

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01250/96-001

Docket Nos. 030-01250

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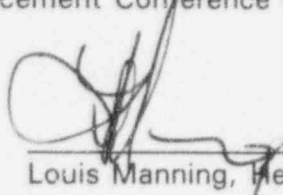
Licensee: New Britain General Hospital
100 Grand Street
New Britain, Connecticut 06050

Facility Name: New Britain General Hospital

Predecisional Enforcement Conference Conducted at: King of Prussia, PA

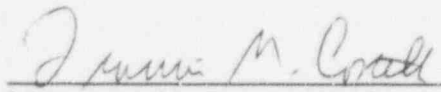
Predecisional Enforcement Conference Conducted: November 18, 1996

Prepared by:


Louis Manning, Health Physicist

12/11/96
date

Approved by:


Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1

12/12/96
date

Predecisional Enforcement Conference Summary: A transcribed predecisional enforcement conference was held at NRC Region I in King of Prussia, Pennsylvania, on November 18, 1996, to discuss the apparent violation identified as a result of NRC Office of Investigations (OI), Region I, investigation findings. The licensee confirmed that the apparent violation occurred as a result of the action taken by a former employee. The licensee confirmed that the dose calibrator constancy records were falsified on November 29, 1995.

Details

1.0 Attendees

New Britain General Hospital (NBGH)

Clarence Silvia, Senior Vice President, Administration

H. Kennedy Hudner, Attorney for NBGH

Peter J. Mas, Radiation Safety Officer

NRC

Charles W. Hehl, Director, Division of Nuclear Materials Safety

Marian Zobler, Acting Regional Counsel

Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Branch 1

Frances Costello, Technical Assistant

Judith A. Joustra, Senior Enforcement Specialist, Enforcement and Investigation Coordinator

Louis Manning, Health Physicist

2.0 Summary

On November 18, 1996 a predecisional enforcement conference was held at NRC Region I Office, King of Prussia, PA. The conference provided an opportunity for the licensee to discuss the apparent violation, and to provide an explanation of the circumstances surrounding the falsification of the New Britain General Hospital's dose calibrator constancy records.

The Director of the Division of Nuclear Materials Safety (Director) gave an opening statement and provided the reasons for the pre-decisional enforcement conference. The Director explained that this meeting would provide the licensee an opportunity to discuss the events surrounding the apparent violation, to accept or deny the apparent violation, provide corrective actions taken as a result of the apparent violation, and provide any additional information that would enable the Commission to make an enforcement decision. The investigation findings were transmitted to the licensee via the investigation synopsis enclosed in NRC letter dated November 5, 1996. The Director said that this meeting would give the NRC an opportunity to hear any additional information that the licensee had to substantiate or negate the OI findings.

The Branch Chief reviewed the NRC staff's understanding of the issues surrounding the dose calibrator constancy records. The licensee was given an opportunity to discuss their views surrounding the records in question. The licensee confirmed that the dose calibrator was calibrated by the Radiation Safety Officer on November 28, 1995 as a result of inconsistencies noted during the annual dose calibrator accuracy test. The licensee also confirmed that the dose calibrator constancy results recorded on November 29, 1995 were falsified. The licensee provided their corrective action and outlined their actions taken to prevent recurrence.

The Senior Enforcement Specialist explained the enforcement options available to the Commission.

The meeting was adjourned.

06-02388-01

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION 1

In re: MICHAEL J. MUSZYNSKI, JR.
NEW BRITAIN GENERAL HOSPITAL, Licensee

Enforcement Conference taken by Robert W. Harley,
Registered Professional Reporter and Notary Public, at
offices of the United States Nuclear Regulatory Commission,
475 Allendale Road, King of Prussia, Pennsylvania, on
Monday, November 18, 1996, commencing at 10:10 a.m.

NRC MEMBERS PRESENT:

CHARLES W. HEHL, Director, Div. Nuclear Materials Safety
MOHAMED M. SHANBAKY, Chief, Nuc. Materials Safety Branch 1
MARIAN ZOBLER, Esquire, Acting Regional Counsel
JUDITH JOUSTRA, Senior Enforcement Specialist
JAMES SMITH, Hdq. Office of Enforcement (by phone)
FRANK COSTELLO, Technical Assistant
LOUIS MANNING, Health Physicist

ALSO PRESENT:

CLARENCE SILVIA, Senior Vice President Admin., NBGH
E. KENNEDY HUDNER, Esquire, Counsel for NBGH
PETER J. MAS, RSO, Health Physicist, NBGH

1 MR. HEHL: We can go ahead and get
2 started. I think as we indicated in the letter that
3 was sent to you, this is an enforcement conference.
4 Whenever the Commission is faced with a decision
5 regarding enforcement on issues that have a potential
6 for what we refer to as escalated enforcement, we
7 normally provide an opportunity for the licensee to
8 come in, sit down with us and talk about the issues so
9 that we can get a firsthand perspective on how you view
10 these issues. Certainly we're interested in corrective
11 actions that may have been put in place.

12 In this particular case we're
13 dealing with issues having to do with falsification of
14 records, and as indicated in the synopsis of the Office
15 of Investigation Report that was generated based on the
16 investigation into these matters, it appears there was
17 a falsification of records.

18 Even though it appears that the
19 falsification was done by an individual, the NRC has
20 looked very closely at the licensee as an entity to
21 focus on what if any licensee culpability there was in
22 the actions that were taken by the employee. And
23 historically the Commission has held the licensee
24 responsible for the actions of the employee.

1 So part of what we would like to
2 do today, and in just a moment we'll go around and let
3 everybody introduce themselves. We also have an
4 individual on the phone from our headquarters
5 organization. But part of what we'd like to do today
6 is certainly hear from you as to any additional
7 information that you can provide to help us in making a
8 decision; not only a decision on action if any against
9 you as a licensee but also any additional information
10 you have with regard to the performance of your
11 employee involved in this incident. But also certainly
12 we'll be looking to hear if any corrective action or
13 what kind of investigative activities you undertook to
14 look at this particular event.

15 So with that as a groundwork for
16 where we're going today, let me go ahead and just
17 introduce myself. Again I'm Charles Hehl. I'm the
18 Director, Division of Nuclear Materials Safety in
19 Region One.

20 MR. COSTELLO: Frank Costello.
21 I'm a technical assistant.

22 MS. ZOBLER: Marian Zobler, Acting
23 Regional counsel.

24 MS. JOUSTRA: Judy Joustra, Senior

1 Enforcement Specialist.

2 MR. MANNING: Louis Manning,
3 Health Physicist.

4 MR. HUDNER: My name is Kennedy
5 Hudner. I'm an attorney with the hospital.

6 MR. SILVIA: Clarence Silvia,
7 Senior Vice President of administration.

8 MR. MAS: Peter Mas, RSO and
9 Health Physicist for the institution.

10 DR. SHANBAKY: My name is Mohamed
11 Shanbaky. I'm a Branch Chief for Licensing and
12 Inspection, Region One.

13 MR. HEHL: And I think we have Jim
14 Smith from our headquarters, Office of Nuclear
15 Materials Safety and Safeguards.

16 MR. SMITH: Yes. I'm the Regional
17 Program Events Coordinator here at headquarters.

18 MR. HEHL: We'll try to turn up
19 the volume a little bit here, Jim.

20 MR. SMITH: Okay.

21 MR. HEHL: Let me add too that
22 this is an administrative process. This is not a
23 hearing. If the NRC does impose some sort of an
24 escalated sanction that would be issued, at least

Enforcement Conference of November 18, 1996

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1 initially, if it's a violation, as a proposed violation
2 you would have an opportunity at that time to respond
3 in writing to that issue. And then, depending on your
4 response, whether or not we decided to impose the
5 action subsequent to receiving your written response,
6 at that point in time you would then have hearing
7 rights in a more formal proceeding.

8 I think that's the way it works.

9 But let me go ahead and let I
10 think Dr. Shanbaky basically talk a little bit more
11 about the issues we're going to discuss. And then
12 we'll turn it over to you for your comments.

13 DR. SHANBAKY: Okay. Last week we
14 had the enforcement conference with your previous
15 employee, Mr. Mike Muszynski, and we asked him about
16 what happened, and he gave us his perspective on what
17 had happened. And today we'll go over the apparent
18 findings here based on the OI investigation synopsis
19 that was sent to you. And we're very anxious to listen
20 to your side of what actually happened, what took place
21 to help us make any future decision.

22 As we were notified by Mr. Pete
23 Mas that certain records for the dose calibrator
24 appeared to be falsified, the Office of Investigation

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1 looked at the records and interviewed people, and they
2 came up with the conclusion that it seems that the
3 records were falsified for the dose calibrator checks,
4 particularly on November 28th, 1995 --

5 MR. HUDNER: 29th, sir.

6 DR. SHANBAKY: 29th, 1995.

7 -- and if this occurred, then the
8 individual would be in violation of 10 CFR 30.10,
9 because 10 CFR 30.10 requires that all employees of
10 licensee and contractors do their job in a way that
11 they would not cause the licensee to be in violation of
12 NRC regulations. If he falsified the records, then the
13 records were falsified and you were in violation of
14 certain NRC requirements and you can get cited for
15 that.

16 But from your side, also you are
17 required that all your records and information provided
18 to NRC has to be accurate in all material respects, and
19 the dose calibrator records for November 1995 were not
20 accurate because they were falsified. That's your
21 involvement here.

22 We recognize that you identified
23 the issue, you reported to the NRC, and you took some
24 what appears to be administrative actions, and we are

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1 here today to listen to you as to exactly what
2 happened, when it happened, and what did you do.
3 So with this I would turn it over
4 to you and listen to your understanding of what
5 happened.

6 MR. SILVIA: Very good. Thank you
7 for the opportunity to present sort of the incident as
8 we understand it and the action that we did take
9 related to it.

10 Just to give some background,
11 Michael was an employee at New Britain General for 23
12 years, and throughout his tenure at New Britain there
13 was no reason to suspect Michael as anything but a good
14 employee. His performance reviews were always fine.
15 There was no indication that we had a problem employee.

16 What did occur is that the RSO,
17 Peter, Peter did his annual recalibration of the dose
18 calibrator. There was an entry made on the 29th and
19 Peter was in the department the following day and he
20 routinely checks the readings, the entries following
21 his calibration and saw that the reading was the same
22 as the day before, which alerted him to the fact that
23 there was a problem.

24 Peter sent a letter, faxed a

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1 letter to the physician in charge of the Nuclear
2 Medicine Department on December 4th, and on December
3 5th there was a meeting with Peter, the RSO, the
4 physician in charge, and the respective managers and
5 directors of the Radiology and Nuclear Medicine
6 Department.

7 At that point what occurred was,
8 on December 7th, there was -- the issue of the
9 falsification was brought up. Michael denied it. It
10 was felt on behalf of the hospital that, if there was
11 any question regarding the falsification of data, that
12 Michael should be removed from performing any NRC
13 regulatory type activities. And as of December 7th,
14 from that point on, he no longer was performing NRC
15 duties.

16 It so happens that during this
17 time back in July, Michael was put on a probationary
18 period for not performing some of his administrative
19 duties and that was going to be concluded in January.
20 And it was felt that, since he was removed from his NRC
21 duties, we were going to let the probation period
22 continue since it was the end of the month, and at that
23 point Michael was terminated.

