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ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction
5	18	Delete "either my secretary or" Reason: inaccurate
6	#4	Delete "the person", change to Dr. Li. Reason: accuracy
#7	1	Delete "enthusiastic". Replace with "interested". Reason: accuracy
7	5	Insert "good" before "health" Reason: grammatical
8	13	Replace "I" with "he". Reason: accuracy
8	17	Replace "we" with "I and people around me". Reason: accuracy
9	16	Add "of P32" after "inventory" Reason: accuracy
10	9	Insert "problem with Yuzing" between "of" and "later". Reason: accuracy
10	24	Insert "I said to him" before "so". Reason: grammatical
11	13	Insert "He told me" before "there". Reason: accuracy
14	3	Insert "that our order for" before P-32. Reason: accuracy
16	23	Delete "this ^(laboratory) and replace them with "laboratories in our building". Reason: accuracy

Page 1/2 Date Nov 13th

Signature

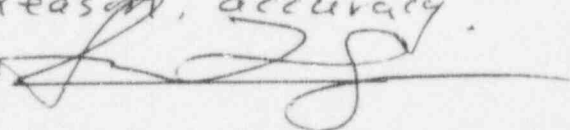


ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction
17	18-19	Delete "That, depending ... " through "a certain amount". Reason, accuracy.
18	2-3	Delete "we are ... that." Reason, grammatical.
18	9	Add "rule" after "this". Reason, accuracy.
19	2-25	Delete and } Reason, nonresponsive.
20	1-6	Delete
20	14-25	} Delete, Reason, nonresponsive.
21	1	
22	15	Replace "Hinds" with "Hynes". Reason, accuracy.
22	21	The same change as above.
24	6	Delete "No". Change to "yes". Reason, grammatical.
24	11	Delete "You ask me". Reason, a sentence fragment, grammatical.
24	18-19	Delete "I don't know". Replace it with "I may not know". Reason, accuracy.
24	21	Delete "it" and change to "the rule book". Reason, accuracy.

Page 2/2 Date Nov 13th

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UNITED STATES OF AMERICA

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NUCLEAR REGULATORY COMMISSION

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INTERVIEW WITH DR. SUSUMU TONEGAWA

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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FRIDAY, OCTOBER 20, 1995

10:33 o'clock a.m.

INTERVIEWERS:

JOHN GLENN, Chief Interviewer, Team Leader

ALAN L. MADISON

THOMAS O'CONNELL

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

10:33 A.M.

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DR. GLENN: Today is Friday, October 20. This is John Glenn with the Incident Investigation Team that was set up by the Nuclear Regulatory Commission to look into an uptake of P-32 at the Massachusetts Institute of Technology. It is 10:30 today, and this will be an interview with Dr. Tonegawa, in whose lab the person worked.

If we could go, I'm Dr. Glenn, and I am in charge of the team. You can introduce yourself.

MR. O'CONNELL: Thomas O'Connell. I'm with the Massachusetts Department of Public Health, Radiation Control.

MR. MADISON: Alan Madison. I'm with the Nuclear Regulatory Commission out of headquarters in Washington.

DR. GLENN: And Doctor, if you could state what your name is, what your position is with the university.

MR. TONEGAWA: My name is ~~Sasumu~~ Tonegawa. I am a professor of biology at the Center for Cancer Research at the Bureau Center for Learning and Memory of MIT.

DR. GLENN: I'd like first just to go over a few of the explanations of why we're here and what we're doing and that sort of thing. The purpose of the IIT is to

1 establish what happened, what was the probable cause of the
2 incident, and then to develop any lessons learned in terms
3 of the experience that you've had here, whether other
4 licensees can benefit if we were to find out why it
5 happened and what could be done to prevent it from
6 happening again.

7 The purpose is not a part of NRC's regular
8 enforcement program or anything of that nature. However,
9 the information we develop here can be shared with our
10 other offices who do those kind of responsibilities.

11 The reason we're here and interviewing you is
12 to find whatever information we can for the people who
13 might know something, those people who are close to the
14 situation.

15 The reason we transcribe it is to allow us one,
16 not to be taking notes as we talk and that sort of thing.
17 The other is to complete, to get a record of the
18 investigations so that whatever conclusions we come up with
19 we can document on what basis we came to those conclusions
20 and support those findings.

21 The transcript will be available for review 24
22 hours or so. I guess if you wanted to come in tomorrow,
23 you could review the transcript then or Monday or whenever
24 would be most convenient. The way you do it is you read
25 it. If you identify errors that occur in terms of the

1 transcription, a word that was misinterpreted, something
2 that maybe you said in error, those sorts of things, you
3 have an errata sheet and you can mark on there, line such
4 and such, it should be this word, or line 20, I forgot to
5 mention, something like that. So you can correct the
6 transcript.

7 Then the transcript and your corrections become
8 a part of the record, the IIT.

9 MR. TONEGAWA: May I ask a question?

10 DR. GLENN: Yes.

11 MR. TONEGAWA: Do you also allow deletion of
12 this in the transcript?

13 DR. GLENN: The way it works is you can say
14 that this was incorrect and shouldn't have been there, but
15 we don't actually allow strike outs of anything that was in
16 the transcript.

17 MR. MADISON: If there's any information that
18 you would consider proprietary in the transcript, we would
19 appreciate that being identified so we can handle it as
20 proprietary information.

21 DR. TONEGAWA: I see.

22 DR. GLENN: Yes. One thing that will happen at
23 the end of the IIT, after we write our report and submit
24 that to the Commission, the transcripts then will become a
25 matter of public record. We will not publish them as such,

1 but --

2 DR. TONEGAWA: But people can seek to know.

3 DR. GLENN: People can request to see them and
4 have access to them. But if there is proprietary
5 information there, that can be protected under certain
6 acts.

7 I think to begin with, it would be helpful to
8 us if you could just tell us a little bit about what you
9 know about the incident, how you learned about it, what you
10 have done since then in terms of any safety problems or any
11 procedures that you've changed in order to be able to avoid
12 similar things happening in the future.

13 DR. TONEGAWA: Okay. I can tell you how I got
14 to know the incident. I was in Japan with my family for
15 summer vacation. Now I didn't put down exact date, but a
16 few days before 26th of August I got a fax from my
17 secretary. I also think I got a telephone call from either
18 my secretary or Dennis King. If you want to know
19 precisely, I can find out.

20 DR. GLENN: The more detailed information you
21 can give us, the better, because one of our analysis
22 techniques is to do a time line and say who was where and
23 when.

24 DR. TONEGAWA: I don't want to say something
25 which may be wrong, so I could fill this in by checking my

1 calendar later. I don't remember right now which one it
2 was, but it was not Dr. Li, but either a secretary or my
3 lab manager. I was told there was a laboratory
4 contamination. My impression was the person was very
5 concerned. It's not a simple, small amount contamination.

6 As I said, I was going to come back in just two
7 or three days so I didn't do anything further than that.
8 That's right. I didn't do anything further than that. I
9 didn't even try to seek to talk to Dr. Li. I may have said
10 how is he, how is Dr. Li, Yuqing. They said he's not
11 there. He can't talk. He's talking with the radiation
12 office or medical department and so on. So I didn't feel I
13 could do anything right away.

14 Then I came back. I think I came back on
15 Friday, the 26th I think. Then it was the weekend. So
16 Saturday, I called the lab. I think I called Dr. Li's
17 house first. I did not get any response so I called the
18 lab. I found Yuqing there, so I asked him what happened.
19 He described on the phone the events, sequence of events.
20 On that day, I talked only on the phone.

21 On the Monday when I came in, the first thing I
22 wanted to do is to see him. I went to try to find him. I
23 found him. To my little surprise, when I asked him I want
24 to talk to him, he said to me, "I don't have anything more
25 than I told you before." He sounded like he wasn't

1 particularly enthusiastic to talk to me, but I can not just
2 let him go, so I told him, I asked him to come to my
3 office. He explained again. I asked several questions. I
4 don't remember every detail of the questions.

