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OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission

Title: Incident Investigation Team

Docket No.

INTERVIEW OF: Dr Richard Calfee

LOCATION: Indiana, Pennsylvania

DATE: Friday, December 4, 1992 PAGES: 1 - 63

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ANN RILEY & ASSOCIATES, LTD.
1612 K St. N.W., Suite 300
Washington, D.C. 20006
(202) 293-3950

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

OFFICE OF INVESTIGATIONS

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In the Matter of: :

INVESTIGATIVE INTERVIEW :

Dr. Richard V. Calfee :

(CLOSED) :

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Indiana Regional Cancer Center

877 Hospital Road

Indiana, Pennsylvania

Friday, December 4, 1992

The above-entitled matter commenced at 10:20 o'clock a.m., when were present:

DR. CARL PAPERIELLO, Deputy Regional Administrator

RON LLOYD, Investigator

MOHAMED SHANBAKY, Investigator

Nuclear Regulatory Commission

P R O C E E D I N G S

[10:20 a.m.]

MR. SHANBAKY: Dr. Calfee, good morning.

THE INTERVIEWEE: Good morning.

MR. SHANBAKY: This is December 4th, 1992, and this is a record of an IIT review here of the incident that occurred on November 16, 1992.

Dr. Calfee, why don't you state your name and your title?

THE INTERVIEWEE: My name is Richard Calfee and I am President of Omnitron.

MR. SHANBAKY: Since when you have been the President of Omnitron?

THE INTERVIEWEE: Since I guess July of 1990.

MR. SHANBAKY: Can you state your educational experience and background?

THE INTERVIEWEE: Sure. I am an engineer by training. I have a Bachelor's and Master's degree in Electrical Engineering from the University of Texas at Arlington and a Ph.D. In Bioengineering from the University of Michigan.

Before I got my Ph.D. I worked in the aerospace industry designing missile guidance and control systems and after that I -- after the Ph.D. I worked on the faculty at the University of Texas Medical School at Houston

for a couple of years.

I then went to Intermedics, which is a manufacturer of Pacemakers and heart valves and defibrilators and stuff like that. I was an officer of Intermedics from approximately 1980 to 1990 where I was in charge of Research and Development and Engineering for the Pacemaker Division.

MR. SHANBAKY: What is your knowledge about the incident, HDR incident here at this facility?

THE INTERVIEWEE: Well, it's all second-hand, obviously. I think it was on December the 1st that we got a call that, you know, something may have occurred and we sent a team, actually put them on the road to come up here -- Dr. Liprie, who is our Radiation Safety Officer, and Tony Bradshaw -- before they even had really confirmed that a source had broken off. They arrived I guess about the same time that that information was, that it had been recovered from the dump.

MR. SHANBAKY: What is your assessment of actually what happened?

THE INTERVIEWEE: Well, what I believe happened, and obviously the engineers need to go over, you know, all the detailed printouts from the error logs and all that sort of thing that we have taken and given you a copy of, is that something occurred during the treatment of the patient,

probably on the treatment of the fifth catheter, that caused the source to separate and that fact, according to the statements I have read, the warning from the radiation monitor and all, was not heeded and therefore the source went home with the patient.

MR. SHANBAKY: When you say the source separated, can you describe the source assembly in terms of this is a source connected to --

THE INTERVIEWEE: No, it's a nickel titanium wire with a cavity in the end of it where the source is located that is then sealed shut on the end, so it is in a sealed cavity. It's a sealed source and it appears as though something caused that to fracture.

MR. SHANBAKY: Okay, so something caused a fracture where?

THE INTERVIEWEE: Apparently proximal to where the source is located, and, you know, what we want to do is obviously analyze the components, the remainder of the active wire, the tip, to try to determine the answer to your question, exactly where did it break and why -- is there evidence of physical damage, you know.

MR. SHANBAKY: Speaking of all that, to do this, do you need to take the machine to your facility?

THE INTERVIEWEE: No. We need to take the wire.

MR. SHANBAKY: You need to take the wire?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Not the machine.

MR. SHANBAKY: All right, not the machine.

There was a question about how the machine could recognize the length of the wire out or the length of the wire in. I'd appreciate it if you'd give me some better understanding of this.

THE INTERVIEWEE: Well, what we believe happened from the record and it needs to be examined from the engineers back at the factory is that something applied force to the wire in the fifth catheter and was to the extent that I guess caused the fracture and was preventing the wire from being retracted and therefore an emergency retract occurred, all right?

MR. SHANBAKY: What is an emergency retract?

THE INTERVIEWEE: We have a secondary system for pulling the wire back if the primary system is having difficult. It pulls harder.

THE INTERVIEWEE: A separate system like motors and gears?

THE INTERVIEWEE: It's just more force, okay, to pull the wire back.

MR. SHANBAKY: It's just applied by the same motor or another one?

THE INTERVIEWEE: A different motor, independent motor.

MR. SHANBAKY: Okay, and what makes that motor kick in?

THE INTERVIEWEE: The fact that the primary drive was detecting this constriction and having trouble pulling the wire back was what would make the secondary motor kick in, if it kicked in. That's speculation at this point.

MR. SHANBAKY: Yes, that's what I don't know if it is already determined that the secondary motor kicked in or not. I heard that it might have kicked in.

THE INTERVIEWEE: Right. We need to look at the error logs and have our engineering people see if they can determine whether that happened or not.

MR. SHANBAKY: Can they determine this from looking at the error messages on the machine?

THE INTERVIEWEE: I hope so, yes. I believe they can.

MR. SHANBAKY: They got the error messages since February yesterday from -- they got the printout.

THE INTERVIEWEE: Yes.

MR. SHANBAKY: They are still examining this?

THE INTERVIEWEE: Yes, our engineer should be in today at the office who is responsible for that code.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: All right, and getting back to so this is the actually the withdrawal of the source mechanism if the source gets sticky or obstructed you get this second motor and it will pull it back -- getting back to my question about how the machine recognized the length of the source drive cable going out and coming in --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: -- how this is done, what kind of sensors you have.

THE INTERVIEWEE: Normally it, you know, measures, it has a switch that measures a zero point if you will as the wires going out, all right? The wire is tracked out by the encoders a given distance, okay? It's retracted and measures the length coming back in and compares those two.

MR. SHANBAKY: Okay. This encoder is a mechanical or we're talking about the mechanical device here like a wheel which would turn and be translated into length?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Or actual sensor at the cable itself?

THE INTERVIEWEE: The encoder has a wheel which is driven by the wire --

MR. SHANBAKY: Okay.

THE INTERVIEWEE: -- and it rotates and it is

translated into length, all right, and there's also a home, what we call a home sensor, a position switch.

MR. SHANBAKY: Right.

THE INTERVIEWEE: That's tripped by the end of the wire going in and coming out.

MR. SHANBAKY: And is these two -- there is a logic here between these two systems or subsystems and which one of them actually gives how many millimeters the cable is out or in?

THE INTERVIEWEE: Well, the work together to do that.

MR. SHANBAKY: It works together?

THE INTERVIEWEE: It is my understanding. My understanding is that you trip the position switch. You start counting the distance out from there, okay, then in returning the wire you start counting it coming back until that switch trips again.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: That is my understanding.

MR. SHANBAKY: You think the engineer is looking at the error data today?

THE INTERVIEWEE: I do.

MR. SHANBAKY: You believe that he will be able to tell us whether the DC motor kicked in or not?

