UNITED STATES NUCLEAR REGULATORY COMMISSION

In re: Roche Professional Service Center, Inc.
Docket No. 030-29240

An Enforcement Conference was held before Loretta B. Devery, Registered Professional Reporter and Notary Public at the United States Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, on Tuesday, October 2, 1990, commencing at 1:00 P.M.

PRESENT:
RICHARD COOPER, Deputy Director, DRSS
KARLA D. SMITH, ESQ., Regional Counsel
MOHAMED M. SHANBAKY, Chief, Nuclear Materials Safety Branch, Section A
RONALD R. BELLAMY, Chief, Nuclear Materials Safety Branch
JOHN E. GLENN, Chief, Medical, Academic and Commercial Use Safety Branch
WILLIAM H. SCHULTZ, Materials Section Chief, Region III
R. KEITH CHRISTOPHER, Regional Enforcement Specialist
JUDITH A. JOUSTRA, Health Physicist

(Continued on next page)

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ORIGINAL

PRESENT: (Continued)

JOHN KERINS, Vice President, Regulatory Affairs, Roche Professional Service Centers, Inc.

ROBERT J. ROSS, ESQ., Counsel for Roche Professional Service Centers, Inc.

ADRIENNE SHIRK, ESQ., Counsel for Roche Professional Service Centers, Inc.

JOHN H. WATERMAN, Director, RA/QA, Medi-Physics, Inc.

JANET REUTHER, Senior Associate, Medi-Physics, Inc.

NICHOLAS S. REYNOLDS, ESQ., Counsel for Medi-Physics, Inc.

PERRY D. ROBINSON, ESQ., Counsel for Medi-Physics, Inc.

MR. COOPER: My name is Dick Cooper. I'm the Deputy Director of the Division of Radiation Safety and Safeguards here in Region I, and I think there's a sign-up sheet going around that I'd like everyone to sign up on, and so that we know who we are, I would request that we just go around and introduce ourselves.

MS. SMITH: I'm Karla Smith, Regional Counsel.

MR. SHANBAKY: My name is Mohamed Shanbaky. I'm the Section Chief responsible for licensing and inspection of medical facilities and pharmaceu 'cals.

MR. BELLAMY: My name is Ron Bellamy. I'm the Branch Chief, Ncuelar Materials Safety Branch.

MS. REUTHER: Janet Reuther, Senior Associate, Metaphysics Pharmacy.

MR. WATERMAN: Jack Waterman, Director of Regulatory Affairs for Metaphysics, Inc.

MR. REYNOLDS: I'm Nick Reynolds from Washington, D.C., until last week with the law firm of Bishop, Cook, Purcell and Reynolds; as of this week with the law firm of Winston and Strawn.

MR. ROBINSON: I'm Perry Robinson. I'm also associated with Winston and Strawn.

MS. SHIRK: I'm Adrienne Shirk, an attorney with Hoffman LaRoche and I'm representing Roche Professional Service Centers,

MR. KERINS: John Kerins, Vice President, Regulatory Affairs, Roche Professional Service Centers.

MR. ROSS: I'm Robert Ross from Washington, D.C., and I represent Roche Professional Service Centers, Inc.

MR. CHRISTOPHER: My name is Keith Christopher. I'm the Regional Enforcement Specialist.

MR. GLENN: I'm John Glenn. I'm Chief of the Medical, Academic and Commercial Safety Branch in our headquarters.

MR. SCHULTZ: I'm Bill Schultz, Materials Section Chief, Region III. We have responsibility for Ohio.

MS. JOUSTRA: Judy Joustra, Inspector, Region I.

MR. COOPER: And coming on the line, if we can get him, is Dick Rosano, who's a member of the Office of Enforcement at headquarters. As you're

aware, I believe, this enforcement conference will be transcribed.

This conference is being conducted based on a special inspection that NRC Region I performed on October 23 and October 31, 1989 of licensed activities at Roche Professional Service Center in Nutley, New Jersey. Seven apparent violations were identified. We will shortly discuss each of those in turn, and as we do so, I'd like you to address several items. The first of which is whether you admit or deny the violation. Secondly, to comment on the accuracy of the facts as we've described them, to add any new information that we don't have that may pertain to each of those and to also discuss any mitigating or extenuating circumstances that may pertain. Thirdly, to identify, if you can, the root cause of the violation; and fourthly, to address any corrective action that you have or will be taking to prevent reoccurrence of the violation in the future.

We will want to concentrate during this conference on the management controls that were in place at the time of the violations that in fact allowed them to occur and whether and to what extent those controls were at fault in allowing the

violations to occur.

Included in the seven apparent violations is one against 10 CFR 30.9 which requires that information provided to the Commission by licensees be complete and accurate in all material respects. The Office of Investigations report that you got a synopsis of in your report, in our letter to you, concluded that the then manager of the Nutley, New Jersey facility made inaccurate statements to an NRC inspector. This issue as it affects the individual will be the matter of a separate activity or proceeding and we do not intend to discuss that at this meeting. Rather, we will discuss that apparent violation as it affects you, the licensee, at the time. And we will consider that discussion and the violation in those terms in our deliberations both on that violation as well as the other apparent six violations.

MR. KERINS: Can I just make a statement? You referred to Nutley, the site is Philadelphia.

MR. COOPER: I'm sorry, I stand corrected. Please make the record reflect that. We expect a high standard of compliance by our licensees, and they're charged with taking prompt and extensive

action, in the event that we find that not to be the case. We expect licensees to be forthright in their dealings with the NRC and candid and open in their discussions, and that's especially important during enforcement conference such as this.

At this point, I'd like to throw it open to you folks to provide any opening remarks that you'd like to make.

MR. KERINS: Well, one thing I'd just make a comment, we had hoped David Gallaher, who was the Vice President for Operations for RPSC -- he couldn't be here today. There was a death in the family over the weekend, so he got tied up with that. So he apologizes for not being here.

We've read the potential violations, and I think that we have some issues that we can talk about. I think some of the action plans essential to that we'll discuss today and some of our investigational findings were discussed in the November 21st meeting that we had that RPSC called with management here at Region III.

MR. ROSS: Region I.

MR. KERINS: Region I, excuse me.

MR. COOPER: That's okay. With that,

before we step through each of the apparent violations, I'd like to get someone to describe to us the organization as it existed at the time of the violations back in 1989, specifically the relationships of the then facility manager to the upper level management. And in addition to that, describe if there are any differences, how that organization is different today.

MR. KERINS: Well, specifically at the time that there was a manager at the site, who if we're referring to Miss Fire, that she was also coming into the site, but immediately prior to that, the manager was also the RSO, which is in most cases in all our facilities. That that person reported then for operational issues into the Regional Manager for Operations. From a regulatory prospective, the corporate group had a VP of Regulatory Affairs, which is myself, and specifically associates that dealt specifically with nuclear pharmacy issues. My group was not specific to nuclear activities. I also dealt with other regulatory agencies as part of that responsibility.

As it exists now, that the manager at the site exists, but that is not -- she is not the RSO.

It's a separate appointment. That was made back as part of the action plan. I don't have the date exactly in hand, but the organization as it exists with the licensees, my position still exists as the VP of Regulatory Affairs. The sale of the company did take place on June 13th, that Janet Reuther, who was the associate directly working for me now is an Amersham employee. And subsequently she was appointed as corporate RSO for the Philadelphia site.

MR. COOPER: Does the RSO who is now separate from the facility manager report to the manager or report to the corporate RSO?

MR. KERINS: The direct line is to the manager, but one of the things that we found in the initial investigation is that there really wasn't a good comprehension at the Philadelphia site on what the regulatory group in corporate was responsible for, and that was the subject of training both back in November of last year and then subsequently that Miss Donnel had some very specific training, I believe in Novemb that Janet conducted. And that some issues that we've discussed with the facility back during the November, early November period, to discuss roles of responsibility and adherenc to compliance

regulations.

MR. COOPER: Okay. With that, I'll turn it over to Mr. Bellamy and Miss Joustra to step through each of the violations and we'll discuss the aspects of those as I previously discussed.