5 My main concern was whether he's in health. So
6 I'm sure I said things like whether he has really proper
7 medical treatment, medical examination. Nothing was done
8 on that basis of that interview.

9 He wanted to take care himself. That's the
10 impression I got. You understand that? He sounded like
11 I'm doing fine, I have to go, because he has to do
12 something, he has to measure, collect the urine. I don't
13 remember exact wording. Don't take me in detail because I
14 can't remember that.

15 So that's the encounter. Since then, of course
16 I was really concerned. Also, I talked I think the same
17 day with Frank Masse.

18 DR. GLENN: With the ARCO.

19 DR. TONEGAWA: The radiation people. They
20 wanted to see me and I wanted to see them. So he explained
21 to me what was done afterwards and so on. At that time, I
22 got to know there are some kind of argument between Yuqing
23 and the Radiation Office. Yuqing apparently -- this
24 impression I have may be transferred to me maybe by Dennis.
25 I don't remember how, who did that, but I am quite sure

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1 Yuqing also said that. He doesn't believe the amount the
2 office, the Radiation Office is telling him.

3 So I was a little bit surprised by the initial
4 series of findings. That's what I'm concerned. Yuqing
5 didn't seem to trust or try to get help from people. He
6 wants to control the problem. I got a little bit strange
7 feeling about that, but you know Yuqing -- we can talk
8 about Yuqing later, but maybe --

9 DR. GLENN: But his concern was that they had a
10 number that was too low? Is that your impression?

11 DR. TONEGAWA: Yes. That's the main thing. He
12 thought that it should be much higher than that, or maybe
13 he thought if it's much higher I should worry about it more
14 or something like that. I don't know. I don't know which
15 way.

16 Anyway, now after that, of course almost every
17 day we talked about this, but the direct encounter between
18 me and Yuqing occurred very rarely, very rarely. Often he
19 was not around. If I see him, I ask him how he's doing.
20 He will tell me basically he was very in to this
21 determining how much ingestion he had. He was very much
22 into that project.

23 I remember in one of those conversations, again
24 I brought up this medical issue. I even questioned that to
25 Frank Masse, whether he's being properly treated medically.

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1 One thing I remember the Radiation Office said it's a safe
2 amount as far as they believed, it's a safe amount, not a
3 health -- it's not an amount that would obviously have
4 health hazard. If so, therefore, there's not much one can
5 do in terms of medical. I have that memory. I heard that
6 from I think it's Frank Masse. It could be Mitch in the
7 Radiation Office.

8 DR. GLENN: The one that wanted -- (inaudible).

9 DR. TONEGAWA: Right. So that was a relief for
10 me. I mean I believed it, because these people are
11 experts, supposed to be experts. A total relief for me.
12 But you know, of course, I could not tell how this
13 happened, how this happened.

14 I have been constantly talking with Dennis
15 King. I know Dennis was trying to make, provide an
16 inventory. So those process I had and he's doing that. He
17 was also more directly attached with Masse and Mitch, not
18 through me. So I don't know all the detail which they --
19 what is reported and so on. They were working
20 independently from me.

21 What else. As I told you, my contact with
22 Yuqing was less than I wished I had.

23 DR. GLENN: Now is this after the incident?

24 DR. TONEGAWA: I am talking about after. Less
25 than I wished I had. He sounded like he didn't care to

1 tell me what's going on. He didn't care or he didn't want
2 to, I don't know. I felt a little bit odd about it because
3 here's my person and I hope, I wish he told me more what's
4 going on, he'd incorporate me into his project of his
5 problem. You understand?

6 DR. GLENN: Yes.

7 DR. TONEGAWA: But it wasn't like that. I came
8 to the sort of feeling if I pushed this, I may get some
9 kind of later, some kind of unexpected issues, like I'm
10 acting to cover up. So that crossed my mind, so I didn't
11 push it. I didn't push it.

12 If I see him, I will ask him how he is and how
13 he's doing. But it wasn't a very frequent encounter, maybe
14 no more than once a week, maybe less even. Often he's not
15 there, because he was running around.

16 Let's see, what else. That's about it.
17 Before, there was another trip I made to Japan after
18 September, in October. I hadn't seen Yuqing at least
19 several days so I was concerned. I felt I should know a
20 little bit more about how he's doing.

21 Oh, before that, I suggested to him purely for
22 his psychological reason, I told him maybe he should take a
23 little vacation. I told him that, because of course he was
24 very stressed. He looked very stressed. So maybe you
25 should relax. You know, you don't have to work in the lab.

1 That's what I mean.

2 Then I think a few days later, I got to know,
3 my secretary asked me to sign some sheet of paper which
4 approves his sick leave or something like that. I don't
5 remember. We have a document here. Some kind of a
6 document which has to be signed by me, by rule.

7 MR. MADISON: Authorized?

8 DR. TONEGAWA: Authorized. So that I did. And
9 then I was going to go to Japan so I called him. I looked
10 for him. I asked the secretary to try to find him, but we
11 couldn't find him. Finally I found him at home. I asked
12 him how he is doing. He said he is doing fine. Right,
13 there was this independent evaluation of the amount he
14 ingested.

15 DR. GLENN: The one by Harvard?

16 DR. TONEGAWA: Yes, that's right. So I knew
17 about that. I knew about that. So he told me that is
18 going on. He said a thing like their value is, I don't
19 remember exactly, but something like over 700 microcuries.
20 He almost sounded like, see I was right. It's much more
21 than MIT said.

22 I asked him how he is in terms of health. He
23 said he's fine. He said he's seeing a psychiatrist. He
24 said that. He's seeing a psychiatrist.

25 I'm sorry my things are fragmentary, because as

1 I talk, I remember, things come back. Going back a little
2 bit in time, going back a little bit, he did tell me, I
3 asked him whether he went to see a social worker, because I
4 know there is one social worker at MIT, a social worker,
5 psychiatrist, psychologist at MIT, a nice fellow that I
6 know. I sort of recommended him. I was trying to tell him
7 such a service is available. I think he said, "I have seen
8 him already." Then he said, "I don't see him any more
9 because I don't trust him" or something like that.

10 The reason I asked him why, and then he said he
11 has a feeling this guy, someone at MIT had already told him
12 before he went to see him some kind of information. He
13 felt some doctor/patient confidentiality is violated. I
14 don't know if it's true or not, that's what he said.

15 DR. GLENN: Do you know the name of this
16 counselor or whatever?

17 DR. TONEGAWA: Name of person, right?

18 DR. GLENN: Yes.

19 DR. TONEGAWA: No. But I can find it out.
20 It's not that I was his patient. I didn't see him many
21 times so I don't remember, but I know the guy.

22 He said he also didn't want to -- he said to me
23 he didn't want to be looked at by MIT medical department
24 because -- and then I said, then how are you going to do, I
25 said. He said he's going to see some other doctor whose

1 service will be covered by his wife's medical insurance.
2 That's what he said.

3 Again, this is not -- I had that feeling, I
4 remember I got the impression that this is rather unusual
5 in my judgement. If I were him, I would probably I would
6 ask for help of people around there much more than he
7 sounded. I don't have that type of preconceived mistrust
8 to people. I thought it's really strange, but maybe that's
9 the way he is.

10 So I went to Japan. I came back. I'm trying
11 to remember have I seen him since then. No, I haven't seen
12 him since then. I think that's the last conversation I
13 had. If you want to know the date, I can find out in my
14 calendar exactly what the date is.

15 So that's all I know. That's as far as I can
16 remember my contact with him, and anything that came out
17 from my contact with him.

18 DR. GLENN: Okay. Just to explore some things
19 that might have allowed the incident to occur. In terms of
20 access to isotopes in your laboratory, how is that
21 controlled? Do you have very much to do with that?

