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Interview of Susan Shankman

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Pages 1-46

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ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction
6	11	delete lipid
9	13	More = Ma
9	14	Zane = Zheng
9	18	hutzkapude = hetts and Capute
12	3	Sittar = Sa Har
12	5	's will delete
12	20	Goddessen = Gottesman
17	19	Caractea = Carrisquille
20	1	have been = be
22	2	Varmouth = Varmus
23	7	I = we
25	3	Varmouth = Varmus
25	7	delete s on extension
28	7	alley = ALI
31	5	Support = technical
31	15	REACT = REA/TS
	20	Caractea = Carrisquille
	24	REACT = REA/TS
32	6	" "
	19	" "
33	1	" "
	5	" "
34	24	delete "12" add s to material

Page 1/2 Date 11/17/95 Signature Shu Shu

ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction
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35	2	Native = reactor
43	8	Sitter = Sattar

Page 2/7 Date 11/17/95 Signature Sen. S. H. C.

1 UNITED STATES OF AMERICA

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3 NUCLEAR REGULATORY COMMISSION

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5 INCIDENT INVESTIGATION TEAM

6 + + + + +

7 INTERVIEW OF SUSAN SHANKMAN

8 + + + + +

9 DEPUTY DIRECTOR, DIVISION OF NUCLEAR MATERIALS SAFETY

10 + + + + +

11 THURSDAY, NOVEMBER 2, 1995

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18
19 INTERVIEWERS:

20 JOHN GLENN

21 ALAN MADISON

22
23
24
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P-R-O-C-E-E-D-I-N-G-S

(12:05 p.m.)

MR. GLENN: The time is about 12:05, the 2nd of November, 1995. My name is John Glenn. I'm the Team Leader of an Incident Investigation Team. We are looking into an incident at the Massachusetts Institute of Technology where a P-32 outbreak occurred.

As part of our assigned duties, we've been asked to coordinate with the AIT that looked at a similar incident at the National Institutes of Health, and this interview will be received and exchanged for the purpose of developing some of that information so that we can have some input in terms of common lessons learned.

The purpose of the IIT was to establish what happened, to identify probable causes, and to develop lessons learned and make recommendations to the Commission. The IIT's charter is not to find fault or take enforcement action, but only with the facts that may lead the NRC in the direction of the actions it needs to take.

We are transcribing this, or recording it and it will be transcribed. That aids us in terms of asking our questions so that we don't have to take notes, and also that we can refer back to the transcript later and make sure that we get our facts correct.

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1 yourself, and then what your normal position is and what
2 your position was with respect to the AIT.

3 MS. SHANKMAN: Sure. Susan Frant, F-r-a-n-t,
4 Shankman. I'm the Deputy Director of what is now the
5 Division of Nuclear Materials Safety and, prior to October
6 1, it was the Division of Radiation Safety and Safeguards.
7 We have responsibility for Region I materials licensees,
8 approximately 2500 of them, of which NIH is one of our
9 broad-scope licensees.

10 On June 30th, as you know, we started an AIT
11 regarding an incident that occurred on presumably June
12 29th at the NIH. It was led by Jim Dwyer, whom I guess
13 you have already interviewed?

14 MR. GLENN: Yes, we interviewed him a couple
15 of days ago.

16 MS. SHANKMAN: Right. And I was assigned as a
17 Team Manager. Ordinarily, in an AIT, the Team Manager has
18 a -- is an SES person who is assigned to coordinate
19 overall activities of the AIT and the Team Leader does the
20 site management of the Team, and the Team Manager usually
21 does the interface with press, senior management of the
22 agency, and that kind of thing, and the Site Leader does
23 most of the Team leadership. However, after several weeks
24 on-site, there were a lot of difficulties in getting the
25 licensee to cooperate with us, and so I became much more

1 active -- and I'll have to look in my records -- but about
2 mid-July, particularly after the water cooler incident, I
3 went down to the site and took active leadership of the
4 Team.

5 MR. GLENN: Alan just reminded me, I forgot to
6 mention one thing about the transcripts. You may already
7 know it, but I want to make sure that you're aware of it,
8 and that is that when we finish the AIT report, the
9 transcripts will be made public and will be in the Public
10 Document Room.

11 MS. SHANKMAN: Right. Okay.

12 MR. GLENN: Okay. Now, you just got through
13 the makeup of the AIT and your role, and I guess that's --
14

15 MS. SHANKMAN: What I was saying is my role is
16 slightly different than it is on many AITs where the Team
17 Manager has an oversight role, and reviews documents and,
18 you know, whatever. I took a much more active role
19 because we were having problems with the licensee's
20 cooperation, and we were also -- we had the second -- I'm
21 always careful how to say it because at this point in time
22 we do not know whether they were two different incidents
23 or it was one incident, however, we did have evidence that
24 a larger number of people rather than the original
25 researcher had been contaminated in some way internally

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1 with P-32. And as you know, on July 14th, the licensee
2 notified us that they believed the source of the
3 contamination of the other 25 people was a water cooler on
4 the same floor as where the researcher had her laboratory.

5 MR. GLENN: Another issue in terms of your
6 setup of the Team that came out of our discussions with
7 Jim Dwyer, what is the role of OI? Was OI originally a
8 member of the AIT, and --

9 MS. SHANKMAN: Yes. Because when it was
10 reported to us, it was reported to us they believed that
11 the lipid internal contamination in which someone or ones
12 had placed P-32 in the food or drink of the researcher,
13 and we asked OI to participate on the Team, much the same
14 as you on the IIT.

15 MR. GLENN: Okay.

16 MS. SHANKMAN: And they gave us Jerry Kenna --
17 and I don't know if Jim gave you what we did. June 30th,
18 he exited the routine inspection in the morning and, at
19 two o'clock, we had an entrance meeting with the senior
20 managers, Dr. Wyatt and Dr. McKinney, of the NIH, with me
21 on the phone and Jim there.

22 MR. GLENN: Okay.

23 MS. SHANKMAN: Donna-Beth Howe, I don't know
24 whether she was there or she was on the phone, and Jerry
25 Kenna, and we held an entrance meeting about the AIT. We

1 then all traveled together, and Jerry Kenna, Jim Dwyer,
2 Donna-Beth, and myself met in Gaithersburg at the Woodfin
3 Suites the morning of July 1, then proceeded to the site
4 and took a tour.

5 There were no senior managers at the NIH
6 available, and they asked that I not come -- in hindsight,
7 it was an issue of protocol -- and I took a tour later in
8 that week, or soon after, but anyway they went. And Jerry
9 Kenna was part of that tour because the security people
10 from NIH were the ones who conducted the tour.

11 MR. MADISON: But you were not part of that
12 tour, Susan?

13 MS. SHANKMAN: No.

14 MR. MADISON: At NIH's request?

15 MS. SHANKMAN: Well, they had indicated to Jim
16 Dwyer that there would be no management available on that
17 Saturday. This is part of -- in fact, it's not -- as I
18 read the AIT report as drafted now, it is not as explicit
19 as it will be, but we had a lot of resistance by the NIH
20 to our authority, but I don't say that with a capital "a".
21 You know, they obviously recognize that we're a regulatory
22 agency, they have to comply with our regulations, that
23 they will tell you, but they did not see that we had any
24 incident investigation involvement, that we were an
25 impediment, that we were interfering with what they were

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1 trying to do. They were not going to be there over the
2 four-day holiday weekend. There was no management there,
3 and they asked that we not make an official tour and have
4 me, as a manager, there because they didn't have the
5 appropriate people.

6 You asked me, Al, did they specifically say
7 that? No. They said that there would be no management
8 there to talk with me.

9 MR. MADISON: Okay. I think that clarifies
10 it.

11 MS. SHANKMAN: But as I say, that's part of, I
12 would say, a pattern of resistance to the whole idea that
13 the AIT should be there.

