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NUCLEAR REGULATORY COMMISSION

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D I S C L A I M E R

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON STATIC ELIMINATION PROBLEMS

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PUBLIC MEETING

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Nuclear Regulatory Commission

Room 1130

1717 H Street, Northwest

Washington, D.C.

Thursday, Feburary 18, 1988

The Commission met in open session, pursuant to notice, at 2:10 p.m., the Honorable LANDO W. ZECH, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

LANDO W. ZECH, Chairman of the Commission

THOMAS M. ROBERTS, Member of the Commission

FREDERICK M. BERNTHAL, Member of the Commission

[By telephone hook-up]

KENNETH CARR, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

J. HOYLE, Secretary

W. PARLER, OGC

V. STELLO, EDO

DR. FRANK YOUNG, FDA

R. BERNERO

P R O C E E D I N G S

CHAIRMAN ZECH: Good afternoon, ladies and gentlemen. Commissioner Rogers is on travel and will not be with us this afternoon. Commissioner Bernthal is ill at home, but I understand he is on a conference call. Can you hear us, Commissioner Bernthal?

COMMISSIONER BERNTHAL: Yes, but it seems to be coming in and out.

CHAIRMAN ZECH: All right.

COMMISSIONER ROBERTS: I don't know how sick you are, Fred, but I admire your devotion to duty.

[Laughter.]

CHAIRMAN ZECH: All right. And I understand also the five Regions are on, and I presume they have been checked out. Is that right, Mr. Secretary?

MR. HOYLE: Yes, sir, they have been checked out.

CHAIRMAN ZECH: All right. This afternoon's briefing is a status briefing before the Commission. The NRC staff will address the current actions being taken to address the failure of 3M static eliminator devices. On January 21st, 1988, Ashland Chemical Company reported an accident involving radioactive contamination which was traced to a static eliminator device. This device uses high velocity air passing near a polonium 210 radioactive source to ionize the air. The air is used to remove dust from containers.

The device is manufactured under NRC license by Minnesota Mining and Manufacturing Company. Subsequent to the Ashland Chemical report, the NRC has issued three immediately effective orders to Minnesota Mining and Manufacturing Company, one suspending distribution of these devices, and two, involving removal of these devices from use in processes that have the potential for the contamination to be consumed by or applied to humans.

Specifically, food, beverage, cosmetics, and pharmaceutical applications have been suspended, and the devices recalled by the manufacturer in accord with NRC orders. Two additional immediately effective orders have been prepared for issuance today. They direct the 3M Company first to suspend the use of all polonium 210 devices within 30 days. Second, recall all polonium 210 static eliminator devices to 3M within 90 days.

Third, to promptly test the devices for detectable radioactive leakage, and if any is detected, notify the users of the device of the potential for contamination in the workplace. And fourth, to notify the NRC or the agreement state of the leaking device.

A report of compliance with the order and any exceptions is also required by the orders. In cases where safety considerations exist that require the continued use of the devices, the order to the users contains a provision to

allow continued use with suitable monitoring under written approval from the NRC or the agreement state for the specific case. These orders are to be published in the Federal Register in approximately five working days.

The NRC has been and continues to work closely with the Food and Drug Administration and with the agreement states to assure that all available actions are being taken to protect the public and workers. Dr. Frank Young, Administrator of the Food and Drug Administration, is here with us today, as he was last week, when the Commission was briefed on these facilities.

We welcome you, Dr. Young, and we appreciate your being with us today.

DR. YOUNG: Thank you.

CHAIRMAN ZECH: I urge the staff and the FDA to continue to work together to assure that we are doing all that we can to protect health and safety.

Do my fellow Commissioners have any opening remarks to make?

[No response.]

CHAIRMAN ZECH: If not, Mr. Stello, you may proceed.

MR. STELLO: Thank you, Mr. Chairman. As you have already indicated, we are pleased to have Dr. Young with us again today, and I have Mr. Bernero with me, who has been following this essentially full-time, seven days a week, to understand the full significance of the issue that we are faced

with.

You have already indicated that you had approved an order and you described the context of that order, and it has in fact been signed, and a copy had been sent to 3M, and the remaining order -- orders will be placed in the Federal Register, as you indicated, in about five days.

We expect that this will be a problem that will be with us, as we indicated last time, for some time. The number of devices is large. The number of facilities where we have found contamination continues to grow. Our purpose today is to brief you on where we stand with respect to our knowledge of the problem, what we have done about it, and what more remains.

With that, I will turn to Mr. Bernero to give you a brief status, and that will be followed by some remarks by Dr. Young.

CHAIRMAN ZECH: All right. Thank you very much. Mr. Bernero, you may begin.

MR. BERNERO: Thank you, Mr. Chairman.

May I have the first slide, please?

[SLIDE.]

MR. BERNERO: I have a slide here just to refresh your memories on the licensing basis or the requirements for a generally licensed device such as we are talking about here. The regulations, and these are rather old regulations -- they go back many years. A device for general licensing has four

key provisions. It should be safely handled by persons who are not specifically trained in radiological safety, and under ordinary conditions, nothing should be released. The radioactive material should be closely or tightly held.

In addition, there are two other requirements that relate to the direct radiation in normal use and the release or dosage in case of fire. They aren't really pertinent here and I don't intend to dwell on them. The 3M license, which is a specific license authorizing general license distribution is also an old proceeding. It goes back to 1965. And I must say that in the record of the licensing as best we can understand it -- obviously, going back so many years you have different people who are no longer with us -- I think it was clear that there was an understood potential for some leakage, no barrier could be perfect if you have an adhesive of these microspheres, but it was not expected to have releases under ordinary conditions. That is the best we can interpret the entire record, although I just say there is no explicit numerical criterion on what constitutes acceptable leakage, there is no thousandth of a percent or one in a million or any number like that.

The license in question or licenses were expanded to multiple devices with increased reporting requirements in 1978, about a decade after they were first issued. I include a picture of the microsphere just to refresh your memories.

Remember, this is the key safety system where the radioactive material is tightly held in this particle so that even if it is released the public risk is not great, because the microsphere is a rather robust form, it is a little too large to be breathed, and it is also quite insoluble, and there are solubility data in the licensing record to support that.

May I have the next slide, please?

[SLIDE.]

