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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 DEVICE PROBLEMS

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PUBLIC MEETING

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Nuclear Regulatory Commission
Room 1130
1717 H Street, Northwest
Washington, D.C.

Monday, February 8, 1988

The Commission met in open session, pursuant to notice, at 1:40 o'clock, 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

P R O C E E D I N G S

CHAIRMAN ZECH: Good afternoon, ladies and gentlemen.

I understand we need a vote, Mr. Secretary, to hold this meeting on less than one week's notice; is that correct?

MR. CHILK: Yes, we do, sir.

CHAIRMAN ZECH: Do I have a vote from my fellow Commissioners, please?

COMMISSIONER BERNTHAL: Aye.

COMMISSIONER ROBERTS: Aye.

CHAIRMAN ZECH: Aye.

The purpose of the meeting this afternoon is for the Commission to receive an information briefing on the use of static eliminators containing polonium-210 and to discuss the effects on public health and safety.

Commissioners Carr and Rogers are not present this afternoon, and I understand that Commissioner Bernthal has to leave at 2:20.

The NRC Staff will discuss actions that have occurred since the initial detection of contamination in late January of this year, as far as our notification is concerned. The Staff will also discuss actions that have been taken and further actions contemplated.

I understand that Dr. Frank Young, Commissioner of the Food and Drug Administration, is with us today, and, Dr. Young, we appreciate very much your being with us. We welcome

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

S. CHILK

W. PARLER

V. STELLO

F. YOUNG

H. THOMPSON

D. CUNNINGHAM

SPEAKERPHONE PARTICIPANTS:

REGION III:

B. DAVIS

B. MALLETT

D. SRENIAWSKI

REGION I SPEAKER

REGION II SPEAKER

you to our agency, and we appreciate the assistance that you have been providing to the Nuclear Regulatory Commission in these past few days regarding this important matter.

DR. YOUNG: Thank you.

CHAIRMAN ZECH: The Commission has called this meeting on short notice because of the importance of the matter and the desire of the Commission to be fully informed and to ensure ourselves that the actions so far taken by the Staff are appropriate.

I should emphasize at the outset that I have been informed that at this time there has not been found any evidence of radiation contamination of any consumer product. We want to hear that today from those at the table, but that's what I have been informed.

Based on the analysis available at this time, even if microspheres gained access to consumer products, I am further informed that it is unlikely that there would be any 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 the Nuclear Regulatory Commission and the Food and Drug Administration. The NRC and the FDA will continue to work with the states and with the companies involved to give us further assurance that consumer products are not contaminated.

The Commission, of course, wants to ensure that we are doing all that we can to protect the public health and safety, including the safety environment of the workers.

Before we begin, do any of my fellow Commissioners have any opening remarks to make?

[No response.]

CHAIRMAN ZECH: Commissioner Rogers, being unable to be here today, has asked me to read for the record a statement that he wishes to submit, and I will read it now, and I quote:

"As you know, I am on planned travel February 8th and 9th, 1988, and am unable to attend the Commission meeting which was scheduled on February the 7th. I would appreciate your reading for the record the following statement on the polonium-210 leakage problem in static elimination devices."

And I continue the quote: "I strongly support the vigorous actions taken by the agency on January 25, 1988 with the general licensee, Minnesota Mining & Manufacturing Company, to cease further distribution of these devices and conduct an exploratory test program when the agency learned of the initial instance of leakage and contamination in Pennsylvania and Texas of the polonium-210 sources in 3-M's compressed air static eliminator devices and subsequently on February the 5th, 1988, with evidence of greater leakage and potential of contamination of these sources in certain food, beverage, and pharmaceutical industries became available to 3-M and to NRC inspectors at 3-M

facilities.

"The prompt issuance of an NRC order on February the 5th to 3-M to recall all of the approximately 22,000 static elimination devices which had been issued in 1987 and to notify the Food and Drug Administration and the Office of Governmental and Public Affairs for distribution of the order to the agreement states was, in my opinion, an example of effective and responsible federal regulatory action in protecting public health, even though preliminary assessments by the agency of potential health effects to the public from presently known instances of leakage did not show them to be of consequence.

"The recall order in no way constrains the agency from taking further regulatory action in this matter as appropriate additional information on leakage or contamination by the devices becomes available from the general licensee and the agency's onsite inspectors.

"It is equally important that the agency protect industrial process workers from potential low-level occupational radiation exposure, as well as the general public as consumers of food, beverage, or pharmaceutical products. As such, the defective static eliminator situation warrants continued close investigation and cooperation by the NRC and the Food and Drug Administration and prompt disclosure of the facts to the public," signed Kenneth C. Rogers, Commissioner, unquote.

With that, Mr. Stello, you may proceed.

MR. STELLO: Thank you, Mr. Chairman.

What I would ask, if possible, if we could depart from our usual procedure in briefing by going to first some summary statements of where we are within the NRC and within FDA.

Commissioner Young, who as you have already pointed out has broken away from a very busy schedule and will need to leave here in about 45 minutes, so in order to provide an opportunity for the Commission to hear his views on this matter and perhaps ask any questions that you may want to, I'll ask Mr. Thompson to give a very short summary of where we are, and then I will ask Commissioner Young to do the same, and then perhaps if you would, we could go directly to any questions you may have of FDA at that point before Commissioner Young has to leave.

CHAIRMAN ZECH: That sounds fine.

MR. STELLO: If that's acceptable.

CHAIRMAN ZECH: Please proceed.

MR. STELLO: Hugh, why don't you try to hold it to a few minutes for a summary, and then we'll get into the details after that.

MR. THOMPSON: Thank you, Mr. Chairman.

Through the inspection activities of the NRC Staff, the agreement states, and the affected licensees, there have

been approximately 23 facilities identified that have contaminated facilities or have contamination levels sufficient to be at the NRC reporting level for these type devices. We have sampled products that would be potentially consumed by humans, individuals. The companies have sampled and the FDA has sampled. He have done calculations based on our knowledge of the performance of the polonium in the microsphere container, and we have concluded at this time first, no product that is consumed by the public in the form of food, drugs, or pharmaceuticals has been found to be contaminated, but even if there were some of these small microspheres were to get into those products, in our judgment, it is unlikely that they would be a significant health hazard.

We do believe that the continued inspection activities that we are doing and that we are conducting today will find other facilities likely to be contaminated and that additional products will need to be sampled as we go through the activities of following up on the additional devices and their applications in the industries.

MR. STELLO: Mr. Chairman, I would add one point to what Mr. Thompson said to give some scope to this. My understanding is that the number of devices that are involved are on the order of 50,000 devices. They are used in a large spectrum of facilities for a variety of purposes, some of which are directly related to safety functions performed by the

devices.

We have concentrated our efforts, along with those of the FDA, to direct our attention to those devices which, if they fail, could find a way into the public domain through food or related products in the cosmetic or whatever industry. There is a great deal that remains to be done, and later this afternoon we'll be giving you a scope of what further action we will need to take with respect to dealing with this fairly large number of devices and how to approach that in a realistic manner.

With that, I'll turn to Dr. Young.

CHAIRMAN ZECH: All right. Dr. Young, you may proceed.

DR. YOUNG: Thank you very much, Mr. Chairman.

I would like to provide some scope of the information that we have received to date, and I appreciate the cooperation that your agency has provided to us.

We were able to be notified quite early upon receipt of the information by the Nuclear Regulatory Agency, and we have the list of the 23 plants that had been referred to us. Of those plants, 13 are in the food/drug/cosmetic device arena that we are involved in. We have taken 32 samples from that material to date. Ten of the samples have been completely analyzed, and in none of the samples was there any evidence of radioactivity.

We feel that is a very high priority for us to continue to interact closely with the Nuclear Regulatory Agency, and we shall do this to be sure that we keep your Commission fully informed, and I have been pleased with the partnership that we have had in analyzing samples. The samples have been both analyzed by our two organizations, as well as states and industrial corporations.

I would also agree that there is no significant hazard likely to be there on the products, but when one is in such an early phase, we're really taking the extra steps to look at each of the products. I should point out that the products will be exposed to human beings in different ways.

In the case of food, of course, one is looking for the passage through the intestinal tract to see whether any of the radioactive microspheres would be retained. In the case of things that are applied to the skin or mucosa, obviously the radiation is going to be closest to the point of application. So our strategy will vary somewhat within each of the products, but it is our full intention to take the list that you provide us with those products that are potentially contaminated, and we will promise to look at each of these products and communicate fully with you and with the press in regard to any hazards that we've found.

But I want to emphasize again, as I started, there is no evidence at this time of any radioactive contamination in

any of the products related to food, drugs, devices, and cosmetics.

Second, from what we know at this point of the type of microsphere, the type of alpha radiation, that it is unlikely that there would be a very significant health effect. But nevertheless, we don't want to leave any stone unturned, and we will work on that as promptly as humanly possible.

CHAIRMAN ZECH: Thank you very much. If you could remain with us for awhile, I might ask Mr. Thompson to go into the briefing a bit, and if we may, we'll just interrupt and perhaps, Dr. Young, direct any questions to you, knowing you can't stay with us for the entire briefing very likely.

Is that all right with my fellow Commissioners?

COMMISSIONER BERNTHAL: Fine.

MR. THOMPSON: Thank you, Mr. Chairman.

I'm not sure whether my slide man is back there in the back or not. I believe he is. But he's learning the difference between the right side up and the wrong side.

CHAIRMAN ZECH: Good.

MR. THOMPSON: This is our training session here.

We do have passed out, I think, a set of the briefing slides to you. They were making a few last-minute modifications to reflect the information.

If I could, would you distribute the copies which are a little bit better of the particular device to the

Commissioners, because I think when the Xerox machine takes this in its normal manner, it treats everything the same way.

