe, and I  
20 still believe that we have all the procedures in place to  
21 prevent this incident from occurring.

22 But, there are improvements to existing policies  
23 and procedures and one of them will be a -- and this I  
24 believe is going to be somewhat revolutionary in the medical  
25 field because it is a problem not just in clinics, but in

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1 hospitals, also, where we have in-service requirements.

2 Whether it is to house staff or housekeeping, or  
3 nurses; you go in and give in-service -- I have done  
4 hundreds of them. I can tell you, looking at the faces out  
5 there, that some of them are thinking about their child's  
6 problems -- they are sick at home, or whatever.

7 So, you fulfill the obligation but how effective  
8 was it? That is a problem not just for Oncology Services;  
9 that is a problem in medicine, in general, where we have  
10 these requirements.

11 To initiate a testing program, it sounds very  
12 simple, but you have to -- you want to do it correctly and  
13 it is not something that you say -- okay, the way to solve  
14 this is we will start giving test.

15 We will have in place -- and I hope within six  
16 months -- a means of testing for assurance of compliance.

17 I want to give some thought as to how to do it,  
18 but that is -- I think that that is one area where not only  
19 Oncology Services has a problem, but I think it is an area  
20 where the NRC has a problem and everybody involved in the  
21 delivery of radiation medicine.

22 MR. MADISON: Let me explain a few things that we  
23 have found out and share these with you, as we have  
24 investigated this event.

25 At that the Indiana facility, from our discussions

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1 with the technologists and with the physicist, the  
2 contractor physicist, it has been -- we have been led to  
3 believe that there has been no training provided to the  
4 radiation technologist in general radiation safety other  
5 than what they have received in their previous schooling.

6 Those individuals were unaware of the use of the  
7 survey meter to the point where one of the technologists did  
8 not know which scale was the most sensitive on the survey  
9 meter.

10 We have also been led to believe that from your  
11 medical physicist, he does not feel that he is responsible  
12 for training those people in general radiation safety and  
13 has not provided any general training radiation safety to  
14 those people.

15 Are there any changes that you would make to your  
16 procedures, your methods of operation, or the contracts that  
17 you have with your contract physicists?

18 THE INTERVIEWEE: I think you have -- there are  
19 two aspects to that. This is a very difficult and delicate  
20 area.

21 You are asking people right now to make statements  
22 relevant to a rather serious incident. If you fail to  
23 recognize human nature in your analysis of their answers,  
24 and the fact that I can already assure you that from the  
25 time that I have been there, that there hasn't been total

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1 consistency in the information that has been presented.

2 I don't want to address those specifics, because I  
3 think they perhaps do not have to enter into this discussion  
4 and may not help things and could hurt things.

5 So leave it to say that there are certain human  
6 factors involved in the recollection to you of information  
7 relevant to the entire incident when you have something of  
8 this rather serious nature.

9 MR. MADISON: Let me give you another specific  
10 example of an inconsistency we found when we viewed the  
11 Greater Pittsburgh facility and the Indiana facility.

12 We found at the Greater Pittsburgh facility a book  
13 that you had provided, of procedures, for guidance and use  
14 in radiation therapy. However, at the Indiana facility,  
15 that book did not exist that we could find.

16 THE INTERVIEWEE: Are you talking about the high  
17 dose rate procedure manual?

18 MR. MADISON: Yes.

19 THE INTERVIEWEE: This manual [indicating?

20 MR. MADISON: Yes.

21 THE INTERVIEWEE: Let me explain.

22 MR. MADISON: Could you identify that manual for  
23 the record?

24 THE INTERVIEWEE: This is a manual entitled,  
25 "Oncology Services Corporation, Department of Physics, High

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1 Dose Rate Treatment Manual", a copy of which I will happily  
2 provide.

3 MR. MADISON: We have a copy already. Thank you.  
4 We received it from the Greater Pittsburgh facility.

5 THE INTERVIEWEE: Okay. This manual, as you can  
6 see the date on this manual is 9/92. Actually, that was the  
7 date that the cover was printed. The date of a certain  
8 amount of the contents is 10 and 11/92.

9 This is a document that I have been working on  
10 over the past few months, four or five months, to bring  
11 together in one location all of the aspects that I feel are  
12 essential to a comprehensive radiation safety program.

13 It is not complete. It is essentially complete,  
14 maybe 80 percent complete.

15 MR. MADISON: Let me clear up one thing real  
16 quick, because I misunderstood this earlier: The "DEC" does  
17 not stand for December, it stands for David Edward  
18 Cunningham?

19 THE INTERVIEWEE: That is correct.

20 MR. MADISON: Thank you.

21 DR. SHANBAKY: This is still in a draft?

22 THE INTERVIEWEE: Yes. What I have done -- once I  
23 got it done to this level, I sent it out to three centers to  
24 have them review it, use it and then, over the course of the  
25 next six months, we would complete it in final form to other

1 centers.

2 I would not send it out to a center like Indiana.  
3 Greg Hay is not an employee, he is a contractor physicist.  
4 Mitch Jarosz is a senior Board Certified radiation physicist  
5 in Pittsburgh. He is appropriate for review and critique  
6 and feedback.

7 MR. MADISON: Jarosz is spelled --

8 THE INTERVIEWEE: J A R O S Z.

9 You would not have this at those sites.

10 MR. MADISON: So the procedures and policies that  
11 you described earlier do not exist at all facilities yet?

12 THE INTERVIEWEE: These procedures -- this brings  
13 together in one location the regulatory and policy  
14 procedures that are in effect either by virtue of the  
15 license, the license application, or state or federal  
16 regulations.

17 MR. MADISON: We asked the technologists and the  
18 personnel at the Indiana facility for procedures, guidelines  
19 that covered radiation safety, radiation safety training and  
20 were not shown anything.

21 Do you have anything or are you aware of anything  
22 that exists now, or existed at the time of the event?

23 THE INTERVIEWEE: They were not aware of the  
24 license -- the license application?

25 MR. MADISON: They do not have any copies of

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1 procedures or governing guidelines that they could show us.

2 THE INTERVIEWEE: They weren't aware of the  
3 license or the license application which has in it a number  
4 of procedures.

5 MR. MADISON: In actuality, they weren't aware who  
6 the RSO was. So I do not believe they have seen a copy of  
7 the license.

8 THE INTERVIEWEE: You are saying they hadn't,  
9 or --

10 MR. MADISON: I do not believe -- I don't know  
11 that for a fact, but they were not aware of who the RSO was  
12 on the license. So that would indicate to me that they had  
13 not seen the license.

14 THE INTERVIEWEE: The fact that they are not aware  
15 of the RSO is not, to me, a surprise. As I said before, by  
16 state law, the person -- and by NRC written guidelines --  
17 the authorized user is responsible for the procedures that  
18 are being carried out under his supervision.

19 The technologists should --

20 MR. MADISON: We can pause for a moment, please.

21 [Pause.]

22 MR. MADISON: Back on the record.

23 THE INTERVIEWEE: I think the essence of what I am  
24 saying is, the technologist reports to the medical director.  
25 The technologist is supervised by the medical director.

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1           The technologist should feel responsible to the  
2 medical director for performing the duties required for her  
3 position.

4           It is ludicrous to think that the technologist is  
5 going to be concerned about David E. Cunningham, who they  
6 may or may not see once a year, when it comes to the  
7 day-to-day functions that they must perform.

8           Now that doesn't mean that responsibility doesn't  
9 exist. It only means that I believe the technologist should  
10 recognize that their responsibility is to the medical  
11 director. I am not saying I don't have responsibility, but  
12 if there is a problem, who are the technologists going to  
13 report it to?

14           The medical director and the physicist on site.

15           So, in essence, the radiation safety officer has  
16 delegated to that site so that those technologists recognize  
17 those individuals.

18           DR. SHANBAKY: Dr. Cunningham --

19           DR. PAPERIELLO: Do you conduct audits of the  
20 sites to determine whether or not these responsibilities are  
21 being carried out?

22           THE INTERVIEWEE: Part of the audit procedure is  
23 in this document. What I have initiated as part of the  
24 audit procedure -- I have a section in this document and,  
25 again, I am referring to the document called Oncology

1 Services Corporation, Department of Physics, HDR Treatment  
2 Manual -- One of the sections in there, after the quality  
3 management program and the statement of responsibility which  
4 addresses the things I have been telling you here about now,  
5 is a training requirement, initial, annual and then a  
6 training compliance form.

7 In this section would be the requirements for the  
8 training at that particular site. Now the manual is  
9 generic. Some sites may have a Nucletron, some sites may  
10 have an Omnitron, some sites may have a Gamma Med.

11 So that will not be in this manual. When it goes  
12 to the site, it would be put in the manual according to the  
13 syllabus that is provided by that manufacturer.

14 MR. MADISON: I think we understand that you are  
15 fully intending to implement these procedures and place them  
16 in all facilities. Is there any change that you would make  
17 in your own performance as radiation safety officer to  
18 improve the operations of the facilities?

19 THE INTERVIEWEE: Okay, that is what I was getting  
20 to here, in a second. I think what I want to try to do is  
21 address the question, how do I have any kind of personal  
22 assurance as to the different aspects of this -- and it  
23 looks as if --

24 Unfortunately, I left this manual in Indiana and a  
25 number of people went through it and somebody took out the

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1 form to have a copy made of, and they didn't put the form  
2 back in there.

3 MR. MADISON: What section would that be in?

4 THE INTERVIEWEE: The compliance form. There is a  
5 paper called training compliance form and I think, Dr.  
6 Shanbaky, when you and I met briefly in the room one morning  
7 and we talked about this somewhat, I think perhaps I  
8 indicated it to you then.

9 This training compliance form, which was in this  
10 manual in Indiana, states the requirements for annual  
11 training. It also requires a positive affirmation by the  
12 individual that was trained and it requires them to submit  
13 it to me here, at the Harrisburg Cancer Center.

14 These are steps that were taken by me before this  
15 incident.

16 MR. MADISON: Correct me if I wrong, you said that  
17 you had not sent this manual to the Indiana Center; that  
18 this manual had gone to three centers but that did not  
19 include the Indiana Center.

20 THE INTERVIEWEE: That is correct.

21 DR. PAPERIELLO: Let me put it this way: Up until  
22 now, or a month ago, have you conducted audits of the  
23 facilities with the HDR units to see -- ensure that your  
24 expectations were being met with respect to radiation safety  
25 training and that not only training was given but that it

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1 was received?

2 THE INTERVIEWEE: Yes.

3 DR. PAPERIELLO: Do you document those audits?

4 THE INTERVIEWEE: No.

5 DR. SHANBAKY: When was that?

6 THE INTERVIEWEE: You said audits, but you didn't  
7 say -- not audits of every site. Okay. Let me say, I mean,  
8 a lot of what is going to come out of whatever you are going  
9 to say to me, I probably already know or have already  
10 initiated.

11 There may be a few things that I am not fully  
12 aware of, but I would be very surprised if there is anything  
13 that comes out that is not part of my plan for  
14 implementation.

15 I think that all of us in this operation recognize  
16 that there is a certain evolution in the development of  
17 procedures and policies.

18 When you realize the need to do something, it  
19 doesn't happen the next day. You have to first think about  
20 it, you develop it; you check it out and then you implement  
21 it.

22 The NRC does the same thing. There is a need for  
23 regulations right now that are in the development stage and  
24 have been in the development stage for quite a while.

25 You have your own time schedule. You can impose a

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1 time schedule on me as a user. I must comply with that.  
2 There is no reciprocity there.

3 DR. SHANBAKY: When was the last audit performed,  
4 Dr. Cunningham?

5 THE INTERVIEWEE: I would have to think exactly  
6 and go back through my dates, but I mean, as part of this  
7 -- as part of this, I have been particularly at the centers,  
8 like Harrisburg, been going over all of our records here and  
9 developing it primarily out of these areas which for me is  
10 more effective from a time standpoint.

11 DR. SHANBAKY: Where are the findings of that?

12 THE INTERVIEWEE: Here [indicating] and here  
13 [indicating].

14 DR. SHANBAKY: Can you tell us something about the  
15 findings? What did you find as a result of this audit?

16 THE INTERVIEWEE: Well, I found that there was a  
17 need for having -- I found that there was a need for having  
18 a clear statement of responsibilities.

19 I recognize that the medical directors, even  
20 though they have been told repeatedly, at conferences, that  
21 they are responsible for the delivery of the treatment and  
22 all the aspects of it, they still concentrate on the  
23 clinical part and because, for the most part, they find  
24 aspects of radiation safety to be distasteful and not  
25 something that they would like to be responsible for -- even

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1     though they are told that it is their responsibility -- You  
2     have to, I think, find some way of ensuring that they accept  
3     that responsibility.

4             It is not always easy to do with medical  
5     directors. They are physicians and some like to march to  
6     their own tune.

7             So, that is one area that I recognize and that is  
8     Section 1, statement of responsibilities, along with the  
9     quality management program.

10            That will list each individual in the delivery  
11     system and itemize their responsibilities.

12            This is a need that I recognize and I think it is  
13     a need that obviously you have recognized. It is no secret.  
14     But I knew about it and I was in the process of developing  
15     it.

16            DR. SHANBAKY: Do you have any findings in  
17     radiation safety, understanding or performance of  
18     technologists at these facilities?

19            THE INTERVIEWEE: Say that, again?

20            DR. SHANBAKY: Did you have any findings in the  
21     area of radiation safety knowledge, understanding and  
22     performance of the technologists at these facilities?

23            MR. MADISON: I believe Dr. Shanbaky means by  
24     "findings", any discrepancies or disparities.

25            DR. SHANBAKY: Weaknesses, or areas that need

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1 improvements. Not necessarily regulator -compliance;  
2 things that need improvements.

3 THE INTERVIEWER: I could say thout exception  
4 that in areas of radiation safety, you nearly always have to  
5 strive for performance -- improving their level  
6 of understanding.

7 Because I thi a lot of these things tend to be  
8 common sense reactions that are over-looked in a stress  
9 situation. This is a very stressful procedure, whether it  
10 is a linear accelerator, brachytherapy -- everything we do,  
11 there is a fairly high degree of stress related to it.

12 Technologists are human beings. They can be  
13 cavalier after they have done a procedure repeatedly.  
14 Invariably, you will find that the awareness to certain  
15 things are very acute initially. As time goes on and they  
16 have done 50 -- 100 procedures, human nature enters in.

17 With the physicians, with the physicists, with the  
18 technologists.

19 So you always have to be vigilant about reassuring  
20 awareness.

21 MR. MADISON: Would you say that there were  
22 general weaknesses, or could you describe some specific  
23 weaknesses that you found in the locations?

24 THE INTERVIEWEE: No, I would -- I mean, I can't  
25 at I can, off the top of my head, think of any

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1 specific -- I mean, I have indicated a couple already, with  
2 the medical directors. The technologists, for the most  
3 part, are very capable and well trained and very aware of  
4 what they are doing.

