EXHIBIT 4

18506

EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Division of Cancer Treatment
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July 8, 1995

Dear Detective Jody P. Luke:

It has been an ordeal for us in these five long days, it is even more bitter for us to review the tragic moment when I found, by chance, that my wife Dr. Maryann Wenli Ma had been contaminated, internally, with very strong radioisotopic materials (later estimated by the RSB to be at least 260 microcuries). I tried several times with quivering hands to start this report, and quitted several times, wishing helplessly that this might just be a nightmare. I realized that this really are the ruthless fact, when I frequently wakened by my wife's sobbing, in her sleepless sadness, with the pillow immersed in tears.

June 29 (Thu), 6:00 PM to June 30 (Fri), 7:30 AM

It was around 6:00 pm of June 29, when I and Maryann were working in a same benchtop. My experiment finished at that time, I customarily pick up the radiation monitor to have a survey of the bench top and the adjacent floor. When I checking the floor around where Maryann's feet. A strong audible signal was alarmed. This surprised me, because we haven't used any radioisotopes of such intensity (eg. P32) for about three monthes, and during our many years of experience dealing with the radiomaterials, nothing like such ever happened. Our first thoughts was that maybe the chair where Maryann's sitting was contaminated. So I asked Maryann stop the experiments, off the seats and carefully survey the the chair, no signal could be picked up. Whereas, whenever the monitor's near Maryann's body, strong signals were heard. The signals were so loud and heinously

intimidating, which made me very terrible. Thinking that Maryann might have accidentally contaminated the radio-isotopes in some other place and got her clothes contaminated, I asked her to take off her lab coat, then the shoes, surveying the shoes, no signal, surveying the feet, very strong signals. I went immediately to her face, hands and head where there's no external wearings, also found very strong signals. Wishing that our monitor might be broken that would pick up wrong signals, I rushed to another lab, grab one another monitor, rushed back, signals still as intense. We were stunned, instantly awared that the contamination must not be external, It must be that the radio-isotopes being ingested internally. It made us even more horrified when we began to think about that Maryann had already been pregnant for about 4 monthes.

I went for the room of our mentor, Dr. John Weinstein, the moment when I slightly recovered from the shock, John's not there. I pick up the phone and call 116 immediately to report the incidence. Put down the phone and turning around, I found John's in front of a computer with a summer student in the back corner of our lab. I reported what happened to him, to my grieved surprise, we could not see a face of concern and seriousness, but a queer smile. In answereing his many strange questions, I repeated the surveys as I previously described, showing him how we got the conclusion that Maryann were contaminated internally. When I told him that I already called 116 for help, he think it was not necessary, but then he called the Radiation Safty Branch (RSB).

The ambulence arrieved very quickly, with two officers coming directly to Maryann. When they heard that she got the radioisotopes ingested, instead of injected (a misunderstanding which might be because that my report is not clear enough), they started to inquire the situations and gave Maryann a routine check-up, reported to the relevant authorities and prepared to send Maryann to a hospital when John transfered a call from RSB, instructed that we waiting there for the RSB officials to have a survey. While waiting, the police officer asked Maryann that why she ingested radiation materials inside, we reply that we were really wondered ourselves. John then asked Maryann where we store our food, which he must be knowing since some of his un-consumed drinks also stored in two of the refrigerators in a public conference room of our whole labs, also many other person's lunch time foods are also stored there. When we told him where, he nervously picked up a monitor and went to the conference room, which is at another corridor. I followed him there, but confusedly, then he found that one of the refigerators got heavilly contaminated. Upon return, John kept on asking that if only the refrigeritor's cabinet was contaminated, how could we contamate Maryann's food. Sensing his question might mis-lead to the

conclusion that we contaminate the food ourselves, also because I was then filled immensely with anxiety, I replied quite rudely that how should we know. There's absolutely no possiblity that we contaminate our food ourselves and got so severe a contamination, especially when he had known already that the refrigeritor also being contaminated. Since no one use and store radiation materials in the conference room, and the refrigerators there were dedicated for saving food, concuring severe contaminations found in there and in Maryann's body clearly translated a deduction that there must be a perpetrator.

Then arrived two RSB officials. After surveying with their own monitor, one official was helping Maryann to find a shower, which turned out at last that the shower room could not be found, while the other official, when heard that the conference room was also contaminated, asked me to show him the route to the contaminated referigerater. After his careful and professional surveying, he pinpoint a spot of strong radiation contamination on the floor, just 6-8 inches in front of the refrigerator where we store our food, and found no contamination inside the cabinet of the refrigerator. Afterward, the officer also survey other people around, only found a strong "hot" spot on the bottom of a Japanease fellow working in our own corridor.

Back to the lab, John was begining to perform the smear tests, which by smear with filter paper at the face and hands of Maryann's. He then asked me to show him how to proceed to do a scintillation countering, which I did and got a results, which indicated that the contamination was not external. John then started to persuade Maryann drink a lot of water, although both RSB officials hadn't been defintely sure whether the contamination is external or internal (since Maryann could not get a shower). Maryann told them that the shower might not be necessary, because she just had had the shower at about 4:00-4:30, when she's felt very tired and had to go back home to eat something and got a shower. We were backing home also for fetching some other foods for the supper, since her experiments that afternoon might last to as late as 9:00-10:00 pm.

Maryann then took back an urine sample. John suggested that we do a scintillation countering to determine the amount of the radiation contamination, which might be more time consuming. I reacted at once by suggesting that the RSB official have a survey of the urine sample directly with the monitor, which she did, and horriblly, we all heard the fearful signals, which told itself that the radiation really were ingested into the body, and in large amount.

While the police officer communicated to arrange to go to the hospital. One of the RSB officials was there, explaining to us that the dosage that they had picked up might not necessarily translate that Maryann's pregnancy should be terminated, while John's argued at that moment with the RSB official (Beth) about the strategy of how to save urine samples to get a correct determination of the amount ingested, which he added that he think that the baby should be worried. The RSB officials' explaination soothed a little bit of our saddened hearts, while John's arguments and acts raised our doubts. When he knew that the police and RSB officer were ready to send Maryann to a hospital, he appeared to be unpreprared and restless.

Around 9:00-9:30, the ambulance arrived at the Holy Cross Hospital. The phsician there gave Maryann an overall check-up and began immediately dilute the blood level contamination by intravenous infusion of fluid. At about 10:30-11:00 pm, Mr. Robert Zoon, Chief of the RSB, went to the hospital for taking back some of Maryann's blood and urine samples. We are very grateful for him, the other RSB stuffs and the police officer who gave us help in our desperate times.

I followed Mr. Zoon back to the NIH, since I'd to drive our car back to the hospital which was then still parked at the campus. In the routes, Mr. Zoon also expressed his indignation describing the person involved in this sabotage as insidious. Only by this period could I got a break to start meditate such confusing event, by the end of that trip, I ended up with my conclusion that I could not think anyone except John who had ever expressed and / or hinted that we should terminate Maryann's pregnancy by abortion. I told this conclusion to Mr. Zoon, which might have been embarssing, since he might not like to be involved in the criminal investigation beyond the radiation safty issues. It really be disconcerted to think that anyone could have commited such crime, as Mr. Zoon commented. It is even more dilemmatic to think that one's mentor is potentially a suspect who was most likely to have commiteed such insidious crime.

I went back immediately to the hospital at about 12:00 pm, just in time to find that John was standing in the bed side, asking Maryann suspicious questions, like what color of the bag that we took our food, what container, what kind of food. As Maryann recollected that when she mentioned that the food including rice, vegetables and shrimps, John got very nervous. My arrival interrupted the inquiry but he quickly resumed such topics, concerning whether Maryann had anything left over in the conference room refrigerator,

which Maryann reply that she did. When I told him that he'd better not go back to the lab since I was told by Mr Zoon not to return there, the conference room must have been sealed off, he showed signs of much a worry. When I told that Mr. Zoon told me that they could find which isotope is involve by a spectrum analysis, he immediately asked whether they could find which chemical formular. Since Maryann's quite tired and sad, and I was too not very involving, he ended up the talks by saying that he believed Maryann should be O.K., but the baby must be worried, suggesting Maryann see her obstetrician Dr. Tseng, instead of staying in the hospital. He also offer to call Dr. Tseng for us, which we declined. After he went away from the hospital (about 12:00-12:30 midnight), Maryann told that John came to the hospital for quite an unnecessary long time . Upon arriving, he went straight to the physician Dr. White, talking for about 10 min, then staying outside the emergency room for about one hour, writting or calculating on a notebook, which he later told Maryann that he's working there. Then he came to Maryann with those strange inquires. At least to us, such behavior really were uncommon to John, and were suspicious.

At about 2:00 AM (June 30), a male nurse came by, saying that he received a telephone call that the strategy of collecting urine samples had been changed, instead of collecting all the urine (which I knew the instruction from Mr. Zoon), he said that he got another instruction to discard the samples already collected and only aliqoted small part of them. At about 3:00 AM, Dr. White came by, saying that he got calls from Mr. Zoon as well as Dr. Weinstein, but he don't know whose instruction to follow, he then came up with a compromizing plan for the collection of urines, which might satisfy both of them.

Maryann was infused with 2000 ml of extra fluid, drink about another 1000 ml, and got well hydrated. The stay in the emergency room made her recovered a little bit from those mental and physical shocks. At about 4:00 AM, I took Maryann leave the hospital.

We went back home at about 4:30, when Maryann had a severe vomitting, very much miserable. If as we were consoled by the RSB officials that the dosage of Maryann's ingestion may not cause severe damage to the body, she must have already been mently hurt ruthlessly. Dumbly, I prepared some food and made her eat. Then, at about 5:30 AM, we went to bed, when I was too tired and quickly becoming asleep, when Maryann was too sad, wakening me several times with her sobbing, which aroused deep sadness for me, for my wife and for the upcoming baby.

We had every reason to report that this crime might be committed by John Weinstein:

1. It was he who suggested several times that my wife aborted the child.He often said that our experiments are so important that he would not like anything to held it up. He might be psychological uncomfortable, since he do not have a child, so we did not tell him about my wife's pregnancy until 3 months later. We told him on June 12. Since then, he kept us talking every weekend trying to persuade us to do abortion. At first, when we said that we felt uneasy to abort the child in the U.S., since it is not as common as in China. He replied that it is just politics, he himself would not mind, if we are happy to abort the baby, he would be happy what ever we would feel happy. Trying to stop the topic, we then told him that we're happy to have this baby. He then said that we'd better first consult with Dr. Tim Myers, who is working with us in the same Lab and just having his own baby, to know how much a trouble it would be .

On June 18 (Sun), he kept us talking , raising this same topic again and again, which made me very angry. I then told him that it's our right to have our baby. Since we had promised that the experiments would not be slowed down, if he's still not happy that we keeping the baby, he can go to find candidates to replace us, and we can then transfer to other lab, to this he apologized.

At first he tried to convince us that since we haven't stopped the experiment involving radiation, the baby we conceived might not be safe. To which we replied that we already consulted the obstetrician that such situation is O.K. He then asked that my wife continue with the experiments involving radiomaterilas, we replied, since I did most of the experiments dealing with radio-isotopes, it might not be necessary for my wife doing it herself, especially at this period of her pregnancy. Also we told him that there's regulations in RSB that pregnant women should be protected from radiation exposure as much as possible. He said that he did not know this.

The following Friday, he gave us a fax from RSB, regarding his inquiry that whether the pregnant women should be protected, it should. There's also a declaration procedure which put it by law that declared pregnancy be protected, but John said that this might cause some trouble for the lab. Since he's the authorized user of the radiation materials, we really expected that he should report or let us report the pregnancy to RSB, but he never mentioned this thereafter.

2. Last Sunday (June 25), he asked us again to go to the lab at 9:00 AM , started talking about various particulars of the experiments, which we had discussed several times before. Sensing that he might raise that topic of abortion again, and causing embarrassment, also because it was already 3:00 pm. I told him that I was really hungry and asked if he could let me eat something before continuing our talk or go out to have lunch with us. To the later, he said yes. So we went to a Chinese restaurant. After dinner, he took back home some of the left-food, we took back some of the other, including some shrimp, which my wife took to the lab the following weekdays in her lunch.

On Monday morning, we went to the library because we need to search the literatures. Around noon time, he went to the library to find us. Since I had not finished copying reference literatures, my wife went back with him, which she told me later that John's quite strange, step down the elevator the moment they were back to the lab, seemingly trying to avoid going back to the lab together with her.

On Wednesday morning, he came to the lab very late (around 1:00 PM) and was very nervous when I tried to greet him. He later gave me two pipettors, one for 1 ml and another is a multipipettor, saying that they're from Federic. But when I asked him that if he went to Federic (NCI off-campus, where John had a collaboration to keep the 60 cell lines) last night, he stumbled. He went to the library at 4:00 pm again, searching us when we were there trying to optimize the experimental protocols. We went out with him from Bldg 10, but he again trying to avoid going back to the lab along with us by saying that he went to DCRT, and would be back to the lab around 5:00 pm for an appointment. At about 5:30 pm, he went back to the lab, having his appointment in the conference room, when I also went there heating food in the conference room's microwave oven for my wife (she's then working with the experiments), then John called me to take back the food from the microwave oven, saying that the good smell of the food made him know that the food was ours.

Since we asked several times about a research paper which we submitted to him and kept by him for 3-4 months, he as well as we did some works on it in this week. On Wednesday morning, he said that he already send the paper on Tuesday night, but we suspected that he just pretended to send the paper to the editors in England, which should not be necessary, since the Journal had a editorial office in the U.S. Also, he said he would like to send the express mail from downtown Bethesda, which he usually send the express mail just in the first floor of building 37.

3. On Thursday morning, John called asking if there was anyone else who could help him to bring up some of the boxes, when it happened that we were the only ones. I helped him bring two boxes from his car up to the lab, found that the boxes were also from Federic, which made us wondering that why he first brought back the pipettors, then the next day, the boxes.

On Thursday afternoon around 6:00 pm, I found by chance that my wife contaminated with radiation materials. I called 116 at once, hoping that my wife would be send to the hospital immediately for necessary treatment, to which John had made every effort to obstruct, which waste 3 more hours. Some of the other details included in the report which we submitted to the NIH Detective Office.

4. At first, we were shocked that such tragedy happened in NIH, happened to us. On Friday (June 30), when Detective Luke talked with us, John Weinstein hung around, trying to "detect" himself what's going on. His presence there dampened our courage to tell Detective Luke about what's in our mind. Since I already told Mr. Robert Zoon, Chief of RSB, on Thursday night that John's the only one who had persuaded us to abort the baby, I assumed that Detective Luke had already got such information from Mr. Zoon and put John Weinstein already in the list of suspects. Since we hadn't fully recovered from the shock, since we didn't have physical evidence ourselves about John, but he had plenty of time erasing or fabricating evidence, we didn't tell anything to Detective Luke then, while John's there still persuade me and my wife to see her obstetrician immediately, reiterating that the baby should be worried.

5. It's very hard for us to go through such huge physical and emotional hit. While we were resting at home, we tried to figure out something that could exclude John as a suspect, since he's still the mentor, he might have more power, he's American national that would get more protection than us. Since we still cherished the opportunity to be trained here in NIH, we almost trying to think about the possibility that we swallow such miserable sufferings ourselves. Then, the following weekend, John called repeatedly, saying that some of the experimental records need to be "improved", trying to ask me go to the criminal scene during weekend nights. Since we were still buried in sadness, I could not leave my wife alone. Also, I could not imagine that we had anything that need "improved" at this time and I thought that this is not a good behavior trying to make forgery. I refused and also told him that he'd better not to go to the lab during weekend nights himself. His

calls to us got more and more frequently, only until then, we began to realize that he's anxious to lead us to the trap that he prepared for us.

6. The more we thought it over, the more we feel the danger of John Weinstein, this danger is not only to us, it is the danger that could harm the entire research community. On keeping the data from publication, and applying for the patent himself, he plotted to monopolize the interests derived from such research. For this part, although very unfair, since we were then still grateful for the work he had been doing to bring us here in NIH, we reiterated that we are not interested to be involved in the patent application. From his frequent suspicious intervention, we know he simply did not understand or believe us. The signs got more prominent after the NCI's evaluation by the Blue-Ribbon Committee, in which he's one of the target for evaluation, when he's worried about the position in NCI and trying to find positions in the outside private companies. Although the most difficult period of method development had been passed, and we believe that my wife's pregnancy could not cause any interference to our current work. But since there's still some work to be done, and John'd not feel himself safe for his own position in NCI, therefore, John Weinstein's selfishness made him trying to stop my wife's pregnancy, so that, as he might be thinking, the work would be proceeded with its full speed. He tries hard to push us finish the work before our two years term, when we had to go back China and he could secured all of the derived benefits without the control of NIH.

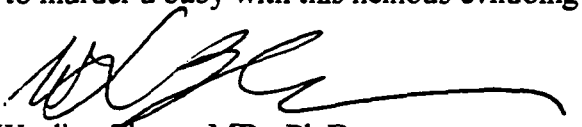
7. To try to assure him that we never thought of taking any benefit from the protocol which he originally let us do, but could not be realized without much of our major modification and hardwork , we even speak publicly that all of the works are derived from his smart idea. He became more and more restless, even asking the question relating whether we're going to have the baby staying in the U.S. or taking back China. We figured out that his worrying was not confined to the my wife's pregnancy, he also worried that we might staying in the NIH longer if we have the baby here, then, even he left NIH, even he kept the data from publishing, he still could not monopolize such interests. This might have disturbed him since he knew very well that it's unfair if NIH were excluded if the patents were filed, since the work was done here.

8. Everything happened in one week. If John went to Federic during Tuesday night, he might be able to fetch back some of the radio-isotopes from there, went back to the lab, he might first store the radioisotopes somewhere in the conference room, then find by chance that night that my wife had some food still left there in the refrigerator. Since it might be

very late that he's tired, and he's not a trained experimentalist, he might unskillfully handle the pipettors (the 1 ml pipettor or the multipipettor that he gave to me the next day), which he inadvertently contaminated widely in the conference room. Thank God. I could not imagine what would happen if he added all the radio-isotopes in my wife's food. The next day, he came to work quite late and nervously. Sensing that everything's O.K., he gave me the pipettors which might be the tools he used to commit such a crime. In the afternoon, he searched us through library, trying to find signs of damage of the radio-isotopes caused. It is around 5:30 pm when he's talking with someone in the conference room, while I heated the food for my wife, he found that the food might not have been used, so he called me to bring back the contaminated food that harmed my wife unpredictably. He did not know that my wife had already got pregnant for 4 months, which is not the most sensitive period. He's expecting that my wife either have a spontaneous abortion or got monitored after the possible declaration of pregnancy that we might make later. He did not know or expect that we could find the contamination by the hand-held beta-counter. He did not expect that we find this so early. He expected that after the weekend, he might already fly to France to have a vacation, as he had scheduled, no one could even suspect him, because he will be far away from the criminal scene. We could not rule out completely that he did this on other weekday nights, since he also stayed in the lab later than us on Monday, Tuesday and Wednesday, nevertheless, we could not rule out the possibility that he did this, and the most probable time was Tuesday night, and that's the only night that my wife left some of the food there overnight.

After we found what happened, he tried everything to minimize the incidence, trying to stop sending my wife to hospital, talking with the physician himself to minimize the times my wife staying in the emergency room. When he found that he could not led me into the trap that he prepared, he might have acted up to frame up us first, in order to get himself uncaught and unpunished.

We thought it over and over again, still trying to find any hint that could exclude John Weinstein. To our sadness, we could find none. We are sad because we worked so hard for him, but in return, he treated us so dirty with a vicious mind. . He might be selfish, he might be psychologically unsound, but trying to murder a baby with this heinous evildoing must never be exonerated.



Wenling Zheng, MD., Ph.D.

EXHIBIT 5

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Hand-Delivered
October 10, 1995

Mr. James M. Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Mailstop 17G21
11555 Rockville Pike
Rockville, MD 20852

RE: Request for Action Pursuant to 10 CFR § 2.206 to Suspend or Revoke the Materials License of the National Institutes of Health

Dear Mr. Taylor:

I am enclosing a Petition Pursuant to 10 CFR § 2.206 to Suspend or Revoke the Materials License of the National Institutes of Health ("NIH"), License No. 19-00296-10, and to Take Other Appropriate Enforcement Action Against NIH.

As a result of NIH's failure to control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20, Dr. Maryann Wenli Ma, a foreign scientist who was conducting research at the National Cancer Institute, was contaminated with Phosphorous-32, a highly radioactive isotope, and received the largest reported dose of internal radiation contamination since the Silkwood case. Dr. Ma was seventeen weeks pregnant at the time of the incident.

Like Kerr-McGee Corporation, NIH has lied to Dr. Ma, to federal regulators, and to the public at large about the magnitude of the exposure and the likely harm to Dr. Ma and her expected baby. However, the scientific evidence demonstrates that Dr. Ma received a 9.2 rem dose, which is greatly in excess of regulatory limits. The intake is over 16 times the recommended gestational ALI of 60 μCi (0.5 rem) for an occupationally exposed pregnant woman. The dose to Dr. Ma's fetus is estimated at 6.4 rem, or factor of 12 above the NRC's

established fetal exposure limit of 0.5 rem for the entire gestation period.

The contamination to Dr. Ma, her husband, Dr. Bill Wenling Zheng, and the 24 other scientists who worked in building 37 occurred as a direct and proximate result of NIH's failure to control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20. Furthermore, NIH failed to take proper actions to assess accurately the level of Dr. Ma's internal contamination or to provide appropriate medical care and follow-up treatment to remove the ingested activity. Instead, NIH greatly underestimated Dr. Ma's internal contamination and provided conflicting and harmful directions to hospital personnel which delayed her treatment and interfered with efforts to analyze properly her contamination. As a result of this malfeasance, NIH exacerbated the health risks to Dr. Ma and her fetus.

These failures call into question the integrity and efficacy of NIH's entire radiation safety program. In addition, the petition charges that NIH has engaged in other serious programmatic violations of 10 CFR Part 20. Accordingly, the NRC should suspend or revoke the materials license of the National Institutes of Health ("NIH"), License No. 19-00296-10, pending resolution of these issues. The NRC must also take other appropriate enforcement action against NIH, including the imposition of civil penalties, for its wilful and reckless violations of 10 CFR Part 20.

Please direct all correspondence about this matter to me and to our co-counsel, Judith Wolfer. Her address is indicated on the enclosed petition.

Sincerely,

Debra S. Katz

Enc.
cc: Judith Wolfer, Esquire
Dr. Maryann Wenli Ma
Dr. Bill Wenling Zheng
Dr. David Dooley
/am

PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

Pursuant to 10 CFR § 2.206, Dr. Maryann Wenli Ma and Dr. Bill Wenling Zheng[1] hereby request that the materials license of the National Institutes of Health ("NIH"), License No. 19-00296-10, be suspended or revoked pending resolution of the issues discussed herein, and that other appropriate enforcement action be taken against NIH for its wilful and reckless violations of 10 CFR Part 20.

Basis for the Request

As a result of NIH's failure to control and secure radioactive materials, to maintain an effective bioassay program, and to otherwise adhere to the requirements of 10 CFR Part 20, Dr. Ma was contaminated with Phosphorous-32 ("P-32"), and received one of the largest reported doses of domestic internal radiation in the past twenty years. Dr. Ma was seventeen weeks pregnant at the time of the incident.

As set out more fully below, on June 28, 1995, Dr. Ma received an intake of radioactive material significantly in excess of regulatory limits, and as a result her fetus received a radiation dose approximately twelve times higher than the NRC's established fetal exposure limit of 0.5 rem for the entire

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[1]Drs. Ma and Zheng are Chinese scientists who came to work at the National Cancer Institute ("NCI"), through the Fogarty Visiting Fellowship. They were assigned to conduct cancer research in the Laboratory of Molecular Pharmacology ("LMP"), under the direction of Dr. John N. Weinstein, the Senior Investigator in that lab.

gestation period.[2] A short time later, NIH determined that twenty-five other NIH employees, including Dr. Ma's husband, Dr. Bill Wenling Zheng, were also internally contaminated with P-32. These contaminations occurred as a direct and proximate result of NIH's failure to control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20. Furthermore, NIH failed to take proper actions to assess accurately the level of Dr. Ma's internal contamination or to provide appropriate medical care and follow-up treatment to remove the ingested activity. Instead, NIH greatly underestimated Dr. Ma's internal contamination and provided conflicting and harmful directions to hospital personnel which delayed her treatment and interfered with efforts to analyze properly her level of intake of radioactive material. As a result of this malfeasance, NIH failed to minimize the health risks to Dr. Ma and her fetus.

I. BACKGROUND.

A. Circumstances Surrounding Dr. Ma's Internal Contamination.

In August, 1994, Drs. Ma and Zheng, a married couple who are preeminent junior scientists from China, came to work at the National Cancer Institute ("NCI"), through the Fogarty Visiting

[2]Evaluation of the analytical results received to date has established a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This intake estimate corresponds to a Committed Effective Dose Equivalent ("CEDE") to Dr. Ma of 9.2 rem.

Fellowship program.[3] Ma Aff., ¶ 3; Zheng Aff., ¶ 3. They were assigned to conduct cancer research in the Laboratory of Molecular Pharmacology ("LMP"), under the direction of Dr. John N. Weinstein, the Senior Investigator in that lab. Ma Aff., ¶ 3; Zheng Aff., ¶ 3.

Drs. Ma and Zheng were assigned to work on a research project in molecular biology, to develop a novel method to display more efficiently the existence of expressed genes. The project, if successful, would have had significant scientific and commercial value. Through their work, Drs. Ma and Zheng developed a procedure which, by amplification of the restriction fragments, efficiently displayed the expressed genes, thereby greatly increasing the likelihood of the methods success. Dr. Weinstein required Drs. Ma and Zheng to work tirelessly on this project in his quest to patent the new procedure. Ma Aff., ¶ 4; Zheng Aff., ¶ 4.

Throughout their employment, Dr. Weinstein advised Drs. Ma and Zheng that their experiments were so important that he did not want anything to hold them up. On April 12, 1995, Dr. Ma learned that she was pregnant. Because Dr. Weinstein had previously admonished that nothing interfere with their work,

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[3]The backgrounds, qualifications, and experience of Dr. Ma and Dr. Zheng are described more fully in their curricula vitae, which are attached as Exhibit 1 to each of their affidavits. See Affidavit of Maryann Wenli Ma, M.D., Ph.D., (Oct. 7, 1995) ("Ma Aff."), attached and incorporated herein as Exhibit 1, and Affidavit of Bill Wenling Zheng, M.D., Ph.D., (Oct. 7, 1995) ("Zheng Aff."), attached and incorporated herein as Exhibit 2.

Drs. Ma and Zheng were nervous about notifying him of Dr. Ma's pregnancy. Ma Aff., ¶ 7; Zheng Aff., ¶ 7.

On Sunday, June 11, 1995, Dr. Weinstein called Drs. Ma and Zheng at home to inquire about Dr. Ma's health. In response, Dr. Zheng advised him that she was pregnant. Ma Aff., ¶ 7; Zheng Aff., ¶ 7.

Dr. Weinstein responded that he wanted to meet with them that afternoon. During the meeting Dr. Weinstein tried to persuade Dr. Zheng, who attended the meeting without Dr. Ma, that Dr. Ma should abort the pregnancy. Dr. Zheng responded that he felt that it was dangerous to have an abortion in the United States due to attacks on abortion clinics, and that he and his wife were pleased to have the baby. Dr. Weinstein persisted in pressuring Dr. Zheng to abort the pregnancy, and insisted that he and his wife should consult with Dr. Tim Myers, another colleague from their lab who had just had a baby, to find out how much trouble it would be. Ma Aff., ¶ 8; Zheng Aff., ¶ 8.

From that time on, Dr. Weinstein inquired about Dr. Ma's schedule almost daily and closely monitored her activities. Further, he continued to try to pressure Dr. Ma directly to abort her pregnancy. Ma Aff., ¶ 9; Zheng Aff., ¶ 9.

On Sunday, June 18, 1995, Drs. Ma and Zheng met with Dr. Weinstein, at his request, for the purported purpose of discussing their experiments. However, rather than talking in any detail about their work, Dr. Weinstein again attempted to pressure them to abort the pregnancy. He insisted that their

project was too important to let anything hold it up, implying that her pregnancy would be an impediment to the work. Dr. Ma assured him that her pregnancy would not interfere with the work and that she would only require six weeks of leave after the birth of the baby. Ma Aff., ¶ 10; Zheng Aff., ¶ 10.

Dr. Weinstein appeared unhappy and tried to convince them that their expected baby "would not be safe" because their experiments had involved radiation. Drs. Ma and Zheng then advised him that they had already consulted with their obstetrician about this concern and concluded that there would be no harm to the baby because the radioactive material they were using at that time, P-33, was of low radiation and low dosage and Dr. Ma was well protected. Dr. Weinstein responded that Dr. Ma should continue with the experiments involving radioactive materials. In response, Drs. Ma and Zheng advised him that she had stopped handling the radioactive isotopes several months earlier when she had first learned of her pregnancy and that Dr. Zheng had handled most of the radioactive isotopes involved in their experiments.[4] Dr. Weinstein disagreed with this approach. Ma Aff., ¶ 11; Zheng Aff., ¶ 11.