14 MR. GLENN: I guess going on with the presence
15 of OI on the Team, speaking with Jim Dwyer, we got the
16 impression that there was some sort of boundary put up in
17 terms of interviewing certain people to --

18 MS. SHANKMAN: Oh, absolutely.

19 MR. GLENN: -- to get information about the
20 incident.

21 MS. SHANKMAN: All right. Well, let me tell
22 you. For that first meeting, we all met together. Jerry
23 Kenna said he would meet with the security folks, and he
24 did. The investigator who was supposed to be handling it
25 for NIH had gone on vacation and, as I said, the Radiation

1 Safety Officer had gone on vacation. Anyway, we did what
2 we could on the site on Saturday, and we went back on
3 Monday, July 3rd, and there was basically very few people
4 there. And on July 4th, there was nobody there.

5 So, we actually -- we started in full bore,
6 with people available to talk to us, starting July 5th,
7 and very soon -- Jerry Kenna had said on July 1st that he
8 believed from his discussions with the NIH security
9 people, that we should separate the investigatory issues
10 from the inspection issues, and that the investigation
11 issues should take precedence. And I really have to -- I
12 have to look back in my notes at what point we were told
13 that we should not talk to, in any way, Dr. Moore
14 (phonetic), Dr. Zane (phonetic), or Dr. Weinstein.

15 MR. GLENN: Was that done through your
16 charter, or was that done through --

17 MS. SHANKMAN: It was done by Jerry Kenna,
18 Barry Lutzkapudo (phonetic) -- I was on-site starting 7-
19 18. Do you have a calendar? Friday was the 14th, right?
20 17th. Monday, the 17th.

21 MR. GLENN: Susan, we're going to take a pause
22 for just a second.

23 (Off the record.)

24 MR. MADISON: Okay, we can go back on now.

25 MS. SHANKMAN: Okay. I would say, very early

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1 on the investigation took over -- Jerry Kenna and Jim
2 Dwyer coordinated what they were doing, but we were told,
3 from Thompson (phonetic) on down, that the OI part of it
4 took precedence, and that we were not to do anything to
5 cause a perturbation of their investigation. That went to
6 a press release that was released. There was a lot of to-
7 do about it, not because of the timing but because it
8 might impede the investigation. It had to do with
9 interviews that we wanted to conduct, but -- and on the
10 18th of July, Jim came down -- we met with the top
11 management of NIH to discuss what they were going to do
12 now that the water cooler had been discovered. And at
13 that same time, the FBI was there. We had a meeting after
14 the general meeting with NIH management that just had the
15 security folks of NIH, the FBI Agent-in-Charge, our OI
16 folks, Jim, myself, and that was all.

17 And I don't want to go into the details of
18 that discussion but, based on that discussion, it was
19 decided that we would not schedule any interviews that we
20 had not cleared with OI, who would clear it with the FBI.

21 MR. GLENN: Okay. So, my understanding is
22 there were no interviews with the exposed lady until
23 sometime later, and that that was a very limited
24 interview.

25 MS. SHANKMAN: Yes, Jerry Kenna, the OI
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1 Investigator assigned to the case, went there at the
2 interview of the researcher and her husband.

3 MR. GLENN: Okay.

4 MS. SHANKMAN: And during that interview --
5 did Jim give you the date of that?

6 MR. GLENN: I believe he did. I don't have
7 the transcript here. If you have the date and can recall
8 it, that will be helpful.

9 MS. SHANKMAN: 7-21, I believe -- that Friday
10 or Thursday -- yes, 7-21 is the date I have in my book.

11 MR. GLENN: Another area I'd like to explore a
12 little bit with you because you have mentioned it and we
13 certainly picked it up from Jim, that the attitude of NIH
14 was not constructive with respect to the activities of the
15 Team.

16 MS. SHANKMAN: Sure. You want me to give you
17 some examples?

18 MR. GLENN: Yeah, if you could give us some
19 examples.

20 MS. SHANKMAN: In the first couple of weeks,
21 Jim was supposed to go back to the site on a Wednesday.
22 He had come back to the office to do some records review
23 and then was planning on going back to the site. And he
24 came to me and he said, "Until I get some of the
25 communication and document review issues settled, there's

1 no point in my going back". And when we talked about it,
2 it seemed that Bob Zoon, who is the RSO, was insisting
3 that any request by Sittar Lodhi, a member of the Team, or
4 Donna-Beth Howe, a member of the Team, had to be
5 communicated in writing by Jim's wire to Bob Zoon, before
6 any of his staff would be tasked with responding to any of
7 their requests.

8 So, I called him and basically said, "This is
9 not a way to help any of us. This adds a burden to both
10 your staff and to our staff". Well, he doesn't want
11 anybody coming to his staff and asking them for
12 information that he hasn't decided was okay to give them.

13 What would you say, would you say that was not
14 cooperative?

15 MR. GLENN: It sure sounds like they weren't
16 cooperative. I guess another area --

17 MS. SHANKMAN: Well, wait, let me tell you.

18 MR. GLENN: Okay.

19 MS. SHANKMAN: Another thing was when we went
20 down and met with Goddison, with Tim Martin. I had
21 discussed with Bob Zoon ahead of time, some of the things
22 that -- the kinds of questions we would be asking and, at
23 that meeting, they said they would have to think about
24 whether security was an issue. And the Deputy Director of
25 NIH got up after three minutes in the meeting and said, "I

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1 haven't heard anything that tells me we have to change
2 what we're doing", and walked out.

3 When they did the survey of people on the
4 fifth floor and throughout the building to see -- they
5 asked for a pattern of drinking from the water cooler.
6 They wanted to make a correlation between people with
7 elevated P-32 in their urine and drinking from the water
8 fountain, to see if they had any outliers. Did anybody
9 absolutely not drink from the water fountain and still had
10 elevated P-32 because then they'd have to check for
11 another ingestion pathway.

12 Five people did not respond to the survey,
13 that had elevated P-32. We asked them, "Well, have you
14 contacted those people?" "No, it is a voluntary interview
15 -- survey." I said, "Well, if you don't contact them, we
16 will". "You can't contact them, it's Privacy Act
17 information." I said, "We are going to contact them, or
18 you can contact them. I will start my calls in five
19 minutes". So, they said, "No, no, we'll do it".

20 I can't tell you how many examples of things
21 like that. Then when they told us about the water cooler,
22 I said, "Have you contacted the water cooler company to
23 see where the bottles were that had been picked up from
24 that building?" "No." I said, "Well, give me the name of
25 the company, we'll contact them if you don't choose to

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1 contact them".

2 "Well, why do you have to contact them?" I
3 said, "Because you have P-32 in a water cooler and, if
4 you're going to find out where it came from, or
5 whatever" -- "Oh, okay. We'll call them next week when
6 we're not so busy". I said, "You can either call them
7 now, or I'll call them now". "Oh, all right, we'll call
8 them now."

9 A lot of things they had to be literally
10 prodded into doing it not -- I mean, I guess I'd be glad
11 to hear your opinion -- but I do not expect that kind of
12 response from a licensed group, that "you have no right to
13 be here, we don't understand why you're interfering with
14 what we're doing", et cetera.

15 And then what I would say a logical follow-up
16 that you would expect, basically until we insisted that
17 they do it, they are not going to do it. Is that enough?

18 MR. GLENN: I guess the only other one is that
19 your speaking with Jim Dwyer, and we also interviewed
20 Donna-Beth Howe yesterday, and it seems apparent that from
21 the beginning they were very reluctant to analyze
22 additional data that might disagree with their initial
23 assessment of the uptake.

24 MS. SHANKMAN: Yes, I would agree with that.
25 They also sat for a long time on urine samples that I

1 believe -- I think we were going to put this in our
2 conclusions -- that they could have identified the fact
3 that the food ingestion pathway that they were
4 concentrating on in the conference room is not the only
5 ingestion pathway.

6 We had, John -- we had a miscommunication, I
7 would call it. Jim Dwyer, I believe, thinks he should
8 have surveyed the entire fifth floor. What happened was,
9 early on we asked them were they going to survey the areas
10 outside the conference room, and they told us they were
11 going to survey beyond the labs, which were part of
12 regular surveys, they were going to survey all non-
13 laboratory areas on the fifth floor.

14 The reason they missed the cooler is, it turns
15 out that they did not believe that the two access
16 corridors were part of the fifth floor.