5 I believe that to be the case here. I believe it  
6 to be the case in Indiana. Indiana had a technologist staff  
7 that was stable. My biggest problem is not a site like  
8 Indiana, where you have stability. My biggest concern and  
9 my biggest worry is you have three technologists, two  
10 technologists at that level -- it is not uncommon in a  
11 hospital or a treatment center to have change in personnel.

12 My biggest concern with change of personnel,  
13 making sure that they are at the same level as the person  
14 that left. That is -- Indiana, I don't want to say that --  
15 I don't want to say that I gave no thought to Indiana, or  
16 wasn't concerned about it. It is part of the network.

17 I talked with Greg Hay, I talked with Dr. Bauer.  
18 Indiana had a very stable staff. Dr. Bauer is a physician  
19 who is fastidious to a fault. I don't know if you reviewed  
20 his records.

21 When I reviewed this charts, I found them to be  
22 adequate, complete to the detail.

23 Greg Hay, as I reviewed his work, I found  
24 similarly that he has been very adequate and comprehensive  
25 and didn't overlook something, and didn't worry about what

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1 was written in the contract -- did not worry about it.

2 Anything that needed to be done to ensure that Dr.  
3 Bauer had the necessary services that he wanted, he  
4 received.

5 To the point that when I hired Mitch Jarosz in  
6 Pittsburgh and I was restructuring Western Pennsylvania's  
7 physics, to bring it under -- more of an appropriate  
8 umbrella, I called Dr. Bauer and discussed the physics  
9 services with him because at that time I had the possibility  
10 of extending corporate physics to Indiana -- by that I mean  
11 an employee.

12 Dr. Bauer thought about it and he came back to me  
13 and he said that Greg Hay is doing such a good job and he  
14 has been here, and over the years he has done excellent work  
15 and he had total confidence in him -- from my review, I  
16 could concur that he was an excellent physicist. I even  
17 tried to hire Greg Hay as a full-time physicist. I made him  
18 an offer.

19 So there was -- it wasn't a question where I  
20 thought we had marginal coverage there. From the technical  
21 staff, the physician and the physics -- it was not a shoddy  
22 organization.

23 DR. SHANBAKY: Is Mr. Hay required to be there  
24 during patient treatment?

25 THE INTERVIEWEE: Obviously he can't be there

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1 during all patient treatments.

2 DR. SHANBAKY: When is he required to be there, at  
3 the Indiana facility?

4 THE INTERVIEWEE: He is there at the discretion of  
5 the medical director.

6 DR. SHANBAKY: How many days in a week does he  
7 spend at Indiana?

8 THE INTERVIEWEE: Dr. Bauer told me that he was  
9 there whenever he was needed. The issue of time -- Dr.  
10 Bauer said that all the work was done, all the quality  
11 assurance was done. All the treatment records were  
12 reviewed, all the treatment plans were completed and,  
13 additionally, if he had to come back for anything, like a  
14 brachytherapy procedure in a hospital, he always did it.

15 This is the idea situation, when you have somebody  
16 who has by history of performance been reliable, rather than  
17 having a situation where you establish a contract, that from  
18 8 to 5, you must be there at the facility.

19 Well, that means to me I have a problem because  
20 that is the only time that I can count on this person to be  
21 there, and the rest of the week, if something comes up, he  
22 can say to me -- well, it says here on paper that I am only  
23 Mondays 8 to 5.

24 That wasn't the case with Greg Hay. He was always  
25 available whenever he was needed. That was one of the

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1 reasons why, when I went to Dr. Bauer and I said -- should  
2 we look at an alternative mechanism? -- that is the one of  
3 the reasons that he said no.

4 This is a comprehensive coverage.

5 DR. SHANBAKY: Getting back to the audit, Dr.  
6 Cunningham, I understand that you did some audit but they  
7 are not documented. Am I correct in saying that?

8 THE INTERVIEWEE: Yes.

9 DR. SHANBAKY: So, going back to this audit, to  
10 perform the audit, you plan them, you conduct them, you  
11 document them, you identify the deficiencies, correct the  
12 deficiencies and you close the log by verifying that the  
13 systems you put in place to correct the deficiencies are  
14 working and all the deficiencies are corrected.

15 THE INTERVIEWEE: Right.

16 DR. SHANBAKY: Now, in your undocumented audit  
17 system, how do you satisfy this process of an audit?

18 THE INTERVIEWEE: Okay, in that context, this  
19 document serves as a reference to the audit.

20 MR. MADISON: But this document is to be used in  
21 the future; it is not being used presently; is that correct?

22 THE INTERVIEWEE: Any document that is -- when you  
23 recognize -- If you do an audit and you recognize as  
24 deficiency, as a radiation safety officer in an audit, you  
25 have that deficiency immediately.

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1           Now you may not be able to put in place the  
2           procedures to correct that deficiency for maybe three hours,  
3           maybe three days, maybe three months -- it depends upon the  
4           nature of the deficiency.

5           This [indicating] represents my audit, my  
6           recognition of deficiencies and my action plan to correct  
7           those. And this is in place right now.

8           Now, is it at every center? No, because of the  
9           reasons that I told you. I will not send out conflicting  
10          information to centers and then two months later send them  
11          something else.

12          The essential aspects of radiation safety, at the  
13          level of delivery, is to make it succinct, clear and as  
14          simple as possible. The worst thing to do is to change  
15          procedures every two, three, four months. The staff can no  
16          way -- all you will end up with is total pandemonium and  
17          they won't know what to do.

18          MR. MADISON: Let me ask you this: If you find a  
19          deficiency, do you allow continued operation prior to  
20          correction of the deficiency?

21          THE INTERVIEWEE: It depends upon the nature of  
22          the deficiency.

23          MR. MADISON: For instance, if a technologist is  
24          not aware of the proper use of a survey meter, do you  
25          allow --

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1 THE INTERVIEWEE: If I was aware of that, I would  
2 not allow that to continue.

3 DR. SHANBAKY: I would like to get back to the HDR  
4 now. What was your involvement, Dr. Cunningham, with the  
5 procurement of the HDR?

6 THE INTERVIEWEE: As you know, HDR equipment --  
7 there is essentially three vendors. Nucletron, Dr.  
8 Sauerwein, Gamma Med, and Omnitron.

9 Our initial unit was a Gamma Med unit and when we  
10 met with the vendor, I met with them and discussed different  
11 aspects of the unit and we made an acquisition.

12 The Omnitron unit came on the market and there  
13 were several physicians -- many physicians across the  
14 country who were quite excited about the possibility of  
15 having a unit with a smaller source -- smaller diameter  
16 source.

17 One of the key treatments with HDR is pulmonary  
18 treatments, endobronchial treatments. With endobronchial  
19 treatments, with the larger diameter source which is used by  
20 Nucletron and as used by Gamma Med, in the right upper lobe,  
21 it may be difficult to negotiate the bend.

22 There has been treatments that we have started  
23 that we had to abort even though the patient went through  
24 all the trauma -- we didn't abort it in the active source  
25 part, but just in the bronchoscopy part.

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1           This is for the pulmonologist and for the  
2 radiation oncologist and for the patient, that is a source  
3 of concern because you have gone through a lot of agony for  
4 nothing.

5           So when the Omnitron unit came out, there was some  
6 excitement about the possibility of having a smaller  
7 diameter source from the clinicians.

8           From the physics standpoint, the source is smaller  
9 in diameter and longer in length. This presents some  
10 difference in terms of the dose distributions, differences  
11 in terms of looking at different features of calibration,  
12 depending upon your calibration techniques.

13          There are different technical factors and those  
14 need to be studied and reviewed. From a safety standpoint,  
15 there is no way that the user can really know the  
16 possibility for safety failures in these units.

17          We don't really test them. Testing is done by the  
18 FDA. We have to rely on the testing procedures of the FDA,  
19 that if this unit is allowed to be sold to the user, that it  
20 is safe.

21          So, the input that I would have is when I am asked  
22 are you aware of any problems? Is there any reason we can't  
23 buy it? Well, I have to say no. At the same time, I say  
24 there was very little experience with the Omnitron units  
25 compared to Nucletron and compared to Gamma Med.

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1 I a member of the Gamma Med Users Group. I have  
2 done some work internationally with that, and maybe we could  
3 talk about that after. But at this point, I had no reason  
4 to say to the company, from a scientific, technical or  
5 safety aspect that we should not buy it.

6 DR. SHANBAKY: So I take it, your recommendation  
7 was to buy the machine?

8 THE INTERVIEWEE: My recommendation was passive.  
9 I couldn't recommend against it. The clinicians were  
10 recommending in favor of it. I didn't recommend to buy the  
11 machines, no, but I didn't recommend not to buy them.

12 DR. SHANBAKY: What was your involvement in the  
13 receipt of the machine, when the machine came to the  
14 facility and the vendor was turning it over to you? What  
15 was your involvement in that?

16 THE INTERVIEWEE: Okay. Excuse me. I want to  
17 move this because we may need some of these papers.

18 This can be appropriately addressed, not just to  
19 the Omnitron machine but any machine, because there is a  
20 potential for problems with any machine.

21 Initially, we had the Gamma Med unit here at  
22 Harrisburg. It was here. When they purchased the Omnitron,  
23 I insisted that the first Omnitron unit come here so that we  
24 could do acceptance testing, performance evaluation,  
25 dosimetry -- anything that needs to be done on it, here,

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1 first, before it went to any other center.

2 The Gamma Med was moved to another center. The  
3 Omnitron came here. We began our analysis and evaluation of  
4 it.

5 There are certain aspects of it, of the analysis  
6 that are routine in nature, things that are related to the  
7 calibration and the quality assurance. Then there are some  
8 things that are more unique because of the uniqueness of the  
9 source.

10 So there is one-time studies that need to be done  
11 and then there are studies more related to the routine  
12 calibration, quality assurance. We have done nine projects,  
13 nine different studies related to these HDR units.

14 We did a study of the transit time, a measurement  
15 of the transit time associated with the time it takes for it  
16 to leave, where it is parked, until it gets into delivery -  
17 -not to accept the value that is given by the manufacturer.

18 If I can find some of these things quickly, I will  
19 point to them; if not, we can --

20 Now this is the results of the transit time study  
21 here. It shows a time of five seconds.

22 MR. MADISON: Dr. Shanbaky, do you feel that is  
23 something you would want to enter on the record?

24 DR. SHANBAKY: Not really.

25 THE INTERVIEWEE: I guess I submit anything that I

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1 feel should be in the record.

2 DR. SHANBAKY: Yes.

3 THE INTERVIEWEE: And I believe that some of these  
4 things should be in the record. What I am trying to  
5 establish is --

6 MR. MADISON: My question was, the document  
7 itself, whether it should be in the record.

8 THE INTERVIEWEE: We did a study of the effects of  
9 leakage of the electrometer on the calibration technique.  
10 This is something that is neglected by a lot of centers.

11 They will use an electrometer. They will use a .6  
12 cc chamber and an electrometer -- a .6 cc chamber works very  
13 well in a direct beam or linear accelerator, but at 20 or 30  
14 centimeters from an HDR, the dose rate is much lower. Your  
15 signal to noise is quite a bit different.

16 What you find out if you do leakage measurements,  
17 you -- typically people will put it on the rate and look at  
18 the leakage, but the leakage is not fixed with time. The  
19 leakage changes with time.

20 So we did studies as to the effect of leakage with  
21 time on a dose --

22 DR. SHANBAKY: Did you change the size of your  
23 chamber as a result of this study?

24 THE INTERVIEWEE: Actually, first we went -- We  
25 didn't change the size of the chamber. We made a couple of



1 changes. We went to a electrometer which had a signal noise  
2 ratio which was ten times better than this electrometer and  
3 at that level, the leakage became less than half a percent  
4 over time.

5 So, that was how we -- which was a better solution  
6 than going to a larger chamber because of inverse square  
7 effects and because of the gradient across the chamber.

8 DR. SHANBAKY: Dr. Cunningham, just for curiosity,  
9 this chamber as you put it -- an air or -- what is the  
10 distance from the HDR?

11 THE INTERVIEWEE: Yes. We did a study --

12 DR. SHANBAKY: Can you describe the set up for  
13 calibration.

14 THE INTERVIEWEE: The calibration procedures have  
15 changed over the course of a few years. We started out with  
16 a .6 cc chamber on a jig at a fixed distance. We did  
17 studies to see the effect -- and that was with a cobalt-60  
18 factor. That is all that was available.

19 Then, through the University of Wisconsin  
20 laboratories, we were able to get a calibration factor for  
21 orthovoltage and for cesium. It is not an iridium  
22 calibration factor, but the effective energy of these two is  
23 much closer than the cobalt.

24 So we sent the chamber out and had it calibrated  
25 both with cobalt, with cesium and with orthovoltage and did

1 a study as to the effects of using one versus the other on  
2 the calibration.

3 Fortunately, for most people who are just using  
4 cobalt, the difference is on the order of one to two  
5 percent. So it wasn't -- [Pause.]

6 Then, as time went on -- so this is an accepted  
7 calibration technique, with an ion chamber, with the  
8 appropriate calibration factor taking into account room  
9 scatter and also taking into account build up on the  
10 chamber.

11 However, when the well-type counters became  
12 available and there were a couple of them available -- the  
13 first one was developed by Herb Attix and his group at the  
14 University of Wisconsin -- We were the first ones to get a  
15 commercial -- the unit that was available and calibrate it  
16 at the University of Wisconsin.

17 We then did a study here which you can see  
18 [indicating] and which we compared calibration techniques  
19 with the HDR 1000, which is the well chamber provided by the  
20 University of Wisconsin. We compared that to our PTW .6  
21 chamber, calibrated with cobalt, compared it to the atom lab  
22 44 which is another well chamber provided, and we compared  
23 that to a different calibrated system.

24 One of these is ortho-cesium and one is not. So  
25 we did extensive inter-comparisons of calibration

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1 techniques.

2 DR. SHANBAKY: Okay. So when you got the first  
3 machine, you actually started looking at what is the best  
4 system to use; what system are you using right now for  
5 calibration?

6 THE INTERVIEWEE: We are always doing that. If  
7 something else comes out, we evaluate it to see if it is  
8 better than what is available.

9 DR. SHANBAKY: Which one are you using right now?

10 THE INTERVIEWEE: Right now, we are using HDR  
11 1000, or a .6 chamber in air. Accepted calibration  
12 techniques.

13 DR. SHANBAKY: You have the written procedures now  
14 at all your facilities to do that?

15 THE INTERVIEWEE: No.

16 DR. SHANBAKY: How are you making sure they are  
17 doing it the way you want it done?

18 THE INTERVIEWEE: They are -- The calibration  
19 procedures for a linear accelerator, for an orthovoltage  
20 unit, for a brachytherapy source or an HDR source, those are  
21 accepted procedures by the profession.

