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ADDENDUM

Page	Line	Correction and Reason for Correction	
6	5	Delete "new"	Wrong word
6	6	Add "NU" in front of "REG"	To complete the word NUREG
6	10	Add a comma after "and"	Punctuation error
		Change "to" to "two"	Incorrect word useage
		Add a comma after "two"	Punctuation error
6	22	Change "excepted" to "accepted"	Wrong word
8	17	Change "long" to "low"	Wrong word
8	19	Change "and" to "in"	Wrong word
13	22	Change "I'll" to "I"	Wrong tense
		Change "discuss" to "discussed"	Wrong tense

Page 1 Date 1/4/96 Signature John E. Glenn John E. Glenn

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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FINAL EXIT OF

INCIDENT INVESTIGATION TEAM

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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FRIDAY, DECEMBER 8, 1995

NRC STAFF PRESENT:

DENWOOD R. ROSS, JR.

JOHN GLENN

ALSO PRESENT:

DAVE LITSTER

FRANK MASSE

MITCH GALANEK

WADE ROUSH

JENNIFER GOREN

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

(10:06 a.m.)

MR. ROSS: Good morning. We're here to discuss the conclusion of an investigation that was done by the Nuclear Regulatory Commission.

We'd like to get some identification of speakers. My name is Denwood Ross. I'm an employee of the Nuclear Regulatory Commission, and my job function is Deputy Director of the Office for the Analysis and Evaluation of Operational Data.

MR. GLENN: And my name is John Glenn. I'm also with the Nuclear Regulatory Commission. My normal function is as a Branch Chief in our Office of Research having to do with rule making. I was the team leader for this particular investigation.

MR. LITSER: My name is David Litser. I'm a professor of Physics and Vice President for Research at MIT.

MR. MASSE: My name is Frank Masse. I'm the Director of the Radiation Protection Programs at MIT and the Institute Radiation Protection Officer.

MR. ROSS: I'll say a few general remarks, and then Dr. Glenn will discuss the results of the investigation. At the end of the discussions, we would be available for questions.

The report of this investigation was prepared and finalized and issued yesterday, and copies are available. The report title is New Reg., number, that is, New Reg. 1535, and it was sent to the NRC's public document room last night.

As you may be aware, there was a similar event in Maryland at the National Institutes for Health. Some conclusions and recommendations common to the two events in question may be discussed soon at an open meeting of the Nuclear Regulatory Commission. The exact time is not known for sure. It possibly might be December 19th, but we're still working on that.

This work that Dr. Glenn will describe is the by-product or work product of what's known as an Incident Investigation Team. It's a formal process for events of significance, and, in general, we average about one of these investigations per year, and they cover all of the licenses that the NRC administers including reactors and materials, field fabrication facilities and source transportation and so on.

At the end of the work, that is, what's the next step is we have to extract what are known as actions. There's conclusions and findings in the report, and then the actions are developed separately. Some of the actions may be generic, say, by rule making. In principle, some

could be for the licensee involved and some reflect back on how the NRC itself functions.

We will track these actions to completion. Frequently, it takes several years. We develop close-out reports, and in our annual reports, we describe what the percentages of completion until we finally closed out all of the actions.

What I'd like to do now is turn it over to Dr. Glenn to discuss his report.

MR. GLENN: Thank you, Dr. Ross.

I'd just like to remind everyone that we had a similar exit about five weeks ago. I promised at that time that at the conclusion we would issue our report and that our findings and conclusions would be available publicly at that time, and I'm here today to complete that promise and to summarize the findings and conclusions that are in the report that was issued last night.

I'll remind everything that this meeting, as at the previous meeting, is being transcribed and that a record of the meeting will be available in the public document room when the documents that support the report are put into the public document room.

I'll also mention that at the conclusion here, we will give MIT a chance to respond to our report and that they also have a period of 30 days in which to submit

a written report to the NRC in terms of any errors that they think may have been identified in the report.

The first item I'd like to discuss is the team's conclusions regarding the exposure of the individual who had the ingestion of P-32.

One thing I would like to note is that the team's job was greatly helped by the availability of very good data from two different methods of measuring the intake. We had, both, excretion data and retention data from whole-body counting.

The quality of the data was very good. It allowed us to do a lot of different things with the analysis that we may not have been able to do if the quality of the data had not been as good as it was.

The statistical error is very small, and I will, in a minute, discuss some of the systematic errors that could occur, but the conclusion of the team was that the estimate submitted by, or the reported dose that MIT submitted to the NRC on October 16th is correct.

It's in accordance with the guidance that has been put out by the NRC. It's in accordance with the recognized biokinetic models put out by the International Commission on Radiological Protection, and we did our independent calculation based on the data and came up with essentially the same number.

The weighted mean of the NRC's estimate was 570 microcuries based on a 580 microcurie estimate based on whole-body counting and a 560 microcurie count based on the urine data.

And in doing that, we rigorously followed new Reg. 4884 which is the NRC's guidance on doing this kind of analysis.

However, again, because the data was so good, we did look to see whether we could, one, quantify the errors that might occur in the measurement process and to see whether the data was good enough to support an individual specific model.

Our guidance does say that in the case of a significant exposure that licensees can do individual specific modeling, and if the data's good enough, that that should be done.

One of the major sources of uncertainty would be the fraction of the ingested material that is excreted in the urine, and there are literature values that run from .6 to
.9 as the fraction that is excreted in the urine.

The ICRP model states .9 as the excepted one; however, if you take an average of what's reported in the literature of .75, you could interpret the urine data to indicate an intake as high as 680 microcuries, so we have

a range of between 570 and 680 based on that uncertainty in the literature.