17 MR. GLENN: Okay.

18 MR. MADISON: Jim mentioned that, yes.

19 MS. SHANKMAN: Okay. And we have searched our
20 soul, so to speak, whether we should have -- and that's in
21 lessons learned, when a licensee -- we all know this
22 lesson, but it's reinforced by this small event, which is
23 that we should have said, "Color in for us this plan of
24 the fifth floor, all the areas you surveyed". Well,
25 anyway -- so they didn't survey those areas, and they

1 didn't process the urine, so they didn't have a concept
2 that there was another ingestion pathway for several
3 weeks.

4 MR. GLENN: Okay. Now, in terms of the
5 interactions that NIH was having with the doctor who was
6 exposed, was there a free-flow of information in terms of
7 the medical condition of this person?

8 MS. SHANKMAN: As Jim probably told you, one
9 of the first things we did was get a medical consultant,
10 and make sure that we had available to us Mike Stabin.

11 MR. GLENN: Right.

12 MS. SHANKMAN: And once we had those, you
13 know, clearances to call those people -- well, I don't
14 have to tell you how getting a medical consultant works.
15 We got Barry Siegel. We spoke to him, and we had him
16 speak to Mike Stabin, and we asked both of them the same
17 two questions. Of course, Mike was more expert in one,
18 and Barry in the other, but we wanted to hear from both of
19 them. One, is there any -- and we also verified, by the
20 way, that NIE had spoken with REACT, and what REACT had
21 told them.

22 MR. GLENN: Okay.

23 MS. SHANKMAN: And we said to them, "Is there
24 any medical intervention indicated by the facts as we know
25 them, even if the dose were higher than indicated?" And

1 the answer we got was no.

2 The second thing is, are we getting enough
3 information for you to be able to make an assessment of
4 the dose. And Mike Stabin said yes. So, those were the
5 two things that we were most immediately concerned with
6 because we did not want to miss an opportunity to get data
7 that would be -- you know, three weeks later, there's no
8 point in getting blood if you didn't get it at the
9 beginning. So, that was -- the one bone of contention was
10 that we needed more blood, a complete blood work-up. And
11 so, based on -- that was another thing, the licensee was
12 very reluctant to ask for any other things. We insisted
13 that we wanted a complete blood work-up, and so they did
14 do that.

15 We also insisted that we wanted some nuclear
16 medicine scans. They agreed to do that. We said it was
17 not invasive, we didn't believe that it would do anything
18 to the fetus, and it just meant her coming in and having
19 Dr. Carastea (phonetic) do it. They finally agreed that
20 they would do that.

21 So, we were very clear at the beginning that,
22 one, there was no medical intervention beyond what had
23 been done and indicated and, secondly, that we needed some
24 other information and we insisted that the licensee do it,
25 and we used the phrase I just used -- "We don't want to be

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1 five weeks down the road and think 'we should have done
2 this'".

3 MR. GLENN: Yeah.

4 MS. SHANKMAN: Okay.

5 MR. GLENN: Okay. Now, my understanding is
6 that at least the Radiation Protection Office at NIH,
7 although they had that nuclear medicine scan and I guess
8 another measurement, they were reluctant to quantify the
9 information that they had?

10 MS. SHANKMAN: Um-hmm.

11 MR. GLENN: And I guess eventually the Nuclear
12 Medicine Department did quantify --

13 MS. SHANKMAN: Right.

14 MR. GLENN: That's right.

15 MS. SHANKMAN: And were reluctant to have it
16 done in the first place.

17 MR. GLENN: And also my understanding is that
18 the results of that quantification were that the exposure
19 was quite a bit higher than the Radiation Protection
20 Office had estimated.

21 MS. SHANKMAN: Yeah. I think what Lawrence
22 Livermore is telling us now is that it was the question of
23 how quickly it was passing through the system so that the
24 original urine sample -- you know, the urine sample, you
25 have a little ramp up, and then you reach a peak, and then

1 it starts to decay because it's not being passed through
2 into the urine, but the scan is showing it to you because
3 it's still in the body. Is that your understanding?

4 MR. GLENN: I think that's what Jim was
5 telling us, yes.

6 MS. SHANKMAN: Right. I mean, that's what
7 Lawrence Livermore is telling us, why there is a
8 discrepancy in the data.

9 MR. GLENN: Yeah. I guess, in speaking with
10 Donna-Beth, we understand that there is a problem with the
11 early data, and I guess --

12 MS. SHANKMAN: Right.

13 MR. GLENN: -- my understanding is now maybe
14 Lawrence Livermore is just ignoring those first couple of
15 samples.

16 MS. SHANKMAN: Right. Because they believe
17 that it hadn't -- that first samples don't tell you what's
18 been ingested because it hasn't been deposited to the
19 urine stream yet.

20 MR. GLENN: Okay. I guess in terms of some of
21 the conclusions that we will be coming to closure on with
22 respect to MIT, in the AIT report, are you making any kind
23 of conclusion about whether this was a deliberate act?

24 MS. SHANKMAN: The reason I'm sighing is
25 there's been so much direction and redirection about

1 whether the AIT report should have been issued prior to
2 the investigation --

3 MR. GLENN: Okay.

4 MS. SHANKMAN: Okay? If the investigation
5 were finished, then the AIT report, of course, will go
6 with whatever they found. If it isn't finished, we've
7 spent a lot of time looking at accident scenarios, given
8 the facts of the laboratory, the researcher, and the other
9 25 people -- you know, how could it accidentally have
10 gotten into the bowels of the water cooler, and how
11 could -- what scenario could we come up with? And I
12 believe that at this point we would say that we could not
13 find a scenario that would fit the facts that would
14 support accidental ingestion. Is that circumvent enough?

15 MR. GLENN: Yeah. It sounds like it's similar
16 to our findings.

17 MS. SHANKMAN: Right. I mean, without a
18 culprit, it's hard to say that it was deliberate, but we
19 cannot find another scenario.

20 MR. GLENN: Okay.

21 MS. SHANKMAN: John, did you read the report
22 from Duke, where they had a P-32 ingestion?

23 MR. GLENN: No. Do you know the date of that?

24 MS. SHANKMAN: We can get you a copy of the
25 report.

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1 MR. GLENN: Okay.

2 MS. SHANKMAN: Yeah. We got it from the State
3 of North Carolina and -- because we went back and
4 researched -- in our quest for how this could have
5 happened accidentally, we went back and found as many P-32
6 ingestions as we could in the AEOD records and throughout
7 the country and, in this one -- what I was going to tell
8 you, the one in Duke, the guy says, "I can't believe that
9 anybody would do it maliciously. I can't figure out how
10 it accidentally happened. It must have been some bizarre
11 occurrence", end of report.

12 MR. GLENN: Okay. I would be interested in
13 your list of previous events. I got one from AEOD, but I
14 don't remember Duke being in there. So, I'd like to
15 compare lists with you.

16 MS. SHANKMAN: Okay.

17 MR. MADISON: Susan, if you have that list, if
18 you could also forward that to us, that would be very
19 helpful.

20 MS. SHANKMAN: Sure, and the report from Duke.

21 MR. MADISON: Yes.

22 MS. SHANKMAN: Okay. And we also have a
23 report from California.

24 MR. GLENN: Okay. I don't think I know about
25 that one either.

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1 MS. SHANKMAN: Okay. That's the one with
2 Bishop and Varmouth (phonetic). Okay.

3 MR. GLENN: Are you aware of the one at Brown
4 University?

5 MS. SHANKMAN: Oh, sure. And we also know
6 that the people who were involved in the one at Brown went
7 to NIH to work recently. I mean, all these things,
8 wherever we heard these fragments, we turned them over --
9 and I guess this is the point -- to OI. We do not believe
10 that those were inspection follow-up items, we believe
11 they were investigatory follow-up items because they speak
12 to deliberateness.

13 MR. GLENN: Yeah. Okay. With respect to
14 security at NIH, did you look at that as part of the AIT,
15 or was that only a part of the inspection?