MR. BELLAMY: Before Miss Joustra walks through the violations, I'd just like to acknowledge that we have received the September 28, 1990 letter from Mr. Jack Waterman, and that reflects I think what pretty much has been discussed in terms of organization, the fact that during the time of the inspection in October of 1989, that Roche Professional Services, Inc. was the licensee in question and it was under their management that we are talking about the apparent violations today. That the sale of the company did occur in June of 1990, and that Medi-Physics, Inc. does acknowledge that they stand ready to insure that any corrective actions that are committed to or we agree upon either today or in the future will be their responsibility to follow through on. And we do have that letter and NRC staff here today has reviewed it and I will ensure that it is put in our docket file so it will be a part of the record.

With that, I'd like to ask Miss Joustra

to walk through the seven apparent violations and give you an opportunity to respond to each of them in turn. Judy?

MS. JOUSTRA: What we'd like to do is go through each of those items as they appear in the report. We'll not go through each example of those, but just to state what the apparent item of non-compliance is. The first item appears in section number 3 under Training Audit Program, and basically it's a failure to provide training as required by Appendix C of the regulatory guide. And that's an apparent violation of Condition 23 of your license. This is training provided to the staff at the facility. Would you like to address them one by one? That would probably be the easiest way, I guess.

MR. KERINS: Acknowledging that, I think we were aware that -- I didn't attend the closing inspectional summary at the time, but we're aware that the inspection certainly did turn up some issues of deficiency regarding training. That I think since that time we've taken a couple different actions regarding that. There have been a number of training sessions that have been held at the site. I think the corrective actions, some of them involved the

responses that we presented in the November 21st letter, that I think they're symbiotic with all of these issues essentially, but training specifically there was -- there are cases that like in November 27th I mean -- yes, November 27th, I think Janet Reuther was at the site, that we committed in that action plan that we would have someone there the week of December 4th. And I think we discussed key issues or licensing issues at the various bullets that I think we presented in the November 21st letter, facility and corporate organizations, lines of communication, management expectation of candid responses to regulators, dealing with regulatory inspections and specifically policies and procedures for employees and authorized users dealing with drawing doses.

During that period that also some training was done with Miss Donnelly who was the new RSO, as far as formal training for her in the RSO responsibilities, and then also there was training with some of the staff regarding constancy checks. That is notable I think. Those are the key items that was addressed at that.

There have been other training sessions

in January, some specific training that addressed for instance the surveys of personnel, that was handled in a training session, that was done on January third, which also included the annual requirement for retraining of personnel.

MR. SCHULTZ: Who conducted those audit sessions?

MR. KERINS: The week of 11/27 was Janet -- Miss Reuther. The 1/3 was done by Miss Donnelly, the RSO.

MR. COOPER: I understood that you had had an outside or independent consultant come in and do quarterly audits, I believe three a year, and internally you did your own fourth audit for the year.

MR. KERINS: Right.

MR. COOPER: And as the inspection report discussed, it appeared that training was raised as an issue in some of those audit findings previously. I'm interested in knowing for how long was the training issue an audit finding from the independent auditor and why was it that that continued to be an issue up until the time of our inspection.

MR. KERINS: Well, I can't give you a specific date of when it started to appear. We've got

to look at the audit reports. It was brought up. I think there was one very specific issue that was the subject of some correspondence back and forth from Miss Moore, who was the outside auditor, and ourselves, and that was regarding this training of a technician to draw doses.

There was a letter that she published that was in the file, I'm not sure whether you observed that record or not, but regarding technicians. It was very specific and it also talked about countermanding of her orders to not have the technician drawing. We subsequently met with Miss Moore, myself and some operations people met with her, and disagreed with what she was saying, that there was no countermanding that went on.

That Miss Moore and the site RSO had actually worked on an outline for this technicians' training. The RSO at the site at that time had actually completed that and so when she made that -- completed that training, she in fact says as management whether it would be appropriate then to go back and have this person trained. We didn't think it was an end-all, but certainly that was the first step to have her drawing doses. When the training was

done, we agreed and we allowed that person to help draw doses.

There was also -- it was Miss Moore's interpretation that that person should be an authorized user and that that person should have credentials of a pharmacist. We disagreed because in pharmacy law, interns and technicians is an established art that existed, an authorized user, not necessarily because we hopefully had an authorized user on site at that particular time when the technician was drawing doses, both under the supervision from a pharmacy perspective and a nuclear perspective, radioactive material handling.

MR. COOPER: So that what you're describing then is the training issues as far as her audit findings were fairly well focused on the authorized user issue you just described plus the technician drawing doses.

MR. KERINS: Well, the technician drawing doses was definitely very focused discussions, that the auditor had a very specific report to file regarding that. And I think we had a subsequent meeting about that. I think she felt comfortable. She felt that there were going to be more training. I

think she had thought that we had completely told the RSO to have the technician in fact draw doses and that was not the case at the meeting. The RSO admitted that wasn't the case at all. So I think there was some miscommunication between the auditor and the site people and even ourselves, and she wasn't able to get a hold of me and that's why she wrote the letter.

Training was brought up in the issue in some of the audits. From our perspective, from the corporate perspective, we thought that there was appropriate action being taken in resolving all of the issues, not just training, but other items that were being brought up. Miss Moore was the outside auditor of record on the license, had been the auditor for a number of years. Because of her time constraints, she was asking to not perform as many audits. That's why we had actually brought in some of our local SAT team. Medi-Physcis had a SAT team composed of essentially radiation safety officers throughout the organization that would come out through that program.

Janet, I would throw out did we ever do -- did RPSC ever do an audit before October? I think they were all done by Miss Moore, weren't they? Do you remember?

MS. REUTHER: We did one in September just before -- I think, I'm pretty sure -- yeah, in September, just before that.

MR. ROSS: This is September '89?

MS. REUTHER: I can't say for sure. I'm pretty sure it was September of '89. We did one that year.

MR. COOPER: The SAT team that you just described, is that the same team that was doing some of your audits independent of Miss Moore's responsibilities back in the '89 time frame, or is that a team that's different from the group that was doing internal auditing before?

MR. KERINS: Well, the personalities may have changed, but it's the same team, if you will. This was a conglomerate of people both from the Roche Professional Service Center, Inc. corporate as well as Medi-Physics, and actually primarily Medi-Physics employees. That radiation safety officers at some of our manufacturing sites were going out as a team, but then there also was Janet was part of that team, and also a health physicist that we had at one of the RPSC sites was participating in that.

MR. SHANBAKY: Did the September audit

require the same training of the technician?

MS. REUTHER: No, it didn't.

MR. SHANBAKY: Did it identify similar problems?

MS. REUTHER: It identified, without going over it in detail right now, I haven't read it in awhile, but I think they did mention some things about training could be improved, but it wasn't --

MS. SHANBAKY: Can you give us some specific recommendations the audit made to improve training?

MS. REUTHER: No, I can't, not right now.

MR. BELLAMY: Is there now a tracking system or a management information system in place that would tell me who has received what training, when and whether these people would be up for their next annual cycle of training?

MR. KERINS: There's no -- certainly no -- I can't talk for Amersham, but certainly from RPSC, there was never no corporate system set up that was delegated down to the responsibility of the site manager and the RSO. And as of such to this day no, we didn't have a specific corporate training. We had recognized that the RSO as being a specific issue that

came out of a Region III issue, so that there was specific training given to Miss Donnelly as a result of those commitments.

MR. SHANBAKY: Did you do any additional audits since September '89 audit?

MS. REUTHER: The SAT team?

MR. SHANBAKY: Yes.

MS. REUTHER: No. I don't want to say that, I'm sorry.

MR. KERINS: Well, there were audits that were done. There were outside audit done. Whether they were done by the SAT team or whether they were done by an outside consultant, yes, that one of the people that we contracted with was -- Janet, Terry's last name?

MS. REUTHER: Vaughn.

MR. KERINS: No, I can't think of the name right now. It will come to me. I can give you that, but certainly there was an audit and in --

MS. REUTHER: Terry Verullo, I'm sorry.

MR. KERINS: Yes, thank you. That conducted an audit, outside auditor's type of inspection. Also in response to the November issue, that Janet was at the site for a considerable period

of time. That again as per the November letter that she was at the November 5th, 6th, 7th meeting that we had. I think Janet was essentially down at the site for a couple of weeks at that point, and then as per commitments the next three months, that she was at the site for five days for general corporate oversight, auditing, training the whole gamut of follow-up.

MR. SHANBAKY: I take it Miss Moore is no longer doing audits for you?

MR. KERINS: Correct.

MR. SHANBAKY: As of when?