I will note, however, that we did do some comparisons, since we had both excretion and retention data, and we essentially tried to solve for the, the excretion faction based on the comparison of those data.

We came up with an excretion factor of 1.0 plus or minus .2 which indicates that .9 is a very reasonable value for this particular individual and that is what we used in our analysis.

Another uncertainty is the geometry factor for the whole-body counting. The counter here at MIT does not look at truly the whole body. It looks at the neck to the knees, so there is a mass of body that is not looked at in the counter, and so we did some estimate of what the uncertainty factors might be there.

MIT has used a geometry factor of .65 based on studies that were done a few decades ago. We looked at that and decided it was a reasonable factor.

However, we did note that as times goes along, more and more of the P-32 is going to be, essentially, locked up in the bone and that perhaps the .65, although it may be a very good factor for tissue, may not be as representative of the bone distribution within the body.

So, we decided that you could have a variable

from a geometry factor of .5 to .65 which could then indicate a range of values from 570 to 740 microcuries.

However, there's an opposing effect in the whole-body counting. The phantom that MIT uses is a masonite phantom with the P-32 contained in water bottles that are used to simulate organs.

Water is, in fact, a very good surrogate for tissue. However, it is not a very good surrogate for bone. It turns out bone has a higher average atomic number, and, therefore, will be more efficient at producing bremsstrahlung, so we would expect that P-32 that is in bone would, in fact, produce more counts per ingested activity than would the tissue component.

There's a factor of about 1.5 in the average atomic number between tissue and bone, and so that would, from the 570 that we measured using the standard model, you could go down to as long as 380 microcuries if that were the only variable.

We take note that those two effects and the whole-body counting tend to counteract each other and that it means probably that the mean value may be more representative than any of these extreme values.

Again, we had a contractor, as well as ourselves, look at the data to see whether we could, in fact, come up with individual specific parameters rather

than the standard biological parameters for publishing the literature for what's called a reference or standard man.

If you vary the parameters to get the best simultaneous fit of the urine and whole-body data, you come up with a value, again, amazingly, of around 550, 570 with a range of about plus or minus 50.

What that attempts is to do a joint fit and come up with an individual specific model comes up with is for, to best fit this data, you need to assume that more of the isotope ended up in tissues than in the standard model, less ended up in bone than in the standard model and that the tissue component was retained for a longer period than in the standard model.

The standard model for the tissue component is 19 days. The best fit was obtained for something around 32 days. As it turns out though, that doesn't make a big difference in terms of the evaluation, and so, again, in the end, we conclude that following the standard model is the correct approach and that the 570 is a good number and that an overexposure did not occur.

Our first conclusion was that the exposed individual most likely ingested P-32 as a result of a deliberate act by a knowledgeable person. That is not a finding of fact. We did not, in fact, identify exactly how the ingestion occurred.

It is a finding though of the weight of the evidence that it's our conclusion that it's more probable that it was deliberate than that it was accidental.

Why did we come to that conclusion? The first is that the exposed individual worked with levels that were normally 50 microcuries and that accidental spills that would be expected working with those kinds of quantities couldn't result in an intake of 500 plus microcuries.

The next fact is that the, the amount of activity that was ingested is comparable to or a large fraction of the, the maximum quantity that's in the lab at any time. It's very difficult to imagine many accident scenarios where the bulk of the inventory ends up being ingested.

The next finding that supports this is that the P-32 in the experiments was shipped to the laboratory in frozen form and was kept frozen in freezers until just before an experiment. Therefore, to get that quantity involved in an accident, it had to have been thawed first, and that should be a relatively restricted opportunity in time and space.

I think the main thing was that our own experience is that if there is an accident with P-32, a spill, the contamination is, in fact, pervasive, that you

find it everywhere.

P-32 is very easy to detect. If it's spilled, you find it being tracked out into hallways, into cars, in homes. You can find it just about everywhere.

Extensive surveys after this incident didn't find any contamination of those kinds of areas.

The other thing is that an inventory performed shortly after indicated that there was a missing amount of activity that is approximately the same value as the activity that was shown to be in this body.

Finally, we determined that there was opportunity for this to occur because the security of radioactive materials was weak in the building in which the laboratory was located. There were many people who could have had access to it, and we also found that there was occasional practice among laboratories of borrowing material, so there was opportunity for this act to occur.

Our second conclusion was that the amount of radioactive material ingested by the researcher is not enough to cause clinical symptoms or acute effects; and, therefore, we concluded that any symptoms that may have been experienced were due to factors other than radiation exposure.

We base this finding on the report of our medical consultant who had access to the individual's

medical records, and I'd like to acknowledge our appreciation to the exposed individual for his cooperation with us. He did give us access to medical records and that sort of thing.

And so our medical consultant had access, and he also looked through the literature, and he depended upon his own experience in terms of treating patients with activities of P-32 ten to twenty times what was involved in this particular case.

Some of the things that he noted in his report were there were no symptoms reported by the exposed individual before the discovery of the contamination, that the symptoms reported by the individual were not consistent with those that would have been expected from the radiation exposure.

In this respect, I will note that we did have blood data for the individual from both before and after the intake and that there was no indication of blood count changes that would have been expected from very large exposures to P-32, so this does say that there couldn't have been an exposure that was much greater than indicated by the bioassay data.

Cases reported in the literature for intakes that were twenty to fifty times larger than involved in this ingestion, these kinds of symptoms were not noted.

There were detectable effects at twenty to fifty times larger doses, but they were not the ones that were reported.

The other thing is that patients who are routinely injected with P-32 for medical treatment with much larger doses do not show the kinds of symptoms reported by the individual.