16 MS. SHANKMAN: Yeah, we looked at it as part
17 of the AIT.

18 MR. GLENN: Okay.

19 MS. SHANKMAN: You know, the petition that we
20 have in-house now, you know, makes the nexus between
21 security and these ingestions because, you know, at NIH,
22 we have one over-exposure, we have one member of the
23 public who was over-exposed, and then we have 24 other
24 incidents. But we believe that whether security was
25 contributive to this event or not, it was something that

1 we had to look at because access to material certainly is
2 an issue. So, of course, we looked at security.

3 And what did we find? We found one incident
4 on the fifth floor of an unsecured, unattended radioactive
5 material. We called that to the attention of the
6 Radiation Safety Branch. That was during the site time
7 that I spent both in June and July and August.

8 MR. GLENN: Okay.

9 MS. SHANKMAN: As you know, another group of
10 inspectors found six incidents in approximately 100 to
11 380, depending on how you're counting, recently, and that
12 prompted the CAL, which I'm sure you've seen, right?

13 MR. GLENN: I'm not sure we've seen that CAL,
14 no.

15 MS. SHANKMAN: Okay. This was done a couple
16 of days ago, or last week, the end of the week --

17 MR. GLENN: No.

18 MS. SHANKMAN: -- and it's several pages long,
19 and we have the licensee's response. So, that's something
20 else that I'm going to send to you.

21 MR. GLENN: If you would.

22 MS. SHANKMAN: You can get it, I'm sure, down
23 there, but I'll send it to you. And that's being formed
24 into an Order, even as we speak.

25 MR. GLENN: Okay
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1 MS. SHANKMAN: You have one CAL in July, and
2 then you have this other one in October.

3 MR. GLENN: Okay. I was unaware of the one in
4 October.

5 Okay. In terms of -- one thing that the IIT
6 is looking at is also the NRC and its regulations and
7 guidance. With respect to security, did the AIT take note
8 of any lacking in our own regulations and guidance with
9 respect to security and control of material?

10 MS. SHANKMAN: Well, there isn't much
11 guidance. It basically says you'll secure radioactive
12 material.

13 MR. GLENN: Okay. I guess an issue we're
14 looking at is that there is some guidance to the staff
15 members in terms of small quantities of radioactive
16 material, and lesser security requirements --

17 MS. SHANKMAN: Right, and the whole issue of
18 exempt from labeling --

19 MR. GLENN: Right.

20 MS. SHANKMAN: -- under Appendix C.

21 MR. GLENN: Do you think that contributed in
22 any way to this incident?

23 MS. SHANKMAN: Well -- I want to be careful.
24 There is a general risk that was considered acceptable
25 in -- I think, implicitly, in the Cs-and-As that went out,

1 in enforcement actions that we've taken, and in the
2 interchange between upper management of this agency with,
3 for instance, Dr. Varmouth and I believe also other --
4 with the research community, that says very small
5 quantities of material, particularly those exempt from
6 labeling -- the agency is not going to concern itself
7 significantly about that and, by extensions, we understand
8 research has needed certain freedom to use certain
9 material, and the safety risk, because you're authorized
10 users, you have a certain degree of education, you're
11 knowledgeable about the effects of radiation -- security
12 of those quantities is not an issue that the agency is
13 going to make a big deal of. And I don't know if you
14 agree with me, but I think that sometimes that's the tone
15 you pick up in many documents that I've read, including
16 responses from the previous Chairman.

17 So, I believe that that whole collection of
18 things contributed at the NIH campus, to a sense, that
19 small quantities of radioactive material basically were
20 okay to share among supervisors, users, not to be -- you
21 know, at lunchtime, if you have to go to the bathroom, you
22 know, there's no need to treat them as if they're in Fort
23 Knox.

24 MR. GLENN: Okay. Again, you didn't
25 necessarily find any nexus, I guess, between that finding

1 and the incident in this case?

2 MS. SHANKMAN: Well, I don't know what we
3 found. There's a quantity of P-32 that got into the water
4 cooler. We don't know where that P-32 came from.

5 MR. GLENN: Okay.

6 MS. SHANKMAN: And I guess when we find out
7 where it came from, then we'll know whether it was
8 security at the NIH, or maybe even at another institution,
9 that allowed that quantity to be diverted.

10 MR. GLENN: Okay. So, you really don't have
11 any finding at all with respect to a likely source of the
12 material?

13 MS. SHANKMAN: Not yet.

14 MR. GLENN: Okay.

15 MS. SHANKMAN: There's a lot of P-32 on the
16 campus, and the amount that was in that water cooler could
17 have been diverted. The issue of the original researcher,
18 what she ingested may have come from the waste stream
19 also.

20 MR. GLENN: Okay. Another area where we're
21 looking at are the reporting requirements of the agency,
22 and whether they're clear.

23 MS. SHANKMAN: That's a problem.

24 MR. GLENN: Do you have any observations on
25 that?

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1 MS. SHANKMAN: I think the fact that NIH is
2 still telling us that this was not reportable, and it was
3 only because they're a big licensee that we knew about it,
4 I find very troubling. When we said, "But if you
5 suspected that it was malicious, would you not have..." --
6 "Well, there's nothing in your regulation that says that
7 malicious acts have to be reported".

8 MR. GLENN: Okay.

9 MS. SHANKMAN: And I think --

10 MR. GLENN: As you heard at MIT, they did not
11 report it --

12 MS. SHANKMAN: Am I aware? Yes.

13 MR. GLENN: -- and their conclusion was it
14 wasn't an over-exposure, and we didn't have any
15 requirements.

16 MS. SHANKMAN: Right. And I think -- I think
17 that one of the lessons I've learned is that if I were to
18 change my regulations, I would have it say that any
19 malicious act involving licensed material should be
20 reported to the NRC, or any suspected malicious act. I
21 think we'd have to propose that and see what the
22 difference is between suspected and confirmed, but I think
23 -- because in the case of NIH, they could say, "Well, it's
24 not confirmed yet", okay?

25 MR. GLENN: I don't know, you may be aware

1 that there is a move within the agency to move forward in
2 that direction already.

3 MS. SHANKMAN: Okay. But what I'm saying is,
4 I think we should have it that any suspected willful act
5 using licensed material should be reported to the NRC.
6 And I also believe that any exposure in excess of 50
7 percent of an alley should be reportable. That doesn't
8 mean that there's a violation.

9 MR. GLENN: Yeah.

10 MS. SHANKMAN: Because -- I know I saw that at
11 MIT. It was 579, you know, and at NIH, they are claiming
12 it is 580, therefore, it's still not reportable. If they
13 can do that so precisely, they should write a paper on
14 internal dosimetry because, clearly, the rest of the
15 internal dosimetry world doesn't believe that you can be
16 so precise that you're getting close to 600 microcuries.

17 MR. GLENN: You could be within a couple of
18 percent --

19 MS. SHANKMAN: Right.

20 MR. GLENN: -- and you've got clear call area.

21 MS. SHANKMAN: Right. So, not to argue it, I
22 would make it around 50 percent would be reportable, and
23 then at least we'd know about it and could discuss it.

24 MR. GLENN: We could review the adequacy of
25 the analysis.

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1 MS. SHANKMAN: Right. And I pick 50 percent
2 because 25 percent sounds too low, then we're really
3 regulating and micromanaging the licensees, and 75
4 percent, as I've learned from NIH and MIT, might be too
5 high. So, I don't know what the right percentage is.

6 MR. GLENN: Okay. I wonder if you could just
7 tell us any other areas where you have lessons learned?

8 MS. SHANKMAN: Okay. One of the areas has to
9 do with the operation of the Team.

10 MR. GLENN: Okay.

11 MS. SHANKMAN: There was some confusion in the
12 contracting of OI and in Lawrence Livermore. And you're
13 familiar with the Lawrence Livermore, you know, trying to
14 get a third party. There was some delay there. There was
15 some confusion in the task agreement sent to Mike Stabin.
16 We sent him one in Region I, in which we asked him to
17 identify the isotope and then quantify the exposure.
18 Headquarters sent them one that said quantify the
19 exposure. And so he did not confirm that it was P-32.

20 So, we had to go back and ask him to take the
21 sample that we had sent to the other part of Oak Ridge,
22 the laboratory, and he had to have them confirm that it
23 was P-32.