MR. KERINS: It's only an estimate. I know Miss Moore said that her time commitments were such that she couldn't fulfill the needs, that she was backing out of the program. I would have to say, it's an estimate that around March or April.

MR. SHANBAKY: 1990?

MR. KERINS: Yes.

MR. COOPER: If she had been finding and questioning things whereas your -- from what I've heard, your internal audits have not resulted in any types of major findings or issues that I've heard here, what now gives you satisfaction that if you continue with the SAT team activity, which basically

is an internal audit, that you're going to get what you need out of that activity, that is an objective inspection of the activity?

MR. KERINS: Well, we're not relying specifically on the SAT team. And I think that there probably was only one audit that was done by the SAT team. So per the two issues, the person that did the SAT audits, I mean we discussed the issues of technician training and things like that, that was a specific issue with Miss Moore, and you know, we felt that we were right from the point of view of where we decided. And you know, we told Miss Moore that in the meeting that we did not think that that person would be, quote, an authorized user. I mean the auditing -- we've continued some auditing over the areas, that it still is a commitment to do that.

MS. JOUSTRA: At what frequency would you be doing those types of audits of the entire radiation safety program?

MR. KERINS: Well, I believe that it was still set up as a quarterly type system.

MR. COOPER: You just alluded to the fact that you wouldn't rely solely on the SAT team for auditing. What's the other --

MR. KERINS: An internal auditor like Theresa Verullo, that was the auditor. I know she's conducted at least one audit. I believe it was April that she conducted an outside audit.

MR. COOPER: Previously you had three outside audits and one, I believe, internal audit for an annual total of four. How are you going to do that now?

MR. KERINS: Well, I mean at this particular juncture, it's -- we're not exactly sure how to deal with this right now. That obviously since the acquisition, that all of the employees of Roche Professional Service Center went over to an Amersham organization. I think dealing with corrective actions coming out of some of the specifics that are identified here, and as a result of this meeting, that working with Amersham Medi-Physics PSI, with Jack Waterman, I think working with him to work between the two organizations until the license is transferred.

MR. COOPER: Are you prepared to comment at this time, Mr. Waterman as to what you might do in an audit area, or is that going to be something that you'll be discussing when you make commitments later on?

MR. WATERMAN: That's right, we certainly will review everything that comes out of today's conference and form some plans, we'll get back to you definitely.

MS. JOUSTRA: In relation to that training issue, we've come across in my inspection and over some audits would be training records. Have you now established good record keeping system for those who have had training?

MR. KERINS: The record keeping, it certainly was revised, because it recognized -- and I think there was some thought that some of the training that we thought was accomplished that we just could not find the documentation and clearly that was reorganized, the training documents.

MR. SHANBAKY: Do you have any administrative procedures to organize and control the training on established frequency and schedules and something which somebody can take and just execute and you'll be okay on training?

MR. KERINS: We don't have a formal package. We were working on a package that was drafted for a formal program. Many of the programs we were using the radiation safety manual as the vehicle,

the text for it. As far as the frequency of doing the training, that we really wanted to assure that we were within the licensed conditions and depending on the individual, more or less based on that.

MR. SHANBAKY: Do you have things like lesson plans or material the instructor used to provide the training?

MR. KERINS: We have some specific plans that were developed that were used. It's not an intact package for training that's, you know, off the shelf type of program here for training a technician. There are some specific items, check lists that we have prepared.

MR. SHANBAKY: Are you looking into coming up with something more comprehensive, or do you feel that this is working adequately for you. I'd like to hear your feelings about this.

MR. KERINS: I think the whole thing, it certainly didn't work as effectively as we would like. I think at this perspective, that again we're looking for the future, that since the resources are not currently available with the transfer, that we can look at this and we can help I think recommend some procedures to the Amersham people. But the company

was sold to Amersham.

MR. SHANBAKY: Maybe this is a good time to ask the question now. What would be the interfaces between you and Mr. Waterman and any turnover of outstanding issues, facility problems, facility improvements that you've had like to essentially transfer to Mr. Waterman, how this process is working now and whether it is -- there is a plan to do this or --

MR. KERINS: Well, there was a plan for the license transition. I think some of the key issues, for instance the Philadelphia incidents, that at an outstanding incident relating to the Philadelphia license was transmitted, it was communicated to Mr. Waterman, he was aware of that. At the same point we were dealing with it because the license was still in our name. Primarily that the interaction I think has been with Miss Reuther because she was a member of my group and also brought in the continuity into that group.

MR. COOPER: Normally in putting corrective action in place you would like to target what the perspective or perceived root cause was so that it matches and corrects that cause. What in your

estimation is the root cause of the training deficiencies that existed in the '89 time frame?

MR. KERINS: Well, I think they were in different planes. Certainly there were communication issues in regard to some statements, some of the reactions I think to the technicians not understanding what our responsibility was that in some cases that we had made decisions, for instance the decision to interpret 35.27 for the visiting authorized user status, that specifically, that was my decision that I thought that was an appropriate interpretation. That was not Miss Fire's or anyone at the sites, in talking to the sites, they really didn't know who we were. That was a training communication problem in itself. That retroactively that we would want to improve that. I think the basic program management, that we feel that the RSO is responsible for the day-to-day maintenance of the program and certainly their immediate supervision in the form of regional managers or operations and certainly at corporate level there were people to contact.

MR. COOPER: Okay, does anybody have any more questions on the training, apparent training violation? Let's go on to the next one.

MS. JOUSTRA: The next item appears in section 4 of the report under Radiation Protection Procedures, and that's the apparent failure of drivers to monitor their hands and clothing. This was obse ved during the course of the inspection on a number of occasions and is an apparent violation of Condition 24 of the license.

MR. KERINS: We have reacted to this, I think at the time back in November when I was at the site, that we've improved some posting considerations with all of the drivers to rake sure that they were aware just from sight that they had to monitor at the back door, which is the primary area of egress and then, in the January, training that was conducted and repeated for drivers, that that was also a specific aspect as far as monitoring themselves before going in and out of the laboratory restricted area.

MR. COOPER: Have you done any monitoring of their activities between the time of the inspection and now and have there been any other instances of these folks not surveying as they're required to do?

MR. KERINS: I have not specifically been at the site since January when I met with Miss Colangelo who returned to the facility. I did discuss

the issues, we've had audits and to some extent since the beginning of the year that Miss Reuther would have been at the site a couple times.

MS. REUTHER: I didn't see anything.

MR. COOPER: Does anybody have any further questions or comments on that particular one? Okay. Let's go to the next.

MS. JOUSTRA: The next item appears in section 6 of the report under Use of Licensee's Radioactive Materials, and this is the apparent failure to have an authorized user physically present when authorized material was being used. This is an apparent violation of Condition 12 of your license.

MR. KERINS: There are two specific incidents that occured in regard to I believe the October 23rd incidents. As I previously mentioned, that from the corporate side I had interpreted -- made an interpretation of the visiting authorized user status, that that was an appropriate vehicle to use. And in fact, if your observations, as I understand it, Miss Joustra, is that that was a specific event that she was an unauthorized user, I think Miss Fire was acting under my direction that that was an appropriate mechanism, for her to be acting as an authorized user

at the site, because she was an authorized user at another site and had been, you know, approved already with NRC and some agreement state licenses, that that was an appropriate mechanism. So Miss Fire should not be in any way I think as far as that specific event of being asserted that that was her decision. That was not the case, that was my decision.

Regarding the September 17th incident, that we found out is part of the investigations that, as noted in November 21st meeting, that when we became aware of this, the full details of this, we were called to the meeting with the NRC, we discussed what the issues were, what the findings were, and we reported that to you all and developed that action plan with that. We were not aware of the September 17th incident in advance. Management, whether it be operational management or myself or Miss Reuther, we certainly were not aware in advance that that was -- that there was going to be a scheduling problem on that specific date.

I think a decision was made that with the patient in mind to have an activity done, but -- and I recognize that it is obviously an unlicensed activity, but we did not have prior notice of that.

MS. JOUSTRA: If you had prior notice of there being a scheduling complication going on with I guess with Becky Fire and the person who the conflict was going on with, the other person that was scheduled to work there, did you have a mechanism at the time to initiate like an on-call if there was an emergency so you could still keep the facility functioning?

MR. KERINS: Not on-call. In some cases we would close down or we'd actually refer our orders to a competitor. And I know since the incident that we have actually closed the facility down when we had a coverage problem.