THE INTERVIEWEE: I hope that he will. I don't

know. There's like I think it is 16 messages recorded.

MR. SHANBAKY: Yes.

THE INTERVIEWEE: Okay? In the after-loader memory, okay, and there were some, error messages that were generated by the physicist in doing his testing. The reason I can't really give you a precise answer is looking at those codes, which are numbers and hexadecimal numbers, I don't know.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay? And I don't know if all 16, if errors were generated by the physicist doing the testing afterwards ran over those 16 or not.

MR. SHANBAKY: Okay. Can you just go over your quality assurance program, quality control measures in testing equipment and supplying equipment and all of this process?

THE INTERVIEWEE: It's -- we have a Quality Control Department. We inspect components coming in. We have signed documents, specifications for all our components. We have device history records on the wires and on the after-loaders and on the catheters and such.

We, you know, do testing according to written protocols, you know, the GMP type of operation.

MR. SHANBAKY: So you do your own testing in accordance with QC procedures?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: You use like industry standards? What do you use in your acceptance criteria?

THE INTERVIEWEE: The documents that we have that specify the part.

MR. SHANBAKY: This is the document you get from the vendor of that part?

THE INTERVIEWEE: I don't know component by component whether it is the document from the vendor. All of our custom made parts have our own engineering drawings.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay, if they are off-the-shelf parts, some of them may use the vendor document.

MR. SHANBAKY: Okay. What tests for example that the cable and the source assembly have been subjected to?

THE INTERVIEWEE: The wire, as we call it --

MR. SHANBAKY: Yes, the wire --

THE INTERVIEWEE: -- is subjected to very exacting physical measurements to make sure that it is the proper size, that the cavity in the end is the proper dimensions and all thicknesses are correct, all that sort of thing.

MR. SHANBAKY: Do you do any other physical tests like tensile strength or embrittlement tests or any metallurgical tests?

THE INTERVIEWEE: I do not know; I do not know

whether that's done. I know in the original evaluation of the materials it was done. I really don't know if that's done. I don't believe it's done on a wire by wire basis.

MR. SHANBAKY: Or even the sample?

THE INTERVIEWEE: What?

MR. SHANBAKY: Or even on the sample basis?

THE INTERVIEWEE: I do not know. I do not know the answer to your question. I am obviously going to look and see.

MR. SHANBAKY: Okay. How big is your Quality Control/Quality Assurance Group?

THE INTERVIEWEE: Probably about four, five people. We have -- our whole company is about 30-32 people.

MR. SHANBAKY: Okay. About the size of the team that's here to investigate.

MR. SHANBAKY: Okay. I understand.

MR. LLOYD: Has the NRC ever come in and done an audit on your QA/QC programs and other kinds of things, vendor type inspection?

THE INTERVIEWEE: The NRC has been in to -- in this case it's Louisiana, it's an Agreement State --

MR. LLOYD: Okay, somebody from Louisiana.

THE INTERVIEWEE: Yes, has been to our facility in Louisiana. In Houston we do not manufacture or handle any radioactive elements at all and so they have not been there

but they have been to our Louisiana facility.

MR. SHANBAKY: Okay.

MR. LLOYD: But one question there.

MR. SHANBAKY: Sure, go ahead.

MR. LLOYD: And get this all clarified. We were talking about this earlier as a team. Is the entire device manufactured and assembled in Texas with the exception of the wire and the source?

THE INTERVIEWEE: The final manufacturing is in Texas. Some of the components like the safe and all of that are manufactured in Louisiana.

The final assembly of the after-loader is done in Texas.

MR. LLOYD: When would the source be installed?

THE INTERVIEWEE: At the customer site. It's shipped directly from our facility in Louisiana, for instance, to here. There's one that arrived yesterday.

MR. SHANBAKY: Yes, right. The distance of the wire out, I'm still not very clear in my mind. Do you get some understanding a little bit or we need to pursue this further?

MR. LLOYD: An additional question I had was when the source is retracted and it shows that it is in the parked position --

THE INTERVIEWEE: Yes?

MR. LLOYD: Is there any radiation detector that detects the actual source?

THE INTERVIEWEE: No, no, there is not.

MR. LLOYD: So you rely on basically the encoders that says the cable has been retracted or the wire has been retracted?

THE INTERVIEWEE: That's correct, you know, plus the radiation monitor which is required in every run.

MR. SHANBAKY: I don't know, I heard this but I am not sure it is true. Somebody said that the -- I believe one of your engineers -- said that when the DC motor kicks in, the decoder uncouples -- you don't actually detect the length of the wire going in or out?

THE INTERVIEWEE: That's correct. That's a safety feature.

The design of the unit is such that if the normal drive system, okay, along the chain is having trouble retracting a hot wire, which is the most important thing it's supposed to do, all right, then any sources of restriction on that such as the pinch roller and the encoder and the other drive motor and all are released, so that the emergency retract motor has the maximum chance to pull the wire back.

MR. SHANBAKY: All right. What are the safety features of the equipment?

THE INTERVIEWEE: There's a long list of those. Numerous. Numerous.

MR. SHANBAKY: All right.

THE INTERVIEWEE: You know, from backup power supplies to backup drive systems to all kinds of error checking on the commands that come from the console computer or the planning system or whatever. It's an extremely long list of safety features that are built into the system.

I'll give you an example.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: If you have a hot wire out, okay, the one thing you always want to do is pull that back. If you have a clinic or hospital power failure, then we have an uninterruptible power supply that can do that and will continue to run the system, okay?

If the uninterruptible power supply fails in addition to the hospital power, we have another backup battery, okay, whose only job it is is to pull the hot wire back with the emergency drive and we test that battery under load every time before we send a hot wire out, okay, so that's the kind of redundancy and the bottom line if all that fails is manual crank.

MR. SHANBAKY: Can you walk me through what is done with the machine upon installation when you bring it to the customer? What is your procedures?

THE INTERVIEWEE: I'm not sure I can walk you through it in detail. Our service and installation people come to the site. They uncrate the machine, unpack it. They, you know, run the conduits. They do testing on the machine. I'm not sure I can tell you in detail everything that's done.

MR. SHANBAKY: Do they test any radiation monitors in the area?

THE INTERVIEWEE: Do they test the radiation monitors? I do not know for sure.

MR. SHANBAKY: How about the instructions to your client, the training of the client? What is involved in that training of the clients?

THE INTERVIEWEE: Well, we have usually two sets of training -- usually the physicist and the dosimetrist or whoever comes to Houston for a couple days for training, and then we usually do some onsite training and I do not know where that was done for this site. I've asked them to get together those records for me to see who was trained and when and where.

MR. SHANBAKY: So you give two types of training. One is at your facility in Houston, and that is you said two days?

THE INTERVIEWEE: Two days typically.

MR. SHANBAKY: Two days typically, and this is to

the physicist. What is entailed in this training as the topics?

THE INTERVIEWEE: It's generally two things. One is how to use the therapy planning system, all right, and secondly is how to operate the after-loader, and certainly the simpler of that is how to load the after-loader because it is all menu-driven.

For instance, we have error messages that are full text messages, unlike our competition that has codes and if you have an error you have to look up in the manual what is Code 37, so it's a reasonably simply machine to use.

We have the emergency procedures which I know you have seen, presume you have seen, and we do not train, you know, the physicist how to be a physicist. That's what they have certified physicists for.