24 MR. GLENN: Okay.

25 MS. SHANKMAN: Am I being clear on that?

1 MR. GLENN: I think so.

2 MS. SHANKMAN: What I'm saying is, the lesson
3 learned is that any contractual support to the Team should
4 be managed by the Team Leader or the Team Manager.

5 MR. GLENN: Okay. Are you familiar with any
6 of the formalities that go along with the IIT and the --

7 MS. SHANKMAN: I've had the IIT training.

8 MR. GLENN: Okay. Do you think any of those
9 would have been useful in this particular incident?

10 MS. SHANKMAN: Absolutely. And I have
11 talked -- originally, we chose to do it in AIT because we
12 believed that there was no over-exposure. And an AIT with
13 a potential over-exposure met the guidance.

14 I believe that when we found the other 25
15 people who had elevated P-32, we should have considered
16 moving it up to an IIT.

17 MR. MADISON: Were you on-site when that
18 occurred, Susan, or were you --

19 MS. SHANKMAN: No, I was not.

20 MR. MADISON: When did you go back to Region
21 I?

22 MS. SHANKMAN: I went down just for the first
23 day and then I came back, and didn't go back until the
24 17th.

25 MR. MADISON: Okay. Thank you.

1 MS. SHANKMAN: All right. Let me go through
2 my list that I have.

3 MR. GLENN: Yeah.

4 MS. SHANKMAN: The other thing is, I believe
5 that any support staff from NMSS who supports an AIT
6 should, like an IIT, be assigned to the Team management
7 there, and not have --

8 MR. GLENN: Two masters.

9 MS. SHANKMAN: Right. And two people giving
10 them vacation, and CWS and, you know, not being able --
11 calling -- I thought they'd be there and they weren't
12 there.

13 I think we should also have better guidance on
14 event follow-up for licensees. I think they should
15 understand, although NIH called REACT, if they hadn't,
16 that it would have been much worse now to assess whether
17 they did the right thing in terms of the medical
18 consequences. Since we are not physicians, I believe we
19 should make sure that, in any licensee -- because they all
20 don't have physicians who are -- you know, Dr. Carastea --
21 we're talking about a whole different quality of people at
22 the NIH, but most licensees don't have those people
23 available to them. And I think that -- I'm not sure that
24 everybody knows REACT and would know to call. What is
25 your experience, John?

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1 MR. GLENN: In our case, they didn't call
2 REACT, but they did, in fact, get the medical -- you know,
3 seen by a doctor.

4 MS. SHANKMAN: Okay. Well, my feeling is --

5 MR. GLENN: And one of our findings is --

6 MS. SHANKMAN: REACT has the kind of
7 experience that they should at least be -- the medical
8 people should at least be aware of them and be put in
9 touch of them.

10 MR. GLENN: Well, one of the possible areas
11 we're going to be looking at is whether, you know, the NRC
12 needs to have guidance for licensees with respect to what
13 they should do in a response like this.

14 MS. SHANKMAN: Right. And what I'm suggesting
15 is, I don't think we should get into very detailed
16 guidance, you know, if this exposure, do this, you know,
17 in terms of medical remedies, but I think they should know
18 the kinds of medical advice available to them, and I speak
19 to REACT because I think, as an agency, we have confidence
20 that their experience is the kind of experience we would
21 like brought to bear on any over-exposure.

22 MR. GLENN: Well, I think there is -- we've
23 all seen a tendency of licensees to want to believe the
24 best, and getting some --

25 MS. SHANKMAN: I understand those

1 requirements, REACT, and the availability of them to us.

2 MR. GLENN: Okay. You think that was a
3 problem in this case?

4 MS. SHANKMAN: Well, we did check that they
5 had called REACT. We did do that, but I don't know that
6 everybody would do that.

7 MR. GLENN: Well, I guess that -- it is a part
8 of the Emergency Response Manual, you know, procedures --
9 I've seen it -- that book. There is a section that talks
10 about REACT, and how they're available to give us advice
11 in emergencies.

12 MS. SHANKMAN: Right. I guess maybe it should
13 be in with the AIT guidance and the -- I don't know
14 exactly. I think maybe we should just review that, John.

15 MR. GLENN: Yeah.

16 MS. SHANKMAN: And it's accessible when you're
17 -- you know how quickly you have all these senior managers
18 discussing what should this be with an incident, how
19 significant is it, what's the right agency response, and
20 da-da-dum, and here's your charter -- and I don't think
21 anybody goes to those Emergency Procedure Manuals at that
22 point.

23 MR. GLENN: You're probably right.

24 MS. SHANKMAN: Let's put it in the book
25 they're going to look in.

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1 MR. GLENN: Yep, hear you.

2 MS. SHANKMAN: The authority needs to be
3 clarified in terms of incident response. I think maybe --
4 I'm assuming you're going to work on a follow-up generic
5 letter, and the resistance we got from NIH, and even the
6 initial CAL response we got from Dr. Massey (phonetic)
7 indicated to me that -- you know, Frank basically said,
8 "Yeah, yeah, we're going to do all these good things", and
9 you know that John Kinneman had to sit down with him and
10 say, "Not good enough, Frank. We need to hear what all
11 those good things are".

12 MR. GLENN: Yeah. I did my duty in getting
13 Frank to actually put it in writing and send it, which is
14 what I think he was intending to do earlier than this.

15 MS. SHANKMAN: Yeah. Now, we're talking about
16 two very sophisticated licensees in which I would tell you
17 that I have great confidence in their health physics staff
18 available to them, and medical staff in the Boston area
19 and in the Washington area, but I worry about a licensee
20 with lesser sophistication and lesser resources available
21 to them, understanding the role of the NRC where, in fact,
22 we need to be there and looking over their shoulder.

23 If I recall, the AIT at Backus (phonetic) was
24 the first material of AIT in a very long time.

25 MR. GLENN: Yes.
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1 MS. SHANKMAN: So, I think the materials
2 world, unlike the reactive world, does not have in their
3 kin, AITs, IITs, what that means, and that we're a
4 different agency when we're in that mode -- different than
5 the licensing agency or the routine inspection agency.

6 MR. GLENN: That's what I think about the IIT,
7 that it's very clear from the beginning, the different
8 animal. And it puts a lot of responsibility on the Team
9 Leader, but the Team Leader also has the authority to make
10 things happen.

11 MS. SHANKMAN: Exactly. So, I think maybe we
12 need to let them know that there's an AIT world.

13 MR. GLENN: Yeah.

14 MS. SHANKMAN: You don't want to have to use
15 an IIT, it's very expensive, time-consuming and, you know,
16 your life is different, right?

17 MR. GLENN: Right.

18 MS. SHANKMAN: The fact that the investigation
19 -- we need to tease that out when we have something that's
20 malicious.

21 MR. GLENN: Yeah. And, obviously, when we had
22 some problems there, too. It sounds like we had them in a
23 much smaller degree than you had them.

24 MR. MADISON: We addressed it right away --
25 well, fairly soon after we got on-site, by splitting that

1 part off.

2 MS. SHANKMAN: Right. We split it off, too,
3 but we're not out of the woods. Every single piece of
4 paper that we do has to be reviewed by OI and the FBI.

5 MR. MADISON: Oh, yeah. And the thing is, we
6 made a nice, clean break, when we said, "We're looking at
7 this, and we won't look at that", and essentially we share
8 information with them, but we don't have everything
9 cleared by them.

10 MS. SHANKMAN: And you don't have the FBI.

11 MR. GLENN: And we don't have the FBI either, right.

12 MS. SHANKMAN: Yeah. And that's made a
13 difference. We ought to have limited engagement in this.

14 MR. MADISON: We weren't restricted in access
15 to the individual involved either.

16 MS. SHANKMAN: Right. It's been a difficult
17 thing. For instance, we had some follow-up questions we
18 would like to ask the researcher and her husband. We made
19 an appointment --

20 MR. GLENN: We have six hours of testimony
21 from our exposed researcher. I mean, he was a wealth of
22 information.

23 MS. SHANKMAN: Okay. Well, we had some
24 follow-up questions. We made an appointment, and Jim
25 Dwyer and I were driving down because we chose

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1 interviews together.

