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NUCLEAR REGULATORY COMMISSION

Title: MIT: Incident Investigation Team
Interview of Dr. Carl J. Paperiello

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ADDENDUM

Page	Line	Correction and Reason for Correction
5	14	"uptake and an individual" should be "uptake to an individual"
5	20	"uptake" should be "discrepancy"
~~10~~ 10	7	"rather" should be "referenced or"
16	10	"milligion" should be "millirem"
	11	ditto
17	9	"cost and" should be "constant"
22	7	"Valium" should be "thallium."

Page 1 Date 11/16 Signature John E. Glenn

ADDENDUM

Page	Line	Correction and Reason for Correction
10	16	extremely high. → extremely high dose levels.
16	10	milligram → milliriem - Wrong Units
16	11	milligram → milliriem "
16	24	milligram → milliriem "
17	1	milligram → milliriem "
17	3	reputed → refuted Wrong word.
22	7	Vadium → Thallium Wrong word.
22	9	form → from Spelling
31	12	35 → 33 Part 35 is wrong Part 33 is broad Scope
37	13	radiogneumonic → radiometric
39	23	coal → radiometric → cold

OK

Page 1 Date 9 Nov 9 Signature Carl J Paperiello

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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INCIDENT INVESTIGATION TEAM

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INTERVIEW OF DR. CARL J. PAPERIELLO

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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TUESDAY, OCTOBER 31, 1995

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9:02 A.M.

INTERVIEWERS:

JOHN GLENN, Team Leader

ALAN L. MADISON

ELIZABETH ULLRICH

GREGGORY P. GONECONTO

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

(9:02 a.m.)

MR. GLENN: Today is October 31, 1995. This is an interview being conducted as part of the Incident Investigation Team looking at an exposure to P-32 at the Massachusetts Institute of Technology in August of this last year.

The purpose of this interview is to interview Carl Paperiello, who is the Director of the Office of Nuclear Materials Safety and Safeguards, to get his perspective on the regulations and the guidance as a senior manager of the agency.

My name is John Glenn. I'm the leader of the IIT, and I would like the other members of the team who are present and other observers with the team to introduce themselves for the record at this point.

MS. ULLRICH: I'm Betsy Ullrich. I'm a senior health physicist from Region I.

MR. MADISON: I'm Alan Madison. I'm in the Diagnostic Evaluation Incident Investigation Branch in AEOD.

MR. GONECONTO: I'm Greg Goneconto. I'm a Special Agent with the NRC's Inspector General's Office, and I'm sitting in today as an observer.

MR. GLENN: Carl, if you could state your name

for the record and a little bit about your background and position.

DR. PAPERIELLO: I'm Carl Paperiello. I'm Director of the Office of Nuclear Materials Safety and Safeguards. I've been with the NRC for going on 20 years, started out as a health physics inspector. I am a certified health physicist, and I've worked my way up through the ranks from the Inspector through the various regional offices to Director of the Industrial and Medical Nuclear Safety Division in NMSS to the Office Director.

MR. GLENN : Okay. Briefly, Carl, I'll just cover why we're doing the interview and some of the rules that we're abiding by. The purpose of the IIT is to establish what happened, to identify probable causes, and to develop lessons learned and make recommendations.

We are not the group that is assigned to find fault or take enforcement action or those kinds of things. We're interviewing people like yourselves, because you are knowledgeable about the regulations and the program that the NRC is running.

We are transcribing it so that -- for essentially two purposes. One, it allows us to have a free discussion, not worry about taking notes and being distracted from your answers to our questions, and also it creates a record that we can refer back to as we prepare

our report.

The transcript will be available for you to review, make corrections, and so forth, and that should be by tomorrow we would have that available. So if you could notify Cheri Siegel who is our administrative contact when you would like to come and review it, we'll make it available to yo.

At the end I'll hand you a sheet that has all of those good words on it, and also Cherie's telephone number.

At the conclusion, the record will probably be made publicly available and put into the PDR, so that you're aware of that. With that, I'd like to begin the questions. Then when I'm through with questions, I'll ask the team whether they have any further questions.

One of the issues that we're dealing with with this particular incident is the fact that MIT did not report this to the NRC, and we didn't learn about it for approximately two months after it first occurred. So we're looking at the reporting requirements, whether they covered this incident, whether they should have covered this incident.

I'd like to focus first on 20.2201(a), which is a regulation that covers theft and loss of material. I guess I'd like your view as to whether it was ever

intended that this section apply to diversions of licensed materials for an unauthorized purpose.

DR. PAPERIELLO: I would offer the opinion, yes, although you would need an attorney who would probably give you a better opinion than me. If I take a look at the words, and the words say lost, stolen or missing, I would consider that pretty comprehensive. It's gone for a reason you don't -- for which you don't have a cause.

They lost it. It's missing or somebody took it. I had it, and now I don't have it, I think. So, therefore, if it was diverted for an unauthorized purpose, I think, my opinion, it's covered by those words. That may not be a lawyer's interpretation.