Our next conclusion was that the security of radioactive materials in storage and control of radioactive materials in use at the Center for Cancer Research were weak, and some of our findings that led us to that conclusion were that the crowded laboratory areas and benches limited the line of sight so that workers really couldn't see people who were entering and in the area and they didn't have constant surveillance of the areas where the material was stored either.

The stock vials which contained the large amounts of activity were stored in an unattended freezer in the laboratory, and the freezer did not have a lock before the contamination incident.

I will note that before we arrived, that had been locked. We did find other problems, and I'll discuss those at the last exit.

We were told by licensee personnel that radioactive materials were locked during evenings and

weekends when unattended; however, when the team was here, we found that, in fact, we could have access to these areas where they were stored in the evenings and on the weekends. And, in fact, we were able to enter through the main door to the building where the material was used.

Finally, there were no required procedures for recording material removed from stock vials or recording material used during research, so there was very little personal accountability for radioactive material that was used in the laboratories.

And, again, corrective actions had been initiated before we arrived to improve that process and to make it so that access was limited and that people were, in fact, logged in and out when they took material.

Our next finding was that the Radiation Protective Office exercised weak oversight with regard to storage and control of radioactive material in use in unrestricted and controlled areas.

The findings we based this conclusion on were that the radiation protection procedures informed users only that they must store radioactive materials to prevent unauthorized removal, but did not suggest acceptable methods of doing so.

Also, the MIT radiation protection procedures did not include requirements for maintaining constant

surveillance of radioactive materials used in unrestricted or controlled areas which were not in storage.

Surveys in audit forms that the Radiation Protection Office staff members used did not list security of radioactive material among the items for routine review.

Finally, the Radiation Protection Office staff, including the Radiation Protection Officer, stated that the Center for Cancer Research was locked during the evenings and on weekends and that only individuals knowing the key pad could enter the building. When we tested that, we found that it didn't pass the test.

Our next conclusion was that NRC's regulatory standards and guidance for security and control of by-product material were inconsistent, and this is a little complicated, so I'm going to try to walk you through our reasoning on that.

The first thing we noted was that the regulations in our Part 20 are very clear in what they state. One, the licensee shall secure from authorized removal or access licensed materials that are stored in controlled or unrestricted areas; and, two, the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Very clearly, there is no escape clause. There is no lower limit of quantity of licensed material to which these regulations apply. That was reinforce when these regulations were being adopted a few years ago in the statements of consideration, and there was a comment that asked about, well, did we really mean that particularly for areas where small quantities were used in university research.

The NRC response stated that locking radio tracer laboratories when they're not being used is a small nuisance compared to the consequences of unauthorized access or theft, so, again, we essentially said the clear meaning of the words is the clear meaning of the words.

However, with the adoption of the new Part 20, we also issued some guidance documents, questions and answers regarding the interpretation of Part 20, and there was a question that asked if the regulations that covered this area would be imposed, first, on all quantities of licensed material, however small, and, B, specifically, on quantities that are exempt from labeling in accordance with the regulations.

We said: 'No, it would not apply to all material no matter how small the quantity, and, no, it would certainly not apply to those quantities of material that didn't require labeling.'

So, we now have a contradiction between our statements of consideration and our questions and answers. We then had a follow-up question, someone who read the answer to our first question and said that that was a very useful interpretation, but inquired about the supporting justification since it was not evident in the regulations.

We, again, answered that what we said before held.

We've also put out license specific guidance that reaffirms the position that for small quantities, those less than those requiring labeling, did not require the same standard of security and control as was in the regulations.

A compounding factor is that these small quantities that do not require labeling, according to the regulations in Part 20, are very similar in quantity to a list of activities in our Part 30 which can be exempt from licensing, so there is a very close similarity between materials that a person who doesn't have a license from the NRC can receive and these unlabeled quantities.

Finally, we noted that although the NRC regulations included many requirements to report thefts, losses and incidents involving very small quantities of licensed material, the NRC regulations required only records of receipt and disposal of licensed material.

We do not have specific guidance or requirements for the accountability of materials in use. Our next conclusion was that while the team found weaknesses in the actions taken by the Radiation Protection Office, the licensee's overall response was good.

Some of the strengths that we identified: the Associate Radiation Protection Officer and Assistant Radiation Protection Officer arrived on site within one hour of notification, and they had previously communicated with the people on the site who were tending to the exposed individual.

The Radiation Protection Office staff took immediate actions to confirm the lack of external contamination on the researcher, and they also surveyed the laboratory and surroundings and the personal residence of the exposed individual. All of that was done promptly.

The Radiation Protection Office staff took follow-up actions to expand these surveys and to confirm the initial findings. They used two methods of bioassay: whole-body counting and urine analysis. And I've already pointed out that that was extremely helpful to us in terms of assessing the actual intake to the researcher.

The other thing is that they continued the sampling for approximately 60 days which, again, allowed

us to do a lot of interpretation.

The staff took appropriate actions to ensure proper calibration, the whole-body counter and liquid scintillation counter, and the licensee took actions to suspend all use of radioactive materials in the affected laboratory until an inventory could be performed, and before restoring authorization to use materials, they took actions to secure all stock radioactive materials in the laboratory and to reduce the likelihood of recurrence of this event.

We did identify some weaknesses. One, the radiation protection staff did not give researcher, A, written instructions on urine collection. This resulted in some confusion and some misleading initial data, so the very earliest excretion data was not useful because of this confusion.

I'll just mention that in terms of actions, we think this also may come back to the NRC as well because in looking at our own guidance, we have not provided licensees with much guidance in this particular area on the collection of samples.