Dr. Zheng then advised him that there were regulations in NIH's Radiation Safety Branch ("RSB") which required that

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[4]Since Drs. Zheng and Ma worked on the same project, they were able to allocate their responsibilities to minimize Dr. Ma'S contact with the radioactive materials. Ma Aff., ¶ 11; Zheng Aff., ¶ 11. This decision by Dr. Zheng was both a reasonable and responsible action and in keeping with the proactive ALARA philosophy promoted by NRC regulations and guidance documents.

pregnant women be protected from radiation exposure as much as possible. Dr. Weinstein denied knowledge of any such regulation, and again pressured Dr. Ma to have an abortion. For example, Dr. Weinstein stated that Dr. Zheng was incorrect in his belief that having an abortion was not safe in the United States. He insisted that many pregnant women died during delivery, but that he had never heard of anyone dying in an abortion clinic. Dr. Zheng responded that it was their right to have their baby and that if he, Dr. Weinstein, was unhappy that they were keeping the baby, he could find candidates to replace them and they would transfer to another laboratory. Ma Aff., ¶ 12; Zheng Aff., ¶ 12.

On the late afternoon of Friday, June 23, 1995, Dr. Weinstein gave Dr. Ma and Dr. Zheng a telefax he had received from the RSB in response to his inquiry about whether pregnant women should be protected from radiation. The fax listed the date and time at which it was sent to Dr. Weinstein as 6/19/95 at 15:03. See RSP Procedures: Declared Pregnant Women, attached and incorporated herein as Exhibit 3. The document included a declaration form, which, if filled out, would have given Dr. Ma heightened protection from exposure to radiation and radioactive materials during her pregnancy. Ma Aff., ¶ 13; Zheng Aff., ¶ 13.

Pursuant to the declaration procedure, a 0.5 rem limit is applied to the dose an embryo/fetus may receive due to the occupational exposure of the mother. The 0.5 rem dose limit (equivalent to 10% of the annual whole body dose limit for occupationally exposed adults), applies to the sum of internal

and external doses received by the embryo/fetus due to occupational exposure of the mother. Dr. Weinstein insisted that if Dr. Ma filled out the declaration form, it would "cause trouble for the lab." By these and other remarks, Dr. Weinstein coerced Dr. Ma not to submit a Declaration of Pregnancy to RSB, even though it was her clear desire to receive maximum protection for her fetus from exposure to radiation and radioactive materials. Ma Aff., ¶ 14; Zheng Aff., ¶ 14.

On Sunday June 25, 1995, Drs. Ma and Zheng met with Dr. Weinstein to discuss their experiments. The meeting was long and unpleasant and at approximately 3:00 p.m. Drs. Ma and Zheng suggested that they treat Dr. Weinstein to a Chinese food dinner at a local restaurant. Dr. Ma had leftovers from the meal, including fish and shrimp, which she took to work for lunch the following week. Ma Aff., ¶ 15; Zheng Aff., ¶ 15.

On June 28, 1995, Dr. Ma ate her Chinese food leftovers, which she had stored in the conference room public refrigerator. That night she experienced sharp pains on the right side of her liver area. Ma Aff., ¶ 16; Zheng Aff., ¶ 16.

Throughout the day of June 29, 1995, Dr. Ma experienced increasingly sharp and persistent pains in her liver area. During the afternoon, Drs. Zheng and Ma were working on the same bench top in their laboratory. At approximately 5:30 p.m., when Dr. Zheng's experiment was concluded, he surveyed the bench top and adjacent floor with a Geiger-Muller counter as he routinely did upon completion of experiments involving use of radioactive

materials. When the detector approached Dr. Ma's feet, a strong audible response was noted. After ruling out other areas of contamination, Drs. Ma and Zheng determined from surveying Dr. Ma's body that she was the source of the contamination.[5] Ma Aff., ¶16; Zheng Aff., ¶ 16.

Unable to locate Dr. Weinstein to report Dr. Ma's contamination to him, Dr. Zheng called NIH's emergency "116" number to report Dr. Ma's radiation contamination as called for by RSB procedures. Soon after Dr. Zheng did so, Dr. Weinstein appeared in the laboratory and Drs. Ma and Zheng reported to him that Dr. Ma had been contaminated and that they had called "116" for help since he could not be found. Dr. Weinstein stated that he thought that was unnecessary. Ma Aff., ¶ 17; Zheng Aff., ¶ 17.

A short time later, an ambulance arrived and attempted to arrange for Dr. Ma's transfer to a hospital. However, in the interim, Dr. Weinstein received a telephone call from the RSB, which directed Drs. Ma and Zheng to remain at the lab until RSB conducted a survey of Dr. Ma. Ma Aff., ¶ 18; Zheng Aff., ¶ 18.

While waiting for RSB officials to arrive, Dr. Weinstein questioned Dr. Ma about where she stored her food. This question

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[5]Because Dr. Ma did not learn of her internal contamination until at least a day after ingesting the radioactive materials, she unwittingly carried radioactive materials home with her. On June 30, 1995, RSB officials conducted a survey of Dr. Ma's car and apartment and determined that she had contaminated her car and her certain areas of her apartment. They also determined that she had contaminated a number of articles of clothing. Ma Aff., ¶ 29.

was peculiar because they, like all members of their laboratory including Dr. Weinstein, stored their food in the two refrigerators located in the public conference room. Dr. Weinstein then surveyed the refrigerator and determined that it was contaminated. No radioactive materials were ever stored in the conference room, and the presence of radioactive contamination near the refrigerator led Drs. Ma and Zheng to fear that Dr. Ma's food was deliberately contaminated with radioactive materials. Ma Aff., ¶ 19; Zheng Aff., ¶ 19.

A short time later, two officials from RSB arrived and surveyed Dr. Ma with their own monitors. After they confirmed Dr. Ma's contamination, the RSB officials tried unsuccessfully to locate a shower to try to decontaminate Dr. Ma. The RSB officials also surveyed the conference room and located a spot of radiation contamination on the floor six to eight inches in front of the refrigerator in which Dr. Ma had stored her food. They found no contamination inside the refrigerator. Ma Aff., ¶ 20; Zheng Aff., ¶ 20.

Rather than expediting Dr. Ma's transport to the hospital for medical treatment, Dr. Weinstein performed smeartests, which indicated that her contamination was not external. Dr. Weinstein then directed Dr. Ma to drink large quantities of water. RSB officials directed Dr. Ma to provide a urine sample, which confirmed that her contamination was internal. Ma Aff., ¶ 21; Zheng Aff., ¶ 21.

One of the RSB officials tried to console Dr. Ma by advising her that the dosage she had picked up might not be harmful to the baby and might not mean that she would have to abort her pregnancy. Dr. Weinstein interrupted these remarks and tried to convince Drs. Ma and Zheng that "the baby should be worried." During this period, Dr. Weinstein and the RSB official argued about how to save the urine samples to get a correct determination of the amount of radiation Dr. Ma had ingested. Ma Aff., ¶ 22; Zheng Aff., ¶ 22.

At approximately 8:35 p.m., over three hours after Dr. Ma reported her contamination to RSB, the ambulance arrived at Holy Cross Hospital. Dr. Ma was examined by Dr. Peter White, who ordered that she be given intravenous infusions of fluid to dilute the contamination of her blood level. Ma Aff., ¶ 23; Zheng Aff., ¶ 23. Dr. White had no expertise in the area of treatment of radiation contamination and relied on the directions given to him by NIH personnel. See Affidavit of Debra S. Katz, attached and incorporated herein as Exhibit 4, at ¶ 3. Robert Zoon, NIH's Radiation Safety Officer, arrived at the hospital to consult with Dr. White and to retrieve some of Dr. Ma's blood and urine samples. Mr. Zoon directed Dr. White to collect Dr. Ma's urine for a twenty-four hour period, and to collect the total volume excreted. Katz Aff., ¶ 4; see Portion of Medical Record of Dr. Maryann Ma, attached and incorporated herein as Exhibit 5.

Dr. White also sought the assistance of the Radiation Emergency Assistance Center/Training Site ("REACTS") at Oak

Ridge, Tennessee, to best determine how to mitigate the effects of Dr. Ma's intake. However, the hospital's telefax machine experienced difficulty receiving information from ORISE and its input was not received. Katz Aff., ¶ 5. No efforts were made to hasten the removal of the ingested radioactivity, other than giving Dr. Ma intravenous infusions of fluid. Ma Aff., ¶ 27; Zheng Aff., ¶ 25. One protocol reported by the National Council on Radiation Protection and Measurement in their Report Number 65 that has proven effective would have been to administer large doses of phosphate orally as the buffered sodium salt, administer calcium intravenously, and administer 200 units of parathyroid extract I.M. every six hours.[6] NCRP also recommended several other treatment options that should have been evaluated for use in this case. However, only proper medical expertise such as REACTS could have determined if any of these treatments administrations would have been a safe course of action given that Dr. Ma was seventeen weeks pregnant. Employment of effective decorporation therapy could have significantly reduced the radiation dose to both Dr. Ma and her fetus. See Affidavit of Dr. David A. Dooley, Ph.D. (Oct. 7, 1995), attached and incorporated herein as Exhibit 6, at ¶ 12 and Exhibit 2 to Dooley Affidavit, at p. 5.

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[6]This intervention was provided when an accidental over-administration of P-32 occurred, and resulted in a 38% reduction of radiation dose to the bone marrow even though it was not administered until nine (9) days after the initial ingestion. See Exhibit 2 to Dooley Aff., p. 5.

At approximately 10:00 p.m., Dr. Weinstein arrived at the hospital and began to question Dr. Ma about the food she had eaten and the container in which it was stored. Dr. Weinstein then told her that he thought that she would be "okay" but again repeated that the "baby must be worried." Ma Aff., ¶ 24; Zheng Aff., ¶ 22.

After leaving the hospital, Dr. Weinstein called Dr. White several times that night and during the early morning hours. During one of these calls, he instructed Dr. White to aliquot only a small part of the samples already taken and to discontinue his efforts to collect all the urine over a 24 hour period. Katz Aff., ¶ 7. This instruction was in direct contravention of Mr. Zoon's directions.

At approximately 2:00 a.m. on June 30, 1995, a nurse told Dr. Ma that he had received a telephone call informing him that the strategy for collecting urine samples had changed. He advised her that instead of collecting all the urine, which was the precise instruction given by Mr. Zoon, he was to aliquot only a small part of the samples already collected. Ma Aff., ¶ 25; Zheng Aff., ¶ 24.

At approximately 3:00 a.m. on June 30, 1995, Dr. White advised Dr. Ma that he had received conflicting instructions from Mr. Zoon and Dr. Weinstein about the urine collection, and that he did not know whose instructions to follow. Dr. White advised Dr. Ma that Dr. Weinstein had directed that he not save all the urine samples but merely that he aliquot only a small part of the

samples already taken. Dr. White advised Dr. Ma that he developed a compromise plan for the collection of urine. Ma Aff., ¶ 24; Zheng Aff., ¶ 26.

Sometime after 3:00 a.m., Dr. Ma was told that the hospital had done all it could, and that no further treatment was warranted. She was discharged from the hospital with instructions to "maintain good hydration" and to follow up with Mr. Zoon, Dr. Weinstein, and her Ob/Gyn. Dr. Ma was not directed to collect her urine over a 24 hour period. When Dr. Ma returned home, she experienced severe vomiting.[7] Ma Aff., ¶ 28; Zheng Aff., ¶ 26.

On the night of June 29, 1995, Mr. Zoon told Dr. Zheng that neither he nor Dr. Ma were to return to the laboratory while this matter was being investigated. Dr. Zheng notified Dr. Weinstein of this direction on the morning of June 30, 1995. However, that weekend, Dr. Weinstein called them repeatedly at home and told them that their experimental records needed to be "improved." He tried to induce them to return to the lab even though they had been directed by Mr. Zoon not to do so.[8] Ma Aff., ¶30; Zheng Aff., ¶ 27.

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[7]This vomiting continued throughout Dr. Ma's second trimester. Ma Aff., ¶ 28.

[8]Drs. Ma and Zheng later learned that Dr. Weinstein had told a number of people, including another senior investigator, Dr. William Boner, that they already had a child in China -- which is untrue -- and that under the China one-child policy, it was necessary that they abort the pregnancy. He suggested that they had contaminated themselves to abort the pregnancy. Ma Aff., ¶ 31; Zheng Aff., ¶ 28.

By the morning of June 30, 1995, NIH had determined that the source of Dr. Ma's contamination was Phosphorous-32. At approximately 8:00 a.m., Mr. Zoon informed James Dwyer, an Inspector with NRC, Region I, that an incident involving internal contamination of a researcher had been reported to the Radiation Safety Office at approximately 5:30 p.m. the previous evening. See Preliminary Notification of Event or Unusual Occurrence PNI-9525, attached and incorporated herein as Exhibit 7. He further advised that:

> The licensee identified the researcher as a 32 year old female who is in her fourth month of pregnancy but had not declared herself to be pregnant to the licensee.
>
> The emergency response and follow-up by the licensee confirmed the existence of a detectable radioactivity burden, however, it does not appear that an annual limit on intake was exceeded. The licensee identified the ingested isotope to be phosphorous-32 (P-32).
>
> The incident is under investigation by the licensee. There are no adverse health consequences expected for the researcher or the fetus. The estimated ingestion is approximately 300 microcuries of P-32. The licensee believes that the event probably occurred around noon on Wednesday, June 28, 1995.

(emphasis added). This estimate was not based on a 24 hour sampling of standard systemic excreta data, as recommended by NUREG/CR-4884, Interpretation of the Bioassay Measurements (1987) and NCRP 87 (1987), and thus led to a significant underestimate of Dr. Ma's internal dose resulting from the ingestion of P-32. Dooley Aff., ¶ 11.

Following the detection of Dr. Ma's contamination, RSB took and received from Holy Cross Hospital a total of twenty-five samples from Dr. Ma, spanning the period of June 29, 1995 through

July 27, 1995. At NRC's request, NIH sent the Oak Ridge Institute for Science and Education ("ORISE") four of the first fifteen specimens taken on June 29 and 30, 1995, to confirm the isotopic analyses performed by the RSB. ORISE was also asked to confirm the isotopic analyses performed by the RSB with respect to three urine samples and one blood sample. None of the samples which was analyzed appear to be taken from a full 24 hour period. Further, NIH failed to take any fecal samples. Dooley Aff., ¶ 11.

On June 30, 1995, Dr. Ma reported to NIH's Occupational Medical Service and was examined by Dr. Lynn Stansbury.[9] Dr. Stansbury told her that she was unable to treat her and merely directed her to consult with her private physician by telephone. Dr. Stansbury failed to provide any medical care or follow-up treatment to remove the ingested activity. Ma Aff., ¶ 33.

On the evening of June 30, 1995, NIH's Nuclear Medical Department conducted a whole body scan of Dr. Ma.[10] Dr. Jorge A. Carrasquillo, Acting Chief, Nuclear Medicine Department, estimated that she had a total of 862 μCi retained at the time of the scan and that substantial exposure was detected in the area

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[9]While Dr. Ma was waiting at the Occupational Medical Services to meet with an NIH detective, Dr. Weinstein appeared and insisted that she had to see her Ob/Gyn immediately. He again stressed that the baby "must be worried." He offered to call her doctor several times, however, she declined. Ma Aff., ¶ 34; Zheng Aff., ¶ 29.

[10]This scan was conducted after RSB officials determined that areas of Dr. Ma's car and apartment and personal effects were contaminated. Ma Aff., ¶ 32.

in which the fetus is located as well as in her liver. See Memorandum from Dr. Jorge A. Carrasquillo to R. Zoon, attached and incorporated herein as Exhibit 8.

Rather than waiting until an accurate and complete analysis was conducted, and ignoring the contrary results of the whole body scan, on July 3, 1995, the NRC issued a press release advising that "[t]he woman is believed to have ingested about half of the annual dose limit of the radioactive isotope." See NRC Press Release (July 3, 1995), attached and incorporated herein as Exhibit 9.

Drs. Ma and Zheng had discontinued using P-32 in their experiments in March or April of 1995, and had not had access to this material since that time. Accordingly, NIH and NRC reached the conclusion that Dr. Ma's contamination was not accidental and that someone had apparently deliberately planted P-32 in her food or drink. On July 3, 1995, NRC sent an Augmented Inspection Team to NIH to investigate Dr. Ma's contamination.

By letter dated July 5, 1995, ORISE provided NIH with its estimate of Dr. Ma's intake. Like NIH, ORISE failed to base its analysis on the actual volume Dr. Ma excreted over time, which is critical for proper interpretation of standard bioassay models, and estimated her intake at 265 μCi. See Letter to M. Noska from M. Stabin (July 5, 1995), attached and incorporated herein as Exhibit 10.

On July 8, 1995, Mr. Zoon provided Dr. Ma with a copy of ORISE's calculation and informed her that NIH's estimate was "more or less the same."[11] Ma Aff., ¶ 35; Zheng Aff., ¶ 30.

On July 14, 1995, Mr. Zoon advised the NRC Region I that NIH had detected radioactivity in a water cooler during its investigation of Dr. Ma's intake. He further advised that urine bioassays had identified approximately 25 additional NIH employees who worked on the same floor as Dr. Ma with low level internal P-32 contamination. See Preliminary Notification of event or Unusual Occurrence PN1-9525A, attached and incorporated herein as Exhibit 11.

On July 17, 1995, Anne Thomas, an NIH spokeswoman, told The Washington Post that:

> The woman underwent intravenous hydration treatment to dilute the radioactive isotope, and this hydration therapy significantly reduced the [radioactive] activity in the urine. . . . The doctors who examined her do not believe this will cause any long-term medical complications for her or her fetus."

See Washington Post, dated July 18, 1995, attached and incorporated herein as Exhibit 12 (emphasis added). These statements were false and misleading both to Dr. Ma and the

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[11]Upon information and belief, NIH is not a qualified bioassay laboratory practicing to the standard of care as established in the draft ANSI Standard N13.30 and to our knowledge does not operate under an acceptable quality assurance program. The absence of such assurances raises concerns as to the ability of NIH to validate bioassay analyses at a future date. Dooley Aff., Exhibit 2, p. 6.

public at large.[12] Dr. Ma was never told by any of the physicians who examined her that her intake of radioactive material would not cause any long term medical complications for her or the baby. In fact, at the time that she was being treated at the hospital, hospital personnel had no idea of the level of her internal dose or even what radioactive isotope she had ingested.

By letter dated July 28, 1995, Mr. Zoon advised NRC's Region I that "the total intake of the individual involved in this incident [Dr. Ma] is continuing and could result in an estimated intake potentially exceeding the 10 CFR Appendix B ALI of 600 μCi."

By letter to Dr. Harold E. Varmus, Director of NIH, dated August 18, 1995, Dr. Ma's attorney demanded that NIH transfer to an independent laboratory, TMA/Norcal, a portion of the urine specimens Dr. Ma provided during the period of June 29, 1995, through July 27, 1995. NIH agreed to this request and transferred eleven samples to TMA/Norcal on August 24, 1995. Katz Aff., ¶ 9.

By letter to NIH dated August 25, 1995, Dr. Ma's counsel requested that NIH pay for the 24 hour samples to be independently analyzed due to the serious nature of the exposure and the extenuating physical circumstances of Dr. Ma (that she

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[12]It is an absolute falsehood that hydration therapy significantly reduced the radioactive activity in the urine. The bioassay data confirms that this effort did nothing to accelerate the elimination of the P-32 or reduce the dose to Dr. Ma or her unborn child. Dooley Dec., ¶ 13.

was seventeen weeks pregnant at the time of the initial intake.) See Letter from D. Katz to P. Kvochak (Aug. 25, 1995), attached and incorporated herein as Exhibit 13. Dr. Ma's counsel further advised NIH that the information analyzed by ORISE is inadequate to have reached a proper, independent determination of Dr. Ma's level of internal contamination, consistent with the recommendations of NUREG/CR-4884 and those of NCRP Report 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition (1987). NIH denied this request.

By letter dated August 28, 1995, Dr. Ma's counsel advised Charles W. Hehl, Director, Division of Radiation, Safety and Safeguards, NRC, of her concern that the analysis conducted by the NIH was inadequate to reach results which could be scientifically validated and verified. See Letter from D. Katz to C. Hehl (Aug. 28, 1995), attached and incorporated herein as Exhibit 14.

By memorandum dated August 29, 1995, NIH transmitted its final assessment of Dr. Ma's intake to the NRC. It concluded that Dr. Ma's individual effective dose equivalent was 4.17 rem and that the fetus' dose equivalent was 3.2 rem. NIH assigned Dr. Ma an intake of 500 μCi. See Memorandum from S. Googins to R. Zoon (Aug. 29, 1995), attached and incorporated herein as Exhibit 15.

The analyses were not conducted in accordance with ANSI N13.30, which establishes performance criteria for the conduct of

in-vitro and in-vivo radiobioassay analysis.[13] Further, the NIH failed to continue the collection and analysis of excreta (urine and feces) to ensure that Dr. Ma's excretion of P-32 followed the mathematical model NIH had used to predict her internal dose. This model was that of a 154 pound reference man (ICRP Report 23) not a 90 pound pregnant female. Additionally, NIH did not account for the effect of hydration therapy when initial evaluating the urine data. Dooley Aff., ¶ 11 and Exhibit 2 to Dooley Aff., p. 2-5.

By letter dated August 30, 1995, Mr. Hehl informed Dr. Ma's counsel that:

> NRC has confidence in NIH's ability to analyze these samples accurately. This confidence is based on the results of the previously discussed confirmatory analyses performed for NRC by [ORISE] as well as confirmatory analyses of water samples from the contaminated water cooler which were performed by the NRC Region I laboratory.

See Letter from C. Hehl to D. Katz (Aug. 30, 1995), attached and incorporated herein as Exhibit 16.

Because of concerns about NIH's failure to calculate accurately Dr. Ma's dose, Dr. Ma's counsel retained the services of Dr. David A. Dooley, a certified Health Physicist with expertise in internal dose assessment. Katz Aff., ¶ 14. At Dr. Dooley's direction, TMA/Norcal Laboratory in Richmond,

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[13]Although it is a draft standard, it has been accepted by the internal dosimetry community as an outline depicting the minimum standard of care in the performance of such analyses. NIH does not adhere to this standard.

California,[14] conducted radioanalysis of excreta samples collected from Dr. Ma during the period of June 29, 1995 through August 23, 1995. Dooley Aff., ¶ 3. Using the ICRP 30 Model for inorganic phosphorous ingestion, Dr. Dooley concluded that the analytic results established a preliminary estimate of an intake of 1000 μCi of P-32 for the ingestion pathway. This preliminary intake estimate corresponds to a Committed Effective Dose Equivalent of 9.2 rem. This dose is more than double what NIH calculated for this incident, and is more than 4.2 rem in excess of federal regulatory limits for annual intake by a non-pregnant woman. See 10 CFR § 20.1201(a)(1)(I) (an annual limit which is the total effective dose equivalent being equal to 5 rems). It is more than 8.7 rem in excess of (or 18 times higher than) federal regulatory limits for the annual intake of a declared pregnant woman. ORISE performed a re-evaluation of the intake in August of 1995. Their assessment closely agrees with Dr. Dooley's assessment that the intake results in an internal dose in excess of regulatory limits. Dr. Dooley further concluded that Dr. Ma's fetus received a dose of between 3 rem and 6.4 rem, which is 6 to 12 times greater than the federal regulatory limit for a fetus. Id., ¶ 5.

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[14]This laboratory is considered one of the best nuclear industry analytical laboratories in the world. Unlike the RSB lab, it holds a CLIA license.

B. NIH Officials Deliberately Disregarded NIH's Legal Requirements Concerning the Security and Handling of Radioactive Materials.

During the summer of 1994, NIH officials deliberately failed to lock up radioactive material as part of a so-called "experiment" with a "liberalized" policy concerning the security and handling of radioactive materials.[15] See "NIH failed to lock up radioactive materials in '94", Bethesda Gazetta (Aug. 2, 1995), attached and incorporated herein as Exhibit 17. Upon information and belief, the NRC failed to take any action to date to sanction the Agency for its deliberate and wilful violation of 10 CFR § 20.1801. Id.

After discontinuing this "liberalization" experiment in July, 1994, Dr. Varmus began to petition the NRC for a permanent rule change to enable researchers to discontinue the required practice of locking up certain categories of radioactive materials. Id.

By letter to NRC Region I dated October 31, 1994, Dr. Varmus sought an amendment to License No. 19-00296-10 to establish and implement permanently a policy NIH previously submitted to the NRC for comment on June 3, 1994, entitled an Interim Security Policy. See Letter from H. Varmus to J. McGraph (Oct. 31, 1994), attached and incorporated herein as Exhibit 18. Through this request, NIH sought a permanent exemption to relieve it of the legal obligation under 10 CFR 20 to maintain under lock and key

[15]NIH failed to seek approval from the NRC a priori and unilaterally violated a Condition of its material license and Support I of 10 CFR §§ 20.1801 and 20.1802.

or under direct oversight at all times, radioactive materials, including P-32, which do not exceed ten times the activity listed in Appendix C of 10 CFR Part 20 on a per container basis. Id.

Press accounts suggest that following the Ma contamination incident, NIH has discontinued its efforts to receive an exemption from the requirements of 10 CFR §§ 20.1801 and 20.1802. However, these same press accounts quote an NRC official, Ronald Bellamy, as stating that "NIH has not informed the NRC in writing of the decision, although NRC officials expect such notification." See Exhibit 17.

C. The NRC Has Failed to Take Enforcement Action Against NIH for Its Repeated Violations of 10 CFR Part 20.

During the period of 1986 to the present, the NRC has cited NIH repeatedly for its failure to store radioactive material in a safe and secure manner, and for its contamination of workers with radioactive materials, including P-32. Despite these repeated citations, NRC has failed to take any enforcement action against NIH. Indeed, the NRC, to date has failed to take any enforcement action against NIH for its wilful refusal to adhere to the requirements of 10 CFR §§ 20.1801 and 20.1802. See Section I(b), supra.

On February 26, 1987, the NRC cited the National Cancer Institute for a violation of 10 CFR § 20.201. The incidents reported included the contamination of a sink with Iodine-125, an external contamination of a researcher to Phosphorus-32, and the improper training of the researcher in the handling of radioactive material. See Letter to Director from R. Gilden

(March 11, 1987), attached and incorporated herein as Exhibit 19. The NRC took no enforcement action against NIH for these violations.

In an inspection conducted on July 8-12, 1991, the NRC cited NIH for its "failure to maintain constant surveillance of radioactive materials in the nuclear pharmacy," in violation of 10 CFR § 20.207. The inspectors noted that the pharmacy in Building 10 was insufficiently monitored and that they were unchallenged by NIH personnel as they entered the area. NRC inspectors found three lead boxes containing licensed material on a bench top. See Inspection Report (July 8-12, 1991), attached and incorporated herein as Exhibit 20. The NRC took no enforcement action against NIH for these violations.

In an inspection conducted on July 20-24, 1992, the NRC cited NIH for a violation concerning the overexposure of a radiopharmacist. Specifically, NIH was cited for "failure to perform an adequate survey of a radiopharmacist to assure compliance with the regulatory limit for exposure of the skin." The cause of the violation was attributed to use of inappropriate dosimetry to determine the exposure, as well as the length of time -- 90 minutes -- before appropriate decontamination procedures were used. See NRC Inspection Report (July 20-24, 1992), attached and incorporated herein as Exhibit 21. The NRC took no enforcement action against NIH for this violation.

On January 13, 1993, the NRC cited NIH for four violations relating to an incident involving an extremity contamination with

Phosphorous-32 which resulted in the overexposure of a researcher's finger: 1) extremity exposure in excess of regulatory limit in violation of 10 CFR § 20.101(a); 2) failure to ensure that radiation safety activities are performed in accordance with approved procedures 10 CFR § 35.21(a); 3) failure to supply personnel monitoring equipment to an individual who is likely to receive a dose in excess of 25% of 10 CFR § 20.101(a)(1); and 4) failure to notify an individual of exposure to radiation in violation of 10 CFR § 20.409(b). Although NIH was not cited for a violation of 10 CFR § 20.401, the report noted that the calculation of the individual's radiation did not strictly conform to the regulatory guidelines. See NRC Inspection Report (Jan. 13, 1993), attached and incorporated herein as Exhibit 22.

On December 2, 1993, the North Bethesda Congress of Citizen's Association filed a 2.206 petition with the NRC requesting that License Condition 24, authorizing NIH to dispose of licensed materials by incineration, be suspended due to lack of environmental assessment and lack of adequate monitoring to ensure that the radioactive effluent releases are within regulatory limits. See Letter from A. Allen to J. Taylor (Dec. 2, 1993), attached and incorporated herein as Exhibit 23. No enforcement action was taken by the NRC against the NIH at that time and no restrictions were placed on its license.

On April 26, 1994, the NRC cited NIH for its failure to notify the NRC of an irradiator failure in accordance with 10 CFR

§ 21.21(c)(3)(I), which it concluded had created "a substantial safety hazard as defined by 10 CFR 21.3(m) . . . " See Letter from C. Hehl to W. Walker (Apr. 26, 1994), attached and incorporated herein as Exhibit 24.

On July 27, 1994, NRC Region I cited NIH for multiple violations that were noted during an inspection conducted on April 4-8 and 20, and May 9-13, 1994. See NRC Inspection Report (July 27, 1994), attached and incorporated herein as Exhibit 25.

The first violation referred to failure to survey following a P-32 contamination incident which took place on August 24, 1993. The report stated that "a Notice of Violation is being issued for the failure to perform a daily survey in accordance with Condition 31 of License No. 19-00296-10, which references Section 10.13.2 of the application dated July 28, 1986. This section requires, in part, that users survey their laboratories and themselves for contamination on a daily basis when radioactive materials have been used." It further states that "[t]his is a repeat of a violation that was identified in January 1993, when an individual also failed to perform a survey of the laboratory and himself when working with P-32, and resulted in some skin contamination to himself."

This incident also resulted in the inspector noting an uncited violation based on the fact that "[t]he licensee's standard procedure for P-32 use authorization was circumvented." The NRC failed to cite this violation because it concluded that the licensee's corrective action was "decisive and

comprehensive." Yet NIH's response did not extend beyond suspending the authorization to work with isotopes for the individuals involved. That is, no comprehensive procedural modifications were undertaken by the licensee.