22 DR. TONEGAWA: Well, in principle, generally
23 not. Generally not. I have Dennis, if there is anybody
24 who is overseeing it, it is Dennis King. The extent I know
25 is where the isotopes are stored, in which freezer and

1 which refrigerator. I know approximately how much is being
2 ordered regularly. We discuss this once and a while at our
3 meeting. So I know that I think P-32 is one millicurie per
4 week. There may be some additional ad hoc orders, things
5 like that.

6 As far as the use of it, they have a quite free
7 -- researchers, until this instance happened, had quite
8 free access to it. So they take out a bottle, take out a
9 certain amount. I don't think we had the sign-out book. I
10 don't think we had that. But they are supposed to write
11 down in their lab notebook which batch and how much is
12 used.

13 MR. MADISON: Is this typical of all the labs
14 in the Cancer Center?

15 DR. TONEGAWA: Well, I can not tell you that.
16 I think you should ask other people. But I am not
17 surprised if that is the case. I am not surprised.

18 Also, I want you to understand there is a
19 borrowing of isotopes, inter-laboratory. It's not -- that
20 also depends on which floor, for instance. Some floors are
21 much more integrated. Multiple labs are more integrated so
22 they have free access to not only isotope, many other
23 things.

24 So there is an interlaboratory borrowing
25 definitely. So some people take from us. The thing is,

1 often we don't distinguish people from this lab versus
2 people from that lab in terms of the use of some very
3 commonly used material.

4 DR. GLENN: So this borrowing would be
5 informal? It wouldn't be, hey I'm going to take this,
6 please note it. It would just be, come in and take what
7 you need.

8 DR. TONEGAWA: Particularly -- not for material
9 like this, because these are things which decay. So we
10 throw out and it's too low a specific activity. People
11 help each other for their experiments. Right now it's much
12 more controlled, as you know. It's locked. Limited
13 persons have a key to the refrig or freezer. They know
14 exactly how much is taken not only in the notebook of each
15 person, but in the record of who took how much on what day.

16 MR. MADISON: Is that a permanent change or is
17 that just a temporary?

18 DR. TONEGAWA: Well, we were -- I mean Frank
19 Masse imposed that to us. I don't know. I don't think
20 they have -- I don't know. Okay, I shouldn't get into
21 trouble by saying something I don't know. But let me put
22 it this way, I'm not surprised that it's not imposed to
23 other labs yet. It may be since then. I don't know.

24 DR. GLENN: What is your general sense of the
25 security of the laboratory? Would it be possible for

1 someone who really doesn't have any business in any of the
2 laboratories to get in?

3 DR. TONEGAWA: Yes. This is a difficult issue,
4 laboratories. We in our lab, we constantly remind each
5 other that between six and seven we lock up outside doors.
6 Then the doors which have access to the corridor we have
7 within our group that we remind each other that we have to
8 do that. I often go around that time and you know, this is
9 not a key-based locking, but it's a button thing. So I
10 push the button and they automatically lock.

11 However, I am not there all the time. Also,
12 people -- I have seen, I'm sure it's not locked every day.
13 It's really difficult because people work 24 hours around.
14 People still working there. They unlock it.

15 There is no strong pressure to have a very
16 strong security among them, unless there's some things that
17 are stolen. Occasionally something gets stolen, and then
18 the people become very sensitive to it, and for weeks or
19 two we are very tight. But then it's so inconvenient,
20 going back and forth because they have a room they have to
21 go and so on, so they tend to relax it. This is a problem.
22 But it's the building doors also. It's not just our labs.

23 In that sense, as you know, this laboratory is
24 relatively accessible for anybody on the street.

25 DR. GLENN: The entire building?

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1 DR. TONEGAWA: The entire building. You know,
2 I'm not criticizing the practice of MIT or security
3 building and grounds, I am just stating in general it's a
4 difficult thing. It is not like a company's, private
5 company's laboratory where it automatically locks up. The
6 guard is there to come up and lock up. You can't even
7 enter unless you have a very special key or something like
8 that. The university I would say, the university although
9 we are very conscious of security, particularly when
10 something happens we are very conscious and we try to, but
11 it's a relatively accessible facility by anybody on the
12 street.

13 DR. GLENN: Are there any areas in your
14 laboratory that are set aside as being restricted for
15 purposes of using radioactive material?

16 DR. TONEGAWA: Yes. It depends on which
17 radioactive material. I-1 Iodine is known to be volatile.
18 That, depending on amount, there are different hood
19 designated, if it's beyond a certain amount there is a
20 separate facility in the same building where everybody has
21 to go in. It's very restricted.

22 For other isotopes like the P-32, tritium, C-
23 14, S-35, we do have a hood, a particular chemical hood,
24 where we handle relatively large amounts. But all
25 laboratories we allow to use, the entire laboratories,

1 basically the entire except office area where it is off
2 limits, you can't do that there. We are allowed to do
3 that.

4 So as you know, because of that we are not
5 allowed to eat in the laboratory. Therefore, we have a
6 lunchroom. I think that is quite well adhered to. People
7 occasionally may carry coffee cups and go through the lab,
8 one end of the lab. But generally, people are very
9 conscious of this.

10 DR. GLENN: Do you remember any time where you
11 found somebody violating that restriction on food and drink
12 in the laboratory?

13 DR. TONEGAWA: That's what I said. Do you call
14 this violating if somebody takes coffee from one end of the
15 room to the other end, goes through the lab. As they do,
16 they may have one or two sips.

17 DR. GLENN: Have you ever seen anybody with a
18 sandwich at their lab or their work bench or a cup of
19 coffee?

20 DR. TONEGAWA: No. I don't see that. In the
21 old days we always did, by the way. We are much more
22 conscious about this problem for the last 10, 15 years. So
23 I remember when I was a student 30 years ago, we ate in the
24 lab. But not now.

25 DR. GLENN: What about mouth pipetting? Does

1 anyone do that?

2 DR. TONEGAWA: Mouth pipetting is -- another
3 thing which has really changed during the last 25 years
4 when the recombinant, so-called the recombinant DNA
5 technology was introduced, there are potential hazards,
6 this was sort of a -- there was a little bit of an excess,
7 over reaction to this initially because of the unknown
8 things about this DNA, you know the organism DNA, can get
9 into your mouth and alter your genetic constituent and
10 something like that.

11 It doesn't really happen at a high frequency,
12 but we were very cautious at the beginning because we did
13 not know. There was a real clear change in our laboratory.
14 If other laboratories, like a pathology lab, this was
15 practiced many years, okay? Because they really handled
16 dangerous, dangerous material, infectious agent. They
17 don't do mouth pipetting.

18 But in so-called molecular biology, we don't
19 handle the really dangerous material usually. Most of the
20 material is quite safe. But because the practice was
21 introduced, to use mechanical pipettes. There's something
22 called Eppendorf pipettes, which I had never seen such a
23 device before that time. It was invented for molecular
24 biologists. That's mechanical, so it's routinely used
25 there.

1 So in that sense, ordinary practice has really
2 changed since then. I really I don't remember seeing
3 anybody using a mouth pipette. You know, 15 or 20 years,
4 there was a period of transition where they mixed. When I
5 was working at the bench, sometimes I used it. I did use
6 mouth pipetting. But this is many years ago, 15 years ago.
7 Now it's rare.

8 DR. GLENN: Is there any difference in terms of
9 the security between the areas in the laboratory, say
10 offices and the lunchroom, and those areas where isotopes
11 can be used? Is there any difference in terms of locking
12 up or who can come in the door or anything of that nature?