MR. BERNERO: You reviewed some of the chronology. I have two slides here, Number 1 and Number 2, of chronology, and all I would like to say is, rather than go into the specifics of the order which you already summarized, I would like to characterize the thrust of the investigation. At the very beginning it appeared, since this was a chemical works and an isolated report, it appeared that we were dealing with an exceptional case, and if you read the order, if you read the record, if you were involved at all in the discussions at the time, there was an appearance of focusing on an exceptional case and as the data grew and this first chronology sheet shows more failure data coming in in the weeks following the initial report and the initial investigation, it led us to the concern toward more widespread application, but still focused on the compressed air devices.

The even numbered, 902, 902F, 906, and 908, are the serial numbers of the static elimination devices used with

compressed air, the highest velocity.

Still, the focus was on exceptional cases or exceptional circumstances with an alarming increase in the number. The food, beverage, cosmetic, and pharmaceutical uses, packaging, that we encountered, and we are finding failures there, that raised a concern with our sister agency, the FDA, and of course a great deal of priority given to pursue those applications, one, to find and stop the leakers, and secondly, to examine the products wherever they were actually or potentially contaminated.

May I have the next slide, please?

[SLIDE.]

MR. BERNERO: If you go to the second chronology, 3M, in accordance with the first order, submitted to us a letter report containing a plan on February 8th, and there was a subsequent meeting on that plan on February 11th.

The February 8th report had a body of data that was available to 3M apparently at that time, and their focus was on environmental causes, the situations in which the devices were being used. I will show you one of their data sheets in a moment.

Their plan, which I have also reproduced for your reference in a subsequent slide, was a minimal one focusing on the possible misapplication of some devices. In other words, they have a position called static analyst, a person who looks

at the application in the field to see that it is suitable for the device and there could have been misapplied devices, again the focus on exceptional circumstances.

The meeting on the 11th, we discussed those materials. The 3M top management was present. They did not have any more data to offer but they requested access to the data we had. By that time, the resources and field work being done by the NRC, by the agreement states and by the FDA, was producing a preponderance of data that was not immediately and directly available to 3M, because we were out getting it or the states were out getting it.

We agreed to have technical staff of the states, NRC and 3M pool this data, and that meeting is taking place tomorrow, and in discussing the plan of action, 3M agreed to submit a more detailed plan by February 26th, which is two weeks after the meeting.

Now, as we continued all last week, we got more and more data. Remember, the first order suspended the distribution of the compressed air devices in food, beverage, cosmetics and pharmaceutical, but did not withdraw the existing ones. What we did in order number three on February 12th, and I must say at the February 11th meeting, 3M said it was their intention to do this, we withdrew all models of all the devices from production and packaging of food, beverage, cosmetics and pharmaceutical products.

If you look at the next sheet, this is a table drawn directly from the 3M February 8th report, if you look at the upper cross line, bottling industry, they were analyzing by industry application, and you see a distribution of failure in bottling that seems to be significantly higher than the occasions of failure in other applications.

Also, if one looks at the food industry, over on the righthand side, you see 30 with a footnote "4" and 3 with a footnote "5," the data there was puzzling because there were situations where contamination was not found on the nozzle, but was found in the plant, and so there appeared to be some sort of failure patterns there.

Again, the focus here was on adverse environment that would be exceptional, not typical.

The plan that I mentioned earlier is this next slide. This is lifted verbatim from the report of February 8th by 3M.

[SLIDE.]

MR. BERNERO: You can see by perusal of it that it is fundamentally reviewing the list of distribution, improving product literature, improving static analysts' training in order to weed out exceptional causes of failure.

[SLIDE.]

MR. BERNERO: In the meanwhile, the NRC staff sent an inspection team up to 3M and gathered the data from their own records. What I have here is a table which was used in our

February 11th meeting. I have added a few notes to it for your information.

Basically, for the distribution set that was distributed in 1986, from the 1986 reports. If you look at the prices, they are broken down by model number into the brackets of compressed air use, static bars and blown air. The numbers are representative. 1987 would have been somewhat different and 1988 even different still. The basic distribution of devices is rather significant, I think.

Fifty-seven percent of all the devices are compressed air; 34 percent are static bars and only 8 percent are blown air.

From the 3M records, the next column, we found detectable leakage at the plant, at the 3M plant of these devices as listed, but as reported, the two columns on the righthand side, were data that was analyzed and then filtered in a way by saying, well, there was a damaging environment, so that accounts for the release and therefore it is not a leaking device, it is a damaged device. 3M made that distinction.

In addition, 3M had a procedure for sampling in the plant we found inadequate. They have since corrected it, after this inspection. As a result, one must look at the raw data in the more or less center column, the number leaking "all," that column, as equal to or greater than data, that if a proper procedure had been used, not only would the ones listed have

shown up as leakers but probably more. It had to do with a screening swipe that had sort of a decontaminating effect.

CHAIRMAN ZECH: Were we aware of this definition they were using, this criteria they were using for leaking devices as far as calling some damaged and some undamaged?

MR. BERNERO: Not until we did this inspection and analyzed the data that you see. They were informed of that at the time.

The thing to see here is when we go back to this data, which may be an under call, we see the distribution involving other model numbers and the rather interesting thing, for most of them, it is about a tenth of a percent failure rate that is reported.

With that, we used this list, recognizing the frailty of the data, we used this list as a source --

CHAIRMAN ZECH: Where do you see a tenth of a percent?

MR. BERNERO: The numbers in brackets, .04 percent, .7 percent and so on, those numbers represent a failure rate obtained by comparing 5 to 13,138 or 62 to 8,700.

CHAIRMAN ZECH: It looks to me like .9.

MR. BERNERO: Yes, it is between half a percent and a tenth of a percent. I just rounded it off.

CHAIRMAN ZECH: If it is .9, it is about one percent.

MR. BERNERO: Yes, it could be as high as one

percent. It is as low as .04 percent. Most of them are in the cluster of a half to one.

CHAIRMAN ZECH: Do we consider one high? That seems to me to be something we should be concerned with.

MR. BERNERO: The concerns that one gets looking at these data, the concerns are that in the first place, it is getting close to the failure level certainly that one would say, hey, that's too much, that can't represent ordinary conditions. It is distributed over other model numbers. It is not merely in the compressed air devices.