The calculations associated with the licensee's initial intake assessment were weak, and the licensee initially failed to properly account for the geometry factor of the whole-body counter.

This was corrected rather rapidly, but in a conclusion I'm coming to in a short while, I think it did play a role.

The licensee did not apply increased controls of radioactive materials to the entire Center for Cancer Research; however, when this weakness was found by the team, the licensee responded by securing all radioactive materials in the Center.

Our next conclusion was that management oversight to the Radiation Protection Program was weak. The licensee did not use a process of management review and self-assessment to find weaknesses in their program and to take appropriate remedial actions.

We based this finding on violations that had been documented in the NRC Inspection Report in 1995 that included the failure of the Radiation Protection Committee to review the program in 1993 which was a commitment in the license.

In our interviews with Radiation Protection Committee members, they stated that they did not perform audits of the Radiation Protection Program and did not perform random checks or performance outside their own laboratories.

Radiation Protection Committee members also stated that they depended on the Radiation Protection

Office to inform them of problems and program status. The Committee was not notified of the August 14th event until the week of September 12th.

I'll just note that in the interviews with the committee members, most of them, when we asked specific questions about practices that we had observed in the Cancer Center, indicated that they would not have permitted those in their own laboratory.

And we think that's an advantage of having the independent look by an outsider who's not directly affected by the program and other than the normal oversight group that does it on a routine basis taking a look because that third party who's not used to what's going on, isn't making assumptions about what is going on can, in fact, have insight and can help the institution improve their program.

The final conclusion relates to the reporting requirements. The NRC reporting requirements were not specific regarding intentional contamination, the NRC reporting requirements for intake were unclear; however, sufficient data was available within the first week to indicate the event threatened to cause an overexposure.

Certainly, one of the things we were able to do in short time was to look through the regulations to determine that NRC regulations do not require licensees to

report deliberate acts involving ingestion of radioactive materials.

We noted that the licensee stated that the decision not to report the event was partially based on their finding that the dose to ingestion of P-32 would be delivered over a period of weeks instead of a 24 hour period.

When we interviewed NRC personnel to ask for interpretation of this, we got different interpretations from different members on the staff, some people who felt that it was clear that committed effective dose equivalent meant that the dose was received immediately upon intake and others who felt that the plain meaning of the words of the regulation was that the dose itself had to be received over 24 hours.

The licensee stated that their decision not to report the event was primarily based on their findings that all data indicated that the quantity involved in the intake was less than the limit stated in the regulations.

However, we feel that the data available in the first week indicated a possible dose in excess of 600 microcuries. Additionally, we noted that the researched, himself, gave the licensee estimates in excess of 600 microcuries within the first week.

We feel those factors met the threshold in the

regulation of "threatened to cause." In particular, we noted that there was contradictory data. Some of the data in the first week projected a result that was less, some of the data projected a dose that was greater than the limit, and our conclusion was that the threshold of "threatened to cause" was met.

Finally, we attempted to do a root cause analysis. However, the team concluded that since we could not, in fact, say what caused the ingestion, we could not come to a conclusion as to motive or intent or exactly how it occurred, that the best we could do was to identify some contributing causes of the ingestion.

I'll take note that these causes are really more things that could have been done to perhaps prevent or deter the incident from occurring.

Our first contributing cause was that MIT's program for control and security of radioactive materials was not effective to deter or detect diversion of radioactive materials.

We're not saying that security and control in itself could prevent a person who is authorized to use radioactive material from doing something with that radioactive material that they shouldn't; however, we do feel that strict accountability and security of materials is a very big deterrent towards anyone attempting to do

something like this.

Our second contributing cause was that the NRC did not have reporting requirements in place to collect information about deliberate acts to access their frequency.

One of the things I learned since the last time I was here and gave the exit interview was that there were many more of these kinds of events than I personally had been aware of and that most people in the NRC were aware of, and we have a section in the report that goes through these precursor events.

But there had been some very similar events and some with much larger consequences than the event that occurred at MIT, and because we did not have a reporting requirement for deliberate acts, these were not being captured in a consistent manner, and some of them weren't being captured at all because there was not a requirement for reporting.

We learned of some of them through meetings that were being held about the same time as the IIT was progressing.

And the third contribution cause was that the NRC did not disseminate information about known precursor events and did not inform licensees of the circumstances of a similar incident at the National Institute of Health

until four months after the incident was reported.

Again, we're not saying that simply getting this information out would prevent deliberate acts, but we think that if we expect licensees to be evaluating their own programs, developing their own deterrents to this kind of activity, that there was a burden on the NRC to get what we did know out and to get it out promptly.

As Dr. Ross mentioned, we will be providing suggested actions based on these conclusions to the Executive Director for Operations, and he will determine which of those to send forward to the program offices who have responsibility for implementing any changes that come out of here.

At this point, I've discussed the findings and conclusions, and I'd ask MIT if they have any response at this time to make.

MR. LITSER: Thank you, Dr. Glenn, Dr. Ross.

I don't have a lot to say. I have a few things I would like to say. First of all, I think both, we and the individual who ingested the Phosphorous 32, will be pleased to know that there are apparently no health consequences of this and that's been one of our primary concerns, and I'm sure his as well.

I think, too, that in their response to this incident, our Radiation Protection Office really performed

admirably, and I would like to compliment them publicly on their having done so.

I think there are a number of things for us all to learn here. I think our procedures certainly have not been as stringent or strict as perhaps they ought to be.

It's a characteristic of university communities that we tend to operate in an open and unfettered and, hopefully, creative way, and occasionally that gets us into situations which we would rather avoid, so I think we are going to have to change many of our things as we do them.