MR. GLENN: Would it make a difference if the material appears -- if the theft occurred, but the material appears to be found? In particular, I'm thinking that, if there's an inventory discrepancy which is discovered, but there is also an uptake and an individual which is approximately the same size as that uptake, would that essentially say, yes, there may have been missing material. There may have been a theft. There may have been a loss, but we now know where that material eventually ended up.

DR. PAPERIELLO: I don't know. You would have

to cover that with an attorney. I could offer an opinion. I'd say, yes, that you could say that's the answer I'd like it to be, and I couldn't tell you.

MR. GLENN: Okay. Although it doesn't appear to be a factor in this case --

DR. PAPERIELLO: Let me give you an analogy. Let's suppose I lost a seed -- okay? -- and I later found it, and it was not in an unrestricted area. It wasn't in one corner of the safe. It was another corner of the safe. I would not expect that to be reported. That's why -- you know.

MR. GLENN: Okay. My next question, actually, I guess, wants to refine that a little bit more. Although we aren't talking about a major quantity of material that was unaccounted for here, there is a reference in the reporting requirement that refers to exposure to persons in an unrestricted area.

In this case, where it was an occupationally exposed individual who had the uptake, the question would be: Do you think the regulation is referring to the right distinction there? Should it be in an unrestricted area or should it be to a member of the public?

DR. PAPERIELLO: No. I think it was intended that the material was lost and it could be in the public domain. It's lost again from one corner of a safe to

another corner of the safe, it couldn't result in something bad. So I think the words were intended to be there.

MR. GLENN: So it's more the control of material rather than who might have been exposed?

DR. PAPERIELLO: That's right.

MR. GLENN: Are there any questions on that section of the regulations? Okay. I'd like to move on now to 20.2202(b) and, I guess, 2202 in general, but this is the 24-hour period reporting, and this was the one that we were taking a particular look at to see whether they should have, in the very early stages, given that they didn't conclude at the end that we had an overexposure, but in the early days could they have been that sure of it. So we took a good, careful look at 2202(b).

One issue that the licensee has raised is that the notification requirement talks about an exposure to an individual to receive in a period of 24 hours a total effective dose equivalent exceeding 5 rems. They point out that an internal dose is delivered over a period of time greater than 24 hours. So that would preclude having to report a single episode internal exposure. Do you have a view on that one?

DR. PAPERIELLO: Let me think about that one. I'm checking the definition of a what a total equivalent -

- Yes. My opinion is, if you ingest a material that gives you a -- in 24 hours that gives you a total effective dose equivalent of 5 rem, it's reportable. The total effective dose includes committed dose, and committed dose is delivered over a longer period of time.

So, therefore, I think the licensee's interpretation is wrong. The fact that the dose is protracted is still covered. Total effective dose equivalent includes committed dose equivalent, which we know is protracted.

So the question is: I have an ingestion in 24 hours of material that is going to give me a committed dose equivalent of 5 rem or more is 24 hours.

MR. GLENN: And is that clear in the regulations with respect to at least annual dose?

DR. PAPERIELLO: Say again.

MR. GLENN: Are the regulations clear that committed effective dose equivalent is accounted for in the annual dose in the year the uptake occurs?

DR. PAPERIELLO: I think so.

MR. GLENN: Part 2 of this same section refers to a release of radioactive material inside or outside a restricted area. Do you consider a spill to be a release?

DR. PAPERIELLO: Yes.

MR. GLENN: Do you consider an accidental

ingestion to be a release?

DR. PAPERIELLO: Probably not.

MR. GLENN: Okay. Would you consider an intentional intake caused by a licensee employee to be a release?

DR. PAPERIELLO: Probably not, not within the context of this being written. This was written with the intent of an airborne or a splash.

MR. GLENN: Next, I'd like to --

DR. PAPERIELLO: If you look at the training manual, it's implied in there, too, when you talk about annual limits of intake and the like.

MR. GLENN: Could you be a little clearer in your reference to training manual?

DR. PAPERIELLO: Yes. Give me a -- If an individual had been in that location for 24 hours and could have had an intake greater than the annual limit of intake to licensee -- This is page -- There's no page number -- 22.2202-6, REV0793; but you could infer it.

I've always assumed this to be a liquid or an airborne release, not a deliberate ingestion. I don't think we considered deliberate ingestion when we wrote Part 20.

MR. GLENN: There is also a requirement in 20.2203(a)(3) that is sort of a general catchall that says

a licensee shall submit a written report 30 days after learning of any consequence -- levels of radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license or an unrestricted area in excess of 10 times any applicable limit set forth in this part of the license.

Would you think that is referring to rather expressed limits that are in a license condition?

DR. PAPERIELLO: Let me check that again. My reading, and just saying reading what the words, that it deals with the limit in the license and doesn't say anywhere else; whereas, in the unrestricted area it's in excess of ten -- set forth in this part or in the license, and we don't use that thing in the thing above. I think the reason why it's not used in the above, because in the restricted area you can go up to extremely high.