CHAIRMAN ZECH: Were we aware of these percentages, almost one percent? When were we first aware of that?

MR. BERNERO: I would say we found this out in the last two weeks, about a week and a half ago.

CHAIRMAN ZECH: Is there anything in our regulations that require a certain number as far as a leakage percentage or do we require any reports from them if it looks to them like the leakage is higher than it should be?

MR. BERNERO: We require reports at .005 microcuries detected activity released. That derives from the regulations. That is not the detectable level. There is no criterion either in the license or in the regulations that says what percentage of leaking devices constitutes unacceptability or acceptability.

CHAIRMAN ZECH: Maybe there should be.

MR. BERNERO: The regulations, in that first slide, the regulations just say in ordinary use, the material should not be released.

CHAIRMAN ZECH: Maybe there should be. I assume you will look at this.

MR. BERNERO: It is something we will definitely look at.

The other thing that I would point out as a cause for concern looking at this data is if the models are so different, than we have a lot broader problem than the focus we had at the beginning of focusing on the compressed air models and the exceptional case.

[SLIDE.]

MR. BERNERO: The next two sheets are a list that we have tried to keep available to you as we went along. It is a list of sites with failed devices. If you look at the footnote on the lower right, contamination at these facilities exceeded .005 microcuries. That is 11,000 disintegrations per minute. That's the reportability criterion in the regulations. We use it as a threshold to sort this list, although we knew there were other facilities where less than that level of contamination was detected, was found, but it was below the reported level.

This is an incomplete list. It changes daily. It does show, however, many diverse applications and different

models of the devices are involved, and what is more troubling is it shows many different, very different pathways for exposure to persons. If you go to the second page, you will see number 37, the Moto Photo Shop in North Dartmouth, Massachusetts. That occurred last Saturday. It was discovered last Saturday. This is one of these photo developing shops you find in a shopping mall.

Our inspectors found quite a bit of contamination leaking from the device used to cut the static on the film that was being developed. It was a compressed air model. How much of it tracked out into the mall or what is just unknown. You can see the many different pathways to man that can be seen. Of course, many of these are food, beverage, cosmetic and pharmaceutical applications.

CHAIRMAN ZECH: Do your orders require all these devices be recalled?

MR. BERNERO: Yes, they do. I am going to give you a summary of the orders.

CHAIRMAN ZECH: The ones on this sheet, the devices are all being recalled?

MR. BERNERO: Yes. They are either recalled immediately, if they are food, beverage, cosmetic and pharmaceutical, they are already recalled and that is in motion, or they are recalled by today's orders on a timeframe if they are other applications, with only a safety exclusion

that I will explain.

One other thing. I haven't even had time to type this up in a usable form. We have had telephone call-ins from the agreement states and in a rough summation of all the agreement states, they have surveyed by now 828 facilities and found detectable contamination, not reportable but detectable contamination at 118 facilities of the 828. That is approximately 15 percent. That of course, would clearly be an unacceptable level of release.

[SLIDE.]

MR. BERNERO: You may recall from a week ago when you were briefed on this, the current safety conclusion was the very thing, and I consciously used the very conclusion, because we are still holding to this conclusion. Based on the data we have at this time, even if these microspheres gained access to the workplace or to the consumer products, it is unlikely there is a significant health hazard to the public. That does not excuse us of vigorous evaluation of the potential safety significance and getting out there to find what is contaminated and to stop it.

In order to do that, we felt, considering the broad range of models and applications involved and the growing failure rates, the more we looked at it, the higher the failure rate appeared to be, we generated the two orders of February 18th that were signed and started out this morning, and the

summary is there are two orders because of the parties involved.

We have one order as to 3M and the other order is to the general licensees using the 3M static elimination devices. In essence, the orders suspend the transfer and use of these devices, recall them to 3M for tests and appropriate use of the test results, and there is an exception in the order for competing safety risks.

[SLIDE.]

MR. BERNERO: I would summarize the orders. The 3M order, and I have tried to paraphrase the five elements of the order --

CHAIRMAN ZECH: You mean the order to 3M?

MR. BERNERO: Yes.

CHAIRMAN ZECH: From NRC?

MR. BERNERO: Yes. The order to 3M from NRC says, first of all, suspend transfer of these devices except as specifically authorized by NRC. Secondly, immediately notify the general licensees. This is the priority way for the general licensee to learn of this. They will get a copy of the orders through 3M in this order clause.

Third, instruct the users to return the devices, you know, the packaging and things like that, identification, as soon as feasible but no more than 90 days from the date of the order.

Fourth, 3M will test the returned devices for leakages, one of the important pieces of data, which may indicate contamination out there in the field that needs to be found, and therefore, the results of the tests where leakage is found, detectable leakage, notify the user who sent the device in, the NRC and the affected agreement state.

Lastly, provide status reports on the progress in doing this at 30 day intervals.

In addition, this order, and I separated it here, is a show cause order. It is an instruction to 3M to show cause in 60 days why this license shouldn't simply be revoked, and then just proceed with the clean-up.

The corollary order to the general licensees, and this is under our regulations, to them, we order suspend the use of the devices. Secondly, send the devices back to 3M within the 90 days, and thirdly, we do leave a loophole, if you will, temporary continuation of use is possible where it is essential for safety. This is fire, explosion or other hazards, in order to suppress it. It would require written approval of the NRC or the agreement state involved and it would be under surveillance to be specified by them. That would be unique to the application. That exception does not apply to food, beverage, cosmetic, pharmaceutical or medical devices. It applies only to what we would call industrial or commercial applications.

COMMISSIONER ROBERTS: Who makes the call on the first element of essential for safety?

MR. BERNERO: The user says, I need it, and has to ask for permission. The order is written to have the affected regional administrator or the affected agreement state authority make the call of whether it is acceptable and the conditions under which it would be acceptable.

Note, it is temporary and it would give an opportunity for alternative courses to be sought, and of course, the time period can be controlled that way.

Keep in mind, the half life of these devices, the half life of the isotope, is relatively short, so that the isotope drops in radioactivity level by approximately a factor of six in one year.

CHAIRMAN ZECH: A half life is what?

MR. BERNERO: 138 days. It really decays rather substantially in a year.