13 DR. TONEGAWA: No. Not anything designed.
14 Practically, as you know, there is, because for instance
15 the refrigerator where the people put their lunches is in
16 my office area. That's one of the busiest. It's almost
17 part of a corridor or so in the office area. There's a
18 copying machine right next to it which is frequently used.
19 I mean, you should go and look at it, but frequently used.
20 There is lots of traffic in day time, people going in and
21 out. It's also a corridor. So in that sense, it's
22 difficult to do anything. If we want to do something in
23 hiding, it's not the place you would do it. In that sense,
24 it's -- so practically there is, but it's not as if that
25 area is locked up and you need a key every time you enter

1 that area.

2 DR. GLENN: Would that situation change during
3 the weekend, because again, the office people would be
4 gone.

5 DR. TONEGAWA: Sure. Weekends have less
6 traffic definitely, and early morning, you know like early
7 hours, like 2, 3, 4, 5, I'm sure.

8 DR. GLENN: Again, you mentioned before that
9 you get people from other laboratories coming in and using
10 materials. How sensitive do you think people would be to
11 an outsider coming into the lab and poking around in the
12 isotopes?

13 DR. TONEGAWA: If it's people we know, we are
14 totally blind. They are like our people. If it's somebody
15 we don't know, then people will immediately ask, you know,
16 can we do anything for you? So people pay attention.

17 There are also delivery people and kitchen and
18 dishwashing people and things like that. So there are
19 other personnel also going in and out. But if you're
20 talking about the scientists in the building, we are
21 familiar, then we don't pay very much attention.

22 DR. GLENN: Have you had a chance to review
23 what happened the evening that Dr. Li was exposed in terms
24 of I guess he called the police. Then they took him to the
25 medical center. Have you reviewed any of that to see

1 whether you think MIT did the appropriate things in terms
2 of handling Dr. Li?

3 DR. TONEGAWA: Okay. Let me put it this way.
4 If you mean whether I reviewed in terms of something
5 written carefully, the answer is no. I have never been
6 given such a thing. Actually, if there is something like
7 that, I would like to see it, because I feel very
8 uninformed about this, by the way.

9 I want to tell you this. I feel very
10 uninformed about it. Maybe it's not necessary for me to be
11 informed as a matter of fact. I don't know. So everything
12 I know is based on what I hear from Yuqing, Dennis, and
13 then our Radiation Office. I have some conversation with,
14 particularly these days, with head of the Cancer Center,
15 Dr. Hinds.

16 I don't know. All of my information, anything
17 significant, factual things, come from those sources. So I
18 don't have independent evaluations of anything, something
19 you can not easily find. So we're all saying the same
20 thing. Usually I get the same information from Masse and
21 Richard Hinds, for instance, because they talk also.

22 So my simple answer to your question is no. I
23 do not think of anything which they didn't do it right. At
24 the same time, I am not following it exactly in detail.

25 DR. GLENN: Lyle, do you have any questions?

1 MR. MADISON: Just a couple. Are you the
2 authorized user in the sense of the radioactive materials
3 that are kept in your laboratory?

4 DR. TONEGAWA: Personally?

5 MR. MADISON: Yes.

6 DR. TONEGAWA: I don't know actually.

7 MR. MADISON: Or is Dr. King?

8 DR. TONEGAWA: Is my name listed? What do you
9 mean? You have to explain. You have to say it again.

10 MR. MADISON: I think there's a term,
11 authorized user.

12 DR. GLENN: The permit, your name is the name
13 that's on the permit for the isotopes that are used in your
14 laboratory?

15 DR. TONEGAWA: For the lab?

16 DR. GLENN: Yes. Did the Radiation Safety
17 Committee approve you?

18 DR. TONEGAWA: I'm sorry to tell you I don't
19 even know.

20 MR. O'CONNELL: I think it's defined as
21 project.

22 DR. TONEGAWA: My name is probably listed as
23 the head of the laboratory. Do you understand?

24 MR. MADISON: I understand. I just wondered if
25 it was you or Dr. King.

1 DR. TONEGAWA: I am not a contact person with
2 the Radiation Office. Dennis is.

3 MR. MADISON: So would you have received any
4 specific training or retraining on handling of radioactive
5 materials?

6 DR. TONEGAWA: No. But not since I stopped
7 working in the lab, because I don't touch them.

8 MR. MADISON: Do you know what the requirements
9 are for your staff in that area, of retraining and
10 training?

11 DR. TONEGAWA: You ask me, I haven't read the
12 rule of using isotopes in many years. That's my honest.
13 So if you give me an exam, I may fail.

14 MR. MADISON: This is not an exam.

15 DR. TONEGAWA: What I am trying to say is
16 trying to convey to you the extent of my knowledge.

17 MR. MADISON: I understand.

18 DR. TONEGAWA: You understand that? I don't
19 know every detail. But I used to work in the lab. So I
20 know there's some practice if I have to work with isotopes
21 in the lab, I might just look through it. Then most of
22 them must be something I already know. You understand?

23 MR. MADISON: I understand.

24 DR. TONEGAWA: Because I don't think it has
25 much changed since I did.

1 MR. MADISON: Those are the only questions I
2 had.

3 MR. O'CONNELL: I'm all set. No questions.

4 DR. GLENN: Okay. Is there anything that we
5 haven't touched upon that you think we should know about?

6 DR. TONEGAWA: I try to remember. No. I don't
7 think so. I mean anything I say beyond what I said has
8 some element of speculation. So I don't think you are
9 interested in that. Also, it's probably not the right
10 place to say, the right environment to say.

11 DR. GLENN: Okay.

12 MR. MADISON: Is there anybody else that you
13 think we should talk to that we haven't referred to?

14 DR. TONEGAWA: Oh, that's right. I don't even
15 know whom you have been talking to. That's public
16 information right or it's not?

17 MR. MADISON: We haven't hidden it.

18 DR. GLENN: I don't have a list that I can give
19 you.

20 DR. TONEGAWA: I had a copy, but I don't
21 remember who. Can I just say there is someone sort of a
22 senior post-doc in the lab. The lab is students, graduate
23 students, undergraduate, graduate students, technicians,
24 post-doctoral fellows. Dennis King is the lab manager,
25 secretaries. Then among these post-docs the one guy who

1 has a slightly different, it's a distinct title, senior
2 post-doctoral fellow. His name is Juan Lafaille.

3 He has been with me many years, like seven or
4 eight years. He is just moving to NYU as a faculty member,
5 but he's still around. I don't remember his name on the
6 list that you wanted to interview. It may be a good idea
7 to hear him, because he knows a lot about the lab. He's
8 been here a long time. He's a mature, a very mature
9 person. It's not that I know that he has something useful
10 to tell you. When I saw the list on it, Dennis gave me a
11 couple pages of the list, I thought Juan is not listed.

12 MR. MADISON: We appreciate the suggestion.

13 DR. GLENN: I think I gave you a copy of this
14 the other day, but another copy of the list that talks
15 about how to review the transcripts and their availability.
16 If after the report has been issued, you want a copy of the
17 transcript of your interview, you can get that.

18 DR. TONEGAWA: Yes. I want to see that.

19 DR. GLENN: You will need to request it.

20 DR. TONEGAWA: How do I request?

21 MR. MADISON: It is explained right there in
22 the exhibit that we have given you.

23 DR. TONEGAWA: We do it by writing or what?

24 MR. MADISON: Yes, sir.

25 DR. TONEGAWA: You mean to request my portion

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 of the transcript, right? Is that what you mean?

2 MR. MADISON: Right.

3 DR. GLENN: This interview will have an
4 individual transcript. And as we have explained in the
5 past, you can review that within 24 hours. It will be
6 available tomorrow to review if you wish. But to get a
7 copy, once the report is issued, all the transcripts in the
8 report go in the public document room. If you wish a copy
9 to keep, you can request it at that time.

10 DR. TONEGAWA: Oh, I see. But for tomorrow, I
11 don't need to request, right? You automatically give me --

12 DR. GLENN: No. You should request if you wish
13 to review.

14 DR. TONEGAWA: Oh that too?

15 DR. GLENN: Yes. We'll give you a phone number
16 you can --

17 DR. TONEGAWA: I don't think I said anything
18 wrong, but I should review it.

19 DR. GLENN: Certainly. We have a transcript
20 custodian, so you'll need I think just to come over here.

21 MR. MADISON: We'll give you a number that you
22 can contact and set up an appointment to come over at your
23 convenience and do it.