MR. SHANBAKY: Do you provide any safety precautions in the use of the machine?

THE INTERVIEWEE: I think so -- in the documentation there are safety precautions.

MR. SHANBAKY: During the training?

THE INTERVIEWEE: I don't know in detail. Dr. Ann Wright is in charge of our Training Department.

MR. SHANBAKY: Can you spell his name, please?

THE INTERVIEWEE: Her -- Ann.

MR. SHANBAKY: Her name, Ann.

THE INTERVIEWEE: Ann Wright, W-r-i-g-h-t.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: And she is a very well-known physicist. She is the past President of the, immediate past President of the APM and ACPM so she is --

MR. SHANBAKY: She is a member of your staff?

THE INTERVIEWEE: Yes. She is an executive with our company.

MR. SHANBAKY: Okay, all right, and what type of training is given at the facility and what is the length of that training?

THE INTERVIEWEE: It's usually --

MR. SHANBAKY: At the client facility.

THE INTERVIEWEE: At the client's facility?

MR. SHANBAKY: Yes.

THE INTERVIEWEE: It's really more familiarization with the operation of the after-loader as opposed to the operation of the planning system, all right, and it's not a required part of the training because we have obviously trained the people, you know, at our facility in Houston, so, you know, they do not in all cases get the onsite training, if we train, for instance, their chief physicist in the full operation of the machine.

Sometimes they train their own staff, as they have new staff that comes on, they train their regular staff.

MR. SHANBAKY: Okay. Do you train your client to troubleshoot in the machine?

THE INTERVIEWEE: No, not in general. If there's an error condition or something there are no user serviceable parts in the machine so if the machine is broken, we send someone to fix it.

MR. SHANBAKY: What the client is allowed to do in terms of service to the machine?

THE INTERVIEWEE: Nothing.

MR. SHANBAKY: So I take it you are doing the service to the machine?

THE INTERVIEWEE: Yes.

MR. LLOYD: Is that something they have to pay for, to get some sort of an extended service agreement?

THE INTERVIEWEE: To get, I believe so, extended service agreements after the first year, a warranty, and we do all of that servicing.

MR. SHANBAKY: Do all your clients have extended service warranty?

THE INTERVIEWEE: Yes, they do.

MR. SHANBAKY: Okay. How about this facility here? The Indiana Cancer Center?

THE INTERVIEWEE: I do not know if they are under their original warranty or an extended. I can't tell you.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: But I know that Oncology Services in general has, you know, in all the ones after the end of the first year they purchased the service agreement. There's really not much choice. They really have to do it.

MR. SHANBAKY: Okay. Why is that?

THE INTERVIEWEE: Because they are not licensed to change the sources and that's part of that, is, you know, exchanging the sources. Our people do that.

MR. SHANBAKY: Okay. You answered my question. I was going to ask you who changed the source.

THE INTERVIEWEE: We change the source.

MR. SHANBAKY: All right. How about the routine maintenance of the equipment. Can you describe what is done routinely and the frequency of this routine maintenance?

THE INTERVIEWEE: Well, every 90 days the source gets changes and so we have a service person come in to do that and they do preventative maintenance. They, you know, they clean the drive rollers. They check the switches. They recalibrate the machine. If the physicist wants, they will help them recalibrate the source, okay, while they're there.

MR. SHANBAKY: What examinations do they do? Do they do any tests or verification of operability that everything is working as intended?

THE INTERVIEWEE: They do. They do a -- for instance, we control the wire to within plus or minus one

millimeter.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Over the range of zero to 1500 millimeters, so they do a calibration check and adjustment if necessary to that system.

They often, you know, participate with the physicist. You know, we calibrate the source wires at our facility and supply them with the calibration. If they choose to do their own calibration, then they often do that, the physicist with our technician running the wire out for them and that sort of thing, to do that calibration.

Sometimes they do it on their own without our technician involved, so --

MR. LLOYD: Who actually makes the source wire?

THE INTERVIEWEE: We do.

MR. LLOYD: You actually do?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: How about the tests of any safety feature on the machine? What systems, subsystems are tested and how often?

THE INTERVIEWEE: I'm not sure I can answer that question in detail. I don't know, you know, what all is on the checklist that they do at preventative maintenance time.

I know at, you know, final manufacturing tests tests everything.

MR. SHANBAKY: Is this checklist, doctor, included in the Omnitron documents? I so some of them floating here, like an owner manual or something, the frequency of those tests and --

THE INTERVIEWEE: I don't know. I do not know.

MR. SHANBAKY: Okay, because I was trying to save you sending us everything if --

THE INTERVIEWEE: Right.

MR. SHANBAKY: -- if it's here we can --

THE INTERVIEWEE: We have, you know, a new product that is added on to our system called a Physics QA Package that allows the facility to produce checklists, you know, daily checklists, periodic checklists, source exchange day checklists. That has, you know, a whole list of things to check and, you know, various sites do different tests on their own at this point in time but I can't answer the specific question of what our service technician checks every time.

MR. SHANBAKY: Does he have written procedures?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: In addition to the checklist, now I am talking about detailed procedures, how to perform the function rather than did you do it.

THE INTERVIEWEE: I don't know. I don't know for each and every function where there is a written procedure

of how to do that. I do not know

MR. SHANBAKY: Some may have written procedures. Some functions may not have written procedures that --

THE INTERVIEWEE: I do not know. I know our service personnel are trained in how to do all of these functions, okay. I do not know if they have a written procedure that goes with them.

MR. SHANBAKY: So I don't know, I'm trying to still understand this. You don't know if -- who would know whether you have written procedures or not?

THE INTERVIEWEE: I'll go back and see if -- on the checklist?

MR. SHANBAKY: Yes, in addition to the checklist.

THE INTERVIEWEE: If there is a written procedure for each --

MR. SHANBAKY: Right.

THE INTERVIEWEE: -- item on the checklist.

MR. SHANBAKY: Right.

THE INTERVIEWEE: I don't know. I will check when I get back.

MR. SHANBAKY: All right.

MR. LLOYD: Would Ann Wright know the answers to those kind of questions?

THE INTERVIEWEE: She might, although she has training in physics. She doesn't have the service

department.

MR. SHANBAKY: Since we are at procedures, I would also like to understand what is your methods for generating these procedures using ASME standards and ANSIs, how the procedures are generated, how they are reviewed, approved, if this is what you want or the top head of the engineering group wants, you know -- help. I would like to understand this process of generating procedures and approving the procedures.

THE INTERVIEWEE: Okay. Your specific question is for periodic maintenance what is done?

MR. SHANBAKY: Right.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: And I understand that whatever is required on the checklist, you do on the checklist, we need to get a copy of the checklist.

THE INTERVIEWEE: Right.

MR. SHANBAKY: And then the "how to," the procedure, the detailed procedures that connect or disconnect this lead with this lead.

THE INTERVIEWEE: Most of the stuff is really simple --

MR. SHANBAKY: If it is very simple processes, you don't need the detailed procedure to tell you how to turn it on --

THE INTERVIEWEE: Exactly -- how are they determined. Okay.

MR. SHANBAKY: Okay. All right, and the training of the service representatives, your service representative. What training does he get?

THE INTERVIEWEE: Okay. Okay?

MR. SHANBAKY: Now getting to another area now, is the emergency procedures that you give to the clients.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: What is entailed in these emergency procedures?

THE INTERVIEWEE: It's, you know, it's a pretty simple sheet. Have you seen it?