This order is also published in the Federal Register. That is the formal way to promulgate it, but the expeditious distribution of it is through the order to 3M.

CHAIRMAN ZECH: Which we have done?

MR. BERNERO: Yes, that's the fastest way to get it to all.

That's the summary. I would like to turn it over now.

MR. STELLO: Mr. Chairman, with your permission, I will turn to Dr. Young for one comment, but I don't know that the presentation was clear and I would like to make sure it is.

This order is immediately effective. These devices are cease and desist now. The timing of the issues are more with respect to the timing to be returned to 3M.

CHAIRMAN ZECH: I was going to ask about the 30 and 90 days. It is immediately effective?

MR. BERNERO: Yes, to summarize, the food, beverage, cosmetic and pharmaceutical devices are already under order for return by, I believe, it is March 2nd. That is in progress. That is going on right now.

This order recognizes that. It is explicitly recognized. Then what we are dealing with are the rest of the devices, what I call commercial and industrial. Those have as soon as feasible but not longer than 90 days.

CHAIRMAN ZECH: To do what?

MR. BERNERO: To return them. It says cease immediately. Of course, that is going to be a variable time depending on when the individual licensee got the word and so forth.

[Commissioner Roberts left the room at 2:40 p.m.]

CHAIRMAN ZECH: We have given orders now to cease and desist their use.

MR. BERNERO: Yes.

MR. STELLO: Effective immediately.

CHAIRMAN ZECH: Of not only the food and drug type, pharmaceutical, cosmetic devices, but all the others also?

MR. BERNERO: All models, all applications.

CHAIRMAN ZECH: All models, all applications of these devices. The order calls for them to cease with their use immediately and to recall them; is that correct?

MR. STELLO: That is correct.

DR. YOUNG: First of all, Mr. Chairman, I want to thank your staff for the very thorough interaction with our staff and the cooperation that you have given us in the ability to fulfill our mission.

CHAIRMAN ZECH: I appreciate that.

DR. YOUNG: They have done a tremendous job, and I know they have been working around the clock oin it.

CHAIRMAN ZECH: I know they have been working very hard, and I appreciate what you and your people have been doing, too, Doctor. This is our joint responsibility.

DR. YOUNG: Yes, it is.

CHAIRMAN ZECH: And we want to make sure that you get the continued cooperation of our staff. If you don't, please let me know.

DR. YOUNG: They have been very cooperative. And I also fully support your action that is taken to remove these from the marketplace. I think that's particularly relevant,

because I do have a letter that I know the 3M Company sent out as of February 15th, '88, that said if firms believed that the device was imperative for continued use, to contact FDA for approval for that continued use, and I want to state for the record that we fully support your action that no approval of such continuation should be provided.

We have done the following things since our last meeting:

First of all, we have inspected each of the 16 firms that have now been identified, 13 plus the original ones that were on, and have collected samples from 13 of these and completed most of the analyses.

Altogether, we have analyzed over 1300 samples, and we will continue to have our Winchester Laboratory working a two 12-hour shift to deal with this.

We have also divided our products into those that might present a risk and have looked at those first, and then followed up on others that we would think would be less risky.

For example, we were looking first at devices that were in things such as nasal sprays or anything that would go directly into the body, in contrast to lotions or creams, where we know that the penetration of the skin would be low.

We have looked, as your lists have provided, and found about 263 firms that do fall within the Food, Drug and Cosmetic Act that are either producing drugs, biologics,

devices, cosmetics or foods.

Of these, we have found in your plants that had detectable radiation above the limit no samples that were positive.

We have found one fragment of a microsphere in one of the plants that you had detectable activity, but not above the background, and this was very helpful again to have your total list of those that have any detectable activity.

We are going to take the strategy of looking at all of these firms first with those that were detectable and out of compliance. We have found no evidence of contaminated product there. Detectable but not out of compliance, as you define it, and then all other plants. And we will look in that fashion.

We continue to believe, as you have pointed out, from our analyses that there is no evidence of any public health hazard at this time and no hazard to health. Even in the event that an entire microsphere were ingested or an entire microsphere were inhaled, we do not believe, based on the calculations and the calculations that we have received from your agency, lead us to feel very strongly that there would not be a health hazard. And I think the important thing for the American people to realize is that although we are out and going to inspect all of the plants, and though we will examine the samples, we are doing this to provide an extra layer of safety so that we can be sure that there is not that rare gun

out there that may be leaking more than we would anticipate.

We are very comfortable at this time, based on the evidence that we have, that there is neither a hazard to public health or a hazard to individual health.

CHAIRMAN ZECH: Thank you very much, Doctor. Does that complete --

MR. STELLO: That completes our presentation, Mr. Chairman.

CHAIRMAN ZECH: All right. I will ask for comments from my fellow Commissioners. Commissioner Roberts had to leave for a few moments for a previous appointment.

Commissioner Carr, do you have any questions?

COMMISSIONER CARR: No.

CHAIRMAN ZECH: Commissioner Bernthal, I know you are on. I hope you have been able to hear us all right. Do you have any questions?

COMMISSIONER BERNTHAL: No, I don't. I think I got about 75 percent of it.

CHAIRMAN ZECH: All right.

Well, let me ask a couple.

First of all, what is the total number of devices that we have that we are talking about? Do we know, the total number of devices?

MR. BERNERO: Well, if you use the chart that I had to show the distribution of models, in 1986, it was

approximately 42,000 devices, and the current number is probably not too far from that. I don't know the exact number, but that's a reasonable figure for the total. And the breakdown of them is on that chart that I used where they are broken down into compressed air, static bars and blown air.

CHAIRMAN ZECH: Now, that's the total number, 42,000?

MR. BERNERO: 42,000 devices, units, and they are all --

CHAIRMAN ZECH: Of all kinds?

MR. BERNERO: All kinds; all forms, all model numbers.

CHAIRMAN ZECH: All right. I have been told that there is another manufacturer of similar devices, and that a site visit was scheduled for last week, I think that's correct. What was the result of that visit? And is the Staff sure that we don't have a similar situation with that licensee?

MR. BERNERO: Okay, that staff visit was made. It's actually a New York State licensee. The New York State licensee uses a somewhat different technology.

CHAIRMAN ZECH: Is it a different manufacturer than 3M?