[Slide.]

If I could this afternoon, I would like to talk a bit about the device, what the problem was that we found with the device, the risk, which I think you've just heard some information on it, some of the actions that both the NRC, the FDA, and the states have been taking in response to this particular issue, and the future actions and issues that we think are critical for us to address this in an effective way.

[Slide.]

The device is about two inches long, and it is used primarily in -- this is a 900 Series device that is produced by the 3-M company, and it is used in airlines and in a multitude of processes that we had identified earlier, just a few of the processes.

The air will come in, as you can see from the lefthand side, pass over the polonium-210 microspheres which are bound in a slight epoxy -- that's about a two-inch long device -- and pass out on the righthand side. It could pass out into an array of different types of configurations. It could go into an air manifold; it could go into a filtering system that would be used for the bottling of some various products, or it could be pretty much open just in a straight line, so there is just a number of arrangements that it could

occur in.

What we were having, as you can see, the microspheres would be bound right in that epoxy, and some of those microspheres have been becoming dislodged and entering into the environment.

[Slide.]

The microsphere itself is a ceramic, very hard substance, zirconium pyrophosphate, in which a solution containing polonium-210 is absorbed in it. That sphere is then fired up around 700 degrees Centigrade with a small -- a very thin nickel coating as its particular characteristics.

The diameter is somewhere between 22 and 43 microns, and it's a fairly dense particle.

If you look at the next slide, I don't know that we have a slide on it, but in your handout you will see a picture of these microspheres compared to the human hair. That kind of shows you a number of these things.

And the next picture that you have in your handout is a micron electronic blowup, magnification of what one of those spheres actually would look like.

We will have some copies of these for the public at the end of the briefing.

The initial event occurred --

CHAIRMAN ZECH: Before you go on, could you tell us just very briefly, I think it's important, that we're talking

about polonium and not plutonium. Would you please give us a very brief definition of polonium and perhaps the difference, as I understand it, the chemistry and the radioactivity are completely different? But I'd like you to tell us a little bit more about that, if you would very briefly.

MR. THOMPSON: All right. I'd like to turn to Mr. Cunningham to do that.

CHAIRMAN ZECH: Fine. Just very briefly.

MR. CUNNINGHAM: Polonium is found in nature. It is part of the decay chain of radium. It's lower in the decay chain than radon, for example, but it is part of the same decay chain, so it is found in nature. But the polonium that is used in these devices is made in a reactor because of the problems of concentrating it from nature.

It is an alpha emitter, about 5 meb energy. Alpha particles will not normally penetrate the skin. It is a relatively short half-life material, about 138 days.

Plutonium, of course, is a heavier particle. It does have an alpha radiation. It is a fissile material; polonium is not. It is very close to lead in the chemistry of the thing.

CHAIRMAN ZECH: That's fine for now. Thank you.

You may proceed, Mr. Thompson.

MR. THOMPSON: Okay. The initial event, as you mentioned earlier, Mr. Chairman, did start with the Ashland Chemical Company. There was a customer of the Ashland Chemical

Company who had been detecting small amounts of alpha activity in some of the sulfuric acid in some of their products, and they began to search around to try to identify how that activity had been identified at their facility. They started last summer. Toward November and December, as I understand it, they concentrated their investigation on trying to eliminate some of the chemicals that were supplied to them, and, in fact, on January 21st, this particular company took a survey team to the Ashland Chemical Company and identified the alpha contamination at that facility.

COMMISSIONER BERNTHAL: Hugh, let me ask one question. How pure is the material in these microspheres? In other words, to what level can you assure that there are no radioactive contaminants that might be longer-lived, for example?

And by the way, plutonium is close to lead in the periodic chart, but it's chemistry is not similar to lead, nor is bismuth which is closer to lead. I think that should be mentioned. It has quite a different chemistry.

The fact of the question, do we expect any contaminants at all, or is this carrier-free material?

MR. THOMPSON: I am not personally able to answer that question. We do have the key Regions who have been involved in doing the inspection activities at the facilities.

Region III, Bert Davis, do you have anyone who could

answer Commissioner Bernthal's question concerning the possibility of contamination on the quality control on the polonium that's bound in these spheres?

CHAIRMAN ZECH: We have Mr. Davis on the speaker, I believe. If you heard that, go ahead, please.

MR. DAVIS: This is Bert Davis, Region III. I'm sorry that we cannot answer that right now, but if we can get an answer for you, we'll provide it later.

CHAIRMAN ZECH: Thank you very much.

MR. THOMPSON: NRC was notified by the Ashland Chemical Company's consultant, who verified the contamination of that product the next day, which was January 22nd, and Region I then dispatched a team to the site. We verified that there was contamination at the Easton site, and the State of Texas subsequently found additional contamination on the 24th of January, resulting in NRC issuing an order suspending the distribution of these devices by 3-M on January 25th. I'll discuss in just a moment precisely what the purpose of that order was.

CHAIRMAN ZECH: 1988.

MR. THOMPSON: 1988; yes, sir.

Two other of the Ashland Chemical plants showed no contamination.

COMMISSIONER ROBERTS: Well, I guess this is implied. Did those two other plants use this same device?

MR. THOMPSON: Yes, sir. I believe that is correct. That's my understanding, that they used that device.

If anybody has other information that they didn't, I'd like to know that.

The initial findings of that inspection, which was done by Region I, was that in fact contamination was coming loose from the polonium static air eliminators but appears not to be dissolving. We concluded that based on sampling of the chemical companies' products, in which we found particulate matters in that product as well as when we sampled the urine from the workers which would give an idea of some aspect of the material being in solution, dissolving in the stream, if it had been inhaled -- not inhaled but if it had been ingested by the workers, that it would be likely to be identified in that sample.

Region I did hold the products of the Ashland Chemical Company until we found through our sampling process that those had been acceptable for industrial use and release.

COMMISSIONER BERNTHAL: Let's see. Your slip of the tongue raises a question. What about inhalation? Even though these things have quite a high density, they are terribly small and presumably can become airborne. Do we know anything yet about the possibility of inhalation?

MR. THOMPSON: We have looked at the aspect of inhalation and we are discussing the specific risk that is

associated with that. Our initial judgment was that the particles would likely not reach the critical parts of the lung but I guess I would like to turn to Dr. Young who may want to give us his judgments on the likelihood of those particles being inhaled.

DR. YOUNG: Your question is both an interesting one and an important one. The particles are very heavy. Therefore, there will be a different kinetic analysis required for this in a particle which is fairly airborne.

We would not expect these to reach the alveolar sacs, however, they would lodge somewhere either in the nasal passages to the trachea, the bronchi, the brochials. My estimate would be that it would be more the smaller air passages if they were to gain access to the lung itself, but a substantial number should be filtered out in the nose hairs.

Be that as it may, where they would lodge, they would emit radiation in about a 5 to 10 micron track, which would produce a substantial degree of ionization there. Thus, it is very important to determine whether the products themselves are contaminated and what the likelihood of that would be in introducing any risk to either workers or consumers.

The good news is to date, but yet on limited samples, there is no evidence of contamination.

COMMISSIONER BERNTHAL: Either by inhalation or ingestion?

DR. YOUNG: No evidence of contamination of the products. In regard to the ingestion, the safety factor there would be, as I have been told by our folks in the Center for Radiation -- I'm sorry -- Devices in Radiological Health, it is unlikely that more than one percent of the radioactivity would be removed from the microsphere by acid and such, but therefore, the comfort of it not being in the urine would indicate low amounts were taken in and not removed, but it does not of course say whether or not any of the microspheres would remain in the body or would pass out, because of the density, it would be hoped that a substantial amount of these that were ingested might clear the intestinal tract. Of course, they could lodge in villi, on things such as the appendix or other areas.

Nevertheless, I think the key issue will be to determine whether the products themselves are contaminated and what the likelihood would be there.

COMMISSIONER BERNTHAL: Wouldn't inhalation in your judgment be a greater health risk were that to occur or are you unprepared to comment on that at this point?

DR. YOUNG: I think it is very early in the analysis to know. This could be said clearly; in the case of the product, it will depend on what the product is as to the route of exposure. The use of a food would obviously be a gastrointestinal tract, only if it was a product that was used

in a nasal spray or something like that, would you worry about an inhalation route. We can analyze that very rapidly by looking at all the products.

For the worker, I think your question is more relevant. The fact that they are fairly heavy particles, they would settle more rapidly than would the normal poly-dispersed dust. I do think there would be some concern and obviously as a person concerned with health, all of us would be concerned about that. Yet, there is not sufficient evidence to give the magnitude at this time.

CHAIRMAN ZECH: In the facilities where we have found contamination, has it been found, for example, on the floor or is it in the air? My question really is, Dr. Young, pointed to the fact that you say this heavy material would tend to settle on the floor. Do we know where the contamination has been found in the facilities?

DR. YOUNG: I asked that question of Mr. Thompson and he can add more to it. From the information he gave me, the particles are primarily on the floor areas and were able to be picked up by swabs and not within the air in the rooms.

MR. THOMPSON: That's the primary pattern. I believe Region I may have some more specific details. There have been some contamination in a few places, particularly one of the plants out in Arizona, where the contamination dropped about 25 feet from where the product was actually going, and there

turned out to be a pattern of about 10 feet diameter where the large majority of the concentration was found and the contamination was found, but there turned out to be small parts of it in some of the printing oil that goes on these bottling cans. It was very difficult to clean up. The assessment was there were still particles but some of them had actually kind of bounced and may have been carried onto small parts of the stairwell, parts of the machinery, some difficult areas to clean up.

In general, Region I, I think you have done more inspections than the others right now, is that the general pattern you are finding, which would be indicative of most of it, that it is a floor type contamination?