22 There are differences in individual techniques  
23 which are not inappropriate and physicists that are trained  
24 will have somewhat differences in the way they do it, with  
25 the appropriate correction factors. This is -- there is

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1 nothing wrong with that.

2 DR. PAPERIELLO: In your treatment -- I am  
3 probably using the wrong term -- but in the computer codes  
4 that you used to calculate dose, do you rely on the  
5 measurements you -- and I mean you and the other physicists  
6 make of source output, or do you rely on the certification  
7 by the vendor of the source strength?

8 THE INTERVIEWEE: We use our own measurements.

9 DR. SHANBAKY: Your electrometer and all other  
10 associated stuff is calibrated by a certified --

11 THE INTERVIEWEE: We use the University of  
12 Wisconsin because their turn-around time is very good.

13 DR. SHANBAKY: Are you aware of a prior  
14 calibration of the source before you receive it?

15 THE INTERVIEWEE: We receive a certificate with  
16 it.

17 DR. SHANBAKY: What certificate?

18 THE INTERVIEWEE: Certificate -- it is a leak test  
19 certificate with an activity on a given date.

20 DR. SHANBAKY: Do you have any idea how this  
21 activity came about?

22 THE INTERVIEWEE: Yes. They are measured.

23 DR. SHANBAKY: Measured like the way you described  
24 it here, or --

25 THE INTERVIEWEE: How does the manufacturer

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1       measure it? What is their technique?

2               DR. SHANBAKY: Yes.

3               THE INTERVIEWEE: I am told that they use .6  
4       chamber in air. I am also told that they are switching to  
5       the HDR 1000. So they actually changed.

6               DR. SHANBAKY: The HDR 100 is a well detector?

7               THE INTERVIEWEE: Yes. I can show you.

8               DR. SHANBAKY: We can look at it after.

9               THE INTERVIEWEE: It is a well chamber.

10              So the advantage with the well chamber is you are  
11       measuring in a rate mode and not in the integrate mode.

12              DR. SHANBAKY: Do you still have the same  
13       correction -- temperature, pressure and all the other  
14       calibration factors are?

15              THE INTERVIEWEE: Oh, yes, whatever is  
16       appropriate. For example, here is a study we did on the  
17       effects of wall scatter [indicating]. Now these are  
18       published -- there have been other studies. You know,  
19       people have been doing this for a while, but we,  
20       nevertheless, did it here to establish our own verification  
21       of material that is in the literature.

22              So this is a study of the effect of wall scatter  
23       on our measurements here at Harrisburg. This is the study  
24       of the effect of different thicknesses of build up caps on  
25       our system here in Harrisburg.

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1           Many, many man-hours are involved in these studies  
2           because they all take time.

3           DR. SHANBAKY: Who is doing the calibration of the  
4           source at the Indiana facility?

5           THE INTERVIEWEE: Greg Hay.

6           DR. SHANBAKY: Does he send you the record for  
7           your review, or does he keep the records there, Dr.  
8           Cunningham?

9           THE INTERVIEWEE: He keeps them.

10          DR. SHANBAKY: Anybody review those records, other  
11          than Hay -- other than the originator? He is the  
12          originator?

13          THE INTERVIEWEE: Right; no.

14          DR. SHANBAKY: Do you feel that the radiation  
15          safety officer should be reviewing those records?

16          THE INTERVIEWEE: Let me answer that.

17          DR. SHANBAKY: That is what I am looking for.

18          THE INTERVIEWEE: I don't think -- I don't believe  
19          that it is compulsory that the radiation safety officer  
20          review every calibration that is done on every instrument  
21          that is used to deliver treatment.

22          Now what I do with external beam is, I will review  
23          annual calibrations. It would be -- there is no reason to  
24          say, from my standpoint, a radiation safety standpoint, that  
25          the potential for damage or harm to the patient is no more

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1     than serious with the high dose rate unit than it is for the  
2     linear accelerator. They are both potentially very -- could  
3     have very significant impact if improperly used.

4             It is an ineffective use of time when we -- this  
5     linear accelerator is calibrated daily -- daily. I have  
6     different rules for different linear accelerators, depending  
7     on their history of stability. The minimum that I require  
8     is a weekly calibration check on the linear accelerator, and  
9     that is the minimum.

10            Some I require daily. That would mean that all I  
11     would be doing -- if I were reviewing every calibration on  
12     every delivery system, physically it would be impossible to  
13     do.

14            DR. SHANBAKY: How about sampling basis?

15            THE INTERVIEWEE: With the linear accelerators, I  
16     review the annual --

17            DR. SHANBAKY: How about HDR?

18            THE INTERVIEWEE: HDR, the HDR units that we have  
19     out there -- and one of the reasons that this manual here  
20     [indicating] is coming about is because we started out here  
21     [indicating], and we initiated the program here. Then other  
22     facilities received the HDR.

23            The development of our program has been growing  
24     with the number of units that we have out there. So some  
25     things which there wasn't a need for initially, the need for

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1 it is now becoming apparent because the facilities are more  
2 remote.

3 Initially, if the work was not being done by me,  
4 it was being done by somebody direct under my supervision,  
5 and if you look at a lot of these records, you will see that  
6 I have co-signed them.

7 In the case such as Indiana, obviously, if you  
8 look at the records, that is not the case. So, will I  
9 implement a program to check their calibrations? I will  
10 continue to do it with the linear accelerators and give some  
11 thought to the HDR.

12 What has happened in the past is that anybody has  
13 called me if they have done a calibration -- and this  
14 happened in Pittsburgh and at one other center which I can't  
15 remember. But they did a calibration and came up with a  
16 difference of three percent or so, four percent, with the  
17 manufacturer.

18 So we addressed that and resolved that difference.

19 On the other hand, when the difference is more  
20 than one or two percent of the certified value from the  
21 manufacture, then they have proceeded with that calibration.  
22 So I was fairly comfortable with that level of evaluation.

23 DR. SHANBAKY: Let's move to the prime alert.

24 THE INTERVIEWEE: Are we going to come back to  
25 calibration?

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1 DR. SHANBAKY: No, we need something on the record  
2 about the procedure you have at the facility here.

3 MR. MADISON: What records do you want?

4 DR. SHANBAKY: The record of the calibration  
5 method, the comparison between different chambers and any  
6 procedures associated with that calibration.

7 MR. MADISON: Specifically, Indiana or in general?

8 DR. SHANBAKY: Do you have any calibration  
9 performed at Indiana?

10 THE INTERVIEWEE: Not here. But here, we are  
11 talking about the program -- right?

12 DR. SHANBAKY: Right.

13 THE INTERVIEWEE: Indiana is part of the program  
14 but it is not the whole program.

15 DR. SHANBAKY: So we need these records about that  
16 calibration.

17 THE INTERVIEWEE: I am not sure exactly what the  
18 regulations say as to a requirement of frequency of  
19 calibration.

20 DR. SHANBAKY: You have the license.

21 THE INTERVIEWEE: We do. Here is the calibration;  
22 we do weekly.

23 DR. SHANBAKY: On HDR?

24 THE INTERVIEWEE: We do weekly and up until very  
25 recently when I switched to monthly.

1 DR. SHANBAKY: So you are doing it.

2 THE INTERVIEWEE: Some places, I know -- other  
3 facilities, not Oncology Services, but would do it once --  
4 when it was installed and then decay it.

5 DR. SHANBAKY: Right.

6 THE INTERVIEWEE: We do it this way for several  
7 reasons. I have people that come here that are in a  
8 training mode. I have one Master's physicist who is pushing  
9 me now to be involved with the HDR program. He has already  
10 been involved with eight procedures and he is not permitted  
11 to have anything to do with HDR other than in the training  
12 mode where he is not doing anything -- he may be doing it,  
13 but somebody is standing over his shoulder.

14 DR. SHANBAKY: Let's get to the prime alert. I  
15 want to understand the purpose of the prime alert. What is  
16 the design basis for the prime alert? What purpose, what  
17 function it should be performing for you?

18 THE INTERVIEWEE: It is a monitor of the presence  
19 of radiation..

20 DR. SHANBAKY: At which level?

21 THE INTERVIEWEE: Two MR per hour.

22 DR. SHANBAKY: What is your views of the  
23 performance of the prime alert?

24 THE INTERVIEWEE: My views? I believe that the  
25 prime alert is a radiation detector, like a survey meter.

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1 Survey meters, prime alerts must be checked for correct  
2 operation. The mechanism for checking that is with a live  
3 source.

4 There is -- the presence of the linear accelerator  
5 provides an easy mechanism for a daily quick check -- daily  
6 quick check of the prime alert. In addition to that, the  
7 presence of a check source allows for a non-electronic check  
8 of a prime alert.

9 MR. MADISON: Do you have a check source at the  
10 Indiana facility for the prime alert?

11 THE INTERVIEWEE: Greg Hay has the check source.

12 MR. MADISON: Is he required to check the prime  
13 alert periodically?

14 THE INTERVIEWEE: He told me that he checks it --  
15 I think he told me monthly that he does it -- at least  
16 monthly.

17 MR. MADISON: Does he document that, or is that  
18 just a --

19 THE INTERVIEWEE: Really, he told me he did it  
20 monthly. Now, I am trying to think where we document --  
21 where we document it. It is on our -- we document it on our  
22 -- not on our HDR record, but the monthly check is  
23 documented on our monthly linear accelerator report.

24 DR. SHANBAKY: But you said it is being checked  
25 daily?

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1 THE INTERVIEWEE: With the linear accelerator.  
2 There is a mechanism for checking it daily.

3 DR. SHANBAKY: To your knowledge, were you aware  
4 of any problems with the prime alert?

5 THE INTERVIEWEE: No, not problems -- not problems  
6 related to malfunctions or design problems.

7 DR. SHANBAKY: What kind of problems are you aware  
8 of?

9 THE INTERVIEWEE: There have been prime alerts,  
10 like survey meters, that have required servicing. Which  
11 ones and the frequency, I don't know. I don't remember.

12 MR. MADISON: You are not aware of any inherent  
13 problems?

14 THE INTERVIEWEE: Not in the design or the  
15 functioning of the prime alert. As far as I know, when a  
16 prime alert is on the wall, it is functioning properly. We  
17 keep extra prime alerts and if there is any suspected  
18 problem with one, we over-night it, the one that we keep  
19 here.

20 DR. PAPERIELLO: What is your experience with  
21 their reliability?

22 THE INTERVIEWEE: Reliability -- I think it has  
23 been adequate.

24 DR. PAPERIELLO: Can you quantify that somehow?

25 THE INTERVIEWEE: I have never personally

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1 evidenced a malfunction. I think that there have been  
2 occasions where you get a red flash and --

3 DR. SHANBAKY: With no radiation?

4 THE INTERVIEWEE: Well, there is always radiation  
5 present.

6 DR. SHANBAKY: No, but you said you get --

7 THE INTERVIEWEE: You get a red flash.

8 DR. SHANBAKY: With radiation --

9 THE INTERVIEWEE: Well, on a survey meter -- or,  
10 you will get a reading.

11 DR. SHANBAKY: What is peculiar about this?

12 THE INTERVIEWEE: What is peculiar is you have a  
13 threshold of 2 MR per hour, but there is a distinct  
14 difference in the operation of a unit when it is in  
15 radiation field at 2 MR per hour and a spurious red flash.

16 DR. PAPERIELLO: What is that?

17 THE INTERVIEWEE: The continuous flashing.

18 DR. PAPERIELLO: In other words, when you have a  
19 field above 2 MR --

20 THE INTERVIEWEE: It flashes continuously, yes.

21 DR. SHANBAKY: What is the dose rate -- when you  
22 fire up the accelerator at the Indiana facility, what is the  
23 dose rate beside that prime alert? What is the prime alert  
24 going to see? Is it 3 MR per hour, 10 MR per hour -- how  
25 many MR per hour?