The second cited violation involved a failure to provide security of radioactive materials, in violation of 10 CFR § 20.1801. The NRC found that the licensee failed to secure radioactive materials from unauthorized removal or to limit access to licensed materials located in unrestricted areas in Building 10. Specifically, the inspector noted two unlocked refrigerators, which contained radioactive materials, including P-32.

The third citation was for "failure to refrain from drinking and eating in a restricted area," in violation of NIH General Requirements and of Condition No. 31 of License No. 19-00296-10.

The fourth cited violation was for failure to perform an adequate survey of the licensee's ash disposal in violation of 10 CFR 20.201, which was found to contain amounts of I-125 in excess of the NRC's regulatory limit and above licensee's recorded 0.3c mCi.

The above incidents demonstrate a pattern of reckless disregard for NRC regulations by NIH. Even more alarming, they demonstrate that the NRC is unwilling to take appropriate enforcement action against NIH for its repeated violations.

D. NIH Was Lax in its Control of Radioactive Materials in the Laboratory of Molecular Pharmacology.

Drs. Ma and Zheng began work at NIH in Dr. Weinstein's lab on or around August 16, 1994. The following week, Dr. Weinstein directed them to begin conducting experiments using S-35 or P-32, labeled dNTP, which are radioactive materials (RAM). Dr. John Boulawini, their predecessor, had ordered the radioactive reagents before he departed from NIH. Dr. Weinstein insisted that Drs. Ma and Zheng begin working with the materials before they were given training by RSB in the safe use and handling of radioactive materials, and before they were assigned user identification numbers. On one occasion, he directed them to use Dr. Boulawini's user identification number to order radioactive reagents before they were assigned their own user numbers. On another occasion, he directed them to use his (Dr. Weinstein's) identification number to order radioactive reagents before they were assigned user numbers.[16] Ma Aff., ¶ 40; Zheng Aff., ¶ 33.

Once the radioactive reagents arrived at NIH from the manufacturer, RSB distributed them to the specific users. The user is responsible for storing the radioactive reagents in specifically designated refrigerators and freezers. The refrigerator and freezer in which Drs. Ma and Zheng stored their reagents was used by the entire group. Neither the refrigerator nor the freezer were locked. While the lab is supposed to be

[16]Dr. Weinstein was responsible for providing written authorization for each of the orders for radioactive materials members of his lab requested. Ma Aff., ¶ 40; Zheng Aff., ¶ 3.

locked during non-working hours, it was frequently left unattended. Further, everyone in the LMP was able to open the doors of the LMP lab with the same key and would have been able to gain access to any of the materials in the refrigerator or freezer. There was no procedure in place for signing in to gain access to the refrigerator or freezer or to otherwise document that one had done so. In addition, no one in the lab checked to see if records were kept documenting the use of radioactive reagents. Thus, the security over this material was non-existent. Ma Aff., ¶ 41; Zheng Aff., ¶ 34.

The LMP lab was also lax in its use of dosimetry. When Drs. Ma and Zheng first began at work at LMP, they were given dosimetry which they wore. However, the dosimetry was never collected after a month, a quarter, or at any other time interval, and they were never reissued new dosimetry. During the period in which Dr. Ma received her internal radioactive contamination, she was not assigned any dosimetry. Accordingly, NIH is unable to document properly either her exposure history or Dr. Zheng's exposure history while at NIH. Ma Aff., ¶ 42; Zheng Aff., ¶ 35.

II. THE NRC SHOULD SUSPEND OR REVOKE NIH'S MATERIAL LICENSE BECAUSE ITS RADIATION PROTECTION PROGRAM FAILS TO ENSURE COMPLIANCE WITH 10 CFR PART 20.

10 CFR § 20.1101(a) and (b) require each licensee:

> to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

to use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

As the foregoing facts make clear, NIH's radiation protection program has failed woefully in its regulatory obligation to protect Dr. Ma and other NIH scientists from the significant risks posed by internal radioactive contamination. The record demonstrates that NIH has failed to secure radioactive materials from unauthorized removal or use, and has failed to maintain constant control and surveillance over these materials. It has also failed to achieve occupational doses that are as low as reasonably achievable and to adhere to NRC regulatory requirements to control the use of radioactive material in such a manner to ensure that the total dose to Dr. Ma and her fetus did "not exceed the standards for protection against radiation prescribed in the regulations." 10 CFR § 20.1001. As a result of these failures, Dr. Ma received a radiation dose significantly in excess of regulatory limits, and her fetus received a radiation dose approximately twelve times higher than the regulatory limits. Following Dr. Ma's internal contamination, NIH failed to perform adequate bioassays and sampling, and to provide appropriate medical intervention and consultation.

The medical intervention provided by NIH was completely ineffective. No discernible enhancement of P-32 elimination occurred as a result of the hydration therapy that was administered. Dooley Aff., ¶ 12. Further, NIH failed altogether

to use or to direct the use of protocols that have proven effective in the past in the removal of ingested activity. Id., ¶ 12.

As detailed below, NIH's radiation protection program has failed to ensure compliance with the following regulations: 10 CFR § 20.1201; 10 CFR § 20.1202; 10 CFR § 20.1204; 10 CFR § 20.1208; 10 CFR § 20.1501; 10 CFR § 20.1502; 10 CFR § 20.1801; 10 CFR § 20.1802; 10 CFR § 20.2106; and 10 CFR § 20.2203.

A. NIH Violated 10 CFR §§ 20.1201 and 20.1208, By Failing to Limit Dr. Ma's Occupational Dose to Either 5 Rems or 0.5 Rem For A Declared Pregnant Woman And Thereby Exceeded the Acceptable Dose to Dr. Ma and Her Fetus.

10 CFR § 1201 requires the licensee to control the occupational dose to individual adults, except for planned special exposures to the following dose limits:

1) An annual limit, which is the more limiting of--

(I) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

10 CFR § 20.1208(a) further requires the licensee to ensure that the dose to an embryo/fetus during the entire pregnancy does not exceed 0.5 rem due to occupational exposure.

Dr. Dooley, an expert in internal dose assessment, concluded that the analytic results of the specimen analysis performed by TMA/Norcal established a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This preliminary

intake estimate corresponds to a Committed Effective Dose Equivalent of 9.2 rem. This dose is more than double what NIH calculated for this incident, and is more than 4.2 rem in excess of federal regulatory limits for annual intake by a non-pregnant woman. Moreover, it is more than 8.7 rem in excess of (or 18 times higher than) federal regulatory limits for the annual intake of a pregnant declared woman. 20 CFR § 20.1208(a). Dr. Dooley further concluded that Dr. Ma's fetus received a dose of between 3 rem and 6.4 rem, which is 6 to 12 times greater than the federal regulatory limit for a fetus. Dooley Aff. ¶ 6. These calculations were confirmed by subsequent re-evaluation of the data performed by ORISE.

As discussed supra, Dr. Weinstein interfered with Dr. Ma's exercise of her right to declare herself as a pregnant woman, in violation of 10 CFR § 20.1208. It is petitioners' contention that by repeatedly pressuring Dr. Ma to have an abortion, by deliberately withholding the Declaration of Pregnancy form from Dr. Ma after receiving it from RSB, and by insisting that Dr. Ma's declaration of pregnancy would cause "a lot of trouble for the lab," Dr. Weinstein constructively denied Dr. Ma her right to receive protection for her fetus from ionizing radiation in excess of 0.5 rem. However, given Drs. Ma's and Zheng's notice to Dr. Weinstein of her desire to receive such protection, the licensee must be estopped from contending that Dr. Ma was not a "declared" pregnant woman and therefore not legally entitled to such protection.

B. NIH Violated 10 CFR §§ 20.1202, 20.1204, 20.1205, 20.1501 and 20.1502 By Failing to Measure and Calculate Accurately Dr. Ma's Total Occupational Dose, Including Her Dose as a Result of Her Internal Contamination With Phosphorous-32, and By Failing to Monitor Her Radiation Exposures Throughout Her NIH Employment.

10 CFR § 20.1202 requires the licensee to be able to demonstrate compliance with §§20.1502(a) and (b)[17] by summing up external and internal doses. However, NIH is incapable of accurately calculating Dr. Ma's exposure history while at NIH because it: failed to monitor her exposure to radiation and radioactive materials throughout her employment through use of an appropriate dosimetry program, or to routinely monitor her for radiological intake, and failed to calculate accurately Dr. Ma's internal contamination on June 28, 1995.

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[17]10 CFR § 20.1502 requires each licensee to monitor exposures to radiation and radioactive materials at levels sufficient to demonstrate compliance with the occupational dose limits of Part 20. At a minimum, each license is required to supply and require the use of individual monitoring devices by:

(b) Each licensee shall monitor (see §20.1204) the occupational intake of radioactive material by and assess the committed effective dose equivalent to -

1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1. Columns 1 and 2, of Appendix B of §§20.1001-20.2401; and
2) Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

Given Dr. Ma's use of radioactive materials in LMP, NIH was required to supply appropriate dosimetry to her. It failed to do so. Ma Aff., ¶ 42.

As the Affidavits of Drs. Ma and Zheng make clear, NIH failed to monitor and assess their dose in an ongoing manner, in violation of 10 CFR §§ 20.1501 and 1502. With respect to the dosimetry Drs. Ma and Zheng were assigned dosimeters when they first arrived at NIH, it does not appear that the dosimetry was ever collected or analyzed thereafter. Further, Drs. Ma and Zheng are not aware of any dosimetry that was assigned to them at the time of the contamination, and were not wearing any dosimetry at that time. Accordingly, NIH has no valid information about their exposure histories while at NIH.

Second, NIH grossly underestimated Dr. Ma's internal contamination. NIH calculated Dr. Ma's individual effective dose equivalent was 4.17 and assigned her an intake of 500 μCi. This analysis was not conducted in accordance with ANSI N13.30, which establishes performance criteria for the conduct of in-vitro and in-vivo radiobioassay analysis. Nor did it take into account the effect of the hydration therapy she was administered. When, as here, a true 24 hour urine collection is not obtained, correction for the concentration measurement is required to account for the dilution to the urine that occurred as a result of the hydration therapy.[18]

As the report of Dr. Dooley makes clear, NIH's calculation is incorrect. The NIH dose assessment evaluated the excreta data

[18]As the report of Dr. Dooley makes clear, since NIH did not properly perform any correction for this factor, the relationship between the measured radioactive concentration of these samples can not be related to the total 24 hour excretion. Dooley Aff., Exhibit 2, at 3.

using two mathematical models, the unweighted least squares fit (ULSF) method as outlined in NUREG/CR-4884 and the weighted least squares fit (WLSF) method identified by Skrable. NIH used the WLSF method to assign its final dose. This method is unacceptable when the actual excretion does not follow the anticipated model because it can lead to a "gross underestimation of the true error when the actual excretion varies from the model prediction." Dooley Aff., Exhibit 2, at 4.

NIH also failed to take suitable and timely samples from Dr. Ma to accurately calculate her dose, in violation of 10 CFR § 20.1204(a). First, immediately following detection of Dr. Ma's contamination, NIH should have taken a full 24 hour sample. Because Dr. Weinstein intervened and countermanded the directions given by Mr. Zoon, the urine samples collected during the first two days following the intake were collected as spot samples. Rather than collecting the entire urinary excretion compartment over a 24 hour period as recommended by NUREG/CR 4884, a series of samples were collected at each voiding. This sampling program did not ensure collection of the entire integral excretion over the required 24 hour period. As a result, the value of this early data is significantly diminished.

Second, NIH should also have continued sample collection and analysis until the activity level of the samples no longer yielded useful results. This allows for a more accurate determination of the actual excretion pattern and resulting dose. The NIH dose evaluation was based solely on samples collected

during the first month following the intake. However, urinary excretion patterns appear to deviate significantly from the norm and the NIH sampling program failed to compensate for this deviation in that complete 24 hour urine samples were not collected. This represents a large potential for significant error. Dooley Aff., Exhibit 2, at 3-4.

The initial dose estimate performed by NIH relied entirely on an analysis of urine samples, and was not confirmed through the analysis of fecal samples. The ICRP 30 model for inorganic phosphorus excretion predicts that 20% of ingested phosphorous will be excreted through the feces. The dose evaluation presented by Dr. Dooley used fecal samples to confirm the intake assessment derived from urinary data analysis. NIH's failure to collect fecal samples precluded its identification of the discrepancy in its dose estimation. Its failure to do so led to initial inaccurate calculations which significantly underestimated Dr. Ma's internal contamination.

C. NIH Failed to Control and Secure Radioactive Materials, in Violation of 10 CFR §§ 20.1801 and 20.1802.

NIH has failed to secure radioactive materials from unauthorized removal and to ensure the security of radioactive materials used under its auspices, in violation of 10 CFR §§ 20.1801 and 1802, which provide as follows:

> The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.
>
> The Licensee shall control and maintain constant surveillance of licensed material that is in a

controlled or unrestricted area and that is not in storage.

It is beyond dispute that the P-32 used to contaminate Dr. Ma and twenty-five other NIH employees was improperly removed and NIH failed to maintain control or constant surveillance over it. NIH's failure to do so led directly and proximately to their radiation exposure and subsequent dose.

The Affidavits of Drs. Ma and Zheng make clear that NIH is completely lax in its control of and security over radioactive materials. Ma Aff., ¶¶ 40-42; Zheng Aff., ¶¶ 33-35. These materials are stored in unlocked refrigerators and freezers in laboratories which are routinely unattended. Id. No documentation is made of an individual's access to this material or removal of this material from restricted or controlled areas. Id.

Indeed, during 1994, without approval from NRC, the Director of NIH instituted his own policy which greatly reduced the security and control over radioactive materials Institute-wide. Dr. Varmus took it upon himself to relieve NIH of its legal obligation to maintain under lock and key or direct oversight at all times radioactive materials, including P-32, which do not exceed ten times the activity listed in Appendix C of 10 CFR per container. Id. His conduct was wilful and in deliberate violation of NIH's commitments to the NRC pursuant to 10 CFR § 20.1801 and must not be countenanced.

D. NIH Failed to Perform Surveys as Necessary to Comply with the Requirements of Part 20, and which are Reasonable Under the Circumstances to Evaluate the Extent of Radiation Hazards That May be Present, in Violation of 10 CFR § 20.201(b).

10 CFR § 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR § 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of circumstances.

After learning of Dr. Ma's radiological intake, it apparently took NIH two weeks to discover that a water cooler in the same general area as the public refrigerator was radioactively contaminated, and to determine that 25 additional NIH employees who worked on the same floor as Dr. Ma were internally contaminated with P-32. See Exhibit 11. NIH's failure to conduct in a timely manner surveys of personnel and Dr. Ma's surrounding work area is a clear violation of both 20 CFR § 20.201(b) and a commitment it made to the NRC on October 14, 1992.

By letter to the NRC dated October 14, 1992, NIH assured the NRC that the following corrective steps would be taken to avoid further violations:

> The RSB will continue to emphasize to all users the importance of notifying Radiation Safety promptly for spills of radioactive materials when there is personnel

contamination. Contaminated individuals will be instructed to immediately decontaminate any radioactive material from skin areas. It will be emphasized to radioactive material users that they will not delay decontamination for any reason whatsoever.

Rather than immediately taking Dr. Ma to the hospital, RSB personnel and Dr. Weinstein questioned her and engaged in other useless activities, which delayed her transport to the hospital by over three hours. Moreover, Dr. Weinstein interfered with the hospital's efforts to take and preserve samples, in direct conflict with NUREG/CR-4884, Interpretation of the Bioassay Measurements (1987), published by the NRC, which recommends that standard systemic excreta data be collected for a full 24 hour period following an internal radiation contamination event.

III. CONCLUSION.

As a result of NIH's failure adequately to control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20, Dr. Ma was contaminated with Phosphorous-32, and received a 9.2 rem dose at a time when she was seventeen weeks pregnant. The dose received by Dr. Ma and her fetus is greatly in excess of regulatory limits. The internal contamination of Dr. Ma and the 25 other scientists who worked in Building 37 occurred as a direct and proximate result of NIH's failure to control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20. Furthermore, NIH failed to take proper actions to assess accurately the level of Dr. Ma's internal contamination or to provide appropriate medical care and follow-up treatment to

remove the ingested activity. Instead, NIH significantly underestimated Dr. Ma's internal contamination and provided conflicting and harmful directions to hospital personnel which delayed her treatment and interfered with efforts to properly assess her level of radioactive intake. As a result of this malfeasance, NIH failed to minimize the health risks to Dr. Ma and her fetus.

Accordingly, the NRC should suspend or revoke the materials license of the NIH, License No. 19-00296-10, pending resolution of these issues. The NRC must take all other appropriate enforcement action against NIH including imposition of a civil fine, for its wilful and reckless violations of 10 CFR Part 20.

Respectfully submitted,

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Dated: October 10, 1995

PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

AFFIDAVIT OF MARYANN WENLI MA, M.D., PH.D.

I, Maryann Wenli Ma, M.D., Ph.D., do solemnly declare as follows:

1. I am submitting this affidavit in support of the Petition Pursuant to 10 CFR § 2.206 to Suspend or Revoke the Materials License of the National Institutes of Health (NIH), License No. 19-00296-10, and to Take Other Appropriate Enforcement Action Against NIH. As set out more fully below, as a result of NIH's failure to adequately control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20, I was contaminated with Phosphorous-32, a highly radioactive isotope, and received a dose of radiation greatly in excess of regulatory limits. At the time of my contamination, I was four months pregnant, and consequently, my fetus received a dose of radiation approximately twenty times greater than the regulatory limits. A short time later, NIH determined that twenty-five other NIH employees, including my husband Bill Wenling Zheng, received internal radiation contamination as a direct result of NIH's failure to adequately control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20. After learning of my contamination, NIH failed to take proper actions to assess the level of my internal contamination or to remove the ingested activity. Instead, NIH officials greatly underestimated my

internal contamination and provided conflicting and harmful directions to hospital personnel which delayed my treatment and hindered efforts to properly analyze my contamination.

2. In 1990, I received my M.D. degree from The First Medical College and Medical School, Ji-Nan University (Guang Zhou), in the People's Republic of China. In 1993, I received my Ph.D. in Cell and Molecular Biology from Peking Union Medical College, Chinese Academy of Medical Sciences in Beijing, China. In 1994, I received the Top 100 Outstanding Chinese Young Scientists Award for my pioneering work in the area of Cell and Molecular Biology. A copy of my curriculum vitae is attached and incorporated herein as Exhibit 1.

3. In 1994, I was selected for the Fogarty International Visiting Fellowship, through which I was assigned to conduct cancer research at the National Cancer Institute ("NCI") of NIH, in the Laboratory of Molecular Pharmacology ("LMP"). Dr. John N. Weinstein is the Senior Investigator in that lab.

4. I started my work in Dr. Weinstein's lab with a research project in Molecular Biology. Its aim was to develop a novel method for displaying more efficiently the existence of expressed genes. The method, named Restriction Display (RD-PCR), would have had significant scientific and commercial value, if successful. Through our work, Bill and I developed a procedure which, by amplification of the restriction fragments, efficiently displayed the expressed genes, thereby greatly increasing the likelihood of the method's successful. In fact, by the time the

contamination incident occurred, the method had already been established. Dr. Weinstein required Bill and I to work tirelessly on this project in his quest to patent the new procedure. Trace amount of P32 or P33 labelled dNTP was incorporated into the experimental system during certain step of RD-PCR to display the expressed gene fragments.

5. In or around March or April, 1995, we stopped using P-32 in our experiments because it smeared the bands of our results. We determined that P-33, which was less radioactive, provided better results.

6. On April 12, 1995, I learned that I was pregnant. Bill and I were very excited about having a baby, and I called and wrote our families in China immediately to tell them the good news.

7. At various times during our employment, Dr. Weinstein advised Bill and me that our experiments were so important that he would not like anything to hold them up. For this reason, we were very nervous about informing him of my pregnancy. However, on June 9, 1995, Dr. Weinstein noticed that I was walking with one hand supporting my back and asked if anything was wrong. We told him that we had made an appointment with a doctor. On June 11, 1995, Dr. Weinstein called us in to see him and asked whether I had seen the doctor. Bill told him that I was pregnant. Dr. Weinstein responded that he wanted to meet us that afternoon. Bill attended the meeting without me.

8. That evening Bill recounted to me that Dr. Weinstein had tried to persuade him to abort the pregnancy. Bill also told me that he advised Dr. Weinstein that he felt that it was dangerous to have an abortion in this country due to attacks on abortion clinics; that many of the doctors who performed abortions in this country were not competent; and that we were happy to have the baby. Bill told me that Dr. Weinstein would not allow the conversation to drop, and followed him to the elevator to tell him that we should consult with Dr. Tim Myers, another colleague from our lab who had just had a baby, to find out how much trouble it would be to have a baby.

9. From that time on, Dr. Weinstein inquired about my schedule almost everyday and monitored my activities. On June 12, 1995, he asked me if I was okay. I responded that I was pregnant. After a pause, he congratulated me. I thanked him and told him that we were happy to have the baby.

10. On June 16, 1995, Dr. Weinstein asked us to discuss our experiments with him over the weekend. On June 18, 1995, we met with him as requested, however, rather than talking in any detail about our work, Dr. Weinstein pressed us about the pregnancy. He stated that our project is so important that he did not want anything, like my pregnancy, to hold it up. I told him that my pregnancy would not interfere with my work and that I would only need six weeks of leave after the birth of the baby. I further advised him that my parents would take care of the baby after I

returned to work and assured him that I would do my best with the experiments.

11. Dr. Weinstein appeared unhappy and tried to convince us that since our experiments had involved radiation, the baby we expected would not be safe. We advised him that we had already consulted with the obstetrician about this concern and that since the radioactive material was of low dosage and I was well protected, there would be no harm to the baby. Dr. Weinstein responded that if this were so, I should then continue with the experiments involving radioactive materials. We then advised him that I had stopped handling the radioactive isotopes several months earlier when I first learned of my pregnancy and that Bill handled most of the radioactive isotopes used in our experiments. (Since Bill and I worked on the same project, we were able to allocate our responsibilities to minimize my contact with the radioactive materials.) Dr. Weinstein disagreed with this approach. Bill then advised him that there were regulations in the RSB which required that pregnant women be protected from radiation exposure as much as possible. Dr. Weinstein responded that he did not know about any such regulation.

12. Dr. Weinstein then stated that Bill was incorrect in his belief that having an abortion was not safe. He stated that he knew many pregnant women died during delivery, but that he had never heard of anyone dying in an abortion clinic. Bill became angered by his remarks and stated that it was our right to have our baby and that if he, Dr. Weinstein, was still not happy that

we were keeping the baby, he could go find candidates to replace us and that we would transfer to another laboratory.

13. On June 23, 1995, Dr. Weinstein gave us a telefax from the RSB in response to his inquiry about whether pregnant women should be protected from radiation. The fax listed the date and time at which it was sent to Dr. Weinstein as 6/19/95 at 15:03. The document included a declaration form, which, if filled out, would have given me heightened protection from radiation during my pregnancy. Pursuant to the declaration procedure, a 0.5 rem limit is applied to every pregnant woman. Dr. Weinstein insisted that if I filled out the declaration form, it might cause trouble for the lab. By these and other remarks, Dr. Weinstein pressured me not to submit a Declaration of Pregnancy to RSB at that time. At the time we learned of my contamination, my husband and I had not yet reached a final determination as to this issue.

14. Beginning at 9:00 a.m. Sunday June 25, 1995, we met with Dr. Weinstein to discuss our experiments. The meeting was long and unpleasant and at approximately 3:00 p.m. we suggested that we would treat Dr. Weinstein to a Chinese food dinner at a local restaurant. We had leftovers from the meal, including fish and shrimp, which I brought for lunch the following week.

15. At about 6:00 p.m. on June 28, 1995, I ate my Chinese food leftovers, which I had stored in the conference room public refrigerator. That night I experienced sharp pains in my liver area.

16. Throughout the day of June 29, 1995, I experienced increasingly sharp and persistent pains in my liver area. During the afternoon, Bill and I were working on the same bench top in our laboratory. At approximately 5:30 p.m., when the experiment was concluded, Bill surveyed the bench top and adjacent floor with a Geiger-Muller counter with a pancake type probe, as he routinely did upon completion of his experiments. When the detector got close to my feet, a strong audible sound alarmed. At first we believed that the chair in which I was sitting or the lab clothes that I wearing had gotten contaminated. However, we ruled that out and determined from surveying my body that I myself was contaminated.

17. When we were unable to locate Dr. Weinstein to report my contamination to him, Bill called NIH's emergency "116" number to report my radiation contamination. After we did so, Dr. Weinstein appeared in the laboratory and we reported to him that I had been contaminated and that we had called 116 for help. Dr. Weinstein stated that he thought that was unnecessary.

18. A short time later, an ambulance arrived and attempted to arrange for my transfer to a hospital. However, in the interim, Dr. Weinstein received a telephone call from the Radiation Safety Branch ("RSB") which he transferred to us. RSB directed us to remain at the lab until RSB conducted a survey.

19. While we were waiting for RSB to arrive, Dr. Weinstein asked me where we stored our food. This question was peculiar because we, like all members of our laboratory including Dr.

Weinstein, stored our food in the two refrigerators located in the public conference room. Dr. Weinstein then surveyed the refrigerator and determined that it was contaminated. No radiation materials are stored in the conference room, and the presence of radiation near the refrigerator led me to fear that my food was deliberately contaminated with radioactive materials

20. A short time later, two RSB officials arrived and surveyed me with their own monitors. After they confirmed my contamination, they attempted to locate a shower in order to decontaminate me. However, we were unable to locate a shower after spending approximately one hour searching for one. The RSB officials also surveyed the conference room and located a spot of radiation contamination on the floor six to eight inches in front of the refrigerator in which we stored our food. They found no contamination inside the refrigerator.

21. Rather than expediting my transport to the hospital for medical treatment, Dr. Weinstein performed smear tests, which confirmed that my contamination was not external. Dr. Weinstein then directed me to drink a lot of water. I was also directed to provide a urine sample which also confirmed that my contamination was internal.

22. One of the RSB officials tried to console me by advising me that the dosage I had picked up might not be harmful to my baby and would not necessarily mean that I would have to abort my pregnancy. Dr. Weinstein interrupted her remarks and tried to convince Bill and me that the baby "should be worried."

During this time, Dr. Weinstein and an RSB official argued about how to save the urine samples in order to get a correct determination of the amount of radiation I had ingested.

23. At approximately 8:35 p.m., the ambulance arrived at Holy Cross Hospital. I was examined by Dr. Peter White, who ordered that I be given intravenous infusions of fluid to dilute the contamination of my blood level. Some time later Robert Zoon, NIH's Radiation Safety Officer, arrived at the hospital to consult with Dr. White and to retrieve some of my blood and urine samples.

24. At approximately 11:00 p.m., Dr. Weinstein arrived at the hospital and began to question me again about the food I had eaten and the container in which it was stored. Dr. Weinstein told me that he thought that I would be okay but again repeated that the baby "must be worried." He offered to call my obstetrician, which I declined.

25. At approximately 2:00 a.m. on June 30, 1995, a male nurse told me that he had received a telephone call informing him that the strategy for collecting urine samples had changed. He advised me that instead of collecting all the urine, which was the precise instruction given by Mr. Zoon, he was to aliquot only a small part of the samples already taken.

26. At approximately 3:00 a.m. on June 30, 1995, Dr. White advised me that he had received conflicting instructions from Mr. Zoon and Dr. Weinstein about the urine collection, and that he did not know whose instruction he should follow. Dr. White

advised me that Dr. Weinstein had directed that he not save all the urine samples but merely aliquot a small part of the samples already taken. Dr. White advised me that he came up with a compromise plan for the collection of urine by which he would pool the entire sample of urine in a large container but would also save a small amount every time a sample was produced.

27. While at the hospital, no efforts were made, other than giving me intravenous infusions of fluid, to remove the ingested activity. I was not given any type of replacement therapy to assist in the removal of the P-32.

28. Some time after 3:00 a.m., Bill took me home from the hospital. I was not instructed to continue to collect my urine over one hour intervals or at any other interval. When I returned home, I experienced severe vomiting. This vomiting continued throughout my second trimester.

29. Because I did not learn of my internal contamination until at least a day after ingesting the radioactive materials, I carried radioactive materials home with me without knowing that I had done so. On June 30, 1995, RSB officials conducted a survey of our car and apartment and determined that I had contaminated the seat and floor mat of the car and certain areas of our apartment. They also determined that I had contaminated a number of articles of my clothing.

30. On the night of June 29, 1995, Mr. Zoon told Bill that we were not to return to the laboratory while this matter was being investigated. Bill notified Dr. Weinstein of this

direction on the morning of June 30, 1995. However, that weekend, Dr. Weinstein called us at home repeatedly and told us that our experimental records needed to be "improved." He tried to make us to return to the lab even though we had been directed by Mr. Zoon not to do so.

31. We later learned that Dr. Weinstein had told a number of people, including another senior investigator, Dr. William Boner, that we already had a child in China -- which is untrue -- and that under the China one child policy it was necessary that we abort the baby. He suggested that we had contaminated ourselves to abort the pregnancy. We also learned that Dr. Weinstein has suggested to others that Bill contaminated me because he learned that our expected baby is female and wanted me to abort the pregnancy. These suggestions are outrageous and have been extremely damaging to our professional reputations and careers.

32. On June 30, 1995, I went to the RSB for a whole body scan. (This scan was conducted after RSB officials determined that areas of our car and apartment were contaminated.) Dr. Jorge A. Carrasquillo, of NIH's Nuclear Medical Department, conducted the scan. He estimated that I had a total of 862 μCi retained at the time of this scan and that substantial exposure was detected in the area in which the fetus is located, as well as in my liver.