MR. SHANBAKY: I have seen the sheet. I have seen like one page --

THE INTERVIEWEE: Right.

MR. SHANBAKY: -- with like bullets on that page.

THE INTERVIEWEE: Yes.

MR. SHANBAKY: It is --

THE INTERVIEWEE: It basically, you know, says if you have any emergency with the source being out, what to do, you know, step one, two, three, and so it's a pretty simple set of criteria.

MR. SHANBAKY: Okay, it said what to do but I don't know if it said how to do it.

THE INTERVIEWEE: Well, it's things like, you know, remove the catheters from the patient. It depends on where they are as to how you do that. You know, pull the machine away from the patient. Take the patient out of the room and survey them, you know. That sort of thing.

MR. SHANBAKY: Okay, but do you have any other set of instructions or procedures which will go with this emergency, this one page?

THE INTERVIEWEE: I don't believe so, no.

MR. SHANBAKY: In terms of radiological safety precautions, use a tweezer, use a remote tool, minimize strain near that area of the machine or --

THE INTERVIEWEE: I don't believe so.

MR. SHANBAKY: Or surveys, radiological surveys, anything of this nature?

THE INTERVIEWEE: No, I think it says to leave the room and lock the door and call the appropriate personnel, you know, who are certified and trained in this operation.

MR. LLOYD: Do you require that one page of bullets or emergency procedures to be posted in the room or on the machine?

THE INTERVIEWEE: I think almost everyone's license requires that, okay? It's your requirements to the licensee as opposed to ours.

MR. LLOYD: In your opinion, do you think the

facility followed those emergency procedures?

THE INTERVIEWEE: Well, they did not detect, they did not -- as my understanding applies, they did not recognize that their emergency radiator monitor flashing, indicating that they had a problem, so, no, they did not recognize that they had an emergency and therefore they did not follow them.

MR. SHANBAKY: You mean that they did not recognize the alarm or they did not recognize the emergency?

THE INTERVIEWEE: They did not recognize that a problem had occurred is my understanding.

MR. SHANBAKY: So getting to this, what is your views now about this client's proficiency and understanding the use of this unit?

THE INTERVIEWEE: That is a real difficult question for me to answer. You know, I know that they have good people here and it's my judgment that they have good people here. I obviously believe that the physician and the technician should have heeded their radiation monitor. I mean that's obvious. I cannot explain why they did not.

MR. SHANBAKY: Is there anything else on like the CRT that will tell them that they've got a problem with the source out -- in addition to the radiation, the radiation monitor is separate from the machine.

THE INTERVIEWEE: If -- if it had broken and not

been, and this is speculation on my part, okay, until we get through the engineering analysis, if the length check had detected a change in the length of the wire, then there would have been a message to that effect on the CRT for them to check further, okay?

Since that apparently did not happen, we believe because an emergency retract with the secondary system took place, then on the screen during the emergency retract would have been a message that said, you know, DC motor making emergency retract, okay, in a red box.

MR. SHANBAKY: In the red box?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: And what understanding of the technician, the technologist that is operating the machine is of this DC motor is on, whatever the message is, what did they give, were ving any instruction what this means?

THE INTERVIEWEE: I do not know and I think a -- you know, I do not know if they noticed that message. You know, if an emergency retract occurred, which I believe is the case, and if they noticed that message, okay, during the emergency retract, then I do not know if they would have interpreted that properly.

You know, I think that we probably want to change that message, okay, to remind them under those conditions to be sure and check the radiation monitor. That's my opinion.

I think that that message, it should endure and be stronger.

MR. SHANBAKY: Does the message appear automatically or does he have to go to the keyboard and type requesting error --

THE INTERVIEWEE: No, it appears automatically.

MR. SHANBAKY: -- condition? It appears automatically, and after how many insertions and retractions does this appear, "failure," because what I understand the insert the wire, the dummy wire, to see if everything is clear --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: -- after the dummy wire goes all the way in and all the way out, establish that the catheter is clear, the actual source is driven in --

THE INTERVIEWEE: Right.

MR. SHANBAKY: After how many trials of the dummy wire that message would appear?

THE INTERVIEWEE: I don't think I understand that question.

MR. SHANBAKY: Does it have to involve the source itself, the source does not appear with dummy wire --

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Like if the dummy wire gets into an obstruction --

THE INTERVIEWEE: Right -- that's its job is to

find if there is any obstructions. That's the purpose of the dummy wire.

MR. SHANBAKY: Suppose the dummy wire finds an obstruction. It will not insert, I take it?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: And it is attracted to the machine?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: And can the technologist insert the wire with the source after that?

THE INTERVIEWEE: No. It has to have a successful dummy run for the active wire to go out.

MR. SHANBAKY: So if this is the situation, I am trying now to understand how there was a successful dummy run because by definition there was a successful run --

THE INTERVIEWEE: There was.

MR. SHANBAKY: And then the source was not successful. It went there and something happened.

THE JNTERVIEWEE: Well, possible, you know, the patient flexed their muscle, okay -- this is a flexible catheter and this is speculation --

MR. SHANBAKY: Okay.

THE INTERVIEWEE: As the active wire went out, okay, and, you know, bent that catheter, for lack of a better word, and caused somehow -- I mean we need to look at this wire and figure out what happened --

MR. SHANBAKY: Right.

THE INTERVIEWEE: -- for the wire to break and the constriction to be detected and an emergency retract to occur.

MR. SHANBAKY: So the dummy wire insertion says you have multiple catheters--

THE INTERVIEWEE: Yes,

MR. SHANBAKY: -- like four or five. The dummy wire is inserted actually in each wire and then followed by the active wire, not testing all the catheters and then the active wire?

THE INTERVIEWEE: It can be either way. It's selectable by the user.

MR. SHANBAKY: Oh, so there is a situation where the dummy wire would be used on all the catheters --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: -- and later on during the treatment you can start with the active wire on all the catheters?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Is there any way that somebody can defeat the dummy wire insertion and just use the active wire directly?

THE INTERVIEWEE: The only way that could be done is in what we call a physics mode, all right, where the

physicist uses that, for instance, to run an active wire out to do a calibration, all right?

MR. SHANBAKY: Yes.

THE INTERVIEWEE: It's not to be used on patients and it has a separate password that only the physicist is supposed to know to be able to get into that mode and that was not involved in this situation at all. The dummy wire checks were done.

MR. LLOYD: So if I understand you, for the patient that we had here there were five catheters?

THE INTERVIEWEE: Yes.

MR. LLOYD: For each time that you inserted a source in one of those, you have to have a dummy source going first --

THE INTERVIEWEE: Yes.

MR. LLOYD: -- and then get a successful run and then you could put the source in?

THE INTERVIEWEE: That's correct.

MR. LLOYD: There would be no condition where he would run the dummy into all five sources and then back up and then run --

THE INTERVIEWEE: That's correct. It could have been done either way. We can look at the record and tell how it was programmed here.

MR. SHANBAKY: He can operate in two modes, either

sequentially or each wire?

THE INTERVIEWEE: I'm not sure that's significant though, which way they did it, okay.

MR. SHANBAKY: Just because of the time lapsed between -- if you insert the wire and you take it out and you put another wire, the likelihood and the time for things to change, the configuration to change, is maybe less than a few minutes --

THE INTERVIEWEE: Possibly but I mean a muscle can squeeze it -- I mean it's a --

MR. SHANBAKY: Yes.

