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NUCLEAR REGULATORY COMMISSION

Title: MIT: Incident Investigation Team
Interview of James Dwyer

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ADDENDUM

Page	Line	Correction and Reason for Correction
14	8	"globalized" → "mobilized"
87	22	"their" → "they are on their"
42	4	"decalibrate" → "re-calibrate"

Page 1 Date 11/10/85 Signature John F. Glenn

ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction	
7	13	NOT "AIT", INVESTIGATION	MISSTATEMENT
9	12	"they" refers to NIH	CLARITY
14	8	Mobilizer	MISUNDERSTANDING
15	3	They separately look for a Shaker — according to ~~person~~ — NOT IN Rad Safety Staff reports	MISSTATEMENT
15	17-25	Submitted direct to Holy Cross because they do not have clearance on radiation Dept	CLARIFICATION
17	5	Hickman at Lawrence Livermore	CLARIFICATION
17	6-10	can use early date for Model but license called for 12-hour, NOT 24-hour, scaling up for 24-hour NOT appropriate because excretion rapidly changing at this point.	CLARIFICATION

Page 1 Date 11/21/95 Signature

ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction	
24	18	Dr. Carrasquillo	clarification
42	10	"brainstorming" not broad sage	clarification
43	1	"	"
44	9	740 - 820	Misstatement
47	21	~~Not responsible~~ Wholly	Misstatement
48	10	-The 26 Number Includes Dr. Y	Misstatement
48	22	~200 million	Omission
49	14	"RDIC"	Omission
52	6-9	A few samples demonstrate the scavenging problem discussed on the bottom of p. 51	clarification

Page 2 Date 11/21/95 Signature

ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction	
55	6-8	One of the inspectors from 1994 assisted me with inspections in 1995.	CLARIFICATION
55	24	Building 37	CORRECTION
57	22-23	More responsibility placed on Mechanical users, less emphasis on documentation	CLARIFICATION
61	21	~80 laboratories on that floor	CORRECTION
62	4	If you are starting Dr. X and Dr. Y, you better start Dr. Weinstein	CORRECTION
63	23-24	I don't recall saying this + I don't know what it means	CORRECTION

Page 7 Date 11/21/95 Signature

UNITED STATES OF AMERICA

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NUCLEAR REGULATORY COMMISSION

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INCIDENT INVESTIGATION TEAM

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INTERVIEW OF JAMES DWYER

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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TUESDAY, OCTOBER 31, 1995

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1:00 P.M.

INTERVIEWERS:

JOHN GLENN, Team Leader

ALAN L. MADISON

SAMI SHERBINI

GREGGORY P. GONECONTO

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

(1:00 p.m.)

MR. GLENN: Okay, today is October 31st. It's approximately 1:00 p.m. This is John Glenn with the Incident Investigation Team for the MIT P-32 exposure.

This is going to be an interview with Jim Dwyer of Region I, who has been the team leader for an AIT at the National Institutes of Health. And we will be trying to get information about that incident to see if there are common lessons learned and facts that we should put together in writing out report.

At this time, I'd like the other people who are with the team to identify themselves.

MR. MADISON: I'm Alan Madison, Jim. I'm with the -- I'm with AEOD, the Diagnostic Evaluation Incident Investigation Branch. I'm on the team.

MR. GONECONTO: And Jim, my name is Greg Goneconto. I'm a Special Agent with the NRC's Inspector General's Office. And I'm sitting in with the IIT as an observer.

MR. GLENN: And Jim, if you could just say who you are and what your position is, and in particular what your duties were with respect to the NIH incident.

MR. DWYER: Okay. I'm a Senior Health Physicist in the Medical Branch, the Medical Inspection

Branch, here in Region I. And I was conducting a routine inspection at NIH, leading a routine inspection on the week of June 26th through the 30th.

And on the morning of June 30th, we had the -- the incident was made aware to us and had been identified the previous evening to the Radiation and Safety Branch.

We quickly rolled over into an investigation, into an incident investigation mode. We exited form the routine inspection that afternoon, and followed that up with an entrance for an AIT.

And I've been the AIT team leader, along with Donna-Beth Howe. Sadhar Lohdi was involved initially, but then left the team. Jerry Kenna has been working separately from the AIT. However, he is a team member, and he's been working with the Office of Investigations, the NIH Police Department and the FBI on the case.

And Susan Shankman is the team manager.

MR. GLENN: Okay. And I'll just mention that Sami Sherbini is on the team and may join us later.

MR. DWYER: Okay. Is Betsy there?

MR. GLENN: No, she removed herself from the interview since she's a Region I employee. So she's not here.

MR. DWYER: Okay.

MR. GLENN: You've given us a little bit of the

narrative already of how the incident occurred. I was wondering if you could just go through a little bit of the facts surrounding the case: who was exposed, what they were exposed to, when they were exposed, this kind of thing.

And then we can ask our -- oh, I'm being reminded -- I forgot to tell you something. I did mention to you before we started that this would be transcribed. We do that with the IIT for two reasons: 1) it means we don't have to take notes when we're asking questions and listening to answers; 2) it gives us a record that we can refer to as we write our report.

You will be given an opportunity to take a look at the transcript and make any corrections on an errata sheet. And we'll make arrangements to get, you know, a copy of the transcript to you so that you can make those comments.

And we'll send you a copy of a handout we have that explains how to do the corrections and how to contact us and that sort of thing.

MR. DWYER: Okay.

MR. GLENN: Okay. Now, we're getting back to the narrative. If you could tell us just a little bit about the facts of the case so that we all start with a common knowledge, and then maybe we'll ask you some

questions that are particularly related to our charter.

MR. DWYER: Okay. I'll jump around, I think in chronological terms, and that's where I'll go. But let me start from where my chronology began. And that was, as I said, on June 30th, arriving with a couple of team members, a routine inspection.

They were on their way out to complete some items that were left on the inspection. I got there around eight o'clock or so after having a team meeting in the morning in the hotel.

And the RSO -- actually I thought that somebody on the staff had died because there were so many long faces. And they pulled me into the Regional Safety Officer's office and he informed me that the previous evening at about six o'clock they were made aware of a contamination incident that they had responded to.

And, you know, they then were starting to fill me in on what had transpired.

Apparently what had occurred, there's a husband and wife team of researchers from Mainland China who have been working at NIH since 19 -- since August of 1994. They have been doing research with mostly low energy beta emitters, occasionally some P-32.

And they were doing PCR experiments, basically using nucleotides. And the -- most of the time, they

would be using in the order of 2 microcuries up to sometimes 20 microcuries in their experiments.

The experiments were fairly far between. At one time, they used some sulphur 35. And they moved away from that because of the volatility problems, the contamination problems that were reported.

They used some P-32 originally. They eventually moved into P-33.

I'm at a disadvantage as far as what happened in the laboratory from March 20th on. I did look at their lab notebooks, and both of their lab notebooks stopped documenting what was going on in the laboratory as of mid-March.

I reported that to OI, and they apparently have followed up on that and have identified some additional record keeping of what was going on in the laboratory. But I haven't been privy to that information right now.

I don't know what difficulties you had at MIT. But because this is an ongoing event when we were there, I was, and the team was, precluded from speaking with either the two principals, the husband and the wife, the pregnant researcher or her husband, or the individual authorized user who they're alleging had something to do with this contamination.

MR. GLENN: Yes. Jim, just let me interrupt

you there, because that is a major difference between the two investigations because we had considerable access to the exposed individual and interviewed him three times for a couple of hours each time.

Whose decision was it that you didn't have access? Was this because of -- was this FBI, OI?

MR. DWYER: It was a -- because of the investigation going on and the concern by OI and the FBI -- the FBI was not involved in this case initially as much as they were after June 17th -- July 17th, rather.

But OI and the NIH police were concerned that we might compromise the investigation. So that was pretty much accepted by the NMSS Region I, you know, the AIT as something we would try and live with then.

Let me correct one thing. When I said we were precluded from speaking with them, we did have one opportunity to speak with the pregnant researcher and her husband. And that was in, I believe, the third or the fourth week in July.

And however, during that interview, the -- can I use their names? I feel silly not using their names because it's all over the press.

MR. MADISON: Yes, we'll have to excise the transcript, whatever is easier for you, Jim.

MR. DWYER: I'll try not to. But if I do, I

won't get any heartburn. Dr. X and Dr. Y were instructed not to address anything having to do with the investigation during our interview, and we were instructed not to ask any questions.

And Jerry Kenna from OI sat in on that interview with the express purpose of making sure that neither one of us crossed the line.

So what we did was we asked questions about, you know, about their work at NIH up until the event occurred and then just some very cursory ideas about what had occurred the night that the contamination was identified.