33. Also on June 30, 1995, I reported to NIH's Occupational Medical Service ("OMS") and was examined by Dr. Lynn Stansbury.

Dr. Stansbury told me that she was unable to treat me and merely directed me to consult with my private physician by telephone. Dr. Stansbury failed to provide me with any medical care or follow-up treatment to remove the ingested activity.

34. While I was waiting in OMS to be interviewed by an NIH detective, Dr. Weinstein appeared and insisted that I had to see my Ob/Gyn immediately. He again stressed that the "baby must be worried." He offered to call my doctor several times, however, we again declined his offers.

35. NIH did not contact me to discuss my contamination or to counsel me about its health implications. Rather, on July 8, 1995, Bill and I contacted Mr. Zoon to request information about my contamination. He provided Bill and I with a copy of ORISE's calculation, which estimated my intake to be 265 μCi and informed us that NIH's estimate was "more or less the same."

36. On July 18, 1995, I read The Washington Post, which quoted Anne Thomas, an NIH spokeswoman, as saying that:

> The woman underwent intravenous hydration treatment to dilute the radioactive isotope, and this hydration therapy significantly reduced the [radioactive] activity in the urine. . . . The doctors who examined her do not believe this will cause any long-term medical complications for her or her fetus."

These statements were false. I was never told by any of the physicians who examined me that my contamination would not cause any long term medical complications for me or my baby. In fact, at the time that I was being treated at the hospital, hospital personnel had no idea of the level of my contamination or what radioactive isotope I was contaminated with.

37. By letter to Dr. Harold E. Varmus, Director of NIH, dated August 18, 1995, my attorney, Judith Wolfer, demanded that NIH transfer to an independent laboratory, TMA/Norcal, a portion of the urine specimens I provided during the period of June 29, 1995, through July 27, 1995. NIH agreed to this request and transferred eleven samples to TMA/Norcal on August 24, 1995.

38. By letter dated August 25, 1995, my attorney, Debra Katz, requested that NIH pay for the 24 hour samples to be independently analyzed due to the serious nature of the exposure and the fact that I was four months pregnant at the time of the initial intake. Ms. Katz further advised NIH that the samples information analyzed by ORISE was inadequate to have reached a proper, independent determination of my level of internal contamination, consistent with NUREG/CR-4884 and those of NCRP 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition (1987). NIH denied this request.

39. By letter dated August 28, 1995, Ms. Katz advised Charles W. Hehl, Director, Division of Radiation, Safety and Safeguards, of the NRC, of our concern that the analysis conducted by the NIH was inadequate to reach a scientifically valid conclusion.

39. By memorandum dated August 29, 1995, NIH transmitted its final assessment of my intake to the NRC, and provided a copy of this transmission to Ms. Katz. It concluded that my individual effective dose equivalent was 4.17 rem and my fetus'

dose equivalent was 3.2 rem. NIH assigned me an intake of 500 μCi for the event.

NIH Is Lax in its Control of Radioactive Materials

40. I began work at NIH in Dr. Weinstein's lab on or around August 16, 1994. The following week, Dr. Weinstein directed Bill and I to begin conducting experiments using S-35 and P-32, labelled dNTP, which are radioactive materials (RAM). Dr. John Boulawini, our predecessor, had ordered the radioactive reagents before he departed from NIH. Dr. Weinstein directed us to begin working with these materials before we were given training by RSB in the use and handling of radioactive materials, and before we were assigned our user identification numbers in November, 1994. On one occasion, he directed us to use Dr. Boulawini's user identification number to order radiation reagents before we were assigned our own user numbers. On another occasion, he directed us to use his (Dr. Weinstein's) identification number to order radiation reagents before we were assigned our own user numbers. It is my understanding that Dr. Weinstein was responsible for providing written authorization for each of our orders for radioactive materials.

41. Once the radioactive reagents arrived at NIH from the manufacturer, RSB distributed them to the specific users. The user is responsible for storing the radiation reagents in specifically designated refrigerators and freezers. The refrigerator and freezer in which we stored our reagents was used by the entire group. Neither the refrigerator nor the freezer

were ever locked. While the lab is supposed to be locked during non-working hours, it was frequently left unattended. Further, everyone in the group was able to gain access to the LMP lab with the same key and would have been able to gain access to any of the materials in the refrigerator or freezer. There was no procedure in place for signing in to gain access to the refrigerator or freezer or to otherwise document that one had done so. In addition, no one in the lab checked to see if records were kept documenting the use of radiation reagents. Thus, the security over this material was non-existent.

42. The lab was also lax in its use of dosimetry. When we first began work at LMP, Bill and I were given dosimetry which we wore. However, to my knowledge, the dosimetry was never collected at the end of a month, a quarter, or at any other time interval, and I was never reissued new dosimetry. During the period in which I received my internal radiation contamination, I was not, to my knowledge, assigned any dosimetry. Accordingly, NIH is unable to document properly my exposure history while at NIH.

Ma Wenli

MARYANN WENLI MA, M.D., PH.D

Subscribed and sworn to before me,
this 7th day of October, 1995.

Notary Public

My commission expires 1/15/96

EXHIBIT 5
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Maryann Wenli Ma, MD., Ph.D.

SSN [redacted]

Current Address:
[redacted]

Working Address:
Lab of Molecular Pharmacology
NCI / NIH Bldg 37 / 5D-18
9000 Rockville Pike,
Bethesda, MD. 20892
Tel: 301-496-9572,
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Objective: Basic and Applied Research on Cancer Cell and Molecular Biology

Qualifications:

- Eight years of various molecular biological research experiences: Molecular Biology, Molecular Oncology, Molecular Pharmacology, Molecular Genetics, PCR related studies.

- Ten years of various cancer cell biology and animal model research experience: Cell culture, Gene transfer, Reporter gene system, Liposomal system.

- Various morphological and structural biology research experience: In situ hybridization, histo- or cytochemistry and immunochemistry, optical and electron microscopic techniques.

- Read, write and speak Chinese and English.

Education:

- MD. 1985-1990: Faculty of Medicine. The First Medical College and Medical School, Ji-Nan University (Guang Zhou). P. R. China.

- Ph.D.1990-1993: Ph.D. in Cell and Molecular Biology. Institute of Basic Medical Sciences, Peking Union Medical College, Chinese Academy of Medical Sciences. Beijing, P.R. China.

- MS. 1987-1990: MS. in Experimental Pathology, Medical School, Ji-Nan University, Guang Zhou, P.R. China.

- MB. 1980-1985: Medical Bachelor Degree: Faculty of Medicine. The First Medical College.

Experience:

- Research Visiting Fellow: 1994, 8: Development of a novel method of displaying differentially expressed mRNAs. Laboratory of Molecular Pharmacology, NCI / NIH.

- Research Fellow: 1993,6-1994,8: Institute of Biotechonolgy and College of Life Sciences. Zhongshan University, Guangzhou. Cloning and Genetic Engineering of a Anti-aging peptides from Herbal Medicine.

-Ph.D. Candidate: 1990,7-1993,7: Institute of Basic Medical Sciences, Peking Union Medical College. Ph.D. Dissertation: The mechanism of the erythroid differentiation factor (EDF) upon the cellular differentiation and nuclear matrix-intermediate filament system of human erythroleukemia K562 cells.

- MS Candidate: 1987,7-1990,7: Department of Pathology, Medical School, Ji-Nan University: MS thesis: The structural and functional study of the highly and poorly differentiated nasopharyngeal carcinoma cell lines.

- Research and Teaching Assistant: 1985,7-1987,7: Department of Histology and Embryology. Trained in histochemistry, cell biology and immunology.

Memberships:

Chinese Association of Cell and Molecular Biology
Chinese Association of Medical Cell Biology
Chinese Association of Medicine

Awards and Fellowships:

-Top 100 Outstanding Chinese Young Scientists Award of the year 1994.
-Fogarty International Visiting Fellowship. National Cancer Institute, NIH. 1994, 4.
-Joint Hong Kong-Zhong Shan University Fellowship Award: Zhong Shan University, 1993-1994.
-Best Ph.D. Dissertation Award: 1993, Peking Union Medical College.
-Best Ph.D. Candidate Award: 1992, Peking Union Medical College.

Publications:

1. The growth and differentiation characteristics of K-RRneo cells. China Science Bulletin. 39: 757, 1994

2. The study of vimentin, lamin and their relationships with the processes of cell denucleation. Acta Exp Biol. 28:333,1994.

3. The gene expression system of mammalian cells. Advances in Biophysics and Biochem. 23:66,1994.

4. The Growth and differentiation characteristics of cybrid K-RRneo cells. China Science Bulletin. 39:871,1994.

5. An efficient technique of whole mount TEM sample preparation: the nuclear Matrix-intermediate filament system of K562 cells. Proceedings of China Medical Sciences. 16:103,1994.

6. The techniques of whole mount TEM sample preparation: in JingBo Zhang eds, Practical Method and Technology in Cell Biology, 2nd Ed. Academia Press, Beijing, 1994.

7. The characteristics and distribution of the intermediate filaments in K562 cells. Acta Anatomic Sinica. 25:33, 1994.

8. Gene transfer study using reticulocytes as the target cells. Acta Chinese Medical Sciences. 16:8,1994.

9. A novel and efficient strategy of gene transfer, cybridization and cybrid selection. Science Bulletin. 38:950,1993.

10. The study of the nuclear matrix-intermediate filaments in cybrid K-RRneo cells cybridized between rabbit reticulocytes and K562 cells. Acta Exp Biol. 26:377,1993.

11. Whole mount TEM study of the nuclear matrix-intermediate filament system of K562 cells. Acta Anatomica Sinica. 24:168,1993.

12. The study of intermediate filaments of the highly and poorly differentiated nasopharyngeal carcinoma cell lines. Acta Chinese Medical Sciences. 15:355,1993.

13. Fusion of neo gene transferred rabbit reticulocytes and K562 cells: A new approach to rapid selection and characterization of cybrids. Chinese Science Bulletin. 38:1826,1993.

14. An effective method of whole mount TEM sample preparation to study cytoskeleton. J. Electron Microscopy. 5:443,1993.

15. The molecular biology of intermediate filaments (Reviews). Medical Review (Mol Biol Sect). 15:62,1993.

16. The relationships between erythroblast denucleation and the nuclear matrix-intermediate filaments. J Chinese Medical Sciences. 48:652,1995.

17. The role of the erythroid differentiation factor (EDF) upon the cellular differentiation and nuclear matrix-intermediate filament system of the human erythroleukemia K562 cells. China Science. (in press)

18. Restriction display of differentially expressed mRNAs (in press).

19. A novel model for the working mechanism of biological cells. Science and Technological Review. 69:3, 1994.

20. Cytolinguistics: The informatics of inner biological cells. Science and Technology Review. 74:3, 1995.

21. The origin and functional mechanism of Jing-Luo. Science and Technology Review. 75:3, 1995.

22. Gene therapy through digestive tract: The elucidation of the mechanism of the traditional Chinese medicine. Science and Technology Review. 78:8,1995

23. Biological Virus and computer virus. Science And Technology Review. 80:3,1995.

24. Dream and thinking mechanism. Science and Technology Review. 84:2, 1995.

PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

AFFIDAVIT OF BILL WENLING ZHENG, M.D., PH.D.

I, Bill Wenling Zheng, M.D., Ph.D., do solemnly declare as follows:

1. I am submitting this affidavit in support of the Petition Pursuant to 10 CFR § 2.206 to Suspend or Revoke the Materials License of the National Institutes of Health (NIH), License No. 19-00296-10, and to Take Other Appropriate Enforcement Action Against NIH. As set out more fully below, as a result of NIH's failure to adequately control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20, my wife, Maryann Wenli Ma, and my expectant child were contaminated with Phosphorous-32, a highly radioactive isotope, and received a dose of radiation greatly in excess of regulatory limits. At the time of the contamination, Maryann was four months pregnant, and consequently, our baby received a dose of radiation approximately twenty times greater than the regulatory limits. A short time later, NIH determined that twenty-five other NIH employees, including myself, received an internal radiation contamination as a direct result of NIH's failure to adequately control and secure radioactive materials and to otherwise adhere to the requirements of 10 CFR Part 20. Furthermore, NIH failed to perform an adequate survey of Maryann, in violation of 10 CFR 201(b), which requires each licensee to perform surveys necessary to assure compliance with 10 CFR

20.101(a). After learning of Maryann's contamination, NIH failed to take proper actions to assess the level of her internal contamination or to try to remove the ingested activity. Instead, NIH greatly underestimated her internal contamination and provided conflicting and harmful directions to hospital personnel which delayed her treatment and interfered with efforts to properly analyze her contamination and that of our baby.

2. In 1988 I received my M.D. degree form the First Medical College (Guang Zhou), in the People's Republic of China. In 1991, I completed my Ph.D. in Cancer Biology and Pathology from Beijing Medical University, Beijing, China. In 1993, I completed my visiting fellow (postdoctoral) study from National Laboratory of Molecular Oncology, Chinese Academy of Medical Sciences, Beijing, China. In 1994, I was assigned a position in Liu Hua Qiao General Hospital as an Associate Professor and Physician in Charge. A copy of my curriculum vitae is attached and incorporated herein as Exhibit 1.

3. In 1994, I was selected for the Fogarty International Visiting Fellowship, through which I was assigned to conduct cancer research at the National Cancer Institute ("NCI"), of NIH in the Laboratory of Molecular Pharmacology ("LMP"). Dr. John N. Weinstein is the Senior Investigator in that lab. My wife also received a Fogarty International Visiting Fellowship and was assigned to Dr. Weinstein's lab as well. We conducted our work collaboratively.

4. I started my work in Dr. Weinstein's lab with a research project in Molecular Biology, designed to develop a novel method for displaying more efficiently the existence of expressed genes. The method to be developed was named Restriction Display (RD-PCR). The project, if successful, would have had significant scientific and commercial value. Through our work, Maryann and I developed a procedure which, by amplification of the restriction fragments, efficiently displayed the expressed genes, thereby increasing the likelihood of the method's success. In fact, by the time the contamination occurred, the method had already been developed. Dr. Weinstein required Maryann and I to work tirelessly on this project in his quest to patent the new procedure. Trace amount of P-32 or P-33 labelled DNTP was incorporated into the experimental system during certain steps of RD-PCR to display the expressed gene fragments.

5. In or around March or April, 1995, we stopped using P-32 in our experiments because it smeared the bands of our results. We determined that P-33, which was less radioactive, provided better results.

6. On April 12, 1995, we learned that Maryann was pregnant. We were very excited about having a baby, and we called and wrote our families in China immediately to tell them the good news.

7. At various times during our employment, Dr. Weinstein advised Maryann and me that our experiments were so important that he did not want anything to hold them up. For this reason, we were very nervous about notifying him that Maryann was

pregnant. However, on June 9, 1995, Dr. Weinstein noticed that Maryann was walking with one hand supporting her back and asked her if anything was wrong. We told him that we had made an appointment with a doctor. On June 11, 1995, Dr. Weinstein called us at home and asked whether Maryann had seen the doctor. I told him that Maryann was pregnant. Dr. Weinstein sounded unhappy to hear the news and responded that he wanted to meet us that afternoon. I attended the meeting without Maryann because she was not feeling well at the time.

8. During that meeting Dr. Weinstein tried to persuade me that we should abort the pregnancy. I was very alarmed by Dr. Weinstein's comments and offered him various explanations as to why we would not do so. At first I told Dr. Weinstein that I felt that it was dangerous to have an abortion in this country due to attacks on abortion clinics. I also told him that many of the doctors who performed abortions in this country were not competent. Finally, I told him that we were happy to have the baby. Dr. Weinstein would not allow the conversation to drop, and followed me to the elevator to tell me that we had better consult with Dr. Tim Myers, another colleague from our lab, who had just had a baby to find out how much trouble it would be.

9. From that time on, Dr. Weinstein inquired about Maryann's schedule almost every day and monitored our activities.

10. On June 16, 1995, Dr. Weinstein asked us to discuss our experiments with him over the weekend. On June 18, 1995, we met with him as requested. However, rather than talking in any

detail about our work, Dr. Weinstein pressed us about the pregnancy. He stated that our project is so important that he did not want anything to hold it up, implying that Maryann's pregnancy would interfere with our work. Maryann responded that her pregnancy would not interfere with the work and that she would only need six weeks of leave after the birth of the baby. She further advised him that her parents would take care of the baby after she returned to work.

11. Dr. Weinstein appeared unhappy and tried to convince us that since our experiments had involved radiation, the baby we expected would not be safe. We advised him that we had already consulted with the obstetrician about this concern and that since the radioactive material was of low dosage and Maryann was well protected, there would be no harm to the baby. Dr. Weinstein responded that if this were so, she should continue with the experiments involving radioactive materials. We then advised him that Maryann had stopped handling the radioactive isotopes several months earlier when she first learned of her pregnancy and that I had handled most of the radioactive isotopes involved in our experiments. (Since Maryann and I worked on the same project, we were able to allocate our responsibilities to minimize Maryann's contact with the radioactive materials.) Dr. Weinstein disagreed with this approach. I then advised him that there were regulations in the Radiation Safety Branch ("RSB") which required that pregnant women be protected from radiation

exposure as much as possible. Dr. Weinstein denied knowing about any such regulation.

12. Dr. Weinstein then stated that I was incorrect in my belief that having an abortion was not safe in the United States. He argued that he knew many pregnant women died during delivery, but that he had never heard of anyone dying in an abortion clinic. His remarks were highly offensive to me and I told him that it was our right to have our baby. I further told him that if he, Dr. Weinstein, was still not happy that we were keeping the baby, he could find candidates to replace us and that we would transfer to another laboratory.

13. On June 23, 1995, Dr. Weinstein gave us a telefax from the RSB in response to his inquiry about whether pregnant women should be protected from radiation. The fax listed the date and time at which it was sent to him as 6/19/95 at 15:03. The document included a declaration form, which, if filled out, would have given Maryann heightened protection from radiation during her pregnancy. Pursuant to the declaration procedure, a 0.5 rem limit is applied to every pregnant woman. Dr. Weinstein insisted that if she filled out the declaration form, it might cause trouble for the lab. By these and other remarks, Dr. Weinstein pressured Maryann not to submit a Declaration of Pregnancy to RSB at that time. We had not yet reached a final determination as to this issue at the time Maryann learned of her contamination.

14. Beginning at 9:00 a.m. on June 25, 1995, we met with Dr. Weinstein to discuss our experiments. The meeting was long

and unpleasant and at approximately 3:00 p.m. we suggested that we would treat Dr. Weinstein to a Chinese food dinner at a local restaurant. We had leftovers from the meal, including fish and shrimp, which Maryann brought to the lab for lunch the following week.

15. At about 6:00 p.m. on June 28, 1995, Maryann ate her Chinese food leftovers, which she had stored in the conference room public refrigerator. That night, Maryann experienced sharp pains on the right side of her liver area.

16. Throughout the day of June 29, 1995, Maryann told me that she was experiencing increasingly sharp and persistent pains in her liver area. During the afternoon, Maryann and I were working on the same bench top in our laboratory. At approximately 5:30 p.m., when the experiment was concluded, I surveyed the bench top and adjacent floor with a Geiger-Muller counter with a pancake type probe, as I routinely did upon completion of experiments. When the detector got close to Maryann's feet, a strong audible sound alarmed. At first we believed that the chair in which Maryann was sitting or the lab clothes that she was wearing had gotten contaminated. However, we ruled out those possibilities, and determined from surveying Maryann's body that she was contaminated.

17. When we were unable to locate Dr. Weinstein to report Maryann's contamination to him, I called NIH's emergency "116" number to report Maryann's radiation contamination. A short time later, Dr. Weinstein appeared in the laboratory and we reported

to him that Maryann had been contaminated and that we had called 116 for help. Dr. Weinstein stated that he thought it was unnecessary for us to have done so.

18. A short time later, an ambulance arrived and attempted to arrange for Maryann's transfer to a hospital. However, in the interim, Dr. Weinstein received a telephone call from RSB and directed us to remain at the lab until RSB conducted a survey.

19. While we were waiting for RSB to arrive, Dr. Weinstein questioned Maryann about where we stored our food. This questioning was peculiar because we, like all members of our laboratory including Dr. Weinstein, stored our food in the two refrigerators located in the public conference room. Dr. Weinstein then surveyed the refrigerator and determined that it was contaminated. No radiation materials are stored in the conference room, and the presence of radiation near the refrigerator led me to fear that Maryann's food was deliberately contaminated with radioactive materials.

20. A short time later, two RSB officials arrived and surveyed Maryann with their own monitors. After they confirmed her contamination, they attempted to locate a shower to decontaminate her. However, they were unable to locate a shower after spending approximately one hour searching for one. The RSB officials also surveyed the conference room and located a spot of radiation contamination on the floor six to eight inches in front of the refrigerator in which we stored our food. They found no contamination inside the refrigerator.

21. Rather than taking Maryann to the hospital for medical treatment, Dr. Weinstein performed smear tests, which indicated that her contamination was not external. Dr. Weinstein then directed her to drink a lot of water. RSB officials directed Maryann to provide a urine sample which also confirmed that her contamination was internal.

22. One of the RSB officials tried to console Maryann by advising her that the dosage she had picked up might not be harmful to our baby and would not necessarily mean that she would have to abort her pregnancy. Dr. Weinstein interrupted her remarks and tried to convince Maryann that the baby "should be worried." During this period, Dr. Weinstein and an RSB official argued about how to save the urine samples to get a correct determination of the amount of radiation Maryann had ingested.

23. At approximately 8:35 p.m., the ambulance arrived at Holy Cross Hospital. Maryann was examined by Dr. Peter White, who ordered that she be given intravenous infusions of fluid to dilute the contamination of her blood level. Some time later Robert Zoon, NIH's Radiation Safety Officer, arrived at the hospital to consult with Dr. White and to retrieve some of Maryann's blood and urine samples.

24. At approximately 3:00 a.m. on June 30, 1995, Dr. White advised Maryann that he had received conflicting instructions from Mr. Zoon and Dr. Weinstein about the urine collection, and that he did not know whose instruction he should follow. Dr. White advised Maryann that Dr. Weinstein had directed him not to

save all the urine samples but merely aliquot a small part of the samples already taken. Dr. White advised Maryann that he came up with a compromise plan for the collection of urine by which he would pool the whole sample in a large container, but also save a small amount in test tubes every time a sample was produced.

25. While we were at the hospital, no efforts were made, other than giving Maryann intravenous infusions of fluid, to remove the ingested activity. She was not given phosphorous salts or any other type of replacement therapy.

26. Some time after 3:00 a.m., I took Maryann home from the hospital. She was not instructed to continue to collect her urine over one hour intervals or at any other interval. When Maryann returned home, she experienced severe vomiting.

27. On the night of June 29, 1995, I told Mr. Zoon about our prior conversations with Dr. Weinstein in which he tried to pressure Maryann and I to abort her pregnancy. Mr. Zoon told me that we were not to return to the laboratory while this matter was being investigated. I notified Dr. Weinstein of this direction on the night of June 29, 1995, when he visited Maryann in the hospital. That weekend, however, Dr. Weinstein called us repeatedly at home and told us that our experimental records needed to be "improved." He tried to make us return to the lab even though we had been directed by Mr. Zoon not to do so.

28. We later learned that Dr. Weinstein had told a number of people, including another senior investigator, Dr. William Boner, that we already had a child in China -- which is untrue --

and that under the China one-child policy it was necessary that we abort the baby. He suggested that we had contaminated ourselves to abort the pregnancy. This suggestion is outrageous and has been extremely damaging to our professional reputation.

29. On June 30, 1995, I took Maryann to the RSB for a whole body scan. While Maryann and I were waiting in the Occupational Medical Service for an interview with an NIH detective, Dr. Weinstein appeared and insisted that she had to see her Ob/Gyn immediately. He again stressed that the "baby must be worried." He offered to call Maryann's doctor several times, however, we again declined his offers.

30. NIH did not contact Maryann to discuss her contamination or to counsel her about its implications to her health, and health of our baby. Rather, on July 8, 1995, Maryann and I contacted Mr. Zoon to request information about her contamination. He provided us with a copy of ORISE's calculation, which estimated Maryann's intake to be 265 μCi and informed us that NIH's estimate was "more or less the same."

31. On July 18, 1995, I read The Washington Post, which quoted Anne Thomas, an NIH spokeswoman, saying that:

> The woman underwent intravenous hydration treatment to dilute the radioactive isotope, and this hydration therapy significantly reduced the [radioactive] activity in the urine. . . . The doctors who examined her do not believe this will cause any long-term medical complications for her or her fetus."

Maryann was never told by any of the physicians who examined her that her contamination would not cause any long term medical complications for her or for our baby. In fact, at the time that

she was being treated at the hospital, hospital personnel had no idea of the level of her contamination or what radioactive isotope she was contaminated with.

32. By letter dated July 27, 1995, Dr. James Schmitt, Medical Director, Occupational Services of NIH, advised me that I had received an internal contamination with P-32. See Letter from Dr. J. Schmitt to W. Zheng (sec) (July 27, 1995), attached and incorporated herein as Exhibit 2.

NIH Is Lax in its Control of Radioactive Materials

33. I began work at NIH in Dr. Weinstein's lab on or around August 16, 1994. The following week, Dr. Weinstein directed Maryann and I to begin conducting experiments using S-35 and P-32, labelled DNTP, which are radioactive materials (RAM). Dr. John Boulawini, our predecessor, had ordered the radioactive reagents before he departed from NIH. Dr. Weinstein insisted that we begin working with the materials before we were given training by RSB in the use and handling of radioactive materials, and before we were assigned our user identification numbers in November, 1994. On one occasion, he directed us to use Dr. Boulawini's user identification number to order radiation reagents before we were assigned our own user numbers. On another occasion, he directed us to use his (Dr. Weinstein's) identification number to order radiation reagents before we were assigned our own user numbers. It is my understanding that Dr. Weinstein was responsible for providing written authorization for each of our orders for radioactive materials.

34. It is my understanding that once the radioactive reagents arrived at NIH from the manufacturer, RSB distributed them to the specific users. The user is responsible for storing the radiation reagents in specifically designated refrigerators and freezers. The refrigerator and freezer in which we stored our reagents was used by the entire group. Neither the refrigerator nor the freezer were ever locked. While the lab is supposed to be locked during non-working hours, it was frequently left unattended. Furthermore, everyone in LMP was able to open the doors of the LMP lab with the same key and would be able to gain access to any of the materials in the refrigerator or freezer. There was no procedure in place for signing in to gain access to the refrigerator or freezer, or to otherwise document that one had done so. In addition, no one in the lab checked to see if records were kept documenting the use of radiation reagents. Thus, the security over this material was non-existent. I have reviewed NIH's Interim Security Policy for Radioactive Materials. The procedures to protect against unauthorized removal of, or access to licensed materials were not adhered to in Dr. Weinstein's lab.

35. The lab was also lax in its use of dosimetry. When we first began to work at LMP, Maryann and I were given dosimetry which we wore. However, to my knowledge, the dosimetry was never collected after a month, a quarter, or at any other time interval, and I was never reissued new dosimetry. During the period in which Maryann received her internal radiation

contamination, she was not, to my knowledge, assigned any dosimetry. Accordingly, NIH is unable to properly document her exposure history while at NIH. NIH would also be unable to properly document my exposure history while at NIH.

BILL WENLING ZHENG, M.D., PH.D

Subscribed and sworn to before me,
this 7th day of October 1995.

Notary Public

My commission expires 1/15/96

EXHIBIT 5
PAGE 15 OF 24 PAGE(S)

Wenling Zheng, MD., Ph.D.

Working Address:
Lab of Molecular Pharmacology
NCI / NIH Bldg 37 / 5D-18
9000 Rockville Pike,
Bethesda, MD. 20892
Tel 301-496-9572,
Fax:301-402-0752

Objective: Basic and Applied Research on Cancer Molecular Biology

Qualifications:

-Eight years of various molecular biological research experiences: Molecular Biology, Molecular Oncology, Molecular Pharmacology, Molecular Genetics, PCR related studies.

-Ten years of various cancer cell biology and animal model research experience: Cell culture, Gene transfer, Reporter gene system, Retroviral system, Liposomal system.

-Various morphological and structural biology research experience: In situ hybridization, histo- or cytochemistry and immunochemistry, optical and electron microscopic techniques.

-Molecular informatics: retrieve, edit, fasta/blasta, map, sort and analyze genetic information through nucleic acid and protein databases, with UNIX based mainframe (GCG, etc.) or PC based programs (MacVector, etc.)

-Clinical oncology experience: Chemotherapy; Biological therapy (with LAK or TIL and gene therapy), Traditional Chinese Herbal Medicines.

- Read, write and speak Chinese and English, read Japanese and French.

Education:

- MD. 1980-1988: Faculty of Medicine. The First Medical College and The Sun Yat Sen's Memorial University of Medical Sciences. (Guang Zhou). P. R. China.

- Ph.D.1988-1991: Ph.D. in Cancer Cell and Molecular Biology. Dept of Cancer Biology and Pathology, Institute of Basic Medical Sciences, Beijing Medical University. Beijing, P.R. China.

- M.S. 1985-1988: MS. in Cancer Pathology, Dept of Pathology, Faculty of Medicine. The First Medical College, Guangzhou, P.R. China.

- M.B. 1980-1985: Medical Bachelor Degree: Faculty of Medicine. The First Medical College.Guangzhou, P.R.China.