THE INTERVIEWEE: I really don't think that's significant, whether they did all five dummy checks in the beginning --

MR. LLOYD: Or one at a time.

THE INTERVIEWEE: Or one at a time.

MR. SHANBAKY: Because the duration of time this is done is -- how long is the time for this test?

THE INTERVIEWEE: It's maybe, you know, four seconds out, four seconds back, okay? Then, you know, switch to the active, you know, four seconds -- it's like 12 seconds maybe in between.

Even if you did the dummy check right before you sent the active wire out, and I don't know which was the case here, I don't remember.

MR. SHANBAKY: We can ask the technologist as to the --

THE INTERVIEWEE: Do you have the printout from the patient? We can look and see.

MR. SHANBAKY: No, our engineer has that. We'll look at that.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: What specific maintenance is done on this machine? Any non-routine maintenance? We talked about your routine.

THE INTERVIEWEE: I don't know whether there was any non-routine maintenance done or not.

MR. SHANBAKY: Okay. We did not get the frequency of maintenance. What is the frequency of maintenance?

THE INTERVIEWEE: Every 90 days.

MR. SHANBAKY: Every 90 days.

MR. LLOYD: So the same time the source is changed?

THE INTERVIEWEE: That's correct. That's correct.

MR. SHANBAKY: All right, just to put it on the record.

MR. SHANBAKY: This looks like an intelligent machine.

THE INTERVIEWEE: Yes.

MR. SHANBAKY: It has some memory. What things we

can retrieve from this machine back to and for November 16th?

THE INTERVIEWEE: Well, we have already printed out the error logs, okay, for your engineers. There's, I'm sure there's patient treatment records in there that can be printed out.

I don't see how personally, you know, the maintenance of the machine or exactly what checks were done relates to why the wire broke, okay, which is the main thing that we are certainly interested in, plus is there any changes that we can make to our software or our messages, okay, that makes the likelihood of a customer, you know, ignoring a warning less likely.

MR. LLOYD: What I think the team was interested in as far as the machine portion of it goes is there any way that the machine itself could have kinked the wire or caused some sort of a problem?

THE INTERVIEWEE: I can't imagine a way that the machine itself could have done that. I mean the possibilities are that it was a defective wire, that it was abused in some way, or that, and pretty far-fetched, that the patient could get the wire in a configuration where they could squeeze it with their muscle and cause the break.

That is why we need to study the wire and see what we can see.

MR. LLOYD: Each time you get an error message on the machine, do you have to go back through and clear that error message before you can continue operation or can you ignore those and continue going on and doing what you want to do?

THE INTERVIEWEE: There are different classes of error messages. There are -- generally you need to clear an error message either by hitting the escape key or pressing the reset button. There are some classes of error messages that the customer can't clear. They have to call our service department and, you know, we would have to investigate it.

MR. LLOYD: Is that eliminated from memory once they've cleared that error message and fixed whatever the problem is?

THE INTERVIEWEE: No. It's in the error log.

MR. LLOYD: Okay, so every one of those should show up in the log?

THE INTERVIEWEE: Yes, there's actually two error logs. There is a console error log, okay, and then there is, you know, a computer in the after-loader, and it obviously it's a, you know, a simpler computer so it remembers only the last sixteen events, so there's two places. That's what I mentioned earlier about there are only sixteen and, you know, we don't know how many are in there

and how many were generated afterwards in subsequent testing at all.

The error log for the console, you know, probably goes back from the beginning of the history of the machine unless that's been cleared by somebody.

MR. SHANBAKY: You said that there are error codes or error statements in this case that can be reset by your clients --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: And some other, other category which I take were more serious, more important.

THE INTERVIEWEE: Right.

MR. SHANBAKY: And can only be cleared by your service representative?

THE INTERVIEWEE: That is correct.

MR. SHANBAKY: This DC drive, DC motor actuation, it will come as a warning and was red and the error message. Is this clearable --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: -- by the client or by your service representatives?

THE INTERVIEWEE: By the client.

MR. SHANBAKY: So the client can actually clear a DC motor --

THE INTERVIEWEE: Yes.

MR. SHANBAKY: -- actuation?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: That just says that the system decided that there was something restricting the path out there, okay, of trying to get the wire back and the difficulty in pulling it back was such that it tripped the threshold and kicked in the emergency retract.

If it retracts the wire, fine, then the client can clear that. If it didn't retract the wire fine then that would be a non-clearable error.

MR. SHANBAKY: What is the difference between the original motor which operates routinely in terms of power and the DC motor? I am just trying to figure out how much it would be yanking on that wire.

THE INTERVIEWEE: It just has to do with the force that is applied to the wire, that's all. They are both friction drive systems.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: The -- you know, they are independent drive systems so that you have redundancy in that ability if one motor should fail. Let's say the primary drive motor fail, okay, then it would be in a frozen position and the wire would be locked. You couldn't move it, all right? That's why we release those drives, okay,

when we pull the emergency wire back.

MR. LLOYD: That's where you lose the encoding.

THE INTERVIEWEE: That's right. That's exactly right and that's really, see, the encoder is on the wire so let's suppose that the encoder locks up. You want to get that wire back so that is the reason that it was done that way. I think that's a good, logical reason for that type of operation.

I do believe though that as a result of this experience we ought to change the message that goes with that.

MR. LLOYD: In your qualification testing with your DC motor, have you done any static testing with the wire where it's firmly clamped and you turn the DC motor on to see if you can exceed your tensile strengths? Are there minimal conditions on your wire?

THE INTERVIEWEE: Yes. It does not pull that hard.

MR. SHANBAKY: Oh, that's what I was getting at.

THE INTERVIEWEE: You know, what it would do under those circumstances, it would, after a period of time it would give you the message that says it was not able to pull the wire back, you know, call Omnitron. That's an unresetable error.

MR. SHANBAKY: What it takes to cut that wire, to

break it?

THE INTERVIEWEE: Force?

MR. SHANBAKY: In terms of --

THE INTERVIEWEE: I don't know, 100 pounds, 200 pounds, whatever that is. Someone else asked that question. It's not something we ever -- it's very strong wire. I would wager that you can't break it.

MR. SHANBAKY: Okay. I think what the concern is, is that maybe the wire is strong but there is a cavity at the tip and we don't know how the strength of that. I think we will learn from actually the cut, you know, the cut whether it occurred at the cavity or at the wire.

THE INTERVIEWEE: Right.

MR. SHANBAKY: I am not sure.

THE INTERVIEWEE: I think it occurred at the back of the cavity, just from what we looked at in there a while ago.

MR. SHANBAKY: Meaning that there is a possibility that there was a cavity there rather than in the solid wire itself?

THE INTERVIEWEE: Yes. That's what it looks like but that's -- we have to analyze it --

MR. SHANBAKY: Right, absolutely.

THE INTERVIEWEE: -- to make sure that's correct.

MR. SHANBAKY: Absolutely.

MR. SHANBAKY: Do you have any other questions?

MR. LLOYD: Have we covered everything that we had on our list?

MR. SHANBAKY: No, not yet. We were getting to the software and how it generated out, is verified.

MR. LLOYD: Back on the machine maybe just for a couple minutes and that is -- have you had any other problems with any of other, what are there, 20 other units out?

THE INTERVIEWEE: There's 25 units out with active wires.

MR. LLOYD: No similar problems have been identified at any of them?