REGION I SPEAKER: In the case of Ashland, in the Easton facility, that is correct. The contamination is largely on the floor. It is on equipment that the devices were used on. In the case of Ashland, the devices were out of service when we were up there so we were not able to take air samples at the time the devices were being used. The contamination exists on floors and surfaces and we have no indication that it was airborne.

COMMISSIONER BERNTHAL: Let me ask a related question. I only have ten minutes or so to go.

As far as we know, is the integrity of these microspheres maintained in all of the contamination we found or

is there any evidence for them having been broken and material escaping from them? In other words, thus far, are we confining the concern to the microspheres themselves or not?

MR. THOMPSON: I don't think we can have specific evidence precisely to address that point. We have sent some samples that we have taken to our laboratory from microscopic analysis to see that. The judgment is that these spheres can crack, can break up under certain circumstances. The evidence in the reports that were provided by 3M, if they do that, they still maintain their structure, the polonium is not released, it is just in a smaller type of ceramic characteristic.

I think we did get some ten micron sized particles in the Ashland Chemical, in the State of Texas, when they did some of their measurements, which indicated that the thing doesn't dissolve quicker, it stays in soluble characteristics even if it were cracked up.

COMMISSIONER BERNTHAL: Now you are talking about ceramic and not about the nickel coating; right? That would have very different dissolution characteristics or leaching characteristics, I should say.

MR. CUNNINGHAM: We do have leaching characteristics without the nickel coating on, still rather insoluble, no solubility.

MR. STELLO: There seemed to be a question that needed to be addressed. Using the standard lung models, if you

did breath in a particle, that came into the lung, I think it would be useful to at least present the magnitude of the dose we are talking about, because it is quite small.

MR. CUNNINGHAM: In the lung itself, if we assume that one of these microspheres of 30 microns diameter and a tenth of a microcurie of polonium, did reach the lower region of the lung, the alveolar sac, it would be about 4.8 rem to the lung, which translates to in effect a full body dose of the equivalent of about 830 millirem. By way of perspective on that, my recollection of the latest NCRP report is a person smoking cigarettes, a typical cigarette smoker, gets about 6 rem to the lung per year, a large contribution being polonium.

If you broke that up into smaller particles, of course, as the particles become smaller, the greater the chance of it reaching the lung, but the activity, the smaller particles go down by the cube, you break that sphere up. It is a change in characteristics.

That is our estimate for the lung dose.

COMMISSIONER BERNTHAL: I think in fairness, I think the Commissioner from FDA can probably enlighten us at greater length than we are prepared to receive today, but my understanding is that these things can be synergistic, both in the case of radon in basements and the case of polonium 210 in tobacco smoke and in this case, polonium 210 with other synergistic materials, it could be much more dangerous than the

dose itself, or at least there is some evidence, I think. The dose itself isn't the only thing to look at, as I understand it. Maybe you would like to comment.

DR. YOUNG: I will only comment briefly on it and would be delighted to provide more information. I think the key issue here is we are dealing with an alpha particle which has an ionization track of about 5 to 10 microns and it is somewhat different than delivering whole body radiation, because you are looking at a point source, which is your concern.

That is why I feel that the most appropriate thing to do is to pull out all stops to determine whether the products are contaminated. That really is our best layer of safety. If we have a product contamination, then we have to go out and deal with that immediately and that helps us on the speculation because then we know where it is likely to be delivered and at what part, if any, and thus, I am pleased to see that we are getting the names of the plants, we are working together and we are looking to see where product is.

You are absolutely correct, Commissioner. You are looking at the track of radiation and that's why we want to see with all that in place. The understanding that I have is even if this was ingested and retained for a short period of time, we are dealing with relatively low levels of radiation and the hazard is not significant. I don't want the American people to

be alarmed at this point of investigation, that we have a crisis of major import. We are really trying to pull out all stops to see that there is or is not any contamination of products.

CHAIRMAN ZECH: Before we go on, I know Commissioner Bernthal must leave in a few minutes. Do you have anything else you would like to get into now?

COMMISSIONER BERNTHAL: No. I think I am finished for the moment.

COMMISSIONER ROBERTS: Can I ask a quick question?

CHAIRMAN ZECH: Please.

COMMISSIONER ROBERTS: Do we know that 3M is the only manufacturer of this device?

MR. THOMPSON: We know there is another manufacturer of a static eliminator device that has radioactive polonium in it. It is manufactured with a different process. I believe we do have an inspector -- it is licensed by the State of New York. I do believe we have an inspector up there today evaluating and looking at that particular device. It is a foil construction whereas this one is an epoxy type construction. We are not aware of any other leakage but we are investigating and following up on that particular activity.

There are static eliminators that are non-radioactive types. Those devices are not part of our investigation at this time.

MR. STELLO: I think it would be important to point out that the company Mr. Thompson is referring to -- it should be pointed out that the number of products involved are several order of magnitudes less, like one or two percent of what we are talking about at 3M. It is a fairly small company.

CHAIRMAN ZECH: We are going to look at that, too, I presume.

MR. THOMPSON: We are doing it as we speak. There is an inspector up there today. It is an agreement state and that effort is being coordinated through our agreement state program, which in fact this has been a very close effort, not only with the FDA but the agreement states and their inspection activities to follow on the devices for which they have regulatory oversight.

CHAIRMAN ZECH: Proceed.

MR. THOMPSON: Dr. Young, if there is anything else you want to add. I am starting to go into some of the details of where we are.

DR. YOUNG: Please go on. I only want to be responsive to any questions that you might have.

CHAIRMAN ZECH: When you leave, can you have one of your colleagues join us at the table?

DR. YOUNG: Surely. I will stay a few minutes beyond. I know this is an important issue. I will try to stay as long as possible.

CHAIRMAN ZECH: Thank you. We appreciate that very much. Proceed, Mr. Thompson.

[SLIDE.]

MR. THOMPSON: Following our evaluation that in fact these devices really were not performing as they were intended to be, that is in the general licenses, we don't anticipate the release of this radioactive material into the work environment or into a particular product. We were focusing on the individual area and the work product at that time was some sulfuric acid.

We had a two pronged approach. We sent a team from Region III up to 3M to investigate that facility's records and the history of the information they had available to them concerning leaking devices. This device had been licensed by NRC for a fairly long period of time and we did not have a broad indication of failures of this device.

CHAIRMAN ZECH: When did we first license this device?

MR. THOMPSON: I am going to say 20 years; 1968. As you know, these devices are renewed every few years, about every five years. I would want to point out sometime in the briefing today that in one of the review processes, in one of the reviews, there was concern expressed by the staff about this particular type of incident occurring.

COMMISSIONER BERNTHAL: When was that?

MR. THOMPSON: I believe it was in May of 1976. There was a realization at that time that use of this type of consumer product, the device could actually have a release of these microspheres and they expressed some concerns with the continued licensing of this device.

The record is not absolutely clear as to precisely what was done, it is one of the follow up actions we will have as to whether or not other devices may have a similar record of review. You should be aware that was part of the record when we went back to review it.

MR. STELLO: Mr. Chairman, I misspoke. The license was originally issued, according to a document I am referring to now, on February 17, 1964.

COMMISSIONER BERNTHAL: One last question and I am going to have to run out the door. I apologize. I am trying to visit some of the Tennessee Valley Authority plants.

You have answered the other question I had. I really was interested in knowing whether you have an idea why these things came unstuck so to speak, and whether it is radiation damage to the epoxy itself. Has that been looked at? Do you have any idea yet what the cause was?

MR. THOMPSON: We have been discussing potential reasons for the cause of this device failure. It is clear that a soluble solvent, water, in fact, in an environment will cause the epoxy to fail to perform its intended function. However,

there is at least one or two other applications in which they appear to be in a very dry environment and in particular drug companies of major concern that we will discuss later on, and in that particular case, there was no clear indication of why there was a release in that device.

That particular company had another process line with an ionizer installed in it. They had a treatment of the cooling of the air, they had some filtration activities and maybe even some filters that seemed to provide a pure quality of air that was passing over the epoxy. However, that is the first focus of the effort that we directed 3M to do, to ensure that they evaluate the cause and understand the performance of this device prior to commencing any redistribution of this series of a device.

COMMISSIONER BERNTHAL: You are saying there were units side by side with different air quality characteristics, one of which failed and one didn't?

MR. THOMPSON: I can't say side by side because I have not been physically out in the field. I understand there is one plant in Piscataway, New Jersey, where the device performed as intended. The additional plant by the same company in Dayton, New Jersey, there were failures in that device and rather significant failures.

COMMISSIONER BERNTHAL: I am sorry. I have to go. Thank you very much and particularly you, Commissioner.

DR. YOUNG: My pleasure. I appreciate the opportunity to help.

[Commissioner Bernthal left the briefing.]

MR. THOMPSON: I would like to make sure Region III and Region I get back on the line since I am beginning to talk about them.

CHAIRMAN ZECH: Region III, are you on?

MR. SRENIAWSKI: Region III is on.

CHAIRMAN ZECH: Region I?

REGION I SPEAKER: Region I is on.

MR. THOMPSON: We had a major two pronged approach, as I mentioned earlier. One was for the Region III team to go to the 3M licensee, to understand what type of information, inspection records they had concerning the devices and their use, with the thousands of licensed devices or a thousand of these devices out there, we wanted to focus both our resources and the resources of 3M on those things that had the most significant safety issues with respect to public health and safety.

In order to do that, I issued the order on January 25th that required 3M to notify all the customers who had this type of device, that is the 902, 906 and 908 series, of the leaking problems they were having. We suspended distribution of this device until there was an evaluation and approval by NRC to redistribute it, required them to develop a survey and

determine the scope and the significance of what needed to be done to arrive at the solution of why this particular device was failing, to analyze specifically what was happening with the Ashland Chemical devices, where we had the failure. In fact, at that time that was the only failure we were aware of, and also to provide NRC with a list of customers who had this particular device.