Experience:

- Associate Professor and Physician in Charge: 1994, 4 to present: Head, Molecular Oncology Section, working on phage display antibody and possible applications in gene therapy. , Medical Center, Liu Hua Qiao General Hospital. Guangzhou, China

- Research Visiting Fellow: 1994,8 to present: Development of RD-PCR: A novel method of displaying the differentially expressed mRNAs.Laboratory of Molecular Pharmacology, DTP/ NCI/ NIH. Bethesda, MD. USA.

-Research Visiting Fellow: 1991,8-1993,8: Characterization of a newly cloned differentiation related gene: RA538, which derived from subtraction libraries. National Laboratory of Molecular Oncology, Chinese Academy of Medical Sciences. Beijing, China.

- Investigator and Physician in Oncology: 1988,8-1991,8: 1). PCR related studies for clinical diagnosis and prognosis of cancer patient. 2). Internship. 3) Cloning and constructing expression vectors of IL-2 related genes. 4). Plan, design and construct the Lab of Molecular Medicine, Medical Center, Liu Hua Qiao General Hospital, Guangzhou, China.

- Research Assistant and Ph.D. Candidate: 1988,7-1991,6: Cloning and characterization of a putative metastatic gene from a pulmonary giant cell carcinoma cell line PG. Dept of Cancer Biology, Institute of Basic Medical Sciences, Beijing Medical University. Dissertation: Chromosomal in situ hybridization to localize a cancer metastatic relevant gene pLC-2.

- Teaching Assistant and M.S. Candidate: 1985,7-1988,7: Dept of Pathology. Began research and training in tissue culture, histochemistry and immunochemistry, optical and electron microscopic techniques. M.S. thesis: Structural patterns of the intermediate filaments organization and their implication to oncogenesis.

Memberships:

American Association for Advancements of Sciences (AAAS)
New York Academy of Sciences
Chinese Association of Cell and Molecular Biology
Chinese Association of Genetics
Chinese Association of Medicine

Awards and Fellowships:

-Visiting Fellowship Award: To the National Laboratory of Molecular Oncology, CAMS, Beijing, China, from the Chinese Department of Science and Technology

-Fogarty International Visiting Fellowship: To the Laboratory of Molecular Pharmacology, National Cancer Institute, NIH, from the Fogarty International Center, NIH, USA.

Publications: (As the first Author)

1. Preliminary chromosome localization of a metastatic relevant gene isolated from a highly metastatic pulmonary giant cell carcinoma cell line. Chinese J of Pathology. 19: 246 -249, 1990

2. Probe amplification system: a new technique for non-isotopic hybridization studies Proceedings of Natural Sciences. 2:378-379,1992.

3. Chromosomal aberration detected by chromosome painting in an esophageal carcinoma cell line EC8712. Chinese J of Med Genetics. 19:210-212,1993.

4. Fluorescent in situ hybridization: Theory and technology. Chinese Medical Journal 66:12-19,1994.

5 A novel model for the working mechanism of biological cells. Science and Technological Review. 69:3, 1994.

6. Cytolinguistics: The informatics of inner biological cells. Science and Technology Review. 74:3, 1995.

7. The origin and functional mechanism of Jing-Luo. Science and Technology Review. 75.3, 1995.

8. Gene therapy through digestive tract: The elucidation of the mechanism of the traditional Chinese medicine. Science and Technology Review. 78:8,1995

9. Biological Virus and computer virus. Science And Technology Review. 80:3,1995.

10. Dream and thinking mechanism. Science and Technology Review. 84:2, 1995.

11. Genetic immunization through alimentary tract for tumor prevention. (in prep).

12. Restriction display (RD-PCR) of differentially expressed mRNAs (in press).

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: July 27, 1995

TO: Mr. Wenling Zhang

FROM: Medical Director
Occupational Medical Service, DS

SUBJ: P-32 Exposure

I recently learned that your urine sample tested positive for a trace amount of P-32. The results are consistent with an intake which is small in comparison to occupational limits on intake established by the Nuclear Regulatory Commission. Therefore, the intake is not expected to result in any medical effect. Nevertheless, you should be aware of your right to record the findings in your Occupational Medical Service (OMS) clinical record.

If you are interested in reporting the incident please call the clinic on 6-4411 to schedule an appointment. If you have any questions regarding this matter please give me a call on the same number.

James M. Schmitt, M.D., M.S.

EXHIBIT 2

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RSB PROCEDURES: DECLARED PREGNANT WOMEN

New NRC Regulation

The human embryo/fetus may be more sensitive to ionizing radiation than post-natal humans. Therefore, for years, the U.S. Nuclear Regulatory Commission (NRC) has recommended that a special limit (0.5 rem) be applied to the dose an embryo/fetus receives due to occupational exposure of the mother. However, the NRC recently revised this policy so that effective January 1, 1994, the NRC (10 CFR 20.1208) will require licensees to ensure that the dose to an embryo/fetus during the entire pregnancy due to occupational exposure of a "declared pregnant woman" (DPW) does not exceed 0.5 rem. 10 CFR 20.1003 defines a DPW as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The 0.5 rem dose limit (equivalent to 10% of the annual whole body dose limit for occupationally-exposed adults), will apply to the sum of internal and external doses received by the embryo/fetus due to occupational exposure of the mother.

Note that x-ray producing machines and naturally-occurring and accelerator-produced radioactive materials are not subject to regulation by the NRC. However, at NIH, radiation safety rules and policies are applied to all types of ionizing radiation. Thus, the new policy applies to all women whose assigned duties at NIH involve exposure to ionizing radiation.

Declaration Not Required

Although she has the right to declare her pregnancy and thereby initiate enforcement of the 0.5 rem limit to the embryo/fetus, an occupationally-exposed pregnant woman is not required to declare her pregnancy at any time. If the woman chooses not to declare her pregnancy, NIH is not under any obligation to track or limit the dose received by the embryo/fetus due to occupational exposure of the mother. However, the occupational exposure of the woman is subject to the same limit as that imposed on non-pregnant occupationally-exposed workers. Also, the woman would still be required to maintain her dose as low as reasonably achievable.

Declaration of Pregnancy

An occupationally-exposed pregnant woman who does choose to declare her pregnancy may do so at any time during her pregnancy by completing the form, "NIH Radiation Safety Branch Declaration of Pregnancy." Note, however, that it is not appropriate for an occupationally-exposed woman to declare pregnancy until she is actually pregnant, i.e., the 0.5 rem limit does not apply to occupationally-exposed women who are anticipating pregnancy. Medical confirmation of the pregnancy is not required, but is available, if the woman wishes it, through the Occupational Medical Service (6-4411).

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This form may be obtained by calling the Area Health Physicist (HP) at 6-5774 (410-558-8123 at GRC). The form shall be submitted to the Radiation Safety Branch in person or by mailing it to Building 21, Room 134 in an envelope marked "Confidential," or FAXing it to 6-3544. Note, however, that confidentiality cannot be guaranteed if the declaration is FAXed since the FAX machine is in a public area of Building 21 and is used by people other than RSB staff.

When an occupationally-exposed woman declares her pregnancy in this manner, NIH becomes legally obligated to limit her occupational exposure to ionizing radiation such that her embryo/fetus does not receive more than 0.5 rem during the pregnancy. The 0.5 rem limit for the embryo/fetus is not expected to affect the scope of work for the majority of women at NIH. However, those women who have the potential of receiving significant external exposures from penetrating radiation and those who work with volatile radioactive materials, especially radioiodines, may have restrictions placed on their use of ionizing radiation following the declaration. Note that once a pregnancy has been declared, the 0.5 rem standard for protection of the fetus will be applied until RSB is notified that the pregnancy has ended or until ten months past the estimated date of conception.

Initial Meeting With Declared Pregnant Woman

It is imperative that the logging, routing, and scheduling procedures be expedited by the RSB. The Area HP should contact or leave a message for the DPW as soon as possible, within five working days of when the declaration was received by RSB, to schedule an initial meeting with the DPW. The purpose of this meeting will be to assess the exposure potential associated with the DPW's use of ionizing radiation.
All declarations of pregnancy will be considered confidential. However, it will be necessary for the Authorized User (AU) (or the immediate supervisor of the DPW if she does not have an AU) to be aware of the declaration. The DPW has primary responsibility for minimizing her exposure to ionizing radiation during the pregnancy. However, her AU or supervisor will assist her by enforcing the precautions and/or restrictions imposed by RSB on a day-to-day basis. Consequently, the AU or supervisor will be required to attend the initial meeting between the HP and the DPW.

Before the meeting, the HP should collect appropriate data, e.g., external exposure history, bioassay history, record of radioactive materials used, etc. During the meeting, the HP will (1) thoroughly review NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" with the DPW (2) present current risk estimates based on recent scientific studies such as BEIR-V, UNSCEAR-86, etc. (3) discuss the DPW's current and anticipated future use of ionizing radiation, especially penetrating radiation and volatile forms of radioactive material

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(4) inform the DPW of her exposure history (internal and external) (5) determine whether or not the DPW has appropriate dosimetry - if the DPW uses gamma-emitters and wears a single badge at collar level, an additional dosimeter may be necessary to monitor fetal dose (6) establish an appropriate bioassay program (7) establish the necessary precautions and restrictions. The HP should also emphasize the importance of following standard precautions, e.g., frequent hand-washing, prohibition of food and beverages in the lab, frequent contamination monitoring, etc.

Any necessary restrictions on the DPW's use of ionizing radiation are to be documented on the form "Radiation Safety Restrictions for Declared Pregnant Woman." The HP conducting the meeting, the DPW, and the AU or supervisor will be required to sign the form. This will serve as verification that the DPW and her AU or supervisor understand the precautions and restrictions and will abide by them until the pregnancy ends. If it is necessary to place restrictions (other than the standard ones printed on the form) on the DPW's use of ionizing radiation, the concurrence of the NIH Radiation Safety Officer (or Deputy) will also be required. The original of the form will be retained by RSB; copies will be given to the DPW and her AU or supervisor.

Recordkeeping Requirements

Declarations of pregnancy and documentation of meetings between HP's and DPW's will be filed in alphabetical order in File Cabinet #8, which is kept locked when not in use. When a declaration is received, it will be logged and filed by the Computer Assistant, DASS, and a copy will be routed to the appropriate HP. In addition, at the time of her formal declaration of pregnancy, each DPW's RSB ID number and estimated date of conception will be entered into the VAX database by the Computer Assistant, DASS. Records on embryo/fetal dose must be maintained with the DPW's dose records.

A computer program will be used to track the DPW's monthly whole body dosimeter exposures and total the deep-dose equivalent from the month of conception on. The program will also have a feature whereby, if appropriate, additional fetal doses (external and internal) resulting from intakes of radioactive material by the DPW may be added to the external deep-dose equivalent. The fetal dose tracking system will be designed such that if a pre-established trigger level is exceeded (e.g., 0.3 rem) for any DPW at any point in her pregnancy, the HP will be notified by the Assistant Chief, DASS or the Chief, DASS immediately. In such cases, the HP will inform the DPW and her Authorized User or supervisor of additional restrictions, if any, which need to be placed on the DPW's use of ionizing radiation to ensure that the total fetal dose will not exceed 0.5 rem.

Theoretically, it is possible that the dose to the embryo/fetus will already have exceeded the 0.5 rem limit or is within 0.05 rem of this dose at the time of declaration. In this case, the DPW's exposure must be limited such that the embryo/fetus does not receive more than an additional 0.05 rem during the remainder of the pregnancy.

A copy of all bioassay results and the calculated dose(s) to the fetus will be placed in the DPW's folder in File Cabinet #8. The HP will also enter the calculated fetal dose in the VAX database program which tracks the total fetal dose.

Assessing Fetal Dose

The three components of fetal radiation dose which would need to be tracked are: (1) the whole body external radiation dose received by the fetus due to occupational exposure of the DPW (2) the fetal internal dose from an uptake of radioactive material by the DPW which crosses the placental barrier (3) the fetal external dose from an uptake of radioactive material by the DPW.

When assessing fetal dose from external exposure of the DPW, only penetrating radiation to which the DPW is exposed will be considered. As long as the DPW does not anticipate a significant change in her workload during the pregnancy, her whole body exposure history can be used to predict the total deep-dose equivalent she will receive during her pregnancy. This will serve as an estimate of the external dose the fetus will receive from occupational exposure of the DPW. It could also serve as one basis for imposing restrictions, if appropriate, on the DPW's use of ionizing radiation.

To assess fetal dose from the DPW's intake of radioactive material, an appropriate bioassay program will be established for the DPW, based on her anticipated use of radioactive material. In addition, if the DPW becomes contaminated or is involved in a spill of radioactive material, she will be required to have an appropriate bioassay.

Any positive bioassay will immediately be brought to the attention of the HP who in turn will inform the DPW and her Authorized User or supervisor (if appropriate). The HP will advise the DPW or User to prevent further intakes of radioactive material during the pregnancy. The HP will then use the procedures in Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus", to calculate the estimated dose (internal and external) to the fetus from radioactivity in maternal blood.

Conclusion of Dose Evaluation Process

Each month, each Area HP will be given a printout of the DPWs in his/her area and the cumulative embryo/fetal doses associated with those DPWs. For each DPW, a copy of the current cumulative embryo/fetal dose and a current printout of the DPW's exposure history will be added to the DPW's folder in File Cabinet #8. The program will continue to sum the dose equivalents until the RSB has been notified that it is no longer necessary or until 10 months past the estimated date of conception. At that time, the DPW's folder will be moved to the file where Landauer dosimetry reports for the DPW are stored. The dose records contained in the DPW folders shall be retained indefinitely, as with any other radiation dose records.

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DECLARATION OF PREGNANCY

In accordance with Title 10 of the Code of Federal Regulations, Part 20, I hereby declare my pregnancy to the NIH Radiation Safety Branch (RSB). This declaration authorizes RSB to evaluate the dose received by the embryo/fetus from my occupational exposure to ionizing radiation and to assist me in limiting that dose to 0.5 rem (500 mrem). I understand that this limit is intended to provide an extra measure of protection for the embryo/fetus since it may be more sensitive to ionizing radiation than an adult. The 0.5 rem limit will be applied from the estimated date of conception, _____, until the end of the pregnancy. I will comply with any restrictions imposed on my use of ionizing radiation by the RSB in order to meet this limit. If I am not contacted within five work days of when this form should have been received by RSB, I will notify my Area Health Physicist by calling (301) 496-5774.

_____	_____
Name (printed)	Phone Number
_____	_____
Social Security Number	Date of Birth
_____	_____
Work Location	Mailing Address
_____	_____
Signature	Date

Send in envelope marked "Confidential" to: **NIH Radiation Safety Branch Building 21, Room 1:4**

or FAX to: (301) 496-3544 **(confidentiality not guaranteed if FAXed)**

Privacy Act Statement. The information requested on this form is essential for maintenance of records for individuals potentially exposed to ionizing radiation, as required by the Code of Federal Regulations, Title 10, Part 20. Certain information is protected by the Privacy Act of 1974. HHS/NIH/ORS 09-25-0166 documents the system of records in which this information is used. The primary users of this information are the staff of the Radiation Safety Branch, NIH. "Routine Uses" may also include disclosure of some information provided on this form to the U.S. Nuclear Regulatory Commission, or if necessary to defend the Government or an employee of DHHS in a lawsuit.

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PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

AFFIDAVIT OF DEBRA S. KATZ

I Debra S. Katz, do solemnly swear:

1. I am an attorney for petitioners Maryann Wenli Ma and Bill Wenling Zheng. I am submitting this Affidavit in support of Petition Pursuant to 10 CFR § 2.206 to Suspend or Revoke the Materials License of the National Institutes of Health ("NIH"), License No. 19-00296-10, and to Take Other Appropriate Enforcement Action Against NIH.

2. On August 30, 1995, I contacted Dr. Peter White, an Emergency Room Physician employed by Holy Cross Hospital. Dr. White acknowledged that he had been the physician in charge of Dr. Ma's care on the evening of June 29, 1995, through the time of her release from Holy Cross Hospital during the early morning hours on June 30, 1995.

3. Dr. White advised me that after examining Dr. Ma, he ordered that she be given intravenous infusions of fluid to attempt to dilute the contamination of her blood level. He further advised me that he had no expertise in the area of treatment of radiation contamination and relied on the directions given to him by NIH personnel.

4. Dr. White confirmed that Robert Zoon, NIH's Radiation Safety Officer, consulted with him after Dr. Ma arrived at the hospital. He further confirmed that Mr. Zoon directed him to

collect Dr. Ma's urine for a twenty-four hour period, and to collect the total volume excreted.

5. Dr. White also advised me that they sought the assistance of the Radiation Emergency Assistance Center/Training Site ("REACTS") at Oak Ridge, Tennessee, to best determine how to decontaminate Dr. Ma. However, the hospital's telefax machine experienced difficulty receiving information and ORISE's input was not received.

6. Dr. White told me that no efforts were made, other than giving Dr. Ma intravenous infusions of fluid, to remove the ingested activity.

7. Dr. White further told me that Dr. Weinstein also appeared at the hospital to discuss Dr. Ma's treatment. According to Dr. Weinstein, either while at the hospital or by telephone after he left the hospital, Dr. Weinstein instructed him to aliquot only a small part of the samples already taken and to discontinue his efforts to collect all the urine over a 24 hour period. This instruction was in contravention of Mr. Zoon's directions.

8. According to Dr. White, because he was not familiar with the correct protocol, he did not know whose instructions to follow concerning the urine collection. Dr. White told me that he developed a compromise plan for the collection of urine by which he would attempt to save total samples and aliquot other samples.

9. By letter to Dr. Harold E. Varmus, Director of NIH, dated August 18, 1995, Judith Wolfer, my co-counsel in this matter, demanded that NIH transfer to an independent laboratory, TMA/Norcal, a portion of the urine specimens Dr. Ma provided during the period of June 29, 1995, through July 27, 1995. NIH agreed to this request and on August 24, 1995, I witnessed RSB officials transfer eleven samples into containers for transport to TMA/Norcal, in Richmond, California.

10. By letter dated August 25, 1995, to NIH, I requested that NIH pay for 24 hour samples to be independently analyzed due to the serious nature of the exposure and the extenuating physical circumstances of Dr. Ma (that she was four months pregnant at the time of the initial intake.) I further advised NIH that the information analyzed by ORISE was inadequate to have reached a proper, independent determination of Dr. Ma's level of internal contamination, consistent with NUREG/CR-4884 and those of NCRP 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition (1987). NIH denied this request.

11. By letter dated August 28, 1995, I advised Charles W. Hehl, Director, Division of Radiation, Safety and Safeguards, NRC, of my concern that the analysis conducted by NIH was inadequate to reach a scientifically valid verification.

12. By memorandum dated August 29, 1995, NIH transmitted its final assessment of Dr. Ma's intake to the NRC. It concluded that Dr. Ma's individual effective dose equivalent was 4.17 rem

and that the fetus' dose equivalent was 3.2 rem. NIH assigned Dr. Ma an intake of 500 μCi.

13. By letter dated August 30, 1995, Mr. Hehl informed me that "NRC has confidence in NIH's ability to analyze these samples accurately."

14. Because of concerns about NIH's failure to calculate accurately Dr. Ma's dose, we retained the services of Dr. David Dooley, a certified Health Physicist with expertise in internal dose assessment. At Dr. Dooley's direction, TMA/Norcal Laboratory in Richmond, California, conducted radioanalysis of excreta samples collected from Dr. Ma during the period of June 29, 1995 through August 23, 1995.

I hereby certify this 7th day of October, 1995, under penalty of perjury, and pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Debra Katz
DEBRA S. KATZ

HOLY CROSS HOSPITAL 1500 Forest Glen Rd. Silver Spring, Maryland 20910 Phone: (301) 905-122

N/ C

PATIENT ACCOUNT NUMBER	BIRTHDATE	AGE	SEX	MS	DATE AND TIME REGISTERED	ARRIVAL MODE AND TIME	MEDICAL REC. NUMBER
[redacted]	[redacted]		F 3	M	06/29/95 08:37pm	MONT/P	[redacted]

PATIENT'S NAME (Last, First, Middle, Title): ZHENG, WENLI MA
PRIVATE PHYSICIAN:

CHIEF COMPLAINT: EXPOSURE INT RADIATION/4WKS PREG
E.D. PHYSICIAN: ER, PHYSICIAN 11
☐ OLD CHART ☐ OA ☐ EKG

LAST TETANUS: | TRIAGE CODE: 2 | WEIGHT: | LMP: | CALL PMD OR ☐ DR. | TIMES CALLED:

TRIAGE NOTES TIME: ALLERGIES: NKDA

TIME	BP	P	R	T
8:20	122/63	80	18	98.0

PHYSICIAN'S ORDERS

TIME	ORDERS	RESULTS
		pH 6-7 ⊖ dip urine dip neg all else

PAST HISTORY:

CURRENT MEDICATIONS ☐ NONE

NURSING NOTES: TIME TO TREATMENT AREA:

Seen

MEDICATION AND TREATMENTS

MEDICATION AND TREATMENTS	TIME	INIT.
LR 250cc/hr x 2 L #20 AG ⊖ FA	9:20	B

977.8
E858.8
F819.7
V22.2

SIGNATURES: ☐ CONTINUATION NOTES
INITIALS: C. Bruce CB; K Ballen

HISTORY AND PHYSICAL FINDINGS:
TIME:

NIH: Dr. Zoon / Radiation safety 942-748; 496-4006 Dr. Stansbury / Occupational 496-4411; Ob: Tseng: 301-216-9447

2040

Exposure in NIH lab to P32 (pt works c̄ P32 nucleic acid precursors for PCR) pt thinks she got ingestion from food which she bought in cafeteria @ NIH — thinks it happened yesterday. Discovered radioactive although NIH determined pt has no external risk.
pt is ~ 1 mos pregnant.
Pt states Ⓡ flank pain last night. No N/V. No fever. No urine / bowel c/o.
NIH feels P32 is being incorporated but apparently has ↑ urine counts. Quantitation is still to be done by NIH.

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Ⓔ lungs clear bil s̄ r/r/w. No CVA tenderness. Abd ABS s̄ m/T/HSM — uterus ~ 18 wk. good pulses / no edema.

Request from Dr. Zoon — aliquots — (total volume / time collection) — wants 24 hour urine collection

CONTINUATION SHEET

FINAL IMPRESSION: Radioactive Isotope Ingestion. PMD

☐ WHEN CONTINUED MEDICAL CARE IS NEEDED, CALL DR.
☐ WE RECOMMEND YOU CALL AND VISIT THIS PHYSICIAN AS SOON AS POSSIBLE IF YOU HAVE A PROBLEM.
☐ WE RECOMMEND YOU CALL THIS DOCTOR TO SET UP AN APPOINTMENT WITHIN 1-2 DAYS.
☐ PATIENT INSTRUCTIONS: FOLLOW Maintain good hydration. F/U Dr.'s Zoon / Webster / Tseng (Ob) INSTRUCTION SHEET(S)

HOME ☒ ADMIT ☐ AMA ☐ TRANSF. ☐ DOA ☐ ED DE ☐
CONDITION ON DISCHARGE: GOOD ☐ FAIR ☒ SERIOUS ☐ CRITICAL ☐
☐ COPY OF CHART GIVEN TO PATIENT UNLESS CHECKED.

EMERGENCY ROOM PHYSICIAN: N/A | CODE | PRIVATE PHYSICIAN | DISCH. NURSE | I UNDERSTAND THE ABOVE INSTRUCTIONS. | ADMITTED Rm. NO. | DISCH. OR ADMIT

0305

PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

DECLARATION OF DAVID ARTHUR DOOLEY, PH.D.

I David A. Dooley, Ph.D., do solemnly swear:

1. I am a Senior Radiological Consultant and Certified Health Physicist. I have specialized expertise in internal dose assessment. I have been President of M.J.W. Corporation Inc. since 1990, which provides radiological and health physics services to the private and public sector. My background and qualifications are set out fully in my curriculum vita, which is attached and incorporated herein as Exhibit 1.

2. I was retained by counsel for Dr. Maryann Ma to assess the internal dose to Dr. Maryann Wenli Ma and her fetus resulting from the ingestion of phosphorous-32 on or about June 28, 1995. My findings are set out in detail in a report I and my staff prepared entitled Preliminary Report on the Dose to Maryann Wenli Ma Due to the Ingestion of Phosphorous-32. This report is attached and incorporated herein as Exhibit 2.

3. At my direction, counsel for petitioners arranged to have radioanalysis of excreta samples that were collected from Dr. Ma during the period of June 29, 1995 through August 23, 1995, analyzed by TMA/Norcal Laboratory in Richmond, California. Eleven of those samples were originally collected by the Radiation Safety Branch ("RSB") of NIH and/or Holy Cross Hospital.

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4. TMA/Norcal Laboratory is considered one of the best radioanalytical laboratories in the world. The lab is a qualified bioassay laboratory practicing to the standard of care established in the draft ANSI N13.30 standard. ANSI N13.30 establishes performance criteria for the conduct of in-vitro and in-vivo radiobioassay analysis. Although it has been a draft standard since 1989, it has been accepted by the internal dosimetry community as a guideline document prescribing the minimum standard of care in the performance of such analyses.[1] NIH does not adhere to this standard. Further, TMA/Norcal Laboratory operates under an acceptable quality assurance program.

5. Using the ICRP 30 model for inorganic phosphorous ingestion, I concluded that the analytic results measured by TMA/Norcal established a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This preliminary intake estimate corresponds to a Committed Effective Dose Equivalent (CEDE) of 9.2 rem. This dose is more than double what NIH calculated for this incident, and is more than 4.2 rem in excess of federal regulatory limits for annual intake by a non-pregnant woman. See 10 CFR § 20.1201(a)(1)(I) (an annual limit which is the total effective dose equivalent being equal to 5 rems). It is more than 8.7 rem in excess of (or 18 times higher

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[1] This is the only instance where an "N" series ANSI standard has been published for use as a draft.

than) federal regulatory limits for the annual intake of a declared pregnant woman.

6. I further concluded that Dr. Ma's fetus received a dose of between 3 rem and 6.4 rem, which is 6 to 12 times greater than the federal regulatory limit for a fetus. This estimate may not take into account the very real possibility that the phosphorous is capable of crossing the placental barrier. Clearly, if a radionuclide is transplacental, the fetus is at risk of receiving significantly more exposure than the dose delivered to the mother's uterus.

7. I have reviewed the analysis of Dr. Ma's dose prepared by NIH and TMA/Norcal. For the reasons discussed in my Preliminary Report and as described below, it is my expert opinion that these analyses significantly underestimate Dr. Ma's exposure.

8. Following the detection of Dr. Ma's contamination, RSB took and received from Holy Cross Hospital a total of twenty-five samples, spanning the period of June 29, 1995 through July 27, 1995. At the NRC's request, NIH sent the Oak Ridge Institute for Science and Education ("ORISE") four of the first fifteen specimens taken on June 29 and 30, 1995, for the purported purpose of confirming the isotopic analyses performed by the RSB. ORISE was also asked to confirm the isotopic analyses performed by the RSB with respect to three urine samples and one blood sample. The majority of the samples analyzed were not collected over a full 24 hour period.

9. By letter dated July 5, 1995, ORISE estimated Dr. Ma's intake at 265 μCi. Like NIH, ORISE failed to base its analysis on the actual volume Dr. Ma excreted over time, which is critical for model interpretation.

10. By Memorandum from S. Googins to R. Zoon (Aug. 29, 1995), NIH set out its "final assessment" of Dr. Ma's intake. It concluded that Dr. Ma's individual effective dose equivalent was 4.17 rem and that the fetus' dose equivalent was 3.2 rem. NIH assigned Dr. Ma an intake of 500 μCi.

11. It is my expert opinion that NIH failed to take sufficient samples from Dr. Ma to accurately calculate her dose. First, immediately following detection of Dr. Ma's contamination, NIH should have taken a full 24 hour sample and continued such sample collection in a consistent and routine basis until such time that sufficient data was gathered to accurately access her dose. It failed to do so. Second, NIH should have continued sample collection and analysis until the activity level of the samples no longer yielded useful results. Without such samples, there is no way that the analytical results can be accurately related to the predictive model which is based on this critical compartment sampling to derive the dose. NIH should also have taken fecal samples. Since the model predicts that 20% of the activity of an internal intake of P-32 should be in fecal matter, and since hydration therapy was used which had a profound effect on the urinary excretion volume, collection of fecal samples were imperative to observe the overall (i.e., 100% of) excretion

pattern and to look at the entire P-32 output from all compartments. This is especially critical since the fecal component would not suffer the dilution effects seen in the urine due to the hydration therapy. Further, the fecal P-32 content would have either benchmarked or thrown the urine results into question based upon the results. Regardless, this lack of proper sample collection by NIH casts significant suspicion on all samples and their subsequent analyses.

12. As indicated in my report, the medical intervention provided by NIH appeared to be ineffective. It also appears from the medical records and other NIH documents that the sole efforts made were to administer a large volume of fluid in an attempt to accelerate the elimination of the radioactive phosphorous from Dr. Ma. However, analysis of subsequent urinary collection reflects that such attempts were unsuccessful. There was no discernable enhancement of phosphorus-32 elimination.

13. Accordingly, it is my expert opinion that a statement reported in The Washington Post that "hydration therapy significantly reduced the [radioactive] activity in the urine" is both false and misleading. I have also read statements issued by NIH suggesting that Dr. Ma's contamination will not have any long-term medical effects for her or her fetus. It is my expert opinion that this statement cannot be substantiated. The NRC specifically recognizes the serious risks to the fetus of exposure in excess of 0.5 rem especially for dose received in the first and early second trimesters. Moreover, Dr. Ma and her

fetus will suffer an increased risk of cancer. The increase in risk will be commensurate with the doses calculated for Dr. Ma and her fetus once all bioassay data has been analyzed. Based on the present analysis, Dr. Ma's lifetime excess cancer risk has increased by approximately 30% to 83% for a committed effective dose equivalent of 9.2 rem. The fetal risk is much more uncertain. Based on NCRP report number 115, which states the risk of excess cancer deaths in the first 10 years of life following in utero x-ray exposure is in the range of 2 to 2.5 x 10^{-4} per rem, the excess cancer risk for a fetal dose of 3 to 6.4 rem is 6 x 10^{-4} to 1.6 x 10^{-3}. However, given that the fetal dose is due to an internal exposure of P-32 and that the critical organ for leukemia, i.e. the red bone marrow, is the major target organ for P-32 dose, the excess cancer risk, especially for the development of leukemia, may be an order of magnitude higher than that predicted from in utero x-ray exposure.