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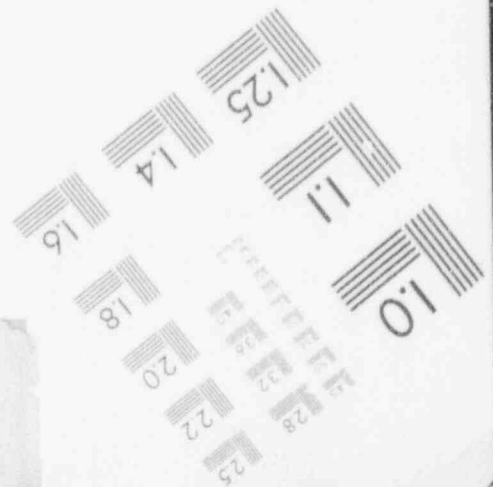
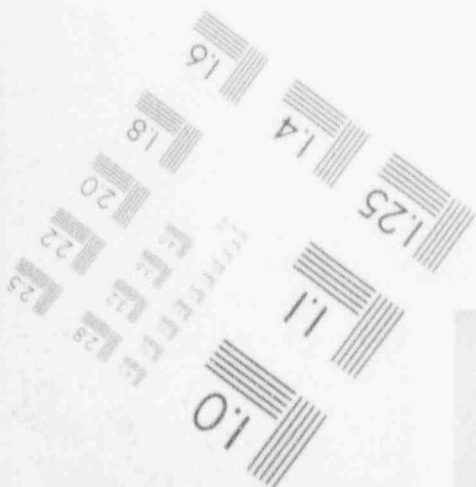
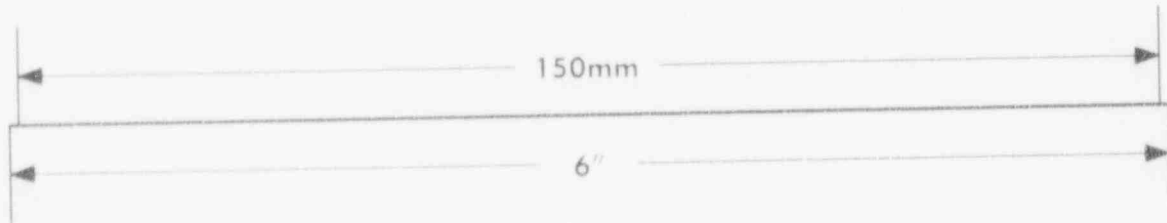
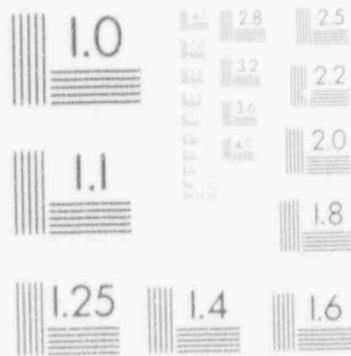
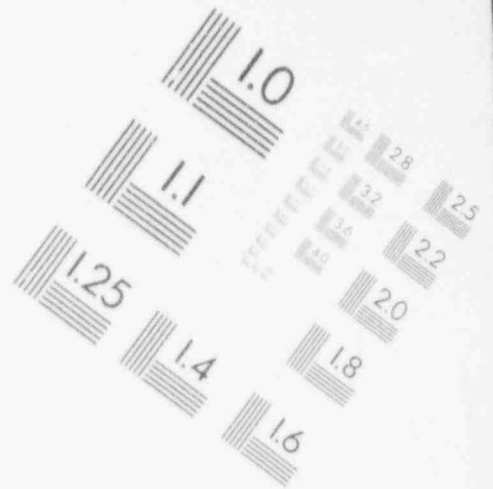
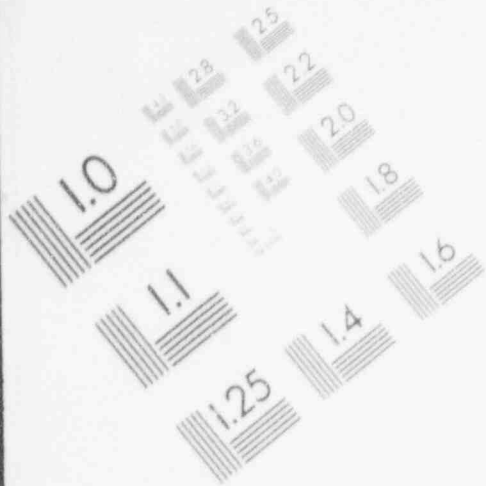
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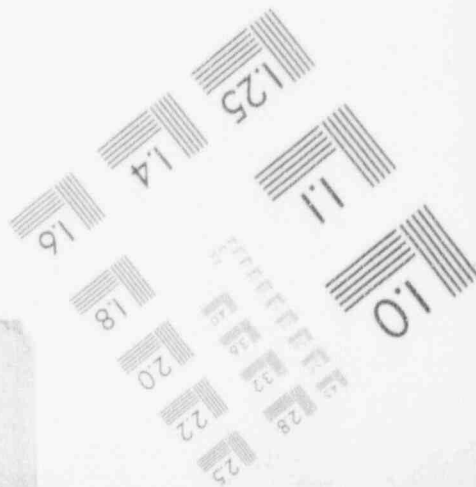
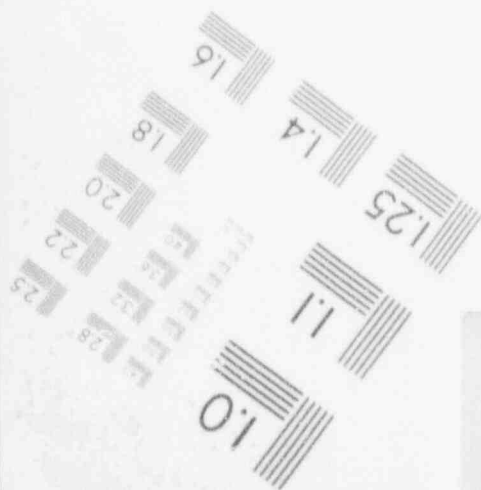
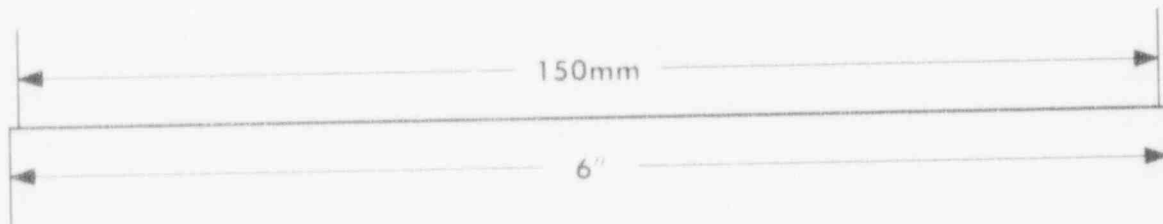
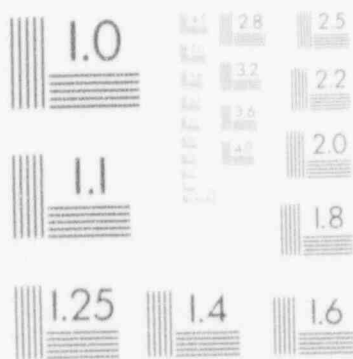
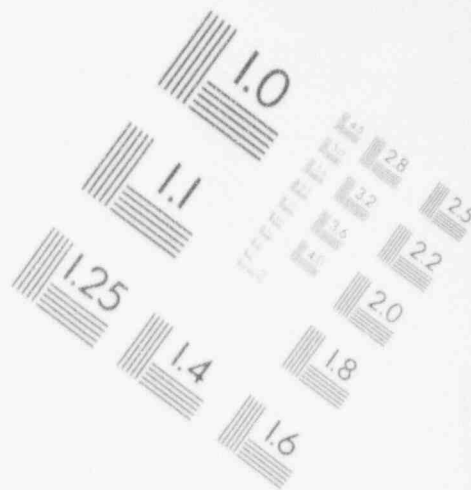
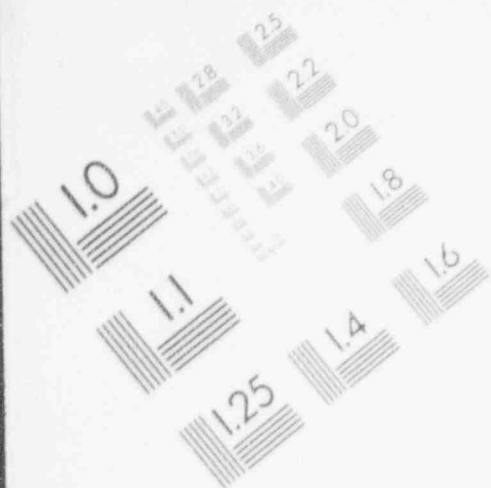
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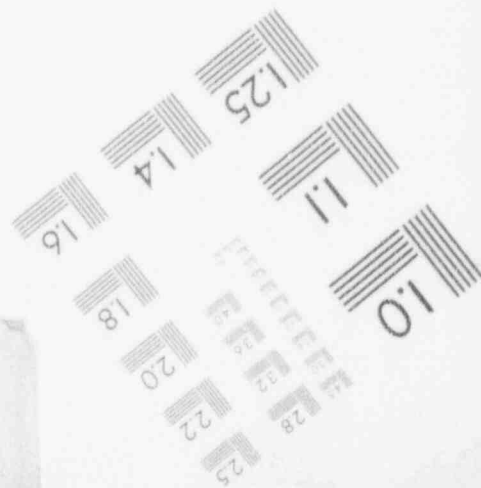
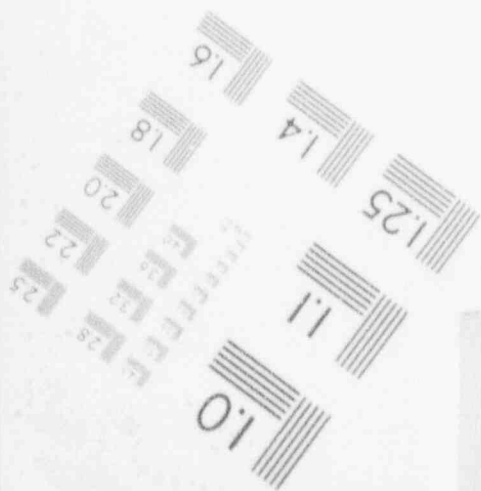
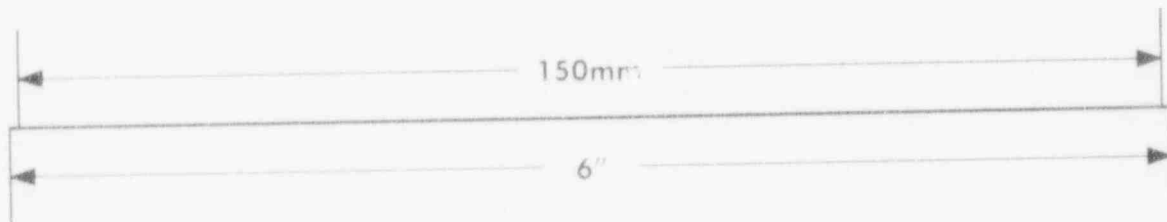
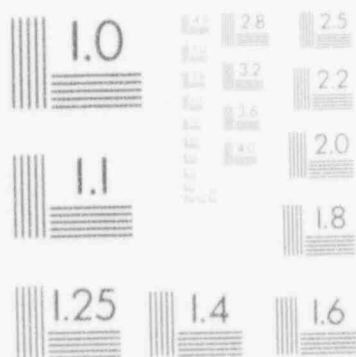
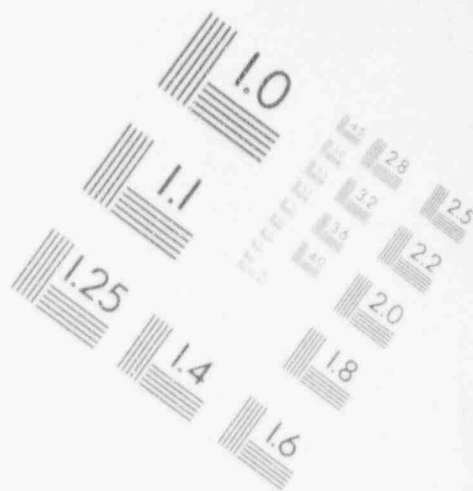
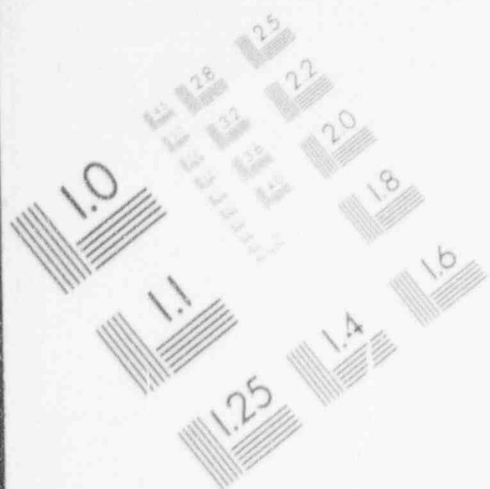
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IMAGE EVALUATION  
TEST TARGET (MT-3)



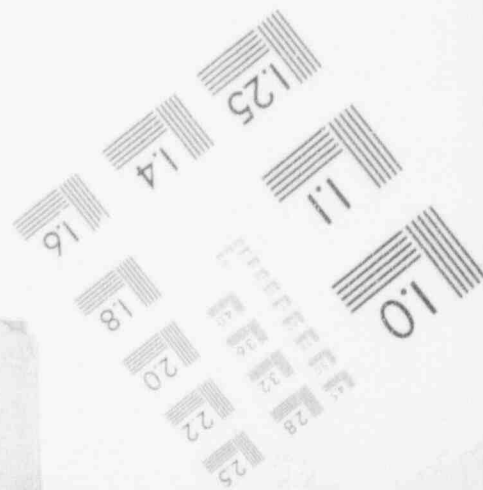
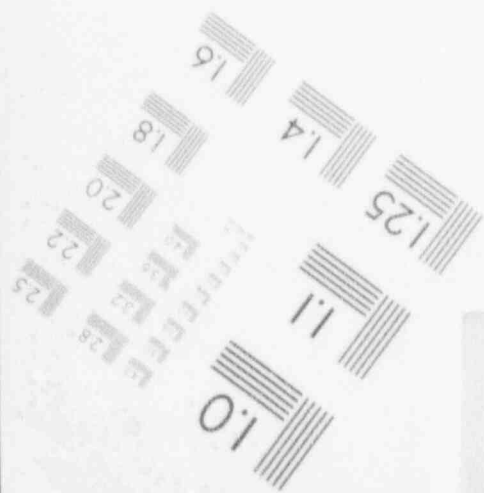
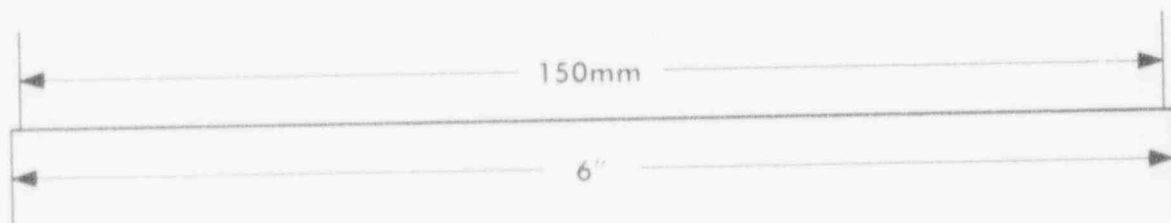
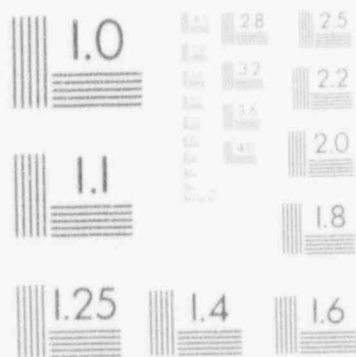
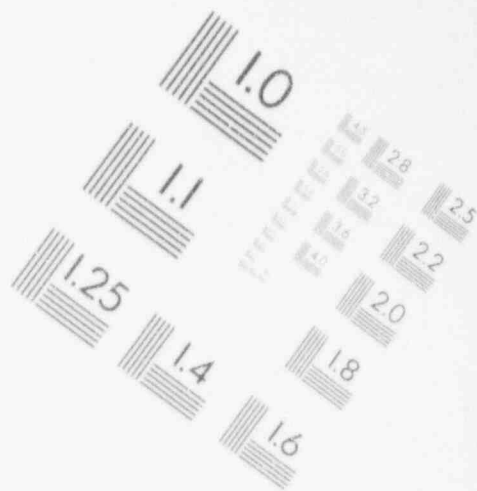
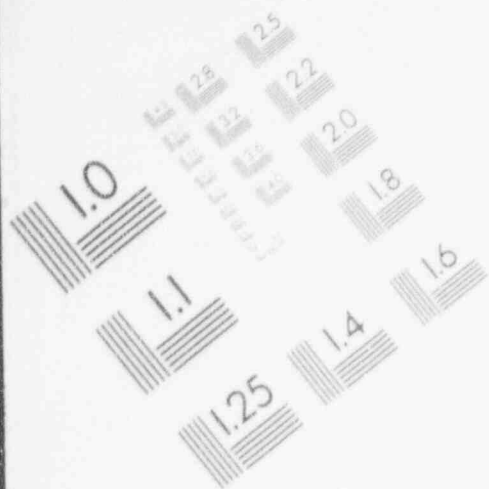
# 1

## IMAGE EVALUATION TEST TARGET (MT-3)



1

IMAGE EVALUATION  
TEST TARGET (MT-3)



1 THE INTERVIEWEE: Well, you know the dose rate at  
2 the isocenter is usually on the order of 200 MR per minute.

3 DR. SHANBAKY: I am talking about the wall where  
4 the prime alert is located.

5 THE INTERVIEWEE: So if you are three meters away  
6 and you are scattering off of a patient, it is going to be  
7 reduced by about ten to the four factor -- roughly -- ten to  
8 the four, so that gives you a feel for what it is.