COMMISSIONER ROBERTS: Is there a question about the ability to provide an accurate list?

MR. THOMPSON: The computerized list of some 20,000 devices, I am sure there are some errors in the names and addresses of people. There was no question they provided the list to us. Whether or not all the information on that list was specifically correct, I don't know. Maybe Region III may want to comment on the quality of the list they provided.

MR. DAVIS: Mr. Sreniawski, who is our Section Chief and was up there, will answer the question.

MR. SRENIAWSKI: That question was posed to the 3M representatives. They said that to the best of their knowledge, they had not double checked it, but there could be some small percentage of errors. We are talking about the 20,000. There could be some small errors, clerical errors that would be present in any normal distribution list.

MR. THOMPSON: Taking that list, we did some -- since we talked initially on the current safety evaluation, I would

like to go to the next slide.

[SLIDE.]

MR. THOMPSON: Once we had the list and while we were at the site, we identified by inspection of the 3M records, that they had devices which had failures, some in fact in the food, beverage and pharmaceutical industry, and we had also directed that the 3M Company do a pilot survey with their own teams aimed at this particular area of their usage in order to get an identification of any leakage that may involve products dealing with these areas.

At the same time, we notified the agreement states of facilities in those agreement states which had a record, a past record of having failed devices, at least by 3M.

When it appeared to start dealing with these food and beverage products, we promptly notified the FDA of the new developments in this particular case. We had notified them, I believe, of the order that we issued initially, but at that time we had no specific concerns with the product being in human consumption.

We certainly increased our coordination then with the FDA, with the focus on those applications, where human consumption was involved. We have again developed this list with the products that we talked about earlier being ones in which both NRC and the FDA have taken samples of those products to have them analyzed at our particular labs.

Some of the facilities that were involved in the beverage industry were identified by the industry themselves in response to the notice they had received. They initiated fairly extensive sampling, hiring consultants at their own facilities and have identified areas where the device could enter into the food process. In those cases, they have also joined in the sampling of their own products in a significant way over the weekend, leaving no efforts unturned to complete analysis of these types of devices.

DR. YOUNG: Mr. Chairman, I could add that in our studies, in answer to Commissioner Roberts' question, there were a few plants that we found that we got the probate plant that had devices that were not on the 3-M list, so I think the strategy that NRC and we are following is to take any company that has a single device and then ask for that company to give us a full range of plants that that device might be located in, and that will help us enlarge that net.

The only difficulty will be, of course, that we'll have to rely on the notice that you put out promptly to try and alert other plants to let us know in the event that it's not on the 3-M list at all, which is the danger of your question.

CHAIRMAN ZECH: Well, let me ask a related question, if I may. We've focused on devices used in consumer products as a first priority, and I think that's certainly appropriate -- food, beverage, pharmaceutical products.

What's your sense of the likelihood that devices used at facilities that are not already covered by the orders that we've put out would pose a public health hazard?

MR. STELLO: That's very hard to estimate at this point. I think by having the order out and the identification, the self-identification, as well as a list, we'll be relying on the kinds of information that we've already had. Through the identification of plants through your Commission, most of the indications to date are just as Hugh mentioned, that the particles appear to be primarily on the floor and other surfaces. Thus again, you're dealing with worker safety, and that's a high priority, and I believe that's what the Commission is working on now.

CHAIRMAN ZECH: Well, I guess my only concern is that we should look at the possibility of expanding the order to include other facilities that might use this device, unless we are absolutely certain that we've covered all the aspects that it might get into the human body.

DR. YOUNG: It's hard to answer your question directly because we're just going over the notes of the locations now.

CHAIRMAN ZECH: No, I understand that.

DR. YOUNG: But as a public health significance, I think we're really dividing it into two major categories, those of the workers in the plant --

CHAIRMAN ZECH: Right.

DR. YOUNG: And then any consumer product.

CHAIRMAN ZECH: Right.

DR. YOUNG: And we would take the packaging also to be considered as a consumer product.

CHAIRMAN ZECH: Certainly.

DR. YOUNG: And that would include the foil, the boxes, and all of those other areas that could come into contact with human beings.

CHAIRMAN ZECH: Yes. And it would be expanded as appropriate. I think that's what you're telling me, isn't it?

DR. YOUNG: That's correct. And we would focus on the boxes in the initial phase and anything including the material that's delivered to the consumer, its packaging, its labeling, anything that could possibly be contaminated.

MR. STELLO: Mr. Chairman, let me -- we're meeting with 3-M Thursday, I believe it is, of this week.

MR. THOMPSON: Thursday of this week; yes, sir.

MR. STELLO: And we intend to develop a program, and we will have that ordering of priorities. We've already dealt with the issue of products which can either be consumed by or applied to humans.

We're going to look at the list of any other products that could be made, that could otherwise be contaminated in any way, shape, or form, and we'll be focusing on those, and then

we have, of course, industrial applications, and we want to progress down them to make sure that we get those that have the potential for public harm, to get the highest priority, and, of course, we're very concerned that we pay attention to where there's a potential for worker safety, too.

There's also another dimension of the problem. Other devices that are manufactured by 3-M appear to be more benign; that is, the ones that are involved here, as you can see, have compressed air forced through the devices. There are other devices they make which just take and process ambient air, others which are used in rollers or what have you in printing presses, and we'll be going down the list considering both the likelihood of a problem with the device, as well as the potential impact on the public health and safety, and we hope to have at least some scope of how to proceed with the rest of them following our meeting on Thursday.

CHAIRMAN ZECH: Well, I certainly agree with the priorities that you're taking. There's no question about that. But I guess my only concern is to make sure that we're looking at the possible threat to the human body from facilities that we have not so far covered in our order.

MR. STELLO: We will. We will.

CHAIRMAN ZECH: And that's what I just want to make sure we continue to look at that.

DR. YOUNG: It's an important point.

CHAIRMAN ZECH: Yes. And I think that we should be mindful that it may well be necessary to issue an expanded order, and so I would ask you, Dr. Young, your people, to not hesitate to let us know if you think that order should be expanded beyond the one that we have out already

DR. YOUNG: Excellent.

CHAIRMAN ZECH: I think we should do it as soon as possible and give that some kind of a priority.

All right. Thank you. Mr. Thompson, you may proceed.

MR. THOMPSON: Yes, sir.

[Slide.]

The next slide shows you kind of a summary listing of the types and locations that we have failed devices. You can see it covers the beverage bottling type industry, some in the food industry, some in the cosmetic and medical products, and some in, obviously, industrial applications.

Now that's a total of 30 places where we have had reports of some failures of the devices. The list we have, I guess, identified with specific facilities, which if I could have the specific facilities up --

[Slide.]

-- identifies only 23 at this time, because there are some calculation levels that deal with the other numbers that are not at NRC's reportable level.

Do we have copies in your package?

CHAIRMAN ZECH: No. We don't have a copy of that one.

DR. YOUNG: Mr. Chairman, as I mentioned, of those 23 that are shown, 13 are FDA-related and regulated plants. We have had seven plant inspections this time as of 10:00 o'clock this morning. Of those inspections, we have collected 32 samples. Of those 32 samples, ten have been completely analyzed, and in none of the samples has there been any radioactivity detected at this time.

CHAIRMAN ZECH: None of the samples of any of the companies on this list?

DR. YOUNG: On this list. And we're still in the process of assaying these. These are difficult assays depending on the product. In liquid, it's a lot easier than it is in dealing with powders. But we will complete these as rapidly as we can. And when I talk about a sample, that's really a lot of material; it's not just an individual container.

CHAIRMAN ZECH: We need copies of this list available, please. Sam, will you make sure that takes place?

MR. CHILK: I'll do it right now, sir.

CHAIRMAN ZECH: Thank you.

DR. YOUNG: And, Mr. Chairman, as any additional plants are identified, our promise to the Nuclear Regulatory

Commission is that we will use our inspectors and our sampling and continue to work in collaboration and work together on these samples.

CHAIRMAN ZECH: Let me be sure now that I understand what you've told me, and I just want to repeat it.

DR. YOUNG: Surely.

CHAIRMAN ZECH: On this list that you've given us with the sites with failed devices, you have told us that your inspections to date -- of how many of them?

DR. YOUNG: We have inspected seven of those, and I can, if you'd like, make an additional copy. I have on my sheet, we have put the ones that we have known to be FDA establishments, and where we have inspected is listed company by company, and I can -- if you can get a copy for that --

CHAIRMAN ZECH: I think that would be helpful, too.

DR. YOUNG: Of those seven that we have looked at, we have also taken a total of 32 samples, and a sample in this case is a large number of individual bottles or whatever the product is. Of those 32, we have completed ten, and there is no sample that has been radioactive at this time.

CHAIRMAN ZECH: Okay. You have not found any radioactivity on the samples.

DR. YOUNG: That's correct.

CHAIRMAN ZECH: That you've taken so far on this list.

DR. YOUNG: That's correct. Nor has the Nuclear Regulatory Commission nor has the manufacturing plant personnel. So that of those that have been examined so far, we have found no radioactivity.

CHAIRMAN ZECH: And no radioactivity as far as the product is concerned?

DR. YOUNG: As far as the product is concerned.

CHAIRMAN ZECH: That's what you're talking about.

DR. YOUNG: That's right. I'm totally, in all of my remarks, I'm talking about the consumer product. In some of these plants, there have been found to be radioactivity, as was described earlier.

CHAIRMAN ZECH: At the facility, though. Some of these plants -- or is it all of these plants that have found --

MR. STELLO: All.

CHAIRMAN ZECH: All of them have contamination at the facility?