In fact, we have already changed many in response to suggestions from the NRC. I think, as you said, the NRC, itself, is going to learn a few things from this as well, so I think that's important.

When you have a chance to learn something where there are no, fortunately, no serious consequences, it's a good thing to take the opportunity to do that. I think some of the things we can do will optimize the situation, that people will still be able to carry out their research, but that we will have procedures in place that will tend to reduce the opportunities for incidents like this in the future.

And I think it will also generally create a

mental environment that people have that these materials perhaps need to be treated with a great deal more respect than you come to do so if you use them every day.

I would like to thank the Nuclear Regulatory Commission for its efforts in this. I've only had a chance to skim quickly through your report. It looks thorough. We certainly have found that the interaction with your staff and investigators has always been a very positive one, and we think that you've done a good job in handling all of this.

I don't want to be defensive about any deficiencies that you may have uncovered in MIT's policies. I do think we need to make sure that we're dealing with the facts, and you have provided us with an opportunity to correct errors of fact in the report, and we shall take that opportunity.

Frank Masse, our Radiation Protection Officer, has had a chance to study the report more thoroughly than I have, and I would like to give him the opportunity to make any comments he would like to make.

MR. MASSE: Thank you, David. Thank you, John, for the report that you've presented.

We will, obviously, take advantage of the opportunity for a written response within 30 days, and it's my understanding that that written response will then

go with the document and become appended to the document and distributed to anybody who gets the document.

MR. GLENN: That's correct. It will be a part of the same record and will be distributed with the report.

MR. MASSE: Okay. We think that's important because we think there are some issues and some factual areas that do need some correction, and we think that it will help in the overall accuracy and effectiveness of all of the work that you people have gone to here also.

We're very pleased, obviously, that the agreement on the dosimetry is as tight as it is. We certainly put a great deal of effort into that, and I'm very proud of my team for all of the work that they went to here, and we're gratified to see that Oak Ridge and Lawrence Livermore agreed with our results.

We're a little puzzled by the range that was adopted by the team. Everybody agreed between 550 and 570 as a quantity of intake, and yet the team put a range of 500 to 700. You know, I wonder about the justification -- 500 to 750. I wonder about the scientific justification or technical justification of a range that is three or four times higher on the up side than it is on the down side of the agreed upon number, but we'll address that in the written response.

I'll go through this thing sort of piece by piece because I think that may be the most helpful way to do it, and as I said, we'll all put it in writing later.

We're still very much puzzled by many aspects of this entire incide`, but one of your, or two of your, findings I find to be very much in conflict.

As I go through the report, I see that you have concluded that in all probability the intake occurred as he ate his lunch on Monday with a lunch that had been carried over from the previous day, left in the refrigerator in the laboratory from the previous day.

Yet, when he surveyed out his laboratory work at 7:00 p.m. that day, he surveyed successfully without any increase in background. We just don't think that's possible.

Based on our experience, which probably is the most experience anybody has in the world at this stage in the game on an issue like this, we do not think it's possible that he could have had a half a millicurie of P-32 in him at 7:00 p.m. that evening and surveyed himself out of the laboratory successfully, and so we would raise that factual question very seriously. We think that's likely to be a problem.

With respect to the whole-body counter, the work that was going on between my team and the researcher

involved in the early stages of this investigation was very much of a cooperative effort, and he was a five year post doc, a very responsible, very knowledgeable researcher, and we let him, and in fact invited him, to sit in with us as we considered what we were doing with respect to the best approach to the measurements and that sort of thing.

The calibration of the whole-body counter for P-32 is something that had to be done specifically for this incident. I had done work with P-32 and with strontium 90 many years ago shortly after I developed this whole-body counting system, and I knew what the ups and downs of trying to count pure beta emitters and the whole-body counter are, but the rest of the team did not.

So, we were discussing that sort of thing, and the question came up about the overall geometry, and it was I that pointed out that we need to correct for the geometry and I that pointed out that the 65 percent factor that needed to be included here went back to the original literature that was published back in the seventies on this and correct this.

It was really part of our process at that stage in the game, and I don't think that we should be criticized for not identifying that immediately. It was not really a problem at that stage in the game, and I'll

point out why as I go along here, but I think that needs to be noted.

The other is that the third party that we brought in to look over our shoulder on our exercise in terms of the dosimetry on this issue, the report does not represent the facts with respect to how that came about.

First of all, the meeting at which that was decided upon did not include either the direct supervisor, who happened to be in Japan at the time, or the Director of the Cancer Center, who happened to be in Europe at the time, but the gentleman who sat in with us was the Chairman of Department of Biology, who was available and was part of the discussion.

It's correct that the researcher asked for an outside opinion, but he knew of nobody who could offer this opinion, and we worked out an arrangement between the three of us as to who might do this.

I retained this individual, I paid this individual, and I instructed this individual to work directly with the researcher, so this was, I think the record should show that we should get some credit for this, and it does not the way it's written at the present time.

There's an error in 211 of your report that you may wish to address right at the very top of the page.

You talk about 1,000 microcuries and 100 microliter quantities being delivered and talk about researchers usually using 10 microliter aliquots, and then you carry that over as 50 microcuries, and, of course, that doesn't check out.

It has to be at least 100 microcuries, and I just thought I'd point that out. It's a minor issue, but you may want to note that.

The next issue I'd like to talk about is the initial, there's some criticism about the initial assessment of the intake in the report, and this goes back to interpretation of the regulations.

You criticized us for not being more thorough in our initial intake, and that same criticism talks about the error in the whole-body counter fraction.

My interpretation of the regulations, as I've indicated to you throughout this investigation, was that there are three levels of reporting requirement.