9 DR. SHANBAKY: What is it, again, on the patient,  
10 directly?

11 THE INTERVIEWEE: About 200 MR per minute.

12 MR. MADISON: Are you aware of any specific  
13 problems with the prime alert at the Indiana facility?

14 THE INTERVIEWEE: No. I asked Greg Hay about it  
15 and he told me that he was not aware of any malfunctioning.

16 MR. MADISON: Were you aware of a practice at the  
17 facility of unplugging the prime alert?

18 THE INTERVIEWEE: No, no. Nor do I believe that  
19 Greg Hay was. You asked before what kind of procedures  
20 would cause -- when you identify a deficiency -- what kind  
21 of procedures would initiate an immediate cessation; that  
22 would definitely be one.

23 DR. SHANBAKY: Where did the technologists get the  
24 idea of a continuous red flashing with no dose rates in the  
25 area? During my discussion with the technologists, they

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1 said the prime alert every once in a while, it goes red  
2 flashing and there is no radiation in the area. They  
3 verified this at least once.

4 They went in the room with a meter and the prime  
5 alert was flashing but there was no dose rate on the meter.

6 THE INTERVIEWEE: It is very difficult for me to  
7 confirm that that is a possibility. I have never  
8 experienced it. I don't know how it could be possible.  
9 Furthermore, I would assume that if they witnessed an event  
10 like that, they would report it to Greg Hay.

11 DR. SHANBAKY: Did they?

12 THE INTERVIEWEE: Not to my knowledge.

13 DR. SHANBAKY: Can you think of anything that  
14 could cause the prime alert to go on an alarm mode with no  
15 dose rates in the area?

16 THE INTERVIEWEE: No.

17 DR. SHANBAKY: Okay. Is there any calibration you  
18 are doing on an instrument, other than the check source  
19 which is done monthly and the daily check with the  
20 accelerator -- is there any other verification of the proper  
21 operability of this survey meter -- this area monitor,  
22 really?

23 THE INTERVIEWEE: As you know, it is an on/off  
24 detector. Calibration -- you cannot calibrate it at several  
25 points. You calibrate it in the range of using it. That is

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1 the purpose of the check source.

2 DR. SHANBAKY: Is there any precaution or maximum  
3 dose rates that an instrument should not be subjected to,  
4 that you are aware of?

5 THE INTERVIEWEE: No.

6 DR. SHANBAKY: Environmental condition, power  
7 supply peculiarities?

8 THE INTERVIEWEE: With that instrument?

9 DR. SHANBAKY: Yes.

10 THE INTERVIEWEE: No, I am not aware.

11 DR. SHANBAKY: Any precautions or limitations  
12 provided to you by the vendor of the machine -- to not be  
13 used in such a manner, any --

14 THE INTERVIEWEE: Not that I recollect.

15 MR. MADISON: We requested a copy of the prime  
16 alert manual. Would you happen to have one here?

17 THE INTERVIEWEE: Yes.

18 MR. MADISON: Could we get a copy of it before we  
19 leave?

20 THE INTERVIEWEE: Yes.

21 MR. MADISON: Thank you.

22 DR. SHANBAKY: In addition to, again, to the  
23 monthly checks, is there any other frequency for checking  
24 electronics in the monitor, or any other maintenance  
25 requirement by the vendor on the equipment? On the prime

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1 alert.

2 Is there any other maintenance requirement or  
3 surveillance requirements or recommendations, other than the  
4 checks -- the source check?

5 THE INTERVIEWEE: My experience and my  
6 recollection is that the monthly check is what is indicated  
7 as necessary by the regulators as well as by our practice,  
8 experience.

9 DR. SHANBAKY: Okay. Your draft radiation safety  
10 manual that we have been talking about, do you have any  
11 plans to provide the technologists with training on the  
12 manual?

13 THE INTERVIEWEE: No. The manual will be directed  
14 to the physicists and the medical director.

15 DR. SHANBAKY: Then how will this be useful to the  
16 technologists?

17 THE INTERVIEWEE: Part of that manual is a  
18 statement of responsibilities, and also a compliance  
19 statement that I indicated earlier. Even though it doesn't  
20 go directly to the technologists, it states the  
21 responsibility for training and feedback for that training,  
22 to me.

23 DR. SHANBAKY: Before we get into the November  
24 incident, I would like you, Dr. Cunningham, to describe to  
25 me the quality management program as it applies to the HDR

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1 treatment.

2 MR. MADISON: As it exists today, or existed at  
3 the time of the event.

4 DR. SHANBAKY: At the time of the event.

5 THE INTERVIEWEE: Quality management?

6 DR. SHANBAKY: As it applies to HDR treatment.

7 THE INTERVIEWEE: Okay. There are different  
8 aspects of quality management. The one that we, I think  
9 perhaps, we have talked about is the calibration. Another  
10 is the computer programs that are used, the treatment  
11 planning computer.

12 DR. SHANBAKY: Is the treatment planning computer  
13 a different computer from what you have on the unit?

14 THE INTERVIEWEE: Yes.

15 DR. SHANBAKY: All right. You can't do treatment  
16 planning on the computer unit with the HDR?

17 THE INTERVIEWEE: No. Not without -- I mean, yes,  
18 and no. Of course you can, it is a PC, but it is not  
19 designed to be used that way. You would have to alter the  
20 way it is given to you, to get into DOS. You could do that.

21 So that is one aspect, is the treatment planning  
22 computer.

23 Then there is the verification of proper  
24 localization of source. There is verification of the timer  
25 mechanism.

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1           So, again, to -- again, as with calibration, there  
2   is a certain amount of work that needs to be done once and  
3   it is more of a way of a project or study, and once you have  
4   established that that particular unit or that particular  
5   design meets certain criterion, then you don't have to  
6   repeat that.

7           Then there is quality assurance aspects that have  
8   to be done repeatedly and both are important. So when a new  
9   unit comes in, the new unit comes here and we talked about  
10  the calibration procedures. Now we can talk about the unit.

11          We did extensive studies on the unit to determine  
12  that the delivery system is something both was functionally  
13  correct and that we understood what it was doing. Sometimes  
14  it doesn't do it the way a physicist would like to do, but  
15  it is important to know that it is not doing it the way --  
16  so if there is a clinical judgment that needs to be made,  
17  for example, how it handles the anisotropic effect at the  
18  end -- they all do it differently. How it handles  
19  differential shielding with the vaginal or rectal  
20  applicators; they all do it differently.

21          So what you need to know is what is it doing, so  
22  when the clinician asks you how much of an effect is this,  
23  you have studied it and you know it is not doing it  
24  correctly; it is not taking into account differential  
25  shielding. The program is not sophisticated enough to do

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1       it, therefore you can expect to have in a shielded area a 10  
2       or 20 percent error in what is indicated in the dose.

3               So these are studies that need to be done one time  
4       with the new units.

5               With the studies that we did related to that is,  
6       we studied the differential shielding, how the computer  
7       handles the differential shielding effects. These are --  
8       this is this particular study here [indicating], which  
9       looked at how the computer plan handles different shielding  
10      geometries and applications.

11              This is an empirical study. So in a water phantom  
12      there are many hours involved with measuring the dose  
13      distribution, the dose distribution in water and then  
14      computing from the treatment planning the dose distribution  
15      and comparing these.

16              That is what this whole study is here  
17      [indicating], which I can make available to you.

18              DR. SHANBAKY: Yes, please.

19              THE INTERVIEWEE: This is a paper that I presented  
20      at the AAPM meeting. Actually, I didn't present this  
21      [indicating], I presented a different paper.

22              So we did an empirical versus a dose distribution  
23      study of differential shielding effects in the vaginal and  
24      rectal applicators.

25              We did a study of the so-called Meisberger

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1 correction factor. This is a common factor that is used in  
2 all computer programs. It is very simple to calculate the  
3 dose fall off from a point source. What gets more  
4 complicated is when you have an elongated source and then  
5 you have an elongated source and you try to take incorrectly  
6 the effects of scatter and attenuation in tissue.

7 The most common procedure is to use a polynomial  
8 which collectively takes into account the effects of scatter  
9 and attenuation.

10 This is a procedure that dates back to the mid-  
11 1960s when Meisberger published a paper for several  
12 different point sources. This is a study that we initiated  
13 for our sources here. We did it and carried the study out  
14 to 25 centimeters because the original Meisberger factors  
15 were only out to 10 centimeters.

16 As we know, in the application of HDR, there are  
17 points of interest that are more than 10 centimeters away  
18 from the source. This people who were using this data have  
19 nothing but extrapolated data outside of 10 centimeters.

20 As you can see here [indicating] in this study,  
21 the difference -- this is the Meisberger polynomial, as you  
22 go outside ten centimeters, and this is our data here  
23 [indicating]. There is a significant differences.

24 So this is a study that we did and reported at the  
25 AAPM meeting in Calgary on the Meisberger factor.

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1 MR. MADISON: Do you want a copy of that?

2 DR. SHANBAKY: Yes, please.

3 Dr. Cunningham, were you aware of the number of  
4 cycles that the source has to be used with HDR?

5 THE INTERVIEWEE: The number of cycles?

6 DR. SHANBAKY: Yes.

7 THE INTERVIEWEE: I am aware that with the  
8 Omnitron there is a current regulatory limit and with the  
9 others there is not.

10 DR. SHANBAKY: What is the regulatory limit?

11 THE INTERVIEWEE: It is built into the delivery  
12 system. There is a counting mechanism and I believe it is  
13 250, but I am not absolutely sure.

14 DR. SHANBAKY: Where did that 250 come from?

15 THE INTERVIEWEE: I believe it came from the FDA.  
16 Again, the manufacturer told us this. They don't share  
17 always the problems that they may have.

18 DR. SHANBAKY: What happens if you use it more  
19 than 250 times? I am trying to develop some feelings for -  
20 -usually they tell you don't do this because this could  
21 happen so you have an understanding for the limits. This is  
22 limits they are putting on the machine.

23 THE INTERVIEWEE: Right.

24 DR. SHANBAKY: What is the basis for the limit?

25 THE INTERVIEWEE: That is a question you would

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1 have to address to whoever put the limit on there.

2 DR. PAPERIELLO: But you are not aware?

3 THE INTERVIEWEE: No.

4 DR. PAPERIELLO: I mean, I am not saying I know at  
5 this point.

6 THE INTERVIEWEE: I can say we asked about it and  
7 were not made aware -- of why it was specifically 250, other  
8 than we were told that it was just perhaps a temporary thing  
9 and eventually that will be removed.

10 DR. SHANBAKY: What else did you do in the quality  
11 management of HDR?

12 THE INTERVIEWEE: Okay. We looked at different  
13 aspects of the source as related to the anisotropic effect  
14 so that we actually measured what the -- we have lots of  
15 different films on this. We actually would take the  
16 measurements with film, and here [indicating] you see the  
17 anisotropic effect.

18 Then we look at the computer program and compare  
19 how accurate the computer program is relative to the actual  
20 anisotropic that you get in the dose distribution.

21 We looked at the accuracy of dwell time  
22 localization. There are two levels of doing that; there is  
23 a routine check and then, when you initially do it, we  
24 did --

25 DR. SHANBAKY: This is, I take it, an equal dwell

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1 time?

2 THE INTERVIEWEE: The dwell time doesn't matter.  
3 It is equal spacing. It turns out it is equal dwell time,  
4 also, but in this case we are looking at the spacing. This  
5 is checking where it should be to where the center of the  
6 density use -- the high density use.

7 So initially when we got the unit, we did many  
8 different studies on this. With the isodensitometer we  
9 compared the results with the computer plans with the  
10 measured results.

11 DR. SHANBAKY: With your quality management  
12 program, do you have a requirement for prescription  
13 verification, as planned, before the patient is treated?

14 THE INTERVIEWEE: The prescription --?

15 DR. SHANBAKY: Yes. You have a prescribed dose;  
16 physicist and authorized user work on the plan and do the  
17 dosimetry and now you are going to execute the treatment  
18 with the patient.

19 Do you have any verification process at that time?

20 THE INTERVIEWEE: Yes. If you look at a treatment  
21 plan -- this is the treatment records [indicating] -- and if  
22 you look at the treatment record, there is a prescription  
23 written in the patient's chart. Then there is a treatment  
24 plan and before the treatment is initiated, there is a  
25 printout which the physician initials, which has the

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1       prescribed dose on it.

2               These are just the plans here.

3       MR. MADISON: Can we take a break for a moment?

4               [Pause.]

5       DR. SHANBAKY: Back on the record.

6               Dr. Cunningham, one of the quality managements of  
7       brachytherapy, if you have a situation with a multi-catheter  
8       implant, five or six catheters, what is the quality  
9       management procedure that will ensure you that the right  
10      catheter in the patient is connected to the right connecting  
11      guide on the machine?

12              THE INTERVIEWEE: Now we are changing from the  
13      previous discussion?

14              DR. SHANBAKY: Right. We are working on  
15      connecting the patient to the machine.

16              THE INTERVIEWEE: So we are not going to talk  
17      about the overall quality assurance program?

18              DR. SHANBAKY: No, just for the brevity of time.  
19      We have the exit interview.

20              MR. MADISON: If there are any documents that you  
21      would like to share with us, to show us more in depth on  
22      your quality management program, we would be glad to look at  
23      those. But I think at this time --

24              DR. SHANBAKY: If you have any important  
25      highlights, things that are --

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1 THE INTERVIEWEE: I think it is all very  
2 important.

3 DR. SHANBAKY: I understand. But anything which  
4 is -- that you are doing and that you particularly did at  
5 the Indiana facility, that would be important for you to let  
6 us know.

7 THE INTERVIEWEE: I think it is important to let  
8 you know not just what goes on in the Indiana facility, but  
9 what goes on in the overall program. I think everything we  
10 are talking about is extremely important.

11 DR. SHANBAKY: We understand.

12 THE INTERVIEWEE: And I am more than willing to  
13 come back after the exit interview and to continue this.  
14 But I think the level of detail that we are going into here  
15 is essential for the IIT to complete and give an accurate  
16 report.

17 DR. PAPERIELLO: We will come back if we have to.

18 DR. SHANBAKY: We will come back even if we have  
19 to do it on another day. We need to finish the exit  
20 interview, and if we need to have further discussion, we  
21 will come back and discuss it.