2 MR. GLENN: Yeah.

3 MS. SHANKMAN: Connie beeped me on my beeper.
4 I called the office, and it was -- the researcher's
5 attorney was on the phone. I got a number, I called her,
6 and she said, "You cannot interview my client today.
7 We'll have to work it out another time". And I said,
8 "Okay. Well, we're on our way down there, how about
9 tonight, tomorrow morning, lunchtime, you name it, we'll
10 be there. My calendar is very busy, I'll call you".

11 So, I made maybe five follow-up phone calls to
12 her, and also checked with OI. They said, "If the
13 attorney says you can't interview them, you can't
14 interview them because you might infringe on their
15 criminal rights", you know.

16 MR. GLENN: Yeah.

17 MS. SHANKMAN: Well, what do you do? We
18 decided that the few follow-up questions we had were not
19 enough to bring in OGC and press for that, you know, to
20 ask, "Well, did you eat the shrimp, or the vegetable?"

21 MR. GLENN: Yeah.

22 MS. SHANKMAN: Okay. Also, the authority of
23 the licensee to obtain samples from someone that's been
24 contaminated. The researcher was very reluctant to supply
25 urine, to have blood samples taken, and to have the scans

1 done.

2 MR. GLENN: Okay. And that's a major
3 difference in the two cases.

4 MS. SHANKMAN: Oh, there are lots of
5 differences. One of the major differences is that these
6 people were not working with P-32.

7 MR. GLENN: Okay.

8 MS. SHANKMAN: So, it's hard to come up with
9 an accident scenario. At least your researcher had P-32
10 in his vault, right?

11 MR. GLENN: Right.

12 MS. SHANKMAN: We talked about -- let me look
13 at one more -- also, the authority of the NRC medical
14 consultant. I had to go to the top levels of the NIH to
15 get them to speak with Dr. Siegel and to release medical
16 records that they had to him.

17 MR. GLENN: Okay.

18 MS. SHANKMAN: Now, I don't know whether
19 that's the resistance of the licensee. They said it's
20 Privacy. I said -- I can't tell you how many times I said
21 to them --

22 MR. GLENN: I think this is the first time
23 I've ever heard of a reluctant -- to share information
24 with one of our medical consultants.

25 MR. MADISON: Physician-to-physician --

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1 MS. SHANKMAN: We just wanted the medical
2 records. "No, no, no." I said, "Well, how about to our
3 medical consultant?" "We'll ask Dr. Schmitt if he'll do
4 that. We'll get back to you by the end of the day." The
5 end of the day, I called, you know, "What's going on?"
6 "Well, you can't have the records." I said, "I will get
7 an order that our medical consultant can get the records
8 as part of our investigation". "Well, we'll get back to
9 you."

10 So, I waited five minutes, then I called the
11 doctor in question and I said, "What is the problem?" "No
12 problem. I'll talk to Dr. Siegel."

13 MR. GLENN: And I think that's probably the
14 difference. Usually, the first contact is made by the
15 medical consultant to their doctor, and if the two doctors
16 do it, you don't have any problem with it.

17 MS. SHANKMAN: Right. Well, I think that --
18 you know, I don't know how to communicate this to the
19 licensees but, in whatever communication you send out, we
20 should just say that, that an NRC medical consultant has
21 the right to have access to any medical information. I
22 didn't want it. I wanted Barry Siegel to have access to
23 it.

24 MR. GLENN: Yeah.

25 MS. SHANKMAN: ~~Let's see.~~ Oh, the other thing
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1 is the relationship with the press. I don't think you had
2 a problem, but we did have the Headquarters issuing press
3 statements without clearing them with AIT.

4 MR. GLENN: Okay. Again, that's something
5 that the IIT procedures are rather clear on, however, we
6 did have one press release go out before I had a chance to
7 review it.

8 MS. SHANKMAN: Okay. I think those are all
9 the things on my list, and I hope I gave you a flavor of
10 the frustration that we had from two sides, the licensee
11 and -- I mean, I don't want to call it frustration with
12 the FBI, but it definitely changed the way in which we're
13 used to doing business on an AIT.

14 MR. GLENN: Just one other thing that we were
15 discussing in terms of our findings. Did you see any
16 problems at NIH that you think might be attributed to lack
17 of institutional oversight of the Radiation Protection
18 Office and Program? Independent means of assessing what
19 the Radiation Protection Office is doing?

20 MS. SHANKMAN: Well, they report through the
21 Security Safety Line.

22 MR. GLENN: Okay.

23 MS. SHANKMAN: So, it's the Office of Research
24 Services. I don't know whether that reporting requirement
25 is a problem. Certainly the researchers report to a

1 different group, and I don't know whether it would work
2 better if the Radiation Safety Branch reported directly to
3 the Deputy Director for Research. They have a convoluted
4 way of getting to him.

5 MR. GLENN: Do they have a Radiation
6 Protection Committee that functions and is fairly active?

7 MS. SHANKMAN: Yeah, they meet monthly. And
8 it has, I would think, appropriate representation on it,
9 but it's person-specific. The current Radiation
10 Protection Committee Chairman, I met with him several
11 times and I attended two meetings. He's very aggressive
12 and feels strongly that radiation safety both in the
13 clinical sense and in the non-clinical community is very
14 important. I believe that if he were not as aggressive,
15 they would not have made their interim security policy
16 permanent, which was something they needed to do for a
17 long time. He's relatively new.

18 So, I think the issue is that it's person-
19 specific. But I think you find that many places.

20 MR. MADISON: Did they have a route of
21 auditing or independently reviewing program performance?
22 They, meaning the RPC.

23 MS. SHANKMAN: The Radiation Safety Committee?

24 MR. GLENN: Yeah.

25 MS. SHANKMAN: Not that I'm aware of. They

1 leave that to the Radiation Safety Branch and the RSO.

2 MR. GLENN: It's my understanding, Susan, that
3 you need to break off about one o'clock.

4 MS. SHANKMAN: Well, this is important -- I
5 can get there a little later, if you have other questions.
6 I'd rather answer your questions now.

7 MR. GLENN: I think I've asked most of mine.
8 Al, do you have any other --

9 MR. MADISON: No. Is there anything else that
10 you would have done differently, other than what you've
11 already mentioned, Susan?

12 MS. SHANKMAN: Of course, what I would have
13 done differently is, I would have gone down more
14 aggressively at the beginning, and interfaced with a
15 higher level at the NIH, and made it very clear that we
16 had the authority to do all the things that we were doing.
17 We were much too polite in the beginning.

18 MR. MADISON: Okay.

19 MS. SHANKMAN: And, John, I believe that you
20 characterized as "that's the advantage of an IIT".

21 MR. GLENN: Yeah, because right up front you
22 meet with them, you lay out the rules and, in our case, it
23 went rather smoothly.

24 MS. SHANKMAN: And the other thing is, I also
25 think the people who are sent on an IIT from the Program

1 Office as well as the Region, are your highest quality
2 people, and I don't believe that that is the same criteria
3 used in this case, the support that we got.

4 MR. GLENN: Okay. I understand. Is there
5 anyone else that we should talk to who was on the AIT?
6 We've talked with Jim. We've talked with Donna-Beth.
7 We've talked with you.

8 MS. SHANKMAN: I think Sittar Lodhi was it for
9 the site activities, and then -- this was also -- you said
10 what I would have done differently -- he went on vacation.
11 He had an extended vacation scheduled. This was before
12 the water cooler was identified. And he has been helping
13 the Team, but has not been a full member since. I would
14 have replaced him. So, we suffer from not having that
15 extra member which we had originally thought we would
16 have. But we didn't know we were going to have letters
17 from attorneys and -- do you know what I mean? The
18 workload has been significantly higher because of the
19 petition and because of the attorneys. I don't know.

20 MR. MADISON: Part of the lesson learned is
21 that you have become involved in more than just the
22 investigative or the inspection program?

23 MS. SHANKMAN: Absolutely.

24 MR. MADISON: It's diluted your efforts as far
25 as the actual inspection

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1 MS. SHANKMAN: Yes. Well, diluted?