THE INTERVIEWEE: Absolutely not.

MR. SHANBAKY: What is the most common failure of the machine?

THE INTERVIEWEE: Well, the most common error message has --

MR. LLOYD: Error message.

THE INTERVIEWEE: -- has to do with the technician not getting the catheter fully inserted into the connector, and it has to be all the way in or the machine detects a problem when it tries to run a dummy wire out. That's the most common error message.

In terms of failures of hardware, it's probably

been a PC failure. There's a 386 computer that constitutes the console and, you know, where that type of failure will occur.

MR. SHANBAKY: How about DC motor actuation error messages? You know what the frequency of this? Is this something common?

THE INTERVIEWEE: I don't believe it is common. I am not sure I can tell you the exact frequency but I don't think that's a common occurrence.

MR. LLOYD: Do you have a new model beyond the 2000 that you are currently developing now?

THE INTERVIEWEE: We have one in development but it is not released or ready for release.

MR. LLOYD: What sort of safety features may it have in addition to the 2000 model? Anything beyond or is this just a --

THE INTERVIEWEE: I'm not sure I can really answer the question.

MR. SHANBAKY: Any radiation detection capabilities built in?

THE INTERVIEWEE: No, it doesn't have that yet but in terms of having a redundant radiation monitor? It doesn't have that. That's something we have talked about the last couple of days, whether you should do that or not, but of course these are usually or often in the room with an

accelerator --

MR. SHANBAKY: You realize redundant means that it would be another area radiation monitor -- that's redundant because that's outside the machine. What I am asking about here, something built in.

THE INTERVIEWEE: I understand. I am saying you could built a prime alert into an after-loader.

MR. SHANBAKY: Inside the unit?

THE INTERVIEWEE: Or on the outside, wherever.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: If a source is out, it's going to find it. The complications that you would worry about is that after-loader sitting in the room, is it supposed to, you know, start ringing bells when the accelerator turns on? You know, I mean it's -- is that an area that there should be redundancy, more than one radiation monitor?

MR. LLOYD: Do you require the people that you sell the devices to to have anything?

THE INTERVIEWEE: Radiation monitor?

MR. LLOYD: Radiation monitors.

THE INTERVIEWEE: Yes.

MR. LLOYD: The number, the types of radiation monitors, the numbers of radiation monitors, the procedures that they might follow, you know, in addition to your packaged machine?

THE INTERVIEWEE: Generally I think the license requires that they have radiation monitors, your license to the licensee, all right? If they don't have one at a site, we supply it at no extra charge so we make sure there is always a radiation monitor at each site irrespective of, you know, any other requirement.

Now we do not test that for them. That is part of their QC responsibility is to make sure their radiation monitor is working.

MR. SHANBAKY: Yesterday we got some information about the error messages. What other data dump we can get from the memory of this machine?

THE INTERVIEWEE: None that I know of that would be useful. You know, we prirted out both the, actually printed out the console error log, the afterloader error log, and then there's a more basic afterloader error log that we went in diagnostic mode and printed that out also. That was supplied to your engineers.

MR. SHANBAKY: To the engineer, okay, so what else other than -- I saw some of them. They are error messages. There is like doses delivered to patients, treatment plans.

THE INTERVIEWEE: That doesn't sound like error messages.

MR. SHANBAKY: No, what I saw yesterday was error messages. Is there anything else in the machine that we can

retrieve in terms of treatment plans --

THE INTERVIEWEE: There are records, files in the machine that save the information that is printed out, okay, the record of the treatment.

MR. SHANBAKY: For each patient?

THE INTERVIEWEE: For each patient.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay, but you already have the record of the treatment for this patient. You could print it out again but you would get the same information.

To get back to, you know, focusing on why did the wire break, that's --

MR. SHANBAKY: Right, absolutely. Absolutely, but I want to have some understanding of how this patient treatment data is generated -- does the machine have anything to do with the generation of the machine in terms of, generation of the records in terms of exposure time, insertion time, the source activity or all this data is actually, is calculated data by the physicist and he enters it in the computer?

THE INTERVIEWEE: The plan for the treatment of the patient, okay, is generated by the physicist.

MR. SHANBAKY: All right.

THE INTERVIEWEE: Okay, or the dosimetrist, whatever. The afterloader itself, the only way it alters

that plan is by decaying the source so if you treat a patient today and then you treat a patient tomorrow with the same plan, when you treat them tomorrow, the treatment will be a little bit longer because the source is weaker, all right?

MR. SHANBAKY: Does the machine say here is the plan; does the physicist enter the centigrade the patient is going to be treated with all the time?

THE INTERVIEWEE: Well, they do the plan. Now the afterloader gets time and position.

MR SHANBAKY: Time and position?

THE INTERVIEWEE: Well, it gets time, position. You know, there is like patient name and intended dose and all that kind of stuff that's just passed through as text.

MR. SHANBAKY: And intended dose?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay, but the afterloader doesn't check that. The afterloader does consistency checks on, you know, are the times outside of reasonable ranges, are the positions in sequence, those kinds of consistency checks that the afterloader does on the plan.

MR. SHANBAKY: Okay.

THE INTERVIEWEE: Okay, but the main thing, the plan that is delivered to the afterloader is go to what

positions for how long.

MR. SHANBAKY: All right.

THE INTERVIEWEE: And the only thing the afterloader does is check that for consistency, okay? In other words you are not treating the same channel twice, you're not trying to back the wire up or anything like that, and then it alters the dwell times to account for the decay of the source.

MR. LLOYD: Back to the wire, since we obviously had a failure on the wire and everybody is interested in finding out why the wire did fail and I believe you are going to take a look at that out at San Diego?

THE INTERVIEWEE: Well, what we are going to do is, you know, microscopically examine ourselves and then there is a nuclear metallurgist that we know of and have used some in the past down in San Diego who can do sims, who can do grain structure analysis, all the things that metallurgists do.

MR. LLOYD: So initially you want to take it to Houston?

THE INTERVIEWEE: I believe it would be our desire to take it to Houston and then from there our current plan is to get it in the hands of this metallurgist.

MR. SHANBAKY: And we will be talking about this later that's really the stuff that we would like to observe

in the future once the testing process starts. We would like to have one of our engineers to observe this.

THE INTERVIEWEE: That's fine.

MR. LLOYD: Because the NRC also has a contract with I believe it is Southwest Research that has done a bunch of stuff for us.

Is there any conflict of interest with having that individual show up and watch whatever tests you are doing in Houston or in San Diego?

THE INTERVIEWEE: No. I have no problem with that.

MR. SHANBAKY: Okay. We will be talking about this. This is for the future planning from the --

THE INTERVIEWEE: ... want to get going.

MR. SHANBAKY: Right, right.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: You are cleared to take the wire now.

THE INTERVIEWEE: I don't know. Is that --

MR. SHANBAKY: I believe you are.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: I believe you are and I will confirm this with my team leader immediately after this meeting.

Now we are here and I would like to hear from you

what is your current plans now. I know that you are going to tell me you want to test the wire now.

THE INTERVIEWEE: That's right.

MR. SHANBAKY: Okay. What else in terms of the generic implication in terms of other units out there?

THE INTERVIEWEE: We have notified all of our customers that this incident has occurred, okay, so that they would be aware of it and have reinforced the recommendation that anyone should obviously routinely monitor a patient after treatment to make sure there is no radioactive source in the patient or in the room or anywhere else except in the safe.