The following week, we had an opportunity to speak with the authorized user, the Dr. Weinstein about -- from his perspective. And we were not put any -- there were not any constraints put on us as to what questions we asked.

And my understanding was that that had something to do with, you know, the legal status of this interview. OI and the FBI could not tell us what questions to ask.

You know, they were not going to participate. And I think if they -- something about since that was the case, that they could use any information that we got in the case. Whereas if it was contributed by FBI -- I don't

pretend to understand all the legalities.

But there was some -- you know, some legal slight of hand going on there. So they weren't too concerned about our interview with Dr. Weinstein. And he didn't come with an attorney, and we asked pretty much whatever questions we wanted.

Otherwise, our information has come entirely -- at least as far as the events, has come entirely from what the Radiation Safety Branch was able to learn the night of the incident prior to the police becoming involved in it.

Because as soon as the police became involved in it, they also were precluded from discussing anything with the researchers or with the authorized user.

MR. GLENN: Okay. So you've really been precluded from any direct interaction questioning regarding the events of the day that it was detected?

MR. DWYER: Right. And now, what I'll tell you now as far as the chronology of those events, come from, you know, the HPs who responded to the incident and that type of thing.

And you know, what I can -- and also the information that was provided by the researchers when we had the interview with them. And the recent information was provided by Dr. Weinstein in our interview with him.

But you know, this is a mix-mash of basically

of what they've said. A lot of the things that were told to us were contradictory to what we had heard from the -- from the HPs, what they had been told when they were -- you know, when they were there on the 29th.

But our understanding, and I'll just launch into this, is that Dr. Y discovered her pregnancy, I believe it was in April, and at that point elected not to use any radioactive materials, even though our understanding is that they were not using very much.

And most of their research was -- involved cold procedures. So it didn't really affect their work too much to do that.

The -- you know, it gets difficult here to separate what's the allegations and everything else. Apparently, according to, you know, Dr. Weinstein, they had developed some interesting results, some interesting experimental results. And they were very hot to publish these results.

And even though they had only achieved this success one time and they were, you know, presenting their results at meetings at the -- you know, on the NIH campus.

And apparently all the response that they were getting was that, you know, this is great, but, you know, can you reproduce it?

And they were not able to reproduce it. And

the Saturday before the incident, this would have been six days before the incident, they apparently had another negative result, as they say.

And they met on Sunday with Dr. Weinstein to discuss that negative result. And there was some agreement that they would continue work on this and to iron out their problems.

And then in the meantime, they would proceed with presenting this or submitting this work for publication with the idea that the supporting work would come later

So Dr. Weinstein was -- took that upon himself to get this paper in shape for publication. Drs. Y and X went back to the laboratory to work.

A lot of their work was going to be done in the laboratory -- in the library, rather.

That week, I don't have my notes in front of me, but they did not use material every day of the week. You know, they may have used some on Monday, probably not Tuesday, maybe a little bit on Wednesday.

But we're not talking about any large quantities and we're not talking about P-32. We're talking about P-33.

The -- let's see, on Thursday the 28th, they said that they were at the library and returned back to

the office -- to the laboratory. And Dr. Y was hungry.

By the way, up until a couple of months prior to that, they were bringing their food in and storing it in a communal refrigerator in a conference room on the floor. As I said up until a couple of months before because she had developed morning sickness, and so she stopped bringing food in.

It was only the previous Tuesday. So that would have been the 27th that they resumed -- starting bringing food back in from home.

They ate food -- they ate lunch together on the 27th. On the 28th, Dr. Y ate alone. She says that she -- that they went into the conference room and Dr. Weinstein and her and his associate were having a meeting in there. So they quickly put the food in the microwave and left, and that Dr. Weinstein later called them and said, "Come in and get your food. It's ready."

And they took the food back, and she ate it at a table in the hall outside of the laboratory. And she reported that the food was overcooked and not very tasteful. And for that reason, she didn't share with her husband. She threw the remainder in the garbage there.

They went home and worked later that night. The next day, they worked in the office. And because they were going to be working late that night, they went home

in the middle of the day.

They came back around five o'clock in the evening, and Dr. X said that he was going to just check on -- he had done an experiment that was completed earlier that day.

And he was apparently doing a routine survey, which he said he did whether he used the material or not. And he detected what he called a slight signal near her feet when he was checking the floor.

And he thought that it was her chair or her coat. And then he determined that it was coming from his wife.

The -- apparently, he tried to find Dr. Weinstein, who was not in his office. The office is directly adjacent to the laboratory. And Dr. Weinstein apparently was not in the office at the moment.

And Dr. X called the 116 number, which is the emergency fire department paramedics for the -- for the NIH campus. They have their own fire department there.

Dr. Weinstein returned. They advised him of tnis, and apparently the paramedics arrived shortly thereafter. Dr. Weinstein commented that he thought it a bit premature that they had called the fire department paramedics because, you know, nothing had been confirmed as to what the problem was.

The paramedics notified the Radiation Safety Office of the emergency response number. The Deputy RSO was at the top of the list, and he notified the Radiation Safety Office.

Pretty much concurrently, Dr. Weinstein called the Radiation Safety Office and there was a parallel notification made. And the Radiation Safety Office globalized to go over.

That was about six o'clock, as I said, on the 29th.

Let me think here. The radiation -- or Dr. X apparently told Dr. Weinstein that he thought that her food had been poisoned because they found contamination in the refrigerator in this conference room.

And they took him over there and, you know, he said that he thought that he found some contamination on a blue bag and on a clear bag that were in this refrigerator.

When the Radiation Safety Office staff came up, there were two of them. Beth stayed with Dr. X. George went to do surveys in the hall and to check out the conference room.

You know, Beth determined that she was -- you know, had not had a recent procedure, started doing surveys and documenting the surveys, identified that it

was not her clothes by having her change into a clean pair of scrubs.

They looked for a shower, and were unsuccessful. They had her provide a urine sample. The urine sample was hot. They advised the Radiation Safety Office and those samples were returned to the Radiation Safety Office.

The -- Dr. Weinstein and Dr. X went into the conference room with George, the HP, and George showed them that the contamination was actually a spot inside there on the floor in front of the refrigerator, and nothing in the refrigerator was contaminated.

Dr. Y was taken to Holy Cross Hospital, which is interesting because Suburban Hospital is right outside the door from Building 37.

I think the State of Maryland believed that they took her to Holy Cross to get her out of the neighborhood so it wouldn't be publicized.

But the paramedics/Radiation Safety Branch, the Licensee, said that they took her there because her only complaint was back pain. And being four months pregnant, they -- you know, Holy Cross reportedly has, you know, a neonatal unit, or at least can handle these problems better in the mind of the people who made the decision than Suburban could.

I don't know how valid that is, but that's the way it was. So they took her to Holy Cross.

George Redman did surveys in the conference room and posted the door, did more surveys in the corridors and the halls leading back to the lab, 5B18, where the researchers worked, documented all of this and left there around 9:00 p.m.

The Radiation Safety Officer went to the hospital. They had instructed the paramedics to tell the emergency room to save all of her urine. The Radiation Safety Officer reiterated that, brought back one blood sample and one or two urine samples when he returned.

Dr. Weinstein remained in the laboratory area. he contacted the Radiation Safety Office and said that he had found a coffee cup on the table where Dr. Y ate her dinner. And in the coffee cup was a 50 cc centrifuge tube with an orange cap, and that the centrifuge tube was contaminated.

So the Radiation Safety Office asked him to store that away until the following day.

Let's see, the samples were measured. They pulled out NUREG CR 4884 and made some preliminary evaluations that she probably had an intake of about half of an ALI, around 300 microcuries.

And you see, Dr. --

MR. GLENN: Jim, I'll just comment that that's kind of eery, because you know, that's almost exactly the same thing that happened at MIT, that the first analysis was -- once they had it in, was around 300.

MR. DWYER: Well talking to David Hittman and Lawrence Livermore, he said that the model, the ICRP model, does not account for the ramping up of the P-32 concentration in the urine. It appears to be a straight -- you know, not a straight line, but at least a straight curve.

Whereas if you start looking at the urine in the first day or so, that really the maximum concentration has been reached. So you'll be coming up one side of the peak and then roll over and go down.

So if you use those first few datapoints in the analysis that NIH is doing, it pulls down the overall average. But it doesn't fit the models. Therefore, in this case, the first two datapoints that, you know, when ORISE looked at it and when Lawrence Livermore looked at it, they're throwing out the first couple of datapoints because the P-32 really had not come in sufficiently enough.

MR. GLENN: Okay, that may be a difference between the two because, at least preliminarily, the conclusion at MIT is that the uptake occurred four or five

days prior to the discovery of the contamination.