There's limits. I mean, I can go up to 500 rem per hour, and now I've got a very high radiation area. In other words, you have radiation area, high radiation areas and very high radiation areas. So there's really no limit on concentrations of either doses or airborne or dose rate in a restricted area, but there are extra controls you have to put on a restricted area as the numbers go up.

So it's not really -- It would only be the

license condition. There are no limits in a restricted area.

MR. GLENN: In particular, could this be interpreted to be applied to, say, a use other than the authorized use on the license? Do you think, if the purpose for which they're using it differs from what's on the license, could be stretched to cover that?

DR. PAPERIELLO: I have no opinion on that.

MR. GLENN: Sort of a catchall question before we leave the reporting requirement: Would you -- Do you feel that a requirement to promptly report any situation that a licensee believes resulted in the deliberate exposure to an individual outside of their assigned duties should be reported?

DR. PAPERIELLO: Yes. That rulemaking has been initiated.

MR. GLENN: Would you set a threshold for that reporting?

DR. PAPERIELLO: At this point, no. We're not.

MR. GLENN: Okay. Any follow-up questions on reporting from other members of the team?

MS. ULLRICH: No.

MR. GLENN: Okay. I'd like now to get into an area of control of access to licensed material, and

particularly in some of the definitions of restricted area, unrestricted area, controlled area. I'll preface this by letting you know that the Radiation Safety Officer at MIT in his interview essentially indicated that the laboratories where beta emitters are used really aren't restricted areas, that they do their work in controlled areas. He characterized these as controlled areas, not restricted areas.

So that is sort of the thrust of the questions that we're asking.

MR. MADISON: First, maybe we should ask if Carl would agree with that interpretation.

DR. PAPERIELLO: I'd have to give that some thought. In the materials program we've had a lot of problems with the definition of controlled area, and if they were -- If we have the example here of where the concept of a controlled area, which means something in a reactor space, was abused, I think that's going to be a lessons learned out of this.

That's interesting. I don't have an answer for you.

MR. GLENN: Okay. I've got some specific questions. We can look at them. You may want to just pass on this.

DR. PAPERIELLO: This has been a historic sore

point with exactly how you can used controlled areas. We had a TAR, which might be applicable. That is, the control of a stairwell in a hospital as a controlled area, so they could avoid imposing the 2 millirem per hour restriction on an unrestricted area, and OGC's determination was that that stairwell could not be a controlled area, because there was no positive control.

Now I'm dealing with memory on this, and I think, if it's controlled, you had damn well control it, and OGC's control was almost as tough as restricted. You lock it or you use a guard. I'm dealing with memory now. I think we'll have to dig that reference out, because I don't see where it makes a difference.

If you call it a controlled area and somebody can wander in unbeknownst to you, it's not controlled. Again, I'm depending on my memory on that case.

MR. GLENN: You don't happen to remember the name of the licensee? We did ask for TAR's --

DR. PAPERIELLO: It was somebody in Philadelphia.

MR. GLENN: Philadelphia? Okay. We can determine whether that's --

DR. PAPERIELLO: It's a Region 1 case. It's a hospital in Philadelphia, something in the last year, maybe year and a half. Okay.

MR. GLENN: One thing, in looking through the regulations Subpart G, which is talking about high radiation areas -- It's clear there that a high radiation area would have to be a restricted area. Are you aware in Part 20 of any other parts where, essentially, the regulation says you have to treat this as a restricted area?

DR. PAPERIELLO: Off the top of my head, no, John.

MR. GLENN: Okay. I think you've already given us some views in terms of what should be the restrictions to make an area a restricted area.

DR. PAPERIELLO: May I read the Training Manual, page -- This is 2103-127. It gives an example -- no, explanations. "You are not permitted to enter a radiological restricted area without authorization. If you are expected to receive a dose which exceeds 10 percent of the occupational limits, you will need some form of dosimetry. You may be escorted or provided with training for unescorted access, as specified in 10 CFR, Part 19."

Therefore, if you enter a restricted area, you have to be authorized, and it means you are either escorted or you are trained, and I think that's pretty much the traditional interpretation of that requirement.

MR. GLENN: That appears rather clear cut, that there should not be wandering visitors coming through.

DR. PAPERIELLO: If I am correct in the OGC interpretation of the controlled area, it is almost the same except you may allow a person to enter a controlled area without an escort, but they still have to be authorized. I mean, you have to have some kind of positive control, the example being in a nuclear power plant where you could go above 2 MR per hour, but you know people normally can't get in there, because of fences, doors and things like that.

MR. GLENN: Okay. Now I'd like to explore a little bit 20.1801, 20.1802, which are regulations that talk about what has to be done as far as securing and controlling material that's either in storage or in use in an unrestricted area.

MR. MADISON: I think you missed one question you were going to ask in that area.

MR. GLENN: Oh, I'm sorry.

MR. MADISON: The last question.