24 DR. SHANBAKY: That's end of July

1 1996?

2 MR. SILVIA: The beginning of
3 January, January of '96. It was the 5th or 6th of
4 January that he was terminated.

5 DR. SHANBAKY: All right.

6 MR. SILVIA: But during that time
7 when the situation was evaluated and his probationary
8 period was concluded, Michael was removed from all NRC
9 duties. And from that point on, from January on,
10 Michael was no longer employed at New Britain General.

11 MR. HEHL: Could I stop you just a
12 second and ask a question.

13 MR. SILVIA: Absolutely.

14 MR. HEHL: You mentioned at the
15 beginning that you had identified the error, Mr. Mas.
16 So you identified that with a review of the records and
17 then brought it to the attention of Mr. Muszynski? I
18 guess -- well, let me tell you. What we heard last
19 week was that Mr. Muszynski brought these issues to you
20 on I guess the 29th --

21 MS. JOUSTRA: The 30th.

22 MR. HEHL: On the 30th.

23 MS. JOUSTRA: He placed a phone
24 call to you possibly to indicate there was a

1 discrepancy in the dose calibrator constancy check?

2 MR. MAS: No. What had occurred
3 was on the 28th of November -- was it November? Yes.
4 I performed the yearly accuracy test on the dose
5 calibrator which consists of assaying the referenced
6 standards that are available to the department and
7 making sure they're within the plus or minus 5 percent
8 of the calibrated activity or calculated activity.

9 Once I did the measurements, I saw
10 that both standards were about 4 and a half percent too
11 low. So they were bordering on that 5 percent action
12 level that's required for you to repair or adjust. And
13 I made the adjustment. Now, this occurred around 4:00
14 in the afternoon.

15 The personnel in attendance were
16 Richard Whitmore, a technologist; he was there and saw
17 the testing that I was doing. Of course I was present
18 and a new physicist that we want to get him on line as
19 as assistant RSO in the future. And I was going
20 through this whole process as an education for him to
21 know what the requirements were for nuclear medicine.

22 Well, I adjusted the dose
23 calibrator --

24 MR. HEHL: This is Mr. Young?

1 MR. MAS: Yes, Mark Young,
2 correct.

3 So I adjusted the dose calibrator
4 calibration points for the cesium and for barium where
5 now they should be reading roughly about half a percent
6 higher than the decay calculated activity. So the
7 morning of the 29th, Mike Muszynski is the morning
8 technologist, he's supposed to do the necessary QA
9 components.

10 On the 30th I returned to New
11 Britain General Hospital and I had gone to the hot lab
12 to look at the records to see how the dose calibrator
13 had been performing after my adjustments. And I
14 noticed that the readings recorded for the morning of
15 the 29th were very much the same readings that had been
16 recorded for the morning of the 28th, and the initials
17 in the records were Mike Muszynski's.

18 Mike Muszynski did come into the
19 hot lab. He had not telephoned me. He did come into
20 the hot lab as I was going over these records. And I
21 pointed out to him something to the effect: Did you
22 notice the difference in these readings?

23 And he said, "Oh, yes. Richard,
24 the technologist, had told me you were here doing

1 testing on the dose calibrator."

2 I said, "Yes, I did the yearly
3 accuracy and they were adjusted." And I asked him then
4 and there if he could explain why the readings of the
5 29th were almost identical to the day before when they
6 should have been reading what he had assayed that
7 morning of the 30th.

8 So Mike Muszynski again did the
9 dose calibrator assay for the morning of the 30th and
10 saw the change, but on the morning of the 29th he did
11 not do those assays. He recorded the numbers that had
12 been there previously.

13 MR. HEHL: So you brought it to
14 his attention that the numbers on the 29th appeared to
15 be in error and then he had no explanation at that
16 point in time as to why?

17 MR. MAS: No.

18 MS. JOUSTRA: I think I may have
19 missed something; I didn't hear. On the 30th when you
20 arrived, had he already performed the constancy checks
21 for that day?

22 MR. MAS: For the morning of the
23 30th, yes.

24 MS. JOUSTRA: And then he

1 acknowledged the fact that there was in fact a
2 difference between the 29th and 30th?
3 MR. MAS: Yes.
4 MS. JOUSTRA: Or did you have to
5 call it to his attention at that point?
6 MR. MAS: No. I called it to his
7 attention. He indicated that there was a difference in
8 the readings, and I said, "Yes, there is, and why
9 weren't these numbers seen the day before?"
10 MS. JOUSTRA: Okay.
11 MR. HEHL: But he did not bring it
12 to your attention --
13 MR. MAS: No.
14 MR. HEHL: -- that these numbers
15 were different?
16 MR. MAS: No. I brought it to his
17 attention.
18 DR. SHANBAKY: Can you tell us how
19 this discussion started? I mean, did he come to you
20 and want to talk about the dose calibrator tests or you
21 went to him?
22 MR. MAS: No.
23 DR. SHANBAKY: What actually
24 happened?

1 MR. MAS: Let me just open this
2 up. So I'm in the hot lab looking at the records, the
3 dose calibrator, and Michael comes in. And I'm
4 examining the numbers and he makes the comment,
5 "Richard had mentioned you were here earlier working on
6 the dose calibrator."
7 And I said to my recollection, not
8 verbatim, but: Yes, I was. I did the yearly accuracy
9 test.
10 And he says, "Oh" -- well, I said,
11 "You'll notice that the assay of this morning" --
12 because I saw his record, his entry of the 30th -- "is
13 different."
14 He said, "Yes. I meant to talk to
15 you about that."
16 I said, "Well, I recalibrated the
17 instrument. So explain to me why these numbers don't
18 appear yesterday morning after I had recalibrated the
19 instrument?"
20 MS. JOUSTRA: And he said?
21 MR. MAS: He had no explanation.
22 He said something to the effect like I don't like the
23 implication behind that.
24 I said, "This isn't something of

1 implication." I said, "These numbers are not correct."
2 But he had no reason for it. He
3 did state, "I did the assay and those were the
4 numbers."
5 MR. HEHL: Why don't you go ahead
6 and go on.
7 MS. JOUSTRA: Do you have a copy
8 of that fax that you sent by any chance?
9 MR. MAS: To Dr. Steer (ph), yes,
10 the one that went out.
11 MR. HUDNER: My name is Ken Hudner
12 speaking for the first time. This is two pages. The
13 first page indicates it's a fax sheet and the fax was
14 sent Monday morning, December 4th; although the letter
15 that's attached to it is dated December 1st.
16 MS. JOUSTRA: Thanks.
17 DR. SHANBAKY: Did you have any
18 discussion with Mr. Muszynski as to the actual date of
19 the constancy calibration? Was it the 28th of November
20 or the 29th of November?
21 MR. MAS: Yes. I did point out to
22 him that I had done that work on the afternoon of the
23 28th and that those numbers should have been evident if
24 he had done the test on the morning of the 29th. And

1 the accuracy report was in the dose calibrator
notebook.
3 DR. SHANBAKY: And what did he say
4 to that?
5 MR. MAS: He had no reply, other
6 than he still stuck to his story that he had assayed
7 the sources, and the numbers he recorded were the ones
8 he saw on the dose calibrator.
9 MR. HUDNER: Dr. Shanbaky, I note
10 that among the papers we gave to the investigator
11 Claudia Pietras were some papers that indicated, that
12 recorded if you will, the adjustment to the dose
13 calibrator on November 28th.
14 DR. SHANBAKY: We have those.
15 But he never contested the fact
16 that the calibration was performed on that 28th or the
17 29th?
18 MR. MAS: Never.
19 DR. SHANBAKY: This is verbally or
20 in writing to you?
21 MR. MAS: Correct. Not that I'm
22 aware of. He never contested the fact that it was done
23 the 28th.
24 MR. HUDNER: Peter, didn't he ever

1 raise the issue of whether or not you had mixed up
2 dates?

3 MR. MAS: I don't believe so. He
4 could have mentioned that, but I don't recall him
5 mentioning it to me directly.

6 MR. HUDNER: I'll note that one of
7 Michael Muszynski's immediate supervisors, Lucy
8 Doucette, has reported to Claudia Pietras that she
9 recalls Michael questioning whether or not there could
10 have been just a mixup in dates that would have made
11 the entry of the 29th either accurate or an innocent
12 mistake. And I know Claudia Pietras and myself have
13 asked Peter Mas that question, and that's when he
14 produced the record to show that on the 28th in the
15 afternoon he and Dr. Young worked on the dose
16 calibrator.

17 MR. MAS: Mr. Young.

18 MR. HUDNER: Mr. Young. Sorry
19 about that. I didn't mean to promote him.

20 DR. SHANBAKY: Did you ever ask
21 Mr. Muszynski why the records were not accurate?

22 MR. MAS: No. Other than telling
23 him that those numbers were incorrect, I took the
24 matter directly to the department physician director

1 Dr. Steer.

2 DR. SHANBAKY: Had Mr. Muszynski
3 explained to anybody at the hospital as to why the
4 figures were not accurate on the 29th?

5 MR. SILVIA: All he has ever said
6 to us is that he took the measurement and that was the
7 measurement. That is all he's ever said.

8 DR. SHANBAKY: So he maintained
9 that he actually took the measurements on the 29th and
10 that's what he got?

11 MR. SILVIA: That's correct.

12 MR. MAS: That's correct.

13 DR. SHANBAKY: Is this possible
14 that these numbers would look like the numbers he got?

15 MR. MAS: No. If you look at the
16 dose calibrator records for the month of November, if
17 you look at it for the next five or six months, you'll
18 see that the numbers he recorded are never reproduced.
19 Even allowing for radioactive decay, the numbers he
20 recorded that day aren't even close to what you'll see
21 in the records in May of '96.

22 DR. SHANBAKY: Have you ever
23 observed any discrepancy in the numbers, what appeared
24 to be accurate numbers in performance of the dose

1 calibrator quality control measures performed by
2 Mr. Muszynski in the past, before that?

3 MR. MAS: Performed by him,
4 nothing stood out that would indicate to me there was
5 something incorrect with the numbers.

6 MR. HEHL: So you haven't
7 identified any other problems with the dose calibrator
8 itself as far as drifting or...

9 MR. MAS: Not relating to this
10 incident, no. We have in the past month, the nuclear
11 medicine technologist, the chief tech now, had asked me
12 to look at the technetium assay because she was getting
13 some 10, 12 percent lower assay than what the
14 pharmaceutical supplier was providing us. I asked her
15 to request a vial of technetium from a different vendor
16 just as a cross check, with the same results, some 10
17 percent lower.

18 At that point I went back to the
19 institution to look at the dose calibrator, you know,
20 from A to Z, all stations, and I even went so far as to
21 contact Sun Nuclear Corporation in Florida, because
22 they constructed, developed this device. And their
23 technologists, service techs indicated that if one
24 assay station were off by 10 or 15 percent, across the

1 board ever single station should be showing a 10, 15
2 percent error.

3 Well, based on that and knowing
4 that apparently we were getting some lower readings
5 here but nowhere else, we took the measure of sending
6 it back to the company for review and inspection and
7 determining whether or not there was a problem. And
8 that was done I think in the last three weeks.