I think that we would in addition to the analyzing of the wire, we would review the text, particular on that error message and see if there is not a way that we can improve it.

That modification could be installed in our locations in the field but we have contacted the clients, the customers, and we have told them it's happened and we have reinforced the recommendation that patients be monitored.

Obviously if that had happened here we wouldn't have the mess we have.

MR. SHANBAKY: I understand. So this went out to all your clients?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: Is it limited to this model or all your other models?

THE INTERVIEWEE: This is our only model.

MR. SHANBAKY: This is the only model you have?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: The 2000 is the only one on the market now?

THE INTERVIEWEE: That's correct.

MR. SHANBAKY: Okay, and in which form is this guidance, a bulletin or information notice?

THE INTERVIEWEE: No, it was a telephone call --

MR. SHANBAKY: Telephone call?

THE INTERVIEWEE: -- the day after we heard about it.

You know, we called and talked to either the physician or the physicist in charge at each of these places.

MR. LLOYD: Did you send any document that followed that up?

THE INTERVIEWEE: We haven't yet.

MR. LLOYD: Not yet?

THE INTERVIEWEE: We documented who we talked to, what time, what day.

MR. LLOYD: Are there any other vendors that

supply similar kinds of cable? Or is this unique to the --

THE INTERVIEWEE: There are other afterloader companies that have their own cable designs, who have incidentally had similar incidents in the past.

MR. SHANBAKY: High dose rate afterloaders?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: Was the source outside in the machine?

THE INTERVIEWEE: Where the source separated from their cable.

MR. SHANBAKY: Separated from their cable?

THE INTERVIEWEE: Yes. To my knowledge there is not another incidence where the patient, you know, went home with the source in them.

MR. SHANBAKY: Okay, all right. Do you have anything else to add in terms of --

THE INTERVIEWEE: The one other thing I should mention that we will do will be, you know, file an MDR report with the FDA.

MR. SHANBAKY: Okay. When is the report required, by the way, because I am not very familiar with FDA?

THE INTERVIEWEE: It's within 15 days after the incident.

MR. SHANBAKY: What type of incidents require this

report?

THE INTERVIEWEE: It's fairly complex, I think, from a regulatory point of view.

I think if there is alleged that there was the possibility of a serious injury to anyone, then you file a report but I am not a regulatory person. I know in our Pacemakers, you know, there was some sort of statistical criteria that the FDA worked out with our product insurance department but we have determined that this is an event that we are going to file an MDR report on.

MR. SHANBAKY: All right. Do you know of anybody else who can provide us information or help us understanding what happened?

THE INTERVIEWEE: Only the analysis that we are going to do, you know, in our engineering department, where we will see if there is any further data we can look at from the error logs, you know, looking at the exact timing of events, you know, when they occurred, and --

MR. SHANBAKY: This is coming down the pike?

THE INTERVIEWEE: Yes, and obviously the metallurgical analysis of the wire.

MR. SHANBAKY: Do you know of anybody that it would be helpful for us to talk to him now?

THE INTERVIEWEE: I don't. I mean I think the focus of this needs to be in two areas -- you know, one, why

did the wire break; and two, why were the radiation monitors ignored?

MR. LLOYD: For the purposes of our report we will need to, from the time that we leave this site, we have a requirement to respond to the EDO, which is our Executive Director for Operations within the NRC to issue a report and then we'll have a Commission briefing at that time.

We would like to have obviously the results from, the metallurgical results.

THE INTERVIEWEE: So would we.

MR. LLOYD: Could you speculate as to how long that might take, assuming you could get the wire witnin a few days?

THE INTERVIEWEE: I would think that it would be within -- you know, depending upon availability of the consultant, the metallurgist, et cetera, I would think that it would be within a week, two weeks. It's certainly within your 45 day window.

MR. SHANBAKY: Do you do destructive testing also, in addition to the visual and non-destructive testing?

THE INTERVIEWEE: There is type testing, not on an individual wire obviously.

MR. SHANBAKY: Like they are going to do any metallurgical tests that it involves actual analysis of the metal or the makeup of the metal?

THE INTERVIEWEE: Yes. I don't know what-all testing. You know, obviously we would consult with the metallurgist doing the testing but I can't tell you what-all in detail they would do.

MR. SHANBAKY: What I am getting at here is the testing is limited to non-destructive testing, maybe we would be considering also --

MR. LLOYD: To look at grain structures and stuff like that, you're going to have to alter the breaks and so on so you can look at this through microscopes and so on.

THE INTERVIEWEE: But I think that's, you know, the fact that if you want a metallurgist from Southwestern Research to accompany it and witness it, yes, I'm sure that these guys probably know each other. You know, it's a pretty small field and that would be fine.

MR. SHANBAKY: I think that is very important. You need this and we need this as soon as we can.

THE INTERVIEWEE: Right.

MR. SHANBAKY: Did we talk about this record here that we are going to be, we'll be sending --

THE INTERVIEWEE: You told me that.

MR. SHANBAKY: You'll get a copy of the record. Okay, you'll make the corrections on the attachment, the errata sheet which will be attached to that.

THE INTERVIEWEE: Okay. Do you have a clearer

understanding now of -- have I helped you, I hope?

MR. SHANBAKY: Absolutely. You were very helpful to us and we really appreciated it.

Do you have any further questions?

MR. LLOYD: I think that's it.

MR. SHANBAKY: Okay. We really appreciated it, Dr. Calfee . Thank you very much.

[Whereupon, at 11:27 a.m., the interview recessed.]

DR. PAPERIELLO: We will go back on the record now.

From my viewpoint, your relationship to the NRC is as a vendor.

THE INTERVIEWEE: Okay.

DR. PAPERIELLO: Of a device used by a Part 30/40, and I am using the words of Part 21, which is the regulations that deal with vendors. You are not a licensee?

THE INTERVIEWEE: That's correct.

DR. PAPERIELLO: Most of what we have in our -- and a Confirmation of Action Letter is an agreement of mutual agreement of things that need to be done or will be done, not need to be done, but will be done.

Most of what is in there, in my view, is already a legally binding requirement under Part 21, because the device failed, and it had a potential consequence in terms

of the public health and safety, and, therefore, you are required to report the cause of the failure, and the like, in any event.

What we are trying to do is get the mechanism of this, and reach a common understanding on that. I understand that Dr. Shanbaky has discussed most of this with you?

THE INTERVIEWEE: Yes.

DR. PAPERIELLO: Can we proceed by Dr. Shanbaky reading you the letter that we are proposing to send you, and then we can change it to meet your needs

MR. SHANBAKY: Okay.

I am going to continue here with the discussion we had just a few minutes ago about the actions that you already did, or you will be doing in the immediate future, next days, maybe weeks.

What Dr. Paperiello just said that this Confirmatory Action Letter items we have here, most of them could be regulatory related or Part 21 related items, but the Confirmatory Action Letter in itself does not constitute an order, or any really strong binding document. This is an agreement between us as to your commitment to the NRC, and we are just documenting this so that everybody can keep track of what will be done, and when it will be done.

Like what we discussed before, these items on the

draft Confirmatory Action Letters will be preceded with a paragraph describing what happened, the stuff which you told me about, the break in the wire and the source leaving the facility here with the patient, and then other results.

THE INTERVIEWEE: Which was my understanding.

MR. SHANBAKY: Of your understanding, or you are partaking, or will take the following actions.