MR. GLENN: Yes. Before we leave restricted area, to your knowledge, are licensees required to identify restricted, controlled, and uncontrolled areas in their license applications?

DR. PAPERIELLO: I don't know.

MR. GLENN: Then getting to the control of the material, the regulations make it clear that if material is in storage, it's got to be secured against unauthorized removal. If it's not in storage, then it has to be under constant surveillance.

Again, going back to MIT's statement about their work areas, is it permissible to work with licensed materials in an unrestricted area, provided the dose to a member of the public will not exceed 2 milligram in an hour or 100 milligram in a year?

DR. PAPERIELLO: Yes. I'll give you an example: A lexiscope.

MR. GLENN: Okay.

DR. PAPERIELLO: Radiography is a little different. They're not in a restricted area, but you generally rope off a restricted area but, you know, gauges. Material is used outside of material that is, strictly speaking, a restricted area.

MR. GLENN: Okay. The next question just sort of clarifies the difference then between a controlled and an unrestricted area. That would be: Is it permissible to work with licensed materials in a controlled area when the doses could exceed the 2 milligram an hour, but the dose to a member of the public would not exceed 100

milligram in a year?

DR. PAPERIELLO: I'll offer an opinion of yes, but I could be reputed on that. I haven't given it a whole lot of thought, and I can't think of examples outside of a nuclear power plant.

MR. GLENN: Could you express your view of what you would expect in terms of an unrestricted area if licensed materials are, say, out on lab benches, this sort of thing, as to what would be adequate for cost and surveillance?

DR. PAPERIELLO: You see it. You're tied to it. You have your hand on it, and if somebody goes to take it, you can say, stop. You have to be able to physically intervene. Now it doesn't mean a bigger person couldn't -- you know, couldn't remove it from you with violence. I don't think that's ever been the intent, that a person has to be an armed guard.

MR. GLENN: But it would be your expectation that that person -- that the person who is in that position to see the material would, in fact, be instructed to challenge anyone who --

DR. PAPERIELLO: That's right.

MR. GLENN: -- comes up to it.

MR. MADISON: They would always have it in their line of sight.

DR. PAPERIELLO: We have issued civil penalties to radiographers who have removed -- who have gone out of the line of sight of their cameras, for gauge users with gauges. It's agency practice.

MR. GLENN: Could you offer an opinion as to what criteria should be used to determine the material which is stored is secured against an unauthorized removal?

DR. PAPERIELLO: Generally, locked. I would assume for certain -- Depending what the area is, I would assume that if I had a tool room -- I've worked at sheetmetal shops. We had a tool room. Valuable tools were stored in a tool room. If I had a radiographic camera, something which you, you know, can't slip into a pocket, if it was stored in a tool room which is normally locked up except when there's a custodian present and the custodian could stop anybody from walking out with the thing, that would be adequately secured.

I think it's equivalent to, if not an occupational worker, somebody either not allowing it, you know, out of their area or, two, the area, if there's nobody present, being locked up, you know, inaccessible.

MR. GLENN: But if the material were, say, out on -- Well, let me give an example, a material that's stored in a box in a refrigerator which is not locked.

Would you consider that to be secured against unauthorized removal?

DR. PAPERIELLO: No, if the refrigerator was accessible.

MR. MADISON: What do you mean by accessible?

DR. PAPERIELLO: Somebody could -- Somebody who is not an occupational worker, not trained, not authorized to use it, could walk in and pick it up and depart with it.

MR. MADISON: If the building were secured, then would that location then quality?

DR. PAPERIELLO: If the building -- It depends on whether or not the entire building is controlled as a restricted area and what kind of positive controls there are. For example, this building I would not consider to be acceptable. There is no way -- If I had a room, an area, with radioactive sources in this building, I would expect it to be locked up. The fact that we have a guard on the front would not prevent somebody from -- if the area -- put it in their briefcase and walk out the door. We have no radiation monitors. We have no way of being secured.

I mean, I can think of a number of ways. On the other hand, if I had radiation monitors all over the building and you couldn't walk out of the door with a

source, that might make it. It might. I'd have to think about it.

MR. MADISON: That's what we wanted to make clear.

MR. GLENN: Finally, there are posting and labeling requirements in Part 20. In your mind, do they signify a change in the significance of the controls that have to be applied to radioactive material, either in storage or --

DR. PAPERIELLO: Some do, John, but I'd have to go through each one and read the regulations. I don't know what each one -- Obviously, an airborne area means something. Labeling of containers has a threshold. Generally, these are signals to people who are trained. They are not meant to be, I don't believe, signals to people who are untrained and, obviously, an untrained person would not know what an airborne area is, would not know what a radiation area is, a high radiation area is, a very high radiation area is. So I would not assume the postings are very useful signals to people other than people who are trained.

MR. GLENN: Let me see if I can characterize this. Are you saying that the postings themselves are not protective, but they are more to inform the knowledgeable people of what --

DR. PAPERIELLO: That's exactly right. They are not protective. They may be protective, but I don't think they are intended to be protective except to a person that's trained.