9 MR. HEHL: Have they gotten back
10 to you on the problem?

11 MR. MAS: No, Biodex, the vendor
12 of the unit in New York simply indicated it would take
13 anywhere between four to six weeks to have the thing
14 serviced and shipped back. We procured a loaner
15 through them, the exact same unit which is this one
16 here, the Atomlab 100. We went through the appropriate
17 QA. So we set it up. But we have no concrete reason
18 for why Tech is showing or purportedly showing 10
19 percent less of an assay but no other station is
20 showing it.

21 DR. SHANBAKY: How long usually
22 did it take Mr. Muszynski to do the QC test, the daily
23 QC test?

24 MR. MAS: To go across this sheet

1 of paper, the most time-consuming period in filling out
2 this paper is probably just in the physical writing of
3 the numbers. Because all you need to do is insert the
4 barium source in the dose calibrator; punch the barium
5 button. You'll get a display, a stable steady display
6 very quickly thereafter. You record the number. You
7 take this out.
8 You put in the cesium source. You
9 press the cesium button. You'll get a digital readout.
10 You record that number. And then you simply chose the
11 Tech, thallium, and all these other stations across the
12 board and record what the display is showing at each
13 one of those stations. So this process could be done
14 within three minutes from start to finish.
15 DR. SHANBAKY: If it is -- that's
16 a little bit difficult here. If it takes that short of
17 a time, why he would take a shortcut and not do the
18 test, if this is true?
19 MR. MAS: I've asked myself the
20 same question. Why take a shortcut on something so
21 simple, as well as something so essential for the
22 workings of the department? In nuclear medicine you
23 cannot progress with doing clinical studies until you
24 verify that your dose calibrator works. That is the

1 backbone to everything else you do during the day.
2 DR. SHANBAKY: When I asked
3 Mr. Muszynski last week as to how long it would take
4 him, he said it would take him a very short period of
5 time, a matter of seconds, and essentially he would not
6 go through all this trouble just to save seconds. He
7 contends that he did the test and it was done in a very
8 short period of time; in the order of less than a
9 minute or so.
10 MR. HUDNER: Dr. Shanbaky, when
11 Mr. Young was talking to Claudia Pietras, she asked him
12 what the probability was of getting those numbers
13 without falsification, of just getting a misreading if
14 you will.
15 Mr. Young did the numbers in his
16 head, and I don't pretend to verify them, but his
17 calculation was that getting those numbers on November
18 29th represents a point five percent probability;
19 one-half of one percent.
20 We would be delighted if we could
21 look at this and say that there was some apparent
22 innocent explanation for having different numbers.
23 Hospitals don't routinely fire 20- or 23-year employees
24 lightly. We've only begun to see the edges of the

1 potential legal ramifications from this.
2 But with these numbers and
3 assurances from Mr. Mas and Mr. Young that you
4 shouldn't be getting those numbers, the hospital pretty
5 much felt that it had to take the action it took.
6 MR. HEHL: We certainly don't want
7 to imply any disagreement with any actions you've
8 taken. Certainly it was a management decision on your
9 part how you treat that.
10 Do you typically -- when you do a
11 change in calibration, do you leave any information for
12 the technicians to follow?
13 MR. MAS: No. This seemed to be
14 quite straightforward, and with the accuracy report and
15 everything else documenting, it literally tests itself.
16 MR. HEHL: Is this left then for
17 the technicians so they have...
18 MR. MAS: That's in the dose
19 calibrator notebook. So both that cover sheet, which
20 is the yearly accuracy -- it shows the three sources
21 measured -- and this one which documents the readings
22 at the different stations, both of those are in the
23 dose calibrator notebook.
24 MR. HEHL: So these are left in

1 the notebook; on the 28th when you got finished with
2 the calibration, those were left then for the
3 technicians in the notebook?
4 MR. MAS: Correct.
5 MR. HEHL: Are there other
6 instances in the past where you've had to make
7 adjustments on this dose calibrator, similar type of
8 calibrations?
9 MR. MAS: We did get a secondary
10 standard, an iodine 131 standard on loan to us from
11 Syncor because we wanted to verify that what they were
12 assaying the iodine sources and what our dose
13 calibrator was assaying at was in agreement.
14 So we did procure their secondary
15 standard, we went through a series of measurements, and
16 I believe the dose calibrator was adjusted upwards so
17 that it read some 2 or 3 percent more than what it was
18 showing on the display itself.
19 MR. HEHL: When was that?
20 MR. MAS: I don't recall but in
21 the dose calibrator notebook there is a sheet that has
22 some annotations to those changes.
23 MR. HEHL: I just wonder if
24 perhaps when you go back if you want to take a look at

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1 that to say to see if there are any difficulties
2 associated with that occurrence. I don't know if
3 you've looked at that yourself, but you might want to
4 think about doing that, because if there's somewhat
5 similar type of circumstances that were generated, then
6 you might want to take a look.

7 MR. SILVIA: I see what you're
8 saying.

9 MR. MAS: See if there's any
10 variations.

11 MR. HEHL: See if there's another
12 indication of some lost data or incorrect data.

13 DR. SHANBAKY: Getting back to the
14 July 7th meeting, after the July 7th meeting I
15 understand that Mr. Muszynski was essentially barred
16 from performing any NRC activities?

17 MR. HUDNER: December 7th.

18 DR. SHANBAKY: December 7th, I'm
19 sorry. And then in January, beginning of January, '96
20 there was some administrative action taken, that he was
21 let go in January?

22 MR. SILVIA: Yes.

23 DR. SHANBAKY: Okay. Is this
24 action related to the issue of falsification of records

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1 was in the hot lab he was supposed to have been
2 supervised by the other technologists, but he was not
3 to be handling radioactive materials directly or making
4 entries into a logbook without someone there to -- the
5 entries in the logbooks, someone had to verify those
6 entries.

7 MR. HUDNER: There was one
8 incident --

9 The iodine 131 decontamination
10 (ph)?

11 MR. MAS: That's correct.

12 MR. HUDNER: -- that occurred
13 around December 12 or 13 or 13, 14 in which he was
14 required to make data entries I believe on both days.
15 On both days either Dr. Steer or Peter Mas were in the
16 room with him taking the readings and then dictating
17 the readings to him to be recorded.

18 MS. JOUSTRA: Are we talking about
19 decontamination of the room or are we talking assaying
20 of the dose?

21 MR. MAS: This was assaying of the
22 dose, initially the assaying of the dose, because he
23 was the only technologist at that time which was very
24 familiar with the hospital's process for therapeutic

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1 or because of other performance problems that
2 Mr. Muszynski had at the hospital?

3 MR. SILVIA: It was a combination
4 of the performance problems that he had had. He was
5 under what the hospital calls a probationary period.
6 That is, they put a performance improvement plan in
7 place for him and they did that six months ago. At the
8 end of January is when that concluded. This incident
9 along with the other performance activities were part
10 of his termination in January.

11 MS. JOUSTRA: On 12/7 when he was
12 removed from NRC duties, could you be a little bit more
13 specific? What does that include? Did he actually
14 handle any nuclear medicine type procedures at all?
15 Did he administer any doses at that time or was he out
16 of the records and documentation aspect --

17 MR. MAS: Yes, he was taken out of
18 the records and documentation. He was allowed to scan
19 patients. In other words, patients would be injected
20 and he would bring them into the room and do what the
21 scan or the study was required.

22 MS. JOUSTRA: Did he assay doses
23 and administer that or just scan?

24 MR. MAS: Just scan. Anytime he

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1 uses of iodine.

2 So Dr. Steer felt that he needed
3 to rely on him and I told him it would be acceptable as
4 long as there could be direct supervision of his
5 activities in the hot lab; anything he did we could
6 vouch for the accuracy of the information recorded.
7 Under those circumstances we allowed his participation
8 in that one patient therapy.

9 MR. HEHL: But he was always under
10 the supervision of yourself or...

11 MR. SILVIA: Dr. Steer.

12 MR. MAS: Dr. Steer, the medical
13 director.

14 DR. SHANBAKY: Was he involved in
15 the surveying and the decontamination of the patient's
16 room on December 14th?

17 MR. MAS: Yes. He was doing the
18 patient surveys to determine that they were less than
19 30 millicuries activities. So I would come in in the
20 evening or later in the day, verify that the patient
21 was less than 30 millicuries for their discharge. That
22 was the other action he had with those patients, doing
23 the MR per hour radiation level surveys.

24 DR. SHANBAKY: How about the

1 release of the patient's room?
 2 MR. MAS: Release of the patient's
 3 room I believe for this case was done with Richard
 4 Whitmore the technologist who was also upstairs doing
 5 decon with Mike Muszynski and myself.
 6 DR. SHANBAKY: So you were there
 7 on December 14th when there was...
 8 MR. MAS: A therapy case.
 9 DR. SHANBAKY: ...a hospitalized
 10 patient?
 11 MR. MAS: Correct.
 12 DR. SHANBAKY: And you have to
 13 release the room on that date. You observed the
 14 surveys performed by Mr. Muszynski?
 15 MR. MAS: No, I didn't observe
 16 them because I would be in Hartford Hospital, but I did
 17 review his entries and I did confirm the patient was
 18 less than 30 millicuries.
 19 DR. SHANBAKY: How about the
 20 contamination of the room, the wipe tests and removal
 21 of all contaminated material from the patient's room on
 22 the 14th?
 23 MR. MAS: Those were performed --
 24 I believe I was present with Mike Muszynski when we

1 were cleaning up the room, removing articles that
 2 needed to be placed into storage.
 3 MS. JOUSTRA: Who has the
 4 authority to actually release the room? In this
 5 particular case who had the authority?
 6 MR. MAS: I think Michael did have
 7 the paperwork necessary to instruct the nurses that the
 8 room could be used, you know, released for their future
 9 patient care.
 10 MS. JOUSTRA: And he did in fact
 11 do it in this instance or just have the paperwork?
 12 MR. MAS: I can't recall. I do
 13 make entries into my logbooks. I can go back and check
 14 on them. Because when there are therapy patients at
 15 the hospital, I make sure that they're less than the 30
 16 millicuries before they can leave, and we round up the
 17 necessary materials and articles that need to be stored
 18 if there is any contamination.
 19 MR. HUDNER: I'll just note,
 20 because some of the dates seem to be critical, that
 21 Mr. Mas was on-site at the hospital on December 12, 13,
 22 and 14.
 23 MR. MAS: For this patient's
 24 visit, exactly.