MR. COOPER: What was the root cause of that problem do you think.

MR. KERINS: Well, the October 23rd situation?

MR. COOPER: The September 17th one. I understand the other one.

MR. KERINS: The September 17th, I think it was a decision that was reached individually by Becky that -- Miss Fire, to put the patient's care first, that she recognized that she understood that the technician on shift was generally qualified to draw doses, because in a hospital environment they

routinely draw doses, so that there would not be a compromise in patient care at all. She did not contact regional management or myself and said that we have a problem. I think she was hoping too to the last minute that the pharmacist that was on duty would stay until all the doses were drawn.

MR. COOPER: Looking beyond that though, there was only the one pharmacist on duty who was an authorized user, as I understand it, at that point in time, and that necessitated, when he left Miss Fire trying to get there in the meantime, which sounds if you step back from it like a staffing problem, like there weren't enough authorized users at the time associated with that facility, that if one left and that was the only one, you had to either shutdown or refer the business to a competitor. Is that a valid observation. And if so, what have you done to fix that?

MR. KERINS: In part I think it's valid. I think September 17th was a weekend. It's not an established shift that you have full coverage like you would on a Friday. It's essentially on an on-call type of basis. There are some routine orders that come in every Sunday, but they would come in, they're

stat emergency calls.

In regard to training, training has been an issue that we have tried to work with recruiting. Training radiopharmacists was a problem. We tried very positively I think to actually work with some universities with their pharmacy programs, like Purdue University, work with them to attract their people and have them come into the organization at various sites. Two of the people at the Philadelphia site came from that program. They were also recently new. And were not -- one of the individuals was not a user yet of record, that that amendment had been submitted back in I think September 20th to add some people to the users list. So that I think there was a critical issue just at that time with authorized users. Miss Fire had accepted a transfer to Philadelphia, so she was in the process of moving anyhow, and then a specific incident came up on the 17th.

MR. COOPER: Do you have any facilities including the Philadelphia one today that are somewhat understaffed from the standpoint of authorized users' availability?

MR. KERINS: Well, there is a shortage of radiopharmacists, authorized users. We've added

people to sites as much as people, we've also added -- tried to update licenses with enough back up from different licenses. The Philadelphia site, the last amendment that was approved, and we included other people onto that license from management, other sites, to see that they could work if there was an issue, and we did have that happen right after the November incident that brought people in from other sites.

MR. COOPER: So just to clarify, if today there was one authorized user at Philadelphia, and for whatever reason he or she had to move elsewhere to cover another facility, the people at Philadelphia understand that they either shut the facilities down or refer the business elsewhere?

MR. KERINS: I think their understanding clearly is that they would call corporate management and raise a concern that this was going to be a problem, that they couldn't operate because there was no authorized user. And certainly if that was a pharmacist, they would not be preparing doses or handling radioactive material.

MR. BELLAMY: You're not aware of any time since the late fall of 1989 where there's been operations at the facility without an authorized user?

MR. KERINS: Well, we have -- subsequently we became aware of the Cincinnati facility that issues -- that we determined at that site that became available which we reported to Region III that actually that involved not Miss Fire but some other representatives at the site. And I think that we copied -- I know we did we copied Dr. Bettenhausen at the time of those incidents. So yeah, there have been incidents. Now they've -- some of those incidents were at the same time, some of them were before, and then I think that we had subsequently had some other transgressions at that site because there was two issues. There were pharmacy issues at that site and nuclear issues primarily. It occurred before that, we're not aware of any before the Philadelphia incident.

MR. BELLAMY: But no others at Philadelphia?

MR. KERINS: No, correct.

MR. SHANBAKY: Assuming that 35.27 would apply, and I don't think it does, is Miss Becky Fire a registered pharmacist, and that's the first question, and in Pennsylvania?

MR. KERINS: No, she's not.

MR. SHANBAKY: Does the Commonwealth of Pennsylvania require a registered pharmacist to run this facility?

MR. KERINS: Yes. Well, not to run the facility, certainly for dispensing doses, to dispense prescription drugs.

MR. SHANBAKY: So even assuming that 35.27 applied, what happened was potentially in conflict with the Commonwealth of Pennsylvania requirement.

MR. KERINS: There was a dual licensing problem for the September 17th issue. I think earlier issues or October 23rd issue that we had two people on, that we would have an authorized user on shift and then we'd have a pharmacist that was licensed by the State. But particularly for the September 17th, Miss Fire was not licensed by the Commonwealth for her pharmacy license. And we did report that to the Board of Pharmacy. I'm not sure of the exact dates, but I could look it up right after our meeting, because that was a topic of the November 21st meeting that we were going to notify the Board of Pharmacy, and we did. I think a copy of that was actually sent to the Region. I have a copy of it.

MR. GLENN: Could you clarify about -- it would be my understanding that Pennsylvania would require that a pharmacist be on site at all times when dispensing drugs, so you have a dual responsibility for an authorized user and for a pharmacist?

MR. KERINS: Right, that in some sites that -- as in an interim period, that we were using -- that say Miss Fire could dispense doses under the supervision of a pharmacist on site, forgetting about the authorized user situation, but under pharmacy practice.

MR. COOPER: In your opinion, would any increased corporate oversight of these satellite offices, in this case the Philadelphia office, have prevented or mitigated this from occurring?

MR. KERINS: Well, yes. I think if we -- I think we relied somewhat too much on the site actions and the outside auditors and thought that they were being resolved. I think there had been a previous inspection by the NRC and there were no items of violation for that. We recognize what that means. So that certainly addition of more oversight by corporate group or upper management I think would have been beneficial.

MR. COOPER: After this event in late '89, from then till now, have you instituted any type of program that would have provided that additional oversight?

MR. KERINS: Not specifically. I think in Philadelphia that we committed to a number of very detailed amount of times that we were going to visit the sites, get back on track, committed to times when various people were going to be at the site. Part of this, as per the commitment, is that we asked that Janet be officially titled corporate RSO for the site. We changed the RSO from Miss Fire, although she really was never made RSO, but to a separate individual.

MR. COOPER: Do each of your facilities have a separate RSO and facility manager?

MR. KERINS: No. I think primarily it's the opposite, where the manager is the RSO. There are some cases that it exists. Cincinnati is another example of site -- Janet, other sites that I happen to know, there are other sites throughout the organization that are separate.

MR. COOPER: So the increased oversight that you provided was only relevant to the Philadelphia facility?

MR. KERINS: Correct.

MR. COOPER: Is there any reason why you didn't consider that across all facilities?

MR. KERINS: Well, I would take that back. I guess that's also because soon thereafter we also became aware of the Cincinnati incident, so that we also addressed some issues there. I think very specifically we were -- we did not recognize that personnel licensing would be an issue. That certainly the audits were not designed, any SAT audits, that we did not specifically design that as criteria to look for. We did direct two things that we had issued in February, that a result of both the Cincinnati and the Philadelphia issues was that there was a directive that went out to all of the managers of all the pharmacies clearly indicating our expectation that all licensing be held, whether it's pharmacy licensing issues, whether it's site licensing issues, whether it's individual licensing issues, whether nuclear or pharmacy-related, and that clearly that we wanted to know if there were any scheduling problems and that we would react to that or deal with that. So we took that -- I think February 26th a directive went out to the staff.

Secondarily is that I had directed then to the SAT auditors that specifically they look at personnel licensing. That's because, as I said, I don't think we were attuned to specifically looking to see that on a specific date when doing an audit was the pharmacist's license, both from a pharmacist and an authorized user type of perspective, but directions were given to certainly include that in the auditing finding.

Well, there was an expectation on our part, the corporate part, that we expected all people would be working within their personal licensing requirements, whether pharmacy or nuclear-related, and we reiterated that expectation. That was expected that they work within all bounds of their own professional licenses or licensed conditions.

MR. COOPER: Any other questions on that issue?

MS. JOUSTRA: The next item appears in section 7 of the report under Instrumentation. Actually it would actually appear in that section. The first one we'll deal with the dose calibrator constancy check, and the fact that it exceeded plus or minus 5 percent of the acceptable value.