MR. BERNERO: Yes, it's a different company, different manufacturer, and a different way of doing it.

CHAIRMAN ZECH: How many devices have they got?

MR. BERNERO: If I remember the number, it's

approximately 1500, a little bit over --

CHAIRMAN ZECH: Is that included in the 42,000?

MR. BERNERO: No, no. This is --

CHAIRMAN ZECH: These are in addition?

MR. BERNERO: These are polonium-210, but they have gold foil, it's not a microsphere --

CHAIRMAN ZECH: Are we examining those?

MR. BERNERO: They have been looked at, and the State of New York -- apparently they are distributed only in New York, and that is an agreement state. But our staff has been out there, has looked at the devices. There is no evidence of failure in those devices.

There is another supplier that is an NRC licensee in California that we are tracking down now that is licensed to make static eliminators using polonium-210 of a much, much smaller size, at least an order of magnitude smaller in size. They are things like static brushes for --

CHAIRMAN ZECH: But we are contacting that manufacturer?

MR. BERNERO: Yes, we are contacting them to see what --

CHAIRMAN ZECH: Have we contacted them yet?

MR. BERNERO: I can't say that for sure. We're working through Region V.

CHAIRMAN ZECH: Region V, are you on the phone? Do

you know?

MR. BERNERO: An important feature there is it's a significantly smaller device to begin with. The inventory of radioactive material in it is at least an order of magnitude smaller.

CHAIRMAN ZECH: But that is another manufacturer other than the 3M and the New York --

MR. BERNERO: Yes.

CHAIRMAN ZECH: How many more do we have?

MR. BERNERO: We know of no others.

CHAIRMAN ZECH: I see. Well, let's find out if they've been contacted. If not, contact them as soon as possible.

MR. BERNERO: Absolutely. We are tracking that down.

CHAIRMAN ZECH: And I presume that we are going to do an inspection of that firm also.

MR. BERNERO: Yes, indeed.

We believe California is inspecting -- see, California is an agreement state, and we believe California is inspecting. We don't have their report yet, but California is one of the states participating in this meeting tomorrow. The five states are participating, in my last news, and they are all major user states -- that is, California, Illinois, Florida -- oh, I forget the other two, but states with a large inventory of these devices.

REGION V SPEAKER: You made a comment a moment ago about the facility out here in California.

CHAIRMAN ZECH: Yes, Region V, go ahead.

REGION V SPEAKER: You were making reference to neutron products which is in the local area here. We had a call yesterday from Steve Baggott to send the complete license file back to him, which is being done today. The inspection on this -- they have been inspected four times over the last two years, and they have always had a clean inspection. They have nothing in the way of a bad enforcement history or inspection history on those people.

CHAIRMAN ZECH: All four inspections, you say, were clean inspections? That means you detected nothing improper, no problem with our regulations?

REGION V SPEAKER: That's right. They were clear inspections.

CHAIRMAN ZECH: All right. Clear inspections. All right. Thank you very much.

Dr. Young, perhaps you could help me with this one. On the solubility of polonium microspheres, if they were ingested or inhaled or otherwise taken into the body, do we have any indication that they would be soluble, and if so, what would be the result?

DR. YOUNG: The microspheres have been studied both commercially and in laboratory animals. The only area that we

think would be any problem would be in the hydrocholoric acid in the stomach. Based on the information that your agency provided in regards to acid solubility, we are looking at below a tenth of a percent leaching from this in months.

CHAIRMAN ZECH: What would that do to the human body?

DR. YOUNG: That would essentially be negligible. There should not be any detectable radioactivity that would be released in the -- the result is insignificant.

CHAIRMAN ZECH: All right.

MR. BERNERO: I might add to that, Mr. Chairman, we also have some results from our own lab in Idaho, where they have taken pristine microspheres and done solution tests for 40 hours in Coca Cola and beer, and have found negligible solubility.

CHAIRMAN ZECH: I see. Are we still doing more of those tests now?

MR. BERNERO: Yes. More tests are going on, I believe.

CHAIRMAN ZECH: And Dr. Young, are you involved in those tests, too?

DR. YOUNG: No, that is being done in your laboratories, but we rely very heavily on the work that's been done with concentrated hydrocholoric acid, since that study has shown that there is less than a tenth of a percent of solubility.

CHAIRMAN ZECH: Well, we are providing the FDA with the --

MR. BERNERO: Yes. The FDA has the information. The licensing basis of this device, the microsphere, included extensive solubility data and that included hydrocholoric acid stronger than beverages --

DR. YOUNG: I think we used 6 normal or something like that.

MR. BERNERO: A hundred normal. It's a pH of 2. And that is pretty acid. You wouldn't have a very good stomach if you --

DR. YOUNG: I think there is not a problem from what we can see from the work that was done as part of your license.

CHAIRMAN ZECH: All right.

DR. YOUNG: The ability to -- and also it should be emphasized that transit time for this going from the mouth out into the feces is probably on the order of two to four days. So it's not going to reside any period of time, and with that very low dissolution rate, it's a negligible risk.

CHAIRMAN ZECH: All right. Just to make sure that I am clear on all this, do our orders that we have got out that are currently drafted or have been issued cover all of the polonium-210 static eliminator devices that have been distributed by any licensee that we are aware of?

MR. BERNERO: No. They cover only the polonium-210

static elimination devices that 3M has distributed under the NRC license. They do not apply to this company in California that Region V just spoke of, and they do not apply to the polonium-210 devices that I mentioned the New York company has.

CHAIRMAN ZECH: All right. But I presume that as you are investigating those companies --

MR. BERNERO: Yes, certainly.

CHAIRMAN ZECH: -- if you find any need to put out a similar order, you will do so?

MR. STELLO: Excuse me, Mr. Chairman. You recall both of those companies are in agreement states?

CHAIRMAN ZECH: Yes, I understand that.

MR. STELLO: The orders would --

CHAIRMAN ZECH: But we'd make sure that --

MR. BERNERO: Except through an administrative peculiarity, the California one is actually an NRC license.

CHAIRMAN ZECH: All right. Well, in any case, we want to make sure that we have covered all the bases.

MR. BERNERO: We are following up with vigor to make sure that we have all of the bases and we are also looking at the other potentially relatable licenses.