24 DR. TONEGAWA: Do I have to come personally or
25 can I send my secretary?

1 DR. GLENN: No. Only parties that are --

2 DR. TONEGAWA: I have to come?

3 DR. GLENN: You have to be here.

4 DR. TONEGAWA: To here? To this office, this
5 area?

6 DR. GLENN: This area. Yes, sir.

7 DR. TONEGAWA: So when is the copy available?

8 DR. GLENN: It should be available tomorrow or
9 Monday.

10 DR. TONEGAWA: Would Monday be okay?

11 DR. GLENN: Monday is fine.

12 DR. TONEGAWA: All right. So you don't
13 finalize it until I see it, right?

14 MR. MADISON: The transcript is a final
15 document. What we would be looking at is as we have again
16 explained in the past, and explained in that exhibit,
17 there's an addendum sheet, an errata sheet, that you would
18 make corrections on the errata sheet.

19 DR. TONEGAWA: Oh, I see.

20 MR. MADISON: And explanations, clarifications,
21 anything you wish would be done on the errata sheet, and
22 that becomes then part of the transcript.

23 DR. TONEGAWA: But the original thing will be
24 even if it's the wrong grammar and everything, it will be
25 there?

1 MR. MADISON: I'm afraid we all suffer from
2 that. If we've made grammatical errors, they will appear
3 in the transcript.

4 DR. GLENN: Sometimes it's our fault, and
5 sometimes we say it's their fault.

6 DR. TONEGAWA: That's okay with me, because I
7 feel comfortable about that, but is this still on
8 transcript right now?

9 DR. GLENN: Yes.

10 DR. TONEGAWA: I suggest if I already talked
11 with you beforehand in my office --

12 MR. MADISON: On some administrative matters?

13 DR. TONEGAWA: Treatment of the transcript. If
14 you tell me this right now, I feel like other people who
15 come to you for the first time, haven't used to deal with
16 this before they even start, so that they can read, and
17 give them time to read.

18 DR. GLENN: I did try to run down the primary
19 points, but certainly we're getting into more detail about
20 the review of the transcript at this point.

21 DR. TONEGAWA: Did you get my point?

22 MR. MADISON: Yes.

23 DR. TONEGAWA: Not after. Don't you think?
24 Don't you think it's more fair to give them before and also
25 give some time to read?

1 MR. MADISON: I believe Dr. Glenn did try to
2 explain that, yes, at the beginning of this interview.

3 DR. GLENN: I didn't give you a copy, but I did
4 run through the fact that it would be available, it could
5 be reviewed.

6 DR. TONEGAWA: No, no, no, no. The thing I did
7 not know is -- I mean, I'm not complaining, okay? I'm just
8 stating this because of my sense of fairness urges me to
9 say it. That is, if the original, everything that's said
10 appears as it is, and then addendum is added for changes,
11 that means the original thing, everything also becomes the
12 record, correct?

13 MR. MADISON: Yes, sir.

14 DR. TONEGAWA: Rather than changing it. Change
15 the one that becomes the record. Correct?

16 MR. MADISON: Yes, sir. I think we've
17 explained that too, that the addendum -- no changes are to
18 be made to the transcript, but the addendum does become
19 part of the transcript.

20 DR. TONEGAWA: If so, I did not get that
21 message in my case.

22 MR. MADISON: Okay. We apologize for the
23 misunderstanding.

24 DR. TONEGAWA: I'm not complaining, but my
25 understanding was on the altered one becomes the record.

1 Do you understand that?

2 DR. GLENN: We understand that that's not the
3 way it is.

4 DR. TONEGAWA: That's why I asked can we delete
5 it, for instance. Remember?

6 DR. GLENN: Yes. And I thought I answered that
7 you couldn't delete it, but that you could make a remark
8 that it was in error or shouldn't have been there or
9 something of that nature. But I did think we covered that.

10 MR. MADISON: Do you have any other questions,
11 Doctor?

12 DR. TONEGAWA: No.

13 DR. GLENN: Okay. The time is 11:22, and the
14 interview is complete.

15 (Whereupon, at 11:23 p.m., the interview was
16 concluded.)

17 khw

18

19

C E R T I F I C A T E

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

Name of Proceeding: INTERVIEW WITH DR. SUSUMU TONEGAWA

Docket Number: --

Place of Proceeding: Cambridge, Massachusetts

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and, thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

K. Wood
Official Reporter
Neal R. Gross and Co., Inc.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

10-95-62
John Stena

October 13, 1995

CHAIRMAN

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: Shirley Ann Jackson *Shirley Ann Jackson*

SUBJECT: NIH INCIDENT: FOLLOW-UP REGULATORY ACTIONS

The NIH incident has evoked concern on my part regarding the sufficiency and completeness of our regulatory procedures governing materials licensees, in general, and our follow-up regulatory actions specific to this incident. Following discovery of the incident in late June, we dispatched an Augmented Inspection Team which is continuing its reviews and analysis of the circumstances surrounding the incident. As the work in connection with the incident continues I would appreciate your addressing the following issues:

1. Based upon the information developed to date, has the staff seen the need for any prompt regulatory action to improve nuclear materials safety at the National Institutes of Health in the interest of protection of public safety? Possible measures might include instructions to the licensee to provide additional materials security, accountability controls, bioassay procedures or others.
2. Are there any deficiencies in our regulatory procedures governing materials licensees that have been revealed by the information developed to date for either the NIH as a regulated entity or any other NRC materials licensees in similar circumstances which utilize nuclear materials in conjunction with research projects? What I have in mind are facility types where the use of nuclear materials is tangential to the primary line of business; i.e., academic and research facilities, medical institutions, some types of industrial users, etc.
3. For the longer term I expect a comprehensive follow-up, with enforcement actions if warranted, for this specific incident. Also, I expect examination of the generic implications for materials licensees where regulatory weaknesses are identified and for which follow-up NRC action is therefore warranted.

I am aware that there are various investigations by the NRC and other federal agencies which are in progress. I do not wish any of the follow-up regulatory actions which I am requesting to impede these ongoing investigations. However, I do believe that we must be cognizant of our safety responsibilities and it is for this reason that I am requesting prompt follow-up regulatory actions.

cc: Commissioner Rogers
SECY
OGC
OPA
OCA

EDO --- 000729

9510300092

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
ENFORCEMENT HISTORY
LICENSE NUMBER 20-01537-02

95-001

(March 8 to 10, 1995)

Contrary to condition of L/N 20-01537-12, an irradiator was located in an unauthorized location. (Level IV)

Contrary to condition of L/N 20-01537-02:

the Radiation Protection Committee (RPC) failed to meet at the required interval. (Level IV)

the RPC failed to review the Radiation Protection program each year. (Level IV)

thyroid measurements were made 7 to 14 days post procedure rather than within 3 days, as required. (Level IV)

the RPC failed to make a quarterly review of occupational radiation exposures. (Level IV)

retraining of laboratory workers was not performed on a two year basis and authorizations were not renewed, as required. (Level IV)

training was not provided for housekeeping personnel each year. (Level IV)

Contrary to 49 CFR 172.604(a), an emergency response telephone number was not placed in the proper location on a shipping paper. (Level V)

Contrary to 49 CFR 172.203(d), incorrect isotope was listed on a shipping paper. (Level V)

93-001

(January 12 to 14, 1993)

Clear (Transportation violation cited and withdrawn)

91-001

(February 11 to 12, 1991)

Clear

88-001

(April 20 to 22, 1988)

(Enforce Conf June 22, 1988)

Extremity exposure of 22.91 rem (18.75 limit) (Level IV)

Failure to survey contrary to 10 CFR 20.201(b) (Level IV)

100-55



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

AUG 29 1995

Robert McCunney, M.D., MPH
Director of Environmental Medical Services
Massachusetts Institute of Technology
77 Massachusetts Avenue 20B-238
Cambridge, MA 02139-4307

SUBJECT: ROUTINE INSPECTION NOS. 030-00763; 030-09177; and 030-21272/95-001

Dear Dr. McCunney:

This letter refers to your April 24, 1995 correspondence, in response to our April 10, 1995 letter.