MR. DWYER: Right.

MR. GLENN: So we were on the ramp down rather than the ramp up.

MR. DWYER: Okay. So anyway, that's with respect to what they had that evening. The next day, they told us about it. They were doing inventory checks and things like that on the floor.

The police became involved, and the police were pretty upset really that they weren't called in the night before because, you know, everybody who works on that floor has access to the conference room.

And so they went back up and changed the lock on the conference room door. More surveys were done in the conference room. And it was -- more contamination was found spread around the floor.

It was not as significant as the contamination that was in front of the refrigerator, but you might expect that someone ignored the caution tape that was on the door and chose to enter the room and spread some contamination, both in the conference room and outside the conference room door going into the hall.

But one thing that was identified that was fairly significant on Friday was that when they were in there doing these follow-up surveys in the conference

room, the HP found a paper bag that had significant contamination on it.

And the paper bag was sitting on this old computer box in the corner, in the back corner, of the room. And you know, this was brought to the attention of the HP who had done the survey the night before.

And he said that that bag wasn't there when he was there the night before. And the reason he can say with great assurance was because when he covered the contamination on the carpet in front of the refrigerator, he used a piece of cardboard. And he took the cardboard from the paper -- from the cardboard box that this paper bag was sitting on.

So that paper bag was impounded as evidence by the -- by the FBI as well as by the police, the NIH police.

They also checked on this centrifuge tube that had contamination. And they found P-32, and later some P-33, in the centrifuge tube.

The liquid was very -- just a second please.

(Asides.)

MR. DWYER: That was Jenny. So anyway, that liquid was analyzed. It was originally P-32. And as the P-32 decayed, it was apparent there was some P-33 in there.

And if memory serves me right, it was about 80 nanocuries per ml of liquid, and I think there was only a ml of a liquid in there. So it didn't, you know, look like, unless it was rinsed out, it didn't look like that's where the material came from.

Now both health physicists who had responded on the 29th of June reported that that centrifuge tube was not on the table where Dr. Y ate when they were there doing surveys, because they specifically surveyed that area.

And as a matter of fact, one of the HPs had set up a survey station at that area. And so they said with pretty good assurance, personal assurance anyway, that that centrifuge tube with the contamination in it was not present when they were there.

Let me back up a little bit. When Dr. Y was at Holy Cross, they started hydration therapy, just gave her an IV. The Radiation Safety Office put the -- put the attending physician in touch with REACTS.

And REACTS had suggested some additional measures that had contra-indications. And it was decided that since she was pregnant and the initial P-32 result looked like it was, you know, half of an ALI, that there would not -- you know, that they chose not to try to do anything herculean to try and bring it down any faster.

There is still some confusion about -- about the sampling. As I said before, Dr. -- Bob Zoon, who is the RSO, had instructed the hospital to save all of the urine.

Apparently at one point, they -- they saved all the urine, but they were -- from each void, they were alliquotting out a sample and then putting the rest of it in a pooled sample container.

There's been some allegations that that was the suggestion by the authorized user, and that he had interfered with this process.

That's something that I think OI knows something about, but the information/communication channels here have been pretty much one-way between OI. When we get some information, we provide it to them, but we're not getting anything back.

So I would expect those people to describe this situation a lot better than I could at this point.

But see, Dr. Y was released at around 3:00 or 4:00 in the morning and sent home. She apparently got sick in the car, resulted in some contamination that ended up being cleaned up the next day by the Radiation Safety Branch.

She also apparently had severe vomiting when she returned home that morning, that Friday morning.

On Friday, they came into the Radiation Safety Branch to provide additional urine samples, and to get a whole body scan. The Licensee has a ACCUSCAN whole body device.

They just wanted to get a baseline number and possibly look at some of the clearance of the P-32 as time went on.

She was there for quite a while, and complained of some more back pain. They sent her to OMS. That's the Occupational Medical Service on campus, which is like their clinic.

There she was -- provided a blood sample, which was pretty much something that was requested by Barry Seigal, our Medical Consultant, as a -- to get an idea of whether there was any blood changes due to this contamination.

He didn't believe that there would be, since we were still talking around 300 microcuries. But at least it would knock off that high end concern.

MR. GLENN: Did you get results on that sample?

MR. DWYER: The problem being is that apparently -- I forget the guy's name. He was a confidant of Joe McCarthy's back in the 50's or something who went to NIH at one time and died of AIDS. And NIH messed up and released that information.

And so they're extremely sensitive to medical and personal privacy, and they wouldn't provide it to me without a release from Dr. Y. And Dr. Y apparently was not authorizing any release.

And the way that we worked it out is that Barry Siegal said that he could get the information from OMS verbally, and that he was going to -- that he would contact OMS.

I got an unofficial response that that -- that that blood profile was normal. And --

MR. GLENN: Okay, but that's privacy information?

MR. DWYER: That's privacy information.

MR. GLENN: Okay.

MR. DWYER: You see, NIH had contacted Mike Stabin prior to our involvement. And he apparently has collaborated with them on other issues before. And he was assisting with them with what they were doing.

And his comment was that he wanted to see the -- you know, several more true whole body -- or true 24-hour urine samples. You know, that was his suggestion and that he was interested in these ACCUSCAN whole body scan surveys, I guess I would call them.

We got -- we got Barry Siegal involved. And Barry Siegal said that he agreed with the medical decision

the night before not to do anything, you know, invasive or giving a stable phosphate or anything else for this -- to this woman.

And what he suggested was, you know, complete blood profile, urine. He suggested feces. And he wanted mostly to have them perform a nuclear medicine-type scan on -- from this patient, from this -- from the researcher.

We discussed it with the Licensee and with Stabin. We had great difficulty coming to conclusions about what was going to occur.

It was finally agreed that they would get 24 hour urines; that they would run the ACCUSCAN whole body scan; that they would do blood profile; and that they would do the nuclear medicine-type scan.

The first nuclear medicine-type scan was done that evening at the Nuclear Medicine Department at NIH. There was significant localization of counts in the liver and spleen area, which Dr. Karaskewa, the physician, said meant that the contamination was in the blood, still in the blood.

And however, he didn't have any quantification of it at that point. He was going to run some phantom studies, and try and quantify what was done.

The Radiation Safety Office supplied her with several plastic containers, and instructed her to collect

all of her urine. She would bring urine samples in and some 24 hour samples, which were over 7 liters in volume.

And I was, you know, not sure how that was possible, but they checked with her making sure that you're not filling this up with water, because you know, we've told you to fill it. Are you sure that you're not having your husband contribute this?

And her response was, "No, no, this is what I did on Saturday. This is what I did on Sunday." So you know, they were going -- using this data as if it was their true 24 hour volumes.

There were follow-up whole body scans which showed a P-32 clearance of about a week, which is close to the eight days that was expected.

There was a follow-up nuclear medicine scan that was done seven days later. And at that time, they also did a -- used a -- I believe it was a four inch sodium iodide crystal from about 15 meters away from Dr. Y to get an account rate, and equated that to some rough phantom studies that they had done with P-32.

And the second nuclear medicine scan wasn't -- I guess indicated that it was about 420 microcuries in Dr. Y at that time. That was on July sixth.

The first one looked to be about 860 microcuries at the time of the scan, which was the evening

of June 30th. And the nuclear medicine -- or the sodium iodide scan, I think going from memory here, was somewhere in the high 300s. And that was also on the sixth.

There was some discussion about the medical care that Dr. Y was getting. And she had indicated that she had been working through this with her own physician, and that he had reported that everything was fine.

I, at one time -- and I'm jumping ahead here. When we finally got to interview Dr. Y, she had indicated to us that -- you know, that she had not -- she had had morning sickness initially in the first trimester, but then it stopped.

And it was following this incident that she had started -- you know, had severe vomiting and the back pain and everything else.

And I was concerned that maybe she was showing the effects of a chemical poisoning, which I referred to our -- to Barry Siegal. Barry said that that pain and the vomiting could be the result of the trauma of having this occur to her, that he would talk to her physician.

He apparently didn't have much -- much luck with her physician. You know, he indicated that he had not been seeing her but once early in the pregnancy, and that he had gotten a phone call from her, you know, the previous day.

Barry was concerned about the medical care that she was getting. And he asked if it would be okay to talk directly with NIH because the person who was in charge of this, who is one of the administrators, is a medical school classmate of his.

And apparently, they discussed it. And Barry came away with a feeling that NIH was doing everything that was, you know, possible to solve this so that, you know, I shouldn't concern myself with the medical end of this.