2 MR. MADISON: Diverted.

3 MS. SHANKMAN: No, not in terms of the actual
4 inspection, but it definitely had an impact on the
5 production of the report.

6 MR. MADISON: Okay.

7 MS. SHANKMAN: I think -- no. When we were
8 on-site, we were dedicated to that activity, and we had no
9 other duties. What I would have done differently is, I
10 would have locked everybody in a room until that report
11 was finished.

12 MR. GLENN: That's exactly what I'm doing.
13 I've got them locked up here.

14 MS. SHANKMAN: I would have done that but, you
15 see, the AIT doesn't have that mandate, and so that's what
16 I would do differently.

17 MR. GLENN: Okay. Just reviewing in terms of
18 some things we would like you to send us a list of those
19 incidents involving P-32, and the copy of the CAL that was
20 --

21 MS. SHANKMAN: Right. Give me a fax number,
22 I'll fax everything to you.

23 MR. GLENN: Let's see, do I have --

24 MR. MADISON: Cherie has that one number she
25 wants us to fax --

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WASHINGTON, D.C. 20005

1 MS. SHANKMAN: John, I just thought of
2 something else. I think we're -- you know, we definitely
3 have to look at changing our inspection program of
4 security and our regulations because I think that the
5 inspection of security over time, when you asked what
6 leads to the attitudes that you see about security, I
7 think the way in which we inspected, and the number of
8 citations across the country, and the publication of those
9 citations.

10 The community pays attention to the things
11 that we pay attention to. And I don't think that we've --
12 how can I say this -- for the safety risk of the materials
13 involved, I'm not sure that we've been doing the wrong
14 thing, but I think this is the point in time to reconsider
15 that.

16 MR. GLENN: Okay. And we certainly will in
17 our report.

18 MS. SHANKMAN: Do you know what I mean? I'm
19 not damning all the inspectors that have gone before.

20 MR. GLENN: Right.

21 MR. MADISON: When we go off the record, I'll
22 get a number for you to fax to.

23 MS. SHANKMAN: Okay.

24 MR. GLENN: Okay. I will be sending you those
25 guidelines for transcripts and I think Cherie has already

1 been working on trying to find a day when we can send some
2 transcripts up to Region I and have someone go back to
3 MIT, plus have you and Jim look at your transcripts. But
4 I will be including those guidelines for your information.

5 MS. SHANKMAN: John, did I tell you anything
6 you didn't suspect already?

7 MR. GLENN: You clarified some issues. I
8 guess I won't say there was anything that was shocking.

9 MS. SHANKMAN: Okay. I didn't think there
10 would be.

11 MR. GLENN: The time is now 1:10, and this
12 interview is complete.

13 (Whereupon, at 1:10 p.m., the interview was
14 concluded.)

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C E R T I F I C A T E

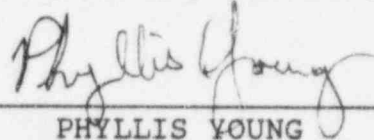
This is to certify that the attached
proceedings before the United States Nuclear
Regulatory Commission in the matter of:

Name of Proceeding: IIT INTERVIEW OF SUSAN SHANKMAN

Docket Number: (NOT ASSIGNED)

Place of Proceeding: ROCKVILLE, MARYLAND

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.



PHYLLIS YOUNG
Official Reporter
Neal R. Gross and Co., Inc.

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WASHINGTON, D.C. 20005



10-95-187

UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 30, 1995

ALL AGREEMENT STATES
MASSACHUSETTS, OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-95-173)

Your attention is invited to the attached correspondence which contains:

INCIDENT AND EVENT INFORMATION.....XX	RECENT INCIDENTS INVOLVING POTENTIAL LOSS OF CONTROL OF LICENSED MATERIAL
PROGRAM MANAGEMENT INFORMATION.....	
TRAINING COURSE INFORMATION.....	
TECHNICAL INFORMATION.....	
OTHER INFORMATION.....	

Supplementary information:

Enclosed for your information and transmittal to Agreement State licensees is Information Notice (IN) 95-51, "Recent Incidents Involving Potential Loss of Control of Licensed Material." The IN describes two recent incidents at medical research licensees' facilities involving intakes of phosphorus-32 (P-32). Initial indications (not yet confirmed) are that deliberate misuse of licensed material, resulting in internal doses to individuals, may be a factor in both of the incidents. The incidents raise issues about security of licensed material that are applicable to all licensees, not just research facilities using P-32. We suggest that you forward the IN 95-51, or the information in it, to your own licensees.

Also, we request that you inform us on whether you have ever had similar licensee incidents involving potential deliberate misuse of radioactive material. If you have had such incidents, we are interested in obtaining any details about those incidents. If you have not had such incidents, that information is important, too. We will use your replies, along with our experience, to gauge the extent of the problem, and to decide whether further action is warranted. Please provide positive or negative replies by December 1, 1995, to the individual named below.

951130278

OCT 30 1995

If you have any questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT:	Stephen N. Salomon
TELEPHONE:	(301) 415-2368
FAX:	(301) 415-3502
INTERNET:	SNS@NRC.GOV

Stephen C. Bangart

for Richard L. Bangart, Director
Office of State Programs

Enclosure:
As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

October 27, 1995

NRC INFORMATION NOTICE 95-51: RECENT INCIDENTS INVOLVING POTENTIAL LOSS OF
CONTROL OF LICENSED MATERIAL

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to two recent incidents involving potential loss of control of licensed material, resulting in internal contamination of individuals. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

Recently, NRC was informed of and responded to two incidents involving phosphorus-32 (P-32) internal contamination of individuals at biomedical research facilities. P-32 is widely used in research institutions, as are many other radionuclides. Although these incidents both involved P-32, the inherent security issues extend to all facilities using licensed material.

Case 1: On June 30, 1995, a licensee informed NRC that an incident involving internal contamination of a female researcher had been reported to the licensee's radiation safety office the previous evening. The researcher was in her fourth month of pregnancy at the time of the incident. Contamination was detected when the researcher's husband, who worked with her at the licensee's facility, performed a routine survey of their lab. The licensee identified the radionuclide as P-32. Accidental contamination appeared unlikely because the woman had stopped working with radioactive material in their lab about a month before, and because the radioisotope (P-32) identified in bioassay samples is not of the same type her lab used. Licensee security officials and the Federal Bureau of Investigation are investigating the possibility that the woman ingested food or liquids deliberately contaminated with the radioisotope. Initial calculations (now being refined by NRC, the licensee, and the researcher's own technical experts) estimated that the researcher ingested tens of megabecquerels (hundreds of microcuries) of P-32.

Subsequent licensee surveys identified a few droplets of P-32 on the floor in front of a refrigerator in a lounge adjacent to labs the couple use and an internally contaminated water cooler in the same building. Urine bioassays of other workers identified approximately 25 additional individuals who have low-level internal P-32 contamination. In early July 1995, NRC sent an Augmented Inspection Team to investigate the circumstances surrounding the contamination incident. While the inspection and investigations are ongoing, NRC has obtained licensee agreement to improve the control of radioactive materials used in its biological and medical research programs.

Case 2: On October 16, 1995, a licensee informed NRC that an incident involving internal contamination of a researcher had occurred at its facility almost 2 months earlier. Licensee officials told NRC staff that they had not reported the incident earlier because their analyses suggest that the researcher's internal dose was below the 10 CFR Part 20 reporting criteria.

According to the licensee, the researcher discovered that he was contaminated during a routine survey of his work area. Also according to the licensee, it subsequently detected P-32 contamination on an item of clothing that the researcher had worn earlier that week, when he had last handled P-32 in the laboratory. The licensee performed urine bioassays, and informed the researcher that he may have ingested what was described as a drop of P-32 containing 21.4 megabecquerel (579 microcuries). The researcher has told licensee campus police that he believes the contamination was not accidental. NRC and campus police are investigating his allegation. Also, the researcher has requested that an independent consultant prepare a second dose estimate.