The first is if it's clear that the ultimate dose will exceed 25 rem, there's a 24 hour reporting requirement; the second is that if there's an indication that there will be an exposure in excess of 5 rem in 24 hours, there is a 24 hour reporting requirement; the third category is that if the exposure is likely to or threatens to exceed 5 rem, then there is a 30 day reporting

requirement.

Okay. Now, our initial action on the night of the recognition of this event was more than adequate to show that we certainly could not get to 25 rem and that we could not get to 5 rem in 24 hours, and once we had gotten to that point, then we knew we had 30 days to work with the data.

So, I did not see any reason for any immediate haste or any excessive effort. I felt there was plenty of time to slowly, carefully and deliberately do our work here, which is exactly what we did, and we had 30 days to report if, in fact, it ever appeared that we had a reportable incident.

You talk in the report about the fact that we several times had indications that there might be a threat. We still had that 30 days to think about that, and I think that's the way the regulations are written, and if that's not the way it was intended that they be used, then they should be changed, but the guidance we have and the regulations that we have to work with clearly indicated that we had plenty of time to work this through.

Now, we did have numbers from the researcher, but the numbers from the researcher, we had plenty of time to review those. They never stood the light of day when you worked with them.

He either would be working with a peak from urinary peak concentration from his excretion or he would be combining urine collected on two different days to get to a high number or we didn't get any support at all for the number that he gave us. It was just a number with no technical backing. We had to go by our own data, and we had to go by our own measurements.

If, in fact, any of these had turned out to be valid, as we worked through very carefully on all these measurements, then, of course, we would have reported them, but we never ever, in any slow, careful, deliberative process felt that we had in excess of a 600 microcurie intake, and I think we should be credited with that.

I think that's the way the system should work, and I interpret that 30 day reporting requirement as deliberately installed to give us time to work the data and be sure of what we're doing, and that's exactly what we did.

With respect to your root cause analysis -- before I get to that, let me talk about the committee issues. We just had an inspection earlier this week, as you know, to close out the inspection for earlier this year and to look at our security response.

There are errors in your report with respect

to the findings on the earlier inspection. You indicate that the Committee only held three meetings in 1993 and 1994. In fact, there were seven meetings held in that two year period.

We could not get a quorum in December of 1993. We had to carry the meeting over to 1994, and then that meeting in January of 1994 was erroneously counted as satisfying the 1993 and the 1994 meeting requirements.

If we had cut that meeting in half and closed one and started another, we would have met all of your requirements. We didn't do that. Okay? But the records should show, and in our response to that, we said that part of our difficulty in meeting our quorum requirements is that we have very senior, very experienced people as members of the Committee.

One answer to that, if it's important to the NRC that the calendar timing be the primary issue here, is that we can just go to less senior members of the faculty as members of the Committee and then always meet our quorum requirements because they, obviously, will have less busy schedules than the more senior people that we have now.

It's a question of which is more important, it seems to me, and that's one of the things we need still need to look at.

With respect to the note in the report that the Committee was not notified, indeed, not only the Committee Chairman, but all of senior management here at MIT were notified as soon as I made the decision to close down radioactive material access to the laboratory in question.

It was in August, as you realize, and there was no possibility of pulling together a quorum of the Committee, and as soon as we could get a quorum of the Committee together, we did early in September, but not only the Chairman, but other members of the Committee were aware of what was going on and were aware that we were working with the data here.

So, I think that is not accurately reflected in your report, and it is something that we ought to look at.

With respect to the root cause analysis, I think the first item there, MIT program for controlling security radioactive materials was not effective to deter or detect diversion of radioactive materials, probably applies to every program in this country, and it probably applies to every program in this country because the NRC simply has not pushed us in that direction in the past.

I see the standard that we're being held to now as an entirely new standard. We'll meet it. I think

we've already shown you that we will cooperate and do whatever we have to, to satisfy the need, but I think we should all be honest about the fact that this is really a new standard and that a lot of people are going to have difficulty meeting it and working with it.

I think we all also have to recognize that it's not going to prevent what happened here, in all probability, and, you know, it's kind of a side issue.

The day that we met, after the weekend when you found that you could get into the laboratories that we thought were secure, we discussed this.

We just don't do our inspections at midnight on Saturday night. I mean, I don't know of anybody that does. We will now, and we have since, as you know, but this is just something that we hadn't considered a necessity in the past, and it is very much a different standard than anything we've faced before.

But if you recall our discussion the morning after, you know, I asked if you thought it had anything to do with this particular incident, and the agreement of everybody there was that probably not, that nobody really felt, in fact, your conclusion is that this was the knowledgeable act or the deliberate act of a knowledgeable person.

Nobody believes that anybody walked in from

Main Street and caused this, and so the security access issues here are something of a side line, and, you know, it's something that we can, obviously, address, but it's something of a side line on this particular issue, and I think we should all be honest about that.

I have to note that, in the past decades, there have been no citations by NRC of any questions of security or access to materials in any of our programs. I also have to note that the deficiencies in our statements and the required procedures and so forth, those required procedures were all reviewed by NRC in our licensing actions, and nobody raised any questions on them.

As you've indicated in your own guidance, there was no clear indication of what you were looking for in security, so I think it has to be emphasized that this is a new standard, and we will meet it.

Others will be way behind us because they're not under the gun, as we are in terms of meeting this, but it should be clearly stated that this is something new, and I think that if, in fact, security and access to materials and so forth does play a role in this particular issue or the issue at NIH, then NRC has to share in the responsibility here.

Thank you.