MR. STELLO: Contamination at the facility. So far none of the products, consumer products, at these facilities have tested positive.

CHAIRMAN ZECH: All right, fine.

MR. STELLO: By either FDA, NRC, or the company themselves. The company programs in many cases have been very extensive.

DR. YOUNG: That's correct.

CHAIRMAN ZECH: Now are we looking at other sites that have failed devices? Do we know that this is a complete list?

MR. THOMPSON: This is not a complete list. From the extent that as additional information is coming in, you know, and inspections are ongoing now, I think there may be two or three additional facilities that would be added to the list. This was prepared earlier this morning.

So the list, as we continue our inspection activities, the list will continue to grow.

I would note that, I think, as we said in all of these cases, in particular with respect to the beverage industry, there have been extensive samplings in all of the beverage cases for which NRC has regulatory oversight for, and the products have, in fact, been found not to contain -- not to be contaminated with any of these --

CHAIRMAN ZECH: Have all the facilities that NRC has interfaced with in this matter and FDA, have all the facilities and companies been cooperative as regards this effort?

MR. THOMPSON: They have been absolutely cooperative. They're obviously all concerned about their names being named.

CHAIRMAN ZECH: Yes, I'm sure they are. But none of them have been uncooperative; is that what you're telling us?

DR. YOUNG: Not to the best of my knowledge, and also it is important to point out that manufacturing has ceased in

these plants, so that there's not anything further that's being introduced.

I think the good news, Mr. Chairman, is that though the samples are limited to date and still ongoing, that no plant yet that had contamination that was evident upon inspection by the Nuclear Regulatory Commission, had any radioactivity in the consumer products that were manufactured there, and that's what we have to keep focusing on.

CHAIRMAN ZECH: I understand. We're also thinking about the workers, too, now.

DR. YOUNG: Absolutely.

CHAIRMAN ZECH: And if there's contamination at the plant, I presume we have procedures underway to not only decontaminate the facility, but to check the workers for any contamination that they may have received.

MR. STELLO: That's correct.

CHAIRMAN ZECH: Those things are going on also; is that correct?

MR. THOMPSON: We are following up with each of the facilities with respect to the actions they are taking to ensure that their employees, within our regulatory area -- the agreement states are following up on other ones -- to ensure that the workers are properly evaluated as part of this program.

CHAIRMAN ZECH: All right. Proceed.

MR. STELLO: While we have the list in front of us, let's recall that this activity -- and I should congratulate the Staff; they've been working pretty much throughout the entire weekend, and I'm sure when we get back to our offices, as we continue, we'll get new information, and this list could very well change today, tomorrow, next week. We are not through.

CHAIRMAN ZECH: I understand the list is not necessarily a complete list. I hope it's accurate as far as you've put it together.

MR. STELLO: It is as accurate as we could make it at the time we walked into this meeting, which is probably why it wasn't included in the packages.

CHAIRMAN ZECH: All right, fine.

MR. THOMPSON: We are confident that the facilities on this list, in fact, did meet our reporting level for the contamination of the 11,000 disintegrations per minute reporting aspect.

CHAIRMAN ZECH: All these facilities have stopped using these devices; is that correct?

MR. THOMPSON: To the best of my knowledge, all of these facilities have not only stopped their process line but they have removed these devices and in most cases they have completed the decontamination activities necessary to allow them to continue processing.

CHAIRMAN ZECH: The Food and Drug Administration is again sampling the products from these companies.

DR. YOUNG: That's correct.

CHAIRMAN ZECH: You have sampled some but not all at this point and you are continuing to sample the others, I presume.

DR. YOUNG: That's correct. We are not allowing any additional lots to go into commerce until we know whether the lots can be traced of those particular plants. That is a very important issue for assuring consumer safety. We are working on that as well right now.

CHAIRMAN ZECH: Thank you. You may proceed.

MR. DAVIS: This is Bert Davis with Region III. We do have one company that had some contamination and cleaned it up, removed the device that was leaking but they had some other devices that were used in critical applications. They wipe tested those and found they were not leaking and they are using them today.

DR. YOUNG: Are they manufacturing food, drug and cosmetic products?

MR. DAVIS: No; they are not.

DR. YOUNG: The concern I would have and would just caution you on is that wherever one is putting something into the consumer line, one has to be sure you can tell whether the lot is clearly marked on the box and on the shipping areas. I

know we have been working very closely with the Nuclear Regulatory Commission and we shall continue to, to be sure that the consumer products when introduced can be tracked.

CHAIRMAN ZECH: Fine.

MR. THOMPSON: I think that points to some of the difficulty we may be facing in the future, that some of these static eliminator devices do have a safety implication with respect to potential fire hazards, with respect to the quality of a heart pacemaker device. We will have some difficult judgments to make with respect to whether those devices are to be automatically removed or whether it is a show cause type of approach.

CHAIRMAN ZECH: I think the Commission should be involved in those decisions. I appreciate the fact that we might have some tough ones. This is a very important issue. Public health and safety is concerned. On those calls that you think you have good reason to allow the continued use of this device, I think you should involve the Commission.

MR. THOMPSON: We certainly will.

MR. STELLO: Mr. Chairman, you recognize that if we find issues out there where we have to take immediate action, the Commission has authorized the staff to do so.

CHAIRMAN ZECH: We are not reneging on anything we have already authorized you to do.

MR. PARLER: It was a question of perhaps putting

various things in a balance, immediate action would not be taken for some reason. If you get to that point, the Commission and the Chairman wants to know about it.

CHAIRMAN ZECH: Yes. Thank you. That is exactly right.

MR. THOMPSON: In fact, we probably are taking some additional actions very soon with respect to making sure that 3M notifies all of its customers of the activities that we are having and addressing now, to the extent that we have some concerns that they have not fully notified all of their customers of the problems.

CHAIRMAN ZECH: What I am saying is I expect the Commission to be completely informed.

MR. STELLO: Absolutely.

CHAIRMAN ZECH: Come to us if you do feel there is something that is to the point where your judgment has any concerns at all.

Go ahead, Mr. Thompson.

[SLIDE.]

MR. THOMPSON: Late last week, we issued a second order. I think it was referred to earlier today. It was immediately effective, confirming the 3M Company's decision to remove these devices, the 902, 906 and 908 series, from any application dealing with food, bottling, pharmaceutical and cosmetic uses. We felt this was the appropriate step to be

taken given the extensive nature of these failures in these devices.

The 3M Company did not disagree with that. In fact, it started removing these types of devices prior to doing that.

We are also, as we talked about earlier, continuing actively our program of sampling the products, where we find the contaminated facility. We have an important meeting with 3M this week. In fact, today at close of business, they should have the report of their results of the surveys they have been doing, at the higher risk facilities and developing an action plan which 3M proposes to take during the coming timeframe to get a complete understanding of the problems occurring.

Our current actions, as we talked about earlier, is the high priority sampling of the human products. 3M's report to us, which is due today, and we also have ongoing right now a review by Region III of the records of 3M of other static eliminator devices. These are the other ones and the ones currently in question, to see if the history of these devices that is available at 3M and their records indicate there may be a pattern that we were not aware of for those devices, as we were not aware of for the 900 series devices.

We do have our order with 3M and NRC and I would note FDA is joining us in Chicago at the meeting on Thursday to receive and evaluate the response that 3M has had to the order. We will basically take any further actions as we need in

coordination with the Commission, where we don't need to take immediate action, if we find the need to take immediate action, we obviously will take immediate action in order to protect the public health and safety.

Two other actions that we are following up on is some evidence at 3M of incomplete reporting of leaking surveillance of these devices to us. We would have believed the leaking devices, the 70 some odd cases that we had identified in our inspections, there should have been some better understanding of the reporting of these devices to us so this would not have occurred.

Also, an evaluation of 3M's assessment of how these devices are being utilized in the environment, when they allow these to be operated under their general license provisions.

[SLIDE.]

MR. THOMPSON: Finally, covering some of the issues that we see, we really need to complete our root cause determination, was it extraordinary ambient conditions, were these devices just too vulnerable for ordinary conditions to be continued. Should we expand our testing and suspension to other models. Are other product samplings needed, if so, which ones. How to evaluate the competing risk. Also, depending on the number, determine that the facilities that had leaking devices are adequately evaluated and decontaminated, the appropriate way to do that, make sure if it involves thousand

and thousands of facilities, our resources will be stretched, but certainly we will want to make sure we have some confidence that the places that become contaminated are certainly cleaned up before the activity is resumed.

MR. STELLO: That concludes our presentation.

CHAIRMAN ZECH: You have given us your current risk evaluation before and I presume that is why you skipped it, you don't have any problem with it. I presume FDA has said the same thing.

MR. THOMPSON: Essentially, Mr. Chairman, we anticipate there will be a continued identification of some contaminated facilities as we continue the inspection activities. As we said earlier, it is unlikely even if some of those microspheres were to enter into the consumer products, it is unlikely it would be a significant health hazard to the public. Nevertheless, we are continuing jointly with FDA and NRC and the agreement states to sample these products as we go through the next weeks.

CHAIRMAN ZECH: All right. Thank you very much.

Questions? Commissioner Roberts?

COMMISSIONER ROBERTS: No questions, Mr. Chairman.

MR. DAVIS: Mr. Chairman, we do have some information regarding Commissioner Bernthal's question on the purity of the polonium, if you would like to record it.

CHAIRMAN ZECH: He is not here but go ahead. We will

tell him about it.

MR. DAVIS: Bruce Mallett, the Branch Chief in our office, is going to do that.