MR. KERINS: We did recognize that there were -- in looking back at the records, there were some cases that it exceeded 5 percent. Again, in retrospect, we thought this was part of the program management that it would be addressed at the local level. Since that issue that we did have specific training, that at least to not only recognize that 5 percent was the limit for constancy check, but that there is appropriate action if it's above 5 percent, whether it's re-calibrating, whether it's redoing reassay, and that was discussed with a number of both the professional and technical staff, if you will, in a training session back in November specifically regarding that issue.

MS. JOUSTRA: Is it still going to be -- is it site management to oversee that?

MR. KERINS: I think we have certainly the front line of compliance is at the site and with the RSO. I think that if there's an issue of program management, that's certainly their responsibility. I think that if another issue came in, for instance visiting authorized user, more esoteric, if you will, or interpretative of the regulation and corporate could be involved in that, but program management,

these are the requirements to do the day-to-day routine safety program, that's the expectation of local management.

MS. JOUSTRA: But if they find a problem with any of those areas, are they to contact corporate?

MR. KERINS: Well, they can do it within themselves, depending on the issue. Obviously if there was a major problem, we would hope that they would contact us and maybe ask for which way to be investigated or what actions to take. I think we've had a case where we've shipped in an ion chamber because that was necessary because of a problem on another site, not Philadelphia.

But part of the training that I think is that if it's 5.2 percent on constancy check, what do you do, you go back and reassay. You look at the calibration. You may have to recalibrate. There are numerous ion chambers at the site in Philadelphia, for instance, so you could shut one down. It's not ideal productivity and efficiency type of thing, but certainly there are remedial actions that can be done.

MR. COOPER: Does your audit program currently cover looking at this type of issue?

MR. KERINS: The audit program specifically looks at all of the routine management type of things. And I think constancy is a line item on there to check, as would be linearity and all of the routine type of checks.

MR. SHANBAKY: What was the cause again of missing the 5 percent, the cause of --

MR. KERINS: Well, I don't have an answer for you on missing it. As I understand, it was done, but it had exceeded 5 percent.

MR. SHANBAKY: Right.

MR. KERINS: I think it was a training issue that the site people that had performed it didn't know what to do at that, and so it was just recorded in the book as being over specifications and no remedial action was taken, investigative type of actions were taken.

MR. SHANBAKY: Who had the responsibility of reviewing the books to make sure that things are done right, that's the day-to-day?

MR. KERINS: Routinely it would be the RSO at a site, that we would expect that the RSO would be reviewing that. In some cases the RSO does a considerable amount of those checks, but it doesn't

necessarily have to be that a person is doing a particular -- the RSO does all of the specific radiation safety program assays, surveys, etc. That could be delegated to a technician, a pharmacist on a shift. Certainly an RSO would only be on one shift a day, and based on vacations wouldn't be there that day. So the authorized user would be responsible, in an RSO's absence be directly responsible for that activity.

MR. SHANBAKY: So I'm trying to understand if this is a technologist or technician training problem that they were unaware that when they exceed the 5 percent they have to do something about it or it extended beyond the technician, it included the RSO and the authorized user and the people who reviewed the records.

MR. KERINS: Well, I am not sure, but I know from the review of when we went back in November, we did include the professional staff too, the pharmacists that specifically, that it wasn't just directed to the technicians, that a number of people were brought up on constancy on how to specifically deal with greater than 5 percent deviations.

MR. COOPER: Short of the training, are

there any procedures that tell the technician or the pharmacist that if in the event that they're doing this check and they exceed a certain value that this is the action you take, or is it just verbalized to them in the training forum?

MR. KERINS: I'm not sure whether it's in the safety manual.

MS. REUTHER: The license application has all that in that.

MR. KERINS: So the action plans would be in that.

MR. COOPER: But what's your expectation of a technician or somebody like that actually breaking out the license or using it in his day-to-day activities?

MR. KERINS: Well, actually part of the training comes from the license. We use the license as this is the requirements, that rather than having some procedures that are site specific or generic that could be different based on state or regulatory functions, we had elected to use the license itself as kind of the goals for the established requirements.

MR. COOPER: But are the people trained that if they have a question that they know where the

license is and they can put their hands on it and read it and understand it or is it hidden away somewhere where everybody probably doesn't even know where the thing is if they need to refer to it?

MR. KERINS: The expectation that it's easily accessible. In Philadelphia I think it's accessible. That I think there's specific training where it is, what specific parts are related to the individual that they should be aware of and in fact where the license is. So that I would say yes to that question.

MS. JOUSTRA: Have you established maybe sort of a cookbook for the daily procedures so they can follow it easy enough during the course of the day if they were to come across say a test that exceeded the proper levels rather than going back and go through the entire application?

MR. KERINS: We were in the process of putting together a whole training document. I think that was just more formalized than using just the licensed condition or any amendment, and I think Janet, you finished that.

MS. REUTHER: Yes.

MR. KERINS: And that, you know, has been

used and been offered to all of the sites as a vehicle for training.

MR. SHANBAKY: Not taking action on 5 percent measurements, above the 5 percent, you said that is most likely due to training of the technologists and maybe other personnel. And if it's a training or was a training problem, how will you make sure that that training you give actually took? And what I'm saying is how you insure or you assure yourself that before you put the people on the floor doing the work they are capable of doing the work, including all of the regulatory requirements and the technical requirements for that position?

MR. KERINS: Well, I mean we assume that the training is appropriate for the types of specific work that the individual is doing, that we have actually assigned some tasks very specifically only to key people, like assays T-I monitoring. For instance, I believe at the Philadelphia site that there's only two people that have been trained to do that besides the pharmacists. And that's one way of just to control that. So those two people would have gone through some kind of training session.

It should be taught initially in the

training. Obviously if there's questions or we're hopefully not leaving the people in a hole as far as frequency, a lot of this was planned into the computer system. That constancy check is also into the computer system, but the computer menu was driven so that a lot of the periodic checks, like the linearity check, that a flag comes up and tells you that the check is to be done, that the manager, the RSO that are following up on that. It's two-stage. I mean, one, that the individual performing his duties should be cognizant of what needs to be done. The second stage is that literally if there's a question, that he can go to a manager or RSO or any other user or qualified individual and find out what to do about it.

MR. SHANBAKY: What I was getting at do you give any exam after you give them the training or a quiz to make sure that they absorb the material and they demonstrate to your satisfaction the knowledge needed to perform their functions?

MR. KERINS: Not generally. There are certainly techniques that we have discussed, exams for instance reading meters, how to read a meter, that I'm not sure whether that was in place in Philadelphia at the time.

MS. JOUSTRA: It was.

MR. KERINS: That has been a technique developed by one of the managers at another site and that is used at all of the other organizations as a test, but universally, no, we do not test on every specific aspect

MR. COOPER: Does the training include just verbal instruction or is it practical factors and demonstrations to the extent that each individual student would be asked to demonstrate on the equipment that he understands how to operate?

MR. KERINS: I think it's a little of both depending on the particular issue. Certainly in some cases it's going to be a verbal review of issues. In certain cases, surveys, it would be a hands-on type of demonstration.

MR. COOPER: Anymore on this item?

MS. JOUSTRA: The next item also appears in the same section, and it has to do with the linearity test in not meeting the required frequency for that test to be performed.

MR. KERINS: As I understand, on the 23rd that when Miss Joustra was in, that the linearity check was late, the quarterly linearity check was

late. Specifically in that area, that we did initiate it, I think that was observed on the 31st when you came back, that it was in process. It was subsequently completed and acceptable. And subsequently has been done quarterly.

MR. COOPER: Let me understand something. Did I misunderstand you to say that at the time or just prior to the inspection by Miss Joustra, that you yourself had recognized the lateness of this check and were in the process of doing the check?

MR. KERINS: No. We were not aware of the check. It would have come up on the facilities system, the computer system. I think -- I believe it was identified in the October 23rd inspection that it was late, and I think site personnel initiated within that week that completing of that linearity check which I think was confirmed on the 31st. Whether it was complete at that point or subsequently complete, I'm not sure at this point.

MS. JOUSTRA: There was some discussion as to whether it was going to be completed then or at a later date. I don't know if they were actually completed on the 31st and there was some delay as to whether --

MR. KERINS: I think it was complete subsequently, a day or two after the 31st, but I know it was complete.

MR. COOPER: What's the -- recognizing that we may have already covered some of this ground, what's your belief as to the root cause of that and what have you done to correct that?