MR. GLENN: Okay. A little bit of follow-up on this. We did request some TARs and some guidance, the health physics positions. I would ask you to look -- This is a Technical Assistance Request to the Health and Human Services, and particularly number 3 which is talking about security of materials where it doesn't require labeling under Part 20. So it's material that's less than a Type C quantity.

It appears from this response that the finding has been that, if it's less than a Type C quantity, perhaps the security and constant surveillance can be relaxed.

DR. PAPERIELLO: I don't know whether or not -- I'm beginning to believe or believe that has been a practice. I don't know when it originated, and I don't know what the history and the regulatory basis is, although there is a practical matter.

There's a practical matter the material is going to get to the point below which it can't be measured. So it may be that that ought to be defined in 1801. In fact, I'm of the opinion that 1801 and 1802

ought to have a defined threshold.

I'll give you an example. You inject me with radioactive material for diagnostic purposes. That shot, before it's administered to me, has to be secured. After it's administered to me, I can walk out. Obviously, I do walk out.

I'll give you my example. I had my Valium shot and then urinated in the bathroom of a Burger King across form the hospital after I had a scan or waiting for the next scan two hours later. Obviously, I released -- and we've had problems with people -- hospitals with hot bathrooms. They were contaminated. They were contaminated from patients.

So as a practical matter, we probably ought to define in the regulations as a threshold, although we may have defined a practical threshold.

MR. GLENN: I'd also like you read -- I guess, again, this was supplied by your people. It's question 129 in the Health Physics Physician's Q's and A's. If you could read that, it appears that it is also saying that below a Type C quantity that we would not be applying strict standards.

DR. PAPERIELLO: This thing says here they don't specify quantities of radioactive material which unauthorized access to, unauthorized removal from or the

maintenance of constant surveillance or were not required in controlled areas. Will these requirements be imposed on all quantities, however small, and on quantities which are exempt from labeling? The answer is -- Will they be imposed on all quantities. The answer is, no, they won't be, and (b) -- and the answer is -- and it says here they won't be imposed on things that are exempt from labeling.

Again, there's an issue of practicality. Obviously, if the material is low enough to be released to the unrestricted area as waste, you have one exemption already. So I think it's a point that probably needs to be put on a more official basis.

MR. GLENN: The regulation should be clear, if in fact we are saying there's a threshold. Okay.

DR. PAPERIELLO: But there is a practical problem. The point is it can get so low it can't be measured.

MR. GLENN: Any other questions on the restricted/unrestricted security of areas? Okay.

Another issue that came up at MIT is licensed material accountability. What we found is there's very good accountability when material comes into the institution. It goes to the Radiation Protection Office. The ordering of material is well controlled. The material is delivered by the Radiation Safety Office to the

principal investigator, but at that point the controls became much more lax, although in the end there is an accountability for material that's disposed of, whether it goes into the sewer, whether it goes into solid waste, liquid waste, and so forth.

To your knowledge, is a licensee expected to have a detailed material balance that shows a chain of custody from receipt of material until it's transferred or disposal?

DR. PAPERIELLO: Not in 10 CFR.

MR. GLENN: Are you aware of any regulations which require a running or periodic inventory of licensed material?

DR. PAPERIELLO: What I'm looking for is to see what we have put in the licensing guide. Page 22, a draft regulatory guide, DG0005, states: "Applicants should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material, account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to ensure that licensed possession limits are not exceeded and material is accounted for throughout the institution at any given time."

I deal with practicalities. I think, certainly, until recently you couldn't do it except with a LAN. It can be done now. I've seen software demonstrated at a Health Physics meeting this summer with mixed results. Some institutions hated it, and some loved it.

So my guess is we're coming into an era where you could do it, but there are limits. I'll give you an example. The standard dose of I-131 for hyperthyroidism is about 10-15 millicuries. The annual limit of intake is 30 microcuries. I could easily divert one percent of the material, and it would be undetected, and there is no way you can measure that accurately.

So the reality of it is you can't. There's limits on what you can do. Furthermore, I'll give you practicality. We have very stringent MC&A requirements for SNM, high enriched SNM. They're much lower and less restricted for low enriched. So I would say the agency has made a practical -- some practical decisions.

The regulations do not require you to keep a detailed balance. We wrote guidance here, but I'll tell you, until recently you couldn't do it. In fact, when this was written, I'm not sure I've ever seen a demonstration of a large university. You would take a LAN, and I just don't know whether the software exists.

So I think the intent was that the material is

only received by authorized users. It is disposed of properly. You don't exceed your possession limits, and I think we've generally interpreted that, if you had controls that you couldn't exceed your possession limit, that was adequate.

I still don't think -- I think there's still practical limits on what you could do. I mean, we go crazy, and that's a euphemism. There's a lot of stress in the MC&A area for SNM from MUF and the like; and if we had to do this with byproduct material, it would be extremely hard to implement, and I don't think it would preclude the kind of diversion that might have occurred at MIT.