David Arthur Dooley, Ph.D.

Subscribed and sworn to before me,
this 9th day of October, 1995.

LESLIE J. MUNDY, REG. 01MU5046127
NOTARY PUBLIC, STATE OF NEW YORK
QUALIFIED IN ERIE COUNTY
MY COMMISSION EXPIRES 07/03/97

Notary Public

My commission expires 07/03/97

EXHIBIT 5
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DAVID ARTHUR DOOLEY

Senior Radiological Consultant/Certified Health Physicist
M.J.W. Corporation Inc.

EXPERIENCE

EXHIBIT 1

M.J.W. CORPORATION INC., 1990 - Present
President

As one of the principals of a privately held corporation, main duties include performing radiological work for the private sector as well as government clients over a broad spectrum of disciplines which include radiological remediation activities, operational health physics, remedial investigations, risk assessment, regulatory compliance, permitting and licensing work, reactor decommissioning, power plant radiation protection and preparation of procedures and manuals required to support all of the above areas. Experience has been divided into the following seven categories.

Decontamination and Decommissioning

- For the Atlantic Richfield Corporation (ARCO), provide radiological consulting support for all aspects of remediation actions for a 10 CFR 20.304 low-level radioactive waste burial facility. Major activities include interaction and response to regulators (federal and state) and review of all documentation to support remediation activities under NRC guidelines for the Site Decommissioning Management Program (SDMP). Job initiated in 1992 and scheduled for completion in 1996.

- Provided complete radiological services including RSO and technical support for a Superfund project (under EPA consent order) in Chicago, Illinois dealing with thorium contamination under a downtown parking lot. Responsibilities included preparation of work plan, health and safety plan, quality assurance plan and procedures, radiation protection procedures, performing overland gamma surveys and radiological support for subsurface sampling and cone penetrometer tests of boreholes. Additional scope will include preparation of remedial options and costs, remedial plan and performance of remedial activities. Job initiated mid-1994 and to be completed in mid 1995.

- Project manager for a major decontamination effort removing Americium-241 from a contaminated sanitary sewer system including interconnecting manholes located in the Town of Tonawanda, New York. M.J.W. designed, built and operated the pipe cleaning apparatus used in decontaminating the 2,200 feet of line and the radiological survey robot used for post decontamination surveys. (1991)

- For the Research Foundation of the State University of New York at Buffalo, prepared a report which evaluated a wide range of management alternatives for the University's 2 MW research reactor ranging from various modes of continued operation to complete facility decommissioning. (1993-1994)

Low-Level Radioactive Waste/Environmental Restoration

- Analysis of regulatory compliance issues associated with DOE environmental restoration (EM-40) activities for Argonne National Laboratory. Task also includes compilation and interpretation of environmental restoration contaminant/waste information. (1994-1996)

- Prepared portions of the Occupational Radiation Protection Sections including dose estimates for facility operation for the Chem-Nuclear Systems, Inc. license application to the Illinois Department of Nuclear Safety for a Low-Level Radioactive Waste Disposal Facility. (1990)

- Over the last four years, provided expert radiological services to a New Jersey law firm representing a company where significant quantities of radioactive material have been discovered on the property from the operations of a previous owner. Positions developed for regulatory requirements (federal and state) and for proposed and actual D&D activities. (1990-1994)

- For Martin Marietta Energy Systems, participated in a corporate environmental audit of the ORNL (X-10) facility at Oak Ridge. Specific area of responsibility for the audit was the site radioactive waste operations. (1992)

Radiation Protection Program Services

- Scientific Ecology Group (SEG, Inc.) personnel performed dismantlement and packaging of warm cell facilities (located at BMRC, Buffalo, New York) used for testing of irradiated metal test specimens under MJW's NYSDOL radioactive materials license, with MJW having Radiation Safety Officer responsibilities for the work. (1994)

- From 5/94 until 11/94 provided health physics management and radiation protection ALARA specialist services to a local Buffalo general contractor (Danforth, Inc.) for modification of existing plant facilities to support storage and retrieval of vitrified high-level waste at the DOE's West Valley Demonstration Project.

- Revised the Corporate Radiation Safety Manual for Hoffmann-LaRoche, Inc. to bring it into line with the requirements of the new NRC regulations effective January 1994.

- Project manager for work involving creation of new and upgrade of existing West Valley Demonstration Project radiological procedures to address changes and requirements of the DOE Radiological Control Manual (DOE/EH-0256T) issued June of 1992.

- Provided health physics consulting services to Buffalo Materials Research, Inc. for replacement of reactor pool liner for a 2 megawatt research and test reactor located in Buffalo, New York. (1992-1993)

- Project manager for an internal dosimetry evaluation project performed at the West Valley Demonstration Project for West Valley Nuclear Services, Co., a wholly-owned subsidiary of Westinghouse Electric Corporation. Several hundred evaluations were performed for a wide range of isotopes including uranium and plutonium using the commercially available dose assessment programs REMedy and INDOSE. (1991)

- Provided health physics consulting services for a wide variety of projects to Materials Engineering Associates, Inc., the parent company of Buffalo Materials Research. (1991-1992)

Reactor REMP Programs

- For Nuclear Energy Consultants (NEC, Inc.) performed a comprehensive audit of the Davis-Besse Nuclear Power Stations' Radiological Environmental Monitoring Program including review of the Off-site Dose Calculation Manual (ODCM) and all implementing procedures. Major focus was placed on performance of Land Use Survey and supporting calculations for ODCM requirements and how they interface into the site annual radiological reports. (1994)

- Provide continuing radiation consulting services to Cintichem, Inc. management to support the Enhanced Environmental Sampling Program and continuing general radiological issues under the NYSDEC Order on Consent. (1990-1994)

- Prepared report, including extensive statisticel analysis of five years of environmental data to support the Enhanced Environmental Sampling Program at the Cintichem, Inc. facility near Tuxedo, New York. This report will tie into the final D&D criteria for the site reactor decommissioning expected to be complete in the 1994-1995 time frame. (1993-1994)

NORM

- Project manager for preparation, submittal and operation of a New York State Department of Labor Radioactive Materials License involving low-level naturally occurring uranium and thorium materials for a major industrial client, TAM Ceramics, Inc. Since 1990 acted as radiological consultant to and Radiation Safety Officer for zirconia operations.

- Completed a comprehensive review and compilation of Naturally Occurring Radioactive Material (NORM) regulations for the 50 States for a major industrial client. Emphasis was placed on potential waste disposal issues. (1993)

Radiation Protection Program Audits

- Team member of New York State Department of Environmental Conservation-approved 3 member group charged with evaluation of radioactive airborne emissions and performing audit studies of site operations with emphasis on waste disposal for a large radioisotope production facility, Cintichem Inc., located in Sterling Forest, New York. (1991-1992)

- Performed the 1992 annual facility radiological audit for Cintichem, Inc. Audit areas consisted of the existing isotope production and radioactive waste handling facility as well as the reactor decontamination and decommissioning work and related waste processing operations.

- Performed a Due Diligence Audit to assist a large foreign corporation in the purchase of a small radioactive waste operation located and operated in Canada. (1993)

- Performed 1993 Annual Facility Safety Appraisal for the West Valley Demonstration Project. Appraisal covered 10 major areas of concern per DOE Order 5480.5.

- Performed the 1992 Annual Facility Safety Review for the West Valley Demonstration project in accordance with DOE Order 5480.5. The safety review covered eleven areas of concern including modifications having safety significance, procedures, unusual occurrences and the condition of the physical facilities.

- Project manager for an extensive programmatic radiation protection audit of Hoffmann-LaRoche, Inc. corporate headquarters in Nutley, New Jersey. (1992)

- Performed an audit of the radiation protection department ALARA program for the Davis Besse Nuclear Power Station located near Toledo, Ohio. (1992)

Radiation Protection Surveys, Measurements, Shielding Calculations

- Performed shielding calculations for a variety of x-ray and radiation diagnostic facilities to be included in the major facility upgrade for Roswell Park Cancer Institute, Buffalo, New York. Work was performed for NBBJ, the site architect, under NYS Dormitory Authority auspices. (1994)

- Provided the Dames & Moore environmental group at West Valley Demonstration Project with real time radon measurement services to verify data previously obtained on radon concentrations in stack effluents. (1992)

- Provided shielding calculation support to Diversified Technologies, Inc. for a new fuel pool cleanup system at the West Valley Demonstration Project. (1993)

- Provided a comprehensive radiological survey of process equipment suspected to have been used to process uranium at ANZON, Inc., Laredo Texas. (1992)

DAMES & MOORE, 1985 - 1990

Manager, Radiological Services - Buffalo, New York Operation, 1989-1990. As Radiological Services Manager, responsibilities were to market, coordinate, review and approve all radiological work performed by the Buffalo office staff. Efforts included responding to requests for assistance from several other D&M offices and coordinating the work effort from Buffalo or on-site as necessary. Several examples of completed projects are presented below:

- Provided radiological consulting services to Allegheny International, Inc. relating to the clean-up of depleted uranium contamination at a former catalyst manufacturing facility and an uncontrolled industrial waste dump site near Cleveland, OH. Services included review of remedial action contractors performance and site characterization.

- Project manager on several radiological tasks (site characterization, licensing applications for NYSDOL and DEC, radiation protection manual, radiological procedures for all aspects of the project and responsibilities as site RSO) for a confidential client seeking to expand manufacturing operations which would create a need for radiation protection controls in a previously non-regulatory environment.

- For the Sumitomo Machinery Corporation authored a NJDEP-approved sampling plan for property and radiological characterization of confirmed quantities of low-level radioactive contamination. Managed on-site characterization activities, radiological data review, tabulation and the final radiological characterization report.

- Provided input to various confidential clients regarding radiological health and safety plans for site investigations where quantities of radioactive materials were known to have been buried; and provided commentary on various radiological property survey reports for D&M offices located in Cranford, NJ, Pearl River, NY and Liverpool, NY.

- For Argonne National Laboratories (Chicago, Illinois), prepared a document which summarized and compared DOE, EPA and the State of Missouri requirements for occupational and public radiation exposures (ARARs).

- For the West Valley Nuclear Services Company, Inc., served as project manager for preparation of a major revision to the site Radiological Controls Manual and the initial site version of the site Internal Dosimetry Manual. This work was performed to meet the requirements of DOE Order 5480.11.

- For the Westinghouse Electric Corporation, Waste Isolation Division, performed tasks related to upgrading the dosimetry processing system at the Waste Isolation Pilot Project, located in Carlsbad, New Mexico, to prepare system for DOE accreditation program (DOELAP).

- For Argonne National Laboratories (Chicago, Illinois), worked as a part of the Dames & Moore team to provide technical guidance to DOE regarding site cleanup (ALARA) criteria for the Weldon Spring Remedial Action Project located near St. Louis, Missouri.

- For the Johnson and Johnson Company, supervised land survey and completed the radiological survey report for a property acquisition which was located near an active NRC licensed reactor facility in California.

- For the U.S. Realty Company (owned by Ford Motor Company), managed the radiological assessment and completed the radiological survey report for a property acquisition located near an active landfill containing known uranium residues from past DOE activities in St. Louis, MO.

- Prepared a radiological pathway analysis for the Sarasota County Water Improvement Project in Sarasota, FL. Results were presented to the County Commissioners, staff and the general public which showed no adverse impact of the proposed ocean outfall for the project's effluent.

- Provided management and technical oversite of several tasks associated with the Illinois Low Level Waste Project including site meteorology, occupational exposures during operation and various aspects of site Safety Analysis and licensing preparation.

- Project Manager, for a confidential client, provided a survey of electric and magnetic fields surrounding an industrial food processing operation. The survey was undertaken at the request of the client to assess radio- frequency (RF) radiation field intensities relative to federal standards and guidelines.

- Participated in the Waste Isolation Pilot Project (WIPP) Pre-Operational Readiness Review Program as a member of the Westinghouse corporate review team. The team provided review of DOE Technical Safety Appraisal areas for both non-nuclear and nuclear-related facilities.

Radiological Engineering Manager - WVDP (1987-1989). Areas of management responsibility included: Safety Engineering, which encompassed occupational safety, industrial hygiene, and fire protection; Plant Dosimetry Program; Plant ALARA Program; Radiation Instrumentation Program; Respiratory Protection Program; Radiation Technician Training Program; Criticality/Shielding Engineering; procedural reviews for all programs; and interface with Radiological Control Supervisors concerning radiological work activities.

Major Accomplishments Include:

- Completed wholesale revision of the WVNS Radiation Protection Manual to conform to DOE Order 5480.11.
- Completed initial draft of WVNS Internal Dosimetry Manual to conform with DOE Order 5480.11 and PNL Internal Dosimetry Good Practices Manual.
- Served as chairman for two WVNS operational readiness review boards for initial startup of vitrification system cold chemical addition and mini-melter operations.

Senior Environmental Scientist, Dames & Moore, (1985-1987). Prepared safety, environmental, accident and shielding analyses reports for West Valley Demonstration Project (WVDP) activities. Provided technical expertise to the firm's environmental monitoring group responsible for all aspects of environmental and meteorological assessment for the WVDP. Prepared environmental evaluations for operation of the WVDP's subsystems for the waste vitrification efforts. Provided technical assistance for the site emergency plan and had responsibility for all environmental dose assessment computer codes. Other areas of responsibility included review, and assessment of impacts of promulgated DOE orders for radiological control, safety analysis performance, radioactive waste management, and several related topics.

Other Experience:

- Radiological Engineer - New York Power Authority (1983-1985), at the James A. Fitzpatrick Nuclear Power Plant, served as radiological engineer supervising both the plant dosimetry and ALARA programs (~14 nonoutage staff and 30 for refueling outages). During tenure, plant dosimetry system was accredited under the NVLAP program, and INPO awarded a "good practice" citation for ALARA program content and practices.

- Radiological Engineer - New York Power Authority Corporate Office (1982), performed radiation protection activities for two nuclear plants including ALARA, training, environmental monitoring, plant effluents and radioactive waste management. Major activities supported the radioactive waste programs at each plant, established plant Radioactive Waste Process Control Programs (PCPs), implemented 10 CFR 61, and planned for long-term radwaste storage and processing.

- Senior Radiological Specialist - (1978-1979) New York State Department of Health (NYSDOH), Buffalo Regional Office, inspected state and privately owned dental, medical, podiatric, hospital, veterinary and chiropractic facilities possessing ionizing radiation equipment for compliance with Chapter I, Part 16 of the New York State Sanitary Code. Key areas of concern were reducing patient exposure, instructing operators in proper methods of radiation safety, and insuring that the X-ray facility was properly shielded to protect the operators and the general public.

- Performed radiological surveys and soil sampling for suspected radiological contamination at the Love Canal area (Niagara Falls, NY) for the New York State Department of Health. Assisted DOE/Oak Ridge personnel in extensive sampling of areas found to be above area background levels.

- As on-site Radiation Safety Officer for NYSDOH during the remedial construction operations at Love Canal, created and implemented routine and emergency radiological health and safety plans.

- Post-Doctoral Fellow - (1980-1982) University of Rochester, Radiation Biology and Biophysics Department. Research included biological effects of electric fields and ultrasound on various plant and animal systems. Work resulted in five published articles.

- Graduate Consultant - (1978) to Nuclear Research Development Corporation, Grand Island, N.Y. Completed a report on the radiological consequences of human ingestion of americium-241 coated gold foils produced by the NRD Corporation for use in domestic fire alarm systems. Report submitted to the NRC.

- Reactor Operator - (1976-1978) Nuclear Science and Technology Facility (SUNY at Buffalo). Licensed by the NRC to operate the 2 megawatt pool-type research reactor.

- Graduate Teaching Assistant - (1974-1978) Taught graduate courses at SUNY at Buffalo, in radiation science, radiation biology, isotope tracer techniques, and basic biology. General topics included theoretical and practical aspects of radiation detection, safe handling and disposal of radioisotopes, surveys, shielding design, calibration of a 250-kVcp therapy X-ray unit and an 18,000-curie cobalt-60 irradiator, and neutron activation analysis at the campus reactor facility.

EDUCATION

Ph.D. (1981), Radiation Biology, State University of New York at Buffalo
M.S. (1977), Interdisciplinary Natural Sciences, Roswell Park Memorial Institute (SUNY at Buffalo)
B.S. (1974), Biology, State University of New York at Buffalo
B.A. (1974), Portuguese, Special Majors Program, State University of New York, Buffalo

ABHP CONTINUING EDUCATION AND PROFESSIONAL ENRICHMENT COURSES ATTENDED

Year	Course Title	CECs
1994	Radiation Protection Standards	16
	Design and Conduct of Bioassay Programs	4
	Low-Level Radioactive Waste Management; Post, Present and Future	4
	Operational Quality Assurance for Radioassay Laboratories	4
1993	Fundamentals of Industrial Hygiene	16
	Implementation of the Revised 10 CFR Part 20	4
1992	Naturally Occurring Radioactive Material: Regulation, Disposal and Health Physics	16
	Everything But the Counting Statistics: Measurement Errors and Pitfalls in Radiological Measurements	4
	Atmospheric Transport	4
	Space Radiation Monitoring: Concerns for Space Station Freedom and the Space Exploration Initiative (SEI)	4
	The Application and Testing of Environmental Models for Radiological Assessments	4
	Regulatory Guide 8.25, "Air Sampling in the Workplace"	4
1990	Transportation Regulatory Update	4
	Decommissioning and Exemptions from Regulatory Control - Status and Implementation of Current NRC Policy Statement and Guidance	4
1989	Fundamentals and Application of ICRP-26 and ICRP-30	1
	Fundamentals of Lasers and Their Safe Use	1

ABHP CONTINUING EDUCATION COURSES (Continued)

Year	Course Title	CECs
1987	Practical Aspects of Calibration Procedures for Airborne Radioactivity Monitors	1
	Interpretation of Bioassay Measurements	1
	A Review of Basic and Current Transportation Regulations	1
	Properties of the Electromagnetic Cascade: A Tutorial Utilizing High Resolution 3D Graphics	1
1986	Radon Measurement Methods	1
	A Monte Carlo Primer for HPs	1
	Health Physics Measurement Quality Assurance	1
	What Every HP Should Know About Radiation and Pregnancy	1
	Radiation Dosimetry and Protection in Diagnostic Radiology	1

PROFESSIONAL AFFILIATIONS

Plenary Member, Health Physics Society;
Associate Member, Radiation Research Society;
Associate Member, Sigma Xi Scientific Research Society;
Member, Western and Greater New York Health Physics Society Chapters;
Member, Health Physics Society Power Reactor Section;
Member, Health Physics Society Environmental Section;
President Western New York Chapter HPS (1988).

REGISTRATIONS

Certified Health Physicist: American Board of Health Physics, 1985, Recertified 1989, 1993;
Certified Radiation Equipment Safety Officer, New York, 1977;
National Registry of Radiation Protection Technologists, 1984.

PUBLICATIONS

Greenburg, G. and D. A. Dooley, (1976) Americium Foil Integrity Tests, performed under contract for the Nuclear Radiation Development Corporation, Grand Island, New York, for submission to the Nuclear Regulatory Commission.

Dooley, D. A., Roswell Park Memorial Institute - SUNYAB, (1975) "The Effects of Temperature on the Rate of Decomposition of Technetium-99m Stannous Ethane-1-Hydroxy-1, 1-Dipbosphonate (Osteoscan®)" (Master's Project, D. M. Blau, Advisor).

Dooley, D. A. and A. K. Bruce, SUNYAB, (1978) "Response of Respiratory Components in X-irradiated Micrococcus radiodurans." (Presented at the 26th Annual Meeting of the Radiation Research Society, Toronto, Canada, May 10-14, 1978). Abstract appears in Radiation Research, 74:575.

Ph.D. Thesis: "Response of Respiratory Components in X-irradiated Micrococcus radiodurans," Ph.D. Dissertation advisor: Dr. Alan K. Bruce, Department of Environmental and Organismal Biology, SUNYAB, Amherst, New York (716) 636-2718.

Dooley, D. A. and A. K. Bruce, SUNYAB, (1980) "Iron Metabolism in X-irradiated Micrococcus radiodurans." (Presented at the 28th Annual Meeting of the Radiation Research Society, New Orleans, LA, June 1-5, 1980). Abstract appears in Radiation Research 83:384.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1981) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." J. Acoust. Soc. Am. Supplement 1, Vol 69, 1981.

Dooley, D. A., P. G. Sacks, M. W. Miller, E. L., Carstensen and S. Lam, (1981) "Yields of Focused Ultrasound-induced Chromosomal Anomalies in Plant Root Meristem Cells." Submitted to Ultrasound Med. Biol.

Dooley, D. A., S. Z. Child, E. L. Carstensen and M. W. Miller, (1983) "The Effects of Continuous Wave and Pulsed Ultrasound on Rat Thymocytes In Vitro." Ultrasound Med. Biol. 9, 379-384.

Robertson, D., D. A. Dooley, P. Economou and M. W. Miller, (1981) "Analysis of Some Growth Parameters of Pea Roots Exposed in 60 Hz Electric Fields." Submitted to Environmental and Experimental Botany.

Dooley, D. A., "Effects of Ultrasound on DNA." Molecular Genetics, Chromosomes and Cells, Seminar Series, November 14, 1980, University of Rochester, New York.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1981) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." Radiation Research 87:473. Abstract only.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1984) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." Radiation Research 97: 71-86.

Miller, M. W., D. A. Dooley, C. Cox and E. L. Carstensen, (1983) "On the Mechanism of 60 Hz Electric Field Induced Effects in Pisum sativum L Roots: Vertical Field Exposures." Radiation Environmental Biophysics, 22:293-302.

Brulfert, A., M. W. Miller, D. Robertson, D. A. Dooley and P. Economou, "A Cytohistological Analysis of Roots Whose Growth Is Affected by a 60-Hz Electric Field," Bioelectromagnetics, Vol. 6, 283-291, 1985.

Dooley, D. A. and P. Burn, (1985) "Environmental Evaluation for the Liquid Waste Treatment System," WVDP-049.

Dooley, D. A. and P. Burn (1985) "West Valley Demonstration Project Safety Analysis Report, Volume IV, Liquid Waste Treatment System."

Englert, J. P. and D. A. Dooley, (1985), "Safety Analysis for Transfer and Storage of Boxed Vessels and Jumpers Removed from the Chemical Process Cell, Revision 4.

Dooley, D. A., R. R. Blickwedehl and R. A. Bell, (1986) "Safety Analysis for Low-Level Class A Radioactive Waste Handling and Disposal Operations."

Dooley, D. A., R. R. Blickwedehl and R. A. Bell, (1986) "Safety Analysis for Low-Level Class B and Class C Radioactive Waste Handling and Disposal Operations for the Radwaste Treatment Drum Cell.

Peterson, J. M., D. A. Dooley and P. M. Petrone, (1986) "Safety Analysis for the Cement Solidification System, Revision 1.

Dooley, D. A., (1987) "Environmental Evaluation for Extended Storage of Class A Radioactive Waste," WVDP-066.

Slawson, J., L. Henry and D. A. Dooley, "A Comparison of Past and Present Operational Health Physics Challenges Presented by Repair Outages at a University Research Reactor," presented at the 36th Annual Meeting of the Health Physics Society, July 24, 1991.

Scalsky, E. D. and D. A. Dooley, "Audit Studies Report," prepared for Cintichem, Inc. for submission to New York State Department of Environmental Conservation, September 1991.

Dooley, D. A. and E. D. Scalsky, "Airborne Emission Evaluation," prepared for Cintichem, Inc. for submission to New York State Department of Environmental Conservation, September 1991.

Dooley, D. A. and J. V. Wierowski, "Final Report for the Town of Tonawanda Project 1918: Decontamination of Sewerlines and Manholes," dated April 22, 1992.

Dooley, D. A. and J. V. Wierowski, "Final Report for the Preparation, Packaging and Shipment of Low-Level Radioactive Wastes Generated by Project 1918 and Previous Tonawanda Wastewater Treatment Plant Decontamination Activities, dated April 30, 1992.

Dooley, D. A., NORM Regulations Report, for TAM Ceramics, Inc., dated December 6, 1993.

PRESENTATIONS

Miller, M. W., E. L. Carstensen, D. Robertson, D. A. Dooley and A. Brayman. 60 Hertz Electric Field Parameters Associated with the Perturbation of a Eukaryotic Cell System. Department of Energy Annual Contractors Review, November 15-17, 1982, Denver, CO.

Dooley, D. A., "Development of an ALARA Program at a BWR," paper presented at the Brookhaven Laboratory-sponsored ALARA Symposium, February 1984.

Dooley, D. A., Determination of Site Specific Ingestion Pathways and Dosimetric Consequences for the West Valley Demonstration Project, Presented to the Western New York Chapter of the Health Physics Society, January 9, 1987.

Dooley, D. A., Evaluation of In Vitro Analytic Results at the West Valley Demonstration Project with Respect to DOE Order 5480.11 Compliance, Presented at the 34th Annual HPS Meeting, Albuquerque, New Mexico, June 1989.

Dooley, D. A., J. C. Cwynar, C. W. McVay and C. J. Roberts, "Comparison of Off-Site Radiation Dose Predictions at West Valley Based Upon Assumed and Measured Performance of the New Liquid Waste Treatment System, Presented by C. J. Roberts, at the 34th Annual HPS Meeting, Albuquerque, New Mexico, June 1989.

Dooley, D. A., Radiological Pathway Analysis for a Proposed Coastal Water Effluent from a Central Florida Water Improvement Project, Presented to the Western New York HPS, March 23, 1990.

Dooley, D. A., Decontamination of an Am-241 Contaminated Municipal Service Line, presented at the Health Physics Society Mid-year Meeting, Albany, New York, February 15, 1994.

10/94

EXHIBIT 5
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JAMES P. GRIFFIN, CHP

Senior Health Physicist
MJW Corporation Inc.

EXPERIENCE

MJW Corporation Inc., 1995 - Present

Senior Health Physicist

As Senior Health Physicist of a privately held radiological consulting corporation, main duties include the evaluation of dose resulting from the intake of radioactive material. Included is the identification of acceptable in vivo and in vitro radiobioassay facilities, development of appropriate bioassay programs, evaluation of bioassay data, intake projection, and dose assessment. Other duties include providing radiological expertise to a variety of private, industrial and government clients.

West Valley Nuclear Services Inc., 1990 - 1995

Senior Health Physicist

- Employed by West Valley Nuclear Services as the Senior Health Physicist in the West Valley Demonstration Project (WVDP) Dosimetry Program. The internal dosimetry duties of this position included development and oversight of the in vivo and in vitro bioassay programs, performance of internal dose assessment, records management and dose reporting. Accomplishments in this area included, creation of the WVDP Internal Dosimetry Technical Basis Document, revision of the WVDP Internal Dosimetry Program Manual and development/implementation of the current in vivo and in vitro program.

- The WVDP utilizes contracted laboratories for the analysis of in vitro bioassay samples. Administering this program I was required to develop the technical requirements for these contracts of perform all phases of the competency evaluation process. This included conducting 18 technical capability audits and technical assessment surveys of vendor laboratories.

- Served as Technical Lead for the West Valley Demonstration Project Dosimetry Program. Responsibilities were expanded to include oversight of the External Dosimetry Program and operation of the Panasonic Thermoluminescent Dosimetry System. Major Accomplishments included revision of the External Dosimetry Technical Basis Document and Quality Assurance Plans. Further accomplishments included successful reaccreditation of the external dosimetry program under the Dept. of Energy Laboratory Accreditation Program (DOELAP).

University of Buffalo - Nuclear Science and Technology Facility, 1982 - 1990

Senior Health Physicist

- Served eight years as the Senior Health Physicist for the Nuclear Science and Technology Facility at the University of Buffalo. In this capacity I was responsible for all aspects of the health physics program for a 2 MW materials testing reactor. This included the development and administration of the dosimetry program and operation of the radioanalytical laboratory.

Harbor/UCLA Medical Center, 1980 - 1982

Radiation Safety Consultant

- Served as the Radiation Safety Consultant for the Harbor/UCLA Medical Center in Torrance, California. Responsibilities of this position included all aspects of the Health Physics program supporting a large clinical and medical research facility. Accomplishments included development and administration of both the external and internal dosimetry programs.

EDUCATION

B.A., Radiation Biology, State University of New York at Buffalo, Buffalo New York
Graduate Studies, Physical Sciences, Saint Bonaventure University, Olean, NY

CONTINUING EDUCATION IN INTERNAL AND EXTERNAL DOSIMETRY

Internal Dose Assessment by Dr. John Poston; May 1991 A one week graduate level course in the performance of internal dose assessment

Workshop on Code for Internal Dosimetry by Dr. Darrell Fisher; March 1992 A one week technical work shop, conducted by the authors of the code, on the use of the Code for Internal Dosimetry (CINDY).