MR. GLENN: I won't respond point on point,

but I will take note in terms of your last comments, and I think if you look at the report in toto, you will see that, in fact, the team did come to the conclusion that the NRC bears a responsibility to look at its regulations to make sure that our expectations are clearly stated, that the guidance we issue is clear in this area and that we revisit just exactly what that standard should be.

MR. MASSE: Okay. Very good. Thank you.

MR. ROSS: I have one question. I was busy taking notes. Of course, we'll have the transcript. I did have one request in your response.

When you were discussing your interpretation of reporting requirements, if you would make it clear in your response whether MIT regarded this as a 30 day notification. I couldn't tell from what you were saying, so if you'd make that--

MR. MASSE: Yes, very definitely we regard it as a 30 day notification.

MR. ROSS: Okay.

MR. MASSE: And--

MR. ROSS: That's good.

MR. GLENN: I believe that will close the formal part in terms of the interaction between the NRC and MIT--

MR. MASSE: Can I make one more point?

There's another thing, there's a theme in the report that is not consistent with our earlier conversations. Okay?

A decision was never made not to report. I think I made that point before. The way I make my decisions is they're always positive decisions. Okay? We kept watching to see if there was a requirement to report. We never made a decision not to report.

There's a subtle different there that's important. Okay? And the way we went through it, Dr. Ross, was to go through a process of elimination. Was there the possibility of a 25 rem dose? The answer was no. That was clear.

The next category is, Was there a possibility of a 5 rem dose in a 24 hour period? In my opinion, that being my interpretation of that segment of the regulations, the answer was no.

Now, we were down to the last reporting requirement which would have been the possibility at some point of considering a 30 day report. Okay?

MR. ROSS: Okay.

MR. MASSE: If, and I looked at, very carefully, at the interim category, whether or not we should be looking at committed versus effective dose in terms of the interim category for reporting.

The reason I finally looked at it in terms of

the actual words in the regulation and considered it as effective dose is because if it were committed dose that was intended there, then your 50 page of allies in your report, in your regulations, would have actually had two conflicting reporting requirements.

If you considered it as a committed dose, then any time you had an ally, you had both a 24 hour and a 30 day reporting requirement. Now, which was it? The only way I could interpret it that made any sense was as the actual effective dose at 24 hours and, therefore, we were down to a 30 day report.

MR. GLENN: Okay. At this point, we'll accept questions from the audience. I would ask that anyone who has a question come up to the microphone, identify who you are and who you represent and then ask your question, and we'll try to respond to it.

MR. ROSS: Before you get into it, we do have several other NRC people. Depending on your question, we might draft them out of the audience and get them to answer.

MR. ROUSH: Thank you.

I'm Wade Roush from Science Magazine, and I write in the News Department. I have several questions, and it looks like I'm the only person who does, so--

UNKNOWN: No, there's someone there.

MR. ROUSH: All right. So, I'm not going to hog the microphone, but the first was about the ingestion itself. Dr. Glenn, you've stated in your summary that the amount of material ingested was not sufficient to cause clinical symptoms or acute affects.

This is more of a question about medicine and radiology, but is anything known about the possible chronic effects of this level of exposure?

MR. GLENN: This level of exposure would be in the same range as normal occupational exposures, and so there is risk associated with low level exposure.

I guess putting this in terms of things people might understand, I think the exposure is equivalent to approximately two CAT scans.

MR. ROUSH: Okay. My other questions are really about the discussions you've been having just here at the end of the session having to do with reporting requirements.

NRC issued a notice to licensees at the end of October that in general terms described the incidents here at MIT and at NIH without mentioning the names of the licensees and issued what were called guidances or pieces of advice about how certain parts of the regulations on reporting should be interpreted.

The gist of that notice was that there was a

requirement to report an incident in which deliberate misuse of activity was suspected, but what you've just said in your presentation was that there was no such regulation in place, and I wonder whether this is an example of another contradiction between existing regulations and interpretations of the regulations and whether part of your follow-up action will be to clarify such contradictions.

MR. GLENN: Certainly the actions are to take a look at the need for -- if we expect deliberate action to be reported, should we have explicit words that say that.

MR. ROUSH: So that will be part of the analysis--

MR. GLENN: That will be part of the actions that are recommended as a result of the team's conclusions.

MR. ROUSH: My last question is about the interpretation of the intent of the 30 day period of an exposure of less than 5 rem in 24 hours is suspected.

Dr. Masse gave his interpretation of the meaning of that 30 day period. He said that he thought it was to give the licensee time to do a deliberate investigation and report if and when necessary.

I wonder what the NRC's response to that

interpretation is, and then I have a follow-up question to that.

MR. GLENN: Okay. I'll give you my interpretation. When I look at the three different reporting requirements, certainly the 25 is saying something really bad has happened, we got to know about it immediately.

I would say the 24 hour reporting requirement, which includes the received in 24 hours, is meant to indicate some sort of acute event, that the exposure is not the result of a chronic problem which didn't have a lot of threat associated with it, but it's something that happened suddenly, didn't reach the 25 rem threshold, but it's something where a person got a whole year's exposure in one event within a 24 hour period and that's why I think there's a group within the NRC who definitely feel that an intake qualifies with that concept, so that would be the 24 hour reporting.

Then the 30 day is any time within a year that you determine that someone has gone over one of our limits, then you have to do a 30 day report, but that gives you time to collect all the information, the history of the person, that kind of thing. So, I think the crucial question comes down to this confusion over in a 24 hour period.

MR. ROUSH: I've spoken with Dr. Masse's counterparts at other universities, radiation protection officials who have told me that in an event comparable to this, they may have gone ahead and called NRC even if they didn't suspect that the exposure had been in excess of 600 microcuries because, if only because the NRC's presence can advance an investigation, can offer a lot of help to the local investigation.