We have reviewed the corrective and preventive actions you have taken or plan to take to correct the violations listed in Items A and B of the Notice of Violation issued with our letter dated April 10, 1995. These actions are acceptable and their implementation will be examined during a future inspection of your licensed program.

Regarding Violation C, you state that the 24-hour emergency phone number was on the large-print emergency notice document required by the Department of Transportation (DOT) in 49 CFR 172.602. 49 CFR 172.604 requires, in part, that an emergency response telephone number be listed on the shipping paper. From conversations with a DOT representative, the emergency notice document does not constitute a part of the shipping paper, and therefore the violation stands since the emergency response telephone number was not on the shipping paper. Please provide corrective action(s) for this violation in your response to this letter.

Regarding Violation D, the issue is not if the radionuclides in the vials were required to be listed on the shipping papers; but rather, the issue is that the information shown on the shipping papers must be correct. This violation stands. However, no additional information is required because the corrective actions described in your April 24, 1995 letter are acceptable.

Although the NRC acknowledges that none of the violations involved excessive or unnecessary personnel exposure the NRC expects facilities which possess licenses of broad scope, such as the Massachusetts Institute of Technology, to establish and implement administrative controls and provisions relating to organization and management, procedures, record keeping, material control, accounting and management review that are necessary to ensure safe operations. The NRC expects licensees, through the process of management review and self-assessment, to identify weaknesses in their program and to initiate appropriate remedial actions. Although the violations cited had minor safety implications when taken individually, the number of violations indicate a lack of appropriate management oversight and supervision of your NRC licensed

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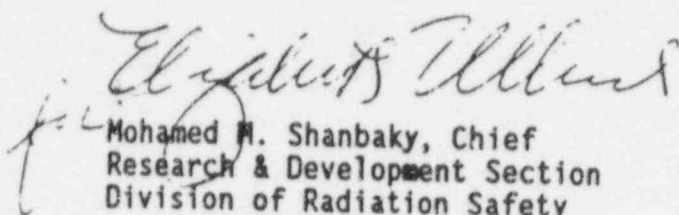
R. McCunney
Massachusetts Institute of Technology

-2-

program. We would appreciate you including a written description detailing improvements in performance in the area of management oversight of your licensed program in your response to this letter within 30 days of receipt of this letter.

Your cooperation with us is appreciated.

Sincerely,


Mohamed M. Shanbaky, Chief
Research & Development Section
Division of Radiation Safety
and Safeguards

Docket No. 030-00763

030-09177

030-21272

License No. 20-01537-02

20-01537-10

20-01537-12

cc: F.X. Masse, Radiation Safety Officer
Commonwealth of Massachusetts

Environmental
Medical
Service

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
MEDICAL DEPARTMENT
77 MASSACHUSETTS AVENUE, 20B-233
CAMBRIDGE, MASSACHUSETTS 02139-4307



April 24, 1995

Docket Nos. 030-00763
030-09177
030-21272

License No. 20-01537-02
20-01537-10
20-01537-12

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

Gentlemen:

Following is our response to the Notice of Violation referenced above:

- A. Citation: The sources were not housed in an AECL Gammacell 40 Irradiator located in the MIT Center for Cancer Research, E17-629. Specifically, the licensee had the manufacturer move the Gammacell 40 irradiator containing approximately 3000 curies of cesium-137 to Room E17-613 prior to applying for or receiving a license amendment authorizing the new location.

The relocation of the AECL Gammacell 40 Irradiator was undertaken as an immediate action related to the reconstruction of the area in which it was housed. Demolition had begun without the knowledge of the Radiation Protection Office and without proper prior planning with respect to relocation of the irradiator. Rather than leave the unit in place with a canvas over it while the surrounding walls were removed, we had the licensed installer relocate it to an available nearby room, temporarily, until plans were made for a permanent location. All conditions of the license for operating the unit in its original room were observed in this temporary relocation. Contrary to the implication in the citation, the sources were never outside of the shield housing. Our mistake was to address the immediate security of the unit and focus ahead on the need for a license amendment once a permanent location was identified rather than await a license amendment for the temporary move. An amendment request was faxed to NRC during the final day of the inspection and an amendment authorizing this temporary move has since been issued by NRC. This facility is now in full compliance, and an additional license amendment will be

15006

Director
208-238
(617) 253-5360
Fax: (617) 253-4879

Biohazard Assessment
20C-214
(617) 253-1740
Fax: (617) 258-6107

Industrial Hygiene
20C-204
(617) 253-2596
Fax: (617) 253-4879

Radiation Protection
Campus RPO 20C-207
(617) 253-2180
Fax: (617) 253-4879

Reactor RPO
NW12-108
(617) 253-4203

Bates UNAC RPO
P.O. Box 95 21 Manning Road
Middleton, MA
(617) 245-6600 Fax: (617) 245-0901

TE07
11

secured prior to moving to the permanent location when that room has been identified.

- B. 1. Citation: The RPC did not meet at least four times per year, once in each calendar quarter. Specifically, the RPC met on 12/1/92, 4/13/93, 6/23/93, 10/27/93, 1/26/94, 5/24/94, 10/5/94, and 1/10/95.

The Committee did, as indicated, hold eight meetings in 25 months instead of the necessary eight meetings in 24 months, one in each calendar quarter. However, this list does not reflect the scheduling attempts and quorum difficulties associated with these meetings during this period. Since the inspection, a meeting was attempted for March 24 and held successfully on April 6. At that meeting, the committee agreed upon a fixed long-range schedule which all members of this busy senior-faculty committee can commit to their calendars on a long-term basis, currently defined as the fourth Tuesday of the second month in each calendar quarter. This fixed arrangement should facilitate the achievement of a quorum and leave ample time to reschedule within the quarter if a quorum cannot be obtained. If the difficulty persists, we will reluctantly consider substituting more-available less-senior faculty for membership on the committee to satisfy the calendar requirement. We now claim full compliance in this area since meetings have been held in both calendar quarters so far this year.

- B. 2. Citation: The RPC did not review the Radiation Protection Program at least once each year. Specifically, the RPC did not review the Radiation Protection Program for 1993. The review was scheduled, postponed to another meeting, and then the review was dropped from the RPC agenda.

As noted in the citation, the formal review of the Radiation Protection Program was missed during 1994 due to a postponement of a scheduled review in a meeting that ran unusually long for other reasons, and was then inadvertently dropped from the subsequent meeting schedule. It should be noted that the formal review was conducted in the previous and following year, and that there were no significant changes or difficulties in the program that were not covered in a neighboring year. The new schedule for RPC meetings described in B1 above, plus a newly implemented audit program related to the revised 10 CFR 20 will now assure a timely review of the program on a regular

schedule. Since the necessary review was held in 1994 and is scheduled for 1995, we are now in full compliance in this area.

- B. 3. Citation: Thyroid measurements were not performed within 3 days of a procedure for persons occasionally handling in excess of one millicurie of radioiodine. Specifically, thyroid measurements were routinely being performed between 7 and 14 days post-procedure.