Okay, as I said, I jumped ahead. The Licensee, once they were in the mode of collecting urine samples and doing these other scans for Dr. Y, started to perform urine bioassays on anyone who had access to that conference room.

And they did find -- I guess Dr. X, the husband, had somewhere in the order of 100 dpm/ml in his urine. They had a couple of other people who they identified as having something greater than their LLD, which was down around 11 dpm/ml.

They were really unable to explain how those people -- how all those people could have -- I think we're talking about three or four people -- could have been contaminated by what was in the conference room.

So they started to expand the urine sampling to

the entire fifth floor of Building 37. And chey started to get more and more numbers.

And they finally came to a point that they couldn't explain it anymore, and they started doing some additional surveys on the fifth floor. And at that point, they identified a cooler that was contaminated with P-32 internally in the reservoir.

There was -- you know, you could get about 60,000 counts on a pancake. They did some smears to identify the P-32, and there was significant contamination on the stainless steel surface on the inside of the cooler.

The water itself at that point was not contaminated. You know, apparently that had all washed through. This was just something that had plated out.

There was some liquid that was contaminated that was in the trap in the basin that's below the spickets. And NIH realized that since that was the only unmetabolized contaminant, they then undertook an analysis. They were going to try a thin layer of chromatography, an aspect to try and identify what the form was, whether it was orthophosphate, or was it an ATP or whatever?

And they tried to do that internally. The individual at NIH that tried to do it appeared to be well

qualified and knowledgeable about what was going on. But his comment was that the material looked to be an organic. But most of the material travelled with the inorganic as an orthophosphate.

And he believed that it was probably something like waste. Also, the fact that it had been sitting at room temperature for -- whenever the contamination occurred, you know, that any organic would have broken down since it's usually stored at a frozen.

So he couldn't do anything with that. We then went to NEN, to their Analytical Chemistry Department to look at it. And they analyzed the sample, and they pretty much came up with the same conclusions.

We, Region I, still has the sample here, although the FBI laboratory is planning on looking at it. They didn't want to analyze it because of the contaminant. We have analyzed it here radioisotopically.

Initially, we saw the P-32 decay away. There was no P-33 in the sample. However, we're still getting what the Licensee tells us is chemiluminescence.

We were a little concerned that the chemiluminescence wasn't varying with temperature and wasn't going away. And Jim Kottan here did some analysis, did some calibrations, with a tritium standard. And he's fairly well convinced that there's some minor amounts of

tritium in this -- in this liquid also.

We've asked the Licensee about that. They've sent us their reports and -- which indicate that there was no P-33 or tritium in the sample. But we're -- they are providing additional information in response to our request.

So we don't have the final numbers in on that. But we're looking at around about 50,000 dpm/ml in that -- in that basin sample that we were analyzing, that looks to us to be tritium.

I feel like I've jumped around and I've missed a lot. Maybe I can address more of it as you ask questions.

MR. GLENN: Well, you've done quite well with a relatively long narrative there. So thank you very much. I guess the first issue: when will your written report be ready?

MR. DWYER: It's in draft, and actually we're giving it to the editor to look at. Basically the things that are not well developed to this point are -- I've got the conclusions and our assessment of their response in bullet form, all the background information, security, you know, waste, inventory.

You know, how they train and authorize users and all that stuff is I'd say 95 percent complete as

written, you know, subject to change.

The chronology -- my chronology went into October. And what I was told to do was to complete it on July 17th, which was, you know, once the cooler contamination was identified.

So the current draft of the AIT report, the chronology only goes through July 17th. Donna-Beth is putting together the dosimetry, you know, parts of this report.

We just got the Lawrence Livermore final assessment on Friday. And I read it over the weekend. Donna-Beth is pouring through it with a little bit more detail. And she's got some questions about it.

I would expect that a completed product for the editor would be in place before the end of the week, assuming that nothing else occurs.

MR. GLENN: Do you know whether we can get a copy of that?

MR. DWYER: As far as -- I mean, I've provided it to Carl Paperiello and Cindy Jones has a copy of it and stuff. I can -- you know, I don't see any reason why I couldn't provide you with a copy of the AIT report in draft.

MR. GLENN: Okay, we would appreciate that. I may have Cherie Siegel contact you so that we get it

logged in as an official document and get it marked appropriately so that we don't release, you know, pre-decisional information.

MR. MADISON: Pre-decisional information, yes.

MR. GLENN: Okay, let me just briefly explore with you event reporting and Licensee response. It sounds like in this case, in terms of event reporting, it was reported within 24 hours simply because you were there.

MR. DWYER: Yes, and I honestly don't believe that they would have reported it had I not been there.

MR. GLENN: But there's no way to know that I guess.

MR. DWYER: Well, there's no way to know except for the fact that they'd - they kept on saying, "You know it's not reportable. You know it's not reportable."

MR. GLENN: Yes.

MR. DWYER: That's correct. And actually, as far as the written report, they did submit the 30 day report simply stating that we're reporting this because of the possibility that it may exceed an ALI. And we're -- this is an ongoing event that your staff is aware of and because they're working with us on it basically.

MR. GLENN: Okay. Now in terms of their response, it sounds like they responded promptly. They did surveys. They did -- they took the urine samples.

MR. DWYER: Yes, my -- one of the things that we're having in the assessment and they're kind of upset about it because it's, you know, 20-20 hindsight, but they -- but I kind of agree with them in one instance.

And that is that they were operating on information from Dr. Y and Dr. X that they got on day one. And that's the only information they had.

Okay, Dr. Y and Dr. X said that they brought all of their liquid, all their food and drink, to the office with them, that they didn't drink out of any community, you know, coffee pots.

MR. GLENN: Oh okay.

MR. DWYER: They didn't do any of this stuff. And that, you know, they said that this food was contaminated, and that was the only thing that she ate that he didn't eat.

And you know, here we had contamination, you know, no place else in the laboratory where they worked or where she ate or in the hall between the laboratory and the conference room except in the conference room in front of the refrigerator where she stored her food.

That was what they were operating under, and that's what they responded to.

And when they did their surveys up there, they surveyed everything between the conference room, the hall

in front of the conference room, the corridor between the C and D hallways, and then the D hallway -- I'm sorry, D corridor down to the laboratory and the entire laboratory and all the laboratories around it and didn't find anything.

And most of these laboratories are kept pretty cold. And most of them have hardly use in them. So there's not that much up there to see.

You know, this can -- so they were focusing on this particular incident as being the ingestion, and that's all they had.

I felt that they were right, and it was -- I thought that their initial response to this was very good. I'm not sure how many of our Licensees would be capable of doing this, except maybe MIT, which is kind of an interesting thing.

We don't have a lot of sophisticated Licensees who -- I mean, even the little ones who have authorization to have a millicurie of P-32, this could happen to them. And I don't even think they have the instrumentation to follow up, let alone the know-how.

So I felt their initial response was very good. However, they focused on this one ingestion possibility and rather than going and doing a very, very good survey of the rest of the floor and other areas.

What they did, one of the -- the Director of the program, the Developmental Therapeutics Program, which is over the top of this lab, you know, he called a meeting and he said that -- you know, he told us that he assigned all these areas, both restricted and unrestricted areas, and had people go and do surveys of these areas.

And then he was requiring that they do continual surveys of these areas. Well, it wasn't until later that we found out that he didn't consider the corridors to be unrestricted areas or even part of the floor, and they were outside of his realm of concern.

So that's why this water cooler wasn't identified for essentially two weeks.

So basically, they focused on this one ingestion. They were very prompt with doing the initial bioassays. I mean, they expanded the scope; they got the samples in. They analyzed them quickly.

When they expanded it to do the whole fifth floor, this is prior to identification of the cooler, our indications are that they fell behind in processing, sometimes two or three days.

And it wasn't until the 13th of July, which is Thursday, that they ended up putting -- I think they counted, you know, somewhere up to 100 urine samples overnight that night, such that on Friday morning, the

14th, they were -- they had -- had identified something like 17 new positive urines or something.

And it's at that point that they've said, "All right. We, you know, obviously have missed something. Let's get back up there and start surveying even more."

So because of that focus, they didn't identify the cooler. And once they expanded the bioassay program to the entire fifth floor, they fell behind.

So if they had processed them promptly, you know, we may have -- they may have identified the cooler even a couple of days sooner than they did.

MR. GLENN: Now Jim, has anyone looked at the issue of whether there may have been one, two or three or more episodes of contamination?

MR. DWYER: We're, you know, still -- you know, we're talking about, you know, problems with security and things like that. But we really don't know, you know, whether security had anything to do with this or whatever because we don't know what the -- how it occurred.

I -- you know, if you ask several different people, you get several different answers. Drs. X and Y will tell you that she was contaminated, and that somebody contaminated the cooler, either concurrently or later to throw everybody off the track.