22 THE INTERVIEWEE: That is fine. I am available.

23 DR. SHANBAKY: We will talk about the QM further.

24 I want to understand the procedures for connecting  
25 the patient to the machine. Who is responsible for this?

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1 Is this the physicist, technologist, the authorized user?

2 THE INTERVIEWEE: The responsible person is the  
3 authorized user.

4 DR. SHANBAKY: Who is doing it?

5 THE INTERVIEWEE: The connection can be done by  
6 anybody who has been trained and is listed as trained. In  
7 the Indiana facility I think I saw somewhere a document that  
8 listed the trained people. Those individuals would be  
9 permitted to hook it up. That is not to say who is  
10 responsible.

11 There is a difference.

12 DR. SHANBAKY: I understand that. I meant my  
13 question the way I phrased it.

14 THE INTERVIEWEE: Okay.

15 DR. SHANBAKY: The individual who is connecting  
16 the patient to the machine, does he have to be under the  
17 immediate supervision of the authorized user?

18 THE INTERVIEWEE: Yes.

19 DR. SHANBAKY: Under the observation of the  
20 authorized user while he is connecting the patient?

21 THE INTERVIEWEE: No.

22 DR. PAPERIELLO: Would you expect the authorized  
23 user, after the connections are made, to verify the  
24 connections as accurate?

25 THE INTERVIEWEE: I would expect on a

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1 multi-channel application, that there would be an  
2 independent verification. Now, the independent verification  
3 may be by another trained person. Ideally, it would be the  
4 authorized user.

5 But I can conceive of a scenario where you have  
6 two trained technologists and one technologist nooked up the  
7 channels and the second one independently checked it, and  
8 the authorized user was there but perhaps didn't actually  
9 check it.

10 Ideally the authorized user would check it.

11 DR. SHANBAKY: Is there any procedures for  
12 verification -- written procedures for verification that the  
13 patient is connected correctly, as intended, to the HDR  
14 machine?

15 THE INTERVIEWEE: Do you mean other than --

16 DR. SHANBAKY: Like, there is a number system that  
17 has to be used, color coding, and someone has to come and  
18 verify this numbering system, color coding, so you know that  
19 tube one is connected to catheter one, and tube two is  
20 connected to catheter two, et cetera.

21 THE INTERVIEWEE: I don't -- I can't recollect any  
22 written procedure for that kind of -- that level of check.

23 DR. SHANBAKY: This is a step in the process with  
24 a potential for error?

25 Let me rephrase my question. Could somebody mix

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1 up the catheters?

2 THE INTERVIEWEE: Yes, I believe they could.

3 DR. SHANBAKY: What would prevent that?

4 THE INTERVIEWEE: There are probably different  
5 procedures, depending on the manufacturer. Color coding.

6 DR. SHANBAKY: There are manufacturers with color  
7 coding?

8 THE INTERVIEWEE: The two that I am familiar with  
9 do not have color coding.

10 DR. SHANBAKY: What else?

11 THE INTERVIEWEE: I would have to take a little  
12 time to think about a procedure that would adequately  
13 address that concern. As I said, we don't have a written  
14 procedure for that and I would prefer not to devise one as  
15 we are sitting here.

16 DR. SHANBAKY: How do the technologists do it, Dr.  
17 Cunningham? He gets the patient and he has to connect the  
18 patient to five tubes, five catheters. How does the  
19 technologist figure out to do the right thing?

20 THE INTERVIEWEE: We require as part of the  
21 quality management program to have films in every case, even  
22 if it is a single-channel bronchial, but certainly in a  
23 multi-channel we have films -- AP, lateral films -- on which  
24 the catheters are marked.

25 The orientation of the film relative to the

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1 patient is a means of knowing how to connect the proper  
2 catheter.

3 DR. SHANBAKY: Dr. Cunningham, we are moving now  
4 to the November 16, 1992 incident. I would like you please  
5 to provide us with your understanding of the facts  
6 associated with the incident.

7 THE INTERVIEWEE: Okay. We haven't finished  
8 quality assurance.

9 DR. SHANBAKY: We haven't done -- Like what Dr.  
10 Paperiello said before, for the sake of time, we may come  
11 back and talk about the quality assurance program. We try  
12 to get these points taken care of.

13 MR. MADISON: We will re-schedule a follow-up  
14 meeting.

15 THE INTERVIEWEE: Okay.

16 DR. SHANBAKY: Let us talk about the November 16th  
17 incident and what is your understanding of the facts  
18 surrounding this incident?

19 THE INTERVIEWEE: My understanding is the patient  
20 was treated with five channel interstitial application to  
21 the anal area, and that the needles were in place. The  
22 patient was simulated and films were taken of the patient.

23 The films were then utilized to do a treatment  
24 plan -- computerized treatment plan. The films were  
25 reviewed by the physicist and by the physician. The films

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1 did not indicate any need for extraordinary precautionary  
2 measures in that there wasn't an obvious kink in any of the  
3 catheters, at least prospectively; that the treatment plan  
4 was performed; that the treatment plan was checked by an  
5 independent verification system.

6 The treatment plan was then provided for the  
7 technologists; that the technologists then set the patient  
8 up and initiated the treatment.

9 That the treatment went through and completed the  
10 checks on the dummy source; that it proceeded with the  
11 active wire insertion and then what is my understanding, the  
12 fourth catheter, that the treatment system interrupted.

13 There was an indication of an error.

14 DR. SHANBAKY: In the four catheter or the fifth  
15 catheter?

16 THE INTERVIEWEE: In the fourth or the fifth. I  
17 would have to look, again, at my records from that.

18 DR. SHANBAKY: Can you look, please?

19 MR. MADISON: We will pause for a moment.

20 [Pause.]

21 MR. MADISON: Back on the record.

22 DR. SHANBAKY: Did you check the data, Dr.  
23 Cunningham?

24 THE INTERVIEWEE: My notes would indicate that it  
25 was the fifth catheter in which there was an interrupt.

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1 DR. SHANBAKY: Okay.

2 THE INTERVIEWEE: So then there was an attempt to  
3 re-initiate the treatment.

4 DR. SHANBAKY: How many times?

5 THE INTERVIEWEE: I believe twice. At that point,  
6 Dr. Bauer was notified. The technologist entered the room.  
7 Dr. Bauer, also --

8 DR. SHANBAKY: What was the condition of the prime  
9 alert at that time?

10 THE INTERVIEWEE: My understanding is it was  
11 flashing.

12 DR. SHANBAKY: Where did you get this  
13 understanding?

14 THE INTERVIEWEE: From recountings that I heard  
15 while I was at the Indiana Cancer Center.

16 MR. MADISON: From whom?

17 THE INTERVIEWEE: I don't recall. The situation  
18 was such from the time the NRC arrived, that at that point  
19 the fact-finding was being carried out by the NRC.

20 Because of the intensity and the level of activity  
21 of the fact-finding that was going on by the NRC at that  
22 time, and because of the ongoing treatments to patients, I  
23 was already alarmed that in the efforts of understanding  
24 what happened here, that we were increasing the risks to  
25 patients that are on treatment.

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1 I believe it was quite disruptive, necessarily so  
2 but it was already quite disruptive.

3 I elected -- I decided to carry on the same level  
4 of investigation that the NRC was doing with the individual  
5 technologists, at that time, would have been prohibitive.

6 In my assessment, in that there was -- that the  
7 source has been located, it was back -- the source was  
8 secure. There was no imminent danger to anyone from that  
9 point on. Anything that happened after that was in the way  
10 of analysis and corrections.

11 I recognize that they have to be done and they  
12 have to be done as quickly as possible.

13 As a person who works daily in the radiation  
14 oncology centers, I believe that it is very risky to create  
15 a sense of fear, stress and anxiety among the staff. My  
16 experience has indicated that you have more errors when you  
17 have this kind of an atmosphere in which the technical staff  
18 is working.

19 You don't have fewer errors when people are  
20 working afraid; I think you have more.

21 I don't think it guarantees compliance and I think  
22 it could jeopardize compliance.

23 DR. SHANBAKY: I forgot my question.

24 THE INTERVIEWEE: I am coming back to your  
25 question.

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1           Now you are going to ask some specific questions  
2       that in order for me to address properly would require me to  
3       have personal interviews with the technologist.

4           The question was, where did I get this  
5       information? I should have this information directly from  
6       the technologist, but because of the level of investigation  
7       that was going on there, I feel it was impossible for me to  
8       do it.

9           DR. SHANBAKY: Are you planning to get this  
10      information yourself?

11          THE INTERVIEWEE: Yes, I am. As soon as some of  
12      the notoriety and the requirements of these kind of meetings  
13      and the requirements of meeting with the press die down.

14          DR. SHANBAKY: Speaking of that, I have to also  
15      just caution you of the fact that you have a time clock  
16      running on many reports --

17          THE INTERVIEWEE: I know that we do.

18          DR. SHANBAKY: -- under 10 CFR 20, under 10 CFR  
19      35, under 10 CFR 30. There are many requirements there for  
20      misadministrations, over-exposures, loss control of  
21      radioactive materials.

22          THE INTERVIEWEE: That is correct.

23          DR. SHANBAKY: And all of this is reportable and  
24      there is specific information required with each of these  
25      reports and also specific time clock associated with each of

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1 these reports.

2 THE INTERVIEWEE: That is correct. And I would  
3 like to review before we leave today those requirements and  
4 the time schedule, and discuss a time schedule which will  
5 accomplish what we are trying to accomplish and address  
6 those things that must be addressed immediately.

7 Things that are other nature -- that we discuss  
8 the time clock.

9 MR. MADISON: I think rather than the IIT getting  
10 involved in that, I would suggest that you contact Region 1,  
11 Headquarters, and resolve that issue with them.

12 That is beyond the IIT charter. We will be glad  
13 to discuss it off the record and help you with.

14 DR. PAPERIELLO: We will give you a list of  
15 requirements that we believe right now are applicable.

16 DR. SHANBAKY: We will go over with you, but the  
17 details, if you need any exceptions -- for good cause, if  
18 you need a day or couple of days, that will be really up to  
19 you and Region 1. We don't want to get involved in anything  
20 related to compliance here.

21 I am just giving you the idea that there are many  
22 reporting requirements and every report has a set of  
23 information that is required to be given within a certain  
24 amount of time.

25 We will go over this when we finish our

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1 discussion.

2 THE INTERVIEWEE: That would be very helpful. I  
3 mean, there have been more than one communication from the  
4 NRC and, although I realize the difference between fact  
5 finding IIT and the compliance, I am still -- I view the  
6 three of you as members of the Nuclear Regulatory Commission  
7 and to a certain extent, that is internal for your agency,  
8 how you conduct those affairs.

9 DR. PAPERIELLO: Our requirements stand.

10 THE INTERVIEWEE: Requirements don't change; they  
11 are statutory in nature.

12 DR. PAPERIELLO: That is right.

13 MR. MADISON: The point that we are trying to make  
14 is the IIT cannot get involved in making decisions, giving  
15 any relief on that -- that would be up to Region 1.

16 THE INTERVIEWEE: I understand that.

17 DR. SHANBAKY: Let's continue with the incident of  
18 November 16th.

19 THE INTERVIEWEE: Dr. Bauer and the technologist  
20 then -- the patient was removed to the examination room.

21 DR. SHANBAKY: Did they try to insert the fifth  
22 catheter again, after the arrival of Dr. Bauer? Did they  
23 attempt to do it once more after the arrival of Dr. Bauer?

24 THE INTERVIEWEE: I think that is what Dr. Bauer  
25 reported at the conference.

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1           The patient was then removed to the exam room.

2           The patient was not surveyed.

3           MR. MADISON: Let's talk about that for a moment.  
4           What is your policy of surveying patients following  
5           treatment?

6           THE INTERVIEWEE: It is required.

7           MR. MADISON: Is that in writing someplace?

8           THE INTERVIEWEE: No.

9           DR. SHANBAKY: Whether the patient is on HDR or  
10          any brachytherapy, is the requirement for surveying patient  
11          applicable to the high dose rate afterloader?

12          THE INTERVIEWEE: Would you repeat that?

13          DR. SHANBAKY: Is there a requirement to survey  
14          patients -- radiological survey of patients -- with other  
15          instrument, other than the prime alert? Is it required for  
16          the HDR treatment at your facilities?

17          THE INTERVIEWEE: It is a policy.

18          DR. SHANBAKY: What is your assessment of the  
19          technologist's understanding of this policy?

20          THE INTERVIEWEE: My assessment is the  
21          technologists, as I was told, were informed on three  
22          separate occasions; that when the entered the room after the  
23          source has been energized, they must take the survey meter  
24          with them.

25          Greg Hay that he, on two occasions, informed them

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1 of this, and that the issue was discussed with Donna -- I  
2 believe it is Green -- from Omnitron. Now hers would be an  
3 advisory statement because that would be outside her purview  
4 to tell them that they need to do that. Hers would be a  
5 recommendation. Greg's would be a directive.

6 DR. SHANBAKY: Is this important; is it  
7 significant that they have to do a patient survey after the  
8 treatment is given?

9 THE INTERVIEWEE: This was --

10 DR. SHANBAKY: This is something that they must  
11 do; you expect them to do and they must do;

12 THE INTERVIEWEE: This is a requirement that we  
13 have had in our program since day one. Ironically, I  
14 believe I initiated it and I am not sure why because with  
15 discussions of different programs, particularly with the  
16 programs in Europe that have had many more years experience  
17 with high dose rate units, that is not a generally followed  
18 procedure.

19 Not every place that I talked to had that as a  
20 requirement, but it was a requirement in our program.

21 Every facility had a survey meter and every  
22 facility would use the survey meter before they entered the  
23 room.

24 MR. MADISON: This was a verbal program, is what  
25 you are saying? You would verbally, orally transmit this

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1 information to them. It was not in writing?

2 THE INTERVIEWEE: Not in writing; that is correct.  
3 And it is not in the license. When the license application  
4 was written and when it was reviewed by the NRC, the issues  
5 that were addressed were issues that were felt to be key  
6 issues at that time, and I think from my standpoint and from  
7 the reviewers standpoint, what is recognized as good  
8 practice and what is required absolutely is sometimes a  
9 function of experience and is not -- I mean, it was not put  
10 in the license even though all of my physicists -- and you  
11 can query any of them here -- I don't believe they have ever  
12 entered the room without a survey meter.

13 I would not permit it.

14 DR. SHANBAKY: What is your --

15 DR. PAPERIELLO: I would note that there are  
16 requirements that are not in the license that are  
17 requirement because they are in Part 35.

18 THE INTERVIEWEE: I would agree with that,  
19 although I have been told that Part 35 does not apply to  
20 HDR, and told that by sources within the NRC.