MR. KERINS: I mean certainly I mean continuing some of the educational things we have already talked about. The linearity check is something that is provided in the computer system, that does provide at least a flag for the pharmacist, the user RSO to know that it's coming due. I think one of the mitigating factors that may have affected in this particular case was the transfer of responsible people, that Miss Colangelo had left, was the RSO; Miss Fire was coming in. I think Miss Fire was only on site approximately a month, although the 15th incident she was coming in, I mean she was still in transit at that point and really didn't come on to the site full time until October.

MR. COOPER: This computer program that you've been referring to, basically identifying what checks are coming due, and I guess also documenting

what has been done, who is it that's responsible for monitoring that? Did you say the RSO or the facility manager if it's the same?

MR. KERINS: I think it's both. It's site specific. That's set up that each of the sites has the option to do that. Some people, as far as using it for even documentation, some people have elected not to do that. For instance, constancy, I think you can log into the computer base, however, it's easier just to have that on some sites. And I think Philadelphia is an example has the written records outside of the computer base. It's still an ongoing system and I presume it's still going to be used in the future, but it's not tied into the corporate office at all. It's driven by the individual site.

MR. COOPER: Anymore questions on that item?

MS. JOUSTRA: The next item appears in section 8 of the report of the radioactive waste disposal and it's the apparent failure to restrict the storage of decayed radioactive waste in a non-restricted area with material at exposure rates that do not exceed apparent background rates. That

would be a violation of the licensed conditions.

MR. KERINS: Subsequently when I was at the site, I believe November 6 and 7, we did do further audits of the site than actually have been -- it's a mezzanine-attic type of situation where the materials were stored and we in fact found a couple more boxes that should have been down in the restricted environment.

We acknowledge that we certainly -- we moved those particular boxes at that time. The boxes are awaiting medical disposal and I think are being resolved this month I believe at the sites where they're all being handled by a waste broker, so they will be surveyed prior to going out just to assure that they're not there. But there is -- it was the storage of syringes, vials, the whole gamut of supplies up in the attic area.

MR. COOPER: What's the process by which a package of waste gets disposed and then stored up in that area?

MR. KERINS: It should be obviously surveyed. The particular site, it's kind of at the entrance of the restricted area. It's kinds of a non-restricted area inside a restricted area because

of the floor situation, but the procedure would be to do a survey on the box and make sure that it's below levels and then it would be stored up there.

MR. COOPER: Who's responsible for doing the survey at technician level?

MR. KERINS: It could be a technician or it could be any level, whether pharmacist, RSO. I don't know that in general that we have specified that any one individual could or could not do it.

MR. COOPER: In this case, I understand the individual apparently who had surveyed the package that was up there that we found had subsequently or prior to that left your organization. So as I understand it, there was no attempt made to communicate with that individual to understand why this happened. What checks and balances do you have in place that would disallow this from happening again or what failed to identify it at that time?

MR. KERINS: I don't know what specifically failed. I presume the procedure was done. I was not aware that the specific person that did the assay left the organization, but we certainly brought it up and I think Janet, myself and I think Miss Fire at the time, we went up to make sure that

there were no other issues. That clearly the expectation is that there shouldn't be any radioactive materials up in the non-restricted area. I believe that was also just one of the issues that was brought up in subsequent training.

MR. COOPER: Do you now do any type of surveys periodically up there to verify that there's nothing there that is above background, or do you rely on auditing by the RSO to accomplish that or some other mechanism?

MR. KERINS: I believe that, Janet, wasn't that the thing that we put on the weekly checklist for the RSO?

MS. REUTHER: Yes.

MR. KERINS: And it was expected that we had the RSO, that obviously she should be attentive.

MR. BELLAMY: So the RSO will now take a survey meter and weekly tour this area?

MR. KERINS: It wasn't an ongoing program, but in November we had made some commitments for time limits that we would have reports that she would do separate assays and training, etc. that would be documented and sent to corporate. And I believe that was one of the issues that she was doing surveys

and obviously scheduling linearities and this type of routine management programs.

MR. BELLAMY: Do you have any other specifics of the additional boxes that you found in early November? A couple means two or three?

MR. KERINS: Well, I believe it was two.

MR. BELLAMY: And the levels on those box were --

MR. KERINS: Well, they were certainly very low. On the low scale, they were -- I mean they were above backgrounds, but there were no field readings. But there certainly were DPM that was coming off there that was detectable. I didn't quantify it.

MR. BELLAMY: What do you do, just for my education, what do you do with waste that is above background before it's ready to be shipped?

MR. KERINS: It would be stored. There's a hot waste storage on site so these two boxes we brought them over to the hot waste room.

MR. BELLAMY: And they're still there now?

MR. KERINS: Right, because of the syringes and vials and even blood components, most of

the waste is treated as biological waste, and obviously with recent regulations regarding that, they're incinerated, held for incineration as biological waste products. As a matter of fact, we usually err on that side.

MR. COOPER: Do you have similar licensed conditions for other facilities regarding storage of items in an unrestricted area that aren't above background?

MR. KERINS: Yes. I mean I think that would be -- again that would be in every license. I think that in many cases, though the facilities -- though it's stored in the hot waste room, that in many cases that it goes directly from that hot waste room out to a broker for handling it. It may not in fact be radioactive at that point, but that's the specific site retention. That is one of the sites that has a separate room in an attic mezzanine second floor arrangement that it's stored.

MR. COOPER: So it's basically the physical configuration drives you to the process that you use at this facility?

MR. KERINS: And I would say yes. It was space that was available, not to clutter the hot waste

room. That it was, once it was cold, that it was an unrestricted material that it would get stored upstairs.

MR. COOPER: Just to clarify a point, the checklist that the RSO uses to weekly separately assay the storage area, is that something that's continued since right after this event and in fact continues today?

MR. KERINS: I believe it has. Janet, can you comment on that?

MS. REUTHER: I'm sorry, are you saying is the checklist still in effect?

MR. COOPER: Right, that require a weekly check.

MS. REUTHER: No, not weekly. We do it monthly at this point.

MR. COOPER: Will it stay at monthly or will it be reduced further after a period of time or can you say right now?

MS. REUTHER: I really can't say at this point.

MR. WATERMAN: We'll review that.

MR. COOPER: Any other questions on that issue?

MS. JOUSTRA: The last item appears in section 9 of the report on the NRC section, the apparent failure to provide complete and accurate information, and that is an apparent violation of 10 CFR part 30.

MR. KERINS: Well, specifically very clearly we expect that as an organization that all people really are going to give candid, accurate information to any regulatory inspector and also to any member of management. The incidents of October 31st through about November 7th, I think there was confusion in our minds exactly what had happened. I think it came to corporate that an inspection obviously had occurred, but there was some issues regarding -- we had heard that there were phone calls between various people at NRC and our staff about that, certain things were represented during the meeting, and then that was changed subsequently. We were certainly at a confusion.

And I think I made the first call to Miss Joustra and then talked to Mr. Joyner I guess on a couple occasions trying to figure out what the issue was. Clearly when we went to the site, or when I went to the site on the 6th and 7th, we expected that and

we told the people that we expect them to tell the truth, I don't care what kind of inspector it is. That's a basic expectation, to tell the truth.

MR. COOPER: Has this been communicated throughout your organization?

MR. KERINS: That was part -- I think the communication was also part of I think our directive to all of the sites that we expect --

MR. COOPER: Would you have a copy of that? Can we make a copy of it or did we get one, do you know?

MS. JOUSTRA: I don't believe we got his directive to the other sites.

MR. KERINS: I don't believe so. I think specifically that what we did as far as in the corporation was disciplinary actions, that we did take disciplinary action I think against Miss Fire regarding I think two incidents, both the Cincinnati incident and Philadelphia, and then also other individuals in the Cincinnati facility.

MR. COOPER: Does anyone have any other comments or questions on that issue? Okay, at this time I'd like to turn it back over to you for any summary or closing remarks you'd like to make after

which I'm going to ask our enforcement officer, Keith Christopher to go through where we go from here.

MR. BELLAMY: Can I just say something too, maybe we should have jumped in a little sooner, and Mr. Kerins, maybe this is a good lead in to your conclusion, but having been sitting here and listened to everything, I heard no disagreement with any of the violations, and I guess I'm looking for a specific yes or no to that question. And also, if there is anything in the report that anybody believes is in error, this is a good time to point it out. So if you would just address those two in your summary, that would be great.