As currently authorized in our NRC license, thyroid measurements in this program involve monthly measurements on all persons routinely performing iodinations, and measurements within 3 working days for persons occasionally performing iodinations with greater than 1 mCi of iodine. A careful review of the entire record reviewed by the inspector shows that in 1993 60 of the 133 thyroid measurements were made within 3 working days of the procedure, and from January, 1994, to date, 90 of the 230 thyroid measurements were made within 3 working days of the procedure. This record is a chronological listing of all thyroid measurements, their results and the most recent radioiodine procedure involving the listed worker. Since the listing does not identify routine vs. occasional iodine users, and since at least 80% of the thyroid measurements are for routine users, it is not clear from this data that the approved schedule has not been properly observed. Two clearly recognized violations in the schedule involved researchers who traveled to China and South Africa and were not measured for 34 and 41 days respectively after iodination procedures. Both were routine users on a 30-day schedule. Both infractions were identified by us, and both projects involved were prohibited from further purchase of radioiodine for iodinations until the deficiencies were corrected.

It should also be pointed out that routine breathing zone air samples are analyzed no later than the next working day for all such procedures, and that our thyroid burden detection efficiency has been optimized to detect a minimum of 1 nCi instead of the usual 10 nCi. Since the effective half-life of ^{125}I in the thyroid is greater than 40 days, we suggest that even a two-month measurement at 1 nanocurie sensitivity will detect lower thyroid uptakes than a three day measurement at the usual 10 nanocurie sensitivity. It is more important that the thyroid data is enhanced by breathing zone measurements that are analyzed within one

working day, particularly when the results of those breathing zone samples are used to hasten thyroid measurements if problems are indicated. We therefore plan to seek to amend this program in the ongoing license renewal to measurements within a fixed one month post-procedure schedule for both categories coupled to prompt breathing zone samples to remove the ambiguity of the current system. This should be acceptable since the very low thyroid measurement results to date clearly indicate that it is most unlikely that any of these workers will receive 10% of their permissible thyroid dose. Hence, it may be concluded that such monitoring is not required under the new Part 20 regulations.

Meanwhile, we have guaranteed compliance with the most conservative interpretation of the current requirements by securing the iodination facilities in such a way that each user must report to the Radiation Protection office for access keys before and after each use and the measurement will be taken at that time, well within the 3 day period. While this arrangement may result in measurements in less than 24 hours post-procedure, the 1 nanocurie measurement capability should assure adequate sensitivity to detect significant problems, even if the thyroid burden has not yet maximized (at 6 hours the iodine burden in a normal thyroid would be at 80% of peak). We believe we are in full compliance in this area.

- B. 4. Citation: The RPC did not perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels were exceeded. Specifically, the extremity exposure of an employee working with millicurie quantities of phosphorus-32 exceeded the licensee's investigational levels (1.875 rem and 5.625 rem) during the first, third and fourth quarters of 1993, and the RPC did not review the employee's exposure.

The quarterly radiation exposure reviews have, to date, focused on whole body rather than extremity exposure. We have now adopted a routine agenda item for all quarterly RPC meetings which will include a review of the extremity exposure as well as the whole body exposure of all radiation workers. This will achieve full compliance with this issue. It should be noted that the extremity exposure involved is well within regulatory limits.

- B. 5. Citation: Retraining of laboratory workers was not performed on a two-year basis in conjunction with the two-year review and renewal of each laboratory use permit. Specifically, Authorization Nos. 7-AJ and 5-AL-2 were renewed 3/94 and 6/94, respectively and retraining did not occur until 2/6/95 and 3/7/95, respectively. Also Authorization Nos. NRL-C, PFC-D, LNS-W, NML-N, and 7-AO expired on 12/31/87, 2/29/92, 10/31/92, 7/31/93, and 12/31/93 respectively and have not yet been renewed, nor had retraining been provided to workers.

Of the hundreds of authorizations in current use at MIT, we acknowledge that there are a small number that were not processed on schedule. However we reiterate that the retraining delays associated with 7-AJ and 5-AL-2 were intentional delays awaiting the relocation and reestablishment of the two projects involved. As was explained to the inspector, no work with radioactive materials was conducted during the interim, and the value of the retraining was obviously enhanced by waiting until the project was about to restart such that the training could be specific to the new conditions. Such flexibility is essential to a good radiation safety program.

With respect to the retraining delays associated with the four projects that continued past expiration of the authorization (the fifth, 7-AO, had terminated work permanently within the first year), all are associated with interdepartmental radiation laboratories that receive routine annual radiation safety retraining in association with the radiation-emitting machines involved. Nonetheless, as the inspection team observed, we have been organizing the program into a database that will track and flag authorization expirations to eliminate such oversight in the future and improve on our past 98% compliance in this area. The listed omissions have all been corrected to achieve full compliance and the data base is operational. This should greatly enhance continued full compliance in this area effective immediately, as we will use the database to initiate a 3-month warning of impending expirations and terminate authorizations that fail to submit the required renewal requests in a timely manner.

- B. 6. Citation: Housekeeping personnel were not given annual reviews of radiation hazards and appropriate precautions by the RPO staff. Specifically, the licensee did not provide training for the housekeepers during 1993 and 1994.

All housekeeping personnel are routinely retrained by EMS each year on a well-maintained schedule. Sufficient sessions are held to cover all shifts, and supervisors also attend to acquire sufficient knowledge to manage day-to-day issues. Biosafety issues are the primary focus, but other safety issues are also covered. We have arranged to expand on this, including a segment on radiation hazards, which will be presented by the RPO staff. The first series of sessions is scheduled for the early fall. This annual retraining session will be enhanced by an annual refresher training summary notice provided to all housekeeping personnel.

It should also be noted that initial training for all new housekeeping workers is automatically provided before they begin work. This includes a segment on radiation safety in which the workers are instructed on radiation signs and labels, waste handling prohibitions and other radiation safety matters.

- C. Citation: An emergency response telephone number was not immediately following the description of the hazardous material on the shipping paper. Specifically, the emergency response number was attached to the shipping papers within numerous other documents. The number could not be retrieved expeditiously in the event of an accident.

The shipment of radioactive waste discussed in this citation was a full trailer-load of waste sent to the disposal facility in an exclusive-use vehicle. The driver of this vehicle spent several hours with the RPO staff during the loading of the vehicle. The shipping papers were reviewed with the driver and he was sent off with a clip-board containing all documentation, the top sheet of which was a large-print emergency notice document, per DOT 172.602, which included the 24-hour emergency phone number and which was signed by the driver after it was reviewed with him. This documentation was provided to the inspector during the inspection. The claim in the citation that "The number could not be retrieved expeditiously in the event of an accident." is simply not true, and we don't understand how an inspector can come to such a conclusion without being present at the time the shipment was initiated. We really don't know how to better satisfy this regulation; this has been our routine practice for many years without previous question. We will request specific advice from DOT.

- D. Citation: The licensee delivered to a carrier for transport licensed material, and the description on the shipping paper that accompanied the shipment did not include the correct name of each radionuclide. Specifically, the radionuclide was mistakenly identified as CM when the correct identification was C-14. This error was duplicated more than a dozen times on two pages of the manifest.

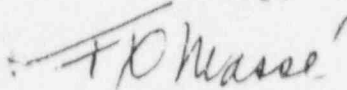
While the description on this violation refers to a shipment of licensed material which implies significant activity, this citation refers to a keystroke error in paperwork on a shipment of deregulated liquid scintillation vials containing less than 0.05 μCi of ^3H or ^{14}C per cc, and hence was being transported for incineration without regard to the radioactivity content (technically, no longer licensed material). The repeated nature of the listing is an automatic computer function through the process by which the record was generated, an inventory form required by the broker that does not constitute an official shipping paper. Unfortunately, the error was not noticed by those processing the paperwork. However, the manifest on the shipment correctly described the contents and the shipment was processed without question or incident. The staff have now been instructed to be more diligent in their paperwork review, even for shipments that are technically no longer licensed material and even when the document has no official relevance to the transportation regulations.