I don't believe that this was one event, solely

because -- you know, initially Drs. Y and X said that they didn't drink anything out of the cooler or any -- you know, that they brought all their own liquids.

When I interviewed them the last week of July, they told us that they did drink out of that cooler. And however, Dr. Y said she drank very little, and her husband drank like a fish out of the cooler.

Well, he had 100 dpm and she had, you know, somewhere up to maybe a millicurie of P-32 in her body. So I don't believe that her contamination came from the water cooler.

You know, her contamination came separately than that. So I believe there's two events.

MR. GLENN: And you can correct me, but I think I heard in your narrative that, in fact, there was a paper bag that was found that --

MR. DWYER: Right.

MR. GLENN: -- that the surveyor swears was not there when the first survey was done.

MR. DWYER: Right. And I also talked about the centrifuge tube. And I can see where somebody might, you know, in their haste if their tired or whatever, they might not have seen the centrifuge tube even though they said they did careful surveys of that whole tabletop.

But I can't imagine that the guy ripped the top

off of that box to provide shielding and protection over that spot on the floor and didn't see the bag.

So -- so yes, that bag appeared sometime after nine o'clock on Friday night and before 8:30 Friday morning -- I'm sorry, nine o'clock Thursday night.

MR. MADISON: Jim, can I -- let me ask did their response -- was their response based upon written procedures or based upon their expertise?

MR. DWYER: What they do is whenever they have an incident, they have things like skin contamination kits and spill kits and things. And they provide training to their HP staff.

They have a very large HP staff. And most of them -- not most of them, but a lot of them are certified. They -- if you're an HP there, you've got your Masters in Health Physics. You know, it's a fairly sophisticated group.

When they -- when they have an incident, as I started to say, they -- you know, they'll have one of their supervisors who is managing it.

When they get done with the incident, they have lessons learned to see how they could do better. And they provide training to, you know, all of the HP staff on what they did and how they did it and what they could do better on this response.

As far as do they have any specific written procedures on how to respond to an incident, I didn't see anything like that. I didn't ask to see anything like that.

And to be honest with you, I'm not sure how valuable that would be, granted -- given that you really don't know what you're going to come up against. You know, you would end up writing a, you know, procedure that would be the size of a bible, you know, to respond to anything, you know, imaginable.

And if it's been something that's imagined, it probably doesn't happened because they've taken, you know, steps to make sure that that type of thing is not, you know, possible.

MR. MADISON: Let's focus down into the area then for the individual researcher that finds themselves contaminated or ingesting contamination. Do they procedures for that?

MR. DWYER: Yes, they have a -- they have emergency procedures that are provided to them verbally and in writing at the time when they go through training.

MR. MADISON: Do they address internal contamination?

MR. DWYER: I don't believe that they do, no. No, except that, you know, if you've got something that's

more than a minor offense, then you, you know -- if it's any kind of contamination, you contact your authorized user.

If it's more than that, then you're to contact the Radiation Safety Branch for assistance.

MR. MADISON: Okay, that's -- that's similar to MIT.

MR. DWYER: Yes. I mean, to give them anything more is probably going to cause them to get into more trouble, you know? They'll either spread it or you won't be able to get an idea of what the -- an accurate quantity is and you won't be able to do dose assessment.

You may end up breaking the skin. You may, you know, do all kinds of things. So it's better left to the experts.

MR. GLENN: Okay, any more questions, I guess, on the emergency response? Maybe move into the dosimetry. Now I guess -- how long did they take urine specimens? How long did they track this whole body counter thing that they had, and what were the results?

MR. DWYER: Okay, they took urine samples for -- I believe it was about a month. And Drs. X and Y continually expressed displeasure with this process. They -- you know, for having to collect all of her urine. And that was something that was taken into consideration.

So they did three of the whole body scans with the ACCUSCAN. They did two of the nuclear medicine scans. And they selected urine samples for a month.

Towards the last week or ten days, they did not collect all the urine. They collected, you know, good 24 hour urine samples, you know, two or three days apart.

And that was what Mike Stabin recommended was needed to do an accurate dose assessment here. You know, he did not -- he was not a proponent of taking it out to the nth degree.

MR. GLENN: Okay. And what were the eventual projections? Were they in agreement with the initial ones, or --

MR. DWYER: Well, the NIH's final assessment is at 500 microcuries. That's what they believe it is. That is using the initial urine data, which both ORISe and Lawrence Livermore said, you know, is probably not a defendable thing to do.

Both ORISE and Lawrence Livermore said that they could reproduce, with an experimental error, the result that NIH came up with if you used those two datapoints.

NIH only used urine data to determine this because, you know, that's what 4884, you know, allows for.

MR. GLENN: Even though they did have the whole

body counting, they did --

MR. DWYER: They had whole body counting, but they didn't have quantification of the whole body count.

MR. GLENN: Did they attempt to decalibrate?

MR. DWYER: No.

MR. GLENN: Okay.

MR. DWYER: Not to my knowledge. They were putting up a great battle about doing that, that it was not an accurate way to do business; that, you know, here you are trying to quantify broad scope and they resisted it.

And they said, "Mike Stabin doesn't care and doesn't want it." And I would talk to Mike Stabin, and Mike Stabin would say, "Well you know, it would be interesting." And I would say, "Well, you know, they're looking at me like I'm off in left field. And would you -- when you're talking with them, which you're talking to them several times a day, express this need?"

And he'd say, "Okay." And apparently, he didn't care about it enough to push the issue because they -- it has not been done. Although Carl had mentioned that, if need be, he would order them to do it.

They did not use the nuclear medicine data, even though Dr. Karaskewa had done a rough quantification of that data, because they didn't have great faith in, you

know, looking at broad scope basically.

They wanted to use the urine. And I suppose if the nuclear medicine scan data has supported their estimates, they probably would have embraced it. But they didn't. So their estimate was based purely on that.

They then got the INDOS program from -- what's his name? I'm losing my mind.

MR. SHERBINI: It's Scrable, Ken Scrable.

MR. DWYER: Scrable, right. And ran that -- their data with that program. And I'm not sure that INDOS supported their estimate of around 500 microcurie ALI.

MR. SHERBINI: How did they get the 500 then, Jim?

MR. DWYER: The 500 was based on 4884 and using all the datapoints.

MR. SHERBINI: How did they do that? Do you know?

MR. DWYER: How did they do that?

MR. SHERBINI: Yes.

MR. DWYER: Well, if you want to get into specifics, Sami, I would suggest that you interview Donna-Beth Howe because that was the part she was responsible for.

MR. SHERBINI: Oh, okay.

MR. DWYER: But my understanding is that they

were going purely on 4884. They were evaluating the 24 hour urine. They were getting a concentration. They were inputting the IRF, and then using that to get a datapoint on what the initial intake was.

And then they would refine it with each intake.

MR. SHERBINI: I see, okay.

MR. DWYER: All right. Okay, Oak Ridge took the data that NIH had for urine, urine only, they did not use any of the other data, and came up with a 720 to 810 microcurie intake.

And that was not using the first two datapoints because they, you know, felt that it was not -- it didn't meet the model -- match the model and that they weren't going to use them.

They -- you know, as I said before, they stated that they could reproduce what NIH did. They just didn't agree with the use of the early datapoints because --

MR. SHERBINI: Yes.

MR. DWYER: -- the P-32 was ramping up.

MR. GLENN: Did NIH have an answer as to why they insisted on using those first two datapoints?

MR. DWYER: They actually placed, you know, great faith in the early data. I mean, they said, you know, you have to use everything you've got.

And you know, I'm not an expert on 4884, but

they, you know, said, "You know, look, it says here that day one, this is the IRF for it, and that's what we're using. This is the procedure."

So you know, why should they discount this datapoint, you know, and to the exclusion of others? They're sitting on it, but they're quite interested in what everyone else is coming up with.

You know, they still believe that it's 500, although, you know, they've got a funny looking curve.

MR. GLENN: Yes. I guess I'll just pass on to you one of the advantages we have with MIT is that they did use INDOS and curve fitting. And they have extremely good agreement, in fact it's suspiciously good agreement, between the whole body data and the urinalysis.

MR. DWYER: Right.

MR. GLENN: But they had an independent consultant check it out, and we're going to be checking it out too. So --

MR. DWYER: Right. Okay, and then we took NIH's data and -- or NIH's assessment with NIH's data, along with the ORISE, Mike Stabin's, assessment. And we provided that to Lawrence Livermore, okay?

And Lawrence Livermore used not only the urine data, but they used the blood data. They used the nuclear medicine scan data. And they used Cindy and every other

program under the planet and did evaluations.