1 MR. HUDNER: If it's important, I
 2 can give you how many hours he was on-site each day.
 3 MR. HEHL: Where does that come
 4 from?
 5 MR. HUDNER: This is a note
 6 Mr. Mas made for me. I asked him to tell me when he
 7 was on-site during 1995.
 8 MR. HEHL: Okay.
 9 MR. HUDNER: I'm happy to leave
 10 this with you, a copy.
 11 MR. HEHL: I mean how is that
 12 determined? Are there key card entries, a logbook?
 13 Basically a logbook?
 14 MR. MAS: Exactly. Depending on
 15 where I go, New Britain or Veterans Memorial Hospital,
 16 I enter the dates I'm there and the time frame.
 17 MR. HEHL: All right. I don't
 18 know that we need that.
 19 MR. HUDNER: I'm happy to...
 20 MR. HEHL: We can certainly make a
 21 copy and get it back to you.
 22 MR. HUDNER: This specifically
 23 came up when I questioned Mr. Mas as to whether or not
 24 he could have been wrong on the dates of November 28th

1 and 29th and 30. In addition to giving me the report
 2 he filled out on changing the calibration on November
 3 28th, he also gave me a log of every day he was there.
 4 MR. HEHL: Were you at some place
 5 on the 29th?
 6 MR. MAS: Well, my primary
 7 employer is Hartford Hospital and our medical-physics
 8 services are contracted to New Britain General
 9 Hospital. Because it was in May of '94 that there RSO
 10 and only physicist resigned from the institution. So
 11 as a gesture of good will between the two institutions,
 12 we worked out an arrangement by which the
 13 medical-physics at Hartford would be contracted to
 14 provide coverage services and nuclear medicine
 15 radiation safety in radiology as well as in medical
 16 oncology; you know, radiation physics there. It turns
 17 out I guess we've been so good they've retained us.
 18 MR. HEHL: But you were then at
 19 Hartford Hospital the 29th?
 20 MR. MAS: And am now, that's
 21 right, a full-time employee of Hartford Hospital.
 22 DR. SHANBAKY: Do you have any
 23 patient administered doses on November 29, '95?
 24 MR. MAS: Patient administered

1 doses of any particular agent?
 2 DR. SHANBAKY: Of anything.
 3 MR. MAS: Oh, yeah. The
 4 department was open. The Department of Nuclear
 5 Medicine was open.
 6 DR. SHANBAKY: The department was
 7 open November 29?
 8 MR. MAS: Yes.
 9 DR. SHANBAKY: Can you share with
 10 us what was the patient doses assayed by the pharmacy
 11 versus the values Mr. Muszynski got with the dose
 12 calibrator?
 13 MR. MAS: Mr. Silvia brought those
 14 materials for you, the radio-pharmaceutical...
 15 MS. JOUSTRA: Have you actually
 16 performed -- I guess on the 30th when you were aware of
 17 the fact that there was a discrepancy of the 29th
 18 readings, did you go back and take a look to find out a
 19 comparison between what was assayed on-site compared to
 20 what was done at whatever the nuclear pharmacy was?
 21 MR. MAS: Well, the discrepancy in
 22 the readings for cobalt -- I'm sorry, for barium and
 23 cesium are specific for barium and cesium. They
 24 wouldn't carry through to technetium assays or any

1 other gamma. They're just specific for the barium and
 2 cesium sources.
 3 MS. JOUSTRA: But you did do an
 4 evaluation on the 30th to determine whether there was
 5 anything unusual in the actual dose assays performed at
 6 the site --
 7 MR. MAS: And nothing seemed out
 8 of order, no.
 9 DR. SHANBAKY: Did you have any
 10 iodine samples for -- iodine doses on the 29th?
 11 MR. MAS: No. Let me say no, in
 12 greater than 30 millicurie quantities. I don't recall
 13 anything that might have been less than 30 millicuries.
 14 DR. SHANBAKY: In any dose.
 15 MR. MAS: A quick review of this
 16 would tell us, but I don't believe I saw any.
 17 DR. SHANBAKY: I think we need to
 18 look at this when we have time (indicating).
 19 MR. MAS: There will be a cover
 20 sheet which indicates the type of study performed.
 21 Okay. So on the 27th they were
 22 all technetium.
 23 On Tuesday the 28th at 1:30 in the
 24 afternoon there's a thyroid uptake done with 4.8

1 millicuries, but it doesn't tell me whether was that
 2 was I-123 or technetium. At 4.8 millicuries, my guess
 3 it would have been I-123.
 4 DR. SHANBAKY: The barium channel
 5 indication would be similar to the I-131? What channel
 6 should be affected by the barium measurements?
 7 MR. MAS: Only that channel. This
 8 instrument has independent calibration controls for
 9 each station; if I go here to Appendix D on this thing.
 10 So each preset station that has a labeled button on the
 11 instrument has its own preset calibration value. So
 12 they are adjusted or changed independently of each
 13 other. So any change made to barium and cesium or
 14 cobalt or gallium would only be reflected at that
 15 station.
 16 DR. SHANBAKY: Okay. And the only
 17 two channels you changed on the 28th were the barium
 18 channel and the cesium channel?
 19 MR. MAS: Correct.
 20 DR. SHANBAKY: Nothing else?
 21 MR. MAS: Nothing else.
 22 Do you care to see these?
 23 MR. HEHL: Why don't we go ahead
 24 and go on and let you continue with your prepared

1 remarks, and then we'll take a few minutes' break a
 2 little bit later and maybe we can sit down and go
 3 through this in a little more detail, because we would
 4 like to give it back to you. It certainly contains
 5 patient information which would be private. So we'd
 6 rather not retain it unless we need to.
 7 MR. SILVIA: I think that
 8 summarizes the incident, summarizes the action that we
 9 took. I think we'd just like to say sort of a couple
 10 things in conclusion, that, you know, we take the NRC
 11 regulations very seriously. Peter does an annual
 12 review with all the technologists to review the
 13 importance of NRC compliance and NRC regulations.
 14 Michael was at that annual refresher in April prior to
 15 this incident happening. And Peter does a thorough
 16 annual training and refresher every year.
 17 We take the NRC regulations as
 18 significant, as important, and because of this Michael
 19 is no longer here in our employ. And I think that what
 20 we just want to say is that this was an incident that
 21 was discovered by the hospital. We discovered it. We
 22 reported it to you. We have taken what we believe is
 23 very swift, decisive action to correct the problem
 24 because of the importance we place on the NRC

1 regulations.

2 We have done everything we can to
3 fully comply and cooperate with the investigation that
4 the NRC undertook. And we'd be happy if we can answer
5 any questions, provide any additional information to
6 you so that we can conclude this action.

7 MS. JOUSTRA: Does the hospital
8 have any position as to why they think he may have done
9 this possibly only on one occasion, what may have
10 provoked it? I know Peter had mentioned something
11 briefly. He had asked himself the same question but
12 didn't have an answer for it.

13 Does the hospital have any insight
14 as to why he may have what appears to all of a sudden
15 do something like this to, something that doesn't
16 seem...

17 MR. SILVIA: It's very difficult
18 for us because here's an individual who has been an
19 employee of the institution for a long period of time
20 and has never really had any problems related to his
21 performance.

22 It does tell us that within the
23 last year of his employ there were some issues. He was
24 for the first time in his career put on a performance

1 plan because of some issues. Most of the issues had to
2 do with him not following through properly on various
3 supervisory functions.

4 Whether this was an indication
5 that at some point during his career he either became
6 lackadaisical, and if this was the issue we don't know.
7 What we do know is that we were within the last year
8 having some problems. Peter was paying close attention
9 to make sure that we were in compliance, and when this
10 did arise we took action.

11 We wish we had a better
12 explanation as to why an individual would do such a
13 thing but we don't.

14 MS. JOUSTRA: Have you obtained I
15 guess any perspective from other staff members as to
16 whether they would consider this an acceptable practice
17 or any idea or indication from them that this has been
18 going on by...

19 MR. SILVIA: We asked and none of
20 them were aware that this took place. None of the
21 people that we talked to felt that -- had any knowledge
22 that there were ever any falsifications made by any
23 employees down there.

24 When we talked to the two primary

1 technologists that were there after Michael's
2 departure, this was not knowledge that they had, they
3 were not aware that this was done, and had never known
4 that there was any falsification.

5 MR. MAS: And as well on their
6 behalf I'll say that I've not sensed or picked up
7 anything from any of the technologists that would cue
8 me into something not being right in the affairs that
9 they handle for the hospital. It's just unfortunate
10 that I managed to find this one bad event.

11 DR. SHANBAKY: About the staff in
12 nuclear medicine, can you describe for us whether you
13 are overstaffed or understaffed or what does it look
14 like in that department?

15 MR. SILVIA: Peter commented. We
16 have a supervisor. We have replaced Michael and we've
17 got a supervisor who has a great deal of experience in
18 nuclear medicine. There are three other technologists
19 that work in the department. Most of them have been
20 there for probably -- the newest employee is the
21 supervisor. Other than that, Lisa has probably been
22 there for a year, year and a half.

23 It's a department that I think is
24 probably adequately staffed. I think that we probably

1 were -- when we had one of the employees out on
2 maternity leave, the staffing was tighter than it is
3 today, but today I think we're fully staffed and
4 adequately staff.

5 DR. SHANBAKY: Anybody on
6 maternity leave back in November 1995?

7 MR. SILVIA: I don't recall. When
8 that happened, we had a temporary agency. We had an
9 employee from a temporary agency during that time.

10 DR. SHANBAKY: Is that nuclear
11 medicine technologist assigned any other collateral
12 activities or collateral duties other than the
13 day-to-day nuclear medicine procedures?

14 MR. SILVIA: Just the bone
15 densitometry.

16 MR. MAS: There's only the bone
17 density room. They operate the bone densitometer which
18 again this is part of radiology. It's in a different
19 section. So of the four full-time technologists, one
20 will be doing bone densitometry. It might be just a
21 half day depending on the workload, but the other
22 technologists are handling the nuclear medicine events.

23 DR. SHANBAKY: Are they usually
24 called upon for other radiological procedures like

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1 x-ray?
 2 MR. SILVIA: No.
 3 MR. SMITH: This is headquarters
 4 I'm going to have to drop off now.
 5 MR. HEHL: Okay, Jim.
 6 MR. SMITH: Bye-bye.
 7 MR. HEHL: What has the hospital
 8 done to convince yourselves that this is an isolated
 9 event?
 10 MR. SILVIA: What makes me believe
 11 it's an isolated event is the audit that Peter performs
 12 routinely. Anytime after he does a calibration, he
 13 goes in to make sure that he sees what he should see.
 14 So if this had occurred the last time he had done it
 15 and there was a falsification, it would have been
 16 picked up at that time.
 17 So we feel comfortable that Peter
 18 does go in and he ensures the accuracy of the
 19 information that's in the log after he does a
 20 calibration. He also monthly goes in and reviews all
 21 of the books, all of the records to see if there's
 22 anything out of line.
 23 So we feel that with the audit
 24 that Peter provides that this was a one-time

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1 occurrence, that if it had occurred before we would
 2 have picked it up before because we have the audits in
 3 place.
 4 MR. HEHL: Do you do a hundred
 5 percent review of records in nuclear medicine monthly?
 6 MR. MAS: I don't look at the
 7 patient records. I go through the hot lab and look at
 8 the documentation of surveys, materials received,
 9 stored, et cetera. Those I review.
 10 MR. HEHL: Okay.
 11 DR. SHANBAKY: Can you
 12 characterize your relationship with Mr. Muszynski
 13 before this event? Was it a working relationship
 14 between you and him?
 15 MR. MAS: It was an amicable
 16 working relationship. I've viewed him as a
 17 professional rendering a service, and I believe he
 18 viewed me the exact same way. There was no animosity,
 19 no friction between us.
 20 There were occasions when I may
 21 have requested documentation like reports regarding
 22 recordable events where we had a technologist not
 23 documenting fully the use of iodines. And so according
 24 to the regulations, it's 30 days from the day that you