21 All I am saying is there is some confusion, and I  
22 am not saying they shouldn't apply. I am saying there is  
23 some confusion as to what sections of the regulations are  
24 strictly applicable to HDR.

25 I think there is still some confusion as to what

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1 sections. My program is beyond what the regulatory  
2 requirements are, as I see it.

3 DR. SHANBAKY: Dr. Cunningham, what is your source  
4 breakage emergency procedures?

5 THE INTERVIEWEE: The source breakage emergency  
6 procedures are, in essence, the same as the failure of the  
7 source to return. You follow the listed emergency  
8 procedures for that manufacturer which would entail going  
9 through the procedures that they have outlined -- hitting  
10 the emergency off switch, going in and -- which is an  
11 electronic retraction.

12 On the Omnitron there are two other means of  
13 retracting the source, and then if that doesn't work, there  
14 is a third mechanical way.

15 With the Gamma Med, you have the emergency off and  
16 then there is a mechanical means of retracting the source.

17 The important thing in failure is to as quickly as  
18 possible, to remove the source from the patient and remove  
19 the patient from the room and then secure the area.

20 Once you have done that, there is no longer any  
21 risk or potential for any harm to any individuals. It then  
22 can be addressed by whatever personnel for the level of the  
23 severity of the incident.

24 But as long as the area is secure and locked,  
25 there is absolutely no risk.

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1 DR. SHANBAKY: Do you have any prior knowledge of  
2 a sticking source in the catheter -- not inserting right in  
3 the Omnitron?

4 THE INTERVIEWEE: No.

5 DR. SHANBAKY: Why are the technologists required  
6 to do survey? I take it they are required to respond to the  
7 radiation alarm on the prime alert.

8 In your judgment, it looks like the outcome of  
9 what they did was different from what you expected. Why did  
10 they do what they did? Why did they not do what you said  
11 was required by procedures? What were the reasons?

12 THE INTERVIEWEE: My opinion? It was an error in  
13 judgment.

14 There is no technologist that has gone through a  
15 training program, that has practiced, that should ignore a  
16 radiation detection device the way they ignored it. Even if  
17 they suspected it of being malfunctioning. It still should  
18 have been treated as an active source.

19 And with the survey meter present on the console,  
20 even if they didn't take it in the room initially, which  
21 they should have, it is absolutely inexcusable not to take  
22 that in and survey the patient.

23 I don't know if anybody is every going to put this  
24 -- admit to it, that that is the catastrophe here. We are  
25 going to uncover some things that could be done better, but

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1 we are never going to account for that -- the poor judgment  
2 on the part of registered and experienced personnel.

3 I don't say this because the personnel there, as I  
4 indicated to you earlier, all of them I believe to be  
5 exemplary. I have no indication anywhere -- and over the  
6 course of years, you learn about the individuals you work  
7 with, directly and indirectly.

8 I believe them all to be fully competent, trained,  
9 high moral character -- extremely high moral character; well  
10 respected.

11 If I had to list the areas, the centers that I  
12 have concern about, this would be way down on the list for  
13 those reasons. I can't explain it. I think it was a gross  
14 error in misjudgment.

15 It is a human error. It is a human error that we  
16 have to find ways to avoid ever happening again. But it is  
17 a human error. No one can dispute the fact that if those  
18 precautions were taken, there would have been an incident,  
19 but the magnitude of the incident would be grossly less than  
20 it is -- than we are talking about now.

21 It would have been similar to the situation that  
22 happened in Pittsburgh, where we know we have exactly the  
23 same procedures and exactly the same policy and in that  
24 case, we had the source properly taken care of with a  
25 minimum of exposure either to the patient or the personnel.

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1           So I can't tell you why this happened. At least  
2           once a night I wake up shaking my head, incredulous that  
3           this could happen.

4           MR. MADISON: You do have certain differences; for  
5           instance, we have a certified medical physicist who is the  
6           only one who is allowed to operate the HDR in Greater  
7           Pittsburgh, whereas you utilized technologists who were not  
8           supervised by physicists or physician directly while they  
9           are operating the HDR unit.

10           You have, also, at the Greater Pittsburgh  
11           facility, a manual in place -- the draft manual that you  
12           mentioned earlier -- and you don't have that in Indiana.

13           There are some major differences between the two  
14           centers.

15           THE INTERVIEWEE: Well, the draft manual we  
16           discussed and I gave you the reasons for that.

17           MR. MADISON: Understand.

18           THE INTERVIEWEE: As to the delivery system, there  
19           are differences. Are those differences appropriate or  
20           inappropriate?

21           If they are -- if the procedures that are followed  
22           in Pittsburgh -- if the procedures that were followed at  
23           Indiana were inappropriate, then what you are saying to me  
24           is that the technologists are not capable of delivering  
25           treatment to a patient.

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1 I have to remind you that that is what they are  
2 trained to do.

3 In fact, the physicist is not ordinarily trained  
4 to deliver treatment to the patient.

5 The person who is supposed to be delivering the  
6 treatment to the patient is the therapist. That is their  
7 job definition. Radiation therapist.

8 MR. MADISON: That isn't the case at Greater  
9 Pittsburgh.

10 THE INTERVIEWEE: There is mechanisms within the  
11 practice of radiation medicine where a physician may deliver  
12 treatment, or an individual under the physician's direct  
13 supervision.

14 MR. MADISON: I understand what you are saying,  
15 Dr. Cunningham. I am just pointing out the differences that  
16 we have seen in the two units that we have seen, for your  
17 further evaluation.

18 THE INTERVIEWEE: And I am aware of those  
19 differences. The role that the physicist plays and the role  
20 that the technologist plays, and the role that the medical  
21 director plays is different and is going to be different at  
22 every facility.

23 There is a shared responsibility and some  
24 individuals are technically better than others. My  
25 responsibility is to make sure that the best people are

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1 involved -- that everybody is involved in the delivery  
2 system and responsible, and there may be a case where the  
3 technologist --

4 Well, let me just say that I don't think that  
5 difference -- I don't believe that difference has anything  
6 to do with the cause of this incident.

7 I believe that the therapists are trained and --  
8 nationally -- they deliver the treatment and that is what  
9 they are trained to do.

10 DR. PAPERIELLO: In this case, we also understand,  
11 although there are some conflicting statements, that the  
12 physician was even aware of the flashing light.

13 THE INTERVIEWEE: That is my understanding.

14 DR. PAPERIELLO: And still nothing was done.

15 THE INTERVIEWEE: That is my understanding. I  
16 believe, my recollection is, his retrospective reaction --  
17 that is the same as mine, and perhaps yours is; just  
18 difficult to believe that the human response was what it  
19 was.

20 In retrospect, I think they all realize what the  
21 monitor was indicating. To collectively have this happen is  
22 difficult to explain.

23 I have to reconfirm that we will be making  
24 improvements, but there is nothing that we are going to  
25 introduce that could prevent this happening.

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1           You could have ten fail safe checks, but if all  
2   ten of those go off and they are ignored, you are going to  
3   have the same occurrence. So one aspect of this, cannot go  
4   unstated, is that there is a human element in everything  
5   that we do.

6           DR. SHANBAKY: Aren't we talking about the safety  
7   culture here, Dr. Cunningham? The example you gave of ten  
8   systems alarming, and if you have ten systems alarming and  
9   people will not respond to ten systems alarming, you will  
10   have the same outcome -- This is a little bit difficult for  
11   me to understand.

12           If you have that, you don't have a situation with  
13   an error in judgment; you start talking about the safety  
14   culture.

15           Do you feel that there is a safety culture problem  
16   at the Indiana facility?

17           THE INTERVIEWEE: Culture?

18           DR. SHANBAKY: Yes. People are pressed by work,  
19   people are trying to get the job done.

20           THE INTERVIEWEE: Let me comment on that.

21           DR. SHANBAKY: I am trying just to understand the  
22   last example you gave.

23           THE INTERVIEWEE: There may be times when a  
24   mistreatment to patient could be due to stress created by  
25   over-work, by trying to do much within a given period of

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1 time.

2 I have also seen technologists who will work at  
3 the same rate and just as fast, to finish treating the  
4 patients by one o'clock, two o'clock in the afternoon even  
5 though they have to remain on site until 4:30.

6 To me, it is very difficult to explain that  
7 mentality. But sometimes there is a real urgency because of  
8 the volume of treatment.

9 Sometimes, there is an urgency to get the work  
10 done but it is not necessarily related directly to the  
11 volume of treatments or the fact that there is more work  
12 that can be done in a period.

13 It is just, again, the human element -- as quickly  
14 as I can get this done, then the remainder of my day is not  
15 quite as hectic. There aren't patients coming and going and  
16 a lot of confusion in the last hour to hour and a half; we  
17 can kind of wind down.

18 My opinion, at our centers, we don't have --  
19 because of the nature of the centers and because of our  
20 staffing -- we have three technologists there, a nurse,  
21 ancillary personnel, a tumor registry -- for a small center,  
22 that center, that facility -- I think it is probably better  
23 staffed than a lot of major facility based on the number of  
24 treatments that they give.

25 Whereas, I say that may be the case -- I don't

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1 believe that could be the case in Indiana.

2 DR. SHANBAKY: Getting back to the error in  
3 judgment, Dr. Cunningham. I understand that one individual  
4 made an error in judgment. We have here three technologists  
5 and a physician, authorized user.

6 I am trying to understand how, collectively, all  
7 these people can make the error in judgment at the same  
8 time, for something which is serious -- a radiation monitor  
9 alarm.

10 How can I understand this? I understand one  
11 individual overlooked something, or responded in the way --  
12 instead of going right, went left -- but, collectively, how  
13 these people --

14 Did they influence each other in the decision?

15 THE INTERVIEWEE: I mean, this is conjecture.

16 DR. SHANBAKY: I am trying to understand.

17 THE INTERVIEWEE: That is all we can do, is  
18 conjecture. It is possible that had there been only one  
19 person involved in this whole procedure and that person went  
20 in the room and saw it flashing, that the correct procedures  
21 would have been followed.

22 I think there is some risk to distributed  
23 responsibility. And with the three present, perhaps that  
24 was an element. It is conjecture.

25 But I have seen incidents where, when more than

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1 one person was present, in life -- in general -- that the  
2 reactions of the people have been less than if one was  
3 present.

4 I mean, I have seen emergencies where people  
5 collapse in a church and if there is one person present,  
6 immediately they go to help. You have a whole room full of  
7 people and the response is not as quick.

8 So there is an element of that.

9 DR. SHANBAKY: Before we start talking about the  
10 actions taken by Oncology Services, do you have any  
11 questions? Maybe we can get back to the QM program?

12 MR. MADISON: I have one question before you move  
13 on.

14 Did you receive any assurances from Omnitron about  
15 the reliability of the equipment in any way, prior to  
16 installation, or subsequent to the installation at the  
17 Indiana Clinic?

18 THE INTERVIEWEE: Well, as you know, when we were  
19 out there -- and I think I arrived -- I forget now, it is  
20 all a blur -- the next day.

21 MR. MADISON: The next day -- meaning?

22 THE INTERVIEWEE: Wednesday, I guess.

23 MR. MADISON: Of December, this year, you are  
24 saying?

25 THE INTERVIEWEE: No, I mean after the incident.

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1 MR. MADISON: The Wednesday after the incident.

2 THE INTERVIEWEE: Sometime that day or the next  
3 day -- that day, I think Sam Liprie and an engineer came and  
4 the next day I think Calfee came, who is the president.

5 You know, basically I heard the same things that  
6 you heard from them; that they can't believe it happened;  
7 that the wire was tested 50,000 times, bending this way, and  
8 at temperatures of 2,000 degrees. They went through the  
9 whole litany of supposed tests.

10 That is the only assurance that I have.

11 MR. MADISON: What I mean is, had you received any  
12 assurances prior to either purchasing, or prior to the event  
13 of November 16th?

14 THE INTERVIEWEE: No, no. Regarding the safety of  
15 the unit?

16 MR. MADISON: Safety, reliability.

17 DR. PAPERIELLO: The integrity of the wire,  
18 primarily.

19 THE INTERVIEWEE: You mean other than the FDA  
20 testing?

21 MR. MADISON: Correct.

22 THE INTERVIEWEE: The 401 K -- or whatever they  
23 call it?

24 MR. MADISON: Correct.

25 THE INTERVIEWEE: No, no.

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1 MR. MADISON: Thank you. That answered my  
2 question.

3 DR. SHANBAKY: Okay. What is your views of the  
4 source recovery operations?

5 THE INTERVIEWEE: Well, when Greg called me and,  
6 you know, I told him -- I think it was around eleven o'clock  
7 or so we had our conversation -- you know, my first reaction  
8 was -- when he said it was a rectal treatment -- When we do  
9 a rectal treatment, we do it with a rectal applicator, which  
10 is a cylinder a centimeter or so in diameter. It is not  
11 left in the patient. So if the source had detached, the  
12 applicator is removed after the treatment so it would be  
13 still in the applicator.

14 So when he said that it was, you know, a rectal  
15 patient, I don't see how it could be possible that it could  
16 be anywhere but at that the site there, or somehow got  
17 discarded from on site.

18 Subsequently, I learned, when I got there, that it  
19 was actually an interstitial procedure.

20 But in any case, when he told me that the source,  
21 when he found it wasn't in -- I said, I told him to contact  
22 the NRC office.

23 Then he took instructions from the NRC, he told  
24 me, and retrieved the source. So I was out of communication  
25 with him until later that evening.

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1 MR. MADISON: Have you had a chance to review the  
2 events of the recovery?

3 THE INTERVIEWEE: Yes. I read his narrative, copy  
4 of which you have. I talked with him about it.

5 MR. MADISON: Do you have any problem with the way  
6 that the recovery transpired?

7 THE INTERVIEWEE: The one concern that I had was  
8 the source was being transported in a way that I wasn't sure  
9 met the requirements of DOT.

10 MR. MADISON: You mean in the back of his pickup?

11 THE INTERVIEWEE: Yes. I didn't know how it was  
12 transported until afterwards. Had he called me, I think we  
13 probably would have decided to secure the source and, you  
14 know, evaluate how we are going to transport it back which,  
15 if we had to, we could have used Federal Express and got  
16 delivery back to the center with -- it would still be a Type  
17 3, possibly Type 2 at that level, but with their container I  
18 think it would still be a Type 3.

19 So, when you are transporting a Type 3, you need  
20 to have placards on the outside of the vehicle. These are  
21 some of the things, that had he called me, we would have  
22 discussed.

23 I think in the urgency of the moment, I think he  
24 felt he was doing what he was directed to do. As he says,  
25 to recapture the source, collect the source.

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1           Maybe they didn't discuss it in much more detail,  
2           so for him that probably meant to get it secured back at the  
3           center. I think maybe it was, get the source secured and  
4           then we can take whatever -- there is no longer any risk of  
5           exposure.