If I have 40 millicuries or 20 millicuries of P-32 in a bottle and I divert a couple percent of it, I do not think you're going to be able to detect it. It would have to be a discrete container, and that's not necessarily the way the material is going to be acquired.

Of course, trying to do the decay is a nightmare, and the question is some of the vendors, when they sell it to you, give you more than you order.

MR. GLENN: One thing that, again, the RSO at MIT pointed out to us is that, I guess, it's common practice for the vendors to essentially have a batch that's put on the shelf. It's calibrated for a day. That day is in the future, and so the material when it's

transferred, in fact, is sold at least on the basis of an activity that is smaller than the shipped activity.

DR. PAPERIELLO: I mean, we should take note. The bulk of the loose radioisotopes used in the United States are used in medicine. All of our large manufacturing firms are all radiopharmaceutical houses, and I don't think as a practical matter you could do it.

Oh, I think you could try to do it, but I don't think right now the software, the analytical equipment, is good enough to turn around and prevent small diversions of material. It just can't be done.

MR. GLENN: Do you think it would be practical to set some kind of threshold for essentially detectability of diversion such as one ALI?

DR. PAPERIELLO: No. Again, I gave you the example, iodine 131. An ALI is 30 microcuries. A standard therapy dose for hyperthyroidism is 10-15 millicuries. Now, granted, a lot of this is done in capsules, but it can be done with liquid. Large institutions are going to have liquids, and you can divert one ALI too easily -- area of medical isotopes, which are the bulk of them. I mean, you know, that's the problem.

It sounds like you would like to be able to do it, but what's an ALI of plutonium? Would you apply this to all people with SNM? They couldn't do it, because an

ALI is far below their MUF limits. I mean, I'm just saying, people need to -- I read your question on the sheet, but people need to realize there are practical problems.

MR. GLENN: Do you think there's a potential for a threshold perhaps based on percentage of material in a container, that sort of thing? I'll give you an example.

DR. PAPERIELLO: You would probably have to set it high enough that it would make -- that it would be almost useless in terms of protecting public health and safety. John, you're going to have to -- You're stuck with about 10 or 20 percent, just because of the fact that what is the capability to assay?

Granted, you can assay to one or two percent, but that takes -- You know that takes a humongous effort to measure that accurately, and if you've got something that is decaying with a relatively short half-life, which most medical isotopes do, you can't do it. What's the limit on a dose calibrater? Ten percent.

I don't think -- You can do it. I don't think it would do anything to protect public health and safety. Besides, take a look at sealed source and device requirements. You have to do inventory, not continually. You got to do inventory every three months or every six

months, and you can do far more damage with a radiographer source than you can with a -- you know, this sort of thing.

You know, it sounds good. It's just, the question is, when you start looking at the practical part of it, you just can't really do it; and if you did do it to the practical way you could measure, it wouldn't prevent the diversion of small quantities of material.

MR. GLENN: Do you think there could be a practical at least beneficial effect, although you might not be able to detect it, by, say, requiring better logging in and out of material for commonly held isotopes?

DR. PAPERIELLO: If the LAN based systems get to be better and reliable, that would probably be an answer. On the other hand -- and that might be somewhat meritorious, but again there's real limits.

Let me give you an example. MIT has a reactor. Does that mean that we would require them to assay to what degree of accuracy anything they irradiated in the reactor? I'm just saying, that would be a real practical -- You start getting into some -- I'm up against the practical problems.

We have periodic inventory of sealed sources, but they're discrete. You can count them. You can look at them. You know, you measure them once and they stay

there, and you can decay them. When you start dealing with loose isotopes, the practical problems become very, very great, and we've only attempted to do it, for the most part, for either plutonium or highly enriched uranium, and even there it creates tremendous, very expensive problems.

MR. GLENN: A complicating factor in this case is also, not only is it difficult to assay the material in terms of activity, but the volumes are extremely small. We're talking microliters of material.

DR. PAPERIELLO: Well, that's exactly a point. I'll give you an example. I have a liquid solution for hyperthyroidism. I give it to the patient. I don't know if they rinse out the bottle after they use it, you know, into the patient's dose, but I'll be you, you could turn around and take the container and rinse it out and rinse out more than an ALI.

MR. GLENN: Okay. Any questions from the rest of the team on that area?

MS. ULLRICH: No.

MR. GLENN: Okay. The final aspect I'd like to review with you is organizational oversight. I will tell you that, in terms of our interviews at MIT, the Radiation Safety Committee members did not believe they had very much of an oversight role of the Radiation

Protection Office. They believed they were there to support the Radiation Protection Office.

When we inquired about annual audits and this sort of thing, the members said, no, that was not what they considered to be a duty of the Radiation Safety Committee. I was wondering if you could just comment a little bit on the role that you would expect a Radiation Safety Committee to exercise at a licensed program of broad scope?