MR. MALLETT: This is Bruce Mallett. Thank you for letting me address this issue. This is polonium 210 and it is made by neutron irradiation of stable bismuth and it is irradiated by Atomic Energy of Canada in their irradiator of aluminum cans. Polonium 210 is then extracted by a melting chemical extraction process at a very high temperature process through a precipitated filter and it is electroplated on the platinum gauges. They call it a gauge, but it is actually like a wire. The stable bismuth used to irradiate is nuclear grade so the purity is in the parts per billion range. After the polonium has been precipitated and plated on the platinum gauges, prior to incorporating it in microspheres, they do a gamma spectroscopy of it. If there is anything else that shows up besides polonium 210, they reject the batch.

MR. STELLO: Thank you.

CHAIRMAN ZECH: Thank you very much.

Let me just ask a couple of questions. With regard to our licensing process itself and the monitoring process, it seems to me that if we issued this license in 1964, that is 24 years ago, how often have we reviewed that license itself or that process itself to make sure that we -- somewhere along the line I have been told that 3M has these devices returned every

three months -- every 13 months; is that correct?

MR. THOMPSON: Yes. The normal practice for this particular device is that it must be, with respect to our current license, leak tested every 12 months. There is an one month grace period, which is the current practice for the general licensee to return it back to 3M for leak testing.

The general licensees normally don't get involved in making contamination surveys, leak testing of this device. They rely almost entirely on 3M's service in the contractual way that currently exists.

CHAIRMAN ZECH: When they return the device to 3M, does 3M monitor it for contamination or radiation leakage?

MR. THOMPSON: They do. Let me ask Region III to respond precisely to what they do, since they just did the inspection.

MR. SRENIAWSKI: Gauges are leased for a year. All the gauges are almost exclusively returned to 3M. The general licensee does not do the leak test. The leak tests are scheduled for 13 months. Your statements are essentially true. It is rare that a licensee would hire a private consultant to do an individual survey and it would only be in the case of an accident. There have been a few accidents and there have been a few cases where 3M or a private consultant has responded, a serious accident like a gauge dropping into a furnace.

MR. PARLER: The accident that he is talking about I

gather is something that happened in the industrial process that possibly could have caused damage to the gauge, to the device, not an accident that could release stuff.

MR. SRENIAWSKI: There have been a few fires which fall into that same category, where the entire building goes.

MR. THOMPSON: I believe in answer to your question, Mr. Chairman, what normally occurs is that there is a test done of the device by 3M when it is received at the end of the lease. They do a drop test and a smear test on the device to see if it had leaking, if the device had been leaking.

CHAIRMAN ZECH: How long have we known this leakage has gone on and the contamination problem? Has 3M known it for a long time or did they just discover it?

MR. DAVIS: This is Bert Davis in Region III. Let me try to answer that. We get a monthly report from 3M, that shows failure rates of devices. That has been running at about 0.03 percent failure. That failure rate is consistent with what is expected as the failure rate at the time the devices were originally licensed.

One of the problems we found in our inspections was that we determined that there were some devices, for example, the 900 series that we have been talking about, that had a higher failure rate than the .03 percent, around 1 percent, and that was not being reported to us in the monthly report.

Apparently the reason was that whenever 3M would

examine the products, when they were returned to the 3M facility, if they determined that the leakage was due to an event, as they called it, which would be damage or a fire or even oil contamination, they would call that a failure due to an event and they were not reporting that to us.

We learned of these things last week.

CHAIRMAN ZECH: What you are saying is they had reported a very small number of problems; is that correct?

MR. DAVIS: That is right. Over the years, they reported a small number of problems and we did not consider those problems. The reason I have given is it was because the number of problems was consistent with what the expectations were when the devices were licensed.

CHAIRMAN ZECH: Has there been any change to the device itself in the years since we have licensed it? For example, how about the adhesive material itself? Has that been changed? If that has been changed, would that have to come to us to review?

MR. DAVIS: We would have to review it. Let me ask if my staff knows. Mr. Sreniawski reports that there was at least one change in the adhesives used during this time interval.

CHAIRMAN ZECH: Did we review that and approve it?

MR. THOMPSON: The license was renewed, I believe the last one was in 1985. Certainly our last renewal did address

that.

Don, was that change made before the 1985 timeframe?

MR. SRENIAWSKI: Yes; it was.

MR. THOMPSON: I guess the question is, Mr. Chairman, whether or not the staff looked at the epoxy change as part of our licensing process.

MR. SRENIAWSKI: We don't know the answer to that.

MR. STELLO: We will get the answer back to you, Mr. Chairman.

CHAIRMAN ZECH: Fine. In 1985, what happened? Did you say we reviewed the whole license in 1985?

MR. THOMPSON: Typically with the material licensees, we review their license every five years and at one time -- we have a provision which is called timely renewal. If a licensee has requested a renewal of his license and has an application submitted to NRC for review and approval, prior to the expiration date, it will remain effective in a status called timely renewal.

This particular license application had undergone a number of renewals. It did have, as I mentioned earlier, that one period where there was staff concern over this particular license and it went for a fairly long period of time without actually being renewed but remained under the timely renewal status.

CHAIRMAN ZECH: Fine. Could you review for me very

briefly again the status of recalling the devices? What have we done as far as limiting their use?

MR. THOMPSON: The first thing we have done has stopped any distribution of these devices to any application from 3M, of the 902, the 906 and the 908 series, static eliminators. These particular ones are used in the high pressure air systems. That involves the entire spectrum of applications of those devices in the industry.

We have also issued a confirmatory order confirming the removal of those devices that are specifically in the food, beverage, pharmaceutical and cosmetic industry, to the extent they have been identified. Those devices are to be removed immediately from the application in the plant, packaged and await further shipping instructions from the 3M Company, which would normally have those devices returned back to 3M since they are leased devices.

COMMISSIONER ROBERTS: I have a question that you may not be able to answer. If I am manufacturer X and I have one of these devices and I must cease using it, are there alternatives for whatever the industrial process is?

MR. THOMPSON: Commissioner, I believe the answer is yes. In discussing it with a number of the manufacturing applicants, I have found certain individuals who had these devices, who thought they were installed and had not been installed, they were sitting in the warehouse. There are those

who have removed them immediately and the plant is able to operate.

I am not aware of any specific device in the discussions with the group we talked to that would not be able to continue operating.

The one concern I am aware of dealt with the pacemakers, the order, I do not believe, covered the medical devices at that time, because of the lack of specific knowledge of where we would actually shut down an industry that made some medical devices.

We did not address other areas such as the static bar eliminators. They are not covered by this order. They may have some concerns with respect to fire hazards at the printing presses. They are thousands of applications of these devices.

Commissioner, I cannot tell you that everybody will be able to continue to operate every part of their facility as designed without a replacement. I do understand there are non-radioactive static eliminators available. Whether they would fit immediately in the process, I don't know.

CHAIRMAN ZECH: Well, I'd like to thank the Staff and the Office of Nuclear Materials Safety and Safeguards in particular for this presentation.

I would also like to thank Dr. Frank Young and his colleagues from the Food and Drug Administration for joining us here today. We value your knowledge and expertise in this

area, and we certainly respect your responsibilities, as well as our own. We appreciate your continuing cooperation with us in this effort.

It looks to me like we are taking the proper steps, but I think we need to continue to take an energetic, yet conservative and cautious approach to the actions that we have talked about here today, but also to act promptly when any action seems called for, and I would like to encourage the Staff to continue working with the Food and Drug Administration, with the states involved, and with the other appropriate agencies of our government, as well as with the industries and the companies involved, too.

The Commission intends to closely monitor all these activities, and we want to make sure that we are fully informed.

MR. STELLO: You will be.

CHAIRMAN ZECH: Thank you very much. We stand adjourned.

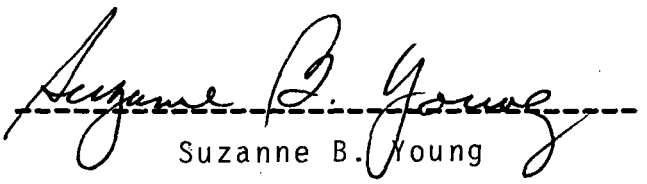
[Whereupon, at 3:07 o'clock, p.m., the Commission meeting was adjourned.]

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 Statis Elimination Device Problems
PLACE OF MEETING: Washington, D.C.
DATE OF MEETING: Monday, February 8, 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.



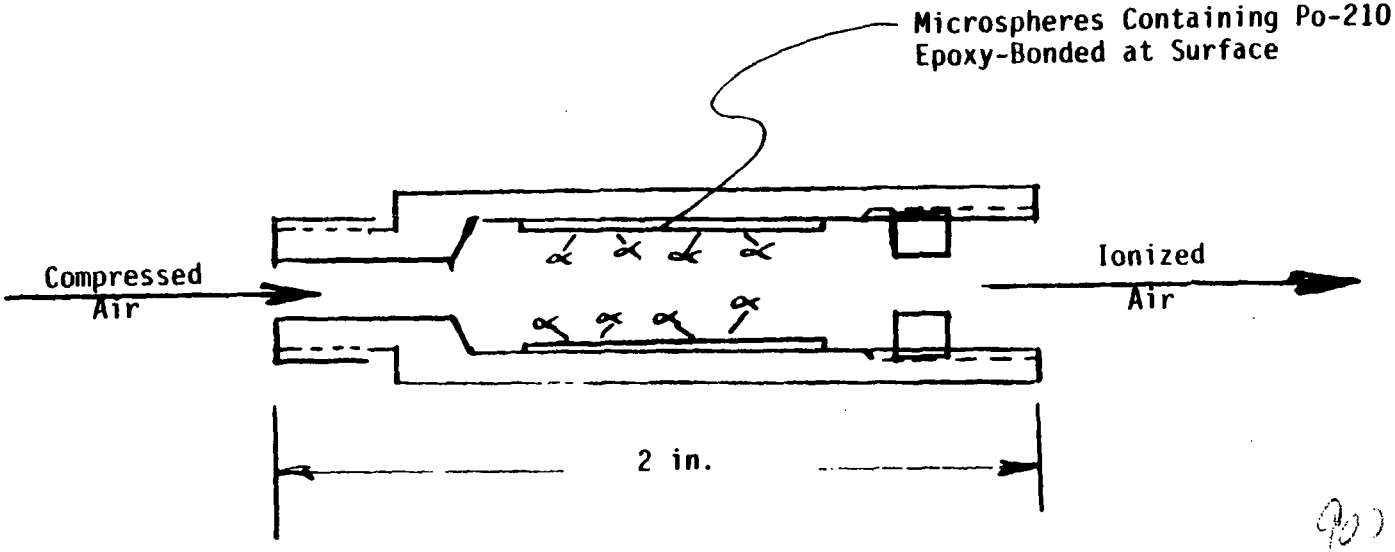
Suzanne B. Young

Ann Riley & Associates, Ltd.