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1 have determined this occurred that you found this.
 2 And I'd mention it to Mike, you
 3 know, you need to document this, this is what occurred,
 4 and put it in writing so that it can be reviewed and
 5 kept as an inspectionable record.
 6 And it took him more than 30 days,
 7 but other than that, there really was no friction
 8 between our functions.
 9 DR. SHANBAKY: Did he have any
 10 friction or conflicts with other people in that
 11 department?
 12 MR. SILVIA: Not that I'm aware
 13 of, no.
 14 MR. HUDNER: Is it fair to say
 15 that one of the reasons why he was on probation was
 16 because he was not adequately communicating what he was
 17 and wasn't doing to Lucy Doucette? I'm not saying
 18 that's friction, but you're asking a question --
 19 MR. SILVIA: That was with his
 20 supervisor, not with a technologist. There might have
 21 been some friction with his supervisor because he
 22 wasn't following through on a number of his supervisory
 23 activities, but in terms of his relationship with the
 24 technologists in the department, there were no issues

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1 that I'm aware of.
 2 DR. SHANBAKY: How about the
 3 physicians in that department?
 4 MR. SILVIA: No. The physicians
 5 were very supportive of Michael; are to this day.
 6 DR. SHANBAKY: So the only
 7 difficulty he had was with the supervisor?
 8 MR. SILVIA: Some difficulty with
 9 the supervisor who had to put him on a probationary
 10 period.
 11 DR. SHANBAKY: Okay.
 12 MR. HEHL: Let me get back to your
 13 audits in just a minute. In the audits that you
 14 performed of the Nuclear Medicine Department in the
 15 past, have you identified any other incidents of
 16 records that appear to be inaccurate?
 17 MR. MAS: In the audit log which
 18 was given to Claudia Pietras, I believe there's an
 19 entry around the beginning of June which indicates that
 20 two weeks of information were missing from a xenon --
 21 the xenon trap QA or such. So I made a note to myself
 22 that when I went to inspect there was that data
 23 missing. At my next arrival, which I guess was a week
 24 later at the institution, that data had been completed;

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1 in other words, the blanks in the record had been
2 filled in.
3 At the time I didn't know what to
4 make of it, whether or not Michael might have had this
5 data, because again it was his initials; whether he
6 might have had this data in his pocket or, you know, on
7 his desk, work space, someplace. So I just made a note
8 to be a little more watchful and wary of log entries.
9 DR. SHANBAKY: Those are the dose
10 measurements from the xenon trap?
11 MR. MAS: Yeah. I believe that
12 was the xenon monitor or the xenon trap QA for leakage.
13 In July Michael had been given a
14 three-week vacation period, and when I looked at the
15 area survey records, they were blank for a five-week
16 stretch of time. So I crossed out those five weeks and
17 wrote into the record "failed to perform" and signed
18 them off.
19 What occurred thereafter was that
20 Michael was asked, you know, what exactly led to this
21 series of lapses, and he mentioned that, number one, he
22 was on vacation; number two, the technologist had not
23 been given any instructions to follow up on his QA
24 tasks and the materials that he normally -- the records

1 that he normally would be completing.
2 The response from the -- rather
3 the corrective action from the administration was to
4 have Michael delineate his tasks and his functions so
5 that they could be presented to any other technologist
6 in the case he were absent to make sure they were
7 completed.
8 MS. JOUSTRA: Let me understand
9 correctly. There were five weeks in which within those
10 five weeks a trap check should have been performed
11 once?
12 MR. MAS: No. The trap check was
13 the first item that occurred around June. This was in
14 August. This was I believe the contamination surveys,
15 the wipe test for the department. So the wipe test
16 record was blank for a five-week period of time.
17 MS. JOUSTRA: Now I'm really
18 confused. You mentioned with xenon first and you said
19 that in fact the monthly QA check on the xenon trap had
20 not been completed.
21 MR. MAS: Actually it was weekly;
22 two weeks of xenon QA check.
23 MS. JOUSTRA: Is that a licensed
24 condition that you've tied yourself to, to weekly check

1 on that?
2 MR. MAS: To be very honest with
3 you I do not know because I don't have a license
4 application. That was submitted by the previous
5 physicist.
6 MS. JOUSTRA: But internally you
7 require this to be performed weekly?
8 MR. MAS: Yes.
9 MS. JOUSTRA: So you were missing
10 two weeks?
11 MR. MAS: Two weeks. I'd go back
12 the following week and that information had been
13 completed in the record.
14 MS. JOUSTRA: So at that point did
15 you realize or know when or why it was now filled in?
16 MR. MAS: No. I made it a point
17 to just -- assuming that Michael may have had this data
18 on the desk, in his pocket somewhere, I simply made it
19 a point to myself to be a little more wary and cautious
20 as to the record keeping that was being done within the
21 department.
22 MS. JOUSTRA: So we still don't
23 know as of today whether or not this test was actually
24 performed or not?

1 MR. MAS: True.
2 MS. JOUSTRA: Where do the other
3 five weeks come in?
4 MR. MAS: Well, in answer to his
5 question --
6 MR. HEHL: Before we leave the
7 xenon, has anybody addressed to Mr. Muszynski this
8 issue of the xenon event?
9 MR. SILVIA: No. We were never
10 informed of the xenon incident. That was something
11 that Peter took note of and what Peter informed to me
12 afterwards. In fact I only knew about this when he
13 wrote this information in the log to Claudia Pietras.
14 This was something that Peter
15 noted and he felt that he was going to keep a closer
16 eye on Michael as a result of that. The institution
17 was not aware of that, and that has never been
18 presented to Michael since he was terminated based upon
19 his performance and falsification.
20 MS. JOUSTRA: How were the checks
21 after that point since you were keeping a closer eye
22 on him? Okay?
23 MR. MAS: Well, with regard to
24 that weekly xenon alert check, yes, they were complete.

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1 But in August when I reviewed the weekly wipe test,
2 there was a five-week stretch there of nothing.
3 MR. HEHL: And this is wipes for
4 the Nuclear Medicine Department?
5 MR. MAS: Yes. So the week prior
6 to his three-week vacation and the week after.
7 MS. JOUSTRA: Okay.
8 MR. MAS: So I, you know, X'd out
9 the log during those five weeks, indicated failed to
10 perform, and I brought it to the attention of the
11 supervisors.
12 MR. HUDNER: One of the
13 supervisors, Tom Saldino, then asked Michael to write
14 down every test that he performs, how it's performed,
15 how often it's supposed to be performed, certain time
16 of day so that there would be a written documentation,
17 so that when he was on vacation again, there wouldn't
18 be that kind of gap.
19 MS. JOUSTRA: So now this
20 five-week period with the surveys of the room, the
21 wipes of the room, we don't have the same problem here
22 with eventually the data being placed into the record;
23 that always remained incomplete?
24 MR. MAS: Correct.

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1 MS. JOUSTRA: That was my
2 confusion.
3 MR. HUDNER: I've seen the record.
4 On the record you actually -- it's actually crossed
5 out.
6 MR. HEHL: Before we leave this
7 area, do you have any reason to believe that the data
8 that was subsequently put into the log on the xenon
9 trap leak QA that that information was inaccurate or
10 incorrect?
11 MR. MAS: No.
12 DR. SHANBAKY: Getting back to
13 your answer to Judy's question about a minute ago, you
14 said you don't have a copy of what was submitted to the
15 NRC with the license, your tie-down conditions?
16 MR. MAS: I don't have a license
17 application. We do have in the hospital a manual
18 called the Radiation Safety Manual where there appear
19 to be documents or sections of documents that were
20 submitted in the license application. But a binder
21 that I could, you know, pick up and say this must be
22 what was submitted by person such and such, you know,
23 no.
24 DR. SHANBAKY: I think those are

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1 important because they constitute regulatory
2 requirements and we'll get you a copy of this if you
3 are not sure whether you have it or not.
4 MR. MAS: I have been running the
5 radiation safety functions very much to the compliance
6 of 10.8 Revision II to make sure that they're currently
7 performing whatever tests are required through 10.8
8 Revision II, and much of the documentation which was in
9 place when I came on seemed to be in agreement with
10 10.8 Revision II.
11 MR. HEHL: But you can't be sure
12 that you're auditing against your license unless you
13 know what your license requires.
14 MS. JOUSTRA: 10.8 I believe
15 requires a monthly xenon trap. If you want to be more
16 restrictive and do more than that, that's fine.
17 MR. HEHL: We'll make arrangements
18 to get you this information.
19 MR. MAS: Perfect.
20 MR. HEHL: Because it's very
21 important that you hold yourself to your license, not
22 just the reg guide.
23 MS. JOUSTRA: Especially if they
24 may conflict with each other; you've got a problem.

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1 MR. MAS: Yes.
2 MS. JOUSTRA: I'm kind of curious
3 as to why you don't have it. Maybe somebody could
4 elaborate on that a little bit. How come that document
5 isn't available?
6 MR. MAS: Well, if I might, the
7 hospital had had a consultant physicist I don't know
8 for how long; you know, starting what year and
9 extending through when. That consultant physicist...
10 (Mr. Costello exited the
11 conference room at this time.)
12 MR. MAS: ... I think is
13 relationship ended in the winter or spring of 1992 when
14 the quality management program came into effect, came
15 into being, because I have seen or rather I have found
16 the QM plan prepared by this consultant and it had been
17 mailed to Region I signed off by the consultant, and of
18 course by the institution as well.
19 It was in the spring when Amecca
20 Azundo (ph), a physicist, a master of science physicist
21 took over as the radiation oncology physicist and
22 apparently also took over the radiation safety tasks.
23 So the consultant must have produced the license
24 application. Amecca took over the radiation safety

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1 office and the medical-physics functions and the
2 diagnostic imaging functions. He basically did
3 everything. He was covering everything in the
4 hospital.
5 When we came to the institution in
6 May of '94, the only binder that I could find with
7 components that seem to be what the license application
8 was about was this red binder called Radiation Safety
9 Manual that had sections taken out and copied and
10 distributed to the various departments according to
11 what their regulatory standards would be, you know, for
12 that licensed duration.

13 So where exactly is the entire
14 complete license application? I mean, I searched the
15 files and the file cabinets and I did not find anything
16 that I could lay my hands on and say this must be the
17 document that went out. So between the consultants and
18 the other physicists, I can't say I know what exactly
19 occurred.

20 MR. HEHL: We'll make arrangements
21 to get you that information, but I'm sure you
22 understand that there is some variation license to
23 license --

24 MR. MAS: Absolutely.

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1 MR. HEHL: -- depending on what
2 the commitments were in the licensing process which,
3 once they're confirmed in the license, they become just
4 as binding as the other regulations. So I would highly
5 recommend that you get very intimate with that license
6 and the conditions and make sure that the program
7 that's being implemented is consistent with that.

8 Then I guess just to summarize
9 what I think I heard with regard to New Britain's
10 activities to put some boundaries or bounding aspects
11 of this event, based on the monthly audits that were
12 performed prior to this event, your feeling is that
13 this is an isolated case?

14 MR. SILVIA: Yes.

15 MR. MAS: Yes.

16 MR. HEHL: You didn't do an
17 independent investigation, though, of this event? Or
18 did you do any kind of independent investigation of
19 this event?