CHAIRMAN ZECH: And how about the possibility of any of these devices being exported to other countries?

MR. BERNERO: What we have done, in the -- it gets kind of tricky, because under our regulations, Part 1.10

authorizes export. Now what we did in the order to 3M, we directed 3M not only to report to the users about these orders -- you know, to send these orders to the users, but to send them to the international distributors. So that the information is there. It gets a little trickier if you want to now take action against the user in a foreign country.

MR. PARLER: It does get tricky. We have no jurisdiction over the use in a foreign country that I know about.

[Laughter.]

MR. PARLER: But we can tell the international community, the IAEA, about the problem, et cetera, et cetera. We can seek cooperation, but we have no jurisdiction that I am aware of outside of our borders.

CHAIRMAN ZECH: But we should certainly inform them.

MR. BERNERO: Except the FDA has a concern.

MR. PARLER: I was thinking just about the Nuclear Regulatory Commission, under the Atomic Energy Act and Energy Reorganization Act.

DR. YOUNG: Mr. Chairman, we would be able to reach that from our regulatory mode. And what we have done is the following two things:

We have notified the State Department so that we could work through this and have that through the networks, and then we are beginning through our network of other regulatory

agencies in the countries that we would identify as we get information from either 3M or NRC, we will use our networks to let those countries know of the problems that we have. So that is already underway. That's a significant issue, because we can't just rest on the United States territory. We have to look at the other parts of the world.

I might also add on another issue, when FDA does its analyses, in addition to doing ours, the way our system works is we require the company who has been the consignee or whom this device has been sold to, to do a large number of assays, and then our assays are done as a check against the corporate assays.

So many, many more assays have been done beyond the 1300 that I mentioned earlier.

CHAIRMAN ZECH: All right, fine.

DR. YOUNG: So that we are continuing to look to make sure there is no safety problem. We don't see anything here at this point.

CHAIRMAN ZECH: Okay, fine. Well, I think whatever we come up with here, too, would be certainly of great interest to the International Atomic Energy Association, and I think we should at least keep them informed, and I presume that we intend to do that.

MR. STELLO: Yes, sir.

CHAIRMAN ZECH: Okay.

Are there any other questions? Commissioner Carr?

Commissioner Bernthal, do you have any before we conclude?

All right. If not, we understand that the health threat in this case is low, as we have been told several times.

DR. YOUNG: That is correct.

CHAIRMAN ZECH: Especially since the polonium is tightly bound in the microspheres and it's certainly unlikely to result in an appreciable exposure to anyone, even in the probable event that someone were to ingest them.

DR. YOUNG: That's correct.

CHAIRMAN ZECH: I presume that's what we are saying.

However, it seems to me that even recognizing this, that we have a responsibility to do all we can within our authority to assure that these devices do not pose any hazard to the public or to workers.

DR. YOUNG: That's correct.

[Commissioner Roberts entered the room at 2:58.]

CHAIRMAN ZECH: And I again certainly urge the Staff to work very closely with the FDA, and with our agreement states, to follow up aggressively on any and all leads to assure that we are doing all we can to protect the public health and safety.

We certainly expect that the Staff will continue to keep the Commission fully informed of all the actions that are

taken on this particular matter.

Are there any other questions?

Commissioner Roberts, do you have anything before we conclude?

All right. Well, thank you very much for a very fine briefing. Dr. Young, thank you for being with us.

DR. YOUNG: Thank you.

CHAIRMAN ZECH: We stand adjourned.

[Whereupon, at 3:00 o'clock p.m., the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached events of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: Briefing on Static Elimination Problems

PLACE OF MEETING: Washington, D.C.

DATE OF MEETING: Thursday, February 18, 1988

were held as herein appears, and that this is the original transcript thereof for the file of the Commission taken stenographically by me, 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 events.

Ann Riley

Ann Riley & Associates, Ltd.

BRIEFING ON
STATUS OF
PO-210 STATIC ELIMINATOR
ACTIVITIES

FEBRUARY 18, 1988

BASIS FOR GENERAL LICENSE - STATIC ELIMINATORS

10 CFR 32.51

- DEVICE CAN BE SAFELY HANDLED BY PERSONS NOT HAVING RADIOLOGICAL PROTECTION TRAINING

AND

- UNDER ORDINARY CONDITIONS OF USE, RADIOACTIVE MATERIAL WILL NOT BE RELEASED

AND

- PERSONS WILL NOT BE EXPOSED EXTERNALLY IN EXCESS OF 10 PERCENT NRC LIMITS (PART 20)