The licensee initially secured all radioactive materials in the lab after discovery of the contamination event. Since then, the licensee has permitted work with radioactive material to resume, after requiring more stringent inventory and accountability in the lab and tightening security. On October 17, 1995, NRC dispatched an Incident Investigation Team to the licensee's site to begin an immediate investigation of the incident. NRC also sent a letter to the licensee requiring that certain steps be taken, ensuring among other things that control of radioisotopes is adequate to provide reasonable assurance against another such incident. NRC's investigation is ongoing.

Discussion

The two recent P-32 internal contamination incidents raise a number of safety and regulatory issues. NRC is reviewing its regulations to determine if they need to be revised in light of these events. Among these issues are radioactive material security and accountability, survey procedures, preparation for bioassays, and reporting requirements. Each of these issues is addressed separately below.

- a. Security. In controlled or unrestricted areas, licensees are required by 10 CFR 20.1801 and 20.1802 to secure stored material, and to control and maintain, under constant surveillance, licensed material that is not in storage. Access to restricted areas is required to be controlled to prevent unauthorized access to licensed material. Licensees should review their programs to ensure that they have a radiation safety program in place that will prevent deliberate misuse of radioactive materials in all licensee areas.
- b. Accountability. 10 CFR Part 20 requires the reporting of theft or loss of materials above defined levels. In addition, the Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope," published for comment in October 1994, states that license applicants:

... should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to ensure that licensed possession limits are not exceeded and that material is accounted for throughout the institution at any given time.

In light of these events, licensees should review their programs to determine whether they need to improve their radioactive material accountability systems, commensurate with the scope of their programs.

- c. Detecting licensed material. NRC emphasizes that conducting surveys with adequate, calibrated equipment is a crucial step in conducting safe operations. Many commercially available survey instruments, such as Geiger-Mueller detectors, are capable of detecting P-32, even after ingestion, in the activity range used in research facilities. In both of these cases, internal contamination was originally detected when the researchers conducted routine surveys of their laboratories and detected high background readings. Licensees should review their programs to ensure that they are conducting surveys with adequate, calibrated equipment.

- d. Bioassay preparation. All licensees are responsible for responding to incidents. Some licensees already have bioassay programs in place to comply with the requirement in 10 CFR 20.1502 to monitor workers whose intake is likely to exceed 10 percent of the occupational dose limits. Interpretation of bioassay data, when regulatory thresholds are approached, may be difficult. Important information on the proper conduct of a bioassay program is provided in Regulatory Guide 8.9, Rev. 1, July 1993, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program" and NUREG/CR-4834, "Interpretation of Bioassay Measurements." Licensees that need immediate medical consultation to respond to an ongoing internal contamination event can contact the Radiation Emergency Assistance Center/Training Site (REAC/TS), which is funded by the U.S. Department of Energy to provide consultation in such situations. The NRC Operations Center can connect callers with REAC/TS.

If internal contamination is detected, health physics consultants are commercially available to assist with bioassay and other response measures. However, licensees that plan to use consultants may want to identify and make arrangements for those resources now, rather than wait until an incident occurs. Licensees that need help in identifying health physics services should contact professional societies or organizations for references.

- e. Food and beverage storage. Generally, licensees have procedures prohibiting eating, drinking, and smoking in radiologically restricted areas. In light of these events, licensees should review their programs to determine how food, particularly lunches, snack foods, and beverages in unsealed containers, are permitted or stored in their facilities.
- f. Contact NRC if deliberate misuse of licensed material is suspected. NRC considers deliberate misuse of licensed material to be of significant regulatory interest, and expects to be contacted in such situations. Although the magnitude of the dose could be within NRC's regulatory limits, the possibility that such a dose was delivered intentionally, and possibly with malice, raises concerns about a licensee's, a contractor's, or any employee's deliberate misconduct, as addressed in 10 CFR 30.10, 40.10, 70.10, and 72.12. In addition, pursuant to 10 CFR 30.9(b), 40.9(b), 70.9(b), and 72.11(b), each licensee is required to "... notify the Commission of information identified ... as having for the regulated activity a significant implication for public health and safety" Notification shall be provided in such cases to the Regional Administrator within 2 working days.

The issues raised in these two cases should lead licensees to consider reexamining their own methods to prevent and, if necessary, respond to internal contamination incidents.

The information in this notice is preliminary, and the investigations and inspections in these two cases are ongoing. NRC may issue further guidance, as necessary, once results are known and conclusions drawn on these two cases.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contacts listed below or the appropriate regional office.



Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Scott Moore, NMSS
(301) 415-7875

B. J. Holt, RIII
(708) 829-9836

Mohamed Shanbaky, RI
(610) 337-5209

Thomas Kozak, RIII
(708) 829-9866

John Potter, RII
(404) 331-5571

Linda Howell, RIV
(817) 860-8213

Attachments:

1. List of Emergency Contacts
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

LIST OF EMERGENCY CONTACTS

- I. NRC Operations Center
Telephone: 301-816-5100 (will accept collect calls)

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Daytime Telephone: 423-576-3131
24-hour Telephone: 423-481-1000 (ask for REAC/TS)
(to consult with a physician)

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

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95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors
95-25	Valve Failure during Patient Treatment with Gamma Stereotactic Radiosurgery Unit	05/11/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-64, Supp. 1	Reactivity Insertion Trans- ient and Accident Limits for High Burnup Fuel	04/06/95	All holders of OLs or CPs for Nuclear Power Reactors and all fuel fabrication licensees.
95-07	Radiopharmaceutical Vial Breakage during Preparation	01/27/95	All U.S. Nuclear Regulatory Commission medical licensees authorized to use byproduct material for diagnostic procedures.

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95-46	Unplanned, Undetected Release of Radioactivity from the Exhaust Ventilation System of a Boiling Water Reactor	10/06/95	All holders of OLs or CPs for nuclear power reactors.
95-12, Supp. 1	Potentially Nonconforming Fasteners Supplied by A&G Engineering II, Inc.	10/05/95	All holders of OLs or CPs for nuclear power reactors.
95-45	American Power Service Falsification of American Society for Nondestructive Testing (ASNT) Certificates	10/04/95	All holders of OLs or CPs for nuclear power reactors.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-Type Male Connectors	09/26/95	All Radiography Licensees.
95-43	Failure of the Bolt-Locking Device on the Reactor Coolant Pump Turning Vane	09/28/95	All holders of OLs or CPs for nuclear power reactors designed by Westinghouse Electric Corporation (W).

OL = Operating License
CP = Construction Permit

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

October 27, 1995

NRC INFORMATION NOTICE 95-51: RECENT INCIDENTS INVOLVING POTENTIAL LOSS OF
CONTROL OF LICENSED MATERIAL

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to two recent incidents involving potential loss of control of licensed material, resulting in internal contamination of individuals. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

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OL = Operating License
CP = Construction Permit

10-95-188

Duke University - Duke University Medical Center

DURHAM, NORTH CAROLINA

February 21, 1990

RADIOLOGICAL SAFETY OFFICE

FACILITY CODE 1710
TELEPHONE (919) 844-2194
P. O. BOX 1193

Mr. Cecil Brown, Chief
Radioactive Materials Section
Division of Radiation Protection
N.C. Dept. of Environment, Health, & Natural Resources
P. O. Box 27687
Raleigh, North Carolina 27611-7687

Dear Cecil:

RADIATION INCIDENT REPORT

Licensee: Duke University Medical Center

License Number: [REDACTED]

Date of occurrence: On or about April 16, 1988.

Incident: Ingestion of Phosphorus 32 Orthophosphate by employee.

Individual Exposed: [REDACTED]
[REDACTED]
[REDACTED]Calculated Ingested Activity: 5.96 ± 3.03 milliCuries.

Calculated Whole Body Dose: 31.15 Rem.

Cause of Incident: Unknown (possible cause scenarios attached).

Remedial Action Taken: No procedural changes; strong re-emphasis on
existing laboratory procedures.

"This report is furnished to you under the provisions of Section 10
NCAC 03C.2520 (c); Overexposures & Excessive Levels & Concentrations."

RECEIVED
FEB 25 1990
RADIOACTIVE MATERIALS

Sincerely,

David B. Jorgensen