20 MR. HUDNER: I'm not sure what
21 you're asking. If you're asking did we make an
22 inquiry, the answer is yes. And that's what led
23 directly to the suspension and ultimate termination of
24 Mr. Muszynski.

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1 MR. HEHL: You did an inquiry into
2 this event?

3 MR. HUDNER: Yes.

4 MR. HEHL: You didn't expand that
5 independently to go back and look at other records?

6 MR. SILVIA: I think, you know,
7 what we had in talking with Peter, his review after he
8 does the calibrations, plus his monthly audit, Peter
9 felt very comfortable that this was an isolated event.
10 So I really didn't think that doing any further
11 investigation was warranted because he had been
12 auditing this as a routine process.

13 MR. HEHL: So your feeling is that
14 the audits would have identified any other shortcuts
15 that the individual might have taken in other
16 activities that they performed --

17 MR. MAS: Correct.

18 MR. HEHL: -- across the spectrum
19 of licensed activities that he performs?

20 MR. MAS: Yes.

21 MR. HEHL: And you think you've
22 covered the whole spectrum of activities that are
23 performed by this individual?

24 MR. MAS: Yes.

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1 MR. HUDNER: That is, sir, in
2 essence, a record audit, and that's what Mr. Mas has
3 been doing on a continuous basis. When we asked him
4 whether there were other issues involving Mr. Muszynski
5 specifically, we came up with a weekly wipe test
6 incident, a question with regard to the xenon alert
7 instrument. But in terms of identifying previous
8 falsehoods, there wasn't anything we could find.

9 MR. HEHL: Have you taken any
10 other action with regard to the other employees there?
11 Aside from the personnel action that you took against
12 Mr. Muszynski in January, were there any other training
13 or any other activities that were put in place?

14 MR. MAS: Well, I've not wanted to
15 discuss the events regarding Mike Muszynski's no longer
16 working at the institution because of the legal
17 concerns. Michael did appeal this and I didn't feel it
18 was my place to inform the technologists as to what was
19 occurring. But in in-services and training I do
20 emphasize the value of maintaining accurate records,
21 you know, without going back to "this is what happened
22 to Mike" or something of the source, without trying to
23 make those connections.

24 MR. HEHL: Did any in-services

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1 occur subsequent to the 30th of February?
2 MR. MAS: I have in-serviced a few
3 personnel in Nuclear Medicine since this, yes, and also
4 personnel in Radiation Oncology.

5 MR. HEHL: All the technicians
6 have been in-serviced?

7 MR. MAS: I believe I'm missing
8 one which is a per diem, someone that they're hiring on
9 a per day event.

10 MR. HEHL: When do those
11 in-services occur?

12 MR. MAS: I have them on a QA
13 schedule calendar so that they're done at least once a
14 year. The radiation oncology QA schedule and the
15 nuclear medicine QA schedule are two different ones.

16 MR. HEHL: So approximately when
17 did your in-service occur following the November 30th
18 time frame, 1995?

19 MR. MAS: I might have a few
20 documents here. So I have one for September 12th of
21 '95, in radiation oncology, radiation oncology occurred
22 also April of '95.

23 MS. JOUSTRA: Has any training
24 been given since this event up the until now which

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1 When we were interviewing various
2 employees as part of your wrap-up and then getting
3 together with Claudia Pietras, employees were quite
4 vocal on the whole series of events from December 7th
5 onward. People understood what had happened to
6 Mr. Muszynski and they understood why they agreed or
7 disagreed, depending on the individual and what they
8 thought of Mr. Muszynski.

9 But it's not like people didn't
10 understand that some very significant corrective action
11 had been taken.

12 MR. HEHL: But nobody discussed
13 with the members of the department any reinforcement
14 until the next routinely scheduled in-service?

15 MR. SILVIA: I think that when
16 you've terminated an individual for falsification, I
17 think that's considerable reinforcement about the need
18 for accuracy of records.

19 MR. HEHL: Was that advertised
20 that he was terminated?

21 MR. SILVIA: And the new
22 supervisor who was brought in was told that there was
23 an investigation and action regarding falsification of
24 data. And so they were made well aware of the fact

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1 would --

2 MR. MAS: Yes, I believe I have.
3 I don't have this here. I'd expect to find it in my
4 logbooks.

5 MS. JOUSTRA: And that would have
6 covered again accuracy of records?

7 MR. MAS: Yes. You know, the NRC
8 Form 3, the map of the United States, you know, go
9 through this. It has several questions and answers.
10 It emphasizes the accuracy of records maintained and
11 the issues of deliberate misconduct which, you know, no
12 employee is desired to be in or found in rather. Then
13 we go through the regulatory guides, the 10 CFR 19, 20,
14 35, the components of risks from radiation exposure and
15 prenatal exposure.

16 MR. HUDNER: If I may, you have to
17 remember this is a small hospital and a small nuclear
18 medicine staff. When Mr. Muszynski was disciplined and
19 removed from NRC duties as of December 7th, it's not
20 like this was a secret within the department. I mean
21 everybody knew about this. He was a popular employee.
22 This became a very hot topic of discussion. When he
23 was then let go in January, this was a big event within
24 the department.

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1 that --

2 MR. HEHL: The new supervisor.
3 How about the other technicians?

4 MR. SILVIA: Yes, they all knew.

5 MR. MAS: I believe they were also
6 made available to Ms. Pietras at the time of her
7 investigation, so they understood why.

8 MS. ZOBLER: Did the other
9 employees seem to think that this was an overreaction,
10 the other technicians?

11 MR. MAS: Not the nuclear medicine
12 employees. We're talking about radiology...

13 MR. SILVIA: When we talked to
14 them, it was very clear that all of them knew how wrong
15 it would be to have any falsification and how important
16 the NRC requirements are. I mean, that was voiced over
17 and over to us by the technologist.

18 MS. JOUSTRA: How about the other
19 way around? You know, I'm looking for something that
20 says management actually went to the staff and said:
21 Here is what is expected of you. Rather than them
22 coming to you and say, gee, we know he did wrong, do
23 they understand what's right, what should be done, what
24 makes it right?

1 MR. SILVIA: You know, I think
2 that, one, we have the annual review that we do. We
3 have employees coming to us, that is, giving us back.
4 I think if anything is an indication of how well your
5 training is it's your employees telling you that they
6 have understood what we have told them at the annual
7 training; that the NRC requirements are important.
8 They mention to us that they do get to review every
9 year and how important it is for accuracy for filling
10 those logs out.
11 So I have to say that I think the
12 sessions that we've had was reinforcement, absolutely.
13 MS. JOUSTRA: And we think one of
14 those sessions occurred after the event?
15 MR. SILVIA: They all do, because
16 we met with them.
17 MS. JOUSTRA: I mean, the initial
18 training where they got the original understanding of
19 what is acceptable.
20 MR. SILVIA: Before that, sure.
21 MS. JOUSTRA: So we have nothing
22 since the event?
23 MR. SILVIA: We've met with all of
24 them since the event.

1 MR. MAS: As far as training. I'd
2 have to go back to my logs to see if there's something
3 I missed there. But I do believe that we have had
4 in-services since then.
5 MS. JOUSTRA: Could you give that
6 information to Louis.
7 MR. MAS: Yes.
8 MR. HEHL: When did these meetings
9 occur, and I guess what was the topic of the
10 discussions you had with the employees?
11 MR. SILVIA: The meetings
12 occurred -- I'd have to get my book out because I don't
13 have the exact dates, but they centered around the
14 falsification that was being investigated by the NRC,
15 what we were looking to find out in our investigation,
16 whether they had any knowledge that there was
17 falsification, whether they were aware of it, whether
18 it had ever occurred before -- those were the topics --
19 and how important it was that we comply with the NRC
20 regulations.
21 MR. HEHL: And your investigation
22 you say took place when? I mean was there -- you say
23 you looked into this issue.
24 MR. SILVIA: I don't have the

1 exact dates.
2 MR. HEHL: Who looked into it?
3 MR. SILVIA: Myself and our
4 hospital attorney.
5 MR. HUDNER: There are actually
6 two attorneys involved here. The hospital has an
7 in-staff attorney named Elizabeth Schlaff, who was
8 initially involved, and then I became involved at the
9 end of March, early April. And part of what I did in
10 trying to get my own facts in hand was spend some time
11 with Mr. Mas discussing, A, how he constructed the
12 events of November 28th and 29th and 30, but also is
13 there something we should have spotted with this guy?
14 That obviously is of importance to you folks and thus
15 becomes very important to us.
16 That is, in essence, a record
17 audit, which didn't turn up anything, and questioning
18 other employees. Is there something you know about
19 that we should have known about or that you reported to
20 us and we didn't act on? And all those questions
21 turned up negative.
22 MR. HEHL: So as part of your
23 follow-up, the hospital's follow-up with this event,
24 you met with the other members of the Nuclear Medicine

1 and Radiology departments --
2 MR. SILVIA: Nuclear Medicine, not
3 Radiology.
4 MR. HEHL: Okay. And I guess
5 reviewed or I guess how would you characterize those
6 meetings then with them? Was it a one-on-one?
7 MR. HUDNER: It was a one-on-one.
8 I mean, in my own terminology, it would be an
9 investigation. I was essentially trying to recreate
10 what happened, what led up to it, what if anything we
11 had screwed up.
12 MR. HEHL: The original one that
13 occurred with the in-house attorney? You're talking
14 about your April --
15 MR. HUDNER: I'm talking about,
16 yes, mine.
17 MR. HEHL: But the original one
18 occurred, what, shortly after the event?
19 MR. SILVIA: No, I don't believe
20 so. I think the investigation that we had is when we
21 brought Ken in, and Ken and I did those meetings with
22 the employees.
23 MR. HEHL: I'm sorry. I
24 misunderstood. So that was April time frame?

1 MR. HUDNER: Yes. Late March,
2 early April.
3 MR. HEHL: What prompted that,
4 just your coming on board to look at the event?
5 MR. HUDNER: At this point this
6 gets a little more involved from the human resources
7 side.
8 MR. SILVIA: Maybe I could --
9 there's a couple things here. One is that, when we
10 terminated Michael, he appealed it or aggrieved it, and
11 the hospital has sort of a peer review of any
12 termination or disciplinary action. And that process
13 goes on for a considerable length of time. It went on
14 for several months where they do interviews, they do
15 investigations. It's peers, employees and some
16 management that are on this group.
17 And the group felt in reviewing it
18 that the hospital did not follow through on the
19 performance improvement plan that they had set in and
20 said that Michael should be reinstated. At that point
21 we did a more thorough discussion with Peter to make
22 sure that we were on very sound ground in terminating
23 Michael because of the falsification. We felt we were,
24 and so that's the action that we took there.

1 So he was terminated in January as
2 a result of the performance improvement plan, together
3 with the NRC violation. When this group voted to bring
4 him back in, the hospital then subsequently terminated
5 him based upon this falsification.
6 MR. HEHL: So the hospital really
7 didn't look into this event until March/April time
8 frame.
9 MR. SILVIA: That's not true. The
10 hospital looked into it right then. The hospital took
11 action immediately when we were notified. We suspended
12 him from action, and he was terminated in January. He
13 never from the date that we -- from then on took part
14 in any NRC regulatory activities.
15 MR. HEHL: As far as addressing
16 the issue with other employees and meeting with other
17 employees, that didn't occur until March/April; is that
18 right?
19 MR. SILVIA: The employees knew
20 when he was suspended from those duties back in
21 December that there was an issue regarding the
22 falsification.
23 MR. HEHL: And that was as a
24 result -- they knew as a result of?