MR. KERINS: Well, I think generally I agree that training certainly was deficient. I think from what I heard in the initial interview and subsequently, I didn't characterize it as specifically as Miss Joustra did, I think 10 people here 3 people there, and that I think generally training was deficient. I will acknowledge that. Going down the list, I would say yes, we agree.

MS. SMITH: So for the record, you're admitting all the violations?

MR. KERINS: Well, I would say that they

did occur. I mean specifics of the authorized user, that did happen.

MR. BELLAMY: That was my interpretation as you went through each one. This is wrong, we disagree.

MR. CHRISTOPHER: I think we recognize that you have not seen a specific set of violations. You have seen a report that refers and characterizes apparent violations and they are not specific to the regulation. And I think Ron's question is more to the factual issue. If you have a problem with the specific text of a written violation in the subsequent formal documentation, you of course are going to have an opportunity to respond and clarify any position that you would once you get that. So I think Ron is trying to speak to the factual information itself.

MR. ROSS: Let me say that I think the record we've made here today speaks for itself on many of these issues, however, before formally admitting or denying, we certainly would like to have a chance to see a final document, whatever that may be so, that at least we have that before us.

MR. BELLAMY: Yes, but knowing what your position is now, and like you said, you know, the

record speaks for itself and you heard my interpretation of the record, we will then -- Mr. Christopher, after you have any summary comments, will go over actually that process. I don't want to steal his thunder.

MR. KERINS: Well, I guess an admission, yes, I think the specific incidents, that without looking down each one of those, training in general, there was some deficient training that I think we have covered ourselves. Certainly the authorized user position regarding the 17th, that was an incident that I think we notified NRC about. The October 23rd, we recognize that it did occur, so yes, I do admit that it occurred on the part of the organization.

The decayed wastes were radioactive materials stored in an unauthorized area, so yes. Failure to provide complete and accurate information to the NRC inspector, I guess that's one I have a little problem with. I wasn't there at the time, so I don't know what was -- when I did an initial investigation, I had a specific interpretation of what I thought was said, what was meant by it what was interpreted, and obviously inflection and things like that, so I guess I can't say definitively that was the

case.

MR. BELLAMY: Thank you.

MR. COOPER: Okay, with that, Keith would you please provide us with your thunder?

MR. KERINS: May I just interrupt for a second?

MR. CHRISTOPHER: Also do you understand that any documents that you do give us would become part of PDR records, so if you have any proprietary information in there, you may want to scrub them. I don't know what you're in the process of giving us, but you may want to take a look at that. Once you give it to us, it ends up in the PDR.

MR. BELLAMY: Are we or are we not accepting something?

MR. KERINS: I think a comment by Mr. Christopher was just raised that if we give it to you that it becomes part of the open record of the meeting.

MR. CHRISTOPHER: The point being I don't know what is in the content, just that you need to look at it and determine whether or not there's any type of privacy or proprietary information that has to be withheld from the document and we can do that.

MR. KERINS: The specific -- I have the memo on the personnel licensing, but the correction I want to make, I thought that it did address the issue of the expectation of telling the truth, and specifically it does not.

MR. BELLAMY: Keep it.

MR. KERINS: Okay, if that's the specific issue, this doesn't address it then.

MR. SHANBAKY: Before we get to Keith, I wonder if you, looking at it from a big picture point of view, if you see any mitigating circumstances here that you'd like to share with us now, aggravating circumstances which contributed to this problem if you handle it in total.

MR. KERINS: Well, I think that specifically at the Philadelphia site that there were issues, turnover, new employees were at the site. a couple of pharmacists that were working at the site were brand new. That we had some pharmacists leaving. That the new pharmacists came in, came out of qualified programs in radiopharmacy. These were not just pharmacists that were subsequently trained.

Certainly the issue that the manager had left and Miss Fire was being brought in, I think that

has the effect of there wasn't a clear person that's directly responsible for the meeting, responsible for the activities at the site in the absence. That was being resolved, that's why we were bringing Miss Fire in. So I think those were mitigating factors. Specifically some of which we brought up in the meeting we had on November 7th and I think on November 21st, I think that the facility itself, that Miss Colangelo was very well liked, was the RSO and manager of the site, she was very well liked by all the staff. As I said, in my initial investigation, I think when Miss Fire came in that she took a very assertive program -- approach to the program. This is the way she wanted it done, that was not necessarily liked by some of the staff, the technician staff that do a lot of the program maintenance. So I think there was a personality conflict unfortunately at the time. And I think she recognized that if she was going to do it over again, she would have addressed that initial start of her tenure quite a bit differently and rather worked with the people, because I think she felt too that the site was generally run very well.

MR. SHANBAKY: So you're saying that management style of Miss Fire may have contributed to

some of the problems?

MR. KERINS: Well, she came in and she was used to doing things her way, that she had -- she's been in radiopharmacy a number of years, had directed facilities and she did things the way she wanted to do them. And I think her approach was to direct people to do that. There's theory X's and theory Y's of management that I think more of theory Y would have been appropriate rather than theory X. And I think it caused some personality problems at the site between some of the technicians especially. I think that came out. That was vocalized specifically to me by the technicians that Becky was coming in to change everything.

It's not an excuse for program management, but it's -- I think it's a mitigating factor to some extent. And I think it probably exacerbated a communication problem that existed. And I think our expectation that we thought the facility was run very well, it's a big facility, it's a busy facility. From customer reliance perspectives, it was a positive operating facility. It was not one that we had customer problems associated with that. We were aware of it as a well operated facility.

MR. SHANBAKY: And was it your expectation that the facility was running well or your assumption that the facility was running well?

MR. KERINS: Well, you know, we expected that the routine management would be done by the local facility. We assumed that, you know, the day-to-day activities were being addressed.

MR. SHANBAKY: And the reason for your assumption?

MR. KERINS: Well, I think we assumed that because in all of the facilities that the RSO, the management staff and the technical staff is aware of what the program requirements are, and they certainly are delegated the responsibility of running that facility on a daily basis. I mean you can't audit quality in no matter what kind of program, you've really got to build it in, and that building this would be from the site level, working with the people in training. And auditing is only a snapshot, whether it's an NRC inspection, whether it's a pharmacy inspection or whether it's a quarterly audit, it's clearly only a snapshot of the facility.

MR. COOPER: Anymore questions? Okay, Keith.

MR. CHRISTOPHER: My much awaited thunder will probably be a little more than a mild rain here, but let me try to capture very briefly the options that I know Mr. Reynolds I know is certainly well informed of. We have three basic options that we can take here. One is after evaluating your responses to these violations today here as alleged, listening to your responses and in caucusing after this meeting, we can proceed in a couple fashions.

First, we can issue an order which would require you to do something in particular, such as bring in independent outside consultants, auditors, or it could go as far to modify, suspend or revoke a license in response to the violations.

Secondly, we can issue a notice of violation and a civil penalty for the violation.

Third, we can merely issue a notice of violation and no civil penalty. Each of those obviously have different degrees of significance to them. We'll reach that conclusion after this meeting, as I said, by sitting here evaluating what you have told us today, reevaluating your corrective actions and trying to come to a rational and reasonable conclusion in accordance with our enforcement policy

as to what, if any, enforcement actions by the NRC should be taken.

We'll be considering such things as your prior performance history at this facility, the extent to which and the promptness of your corrective actions to these particular violations. All of those things will go into a pot which we will in essence try to evaluate and reach a conclusion. Once we have done that, which would take a period of approximately six weeks after it goes to our headquarters review process and through our program offices in Washington, you would be informed of that decision in writing and then be directed at that point what type of responses you can make. It is at that time that you would, if the NRC chose to go that route, you would receive a formal list of violations of regulatory requirements which you would certainly have an opportunity to respond to to deny, confirm or whatnot, separately from what we have talked about here at this meeting.

You should be aware that if the NRC chooses to believe it is appropriate to issue a civil penalty in this case, that we would issue a press release concurrent with the issuance of that document, although we would insure that you had any such

proposal in hand prior to the issuance of a press release in order that you not be caught cold on that. You can also expect to receive an additional document from the staff in a slightly shorter period of several weeks which will be a summary of this meeting and through which you'll also receive a copy of the transcript of the conference.

That is a rather brief nutshell of what we will do here after you leave today, and if I can answer specific questions, I'll be happy to try to do so.

MR. KERINS: I don't think -- I don't think I have any questions.