Participated in the Following Technical Conferences:

- 38th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- 39th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- 40th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- U.S. Department of Energy Intercalibration Committee; Lung Counting Workshops at Lawrence Livermore Laboratory
- 35th Annual Meeting of the Health Physics Society
- 36th Annual Meeting of the Health Physics Society
- 37th Annual Meeting of the Health Physics Society
- USDOE 3rd Annual Conference on Bioassay and Radiochemistry

PROFESSIONAL AFFILIATIONS

HPS/ANSI N13.39 Working Group, Member of the committee charged with the development of the ANSI Standard for Internal Dosimetry Programs. The intent of this standard is to define the elements required for an internal dosimetry program and to general program guidance supporting the other ANSI standards relating to internal dosimetry.

U.S. Department of Energy, DOELAP Assessor; Selected to serve as one of 12 individuals to perform on-site assessments supporting the internal dosimetry U. S. Department of Energy Laboratory Accreditation Program.

The New York and New Jersey Hazardous Material Worker Training Center; Advisory Board Member,

American Health Physic Society; Plenary Member

American Academy of Health Physics; Member

American Nuclear Society; Member

Western New York Region, Health Physics Society; Member

REGISTRATIONS

Certified Health Physicist: Certified by the American Board of Health Physics in the comprehensive practice of Health Physics, 1992

ASME NQA-1 Lead Auditor: Qualified Lead Auditor having performed over 15 validation audits and capability assessments of radiobioassay laboratories, 1991, Requalified 1995;

USDOE Certified Accident Investigator: Certified as a trained accident investigator and qualified to chair an accident investigation board, 1991, Recertified 1994;

10/95

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Preliminary Report on the Dose to Dr. Maryann Wenli Ma

Due to the Ingestion of Phosphorus-32

Prepared for the Law Firms of

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and

Bernabei & Katz

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by the

MJW Corporation Inc.

338 Harris Hill Road, Suite 208
Williamsville, New York 14221

October 8, 1995

EXHIBIT 2

EXHIBIT 5
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DISCLAIMER

This report is only preliminary in nature and represents the analysis of the bioassay dated from bioassay (urine and fecal) samples collected since the time of the incident in late June of 1995 through August 1995. Additional samples are currently being collected and analyzed until such time that they no longer yield useful data. At such time, MJW will issue a final report which accounts for all outstanding data.

Preliminary Report on the Dose to Dr. Maryann Wenli Ma
Due to the Ingestion of Phosphorus-32

1.0 PURPOSE

This report contains the preliminary assessment of the internal dose to Dr. Maryann Wenli Ma resulting from the ingestion of phosphorus-32 on or about June 28, 1995. At the time of the intake Dr. Ma was approximately 17 weeks pregnant. Additionally, a preliminary estimate and a discussion of the involved fetal dose is presented.

2.0 SCOPE

The preliminary intake projections and associated dose assessments in this report are based on excreta samples collected between June 29, 1995 and August 23, 1995. All data utilized results from radioanalysis performed by TMA/Norcal Laboratory, Richmond, California. Further excreta is being collected and analyzed. Sample collection and analysis will continue until the activity level of the samples no longer yields useful results. A final report and dose prediction will be completed upon the receipt and evaluation of that data.

3.0 INTAKE PROJECTION AND DOSE ESTIMATE

This intake projection is based on a radiological evaluation of excreta collected during the time period from June 29, 1995 through August 23, 1995. Upon review of documents collected and National Institute of Health radiological records (Reference 1), this intake is assumed to be an oral ingestion of inorganic phosphorus-32 occurring on June 28, 1995. Since the precise time of intake is unknown, a time of 12:00 is assumed. The ICRP 30 Model (Reference 2) for inorganic phosphorus ingestion was used for this intake projection. The computer models CINDY (Code for INternal DosimetrY; Battelle Memorial Institute) and INDOSE (Skrable Enterprises, INC.) were utilized in the evaluation of this exposure. Data evaluated included the analytical results of 14 urine and 3 fecal samples. All analyses utilized in this internal dose assessment were performed at TMA/NORCAL in Richmond, California. (Excreta sample analysis is further discussed in Section 6.0 of this report.) All data resulting from the analysis of urine collected on June 29 and 30, has been excluded from this evaluation for the reasons outlined in Section 5.0 of this report. Excreta samples continue to be collected and analyzed. A final dose assessment report will be issued when the results of these analyses have been received and evaluated. Evaluation of the analytical results received to date establish a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This preliminary intake estimate corresponds to a Committed Effective Dose Equivalent (CEDE) of 9.2 rem. The associated fetal dose is projected and discussed in Section 4.0 of this report.

4.0 FETAL DOSE ESTIMATE

The published guidance concerning the determination of fetal dose is contained in the U.S.N.R.C. Regulatory Guide 8.36, "Radiation dose to the embryo/fetus" July, 1992. This document acknowledges that the calculation of prenatal exposure for internal radionuclides presents many difficulties such as the lack of quantitative data concerning prenatal nuclide concentrations and mobility of various material across the placental barrier. This Regulatory Guide establishes fetal dose per μCi of maternal intake. These values were based on the assumption that the dose to the fetus is equal to the dose to the mother's uterus. This assumes no radioactive material crosses the placenta, or incorporates in the soft and skeletal tissues of the fetus. There is currently insufficient data to determine the degree that inorganic phosphorus is capable of crossing the placental barrier. Clearly, if a radionuclide is transplacental, the fetus is at risk of receiving significantly more exposure than that dose delivered to the mother's uterus.

Regulatory Guide 8.36 (Reference 3) establishes the estimation of fetal dose as 3.03E-3 rem/μCi of maternal intake. However, not clearly explained in Reference 1, the NIH fetal dose assessment appears to apply a fetal dose factor of 6.40E-3 rem/μCi of maternal intake, based on personal communication concerning a draft NUREG document. Using the value of 6.40E-03 rem/μCi the revised fetal dose based on the preliminary maternal intake estimate of 1000 μCi is 6.4 rem. The dose is 3 rem when based on the original Reg. Guide value. The lack of biokinetic data pertaining to phosphorus in the expectant mother however, results in a high degree of uncertainty in fetal dose projections.

It should be noted for comparison that the recommendations of the International Commission on Radiation Protection (ICRP) and NCRP which have been adopted in federal regulations by the NRC and DOE establish a fetal exposure limit of 0.5 rem over the entire gestation period which establishes a definable margin of safety with regard to fetal development. The estimated fetal dose in this case is a factor of 6 to 12 above this recommended limit and may likely be higher based on whether P-32 has the ability to cross the placental barrier. In addition, the level of fetal development at the time of the ingestion may also render the fetal dose estimate unreliably low.

5.0 INADEQUACY OF NIH CALCULATION OF INTERNAL DOSE

The National Institute of Health internal dose evaluation reported an effective dose equivalent of 4.17 rem (Reference 1). This is substantially less than the dose projection presented in this report of 9.2 rem. The issues discussed in the remainder of this section serve to explain this discrepancy.

5.1 Use of Early Bioassay Data

The dose estimate performed by the NIH included data obtained from the radioanalysis of urine excreted during the two days immediately following the intake. These data points were excluded from consideration for the purpose of this dose evaluation. The results from the analysis of these samples were considered unreliable for the following reasons:

- The urine samples collected during the first two days following the intake were collected as spot samples. Rather than collecting the entire urinary excretion compartment over a 24 hour period, a series of samples were collected at each voiding. This sampling program did not ensure collection of the entire integral excretion over the required 24 hour period. As a result, the value of this early data is significantly diminished.

- Review of the associated documentation indicate that large volumes of fluid were administered in an attempt to hasten elimination of the radioactive phosphorus. The apparent impact of this treatment is evaluated in Section 7.0 of this report. However, it must be noted that this greatly increased the urinary output during this time period. When a true 24 hour urine collection is not obtained, correction for the concentration measurement is required to account for this dilution. It appears that NIH did not properly perform this correction based on our review of Reference 1. This correction could have been accomplished through the measurement of specific gravity (S.G.) of the sample and comparing that to the average S.G. of urine which is 1.024 g/ml. Another method of correction involves the ratio of expected creatinine content verses the measured creatinine content in the urine (Reference 4). Since neither measurement was performed, the relationship between the measured radioactive concentration of these samples can not be related to the total 24 hour excretion.

- Generally, data from excreta collected close in time to the intake is of less value for the determination of internal dose (Reference 4). In part, this is due to the greater variability of the rate of excretion of radioactive material over the collection period of the sample. In other words, the difference in excretion rate from the beginning to the end of a 24 hour sample collected the day following an intake is much greater than that occurring during a 24 hour collection 30 days post intake. This increase in excretion variation substantially increases the error associated with the internal dose evaluation.

5.2 Duration of Excreta Sample Collection

The dose estimate in this report is based on the analysis of excretion collected over a significantly longer period of time than was the dose evaluation conducted by the NIH. This

allows for a more accurate determination of the actual excretion pattern occurring. The NIH dose evaluation was based solely on samples collected during the first month following the intake. However, urinary excretion patterns appear to deviate significantly from the norm and the NIH sampling program failed to compensate for this deviation in that complete 24 hour urine samples were not collected. Therefore, this represents a large potential for error to be introduced into the dose assessment. The preliminary dose evaluation in this report is based on the analysis of samples collected over a period from July 1 to August 23, 1995. The reason this estimate is still considered preliminary is that in vitro bioassay sampling should continue until no further useful information can be obtained from additional sampling. Sampling and analysis are continuing in this case and a final dose assessment will be performed upon the evaluation of pending analytical data.

5.3 Use of Fecal Analysis

The dose estimate performed by the NIH relied entirely on analysis of urine samples and was not confirmed through the analysis of fecal samples. The ICRP 30 model for inorganic phosphorus excretion predicts that 20% of ingested phosphorus will be excreted through the feces. The dose evaluation presented in this report used fecal samples collected over a three day period to confirm the intake assessment. A close agreement was observed with the urine data indicating a 1,100 μCi intake and the fecal data indicating a 1,000 μCi intake. NIH's failure to collect fecal samples precluded their identifying the discrepancy in dose estimation.

5.4 Mathematical Modeling of the Data

The NIH dose assessment evaluated the data using two mathematical models, the unweighted least squares fit (ULSF) method as outlined in NUREG/CR-4884 (Reference 5) and the weighted least squares fit (WLSF) method identified by Skrable et. al. (Reference 6). The later represents the method used by NIH to assign their final dose in this case. The weighted least squares fit method provides a simple methodology in which the sum of the measurements is equal to the sum of the expectation values. Although this method is acceptable when the actual excretion closely follows the anticipated model it can lead to a gross underestimation of the true error when the actual excretion varies from the model prediction (Reference 7). NIH did not use the most appropriate mathematical fit for the data.

The dose assessment presented in this report evaluated three mathematical models relative to the fit of the data, the Ratio of the Means (ROM), the Average of the Slopes (AOS) and the Un-weighted Least Squares Fit (ULSF). A determination of the mathematical fit of each data point was conducted for each of the three methods. This was accomplished by dividing the measured values by the value predicted by the model evaluated. The closer the result is to 1.0, the better the model fits the data. This method identified that the average of the slopes as the mathematical model that most closely fits the measured values. The average results for the ROM, AOS and ULSF methods were 1.56, 1.00, and 2.10, respectively. This data

is graphically represented in Attachment A.

6.0 EFFECTIVENESS OF MEDICAL INTERVENTION

From the review of Reference 1 and several news articles (References 9-11), it is understood that medical intervention was attempted following the detection of this intake.[1] It also is believed that these attempts were limited to the administration of large volumes of fluid in an attempt to accelerate the elimination of the radioactive phosphorus from Dr. Ma. Subsequent urinary collection reflects such attempts in that extraordinarily large renal output was observed over the days subsequent to the intake. The best evaluation of these dilute samples indicates that no discernable enhancement of phosphorus-32 elimination was evident. It is apparent from the urine data that the hydration therapy did not serve to accelerate the removal of P-32 from Dr. Ma's body. Therefore, this technique was ineffective in reducing the dose from the intake.

The National Council on Radiation Protection and Measurements (NCRP) Report 65 (Reference 12) details a case history of an accidental over administration of phosphorus-32 in which treatment was not begun until the 9th day following the incident. Intervention included large doses of phosphate by mouth daily as the buffered sodium salt, calcium given intravenously daily and 200 units of parathyroid extract I.M. every 6 hours. This treatment was continued over an 18 day period, and though started late, accomplished an estimated 38% reduction of radiation dose to the bone marrow. NCRP Report 65 (Reference 12) also presents recommendations for treatment of non-radioactive phosphorus ingestion to be considered in the treatment of accidental phosphorus-32 ingestion. Treatments recommended include gastric lavage with potassium permanganate or 3% hydrogen peroxide, Copper sulfate in a glass of water, or Mineral Oil to hasten elimination. Aluminum hydroxide gel or aluminum phosphate gel are also recommended to help prevent G.I. absorption.

As stated above, it does not appear from the data nor does the written record suggest that any of the above interventions were employed in the case of Dr. Ma's ingestion other than the forcing of fluids.

7.0 RADIOANALYSIS OF EXCRETA DATA

All data used for dosimetric evaluation in this report resulted from analyses performed at TMA/NORCAL in Richmond, California. This included eleven urine samples which were collected by the NIH and selected for reanalysis. This reanalysis was deemed necessary since evidence was not provided by NIH demonstrating that the original analyses had been

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[1] That Dr. Ma received hydration therapy can only be deduced from Reference 1 in that daily urinary output exceeded the typical value by more than a factor of six over an 8 hour sample period.

conducted by a qualified bioassay laboratory practicing to the standard of care as established in draft ANSI N13.30 Standard (Reference 7) and operating under an acceptable quality assurance program. The absence of such assurances raised concerns as to the ability to validate the NIH bioassay analyses at a future date. The following lists some of the essential program elements that a laboratory must implement to ensure that data generated is accurate and defensible:

- Analyses must be performed in accordance with approved written procedures specific to the radioisotope and matrix of interest (i.e. P-32 in a urine matrix). Additionally, these procedures must be controlled documents.

- Procedures must allow for the separation of the analyte of interest from any interfering nuclide. (e.g., K-40 would interfere with the direct measurement of P-32 in urine.)

- Training must be conducted and documented for all technicians performing each phase of each analysis. This training must include initial qualification and annual requalification.

- All devices used to measure and weigh samples and reagents must be currently calibrated in the range in which they are used.

- All reagents utilized must be verified as acceptable under the quality program prior to use. Reagents must also be labeled with the appropriate expiration date.

- When appropriate, tracers must be used to accurately determine chemical yields.

- Adequate quality control samples must be analyzed with each set of samples to demonstrate the ANSI N13.30 performance requirements for precision have been met for that analysis.

- Adequate quality control samples must be analyzed with each set of samples to demonstrate the ANSI N13.30 performance requirements for bias have been met for that analysis.

- A program for the analysis of blind spikes, splits, and blanks must be implemented to ensure the quality of analytical results.

- All standards and standard solutions used must be directly traceable to the N.I.S.T. or an equivalent standards authority.

- Counting instruments utilized for the analysis of radiobioassay samples must be

calibrated for the analyte of interest in the geometry of interest.

- o Instrument operability must be verified prior to the conduct of radiobioassay analyses e.g., daily operability tests are performed and documented. Results of these verifications should be analyzed for the presence of any trends.

- o Documentation verifying and validating all computer codes and software used must be maintained.

The above programmatic items must be in place to ensure that any degradation in bioassay laboratory performance is recognized by the laboratory before adversely affected data would be reported. To date we have not been presented with evidence to confirm that any or all of the above controls were in place at NIH at the time of the sample analysis.

8.0 CONCLUSIONS

- The preliminary report from the MJW Corporation Inc. indicates that Dr. Ma's initial intake of phosphorous-32 was 1,000 μCi (microcuries), which results in a dose of 9.2 rem. This intake is almost two times the recommended annual limit on intake (ALI) for phosphorous-32 of 600 μCi for a non-pregnant occupationally exposed woman, and over 16 times the recommended gestational ALI of 60 μCi (0.5 rem) for an occupationally exposed pregnant woman.

- The dose to Dr. Ma's fetus is estimated at 6.4 rem, or a factor of 12 above the Nuclear Regulatory Commission's established fetal exposure limit of 0.5 rem for the entire gestation period.

- The medical intervention recommended by National Institutes of Health officials for Dr. Ma following discovery of her contamination appears to have had no effect in decreasing her internal phosphorous-32 contamination in any way.

- In July of 1995, NIH reported that it had calculated Dr. Ma's phosphorous-32 intake to be 200 to 300 μCi. In August of 1995, NIH changed that assessment to 500-600 μCi.

REFERENCES

1. Letter to Robert A. Zoon, RSO NIH, from Shawn W. Googins, Deputy RSO, NIH, dated 8/29/95; "Intake Estimate and Fetal dose Equivalent".

2. ICRP Publication 30, Limits for the Intake of Radionuclides by Workers, Annals of the ICRP 2 (3/4) 1979, et. seq., Pergamon Press.

3. U.S. Nuclear Regulatory Commission, Radiation Dose to the Embryo/Fetus, Regulatory Guide 8.36, July 1992.

4. National Council on Radiation Protection and Measurements, Report No. 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, 1987.

5. NUREG/CR-4884, 1987, Interpretation of Bioassay Measurements, Lessard E.T., et. al., Brookhaven National Laboratory, Upton, New York.

6. Skrable, K. W., et. al., Use of Multicompartment Models of Retention for Internally Deposited Radionuclides, in "Internal Radiation Dosimetry," Otto G. Rabe, ed., Health Physics Society Summer School, 1994.

7. Personal Communication with Dr. Ken Skrable, Skrable Enterprises, Inc., October 4, 1995.

8. American National Standards Institute, ANSI N13.30 (Draft), 1989, Performance Criteria for Radiobioassay.

9. The Washington Post, 26 at NIH Exposed to Radiation, p B1, July 18, 1995.

10. The Almanac, Radioactivity Found in NIH Water Cooler, p 6, July 19, 1995.

11. The Washington Gazette, NRC Boosts level of consumed toxins at NIH, p A-9, August 9, 1995.

12. (National Council on Radiation Protection and Measurements Report No. 65 "Management of Persons Accidentally Contaminated with Radionuclides" Section 6.10.)

PETITION PURSUANT TO 10 CFR § 2.206 TO SUSPEND OR REVOKE THE MATERIALS LICENSE OF THE NATIONAL INSTITUTES OF HEALTH (NIH), LICENSE NO. 19-00296-10, AND TO TAKE OTHER APPROPRIATE ENFORCEMENT ACTION AGAINST NIH

DECLARATION OF DAVID ARTHUR DOOLEY, PH.D.

I David A. Dooley, Ph.D., do solemnly swear:

1. I am a Senior Radiological Consultant and Certified Health Physicist. I have specialized expertise in internal dose assessment. I have been President of M.J.W. Corporation Inc. since 1990, which provides radiological and health physics services to the private and public sector. My background and qualifications are set out fully in my curriculum vita, which is attached and incorporated herein as Exhibit 1.

2. I was retained by counsel for Dr. Maryann Ma to assess the internal dose to Dr. Maryann Wenli Ma and her fetus resulting from the ingestion of phosphorous-32 on or about June 28, 1995. My findings are set out in detail in a report I and my staff prepared entitled Preliminary Report on the Dose to Maryann Wenli Ma Due to the Ingestion of Phosphorous-32. This report is attached and incorporated herein as Exhibit 2.

3. At my direction, counsel for petitioners arranged to have radioanalysis of excreta samples that were collected from Dr. Ma during the period of June 29, 1995 through August 23, 1995, analyzed by TMA/Norcal Laboratory in Richmond, California. Eleven of those samples were originally collected by the Radiation Safety Branch ("RSB") of NIH and/or Holy Cross Hospital.

4. TMA/Norcal Laboratory is considered one of the best radioanalytical laboratories in the world. The lab is a qualified bioassay laboratory practicing to the standard of care established in the draft ANSI N13.30 standard. ANSI N13.30 establishes performance criteria for the conduct of in-vitro and in-vivo radiobioassay analysis. Although it has been a draft standard since 1989, it has been accepted by the internal dosimetry community as a guideline document prescribing the minimum standard of care in the performance of such analyses.[1] NIH does not adhere to this standard. Further, TMA/Norcal Laboratory operates under an acceptable quality assurance program.

5. Using the ICRP 30 model for inorganic phosphorous ingestion, I concluded that the analytic results measured by TMA/Norcal established a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This preliminary intake estimate corresponds to a Committed Effective Dose Equivalent (CEDE) of 9.2 rem. This dose is more than double what NIH calculated for this incident, and is more than 4.2 rem in excess of federal regulatory limits for annual intake by a non-pregnant woman. See 10 CFR § 20.1201(a)(1)(I) (an annual limit which is the total effective dose equivalent being equal to 5 rems). It is more than 8.7 rem in excess of (or 18 times higher

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[1] This is the only instance where an "N" series ANSI standard has been published for use as a draft.

than) federal regulatory limits for the annual intake of a declared pregnant woman.

6. I further concluded that Dr. Ma's fetus received a dose of between 3 rem and 6.4 rem, which is 6 to 12 times greater than the federal regulatory limit for a fetus. This estimate may not take into account the very real possibility that the phosphorous is capable of crossing the placental barrier. Clearly, if a radionuclide is transplacental, the fetus is at risk of receiving significantly more exposure than the dose delivered to the mother's uterus.

7. I have reviewed the analysis of Dr. Ma's dose prepared by NIH and TMA/Norcal. For the reasons discussed in my Preliminary Report and as described below, it is my expert opinion that these analyses significantly underestimate Dr. Ma's exposure.

8. Following the detection of Dr. Ma's contamination, RSB took and received from Holy Cross Hospital a total of twenty-five samples, spanning the period of June 29, 1995 through July 27, 1995. At the NRC's request, NIH sent the Oak Ridge Institute for Science and Education ("ORISE") four of the first fifteen specimens taken on June 29 and 30, 1995, for the purported purpose of confirming the isotopic analyses performed by the RSB. ORISE was also asked to confirm the isotopic analyses performed by the RSB with respect to three urine samples and one blood sample. The majority of the samples analyzed were not collected over a full 24 hour period.

9. By letter dated July 5, 1995, ORISE estimated Dr. Ma's intake at 265 μCi. Like NIH, ORISE failed to base its analysis on the actual volume Dr. Ma excreted over time, which is critical for model interpretation.

10. By Memorandum from S. Googins to R. Zoon (Aug. 29, 1995), NIH set out its "final assessment" of Dr. Ma's intake. It concluded that Dr. Ma's individual effective dose equivalent was 4.17 rem and that the fetus' dose equivalent was 3.2 rem. NIH assigned Dr. Ma an intake of 500 μCi.

11. It is my expert opinion that NIH failed to take sufficient samples from Dr. Ma to accurately calculate her dose. First, immediately following detection of Dr. Ma's contamination, NIH should have taken a full 24 hour sample and continued such sample collection in a consistent and routine basis until such time that sufficient data was gathered to accurately access her dose. It failed to do so. Second, NIH should have continued sample collection and analysis until the activity level of the samples no longer yielded useful results. Without such samples, there is no way that the analytical results can be accurately related to the predictive model which is based on this critical compartment sampling to derive the dose. NIH should also have taken fecal samples. Since the model predicts that 20% of the activity of an internal intake of P-32 should be in fecal matter, and since hydration therapy was used which had a profound effect on the urinary excretion volume, collection of fecal samples were imperative to observe the overall (i.e., 100% of) excretion

pattern and to look at the entire P-32 output from all compartments. This is especially critical since the fecal component would not suffer the dilution effects seen in the urine due to the hydration therapy. Further, the fecal P-32 content would have either benchmarked or thrown the urine results into question based upon the results. Regardless, this lack of proper sample collection by NIH casts significant suspicion on all samples and their subsequent analyses.

12. As indicated in my report, the medical intervention provided by NIH appeared to be ineffective. It also appears from the medical records and other NIH documents that the sole efforts made were to administer a large volume of fluid in an attempt to accelerate the elimination of the radioactive phosphorous from Dr. Ma. However, analysis of subsequent urinary collection reflects that such attempts were unsuccessful. There was no discernable enhancement of phosphorus-32 elimination.

13. Accordingly, it is my expert opinion that a statement reported in The Washington Post that "hydration therapy significantly reduced the [radioactive] activity in the urine" is both false and misleading. I have also read statements issued by NIH suggesting that Dr. Ma's contamination will not have any long-term medical effects for her or her fetus. It is my expert opinion that this statement cannot be substantiated. The NRC specifically recognizes the serious risks to the fetus of exposure in excess of 0.5 rem especially for dose received in the first and early second trimesters. Moreover, Dr. Ma and her

fetus will suffer an increased risk of cancer. The increase in risk will be commensurate with the doses calculated for Dr, Ma and her fetus once all bioassay data has been analyzed. Based on the present analysis, Dr. Ma's lifetime excess cancer risk has increased by approximately 30% to 83% for a committed effective dose equivalent of 9.2 rem. The fetal risk is much more uncertain. Based on NCRP report number 115, which states the risk of excess cancer deaths in the first 10 years of life following in utero x-ray exposure is in the range of 2 to 2.5 x 10^{-4} per rem, the excess cancer risk for a fetal dose of 3 to 6.4 rem is 6 x 10^{-4} to 1.6 x 10^{-3}. However, given that the fetal dose is due to an internal exposure of P-32 and that the critical organ for leukemia, i.e. the red bone marrow, is the major target organ for P-32 dose, the excess cancer risk, especially for the development of leukemia, may be an order of magnitude higher than that predicted from in utero x-ray exposure.

David Arthur Dooley, Ph.D.

Subscribed and sworn to before me,
this 9th day of October, 1995.

LESLIE J. MUNDY, REG. 01MU5046127
NOTARY PUBLIC, STATE OF NEW YORK
QUALIFIED IN ERIE COUNTY
MY COMMISSION EXPIRES 07/03/97

Notary Public

My commission expires 07/03/97

DAVID ARTHUR DOOLEY

Senior Radiological Consultant/Certified Health Physicist
M.J.W. Corporation Inc.

EXPERIENCE

EXHIBIT 1

M.J.W. CORPORATION INC., 1990 - Present
President

As one of the principals of a privately held corporation, main duties include performing radiological work for the private sector as well as government clients over a broad spectrum of disciplines which include radiological remediation activities, operational health physics, remedial investigations, risk assessment, regulatory compliance, permitting and licensing work, reactor decommissioning, power plant radiation protection and preparation of procedures and manuals required to support all of the above areas. Experience has been divided into the following seven categories.

Decontamination and Decommissioning

- For the Atlantic Richfield Corporation (ARCO), provide radiological consulting support for all aspects of remediation actions for a 10 CFR 20.304 low-level radioactive waste burial facility. Major activities include interaction and response to regulators (federal and state) and review of all documentation to support remediation activities under NRC guidelines for the Site Decommissioning Management Program (SDMP). Job initiated in 1992 and scheduled for completion in 1996.

- Provided complete radiological services including RSO and technical support for a Superfund project (under EPA consent order) in Chicago, Illinois dealing with thorium contamination under a downtown parking lot. Responsibilities included preparation of work plan, health and safety plan, quality assurance plan and procedures, radiation protection procedures, performing overland gamma surveys and radiological support for subsurface sampling and cone penetrometer tests of boreholes. Additional scope will include preparation of remedial options and costs, remedial plan and performance of remedial activities. Job initiated mid-1994 and to be completed in mid 1995.

- Project manager for a major decontamination effort removing Americium-241 from a contaminated sanitary sewer system including interconnecting manholes located in the Town of Tonawanda, New York. M.J.W. designed, built and operated the pipe cleaning apparatus used in decontaminating the 2,200 feet of line and the radiological survey robot used for post decontamination surveys. (1991)

- For the Research Foundation of the State University of New York at Buffalo, prepared a report which evaluated a wide range of management alternatives for the University's 2 MW research reactor ranging from various modes of continued operation to complete facility decommissioning. (1993-1994)

Low-Level Radioactive Waste/Environmental Restoration

- Analysis of regulatory compliance issues associated with DOE environmental restoration (EM-40) activities for Argonne National Laboratory. Task also includes compilation and interpretation of environmental restoration contaminant/waste information. (1994-1996)

- Prepared portions of the Occupational Radiation Protection Sections including dose estimates for facility operation for the Chem-Nuclear Systems, Inc. license application to the Illinois Department of Nuclear Safety for a Low-Level Radioactive Waste Disposal Facility. (1990)

- Over the last four years, provided expert radiological services to a New Jersey law firm representing a company where significant quantities of radioactive material have been discovered on the property from the operations of a previous owner. Positions developed for regulatory requirements (federal and state) and for proposed and actual D&D activities. (1990-1994)

- For Martin Marietta Energy Systems, participated in a corporate environmental audit of the ORNL (X-10) facility at Oak Ridge. Specific area of responsibility for the audit was the site radioactive waste operations. (1992)

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Radiation Protection Program Services

- Scientific Ecology Group (SEG, Inc.) personnel performed dismantlement and packaging of warm cell facilities (located at BMRC, Buffalo, New York) used for testing of irradiated metal test specimens under MJW's NYSDOL radioactive materials license, with MJW having Radiation Safety Officer responsibilities for the work. (1994)

- From 5/94 until 11/94 provided health physics management and radiation protection ALARA specialist services to a local Buffalo general contractor (Danforth, Inc.) for modification of existing plant facilities to support storage and retrieval of vitrified high-level waste at the DOE's West Valley Demonstration Project.

- Revised the Corporate Radiation Safety Manual for Hoffmann-LaRoche, Inc. to bring it into line with the requirements of the new NRC regulations effective January 1994.

- Project manager for work involving creation of new and upgrade of existing West Valley Demonstration Project radiological procedures to address changes and requirements of the DOE Radiological Control Manual (DOE/EH-0256T) issued June of 1992.