1 MR. SILVIA: He was no longer able
2 to...
3 MR. HEHL: Okay. But did the
4 hospital talk to the employees?
5 MR. SILVIA: I'd have to ask the
6 supervisors.
7 MR. HEHL: Did they address the
8 issue? He was still in a supervisory role?
9 MR. SILVIA: I would have to ask
10 his supervisor who took part in removing him from the
11 NRC duties.
12 MR. MAS: His title was still
13 supervisor. His activities pretty much had been
14 relegated to something short of buck private, where he
15 could not be in the hot lab unless he was supervised.
16 He could not make entries into records unless those
17 entries had been verified by some other individual in
18 the Nuclear Medicine Department.
19 MR. HUDNER: I'm not sure if, as
20 you sit here wearing your NRC caps, you fully
21 appreciate what it was the hospital did in March after
22 the internal review panel said we think there may have
23 been inadequate procedure; we want this man reinstated.
24 At that point Elizabeth Lynch of

1 Human Resources met with Dr. Steer, with Peter Mas and
2 said, you know, if we don't reinstate this guy, we are
3 almost certainly subject to a lawsuit. And I have to
4 learn from both of you now whether you are convinced
5 beyond a shadow of a doubt that there was a problem.
6 They both were. They both told
7 her in no uncertain terms that he should not come back.
8 The hospital confirmed his firing, the grounds given to
9 him were, in addition to the problems with you as a
10 supervisor, interacting with other supervisors, let's
11 make it clear: You're out of here because of
12 falsification.
13 I don't know if you guys have the
14 type of employment problems or employment relations
15 problems that other institutions have, but should he
16 sue the hospital, it was going to be for wrongful
17 discharge, slander and any number of other things. At
18 that point in March the hospital essentially stuck its
19 neck out and said: Based on this one line of data that
20 we think was false, you're out of here for all time.
21 MR. HEHL: And I think we
22 appreciate the concern that this must have generated.
23 We're just trying to get as complete a picture as we
24 can to know exactly what took place. We're not trying

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1 to provide any judgment on what you did, just trying to
2 get a picture.

3 MR. MAS: For the management as
4 well as the administrators and the department directors
5 and myself, there's a certain amount of walking on eggs
6 and being circumspect about what has occurred because
7 you do have still this legal arena out there that has
8 to be dealt with. So we cannot parade up and down the
9 halls with placards saying Mike was fired for fraud
10 because it's not -- it would not be seen well, in
11 addition to realizing that this other legal environment
12 is still yet to be approached.

13 But you can be circumspect about
14 it and speak with people on a one-on-one and they have
15 an understanding of what has occurred and the reasons
16 for it.

17 MR. HEHL: I guess just
18 editorially, and I understand what you're saying, but I
19 guess certainly there would have been an opportunity to
20 go in, and since you now have an employee that after 23
21 years of faithful employment makes a decision for
22 whatever reason to shortcut a procedure and something
23 that appears to be very out of character you would I
24 guess want to assure yourselves that, not only that it

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1 occurred but also to make sure that there weren't other
2 environmental factors or whatever that may or may not
3 have contributed to that decision to take that
4 shortcut.

5 And I guess personally I would
6 have seen an opportunity to re-educate perhaps the rest
7 of the staff as to their responsibilities.

8 MR. SILVIA: That's an excellent
9 point.

10 MR. HEHL: Any other questions?

11 MR. MANNING: I have a question.

12 Mr. Mas, you mentioned that on the
13 date of the 28th that Mr. Whitmore actually physically
14 saw you do the dose calibrator check?

15 MR. MAS: Correct.

16 MR. MANNING: And that the record
17 that you -- the entry for the accuracy test that you
18 performed for the dose calibrator, that you may have
19 left that record there the same night or after you
20 finished the test on the 28th you left the record there
21 for the technologist?

22 MR. MAS: Correct.

23 MR. MANNING: Thank you.

24 MR. HEHL: Okay. We'll take maybe

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1 a ten-minute break. We wanted to review and make sure
2 we went over and clearly understood the pharmaceutical
3 records. And then why don't we reconvene in about ten
4 minutes and I think we'll be pretty close to being
5 done. Maybe we'll just take ten minutes to do that.

6 MR. SILVIA: If there's any -- if
7 you could give us like a list of any other information
8 you want from us.

9 MR. HEHL: Certainly. We'll just
10 kind of break off the record.

11 (Recess taken at 11:40 a.m.;
12 reconvened at 11:45 a.m.)

13 MR. HEHL: We've had a chance to
14 look over the dose information provided by the
15 radio-pharmacy slips and we have a couple questions.

16 DR. SHANBAKY: I think I'd like to
17 look at -- we just took a quick sample of the patient
18 dose assayed on the 29th, 28th, and 27th, and I'm not
19 sure if I am reading this data correctly, but on the
20 29th I got patient the dose that was done by
21 Mr. Muszynski -- that's MM -- lot number 152333. He
22 assayed the dose at 8:00, 8:10 a.m. in the morning and
23 he came up with 17.6 millicuries.

24 MR. MAS: Correct.

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1 DR. SHANBAKY: The pharmacy sends
2 this dose at 20.4 millicuries and assayed for 8:00 in
3 the morning. So I did not correct for any decay here
4 because ten minutes is no big deal. So with this there
5 is a difference of about 14 percent between what the
6 pharmacy is telling and what the technologist assayed
7 here. Is this true?

8 MR. MAS: Yes. If you did the
9 math, I believe you, that there would be 14 percent
10 difference.

11 MR. HUDNER: Can you just show me
12 which of the slips you're working from.

13 MR. MAS: He's looking at the one
14 that's stamped prescription 152333.

15 MR. HUDNER: Thank you.

16 DR. SHANBAKY: I'm just going to
17 do the math again quickly.

18 MR. HEHL: Well, I guess the point
19 being that if it varies by that much, the expectation
20 would be that some determination would be made, right,
21 as to why the significant difference? What would your
22 expectation be?

23 MR. MAS: Well, if the pharmacy
24 shows 20.4 millicuries dispensed as of 8:00 a.m., they

1 place this in the morning. They ship it to you
2 pre-calibrated. So they did not assay this at 8:00
3 a.m. They assayed this at some other time and just
4 provided it to the institution indicating that they
5 estimated the activity would be 20.4 millicuries.

6 DR. SHANBAKY: At 8:00?

7 MR. MAS: At 8:00. Now, that the
8 assay reported here of 17.6 versus 20.4 is off by 14
9 percent, 15 percent may be correct. But the dose is
10 still in a range that the physician would find
11 acceptable to use on the patient.

12 DR. SHANBAKY: Okay. So looking
13 at it that there's no deviation from what the pharmacy
14 assayed, looking at from it whether the dose was in the
15 range, how about the accuracy of the assay itself? I
16 mean the 17 or the 20 may be within the range of this
17 procedures, but how about the accuracy of the test
18 itself? Do you have any cutoff point, like, you don't
19 administer the dose if it's different from the pharmacy
20 by whatever percent?

21 MR. MAS: I think the standard is
22 that it cannot be different by 50 percent for a
23 diagnostic dose and no greater than 10 percent
24 difference for a therapeutic dose. So this falls

1 within that plus or minus 50 percent limit for
2 radio-pharmaceutical doses.

3 DR. SHANBAKY: So your difference
4 is 50 percent for diagnostic procedures?

5 MR. MAS: I believe on a
6 regulatory basis it cannot be greater than 50 percent
7 error.

8 DR. SHANBAKY: I'm taking about
9 your procedures.

10 MR. MAS: Oh, I don't know if
11 there is a procedure within the department that says
12 you can only use doses as long as they assay within XYZ
13 of a calibrated activity. That would require that the
14 techs not only assay but take this stated assay from
15 the manufacturer and then make a correction for it as
16 the time goes on. They don't do that, no.

17 They assay the dose. If it is a
18 clinical agent and it can be used and the physician is
19 in agreement with it, it's used on the patient.

20 MR. HEHL: Would this raise some
21 question as to the accuracy of the dose calibrator?

22 MR. MAS: Only for technetium,
23 because each station is independently calibrated.

24 MR. HEHL: I guess what would

1 your -- if you don't know what the procedure says, then
2 what would your expectation be if the dose calibrator
3 is 15 percent off for technetium?

4 MR. MAS: Much like what we
5 discussed before. That I didn't find when I assessed
6 the dose calibrator recently that we found a 10, 12
7 percent error or rather what's presumed to be an error
8 like about 12 percent in the technetium setting. We
9 looked at the dose calibrator at all stations and only
10 the Tech station was off by some amount.

11 The supplier indicated that if one
12 station in that unit were off by 15 percent, across the
13 board each and every station should be off by 15
14 percent, which is not the case. Our dose calibrator
15 reference sources, the barium and cesium, are still
16 reading in the middle of their plus-minus five percent
17 range.

18 MR. HEHL: What would your
19 expectation be of the nuclear medicine techs I guess if
20 presented with this data?

21 THE WITNESS: If it's brought to
22 my attention, well then --

23 MR. HEHL: You don't train the
24 nuclear medicine techs to make any kind of comparison,

1 to do a qualitative check on the dose calibrator?

2 MR. MAS: Other than if they sense
3 that the doses they've assayed is significantly off.
4 And again we go back to that plus or minus 50 percent
5 issue.

6 MR. HEHL: So when you train, when
7 you in-service the techs, you tell them 50 percent is
8 the closest you need to get?

9 MR. MAS: They are aware that 50
10 percent is the limit for the assay error in a graded
11 pharmaceutical dose. Now, in-house, if the check
12 technologist desires to impose a much tighter limit,
13 well definitely that's his or her call.

14 MR. HEHL: You're not involved in
15 that as the RSO?

16 MR. MAS: No. I don't stipulate
17 what are acceptable doses. That's the physician's
18 call. If they see -- if the tech walks up to him and
19 says, well, they said we got a hundred but really I'm
20 assaying 85, it's the physician's determination.

21 Now, they may have ask me would
22 you please check into this and see whether or not we
23 have a problem with our assays.

24 DR. SHANBAKY: The difficulty

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1 here, it's either the pharmacy's assay is off or your
2 assay is off. That's the issue. As to the dose,
3 you're right. The physician will determine the dose,
4 but we need -- what we would like to understand here
5 is, when you start suspecting your dose calibrator is
6 working right or not, and if you're getting an assay of
7 doses different by 14 percent, 15 percent from the
8 pharmacy, I don't know. I'm not saying that you're
9 wrong. Maybe the pharmacy is wrong.

10 MR. HEHL: Is that the only case?

11 DR. SHANBAKY: No, we have another
12 case on the 27th very similar and that's lot number
13 151631 that was done by Muszynski also on the 27th,
14 11/27, and he assayed the dose at 18 millicuries and
15 received 20.8 millicuries.