STATIC ELIMINATORS

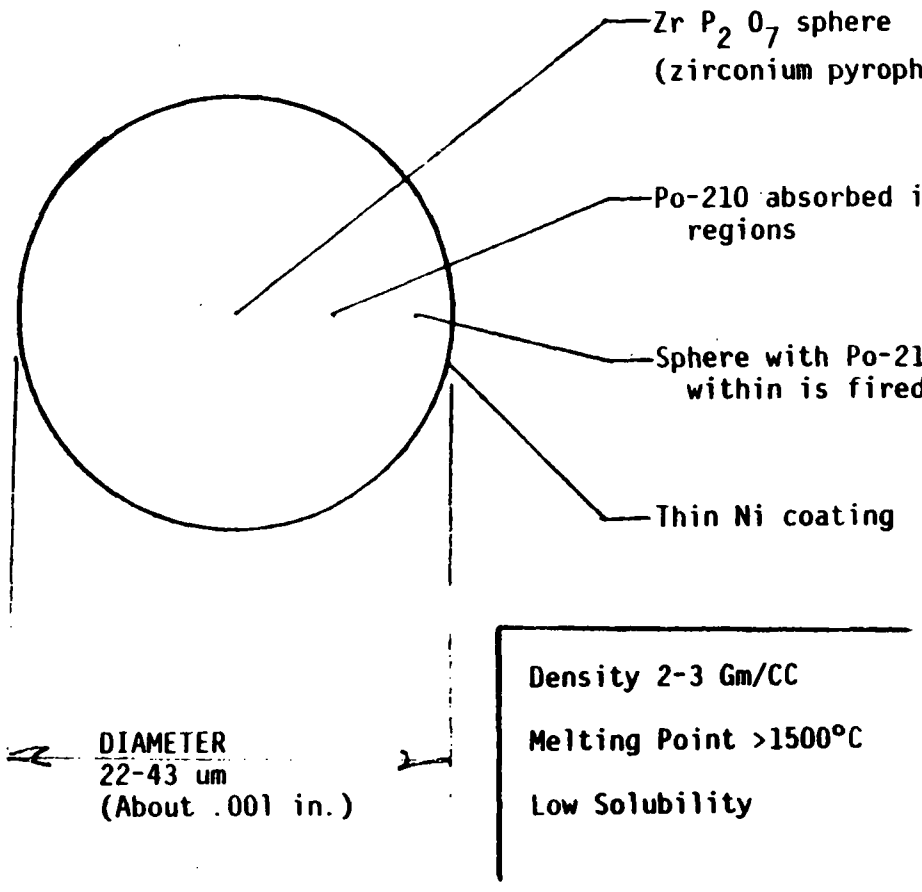
- THE DEVICE
- THE PROBLEM
- THE RISK
- THE NRC/FDA/STATE ACTIONS
- FUTURE ACTIONS/ISSUES