And we're still -- as I said, Donna-Beth is still pouring through that. But their numbers are -- the intakes are looking to be around -- probably average about a millicurie.

They commented that they thought that probably the best estimate of the intake would be an average of what ORISE said and what Lawrence Livermore said. But they weren't -- you know, there's a lot of error bars on this basically.

And the one thing that ORISE -- you know, the reason the ORISE resultant exposure to the researcher and Lawrence Livermore's resultant exposure to the researcher is higher than NIH's is because NIH equated a 600 microcurie uptake to a 5 REM dose, whereas ORISE and Lawrence Livermore are using the 600, being, you know, a regulatory number.

They were actually using a calculated reference one to do the dose calculations. So whereas the ALI 600, the ALI for this pregnant researcher, I believe all was calculated to be around 510 microcuries.

MR. GLENN: Okay.

MR. SHERBINI: I have a question, Jim. Why did the Licensee conclude that this was not a reportable incident?

MR. DWYER: Well, they will still say that it's less than an ALI.

MR. SHERBINI: Is that what they -- that was the basis for the decision?

MR. DWYER: Right. And you know, I recall that we used to -- the regulation used to say that if medical intervention was required, then it was something that was reportable.

And you know, they said that, "Well, no. We didn't send her to the hospital for medical intervention. We sent her to the hospital because she had back pain, not because of her contamination," which I think is bogus. But that's what they said.

And now, you know, I look at the regulations the way they are, and I believe they've changed because I don't think I've missed it before. But they now say that, you know, notify if hospitalization is required because of external contamination, which certainly doesn't fit here anymore.

So I -- the Licensee will say that it was reportable initially. And you know, I would say that it's reportable now because of -- it's appearing to be greater than an ALI.

And they, in fact, did do the written report, which will be required for a greater than an ALI exposure.

MR. SHERBINI: Well, their initial estimate was what, 500 microcuries?

MR. DWYER: Their initial estimate was 300.

MR. SHERBINI: Oh, okay.

MR. GLENN: Okay. Now, the exposures to the other individuals., what was the maximum there in terms of these other 17 or so people?

MR. DWYER: They were in the order of about five percent of hers. I don't have the numbers in front of me. But there were -- besides Dr. Y, there were 26 other people.

Five of them were not radiation workers. In other words, they hadn't had training from the Radiation Safety Office.

Some of them were housekeepers. They had received training, so they're occupationally exposed. Five of them were like one was a secretary, one was a chemist who didn't work with radioactive materials.

And we submitted a TAR to Headquarters, and Headquarters came back and said that these are members of the public. One of those individuals got -- exceeded 100 millirem. I think he got 250.

The actual --

MR. GLENN: Did NIH report that?

MR. DWYER: NIH believes that these are all

occupationally exposed workers. And we're in the process of advising them and writing them --

MR. GLENN: Okay.

MR. DWYER: -- of our determination. But I think the maximally exposed individual, which was a member of -- which was an occupationally exposed worker, I think was around 300 millirem.

And these are all conservative estimates assuming that the contamination occurred on the 28th of June, concurrent with Dr. Y's exposure, and that that individual took in that dose at that period of time.

Whereas if they had only contracted it a week prior to that, it would be a lot lower. We provided those dose estimates to Riddick.

And actually, their estimates were somewhat lower than what NIH did. But they all appear to be within reasonable assessments, so --

MR. GLENN: Well, let me just follow up a little bit on one of the statements that you made. And that was the -- you know, the seven or so liters per day of urine being produced.

It turns out that that's again similar to MIT, at least in the early stages. Now that dropped off later for that individual when he was told not to drink so much liquid.

Did that continue for the full month that samples were collected?

MR. DWYER: She, you know, indicated to us that she stopped really pushing things after a few days. I would say that those seven liter jobs were, you know, within the first four to five days.

But when she -- when she decreased, she still went down to like three to four liters.

MR. GLENN: Amazing.

MR. DWYER: You know, it was still well outside the 1,100.

MR. GLENN: Okay. Again, that's a very similar pattern that we saw with our case.

One last question that I have, and then see if Sami has any more. But were any of the urines and the samples saved, and is either Oak Ridge or Livermore looking at any of the samples independently?

MR. DWYER: We got one of the blood samples and three of the urine samples the first couple of days we were there. And we sent them to ORISE.

And two of them were -- the blood and the original urine sample, which they only collected like 15 milliliters or something, you know, were very small samples, and ORISE said that they had problems with volume.

And they apparently did a lot of sample manipulation. And they weren't able to recover a lot of the volume in order to do the analysis.

Still, it was within 25 percent of what NIH said that it was.

The other two samples which were -- they provided a larger sample, Oak Ridge found that the numbers were right on what NIH said.

Now we also did four urine samples that we processed here in Region I. They were not done as split samples. They were done as, you know -- they had an analysis and they provided us some from the sample.

We analyzed them, and three of them were right on the money and one of them was, I think, 50 percent of what NIH said it was.

I contacted NIH and said, "We've got a problem with one of the numbers." And they submitted us -- to us their analysis of what they had done for those four samples.

And for that same sample that we had a problem with, they had also had a problem with it. And they commented that, you know, this particular sample had a lot of bacterial growth in it. And they didn't believe that it was homogenous anymore.

So it could not be equated to the original

analysis was done, you know, when the sample was first provided.

We figured it would be smarter to get more samples. So we processed an additional seven urine samples as split samples.

And the -- our numbers and NIH's numbers on the splits matched very well. And on a couple of the samples, the data, the numbers, were, you know, decay-corrected, but were different than what was found originally.

And those particular samples, Jim Kottan noted, were -- there was a lot of sedimentation and stuff.

So we feel confident that NIH, number one, knows how to analyze urine samples for P-32, and that the numbers that they reached the data -- activities that they reached -- you know, the results they got were accurate.

I should mention that when the -- when Drs. x and Y got their -- their attorneys and they engaged a consultant, the consultant requested samples from these urines, which he provided to TMA NORCAL in Oakland, California.

And they were going to be doing an analysis. And the consultant -- their consultant came back and said that he believes that the intake was in the order of a millicurie, you know, based on the analysis that he did.

But the petition makes no mention that there

was anything inaccurate about the analysis that was done by NIH. Again, I just think it was how you assessed the dose based on these sample analyses.

And so we're trying to get his results. There's an attempt to get the results, but we haven't done that yet. And whether he'll provide them, I'm not sure. So --

MR. GLENN: I guess from listening to you, it doesn't sound like there's really any disagreement about the raw numbers. It's just the translation of the numbers into the actual uptake that is at question.

And it appears that NIH is sort of closing their eyes to the comments about the early samples.

MR. DWYER: I think so, yes. I -- they are very stubborn. I mean, not just about the, but about everything. And I mean, I know I've been involved in incident response with NIH before, particularly in 1992.

They had an incident involving some lutetium 177 that went -- it went airborne.

And you know, I was working that case with them. And they basically refused to use the methodology referenced in Part 20 at the time, and was it Form 5 that talked about 7 milligrams per square centimeter and that type of thing?

Because they said it was archaic and they were

doing this other thing. And you know, for regulatory purposes, it was very difficult to get them to change what they were doing.

And until new Part 20 came out and specifically referenced in the regulation the 7 milligrams per square centimeter, they weren't going to use it.

As a matter of fact, right now they are trying to get an exemption in their license so they don't have to use 7 milligrams for a square centimeter. So --

MR. GLENN: Well, it sounds like they accept science when they want to and reject science when they think the regulatory position supports those.

MR. DWYER: Well, you can probably say that, yes.

MR. GLENN: Okay. Sami, any more questions on dosimetry?

MR. SHERBINI: No.

MR. GLENN: Okay. Maybe we can explore a little bit here the security of buildings and the control of materials. And you mentioned you're not sure it has anything to do with this particular incident.

But I think we're in the same position at MIT, that we looked at this, and we're not sure that it has anything to do with the actual uptake.

What were you findings with respect to, I guess

first, building security at NIH?

MR. DWYER: Okay, if you'll let me -- let me preface this a little bit. In 1994, there was a violation issued for security, and there was a CAL that was issued and stuff.

And I actually had one of those -- the inspector who would identify the security problems from 1994, on with me at the routine inspection in 1995.

And in the scope of the inspection that he did, as well as another Senior Inspector here, they both came back to me and said they didn't have any problems with security.

I mean, this is -- realize this is done at the time this incident occurred, okay that this routine inspection was taking place, the end of June.

That they had no problems with security and that they thought that it was vastly improved mostly because the Licensee was locking up stock vials and other concentrated solutions.