16 MR. HUDNER: Dr. Shanbaky, which
17 number was that, please?

18 DR. SHANBAKY: You're looking at
19 27. And the lot number is 151631.

20 MR. HUDNER: Okay.

21 DR. SHANBAKY: He assayed the dose
22 at 10:15 according to these records, and the pharmacy
23 assayed the dose here at 10:00; so very similar,
24 projected. The pharmacy's value at 10:00 is 20.8

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1 MR. MAS: No. The only time we
2 had an issue raised, it centered on the iodine 131
3 assays, and because of the discrepancy, we were reading
4 lower than what the manufacturer supplied, we
5 received -- we requested the secondary standard NIST
6 standard from the pharmaceutical supplier so that we
7 could perform our own assays, our own calibrations on
8 the dose calibrator, and an adjustment to the dose
9 calibrator was necessary. I said it was I think some
10 four or five percent.

11 DR. SHANBAKY: When was that?

12 MR. MAS: It's written in the dose
13 calibrator book.

14 DR. SHANBAKY: Is this this year?

15 MR. MAS: No. I believe it was
16 last year. I believe it was last year.

17 DR. SHANBAKY: The last one here I
18 have is on the 28th. That was a study, I believe a
19 bone study on the 28th, and this is lot number 152119,
20 looks like muga scan.

21 MR. MAS: It sounds like for muga.

22 DR. SHANBAKY: And I looked at the
23 assay here. Looks like...

24 MR. MAS: Yeah, technetium. I

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1 millicuries. Mr. Muszynski got 18.0 millicuries. And
2 that's again close to 14 percent error.

3 MR. MAS: I'd like to refer to it
4 as a 14 percent disagreement, because we --

5 DR. SHANBAKY: Yeah, disagreement
6 between you and the pharmacy. I don't know whose
7 fault.

8 MR. MAS: Because we sent out the
9 dose calibrator to verify whether or not there is an
10 error in measurement.

11 DR. SHANBAKY: So this is the same
12 thing? Would the technologist recognize that they are
13 getting different values from the pharmacy? That's one
14 step, that you don't recognize it.

15 MR. MAS: The technologist, yes,
16 they would recognize that they are -- I mean especially
17 in these cases where the time of projected assay versus
18 the time that they are doing the actual assay is so
19 close. And this was the chief technologist himself
20 performing the assay. But at no time during this week
21 or any other were the technetium assays called in
22 question.

23 MR. HEHL: So the issue wasn't
24 raised as a result of these things?

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1 believe that's the one right down there (indicating).

2 DR. SHANBAKY: Again they said
3 that the amount sent to the hospital, 25.1 millicuries,
4 at 9:30 in the morning and the assay showed 18.7 at
5 11:00, 11:12.

6 The difficulty I have with this
7 one is that the pharmacy claimed that the total volume
8 they sent to the hospital is three quarter of a mill,
9 .75 mill. Where the technician got the .84?

10 MR. MAS: I don't know. Because
11 the information is right there on the slip.

12 DR. SHANBAKY: If it is .84 and he
13 or she got 18.7, that would be way way off in terms of
14 your agreement with the pharmacy. That would be in
15 very clear disagreement with the pharmacy.

16 MR. HUDNER: Peter, let me ask you
17 a question. This is marked as .84 CC.

18 MR. MAS: Correct.

19 MR. HUDNER: And the pharmacy has
20 point .75 ML.

21 MR. HEHL: What number was that
22 again?

23 DR. SHANBAKY: That's 152119 on
24 the 28th. This is at 11:12.

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1 MR. HUDNER: Are we measuring
2 apples to apples here?
3 MR. MAS: Yes. That entry should
4 show .84 just as the pharmaceutical slip shows --
5 rather should show .75 just as the pharmaceutical slip
6 shows .75.
7 DR. SHANBAKY: I'm not sure where
8 they got the .84 then.
9 MR. HEHL: Okay.
10 DR. SHANBAKY: And the reason is
11 not because of the .84 or .75. If it is .84, then
12 there would be very big difference between the same
13 results the hospital had and the pharmacy. That's the
14 concern here.
15 MR. MAS: We've gone recently away
16 from handwritten records to a nuclear medicine
17 information system manager. So that a lot of the
18 information which is presented here, it is bar coded
19 and entered directly onto computer. So that human
20 errors, in case this were an example of just plain
21 human error, would be avoided. But they still do have
22 to enter the assay of the pharmaceutical dose before
23 it's injected.
24 MR. MANNING: I have a quick

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1 question. The same one the 28th. There are several
2 xenon slips that came in for patients for ventilation
3 studies. Does the fact that there aren't any xenon
4 doses indicated on the log an indication that there
5 weren't any xenon studies performed that day --
6 MR. MAS: Correct.
7 MR. MANNING: -- or was there
8 another log that keeps track of the xenon studies?
9 MR. MAS: I believe they do
10 include xenons on these, but they will order xenon and
11 stock them through the week. Should they get any
12 late-in-the-day emergency xenon studies, they have a
13 few vials handy.
14 MR. MANNING: If they had a xenon
15 study for the 28th, it would be entered on this patient
16 dose log?
17 MR. MAS: Yes. And actually now
18 that you bring that up, let me double check, because I
19 think there is another notebook, the one that has xenon
20 on the face. I don't know if it's referring to the
21 trap and monitor QA or if it also serves as a xenon
22 patient log. But I do notice through here when they
23 show a lunge profusion study, usually you're doing two
24 things. You're doing ventilation and profusion at the

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1 same time.
2 MR. HEHL: I think -- and I'm not
3 sure where we're going with this other than just to
4 indicate that there appears to be some inconsistencies.
5 What that means, we'll have to try to decipher that.
6 Are there any other questions?
7 (No response)
8 MR. HEHL: Anything else you'd
9 like to add?
10 MR. HUDNER: No.
11 MR. HEHL: Certainly if there are
12 any thoughts or information that you'd like to add in
13 the near future, we'll certainly be happy to entertain
14 that.
15 Judi, why don't you go ahead.
16 MR. MANNING: Could you just fax
17 the xenon stuff? Does it cover the same period of time
18 here?
19 MR. MAS: Yes.
20 MS. JOUSTRA: Just to briefly
21 summarize some of the enforcement sanctions available
22 to the NRC, keep in mind again that the investigation
23 report indicated that there was a falsified record
24 which in turn would then place the hospital in

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1 non-compliance as well. And Mr. Hehl I know briefly
2 described that in the beginning of the conference, so
3 keep that in mind.
4 One of the sanctions available to
5 the NRC would be to issue a notice of violation that
6 would indicate the violation, and a respective severity
7 level would be assigned to that violation. The notice
8 would also require that you respond with corrective
9 actions and basically give a date of compliance.
10 Another option or sanction
11 available to the NRC would be to issue a notice of
12 violation, a proposed imposition of a civil penalty.
13 Again the paperwork is primarily the same. The
14 violation would be indicated as well as the respective
15 severity level, and there would be a proposed civil
16 penalty attached to that.
17 Another sanction would be to issue
18 basically an order to show cause why the license
19 shouldn't be modified, revoked or suspended.
20 If the NRC were to choose either
21 of those last two sanctions, you'd be notified prior to
22 it being released. And also there would be a press
23 release for that, and you'd be notified of the contents
24 of that prior to that occurring.

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1 Again we take into consideration
2 all the information that was obtained here today, as
3 well as information obtained during the investigation
4 itself. And again you know that we had the conference
5 with Mr. Muszynski last week as well and we're weighing
6 all the information from those two meetings.

7 If you have any questions -- I
8 would like just to briefly, before we go any further
9 with it, before we actually close this meeting, if in
10 fact we determine that the hospital was in violation of
11 30.9, would you admit or deny that violation? We need
12 to know that before you leave today. I don't know if
13 you've had a chance to see what that actually entails.

14 MR. HEHL: I think we sent you a
15 copy of the portion...

16 DR. SHANBAKY: Here's the
17 regulation on 30.9. You can read it. It's very very
18 short, very concise and very short on 30.9 delineating
19 hospital responsibilities.

20 MS. JOUSTRA: And if it's
21 Mr. Muszynski's actions which in turn caused the
22 hospital to be in violation of one of our regulations,
23 again we would hold the hospital responsible for the
24 licensee's actions.

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1 (Pause in proceedings)

2 DR. SHANBAKY: Can you show on the
3 record that I provided them with 30.9 requirements in
4 the regulation, 10 CFR 30.9.

5 MR. HUDNER: The answer is -- and
6 this is no surprise given the posture of this entire
7 situation -- is that the hospital does confirm that
8 there was a misrepresentation in the records of the
9 dose calibrator for November 29, 1995.

10 MR. HEHL: Agreed. And I think
11 that's all -- that's certainly what we perceive from
12 the records, and we wanted to verify that and make sure
13 you're seeing the same thing. What that translates to
14 we'll have to make a determination.

15 MR. HUDNER: As we've said, we
16 would have been delighted from the outset if we could
17 have found some way to explain this away as an incident
18 mishap. We have been unable to do that.

19 MS. JOUSTRA: And then from here
20 on, we'll take the information into consideration and
21 you'll receive something from us probably in writing
22 within, say, 30 days or so, as well as a summary of the
23 enforcement conference; either they may come together
24 or in separate Documents.

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1 MR. HEHL: We try to get these
2 things resolved, recognizing that the investigative
3 activities take a little bit longer. But we try to get
4 them resolved in about 30 days.

5 Now, in this case tied with it of
6 course is the potential for action against an
7 individual and that may delay things a little bit
8 longer because we really focus very very hard on those
9 types of cases.

10 Unless there's any other
11 questions, I think we're through. We certainly do
12 appreciate your coming in. I think the information you
13 provided has helped us to try to put things in
14 perspective a little bit. We recognize it's certainly
15 always a difficult situation when you're talking about
16 the actions of a specific employee.

17 One thing we'll mention and we did
18 mention to Mr. Muszynski when he was in, he asked for a
19 copy of the transcript, and we indicated to him as
20 we'll indicate to you that we can make a copy of it
21 available. What happens is normally we would keep the
22 transcript until -- we would not typically put that in
23 the public documents in our document room here in your
24 folder unless two things occurred. I guess when the

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1 case is finally -- when a decision is made, then it
2 would go in there as part of the decision record.

3 If you want a copy, we can
4 certainly get you a copy, but at the time that we would
5 give it to you, then we would also put it into the
6 docket. So just essentially there is a time difference
7 I think between when it finally goes in there --

8 MS. JOUSTRA: I'm not sure if it's
9 a time difference or if it just doesn't go in there at
10 all if you don't request it. I'm not sure.

11 MR. HEHL: I think it has to be
12 part of the record, but we'll take a look at that.
13 Certainly if you decide you'd like a copy of this,
14 we'll make arrangements. You don't necessarily have to
15 decide today. You can let us know.

16 If there's nothing else I think
17 we're done. Thank you.

18 (Proceedings were concluded at 12:10 p.m.)

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CERTIFICATION

I, Robert W. Harley, Registered Professional Reporter, Notary Public, do hereby certify that the foregoing Enforcement conference was taken stenographically by me on Monday, November 18, 1996 and that transcript is a true and correct transcript of same, fully transcribed under my direction, to the best of my ability and skill.

I further certify that I am not a relative, employee or attorney of any of the parties in this action; that I am not a relative or employee of any attorney in this action.

Robert W. Harley, RPR

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