MR. BELLAMY: I'd like to just clarify and make sure that any enforcement action which we take will be addressed to you at the Nutley, New Jersey address?

MR. CHRISTOPHER: That's right.

MR. BELLAMY: That was more a question than it was a statement, and the answer is yes?

MR. ROSS: I think that's appropriate.

MR. COOPER: Let me clarify a point for the record also. I think Mr. Christopher alluded to the fact that we would get you a copy of this

transcript. That's not entirely accurate. We will decide after this meeting, after reviewing the transcript, whether we'll release it to you. I will note that if you desire the transcript to be released to you, that at the same time it's required that we release it to the public, go the public document route. So that we will make a decision after we review the transcript.

With that I'd like to make just a couple of short closing remarks. First, we appreciate you coming here today to this meeting. We are certainly interested in hearing from you after we've communicated to you what the results and conclusions of our deliberations are after this conference. Again, we don't know yet what that conclusion will be. We're interested in working with Medi-Physics in the future, you taking over this operation and look forward to a good relationship with you and encourage you to take what action you need to be involved in the correction of these violations. In fact, I don't know if you'll be in a position to do so by the time frame in which we will conclude our action and transmit that to Roche and yourself I guess, but we would certainly hope that you would buy into the commitments that

Roche makes, if in fact Roche is making those at the time and if in fact they're not, but you are certainly -- you would buy into your own commitments. So I leave you with that thought and again appreciate you coming here today.

MR. KERINS: Can I make just a comment? I think just in regard to I mean the various levels of organization, that obviously I'd be remiss that I think that the corporation has tried from the corporate management on various levels that when we became aware to act appropriately, that certainly from Philadelphia's previous inspection, I think it was, quote, a clean inspection. There were no NOVs issued. There were recommendations I think that were given at that point. So we had that perspective of the Philadelphia site from a regulatory sense, NRC sense.

I think very specifically then that when we uncovered the issue, when we heard about the issues of October 31st and confusions, I think that we instituted on our own our own investigation of what was going on. We contacted the NRC to get whatever information we could from you as to what the issues were at the site because it was confusing. I think that we did our own investigation; we certainly had

one meeting with the NRC. We represented what we thought at the time and I think over the period of a couple months that we found other things that were happening. The September 17th issue, we record that I think we voluntarily reported that to the NRC, that we came in prepared with an action plan at that, I think the reporting to appropriate organizations like the Board of Pharmacy, I think even when the Cincinnati issue came about and that came through the chain of command.

I would say that if anything, the training or the communication worked because it was actually a pharmacist in Cincinnati that brought it to the regional manager's attention that there was an issue in Cincinnati. And I think that we were up front and reported that completely to both Region III and Region I. That there was a similar incident involving Miss Fire was at least part of the investigation that was going on here. I think we've carried out the plans that we had set forth in the November 21st issue, which included various things from training on-site people to even people like Miss Fire who we sent to an alternate site for training, at another NRC site just to go through, work for a week

specifically going over issues like adherence to regulations and that type of training. So I think that we are committed to operate a program and I think that we've tried to be forthright with all of our preparations and make all the reportings that were appropriate.

MR. COOPER: We appreciate that. Does headquarters have any comment or have any questions?

MR. ROSANO: No, not at this time. Although I would like, when this breaks up, I would like Keith to call me prior to the panel meeting at 492-0718.

MR. COOPER: Okay.

MR. CHRISTOPHER: Okay, Dick.

MR. REYNOLDS: Mr. Cooper, can you provide us your schedule for processing and acting upon the license transfer application?

MR. COOPER: I guess I'll defer to Mr. Glenn.

MR. GLENN: I don't think we can answer precisely that question. I think certainly we're going to discuss that after the meeting today and make a decision on how fast we can proceed with that.

MR. REYNOLDS: Do you see it intertwined

with this pending matter?

MR. GLENN: Yeah, unfortunately. One of the reasons we have for wanting to give prior approval to a transfer is so that this kind of issue can be resolved before we get in the middle of the transfer, and certainly it has caused implications for us. I won't go into details, but it is a problem.

MR. KERINS: Is there any specific format? Certainly I think it's in the best interest of the NRC and I think Amersham Medi-Physics and RPSC to resolve. Obviously we can propose certainly corrective actions and send them to Amersham for their concurrence or non-concurrence I guess, but is there any format that's preferred by the NRC that would expedite the issues?

MR. BELLAMY: I'll comment on that. You've heard today the apparent violations. If one assumes that we would issue those apparent violations as notices of violation with whatever correspondence we issue, my staff would look for a very specific response to each of those issues with respect to what are your corrective actions for that specific issue and who has responsibility and what is the time frame for implementing those corrective actions.

MR. KERINS: Okay.

MR. BELLAMY: I don't know if that helps you, but --

MR. KERINS: No, I think that's expected.

MR. WATERMAN: Mr. Cooper, could I offer a closing comment from my side of the table over here? Medi-Physics appreciates the opportunity to attend the conference this afternoon and I think to get some insights into the issues that concern you and some more specifics of what has gone on in the past. Obviously we, through Medi-Physics and Amersham Company will review the situation carefully both across the NRC regulated pharmacies and also the pharmacies that are in agreement states.

We also intend to review this carefully with our parent corporation in England. They bring significant experience and expertise I think to the field of radiochemistry and radiation in particular. That's the whole reason for being and has been since the inception of the company just before World War II. Having done that, we would like then to have the opportunity to come back to you and communicate with you our plans and our positions specifically in response to whatever action comes out of this

afternoon's conference. There is a possibility that we might have a different perspective and might want to discuss with you a different approach to addressing some of the concerns that assure compliance in the future.

MR. COOPER: What do you feel is the time frame by which you would be able to do that? For instance, as I think Mr. Christopher mentioned, I wasn't paying total attention at the time, by which we would normally take our action --

MR. CHRISTOPHER: We're looking about six weeks.

MR. COOPER: Which would normally be about six weeks or so from now. Rather than have Roche respond in one manner to whatever we come up with, assuming we come up with something, and then you come in a week later and say well, that's not right, this is because we've done all our homework and we think since we're taking over the operation we're moving in this direction, I'd rather not have that type of thing occur.

MR. REYNOLDS: May we consult?

MR. COOPER: Sure.

MR. WATERMAN: Mr. Cooper, perhaps a

hybrid response, as my friend and advisor here suggested, whereas Roche would address what's going on in the past and Amersham Medi-Physics could address plans for the future.

MR. REYNOLDS: Response to your enforcement action.

MR. COOPER: Right, I think that would be acceptable because I'd rather not spend our and your resources having another one of these sessions at a future date if we can at all help it.

MR. GLENN: Let me add I guess maybe one thing that we could do is perhaps your responses, your commitments to the future could be framed in such a way that they could be considered part of the licensing section to issue the new license, then we could get those commitments as part of the licensing action.

MR. REYNOLDS: The problem I see in that is we would like licensing action before six weeks plus 30 days, which is what it will take to finish this enforcement conference. Is it infeasible for us to expect licensing action that quickly?

MR. COOPER: I think we're going to have to discuss that.

MR. GLENN: I can't make any commitments.

MR. COOPER: We can't make a commitment here right now.

MR. KERINS: I think from our perspective it's obviously in the best interests I think for both the NRC and the two organizations for the license to transfer. Not that we're trying to snub any responsibilities. Certainly we're willing to give any recommendations for the future that Amersham Medi-Physics would like to use or not use. Unfortunately, we don't have the resources now. They have all been transferred. But we can respond to the past obviously, but at best I think we can respond to future actions I guess in concert with Amersham and come up with a unified response, but again, that's a timing issue.

MS. SHIRK: It would appear to me that the corrective actions that you're requesting are all future oriented, so we are limited. We would be responding to an NOV but not in fact being able to enact it.

MR. REYNOLDS: That's the proposal, that it would be a hybrid response where we take the responsibility for responding on the corrective action

front. And that's acceptable to the NRC?

MR. COOPER: Yes.

MS. SHIRK: So we're talking about a joint response then?

MR. KERINS: Well, is it a joint response. I guess the details of how to respond then --

MR. ROSS: I'm certain that we can work out details.

MR. REYNOLDS: I think Mr. Ross and I can work that out.

MR. ROSS: We can make some kind of accommodation.

MR. COOPER: Okay, thank you very much.

(Proceedings closed.)