So I don't want to discount that finding because it occurred, you know, at the time that this took place.

I mean, when the AIT took place, we went to Building -- to look at the fifth floor of Building 57. One of the people on our team identified, you know, like

20 millicuries of tritium and 2 or 3 millicuries of carbon 14, which had virtually been abandoned in one of the offices because the people had moved to another lab.

And you know, they thought that they had provided -- had given it to somebody and they didn't.

So basically, there was a security problem identified with this particular lab.

As far as the security of the other labs, we didn't have any problems with what they were doing. But the investigator who was part of this, has spent many more hours on the floor than I have.

And his comment to me occasionally during this process was, you know, i went up there early one morning, and i was looking for some of the people.

And you know, this lab was posted and i was -- you know, there wasn't anybody in there and I was able to go in there.

Well, which lab is it?L You know, was there anything in there? Well, i don't know. It just was posted.

And when I would go up there and look around, and I didn't have any problems with what was going on: either there was no material in the laboratory or the laboratory -- the material was locked in the refrigerator or whatever.

You know, could i go up there and find a laboratory that might have 250 microcuries of sulfur that was unsecured? You know, I believe that I could still do that, okay, on campus. But I could tell you that I could do on any campus in the country, you know, and probably find more than that.

The difference is that this laboratory -- this floor, because of what had occurred, locked up pretty tight after that. You know, there's been a follow-up inspection that's gone back to Building 37. And they pulled, I think they said 300 doors or 350 doors in Building 37.

And they did find six laboratories that were unsecured. And you know, they found from 250 mics up to a couple millicuries of chromium in those laboratories.

And we've since had another CAL to deal with that, and I think the CAL is fairly significant in what it's requiring.

But my feeling is that the security on that campus is no different than it is anywhere else.

My major disappointment was when Bob Zoon, the RSO, was notified of these findings by Doug Collins, that he didn't go and lynch somebody because of, you know, the heightened awareness in that building.

You know, you shouldn't have anything going on

there.

But you know, NIH -- you know, I don't believe the security is any different than it is anyplace else. If you talk about inventory control, they have very good control over material coming in. You know, the material has to be ordered by the authorized user. It's centralized receipt.

It's distributed by the Radiation Safety Office to certain people. They have very good control on the waste end of it. Their liquid waste is not -- they don't allow sink disposals of waste. They collect every bit of waste.

And they analyze each individual liquid waste container to see what was in there.

Obviously for solid waste, there's not much you can do about. When a material is being used in the laboratory, they are required to keep some sort of inventory record.

The license is not specific about how they do that. There's a form that's provided to them, but they don't require that they use it.

They place more responsibility probably on the authorized user for control over material, and then they do documentation.

And you know, my only comment there was you

know, you can require as much documentation you want about what was used and where it was used. And you know, if this is done by someone, an insider, which is what everything is pointing to, then you're not going to be able to find it.

The other problem with the record keeping is that they're only estimates that they're putting down on the record.

Most people are not accounting for decay when they're taking it out. And when the sample reaches its expiration date, they're certainly not pipetting it out of the vial to see how much they have left.

You know, they just zero out the inventory and send it to waste. You know, I don't think that's any different than what I see in most facilities.

I'm getting hoarse here, so --

MR. GLENN: No, let me ask you a specific question. Did they try to determine whether they had a discrepancy of the order of 1 millicurie in any of their stock solutions?

MR. DWYER: Yes, they did do inventories up there, you know, that one on the 30th of September. They were unable to identify it. I have records --

MR. GLENN: Jim, did you misspeak? You said 30th of September. Was that --

MR. DWYER: I'm sorry, 30th of June.

MR. GLENN: Okay.

MR. DWYER: Thanks for correcting that. Yes -- no, they were unable to identify it. I will say that the users of the orthophosphate, the one who got the larger doses, those inventories are much more accurate that the ones who are using a millicurie or a half a millicurie at a time because usually the orthophosphate people are using it all at once to label something.

And then, you know, 90 percent of it goes to waste, and then the waste analysis looks out -- there was one -- there was one sample of liquid waste that went out that was done by a researcher cleaning out her lab when some of her co-researchers worked to another building.

And she didn't account for decay, and she believed it was 18 millicuries of P-32 in that container. When they analyzed it, there was more like 10. You know, that raised some concern to me even though she said that, you know, she just took what was written on the vial and just said that was what was in there.

The other container that went out of that building, she thought there was 2.5 millicuries of P-32 in it, when actually there was like 9.8 millicuries.

So you know, that result there coming out of the same laboratory looks like they didn't dump it all

into the same container.

There's not, you know, a whole lot of opportunity on that floor for P-32 in this quantity to disappear in my mind. I mean, there's only a couple of large -- you know, the 10 millicurie P-32. You know, i believe, based on what we've learned from the analyses that were done, that we're probably looking at waste, since there may have been some tritium in there, or there may have been some P-33 in there.

MR. GLENN: That is the apparent difference between the two cases because the laboratory we're looking at really only received about a millicurie, 2 millicuries a week, so that we're really talking the stock solution being the likely source of the material.

MR. DWYER: Well, the other thing is that this laboratory didn't use P-32, okay? So that's why -- I mean, there was no P-32 on the inventory for this particular lab.

You know, now you're looking at -- let's see, there were 480 -- there's like 100 -- I'm sorry, there's 870 laboratories on that floor, okay? So the inventories we're talking about are of all these other laboratories an not of this one.

MR. GLENN: Yes.

MR. DWYER: So that's the major difference.

And the other thing is that we don't know whether it came from another floor, or maybe even another license.

You know, one of the allegations that Dr. X is making is that Dr. Weinstein knows people down at Frederick a the NCI facility at Fort Meade. I think it's Fort Meade in Frederick.

And you know, that he was out there on Tuesday night, and he probably brought something back with him then. So you'll never be able to find it.

So you know, we don't know where it came from or how it was done.

We have an idea of when it was done based on the clothes that she wore and what she said she ate and when she ate, and where she vomited and when and whether it was contaminated or not.

And also, you know, Lawrence Livermore saying that those first two datapoints, you know, indicate that the contamination occurred sometime shortly before this -- before you starting monitoring it.

So we're looking at the 28th as the contamination. But you know, it may be the 27th or it maybe be the 29th. But I feel pretty certain about the 28th.

MR. MADISON: Go back into the involvement with OI. When did the OI become involved in the investigation?

MR. DWYER: I was there on the 30th of June, you know, as a continuation of the routine and moved right into the AIT. The evening of June 30th, on Friday night, Jerry Kenna arrived.

And on July first, that's Saturday, we met people on the fifth floor of Building 37 to just get an idea of the layout. So he was involved from the beginning.

MR. MADISON: And then when were you essentially told not to, you know, directly interview the principals on this case?

MR. DWYER: Well, it was made fairly clear on Friday night, the 30th, that I guess they call our -- our part of the inspection or something "police parlance" I guess it's called and administrative investigation.

And whereas theirs is a different investigation which supersedes ours and, you know, Jerry Kenna had discussions that evening with the NIH police, as well as his management. And it was a discussion about, you know, they should not impede our ability to do the health and safety follow-up and leave the investigation to them.

But that we were not to discuss any of this with the Licensee.

But as far as when did somebody specifically

tell me, "You can't talk to them," I'm not sure that that occurred on Friday or Saturday or Monday. I can't tell you. I can't recall when it was.

MR. MADISON: Were you given a clear distinction or distinct separation as far as in your charter what you were to do? Were you given a charter?

MR. DWYER: Yes, we have a charter. And in the charter, it does say that we are to determine how it occurred. But since Jerry Kenna is part of the AIT team, that wa something that he was going to do.

And we were going to do the rest because we couldn't -- you know, we weren't investigators and we couldn't mix.

MR. MADISON: So you -- Jerry has remained a part of the AIT? That function was not split off?

MR. DWYER: Right. I think if you ask him, you know, he may question whether he is still on the team. But to my knowledge, he had never been released. So he's been pretty much solo, and I don't see him sometimes for more than a week at a time.

MR. MADISON: Okay.

MR. GLENN: I think all the questions I have been --

MR. MADISON: Jim, is there any lessons learned from your involvement right now with the Augmented

Inspection Team at NIH? Are there any things that you would do differently?

MR. DWYER: You know, we've been putting together something here because you talk about, you know, things I would do differently.

First of all, I would never put somebody with my experience and qualifications in as the leader of this AIT.

You know, I'm a 14. I've never been on an AIT or an IIT. I haven't had the training that's, you know, offered for that. I mean, I've had more training, but I think that I should have had, you know, more experience for this to handle it.