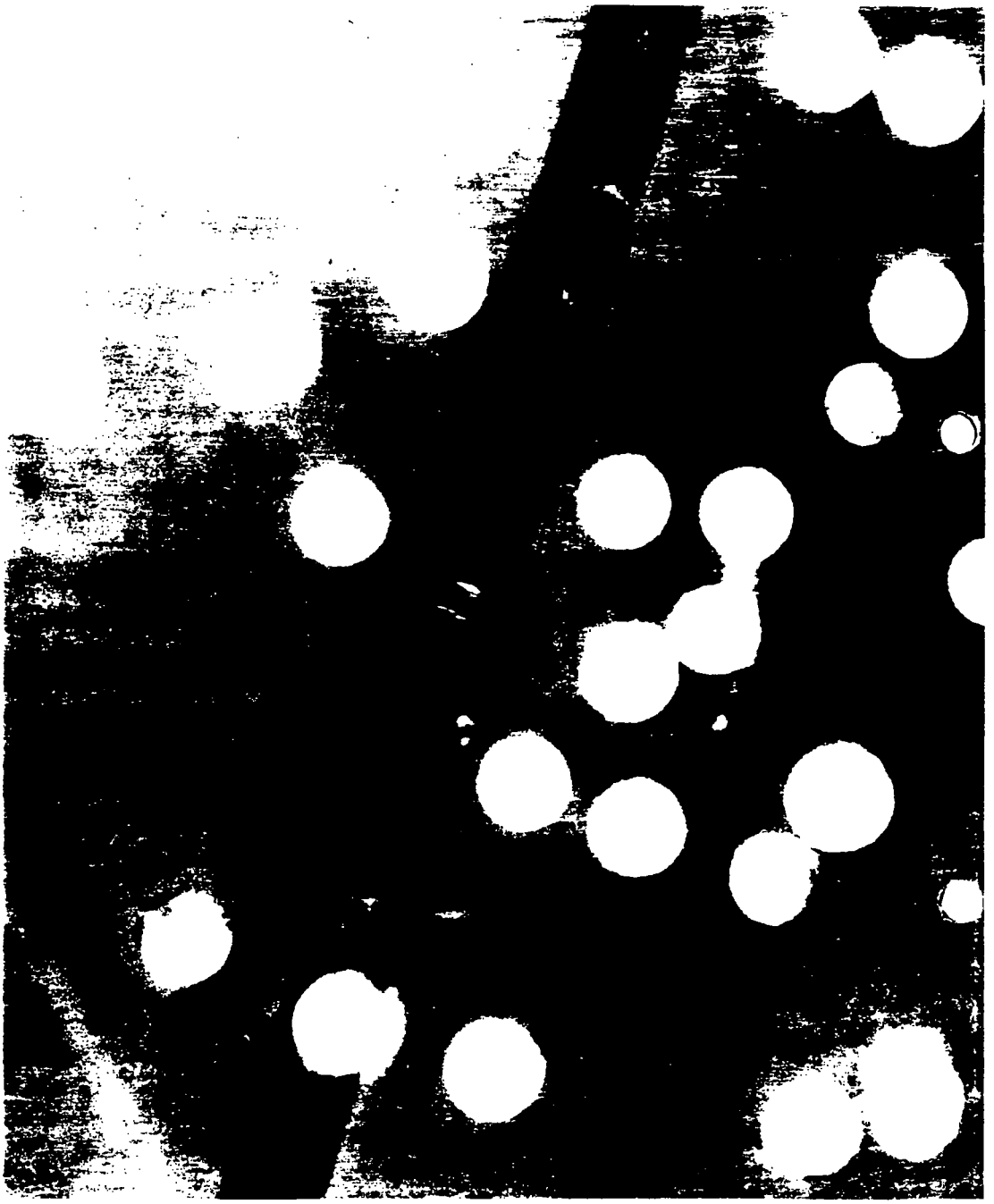
AIR IONIZER



Release of Alpha (∝)
Particles Ionizes
Air in Their Short
Path of Travel

MICROSPHERE





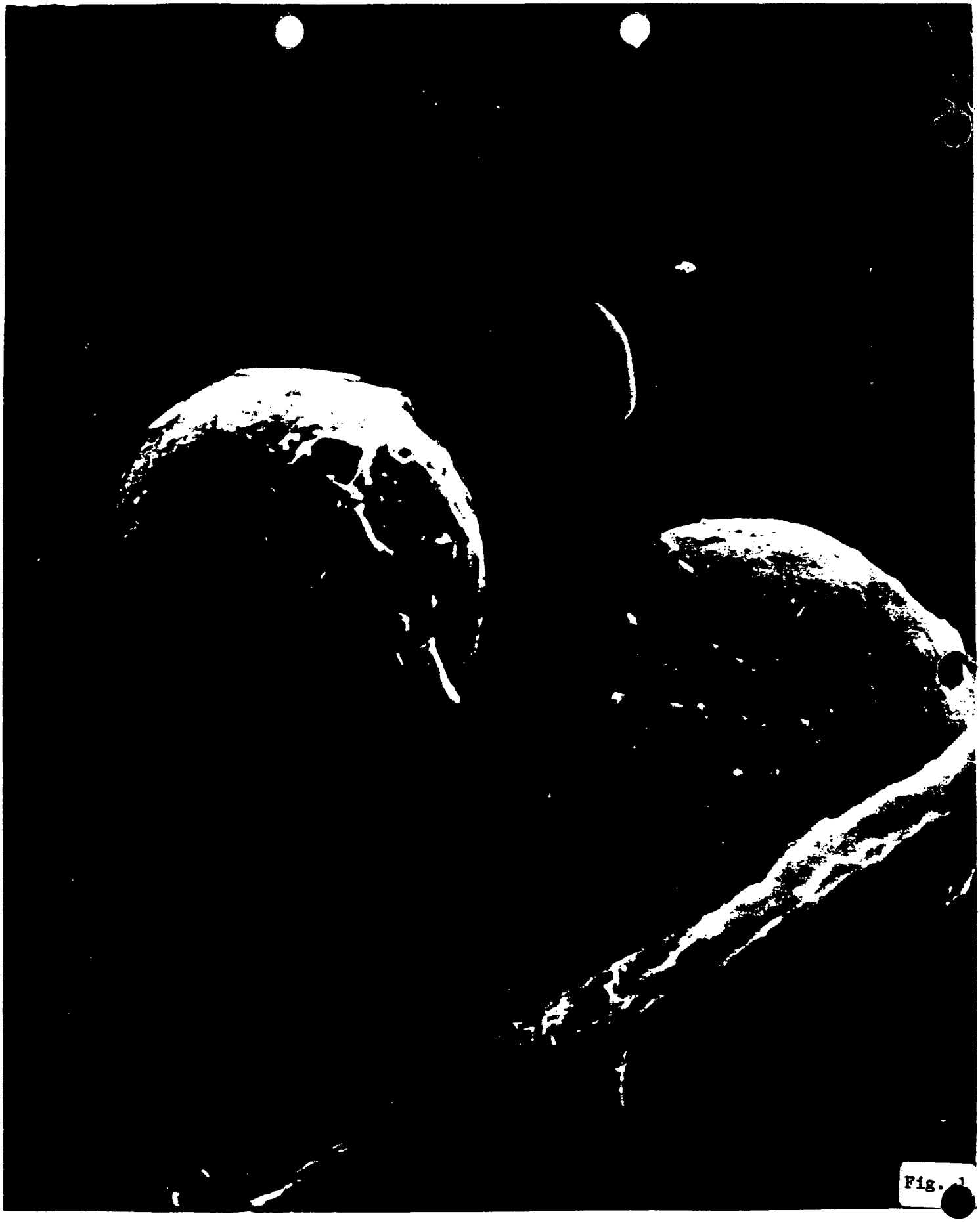


Fig. 1

INITIAL EVENTS: ASHLAND CHEMICAL COMPANY (ACC)

- ACC CUSTOMER QUESTIONED SMALL ALPHA ACTIVITY IN SULFURIC ACID
- JANUARY 21 INVESTIGATION SHOWED ALPHA CONTAMINATION IN PLANT AND ON WORKER CLOTHING
- NRC NOTIFIED--DISPATCHED TEAM TO ACC SITE (JAN 22ND)
- NRC TEAM FOUND CONTAMINATION AT ACC - EASTON, STATE OF TEXAS FOUND IT AT ACC-DALLAS (JAN 24TH)
- NRC ISSUED ORDER SUSPENDING DISTRIBUTION OF DEVICES (JAN 25TH)
- TWO OTHER ACC PLANTS SHOWED NO CONTAMINATION

INITIAL FINDINGS AND ACTIONS

- CONTAMINANT IS COMING LOOSE BUT APPEARS NOT TO BE DISSOLVING
  - SAMPLING OF ACC PRODUCTS
  - SAMPLING OF WORKERS' URINE
- ACC PRODUCTS WERE HELD UNTIL SHOWN TO BE ACCEPTABLE FOR INDUSTRIAL USE
- REGION III TEAM TO 3M - JAN 25TH
- 1ST NRC ORDER TO 3M - JAN 25TH
  - NOTIFY ALL CUSTOMERS
  - SUSPEND DISTRIBUTION
  - SURVEY AND DETERMINE SCOPE AND SOLUTION
  - ANALYZE ACC DEVICES FOR FAILURE MECHANISM
  - PROVIDE LIST OF CUSTOMER TO NRC

CURRENT SAFETY CONCLUSION

- CONTINUED IDENTIFICATION OF CONTAMINATED FACILITIES LIKELY AFFECTED

- 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.

FOLLOWUP ACTIVITIES

- DISCOVERY OF MANY MORE DEVICE FAILURES, SOME IN FOOD, BEVERAGE AND PHARMACEUTICAL INDUSTRY

- INCREASED COORDINATION WITH FDA AND STATES WITH FOCUS ON HUMAN APPLICATIONS

  - 1ST PRIORITY FOR HUMAN APPLICATIONS WHERE FAILURES HAVE BEEN PREVIOUSLY IDENTIFIED IN DEVICES RETURNED TO 3M

  - 2ND PRIORITY FOR HUMAN APPLICATIONS WITH NO KNOWN DEVICE FAILURES

TYPES OF LOCATIONS WITH FAILED DEVICES

BEVERAGE BOTTLING	12
FOOD	5
COSMETIC, MEDICAL PRODUCTS	2
INDUSTRIAL	11
TOTAL	30

NRC 2ND ORDER

- FEBRUARY 5 CONFIRMATORY ORDER, IMMEDIATELY EFFECTIVE
  - CONFIRMED 3M FEBRUARY 3 AND FEBRUARY 5 NOTICES TO REMOVE DEVICES FROM FOOD, BOTTLING, PHARMACEUTICAL, AND COSMETIC USES
- SAMPLING PROGRAM WITH NRC, FDA AND STATES COLLABORATING ON HUMAN USES AND PRODUCTS
- 3M REPORTS AND ACTION PLAN MEETING WEEK OF FEBRUARY 8

CURRENT ACTIONS

- HIGH PRIORITY SAMPLING OF HUMAN PRODUCTS CONTINUES BY NRC, FDA, STATES AND AFFECTED COMPANIES
- 3M REPORTS PER 1ST ORDER ON FEBRUARY 8
- NRC AND 3M EXAMINE RECORDS OF OTHER 3M STATIC ELIMINATOR DEVICES
- 3M/NRC MEETING ON 1ST ORDER REPORT AT REGION III ON FEBRUARY 11
- FURTHER ACTION DETERMINED BASED ON INFORMATION GATHERED
- EVIDENCE AT 3M OF INCOMPLETE REPORTING OF LEAKAGE SURVEILLANCE
- EVALUATE 3M's ASSESSMENT OF ENVIRONMENT FOR WHICH DEVICES ARE TO BE PLACED

CURRENT RISK EVALUATION

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.

ISSUES

ROOT CAUSE DETERMINATION

- ARE THESE DEVICES FAILURES CAUSED BY EXTRAORDINARY AMBIENT CONDITIONS OR ARE THE DEVICES TOO VULNERABLE TO ORDINARY CONDITIONS?

- SHOULD TEST AND SUSPENSION BE EXTENDED TO OTHER MODELS SUCH AS STATIC BARS?

- ARE FURTHER PRODUCT SAMPLES NEEDED? WHICH?

- SHOULD COMPETING RISKS BE DETERMINED?

- DEPENDING ON NUMBER, DETERMINE THAT FACILITIES HAD LEAKY DEVICES ARE ADEQUATELY EVALUATED

CORRECTED COPY

LIST OF SITES WITH FAILED DEVICES*

COMPANY	LOCATION	TYPE OF PRODUCT	WHEN
1. KTI	Carrollton, TX	chemicals	2/4/88
2. KTI	Sunnyvale, CA	chemicals	-
3. Xicor	Milpitas, CA	chemicals	-
4. Coca Cola	Dallas, TX	beverage	-
5. Coca Cola	Dallas, TX	beverage	-
6. Coca Cola	Fort Worth, TX	beverage	-
7. Coca Cola	Needham, MA	beverage	-
8. Anheuser Busch	St. Louis, MO	beverage	-
9. Custom Photo	Austin, TX	--	-
10. Ashland Chemical	Easton, PA	chemicals	-
11. Ashland Chemical	Dallas, TX	chemicals	-
12. McDonnell Douglas	St. Louis, MO	--	-
13. Block Drugs	Dayton, NJ	denture adhesive	2/5/88
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	-
18. Coca Cola	Phoenix, AZ	beverage	-
19. Paul Flum Ideas	St. Louis, MO		-
20. Best Food Unit	Argo, IL		-
21. 3M	Ames, IA		-
22. Pepsi Cola	Tulsa, OK	beverage	-
23. Coca Cola	San Liandro, CA	beverage	-

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

SATURDAY, FEBRUARY 6, 1988: 9:00 P.M. EST

PLANTS THAT EXCEED NRC REPORTING GUIDELINES (23 sites)

NAME	LOCATION	PRODUCT	RESULTS
KTI	Carrollton, TX	Chemicals	
KTI	Sunnyvale, CA	Chemicals	
XICOR	Millpitus, CA	Chemicals	
Coca Cola	Dallas, TX	Soft Drinks	FI
Coca Cola	Dallas, TX	Soft Drinks	FI
Coca Cola	Fort Worth, TX	Soft Drinks	FI
Coca Cola	Needham, MA	Soft Drinks	FI
Anhauser-Busch	St. Louis, MO	Malt Beverages	F
Custom Photo	Austin, TX	Photo ?	
Ashland Chemical	Easton, PA	Chemicals	
Ashland Chemical	Dallas, TX	Chemicals	
McDonald Douglas	St. Louis, MO	Airplane ?	
Block Drugs	Dayton, NJ	Dental Adhesive	FI
Ford Motor	Milan, MI	Cars ?	
Anhauser-Busch	Jacksonville, FL	Malt Beverages	F
Avon	Morton Grove, IL	Cosmetics	F
Ross Laboratories	Casa Grande, AZ	Infant Formula	FI
Coca Cola	Phoenix AZ	Soft Drinks	FI
Paul Flum Ideas	St. Louis, MO	?	
Best Food Unit	Argo, IL	? Food	F
3M	Ames, IA	? Chemicals ?	
Pepsi Cola	Tulsa, OK	Soft Drinks	F
Coca Cola	San Leandro, CA	Soft Drinks	F

F = Known to be FDA establishments
I = Inspected and sampled as of 9:00 P.M., 2/6/88