The first item I have here, Dr. Calfee is that the active wire for the HDR, and I am going to identify the HDR with the serial number and everything in the letter, will be tested to determine the probable cause or causes of wire failure.

Tests will be completed by -- and I put a blank here because we did not really iron out what is the dates for that.

THE INTERVIEWEE: Obviously, it depends on how long the series of tests are. We have reached the consultant this morning, just now, and he is supposed to be faxing his resume over here, I believe.

MR. SHANBAKY: Good.

THE INTERVIEWEE: I would guess that we should be able to have this data collected within two weeks.

DR. PAPERIELLO: Today is the 4th, and two weeks is the 19th.

MR. SHANBAKY: I don't have a --

DR. PAPERIELLO: Why don't we go off the record a minute.

[Discussion held off the record.]

MR. SHANBAKY: Getting back here to this sentence in the first item, tests are undated to be completed by December 23rd, 1992?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: The next item here is, prior to performance of the tests, Omnitron will provide detailed written testing procedures that includes the methods to be used and equipment for each test that will be performed.

So before we do that, and hopefully most of these are standard test procedures.

THE INTERVIEWEE: Okay.

MR. SHANBAKY: The next item, and this would be submitted to Dr. Paperiello.

THE INTERVIEWEE: For approval prior to the test?

MR. SHANBAKY: It is not for approval, it is for looking at them. If we have any questions, we will definitely get back to you right away, but not necessarily for approval.

The next item is, the NRC Staff or any NRC representative will be permitted to observe all tests performed. You will notify the NRC-IIT Team Leader, Dr. Carl Paperiello, of all intended tests a minimum of three

days prior to the performance of these tests. All test data, interpretation, and reports will be submitted immediately upon completion to the NRC-IIT Team Leader, Dr. Paperiello.

Is there any question about Item 3?

THE INTERVIEWEE: No. That sounded clear.

MR. SHANBAKY: Item 4, no tests, maintenance, operations, or any modification will be performed on the HDR unit without prior authorization by the NRC-IIT Team Leader.

THE INTERVIEWEE: That is this?

MR. SHANBAKY: This unit.

DR. PAPERIELLO: Just this one, and we will put the serial number of this unit in the top of the letter. It is just specific, this one unit.

THE INTERVIEWEE: They have been asking us to partially disassemble it in there, which we have been doing.

DR. PAPERIELLO: I don't want the machine returned to service, and I don't want it modified until we know.

THE INTERVIEWEE: Okay.

DR. PAPERIELLO: If you need to run tests on this machine, if you need to bring this back, let me know, and we will authorize that.

MR. SHANBAKY: The only thing is that you will be pulling the wire out of it.

THE INTERVIEWEE: It is already out.

MR. SHANBAKY: That's good.

This items is that Omnitron will issue a written notification/bulletin, whatever you call it in your system, to all of their clients, unit owners, and users of the HDR Omnitron 2000 Model describing the incident, and providing the following safety precautions, the stuff which we talked about during the interview. I need to reiterate this so that I can write it down here.

You already did this by telephone?

THE INTERVIEWEE: We have already done it by telephone. We called the customers who have active wires. We notified them that an incident had occurred where a source had been separated from a wire, and that we reinforced our recommendation that they monitor patients for radioactivity after any treatment.

MR. SHANBAKY: Monitor patients?

THE INTERVIEWEE: Right, after treatment

MR. SHANBAKY: After the treatment.

THE INTERVIEWEE: Maybe a better word would be to survey patients.

MR. LLOYD: Do a survey on the patients prior to release?

THE INTERVIEWEE: Right, instead of monitor, survey the patients.

MR. SHANBAKY: Radiological survey.

THE INTERVIEWEE: Right.

MR. SHANBAKY: Radiological survey of the patient after treatment and prior to their release. They will not be released without that survey. They will not leave, like what happened here, apparently they left. Is that what you told the users?

THE INTERVIEWEE: Yes.

MR. SHANBAKY: Anything else, any other safety precautions?

THE INTERVIEWEE: I don't believe so.

MR. SHANBAKY: Response to alarms, or looking at the CRT for any error messages, or anything of this nature?

THE INTERVIEWEE: The bottom line is, is there any radioactivity around outside the safe, and that is the bottom line most conclusive test you can possibly do.

DR. PAPERIELLO: I want to show you something else. When we send this thing to you, there will be another section on there that deals with legal boilerplate, and basically what it says, if you read the letter and you say, "Hey, this isn't what I understand," you need to let us know immediately.

If you can't -- I think we have fixed the dates, but if you can't make a date, let us know.

THE INTERVIEWEE: Right.

DR. PAPERIELLO: You see that last one, notify

when you have completed the actions, it would be notify me when you have completed the actions, and as I move around, I will provide you with where -- it would be probably best just to send it -- do you have an address of the Commission in D.C.?

THE INTERVIEWEE: No. We probably do in our files somewhere. Do you have a card with you?

DR. PAPERIELLO: No, I am afraid I don't. Do you have one?

MR. LLOYD: You can send that to our branch, which is the IIT Branch.

DR. PAPERIELLO: But he needs an address to send it to. It would be better for all the information to go, even though it is to my attention, it should go to you.

THE INTERVIEWEE: Why don't you put that in the letter?

DR. PAPERIELLO: That's fine. We will fix that and say that is where it should be sent, and put the telephone numbers, and all that.

MR. SHANBAKY: I will put to Dr. Carl Paperiello, and then I will put the address.

Also, one of the standards in here --

Have you finished, Dr. Paperiello?

DR. PAPERIELLO: No, I haven't.

The other thing is, even though we have a

Confirmatory Action Letter out, it is conceivable that the Commission will want to issue an order. If that happens, we will let you know. I can't stop them. People may change their minds.

At this point, this will achieve all the actions I think are needed at this point to diagnose the problem.

THE INTERVIEWEE: Very good. I don't have any problem with that.

DR. PAPERIELLO: Okay.

MR. SHANBAKY: This is standard language that will go out. It is in all of our Confirmatory Action Letters.

Also, this copy of this bulletin or notice to all your users, unit users would be submitted at the same time to the NRC.

DR. PAPERIELLO: We would like a copy of what you are sending out.

THE INTERVIEWEE: A copy of the notification?

MR. SHANBAKY: Right.

Once we get the laboratory who is going to be doing that test, we can take the wire and find the cause of it.

THE INTERVIEWEE: Absolutely.

DR. PAPERIELLO: So we will release the wire once know where it is going.

THE INTERVIEWEE: It will go to Houston first so

that we can just examine it closely under a microscope, which I don't think that would constitute testing, just looking at it.

MR. SHANBAKY: By the way, I forgot that we will try to put it in a fax to you today, but it will most likely it will be out tomorrow, so I need a fax number from you?

THE INTERVIEWEE: Okay. (713) 666-3531.

MR. LLOYD: Put it on your card.

THE INTERVIEWEE: Right.

DR. PAPERIELLO: Are we done?

MP. SHANBAKY: We are done?

DR. PAPERIELLO: We will go off the record.

[Whereupon, at 1:05 p.m., the interview was concluded.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of: Incident Investigation Team

NAME OF PROCEEDING: Interview of: Dr Richard Calfee

DOCKET NUMBER:

PLACE OF PROCEEDING: Indiana, Penn.

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.

Mark Mahoney

MARK MAHONEY
Official Reporter
Ann Riley & Associates, Ltd.