DR. PAPERIELLO: Part 35 as written today is weak, both in terms of the radiation safety officer and the radiation safety committee. Part 35 for medical institutions is pretty strong, and --

MR. GLENN: Let me just clarify. I think you said Part 35 in the first quote. You were referring to Part 33?

DR. PAPERIELLO: Part 33 today for broad scope is pretty weak. Part 35 is pretty strong. Your -- The licensing guide, the draft licensing guide is reasonably strong, not as strong as Part 35, but certainly stronger than Part 33.

That would argue that there our -- at least as of 1994 when this thing was written, that our intent was that the radiation safety committee have -- It says conduct periodic reviews and audit of the Radiation Safety

Program and devote sufficient time, along with the Radiation Safety Officer and the Radiation Safety Officer staff, to review records, reports from the RSO, results of NRC inspections, and written safety procedures, along with observing audit performed by the RSO and Radiation Safety staff.

There's more in here. So there's certainly far more in the licensing guide than there is in the regulations, and it is pretty consistent with Part 35. Part 35 is for medical institutions, and there's certain unique features of medical institutions that wouldn't be applicable in general with broad scope.

MR. GLENN: What role do you expect the Radiological Safety Officer and any people who work directly under him to exercise in a licensed program with broad scope?

DR. PAPERIELLO: Much of the role of an NRC inspector, but that's not what Part 33 says, although again the licensing guide, Appendix H, has rather strong guidelines for the Radiation Safety Officer in terms of actually controlling -- That's not in Part 33.

MR. GLENN: I guess one thing we were hearing is that the Radiation Safety Office sometimes considered that they have sort of a dual role. One is this audit function of the permitees. The other one is a service

organization to the users of isotopes. Do you see an inherent conflict in those two roles?

DR. PAPERIELLO: No.

MR. GLENN: What would you expect the authorized user, permit holder under a broad scope license to exercise -- particularly in terms of cont ol of material and accountability of material?

DR. PAPERIELLO: The authorized user should follow the requirements of the permit which, for him or her, provides the -- to act on the basis of a license, and they would be required to adhere to any other -- all and applicable NRC requirements and license conditions; and the training program of the licensee should be such that the authorizer user becomes knowledgeable of all the applicable requirements and license conditions that are applicable to that particular person.

I wouldn't expect an authorized user of millicurie quantities of tritium or C-14 to know about radiography or worry about at what threshold you post, you know, radiation areas, because you're not going to have a radiation area if you're using a -- So I mean, but they should have sufficient knowledge of those regulations that are applicable to that particular operation.

It is the Radiation Safety Officer's job and the committee's job to not let anybody become an

authorized user until they have the information that they need for the scope of their operation. I mean, it's much like what we would do when we issue a license.

I don't expect a gauge user, for example, to have knowledge of bioassay, you know. You're not dealing with quantities. You're not dealing with loose material, but I do expect you to know those things which are applicable to a sealed source.

I wouldn't expect them to be able to control a very high radiation area, because a moisture density gauge is never going to create a very high radiation area. So -- and I generally consider the authorized user to be in the same level of responsibility.

MR. GLENN: Do you see the authorized user being able to delegate some of his authority to, say, lab managers and to scientists who work under his supervision

DR. PAPERIELLO: That is an interesting question. John, I don't know. The answer, practically, is yes. Part 35 is fairly stringent on what supervision -- what we mean by supervision. So for a physician who supervises the lab techs, it's not clear that we have that spelled out any other way, but we deal with practicalities. In nuclear power plants it's done all the time.

I mean, but again you have a very formal

training program. You have defined procedures. I think a licensee can do it, can delegate it, but there has to be procedures. You can't delegate responsibility. Remember the general rule. I can delegate authority; I can't delegate responsibility.

I read an inspection report recently where it said the authorized user is ultimately responsible, and I said take that out. The ultimate responsibility is with the institution. He can't delegate ultimate responsibility.

That may be where the burden falls, but the institution is required to ensure that it can happen. So I guess -- I don't think we have ever defined limits on delegation by the authorized user. However, the licensee ought to have it in their procedures, and whatever they delegate, they still can't delegate responsibility.

So, therefore, if I delegate to a person in the laboratory the responsibility to do the daily surveys, I had better ensure by checking that the surveys are done.

MR. GLENN: So you would expect the authorized user maybe not to do all of these things but to have a system in place that allowed him to verify that they were completed?

DR. PAPERIELLO: If the authorized user is a physician and they are practicing nuclear medicine, I

expect the technologists are going to be injecting the patients and preparing the doses. That's what happens, but the authorized user -- There has to be a system in place to know that the patients are getting the material that is prescribed.

You know, I can't think of every, you know, configuration you could possibly get yourself in.

MR. GLENN: Well, I guess one of our observations at MIT was that many of the individuals working under the permit of the authorized user are very senior scientists themselves who are working long hours with middle of the night, weekends and so forth, without much opportunity for direct supervision.