6           So, it should have been -- if it were going to be  
7           transported by personnel, it would have had to have been Dr.  
8           Bauer to transport it, but my recommendation would be to get  
9           in a proper transport container, properly secured, and then  
10          to properly label it and use Federal Express.

11          MR. MADISON: Anything else?

12          THE INTERVIEWEE: Probably if I read his narrative  
13          over again, that might -- some other details of it might  
14          stand out. I haven't read it in two weeks. So --

15          MR. MADISON: I realize you have been away from  
16          the company for a short while and out of the country and you  
17          haven't had a chance to, as you said, do your own  
18          investigation of the events.

19          What are your plans concerning restart or  
20          resumption of services prior to completing your  
21          investigation?

22          THE INTERVIEWEE: The decision I have made at this  
23          point, pending some further analysis by me, but the decision  
24          I have made is that a physicist must be present throughout  
25          the entire procedure in a supervisory capacity.

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1           So this is a change. Of course, I sent out a  
2       directive reaffirming the policy of using the survey meter.

3           MR. MADISON: Could we have a copy of that  
4       directive?

5           THE INTERVIEWEE: Yes.

6           MR. MADISON: Do you have further questions, or do  
7       you want to move back to the --

8           DR. SHANBAKY: Before we move back to the QM, I  
9       would like to just have a synopsis of all the actions taken  
10      to the moment by Oncology Services.

11          THE INTERVIEWEE: Probably we need to talk to all  
12      of the management there because some actions were initiated  
13      at State College in my absence.

14          So, I know that treatments were suspended at  
15      Baltimore County General Hospital and at Port St. Lucy and  
16      Indiana. So treatments were suspended; no additional  
17      treatments. Harrisburg and Pittsburgh continue to treat.

18          There are no treatments at Marltown, at Yonkers  
19      and -- what am I forgetting? -- Sandy Lake, I called the  
20      physician and re-confirmed their policy is that the  
21      physicist is on site at all times.

22          MR. MADISON: When did you place that call?

23          THE INTERVIEWEE: Pardon?

24          MR. MADISON: When did that call take place?

25          THE INTERVIEWEE: When did I reconfirm that?

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1 MR. MADISON: Yes.

2 THE INTERVIEWEE: Yesterday.

3 MR. MADISON: Had you notified the other  
4 facilities prior to yesterday?

5 THE INTERVIEWEE: About --?

6 MR. MADISON: About the events at Indiana and the  
7 reaffirmation of your policies?

8 THE INTERVIEWEE: The coordination of this was  
9 carried out with Rogers and State College, and myself. So  
10 basically, what we determined is what centers had patients  
11 that were going to be treated, such as Port St. Lucy where a  
12 patient was scheduled and that was cancelled.

13 MR. MADISON: But you made no company-wide  
14 distribution of the information -- of the event at Indiana,  
15 or any special precautions to be taken?

16 THE INTERVIEWEE: The personal phone calls were  
17 made.

18 MR. MADISON: When?

19 THE INTERVIEWEE: I will have to check. Dr.  
20 Rogers made personal phone calls to every medical director.

21 MR. MADISON: Did we interview Dr. Rogers?

22 DR. PAPERIELLO: Yes, we did. It is in Dr.  
23 Rogers' transcript, I believe. I know I had read that  
24 somewhere, in one of the transcripts.

25 THE INTERVIEWEE: I am sure it was done.

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1 MR. MADISON: Thank you.

2 DR. SHANBAKY: Maybe we could go back to the  
3 quality management program.

4 MR. MADISON: We really only have about ten more  
5 minutes before have to close. Do you want to reconvene? I  
6 am sure there is more information on quality management  
7 treatment that Dr. Cunningham wants to share with us.

8 Should we close this now and move on?

9 DR. PAPERIELLO: I think we should. We should  
10 close and then re-schedule another appointment to discuss  
11 that.

12 MR. MADISON: Is there anything of immediate  
13 concern, additional information that you want to share with  
14 us right now?

15 THE INTERVIEWEE: Not immediate in the sense that  
16 you have to have it today, although I don't know what  
17 sequence of events you have in mind between now and when we  
18 are going to meet again, so I guess I have to say I don't  
19 know.

20 I think that all of this information is important  
21 to you.

22 MR. MADISON: I understand, sir. We will  
23 reconvene the interview at a later date. Again, if you  
24 think of anybody else that you feel the IIT should talk to  
25 that they have not talked to already, we would appreciate

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1       that information.

2               THE INTERVIEWEE: Is the exit interview from the  
3       IIT team, or from Region 1?

4               MR. MADISON: IIT team.

5               DR. PAPERIELLO: Yes. This is an interim -- the  
6       exit today will be an interim exit because, unfortunately,  
7       we got snowed out a week ago. By and large, the information  
8       that I share with you today will be essentially what I would  
9       have stated a week ago. The investigation is not complete.

10              In fact, we have people from our staff are at  
11       Omnitron today, continuing the investigation there. As I  
12       said earlier, and I will say at the exit, I have done some  
13       transcribed interviews of the NRC headquarters' staff. I  
14       will be doing interviews of the Region 1 staff.

15              So this investigation covers not just the event,  
16       but everything that -- the situation -- the basis for  
17       licensing this facility, amendments to the licensing,  
18       effectiveness of our regulations. It goes far beyond just  
19       the bare event.

20              Now, subsequent to this, Region 1 will have to do  
21       perhaps additional compliance oriented inspections to  
22       determine precisely if any NRC requirements were violated.

23              It is not the function of this IIT to address  
24       compliance, and so obviously, the inspection, the  
25       investigation goes into areas which are not a question of

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1 compliance; they may be come an issue of future NRC  
2 rulemaking.

3 We may find our rules are ineffective. As you have  
4 pointed out already, the status of HDR in terms of Part 35,  
5 in a number of peoples' mind, is cloudy.

6 The potential consequence of this investigation  
7 may be additional NRC rulemaking. Obviously, we issued a  
8 bulletin in response to the event.

9 So there may be other areas of NRC regulation that  
10 are not as effective as we think they are, and will have to  
11 be changed.

12 We don't make recommendations, either. We have  
13 fact-finding, we draw conclusions and then the Commission  
14 will direct the staff to initiate a number of actions. That  
15 is what has happened in past IITs.

16 MR. MADISON: Again, in closing, we will give you  
17 a number that you can contact us. We have your number so we  
18 can contact you if have any additional information. Again,  
19 we will be doing a second interview.

20 I just wanted to remind you that the transcript,  
21 when it does become available, we will be in contact with  
22 you to make it available for your review. You can review  
23 that and make any corrections or changes on the addenda  
24 sheet.

25 The addenda sheet will become a part of the

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1 permanent record. We have already given you 3.1 and that  
2 fully explains that.

3 I think this is the end of the interview for this  
4 time. We will be reconvening.

5 [Pause.]

6 MR. MADISON: I apologize. We are going to go  
7 back on for just a moment to close up the documents that we  
8 have requested.

9 We have requested Dr. Cunningham's CV; the recent  
10 directive that you sent out, reaffirming your policies.

11 Correct me if I am wrong; there are documents  
12 relating to nine tests or studies and this would include the  
13 dose distribution study and the Meisberger study; is that  
14 correct? We would be requesting copies of all that.

15 The prime alert manual; the syllabus of training  
16 from Omnitron that you received; copy of the minutes of, or  
17 the syllabus of any seminars or technologists' meetings,  
18 training that you provided to them.

19 Do you have an organization chart for the physics  
20 and engineering group?

21 THE INTERVIEWEE: No.

22 MR. MADISON: Would you think that is necessary  
23 for your records, Dr. Paperiello?

24 DR. PAPERIELLO: I don't think so right now, but  
25 if we do, we will get back to you.

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1 MR. MADISON: Those are all the documents that I  
2 had in my notes. Does anybody else have any other documents  
3 we have requested?

4 [No response.]

5 THE INTERVIEWEE: I have five items; CV,  
6 directive, the nine projects, prime alert manual, syllabus  
7 from Omnitron.

8 MR. MADISON: Anything we can collect today we  
9 will be appreciated.

10 We are off the record.

11 [Whereupon, at 1:44 p.m., the interview of  
12 December 17, 1992, was concluded.]

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REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before  
the United States Nuclear Regulatory Commission

In the Matter of:

NAME OF PROCEEDING: Daid E. Cunningham

DOCKET NUMBER:

PLACE OF PROCEEDING: Harrisburg, PA

were held as herein appears, and that this is the  
original transcript thereof for the file of the United  
States Nuclear Regulatory Commission taken by me and  
thereafter reduced to typewriting by me or under the  
direction of the court reporting company, and that the  
transcript is a true and accurate record of the  
foregoing proceedings.



Official Reporter  
Ann Riley & Associates, Ltd.

## ADDENDUM/ERRATA SHEET

Page Line Correction and Reason for Correction

74 19 "... when the difference is no more..."  
add correction.

257 5 "to take incorrectly" change to  
"try to take correctly into account"

acknowledgment: Pages -115 L 12 to page 116 L 25

I am not sure I understood the question although it is clear in the transcript; my reply seems to address only regulatory assurance. Of course, I had repeated assertions of the safety of this unit from character representatives including Richard Caffee, Sam Kline, Dr. Green, Kevin Lynch, Kent Seibler. This was on several occasions: at meetings, in training at seminars, etc.

p. 117 L 21 wasn't in the "HOC unit"

p. 119 L 4 "whatever action necessary, there."

p. 119 L 6 "So it should have been transported by an approved carrier"

block  
in  
"  
trans

*David E. Cunningham*



# OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission  
Office of Investigations

Title: Investigative Interview of:  
David E. Cunningham  
(Closed)

Docket No.

LOCATION: Harrisburg, Pennsylvania

DATE: Thursday, December 17, 1992

PAGES: 1 - 126

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EXHIBIT 50

PAGE 129 OF 129 PAGE(S)



8990 Kirby, Suite 200  
Houston, Texas 77054  
December 16, 1992

Telephone: (713) 666-6499  
Fax: (713) 666-3531

Bernard Rodgers, M.D.  
Oncology Services Corporation  
110 Regent Court, Suite 100  
State College, PA 16801

Dear Dr. Rodgers:

As requested, enclosed is a listing of the training afforded by Omnitron for personnel at the nine OCS centers which have HDR remote afterloaders. I have listed all the participants, although some were in attendance only part of the time the instructor was there. Also, there may well be others who joined the group from time to time but whose names we did not get.

The training material covered the following:

- 1) Instruction in the use of the treatment planning computer to plan patient treatments,
- 2) Instruction in operation of the remote afterloader, a demonstration of the safety features and emergency procedures to be followed, and a review of the equipment warranty and support services provided by Omnitron, and
- 3) A demonstration of the use of the various applicators provided with the system.

Item (8) of the NRC letter requests records of radiation safety training. I don't believe they are referring to Omnitron HDR training, but to the training received by technologist, physicists, and physicians in radiation safety as part of their basic training. We don't attempt to cover basic radiation safety; i.e., operation and use of a survey meter, but only its application to patient HDR treatment. I would think that furnishing the NRC with a record of each person's certification, their attendance at scientific symposia, refresher courses, and workshops would be adequate.

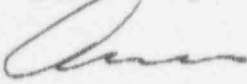
Item (9) asks for lesson plans for emergency response training. This of course refers to inservice training, which is normally designed and conducted by the supervising physicists in cooperation with the chief technologist. You may wish to confer with Dr. David Cunningham on this matter.

CASE NO. 1-92-060R

EXHIBIT 51  
PAGE 1 OF 7 PAGE(S)

If you have any question on the enclosed or if I can help you further please call me.

Sincerely,



Ann E. Wright, Ph.D.  
Senior Vice President

Enclosure

OMNITRON TRAINING PROVIDED AT  
ONCOLOGY SERVICES, INC. CENTERS

DATE	LOCATION	PARTICIPANTS	TRAINER
Treasure Coast Radiation Center Port St. Lucie, Florida			
9/21-22/1991	On site	Kate Driggers Stephanie Rozansky Mark Perman, M.D.	Donna Green, R.N.
12/31/92	On site	Same	Rick Thornton, E.E.
10/22/92	On site	Ken Fryman Stephanie Rozansky Andrew Cohen, M.D.	Donna Green, R.N.
Baltimore County General Hospital Radiation Oncology Center Randallstown, MD			
5/21/92	On site	Ahmad Kuwaifi Sharon Malfatoune Marcus Tepper, M.D.	Donna Green, R.N.
7/27-28/92	Houston	Ahmad Kuwaifi	Ann Wright, Ph.D.
Radiation Oncology Center at Marlton Marlton, N.J.			
2/13-14/92	On site	Alisa Itri Kate LeMunyon Carolyn Horowitz, M.D.	Ann Wright, Ph.D.
Westchester Oncology Center Yonkers, N.Y.			
6/22-23/92	Houston	Bun Chan	Ann Wright, Ph.D.
6/26/92	On site	Bun Chan Keith Merritz, M.D.	Donna Green, R.N.
Exton Area Cancer Center Exton, PA			
2/11-12/92	On site	Paula Salanitro Mark Batog Karen Beauvais R.M. Yelovich, M.D.	Ann Wright, Ph.D.

EXHIBIT 51

Greater Pittsburgh Cancer Center  
Pittsburgh, PA

7/30/92	On site	Mitchell Jarosz Bill Collins John Ondos Kathy Levkulich Michelle Markovitz Roger Tokars, M.D.	Donna Green, R.N.
8/10-11/92	Houston	Mitchell Jarosz	Ann Wright, Ph.D.

Greater Harrisburg Cancer Center  
Harrisburg, PA

2/18-19/92	On site	David Cunningham, Ph.D. Wm. Ying, Ph.D. Connie Hawkins A. Unal, M.D.	Ann Wright, Ph.D.
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Indiana Regional Cancer Center  
Indiana, PA

12/9-10/91	On site	Gregg Hay Sharon Rickett James Bauer, M.D.	Donna Green, R.N.
2/27/92	On site	Gregg Hay Sharon Rickett James Bauer, M.D.	Donna Green, R.N.

Life Care Cancer Center  
Stoneboro, PA

6/11/92	On site	Amrick Chhabra, Ph.D. Gilbert Lawrence, M.D.	Donna Green, R.N.
6/15-16/92	Houston	Amrick Chhabra, Ph.D.	Ann Wright, Ph.D.

Centre Community Hospital  
State College, PA

10/12-13/92	Houston	Chris Snyder	Ann Wright, Ph.D.
10/19-20/92	Houston	John Nagel	Ann Wright, Ph.D.
10/23/92	On site	Chris Snyder John Nagel Jerome Durdell, M.D. Bernard Rogers, M.D.	Donna Green, R.N.

EXHIBIT 51