We believe that the report on this inspection does not accurately reflect the status of this very large program, and we have attempted to point out the ways in which the citations have exaggerated the findings in the above individual responses. We note that none of the items specified involved excessive or unnecessary personnel exposure or radiation safety problems. We believe that for many of these items a reasonable inspector would not have spent the time looking for such detail or would simply mention such observations informally for our attention (in fact, many of these practices date back prior to previous inspections and were not questioned by previous NRC inspectors). We suggest that more objective and accurate reporting by NRC compliance representatives would be more helpful in properly evaluating such programs and in assisting with achieving compliance. Nonetheless, expanding audit functions between management, the committee, and the RPO will take note of the issues raised in this inspection,

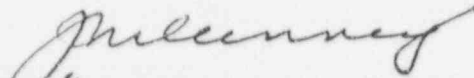
US Nuclear Regulatory Commission
April 24, 1995
Page 8

and every effort will be made to maintain the excellent compliance record that has been typical of this very large program for many years.

Yours truly,



F.X. Massé, CHP, CMP
Radiation Protection Officer



Robert McCunney, MD, MPH
Director of Environmental
Medical Services



Paul Powell
Research Coordinator
Office of Sponsored Programs.

FXM/nlm

APR 10 1995

Docket Nos. 030-00763
030-09177
030-21272

License No. 20-01537-02
20-01537-10
20-01537-12

Mr. Robert McCunney
Director of Environmental
Medical Services
Massachusetts Institute of Technology
18 Vassar Street
Cambridge, MA 02139

SUBJECT: ROUTINE INSPECTION NOS. 030-00763; 030-09177; AND 030-21272/95-001

Dear Mr. McCunney:

On March 8 through 10, 1995, Penny Lanzisera and Kathleen Dolce of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

The numerous violations identified during this inspection are indicative of a need for improvement in your supervision and oversight of your radiological controls program. In your response to the identified violations you should pay particular attention to the root cause(s) for these violations and your actions to improve management oversight of your radiation safety program. Further violations of NRC requirements or repeated or uncorrected violations may result in enforcement actions that may involve monetary civil penalties, suspensions, or revocation of your NRC license. In addition, our inspection examined the activities covered in your facsimiles received on Friday, March 10, 1995 and Monday, March 13, 1995. The findings of the inspection were discussed with you and other members of your staff at the conclusion of the inspection.

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R. McCunney
Massachusetts Institute
of Technology

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Please use the enclosed self-addressed green envelope when you submit your copy to the Regional Administrator, Region I. This will assist us in the timely processing of your response. In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

Docket Nos. 030-00763
030-09177
030-21272
License Nos. 20-01537-02
20-01537-10
20-01537-12

Enclosure:
Appendix A, Notice of Violation

cc w/enclosure:
F. X. Masse, Radiation Safety Officer
Commonwealth of Massachusetts

Distribution:
PUBLIC w/enc
Nuclear Safety Information Center (NSIC) w/enc
Region I Docket Room (w/concurrences) w/enc
D.J. Holody, RI
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APPENDIX A

NOTICE OF VIOLATION

Massachusetts Institute of Technology
Cambridge, Massachusetts 02139

Docket Nos. 030-00763
030-21272
License Nos. 20-01537-02
20-01537-12

During an NRC inspection conducted on March 8 through 10, 1995 violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. Condition 16 of License No. 20-01537-12 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in the Licensee's application dated July 16, 1990.

Item 9 of the application dated July 16, 1990 states that sources will be housed in an AECL Gammacell 40 Irradiator located in the MIT Center for Cancer Research, Room E17-629.

Contrary to the above, as of March 10, 1995, the sources were not housed in an AECL Gammacell 40 Irradiator located in the MIT Center for Cancer Research, Room E17-629. Specifically, the licensee had the manufacturer move the Gammacell 40 irradiator containing approximately 3000 curies of cesium-137 to Room E17-613 prior to applying for or receiving a license amendment authorizing the new location.

This is a Severity Level IV violation (Supplement VI).

- B. Condition 21 of License No. 20-01537-02 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in the Licensee's application dated November 29, 1989 and letter dated June 21, 1990.

1. Item 10 of application dated November 29, 1989 requires, in part, that the radiation protection committee (RPC) meet at least four times per year, once in each calendar quarter.

Contrary to the above, as of March 10, 1995, the RPC did not meet at least four times per year, once in each calendar quarter. Specifically, the RPC met on 12/1/92, 4/13/93, 6/23/93, 10/27/93, 1/26/94, 5/24/94, 10/5/94, and 1/10/95.

2. Item 10 of application dated November 29, 1989 requires, in part, that the RPC review the Radiation Protection Program at least once each year.

Contrary to the above, as of March 10, 1995, the RPC did not review the Radiation Protection Program at least once each year.

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Specifically, the RPC did not review the Radiation Protection Program for 1993. The review was scheduled, postponed to another meeting, and then the review was dropped from the RPC agenda.

3. Item 10 of application dated November 29, 1989 requires, in part, that thyroid measurements be performed within 3 days of a procedure for persons occasionally handling in excess of one millicurie of radioiodine.

Contrary to the above, as of March 10, 1995, thyroid measurements were not performed within 3 days of a procedure for persons occasionally handling in excess of one millicurie of radioiodine. Specifically, thyroid measurements were routinely being performed between 7 and 14 days post-procedure.

4. Item 10 of application dated November 29, 1989 requires, in part, that the RPC perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels are exceeded.

Contrary to the above, as of March 10, 1995, the RPC did not perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels were exceeded. Specifically, the extremity exposure of an employee working with millicurie quantities of phosphorus-32 exceeded the licensee's investigational levels (1.875 rem and 5.625 rem) during the first, third and fourth quarters of 1993, and the RPC did not review the employee's exposure.

5. Item 8 of application dated November 29, 1989 requires, in part, that retraining of laboratory workers be performed on a two-year basis in conjunction with the two-year review and renewal of each laboratory use permit.

Contrary to the above, as of March 10, 1995, retraining of laboratory workers was not performed on a two-year basis in conjunction with the two-year review and renewal of each laboratory use permit. Specifically, Authorization Nos. 7-AJ and 5-AL-2 were renewed 3/94 and 6/94, respectively and retraining did not occur until 2/6/95 and 3/7/95, respectively. Also, Authorization Nos. NRL-C, PFC-D, LNS-W, NML-N, and 7-AO expired on 12/31/87, 2/29/92, 10/31/92, 7/31/93 and 12/31/93 respectively and have not yet been renewed, nor had retraining been provided to workers.

6. Item 8 of application dated November 29, 1989 requires, in part, that housekeeping personnel be given annual reviews of radiation hazards and appropriate precautions by the Radiation Protection Office (RPO) staff.

Contrary to the above, as of March 10, 1995, housekeeping personnel were not given annual reviews of radiation hazards and appropriate precautions by the RPO staff. Specifically, the licensee did not provide training for the housekeepers during 1993 and 1994.

These are Severity Level IV violations (Supplement VI).

- C. 49 CFR 172.604(a) requires, in part, that an emergency response telephone number immediately follow the description of the hazardous material on the shipping paper.

Contrary to the above, on May 11, 1994, an emergency response telephone number was not immediately following the description of the hazardous material on the shipping paper. Specifically, the emergency response number was attached to the shipping papers within numerous other documents. The number could not be retrieved expeditiously in the event of an accident. (License No. 20-01537-02)

This is a Severity Level V violation (Supplement V).

- D. 49 CFR 172.203(d) requires, in part, that the description for a shipment of radioactive material include the name of each radionuclide.

Contrary to the above, on January 27, 1994, the licensee delivered to a carrier for transport licensed material, and the description on the shipping paper that accompanied the shipment did not include the correct name of each radionuclide. Specifically, the radionuclide was mistakenly identified as CM when the correct identification was C-14. This error was duplicated more than a dozen times on two pages of the manifest. (License No. 20-01537-02)

This is a Severity Level V violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Massachusetts Institute of Technology is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.