And I don't believe that all of our people on the team are qualified inspectors. I don't know what -- specifically I'm talking about Donna-Beth Howe. I don't know what NMSS -- you know, how they do that.

You know, we had one member who was on -- you know, had several weeks of vacation scheduled in to go back to India or something. So there wasn't anyway you could get in the way of that.

Especially for some people, as complicated as this was, you know, I felt, you know, unqualified to handle this event.

MR. GLENN: Who did you have on your team?

MR. DWYER: Susan was the manager.

MR. GLENN: And did she -- was she dropped or --

MR. DWYER: No, she's -- actually, you know, initially I -- because I was down there, I would talk to her during the afternoon at the briefing. It wasn't really until after the water cooler was identified and I was on my way back down that I said, you know, "Listen, you need -- I need help with this." You know, you can't -- I can't do this, do everything you want and still be leading the team and negotiating with the Licensees for this and handling the briefings.

And so, Susan came with me at that point, and pretty much we've been working as a team on this ever since.

MR. GLENN: Now, you mentioned that you felt that the fact that you hadn't had the training handicapped you. Did you feel not having a position as a supervisor or a manager in the NRC made you less effective in terms of getting people to cooperate?

MR. DWYER: Not internally, no. I think I got all the cooperation that I --

MR. GLENN: Okay.

MR. DWYER: -- could have asked for. It's just a matter of, you know, here we started this thing, okay?

And first of all, the -- is very difficult to deal with, this particular Licensee, particularly because they felt we had no business being there, that this is not reportable; this is internal and it's criminal and we're handling it, and you're in our way.

So we did as much as we could to avoid getting in their way.

There was, you know, discussion about the criminality and whether we were going to compromise anything. And I told the Licensee that I would not -- or that there would not be any press release until they were aware of it, and had an opportunity to comment on it.

And that completely -- I mean, they gave me a copy of the press release after it occurred. And there's some question here about what the timing was of that; whether somebody at NIH was aware of it, you know, a few minutes before it occurred or whatever.

But you know, whatever poor relationship I had with the Licensee at that point became an absolutely terrible relationship, and there was no dealing with them.

Okay, the other thing is that they're trying to deal with this incident. They're trying to deal with the responses to the public. They're trying to continue to run their routine program.

And we have needs that need to be satisfied.

And a lot of those needs couldn't be done by saying, "Okay, we're going to go interview Dr. Y and Dr. Z or Dr. Weinstein," or something because we weren't able to do that.

So we were dependent on them for a lot of our information.

On the fifth of July, I mean, I spent half the night talking with the RSO trying to, you know, calm him down, that we weren't taking over this investigation and everything else.

And you know, there was some discussion here from Region I with the Licensee that communications would go through me, to and from me.

So when Sadhar or Donna-Beth or myself, given that I had an opportunity to do any real work other than, you know, manage this thing, whenever we had any questions, it would be presented to me and then I would have to take it to the Radiation Safety Office and present it to him.

And then he would require me to justify **everything** that I had requested. And then they would provide -- they would get the information together and they would give it back to me and i would provide it back.

Now, you know, they were not real fast about getting this information back because it was a -- you

know, NIH has its own bureaucracy, and they would have somebody who would generate it and it would have to be reviewed and it had to be provided back to me.

So it was a real handcuff-type of situation. I think if I, you know, experienced this before or something, maybe I would be more amenable to climbing up on a table land jumping up and down and screaming, yelling and hollering.

But, you know, we were -- when we would push too hard, we would hear about it. And we would basically be allowed to back off of it. For instance, after the cooler problem was identified, the Licensee issued questionnaires to everybody on the floor.

This is an attempt to make sure that everybody who had contamination did, in fact, drink from the water cooler, and also had like, do you know when you drank from the water cooler and how much you drank from the water cooler?

And that was -- those names were collected. And anyway, I went to the Licensee and said, "We want to see the copies of the returned responses."

And they would say, "Well, we haven't had a chance to look at them yet." "Well, when are you going to look at them?" "We're going to look at them tonight." "Okay, we'll be expecting it tomorrow morning."

Well, they weren't available in the morning. You know, you push a little bit and then they would finally say, "Well, we have the results." "Well, what are they?" "Well, we haven't given them to the RSO yet and, you know, they would buck back at us.

And I would be told, you know, by -- like I would say to Susan, "Susan, they're not providing them." And she would say, "Oh, you need to give them a couple of hours or something. Let's -- you know, we're pushing too hard." We're pushing too hard.

Sometimes I feel like we're pushing too hard and sometimes I feel like we weren't pushing.

Anyway, they came back to us with -- and finally gave us the questionnaires. And five of the people who were contaminated had not responded to the questionnaire. And you say to the Licensee, "Well, what about these five who haven't responded? Do you know how their contamination" --

"Well, no." "But what about the questionnaires?" "Well, you realize the questionnaire is voluntary."

"Well, to heck with this voluntarily business. You need to find out what's going on here." And you know, then they would respond and come back and they figured out that everybody had drunk out of the cooler.

So I would have profited by having been experienced in this process before, I guess to put it mildly.

MR. GLENN: Yes. Did you get any support in terms of the procedures of an AIT in -- any administrative support from AEOD, anything like that?

MR. DWYER: We had -- you know, we have been hit from all directions for information, whether it's the attorneys or whether it's the media or whatever.

And one of the things that AEOD did for us was to go through their tracking systems and provide some information on previous events on other Licensees that the media wanted. But other than that, no.

MR. MADISON: AIT is chartered by the Regional Administrator.

MR. GLENN: Oh, okay. I'll just mention that i had so much more support than you had. But it's amazing.

MR. MADISON: Any other lessons learned, Jim?

MR. DWYER: Well, I think that -- you know, and this is -- let me bounce around a little bit here. If NRC is going to be concerned with, you know, 50 percent of the ALI or 25 percent of the ALI or something, I think that we need to have our regulations reflect that.

I know that prior to this, even though we didn't talk about ALIs prior to new Part 20, you know, we

still talked about 25 percent thresholds and things like that.

And unfortunately, we lost that in the rewrite. I understand that there is some rewriting going on Part 20 now that will include if there's any willfulness involved here, we want to hear about it.

MR. GLENN: Yes. And in fact, we requested a copy of that and received it.

MR. DWYER: Okay.

MR. GLENN: So we were taking a look at that.

MR. DWYER: Okay. You know, there are some -- you know, really I think NIH is a lot more sophisticated than a lot of our broad scope licenses. And I've never inspected MIT, but I would suspect that they are also.

And you know, we don't have -- you know, for something to this degree, for internal contamination of -- you know, where you're talking about involving a medical -- we don't really delve into that too much with the Licensee and the licensing process.

And I think things like, you know, how to use **REACTS** and in response -- you know, where medical intervention is required and stuff, I think, needs to be -- we need to look at that a little bit more.

This business of having the investigation going on concurrently, I'm not sure if this is due ground for us

or not, but I would hate to see somebody have to go through it again.

You know, it's not really -- you can't do a regular incident, response, investigation because of encumbrances.

And you know, I'm not sure how it gets handled, but something needs to be done to address it before, you know, somebody else goes out there and has the same problem.

MR. GLENN: Okay.

MR. DWYER: Let's see, I'm trying to think here. No, I think that's about it at this point, at least the higher points.

You know, my biggest concern is that I don't -- I think the best thing that could have happened was if they had somebody at a higher level with more experience than me. I mean, right now they've got -- they're putting together a special inspection team that's being led by a Deputy Division Director.

So, you know, maybe that or a Branch Chief was the appropriate level to start with.

MR. GLENN: Okay. You mentioned about how somebody -- maybe we should speak to -- I guess you mentioned Susan. Anybody else who you think might be useful for us to speak to?

MR. DWYER: I mean, if you want to talk to Jerry Kenna, the investigator. Although, I'm not sure about his availability.

MR. GLENN: Maybe we'll try to confirm his status somewhat, but -- okay, we will be faxing you that sheet I was talking about that talks about reviewing the transcripts.

And then you can get together with Cherie Siegel on the phone, and we'll figure out how to get you a copy of the transcript so you can take a look at what you said, and whether anything needs to be corrected.

MR. DWYER: Okay.

MR. MADISON: Jim, what's the best fax number for us to send this to you directly?

MR. DWYER: Let's see, 337-5269.

MR. MADISON: Okay, thank you.

MR. GLENN: Okay. It's 2:45 in the afternoon, and the interview is concluded. Thank you, Jim.

MR. DWYER: Thanks. Bye.

(Whereupon, the interview was concluded at 2:44 p.m.)

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: INT. OF JAMES DWYER

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.

Karina Wood

KARINA WOOD
Official Reporter
Neal R. Gross and Co., Inc.