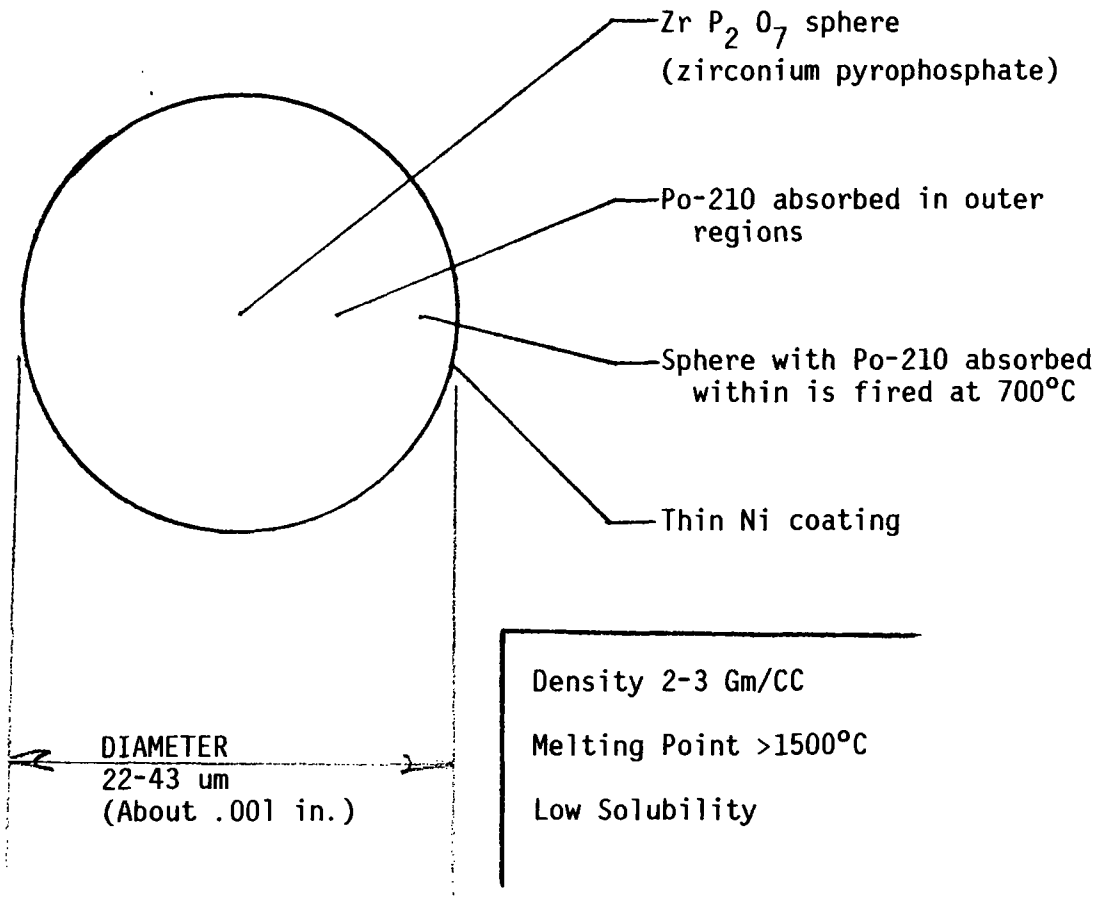
AND

- UNDER ACCIDENT CONDITIONS, UNLIKELY TO CAUSE INTERNAL AND EXTERNAL PERSON DOSE IN EXCESS OF NRC LIMITS (PART 32)

3M LICENSE

- ORIGINALLY ISSUED IN 1965
  - UNDERSTOOD POTENTIAL FOR LEAKAGE, NOT UNDER ORDINARY CONDITIONS
- LICENSE EXPANDED TO MULTIPLE DEVICES
  - INCREASED REPORTING REQUIREMENTS SINCE 1978

MICROSPHERE



3M CHRONOLOGY - 1

- JAN. 21 ASHLAND CHEMICAL CO. REPORT
- JAN. 22 NRC AT EASTON PLANT
- JAN. 25 ORDER #1
  - A. SUSPEND DISTRIBUTION OF 902, 902F, 906, AND 908
  - B. INFORM USERS/REMINDER OF NOTICE REQUIREMENTS
  - C. SEND COPY OF INFO. NOTICE (B) TO RA-III
  - D. TEST DEVICES AND SUBMIT PLAN BY FEB. 8
  - E. ANALYZE CAUSES
- JAN. 22 - FEB. 5 MORE FAILURE DATA RECEIVED
- FEB. 5 ORDER #2 (CONFIRMATORY)
  REMOVE 902, 902F, 906, AND 908 FROM FBCP PACKAGING

3M CHRONOLOGY - 2

- FEB. 8 — 3M REPORT AND "PLAN"
  - VERY LITTLE DATA
  - FOCUS ON ENVIRONMENTAL CAUSES
  - MINIMAL PLAN

- FEB. 11 — 3M/NRC/FDA MEETING AT R-III
  - 3M TOP MANAGEMENT PRESENT
  - VERY LITTLE MORE FROM 3M EXCEPT DECISION ON ALL MODELS IN FBCP AND NEED YOUR DATA
  - NRC FOCUS ON WHETHER THIS EVIDENCE SHOWS THAT ALL DEVICES ARE NOT GENERALLY LICENSABLE
  - FDA FOCUS ON FBCP PRODUCT SAMPLING AFTER REMOVAL
  - AGREED TO FEB. 19 3M/NRC/STATES MEETING AT 3M TO POOL DATA
  - 3M AGREED TO SUBMIT ACTION PLAN BY FEB. 26

- FEB. 5 - FEB. 12 — MORE FAILURE DATA OTHER MODELS

- FEB. 12 — ORDER #3
  - REMOVE ALL MODELS FROM FBCP PRODUCTION AND PACKAGING

TABLE A

3M MODEL 902, 902F, 906 and 908
STATIC ELIMINATOR
TEST DATA

Industry Category	902		902F		906		908		(1)
	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail	
Bottling	-	-	-	-	14	12	16	9	
Cosmetics	-	-	-	-	23	1	-	-	
Electronics	89	1	220	3	93	0	53	0	
Food	2	0	-	-	30(4)	-	3(5)	-	
Medical	36	0	-	-	2	0	14	0	
Photographic	42	0	-	-	33	1	28	0	
Paper	3	0	1	0	3	0	-	-	
Printing	26	0	-	-	33	0	9	0	
Other(6)	17	1	2	0	52	0	6	1	
Totals	215	2	223	3	283(2)	14	129(3)	10	

3M PLAN - FEBRUARY 8, 1988

BASED ON THE FINDINGS OF THIS STUDY, 3M INTENDS TO TAKE THE FOLLOWING ACTIONS:

1. REVIEW THE LIST OF DEVICES THAT WERE RETURNED IN 1987 AND HAVE TRAINED AND SUITABLY EQUIPPED STATIC ANALYSTS VISIT CUSTOMER SITES WHERE TESTING OF THE RETURNED DEVICES INDICATES POTENTIAL PROBLEMS.

2. REVISE THE PRODUCT LITERATURE TO REINFORCE THE WORDING REGARDING THE TYPE OF ENVIRONMENT WHICH MUST BE MAINTAINED TO PREVENT FAILURES.

3. PROVIDE REFRESHER TRAINING TO STATIC ANALYSTS TO BE CERTAIN THAT CUSTOMER APPLICATIONS ARE THOROUGHLY EVALUATED BEFORE LEASES ARE SIGNED. 3M WILL CONTACT THE CUSTOMER BEFORE LEASES ARE RENEWED TO BE CERTAIN THE APPLICATION HAS NOT CHANGED.