MR. MADISON: They've actually got a distinction where they call the -- what you're calling the authorized user, they call the principal investigator, and they call those post doctoral fellows that are doing the research authorized users.

MR. GLENN: Okay. Any clarifying questions in that particular area?

Finally, are you aware of any guidance that would alert broad scope licensees that they need to address deliberate acts as a part of their emergency response?

DR. PAPERIELLO: No.

MR. GLENN: Do you think it's a good idea?

DR. PAPERIELLO: I don't know where to draw the line. I'll give you an example. I'll go back to the iodine 131. I'm a physician. I divert 100 microcuries of I-131 from the patient dose, and I go into the supermarket and I smear it on grapes.

Now you could say that's irrational. To me, how do you deter an irrational -- an apparently irrational act by a person in a position of high responsibility?

I'll give you another example. The physician does not divert iodine 131. The physician diverts a chemotherapy agent, a chemotherapy agent that are radiopneumonic. You will do the same damage to an individual from low doses of chemotherapy agent as you will with radioiodine or any radioactive material. It will probably never be detected.

What happens if a person puts the radioactive material in an area where it's never going to be detected? I mean, there's a real -- In other words, if you say dealing with deliberate acts, it ought to be encompassed within the framework of accidental acts; but I don't know.

When you raise that, the number of possibilities becomes infinite. I turn around and my deliberate act is I pick up my generator which has a lead shield and beat somebody on the head with it. I mean, you

know, the real problem I have -- It sounds like, well, you ought to, but the problem comes down to is where do you draw the line. What configuration do you protect yourself against?

MR. GLENN: Let me refine that question a little bit.

DR. PAPERIELLO: We drew a limit on emergency plans in Part 30. If you possess above a certain amount of material, you need an emergency plan. If you possess less than that, you don't. The agency made a considered decision, and it's based on inadvertent. It's not based on deliberate.

If you redefine the line, you could do that, make that act, but then where do you draw that; and I don't know of a good place to draw the thing, and you get yourself into again impossible configurations. I have to be able to detect the diversion of 100 microcuries of iodine out of a 15 millicurie dose. The answer is you can't do it.

MR. GLENN: Yes. Let me refine the question a little bit and focus on once a licensee has come to believe that it's possible that there's been a deliberate act, do they need to change their emphasis a little bit, because now the threat perhaps is more into the potential, but the consequences of the act they've detected aren't so

great; but now that you know there is someone out there who is willing to do this, does that in fact increase the threat and they should be prepared to deal with that?

DR. PAPERIELLO: Well, on a practical day to day basis, yes; but theoretically, should Federal buildings have been protected against a terrorist driving up in a Rider van? We do it now, because it happened. What about why not protect them against the crash of a commercial aircraft loaded with explosives?

You know, we deal with credible threats all the time. The problem I have in the byproduct material area, where do you draw the line, particularly when you take a look at most of the loose isotopes are medical, and I'd have to do it all in a medical environment. When I look at the medical environment, if I want to do somebody in, the number of substances that I have available are immensely greater than the number of, you know, radioactive materials that are available.

You know, there's going to be practicalities. Sure, you can do it. How much are you going to spend, and where are you going to draw the line? Since we're in the non-radiological as well as radiological, do I have to do something about abuse of coal kits in the nuclear medicine laboratory?

It's just -- It deals with a practical

problem. Yes, you can do it. The answer is at what cost.

MR. GLENN: Okay. Any other questions from other members of the team? Carl, is there any area we haven't asked you about that you think you would like to give us some advice in?

DR. PAPERIELLO: I'm sure there is. I just don't have it off the top of my head. I have a meeting with my staff at 10:30 that we're going to be looking at regulatory changes in response to both the MIT and the NIH event. It will probably involve again stiffening Part 33's RSO and radiation safety committee requirements to look like what's in Part 35, although as a practical matter, you know, I think the licensing guide already puts that in; but, of course --

MR. GLENN: Is it better to have --

DR. PAPERIELLO: -- you know, you're doing it one at a time. I think we can do something in Part 19. For one thing, we ought to train -- make sure all occupational workers are trained in the deliberate misconduct rule, and also the requirements to be trained in the licensee's security, whatever they may be.

You know, in other words, you don't allow people to wander into your laboratory. You know universities are very free and easy. If it's a restricted area and somebody wanders in that you don't know and is

not an occupational worker, since they're not authorized to be there, you know, you should challenge them, that aspect of the whole thing.

I don't know what else we will come up with.

MR. GLENN: Okay. As I mentioned before, I'm giving you a handout that talks about your right to review the transcript and fill out the errata sheet. I put Cherie Siegel's number on the top there. You can contact her and make arrangements.

At this time it's 10:05, and this interview is concluded.

(Whereupon, the proceedings went off the record at 10:05 a.m.)

C E R T I F I C A T E

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

Name of Proceeding: INT. OF DR. CARL J. PAPERIELLO

Docket Number: (NOT ASSIGNED)

Place of Proceeding: ROCKVILLE, MARYLAND

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

Karina Wood

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