I don't know if Dr. Masse is, whether you're willing to respond to questions at this time, but I guess I'd like to just put that issue on the table. Does the NRC wish that some of its licensees would invite it in a little sooner if only because of the help that it can offer in that respect?

MR. GLENN: I can answer that our bias is yes, we would like on close calls to have the information.

MR. ROUSH: Dr. Masse, do you have any comment on that? I mean, it's a close call, and so you decided not, you never decided not to report that you were waiting to see whether to report.

MR. MASSE: I think working alone, we were able to develop a very, very solid bit of data here that I think justifies the way we operated, and I think we got everything done.

We did everything that needed to be done. We

got it all wrapped up very well, all within the reporting requirements and within the regulations.

If the regulations are changed so that there's a clear reporting requirement, then, fine, we obviously will do whatever the regulations call for, but we never felt that we needed help. We always felt that we had everything completely under control.

I can understand why some of my counterparts elsewhere might respond the way you described. Not everybody has the kind of capability that we have, and not everybody can do the kinds of things that we did here, and we did very successfully.

MR. ROUSH: Thank you.

MR. GLENN: Let me do just one little follow-up. I think one reason why we would sort of like people to err on the side of reporting is that, and Frank may be quite correct that in terms of technical ability, knowing what to do and that sort of thing, MIT was as qualified as anyone in the world to do that.

However, there was a dimension to this issue, the potential for a malicious act, that the NRC needed to be looking at its own procedures and perhaps looking over what MIT was doing as well, and so where these new dimensions, perhaps things that we haven't anticipated, come up, we would like to be involved as early as

possible.

MS. GOREN: Hi. My name is Jennifer Goren, and I'm from WBUR radio. I just have a couple of questions.

I'm wondering, is the investigation continuing into how exactly this happened or is this the final report?

MR. GLENN: There is an independent ongoing investigation by the NRC's Office of Investigations, and this report does not address any of their findings.

MS. GOREN: If you don't know exactly what happened, how is it possible to know whether the precautions, the guidelines that are in place now, are adequate or are not adequate?

MR. GLENN: Again, we did the best we could. The contributing causes, we assume that it was a deliberate act. We felt that accountability and security would go a long ways towards deterring and detecting such events, and we've had an information notice that's gone out alerting other licensees to do this, and certainly here at MIT, we've monitored and determined that they have upgraded their security program considerably.

However, the report does take note that we weren't able to get to root cause because we don't know exactly what did happen.

MS. GOREN: Touching on what Dr. Masse said earlier, if this was done by somebody who was a "knowledgeable" person, perhaps from the MIT community, are there any safeguards, you know, locking anything up that could prevent something like this from happening again? Presumably, that person would have access if he or she were in the community.

MR. GLENN: I think the issue of protecting people from the knowledgeable person who is, in fact, the expert who has the authority and the authorization to use material is a very difficult issue.

And I think in terms of the actions that the NRC will have, it's to find out what the right balance is in terms of the threat and the cure, and in terms of my presentation, where I was talking about the confusion between the regulations and the guidance, I don't mean to say that perhaps the guidance doesn't have some good things in it, too.

Perhaps there are smaller quantities of material that don't require as much surveillance, but then as you move up, and you get to more significant quantities, maybe there are some really stringent extra requirements that will be needed.

So, there may not be one simple answer to how you prevent deliberate acts.

MS. GOREN: Also, Dr. Masse mentioned that if it's a problem at MIT, this is a widespread problem at universities and laboratories all around the country. Can you comment on that?

MR. GLENN: We've already sent out the information notice the end of October alerting licensees to this issue, and the actions that come out of here are to look at our regulations and see whether the regulations and the guidance are, in fact, adequate on this issue.

MS. GOREN: Is it the NRC's impression that response to NRC guidelines is lax for attention to them, not response?

MR. GLENN: The findings of the team are particularly directed towards MIT, so I can't make a generic finding with respect to other institutions, but I don't challenge Mr. Masse's comment that there may be similar problems elsewhere.

MS. GOREN: Okay. You mentioned just early on that there were larger incidents, more serious incidents, that occurred elsewhere. Other than the incident at NIH?

MR. GLENN: Yes. In Section 3 of the report, there is a list of these precursor events. I'll take note that there was an event in 1978 in University of California, in San Francisco, that involved an intake of a few millicuries, in other words, ten times the kind of

activity we're talking about here.

And, in addition, there was external contamination in the home which resulted in what appeared to be actual radiation burns on the skin of the individual, so there were precursors that had more consequence than this incident.

MS. GOREN: And I just have two other questions. One of them is I had heard from a Radiation Protection Officer at another university that if it was a person who was knowledgeable who did this, then that person would realize that an exposure of approximately 570 microcuries wouldn't cause health effects or acute effects and that it was more likely an attempt to scare the researcher than to hurt him. Can you comment on that?

MR. GLENN: The team really didn't make a finding on that, and, again, that probably would require that we actually identify the root cause of the ingestion rather than the information we have.

I can only speculate, and it would be nothing more than speculation.

MS. GOREN: Okay. Do you think that the investigations will ever clear up exactly what happened?

MR. GLENN: I hope so.

MS. GOREN: Okay. Thank you.

MR. GLENN: Thank you.

MR. ROSS: That seems to be about it.

MR. GLENN: Any more questions?

(No response.)

MR. GLENN: Okay. Thank you very much.

(Whereupon, at 11:17 a.m., December 8, 1995, the above matter was concluded.)

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: FINAL EXIT OF ITT AT MIT

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.

M. Sandberg

M. SANDBERG
Official Reporter
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