Data on Returned Devices

	Model	No. Returned 1986		From 3M Records No. Leaking (All) 1986	From 3M Reports* No. Leaking (Undamaged)	(Damaged)
Compressed Air	902/902F	13,138		5 (0.04%)	0	1
	906	8,718		62 (0.7%	8	0
	908	1,990		17 (0.8%)	0	0
		23,846	57%			
Static Bars	315/210/220	11,050		95 (0.9%)	17	7
	203	93		0	0	0
	204	787		7 (0.9%)	0	0
	205	2,292		0	0	0
	206	175		1 (0.5%)	0	0
		14,397	34%			
Blown Air	905	2,070		0	0	0
	907	668		5 (0.8%)	0	0
	909	808		0	0	0
		3,546	8%			
		41,789				

*Data from 1985 and 1986 Reports

February 17, 1988

LIST OF SITES WITH FAILED DEVICES+

COMPANY	LOCATION	TYPE OF PRODUCT	PRODUCT TEST RESULTS
1. KTI	Carrollton, TX	chemicals	-o-Pos
2. KTI	Sunnyvale, CA	chemicals	
3. Xicor	Milpitas, CA	chemicals	
4. Coca Cola	Dallas, TX	beverage	-*-NDA, -o-NDA
5. Coca Cola	Dallas, TX	beverage	-*-NDA, -o-NDA
6. Coca Cola	Fort Worth, TX	beverage	-NDA, o-NDA
7. Coca Cola	Needham, MA	beverage	-NDA
8. Anheuser Busch	St. Louis, MO	beverage	-*-NDA #-NDA
9. Custom Photo	Austin, TX	Film	-o-Pos, 20,000cpm
10. Ashland Chemical	Easton, PA	chemicals	-o-NDA
11. Ashland Chemical	Dallas, TX	chemicals	-o-Pos, 200PCi/l
12. McDonnell Douglas	St. Louis, MO	--	
13. Block Drugs	Dayton, NJ	denture adhesive	-*-NDA
14. Ford Motor Co.	Milan, MI	--	
15. Anheuser Busch	Jacksonville, FL	beverage	
16. Avon	Morton Grove, IL	cosmetics	
17. Ross Labs Div. of Abbott Labs.	Casa Grande, AZ	food, similac	-*-NDA
18. Coca Cola	Phoenix, AZ	beverage	-*-NDA -#-NDA
19. Paul Flum Ideas	St. Louis, MO	--	
20. Best Food Unit	Argo, IL	--	
21. 3M	Ames, IA	--	
22. Pepsi Cola	Tulsa, OK	beverage	-#-NDA
23. Coca Cola	San Leandro, CA	beverage	
24. Block Drug (Reedoo)	Humacao, PR	shampoo	
25. CREST Photo Labs.	Pawtucket, RI	developing	
26. South Atlantic Canners (Coke)	Bishopville, SC	beverage	
27. Photo Finish	McColl, SC	developing	

Pos= Positive Results
NDA= NO DETECTABLE ACTIVITY
o- Test performed by Agreement States or General Licensee Contractors

*= Test performed by FDA
#= Test performed by Medi Trace Labs.

+ Contamination at these facilities exceeded 0.005 uCi - 11,000 DPM

February 17, 1988

LIST OF SITES WITH FAILED DEVICES+

COMPANY	LOCATION	TYPE OF PRODUCT	PRODUCT TEST RESULTS
28. Hygeia Coca Cola	Pensacola, FL	beverage	
29. Ford Motor Co.	Utica, MI	paint	
30. Dial Corp	Ft. Madison, IA	microwave lunch packages	
31. Pro Corp	Florence, MA	plastic cases used on PC's	
32. K-Mart	Garland, TX	process film	
33. Xerox Corp	Richardson, TX		
34. Micro Technology	Boise, MD	electronic chips	
35. Miller Container	Milan, IL		
36. McLaughlin Body Co.	E. Moline, IL		
37. Moto Photo	North Dartmouth, MA	film	
38. Ross Laboratories	Alta Vista, VA	food supplement	*Pos, 222,000 dpm (1 microsphere)
39. Super Photo	New Orleans, LA	developing	

Pos= Positive Results
NDA= NO DETECTABLE ACTIVITY
o- Test performed by Agreement States or General Licensee Contractors

*= Test performed by FDA
#= Test performed by Medi Trace Labs.

+ Contamination at these facilities exceeded 0.005 uCi - 11,000 DPM

CURRENT SAFETY CONCLUSION

BASED ON THE ANALYSES AVAILABLE AT THIS TIME, EVEN IF MICROSPHERES GAINED ACCESS TO CONSUMER PRODUCTS, IT IS UNLIKELY THAT THERE WOULD BE A SIGNIFICANT HEALTH HAZARD TO THE PUBLIC. NEVERTHELESS, IN ORDER TO MORE FULLY EVALUATE THE POTENTIAL SAFETY SIGNIFICANCE, SAMPLES OF CONSUMER PRODUCTS RESULTING FROM THESE MANUFACTURING PROCESSES ARE BEING ANALYZED BY NRC AND FDA.

FEBRUARY 18, 1988 ORDERS

- TWO ORDERS
  - TO 3M
  - TO GENERAL LICENSEES
- SUSPEND TRANSFER AND USE
- RETURN TO 3M FOR TEST
- EXCEPTIONS FOR SAFETY

3M ORDER

A. SUSPEND TRANSFER OF DEVICES

B. IMMEDIATELY NOTIFY GENERAL LICENSEES

- DISTRIBUTE GL ORDER

C. INSTRUCT USERS TO RETURN DEVICES

- ASAF BUT NO MORE THAN 90 DAYS

D. TEST RETURNED DEVICES FOR LEAKAGE

- NOTIFY USER, NRC, STATES

E. STATUS REPORTS (30-DAY)

SHOW CAUSE IN 60 DAYS WHY LICENSE SHOULD NOT BE REVOKED

GL ORDER

A. SUSPEND USE OF DEVICES

B. SEND DEVICES BACK TO 3M

- WITHIN 90 DAYS

C. TEMPORARY CONTINUATION OF USE POSSIBLE

- ESSENTIAL FOR SAFETY
- WRITTEN APPROVAL OF NRC OR STATE
- UNDER SURVEILLANCE TO BE SPECIFIED
- NOT FOR FBCP OR MEDICAL DEVICES

° PUBLISHED IN FEDERAL REGISTER

° DISTRIBUTED UNDER ORDER TO 3M