- Provided health physics consulting services to Buffalo Materials Research, Inc. for replacement of reactor pool liner for a 2 megawatt research and test reactor located in Buffalo, New York. (1992-1993)

- Project manager for an internal dosimetry evaluation project performed at the West Valley Demonstration Project for West Valley Nuclear Services, Co., a wholly-owned subsidiary of Westinghouse Electric Corporation. Several hundred evaluations were performed for a wide range of isotopes including uranium and plutonium using the commercially available dose assessment programs REMedy and INDOSE. (1991)

- Provided health physics consulting services for a wide variety of projects to Materials Engineering Associates, Inc., the parent company of Buffalo Materials Research. (1991-1992)

Reactor REMP Programs

- For Nuclear Energy Consultants (NEC, Inc.) performed a comprehensive audit of the Davis-Besse Nuclear Power Stations' Radiological Environmental Monitoring Program including review of the Off-site Dose Calculation Manual (ODCM) and all implementing procedures. Major focus was placed on performance of Land Use Survey and supporting calculations for ODCM requirements and how they interface into the site annual radiological reports. (1994)

- Provide continuing radiation consulting services to Cintichem, Inc. management to support the Enhanced Environmental Sampling Program and continuing general radiological issues under the NYSDEC Order on Consent. (1990-1994)

- Prepared report, including extensive statistical analysis of five years of environmental data to support the Enhanced Environmental Sampling Program at the Cintichem, Inc. facility near Tuxedo, New York. This report will tie into the final D&D criteria for the site reactor decommissioning expected to be complete in the 1994-1995 time frame. (1993-1994)

NORM

- Project manager for preparation, submittal and operation of a New York State Department of Labor Radioactive Materials License involving low-level naturally occurring uranium and thorium materials for a major industrial client, TAM Ceramics, Inc. Since 1990 acted as radiological consultant to and Radiation Safety Officer for zirconia operations.

- Completed a comprehensive review and compilation of Naturally Occurring Radioactive Material (NORM) regulations for the 50 States for a major industrial client. Emphasis was placed on potential waste disposal issues. (1993)

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Radiation Protection Program Audits

- Team member of New York State Department of Environmental Conservation-approved 3 member group charged with evaluation of radioactive airborne emissions and performing audit studies of site operations with emphasis on waste disposal for a large radioisotope production facility, Cintichem Inc., located in Sterling Forest, New York. (1991-1992)

- Performed the 1992 annual facility radiological audit for Cintichem, Inc. Audit areas consisted of the existing isotope production and radioactive waste handling facility as well as the reactor decontamination and decommissioning work and related waste processing operations.

- Performed a Due Diligence Audit to assist a large foreign corporation in the purchase of a small radioactive waste operation located and operated in Canada. (1993)

- Performed 1993 Annual Facility Safety Appraisal for the West Valley Demonstration Project. Appraisal covered 10 major areas of concern per DOE Order 5480.5.

- Performed the 1992 Annual Facility Safety Review for the West Valley Demonstration project in accordance with DOE Order 5480.5. The safety review covered eleven areas of concern including modifications having safety significance, procedures, unusual occurrences and the condition of the physical facilities.

- Project manager for an extensive programmatic radiation protection audit of Hoffmann-LaRoche, Inc. corporate headquarters in Nutley, New Jersey. (1992)

- Performed an audit of the radiation protection department ALARA program for the Davis Besse Nuclear Power Station located near Toledo, Ohio. (1992)

Radiation Protection Surveys, Measurements, Shielding Calculations

- Performed shielding calculations for a variety of x-ray and radiation diagnostic facilities to be included in the major facility upgrade for Roswell Park Cancer Institute, Buffalo, New York. Work was performed for NBBJ, the site architect, under NYS Dormitory Authority auspices. (1994)

- Provided the Dames & Moore environmental group at West Valley Demonstration Project with real time radon measurement services to verify data previously obtained on radon concentrations in stack effluents. (1992)

- Provided shielding calculation support to Diversified Technologies, Inc. for a new fuel pool cleanup system at the West Valley Demonstration Project. (1993)

- Provided a comprehensive radiological survey of process equipment suspected to have been used to process uranium at ANZON, Inc., Laredo Texas. (1992)

DAMES & MOORE, 1985 - 1990

Manager, Radiological Services - Buffalo, New York Operation, 1989-1990. As Radiological Services Manager, responsibilities were to market, coordinate, review and approve all radiological work performed by the Buffalo office staff. Efforts included responding to requests for assistance from several other D&M offices and coordinating the work effort from Buffalo or on-site as necessary. Several examples of completed projects are presented below:

- Provided radiological consulting services to Allegheny International, Inc. relating to the clean-up of depleted uranium contamination at a former catalyst manufacturing facility and an uncontrolled industrial waste dump site near Cleveland, OH. Services included review of remedial action contractors performance and site characterization.

- Project manager on several radiological tasks (site characterization, licensing applications for NYSDOL and DEC, radiation protection manual, radiological procedures for all aspects of the project and responsibilities as site RSO) for a confidential client seeking to expand manufacturing operations which would create a need for radiation protection controls in a previously non-regulatory environment.

- For the Sumitomo Machinery Corporation authored a NJDEP-approved sampling plan for property and radiological characterization of confirmed quantities of low-level radioactive contamination. Managed on-site characterization activities, radiological data review, tabulation and the final radiological characterization report.

- Provided input to various confidential clients regarding radiological health and safety plans for site investigations where quantities of radioactive materials were known to have been buried; and provided commentary on various radiological property survey reports for D&M offices located in Cranford, NJ, Pearl River, NY and Liverpool, NY.

- For Argonne National Laboratories (Chicago, Illinois), prepared a document which summarized and compared DOE, EPA and the State of Missouri requirements for occupational and public radiation exposures (ARARs).

- For the West Valley Nuclear Services Company, Inc., served as project manager for preparation of a major revision to the site Radiological Controls Manual and the initial site version of the site Internal Dosimetry Manual. This work was performed to meet the requirements of DOE Order 5480.11.

- For the Westinghouse Electric Corporation, Waste Isolation Division, performed tasks related to upgrading the dosimetry processing system at the Waste Isolation Pilot Project, located in Carlsbad, New Mexico, to prepare system for DOE accreditation program (DOELAP).

- For Argonne National Laboratories (Chicago, Illinois), worked as a part of the Dames & Moore team to provide technical guidance to DOE regarding site cleanup (ALARA) criteria for the Weldon Spring Remedial Action Project located near St. Louis, Missouri.

- For the Johnson and Johnson Company, supervised land survey and completed the radiological survey report for a property acquisition which was located near an active NRC licensed reactor facility in California.

- For the U.S. Realty Company (owned by Ford Motor Company), managed the radiological assessment and completed the radiological survey report for a property acquisition located near an active landfill containing known uranium residues from past DOE activities in St. Louis, MO.

- Prepared a radiological pathway analysis for the Sarasota County Water Improvement Project in Sarasota, FL. Results were presented to the County Commissioners, staff and the general public which showed no adverse impact of the proposed ocean outfall for the project's effluent.

- Provided management and technical oversite of several tasks associated with the Illinois Low Level Waste Project including site meteorology, occupational exposures during operation and various aspects of site Safety Analysis and licensing preparation.

- Project Manager, for a confidential client, provided a survey of electric and magnetic fields surrounding an industrial food processing operation. The survey was undertaken at the request of the client to assess radio- frequency (RF) radiation field intensities relative to federal standards and guidelines.

- Participated in the Waste Isolation Pilot Project (WIPP) Pre-Operational Readiness Review Program as a member of the Westinghouse corporate review team. The team provided review of DOE Technical Safety Appraisal areas for both non-nuclear and nuclear-related facilities.

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Radiological Engineering Manager - WVDP (1987-1989). Areas of management responsibility included: Safety Engineering, which encompassed occupational safety, industrial hygiene, and fire protection; Plant Dosimetry Program; Plant ALARA Program; Radiation Instrumentation Program; Respiratory Protection Program; Radiation Technician Training Program; Criticality/Shielding Engineering; procedural reviews for all programs; and interface with Radiological Control Supervisors concerning radiological work activities.

Major Accomplishments Include:

- Completed wholesale revision of the WVNS Radiation Protection Manual to conform to DOE Order 5480.11.
- Completed initial draft of WVNS Internal Dosimetry Manual to conform with DOE Order 5480.11 and PNL Internal Dosimetry Good Practices Manual.
- Served as chairman for two WVNS operational readiness review boards for initial startup of vitrification system cold chemical addition and mini-melter operations.

Senior Environmental Scientist, Dames & Moore, (1985-1987). Prepared safety, environmental, accident and shielding analyses reports for West Valley Demonstration Project (WVDP) activities. Provided technical expertise to the firm's environmental monitoring group responsible for all aspects of environmental and meteorological assessment for the WVDP. Prepared environmental evaluations for operation of the WVDP's subsystems for the waste vitrification efforts. Provided technical assistance for the site emergency plan and had responsibility for all environmental dose assessment computer codes. Other areas of responsibility included review, and assessment of impacts of promulgated DOE orders for radiological control, safety analysis performance, radioactive waste management, and several related topics.

Other Experience:

- Radiological Engineer - New York Power Authority (1983-1985), at the James A. Fitzpatrick Nuclear Power Plant, served as radiological engineer supervising both the plant dosimetry and ALARA programs (~14 nonoutage staff and 30 for refueling outages). During tenure, plant dosimetry system was accredited under the NVLAP program, and INPO awarded a "good practice" citation for ALARA program content and practices.

- Radiological Engineer - New York Power Authority Corporate Office (1982), performed radiation protection activities for two nuclear plants including ALARA, training, environmental monitoring, plant effluents and radioactive waste management. Major activities supported the radioactive waste programs at each plant, established plant Radioactive Waste Process Control Programs (PCPs), implemented 10 CFR 61, and planned for long-term radwaste storage and processing.

- Senior Radiological Specialist - (1978-1979) New York State Department of Health (NYSDOH), Buffalo Regional Office, inspected state and privately owned dental, medical, podiatric, hospital, veterinary and chiropractic facilities possessing ionizing radiation equipment for compliance with Chapter I, Part 16 of the New York State Sanitary Code. Key areas of concern were reducing patient exposure, instructing operators in proper methods of radiation safety, and insuring that the X-ray facility was properly shielded to protect the operators and the general public.

- Performed radiological surveys and soil sampling for suspected radiological contamination at the Love Canal area (Niagara Falls, NY) for the New York State Department of Health. Assisted DOE/Oak Ridge personnel in extensive sampling of areas found to be above area background levels.

- As on-site Radiation Safety Officer for NYSDOH during the remedial construction operations at Love Canal, created and implemented routine and emergency radiological health and safety plans.

- Post-Doctoral Fellow - (1980-1982) University of Rochester, Radiation Biology and Biophysics Department. Research included biological effects of electric fields and ultrasound on various plant and animal systems. Work resulted in five published articles.

- Graduate Consultant - (1978) to Nuclear Research Development Corporation, Grand Island, N.Y. Completed a report on the radiological consequences of human ingestion of americium-241 coated gold foils produced by the NRD Corporation for use in domestic fire alarm systems. Report submitted to the NRC.

- Reactor Operator - (1976-1978) Nuclear Science and Technology Facility (SUNY at Buffalo). Licensed by the NRC to operate the 2 megawatt pool-type research reactor.

- Graduate Teaching Assistant - (1974-1978) Taught graduate courses at SUNY at Buffalo, in radiation science, radiation biology, isotope tracer techniques, and basic biology. General topics included theoretical and practical aspects of radiation detection, safe handling and disposal of radioisotopes, surveys, shielding design, calibration of a 250-kVcp therapy X-ray unit and an 18,000-curie cobalt-60 irradiator, and neutron activation analysis at the campus reactor facility.

EDUCATION

Ph.D. (1981), Radiation Biology, State University of New York at Buffalo
M.S. (1977), Interdisciplinary Natural Sciences, Roswell Park Memorial Institute (SUNY at Buffalo)
B.S. (1974), Biology, State University of New York at Buffalo
B.A. (1974), Portuguese, Special Majors Program, State University of New York, Buffalo

ABHP CONTINUING EDUCATION AND PROFESSIONAL ENRICHMENT COURSES ATTENDED

Year	Course Title	CECs
1994	Radiation Protection Standards	16
	Design and Conduct of Bioassay Programs	4
	Low-Level Radioactive Waste Management; Post, Present and Future	4
	Operational Quality Assurance for Radioassay Laboratories	4
1993	Fundamentals of Industrial Hygiene	16
	Implementation of the Revised 10 CFR Part 20	4
1992	Naturally Occurring Radioactive Material: Regulation, Disposal and Health Physics	16
	Everything But the Counting Statistics: Measurement Errors and Pitfalls in Radiological Measurements	4
	Atmospheric Transport	4
	Space Radiation Monitoring: Concerns for Space Station Freedom and the Space Exploration Initiative (SEI)	4
	The Application and Testing of Environmental Models for Radiological Assessments	4
	Regulatory Guide 8.25, "Air Sampling in the Workplace"	4
1990	Transportation Regulatory Update	4
	Decommissioning and Exemptions from Regulatory Control - Status and Implementation of Current NRC Policy Statement and Guidance	4
1989	Fundamentals and Application of ICRP-26 and ICRP-30	1
	Fundamentals of Lasers and Their Safe Use	1

ABHP CONTINUING EDUCATION COURSES (Continued)

Year	Course Title	CECs
1987	Practical Aspects of Calibration Procedures for Airborne Radioactivity Monitors	1
	Interpretation of Bioassay Measurements	1
	A Review of Basic and Current Transportation Regulations	1
	Properties of the Electromagnetic Cascade: A Tutorial Utilizing High Resolution 3D Graphics	1
1986	Radon Measurement Methods	1
	A Monte Carlo Primer for HPs	1
	Health Physics Measurement Quality Assurance	1
	What Every HP Should Know About Radiation and Pregnancy	1
	Radiation Dosimetry and Protection in Diagnostic Radiology	1

PROFESSIONAL AFFILIATIONS

Plenary Member, Health Physics Society;
Associate Member, Radiation Research Society;
Associate Member, Sigma Xi Scientific Research Society;
Member, Western and Greater New York Health Physics Society Chapters;
Member, Health Physics Society Power Reactor Section;
Member, Health Physics Society Environmental Section;
President Western New York Chapter HPS (1988).

REGISTRATIONS

Certified Health Physicist: American Board of Health Physics, 1985, Recertified 1989, 1993;
Certified Radiation Equipment Safety Officer, New York, 1977;
National Registry of Radiation Protection Technologists, 1984.

PUBLICATIONS

Greenburg, G. and D. A. Dooley, (1976) Americium Foil Integrity Tests, performed under contract for the Nuclear Radiation Development Corporation, Grand Island, New York, for submission to the Nuclear Regulatory Commission.

Dooley, D. A., Roswell Park Memorial Institute - SUNYAB, (1975) "The Effects of Temperature on the Rate of Decomposition of Technetium-99m Stannous Ethane-1-Hydroxy-1, 1-Diphosphonate (Osteoscan®)" (Master's Project, D. M. Blau, Advisor).

Dooley, D. A. and A. K. Bruce, SUNYAB, (1978) "Response of Respiratory Components in X-irradiated Micrococcus radiodurans." (Presented at the 26th Annual Meeting of the Radiation Research Society, Toronto, Canada, May 10-14, 1978). Abstract appears in Radiation Research, 74:575.

Ph.D. Thesis: "Response of Respiratory Components in X-irradiated Micrococcus radiodurans," Ph.D. Dissertation advisor: Dr. Alan K. Bruce, Department of Environmental and Organismal Biology, SUNYAB, Amherst, New York (716) 636-2718.

Dooley, D. A. and A. K. Bruce, SUNYAB, (1980) "Iron Metabolism in X-irradiated Micrococcus radiodurans." (Presented at the 28th Annual Meeting of the Radiation Research Society, New Orleans, LA, June 1-5, 1980). Abstract appears in Radiation Research 83:384.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1981) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." J. Acoust. Soc. Am. Supplement 1, Vol 69, 1981.

Dooley, D. A., P. G. Sacks, M. W. Miller, E. L., Carstensen and S. Lam, (1981) "Yields of Focused Ultrasound-induced Chromosomal Anomalies in Plant Root Meristem Cells." Submitted to Ultrasound Med. Biol.

Dooley, D. A., S. Z. Child, E. L. Carstensen and M. W. Miller, (1983) "The Effects of Continuous Wave and Pulsed Ultrasound on Rat Thymocytes In Vitro." Ultrasound Med. Biol. 9, 379-384.

Robertson, D., D. A. Dooley, P. Economou and M. W. Miller, (1981) "Analysis of Some Growth Parameters of Pea Roots Exposed in 60 Hz Electric Fields." Submitted to Environmental and Experimental Botany.

Dooley, D. A., "Effects of Ultrasound on DNA." Molecular Genetics, Chromosomes and Cells, Seminar Series, November 14, 1980, University of Rochester, New York.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1981) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." Radiation Research 87:473. Abstract only.

Dooley, D. A., P. G. Sacks and M. W. Miller, (1984) "Production of Thymine Base Damage in Ultrasound Exposed EMT6 Mouse Mammary Sarcoma Cells." Radiation Research 97: 71-86.

Miller, M. W., D. A. Dooley, C. Cox and E. L. Carstensen, (1983) "On the Mechanism of 60 Hz Electric Field Induced Effects in Pisum sativum L Roots: Vertical Field Exposures." Radiation Environmental Biophysics, 22:293-302.

Brulfert, A., M. W. Miller, D. Robertson, D. A. Dooley and P. Economou, "A Cytohistological Analysis of Roots Whose Growth Is Affected by a 60-Hz Electric Field," Bioelectromagnetics, Vol. 6, 283-291, 1985.

Dooley, D. A. and P. Burn, (1985) "Environmental Evaluation for the Liquid Waste Treatment System," WVDP-049.

Dooley, D. A. and P. Burn (1985) "West Valley Demonstration Project Safety Analysis Report, Volume IV, Liquid Waste Treatment System."

Englert, J. P. and D. A. Dooley, (1985), "Safety Analysis for Transfer and Storage of Boxed Vessels and Jumpers Removed from the Chemical Process Cell, Revision 4.

Dooley, D. A., R. R. Blickwedehl and R. A. Bell, (1986) "Safety Analysis for Low-Level Class A Radioactive Waste Handling and Disposal Operations."

Dooley, D. A., R. R. Blickwedehl and R. A. Bell, (1986) "Safety Analysis for Low-Level Class B and Class C Radioactive Waste Handling and Disposal Operations for the Radwaste Treatment Drum Cell.

Peterson, J. M., D. A. Dooley and P. M. Petrone, (1986) "Safety Analysis for the Cement Solidification System, Revision 1.

Dooley, D. A., (1987) "Environmental Evaluation for Extended Storage of Class A Radioactive Waste," WVDP-066.

Slawson, J., L. Henry and D. A. Dooley, "A Comparison of Past and Present Operational Health Physics Challenges Presented by Repair Outages at a University Research Reactor," presented at the 36th Annual Meeting of the Health Physics Society, July 24, 1991.

Scalsky, E. D. and D. A. Dooley, "Audit Studies Report," prepared for Cintichem, Inc. for submission to New York State Department of Environmental Conservation, September 1991.

Dooley, D. A. and E. D. Scalsky, "Airborne Emission Evaluation," prepared for Cintichem, Inc. for submission to New York State Department of Environmental Conservation, September 1991.

Dooley, D. A. and J. V. Wierowski, "Final Report for the Town of Tonawanda Project 1918: Decontamination of Sewerlines and Manholes," dated April 22, 1992.

Dooley, D. A. and J. V. Wierowski, "Final Report for the Preparation, Packaging and Shipment of Low-Level Radioactive Wastes Generated by Project 1918 and Previous Tonawanda Wastewater Treatment Plant Decontamination Activities, dated April 30, 1992.

Dooley, D. A., NORM Regulations Report, for TAM Ceramics, Inc., dated December 6, 1993.

PRESENTATIONS

Miller, M. W., E. L. Carstensen, D. Robertson, D. A. Dooley and A. Brayman. 60 Hertz Electric Field Parameters Associated with the Perturbation of a Eukaryotic Cell System. Department of Energy Annual Contractors Review, November 15-17, 1982, Denver, CO.

Dooley, D. A., "Development of an ALARA Program at a BWR," paper presented at the Brookhaven Laboratory-sponsored ALARA Symposium, February 1984.

Dooley, D. A., Determination of Site Specific Ingestion Pathways and Dosimetric Consequences for the West Valley Demonstration Project, Presented to the Western New York Chapter of the Health Physics Society, January 9, 1987.

Dooley, D. A., Evaluation of In Vitro Analytic Results at the West Valley Demonstration Project with Respect to DOE Order 5480.11 Compliance, Presented at the 34th Annual HPS Meeting, Albuquerque, New Mexico, June 1989.

Dooley, D. A., J. C. Cwynar, C. W. McVay and C. J. Roberts, "Comparison of Off-Site Radiation Dose Predictions at West Valley Based Upon Assumed and Measured Performance of the New Liquid Waste Treatment System, Presented by C. J. Roberts, at the 34th Annual HPS Meeting, Albuquerque, New Mexico, June 1989.

Dooley, D. A., Radiological Pathway Analysis for a Proposed Coastal Water Effluent from a Central Florida Water Improvement Project, Presented to the Western New York HPS, March 23, 1990.

Dooley, D. A., Decontamination of an Am-241 Contaminated Municipal Service Line, presented at the Health Physics Society Mid-year Meeting, Albany, New York, February 15, 1994.

10/94

JAMES P. GRIFFIN, CHP

Senior Health Physicist
MJW Corporation Inc.

EXPERIENCE

MJW Corporation Inc., 1995 - Present

Senior Health Physicist

As Senior Health Physicist of a privately held radiological consulting corporation, main duties include the evaluation of dose resulting from the intake of radioactive material. Included is the identification of acceptable in vivo and in vitro radiobioassay facilities, development of appropriate bioassay programs, evaluation of bioassay data, intake projection, and dose assessment. Other duties include providing radiological expertise to a variety of private, industrial and government clients.

West Valley Nuclear Services Inc., 1990 - 1995

Senior Health Physicist

- Employed by West Valley Nuclear Services as the Senior Health Physicist in the West Valley Demonstration Project (WVDP) Dosimetry Program. The internal dosimetry duties of this position included development and oversight of the in vivo and in vitro bioassay programs, performance of internal dose assessment, records management and dose reporting. Accomplishments in this area included, creation of the WVDP Internal Dosimetry Technical Basis Document, revision of the WVDP Internal Dosimetry Program Manual and development/implementation of the current in vivo and in vitro program.

- The WVDP utilizes contracted laboratories for the analysis of in vitro bioassay samples. Administering this program I was required to develop the technical requirements for these contracts of perform all phases of the competency evaluation process. This included conducting 18 technical capability audits and technical assessment surveys of vendor laboratories.

- Served as Technical Lead for the West Valley Demonstration Project Dosimetry Program. Responsibilities were expanded to include oversight of the External Dosimetry Program and operation of the Panasonic Thermoluminescent Dosimetry System. Major Accomplishments included revision of the External Dosimetry Technical Basis Document and Quality Assurance Plans. Further accomplishments included successful reaccreditation of the external dosimetry program under the Dept. of Energy Laboratory Accreditation Program (DOELAP).

University of Buffalo - Nuclear Science and Technology Facility, 1982 - 1990

Senior Health Physicist

- Served eight years as the Senior Health Physicist for the Nuclear Science and Technology Facility at the University of Buffalo. In this capacity I was responsible for all aspects of the health physics program for a 2 MW materials testing reactor. This included the development and administration of the dosimetry program and operation of the radioanalytical laboratory.

Harbor/UCLA Medical Center, 1980 - 1982

Radiation Safety Consultant

- Served as the Radiation Safety Consultant for the Harbor/UCLA Medical Center in Torrance, California. Responsibilities of this position included all aspects of the Health Physics program supporting a large clinical and medical research facility. Accomplishments included development and administration of both the external and internal dosimetry programs.

EDUCATION

B.A., Radiation Biology, State University of New York at Buffalo, Buffalo New York
Graduate Studies, Physical Sciences, Saint Bonaventure University, Olean, NY

CONTINUING EDUCATION IN INTERNAL AND EXTERNAL DOSIMETRY

Internal Dose Assessment by Dr. John Poston; May 1991 A one week graduate level course in the performance of internal dose assessment

Workshop on Code for Internal Dosimetry by Dr. Darrell Fisher; March 1992 A one week technical work shop, conducted by the authors of the code, on the use of the Code for Internal Dosimetry (CINDY).

Participated in the Following Technical Conferences:

- 38th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- 39th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- 40th Annual Conference on Bioassay, Analytical, and Environmental Radiochemistry
- U.S. Department of Energy Intercalibration Committee; Lung Counting Workshops at Lawrence Livermore Laboratory
- 35th Annual Meeting of the Health Physics Society
- 36th Annual Meeting of the Health Physics Society
- 37th Annual Meeting of the Health Physics Society
- USDOE 3rd Annual Conference on Bioassay and Radiochemistry

PROFESSIONAL AFFILIATIONS

HPS/ANSI N13.39 Working Group, Member of the committee charged with the development of the ANSI Standard for Internal Dosimetry Programs. The intent of this standard is to define the elements required for an internal dosimetry program and to general program guidance supporting the other ANSI standards relating to internal dosimetry.

U.S. Department of Energy, DOELAP Assessor, Selected to serve as one of 12 individuals to perform on-site assessments supporting the internal dosimetry U. S. Department of Energy Laboratory Accreditation Program.

The New York and New Jersey Hazardous Material Worker Training Center; Advisory Board Member,

American Health Physic Society; Plenary Member

American Academy of Health Physics; Member

American Nuclear Society; Member

Western New York Region, Health Physics Society; Member

REGISTRATIONS

Certified Health Physicist: Certified by the American Board of Health Physics in the comprehensive practice of Health Physics, 1992

ASME NQA-1 Lead Auditor: Qualified Lead Auditor having performed over 15 validation audits and capability assessments of radiobioassay laboratories, 1991, Requalified 1995;

USDOE Certified Accident Investigator: Certified as a trained accident investigator and qualified to chair an accident investigation board, 1991, Recertified 1994;

10/95

Preliminary Report on the Dose to Dr. Maryann Wenli Ma

Due to the Ingestion of Phosphorus-32

Prepared for the Law Firms of

Vecchia & Wolfer

6 Grant Avenue
Takoma Park, Maryland 20912

and

Bernabei & Katz

1773 T Street NW
Washington DC 20007

by the

MJW Corporation Inc.

338 Harris Hill Road, Suite 208
Williamsville, New York 14221

October 8, 1995

EXHIBIT 2

EXHIBIT 5
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DISCLAIMER

This report is only preliminary in nature and represents the analysis of the bioassay dated from bioassay (urine and fecal) samples collected since the time of the incident in late June of 1995 through August 1995. Additional samples are currently being collected and analyzed until such time that they no longer yield useful data. At such time, MJW will issue a final report which accounts for all outstanding data.

Preliminary Report on the Dose to Dr. Maryann Wenli Ma
Due to the Ingestion of Phosphorus-32

1.0 PURPOSE

This report contains the preliminary assessment of the internal dose to Dr. Maryann Wenli Ma resulting from the ingestion of phosphorus-32 on or about June 28, 1995. At the time of the intake Dr. Ma was approximately 17 weeks pregnant. Additionally, a preliminary estimate and a discussion of the involved fetal dose is presented.

2.0 SCOPE

The preliminary intake projections and associated dose assessments in this report are based on excreta samples collected between June 29, 1995 and August 23, 1995. All data utilized results from radioanalysis performed by TMA/Norcal Laboratory, Richmond, California. Further excreta is being collected and analyzed. Sample collection and analysis will continue until the activity level of the samples no longer yields useful results. A final report and dose prediction will be completed upon the receipt and evaluation of that data.

3.0 INTAKE PROJECTION AND DOSE ESTIMATE

This intake projection is based on a radiological evaluation of excreta collected during the time period from June 29, 1995 through August 23, 1995. Upon review of documents collected and National Institute of Health radiological records (Reference 1), this intake is assumed to be an oral ingestion of inorganic phosphorus-32 occurring on June 28, 1995. Since the precise time of intake is unknown, a time of 12:00 is assumed. The ICRP 30 Model (Reference 2) for inorganic phosphorus ingestion was used for this intake projection. The computer models CINDY (Code for INternal DosimetrY; Battelle Memorial Institute) and INDOSE (Skrable Enterprises, INC.) were utilized in the evaluation of this exposure. Data evaluated included the analytical results of 14 urine and 3 fecal samples. All analyses utilized in this internal dose assessment were performed at TMA/NORCAL in Richmond, California. (Excreta sample analysis is further discussed in Section 6.0 of this report.) All data resulting from the analysis of urine collected on June 29 and 30, has been excluded from this evaluation for the reasons outlined in Section 5.0 of this report. Excreta samples continue to be collected and analyzed. A final dose assessment report will be issued when the results of these analyses have been received and evaluated. Evaluation of the analytical results received to date establish a preliminary estimate of an intake of 1000 μCi of P-32 by the ingestion pathway. This preliminary intake estimate corresponds to a Committed Effective Dose Equivalent (CEDE) of 9.2 rem. The associated fetal dose is projected and discussed in Section 4.0 of this report.

4.0 FETAL DOSE ESTIMATE

The published guidance concerning the determination of fetal dose is contained in the U.S.N.R.C. Regulatory Guide 8.36, "Radiation dose to the embryo/fetus" July, 1992. This document acknowledges that the calculation of prenatal exposure for internal radionuclides presents many difficulties such as the lack of quantitative data concerning prenatal nuclide concentrations and mobility of various material across the placental barrier. This Regulatory Guide establishes fetal dose per μCi of maternal intake. These values were based on the assumption that the dose to the fetus is equal to the dose to the mother's uterus. This assumes no radioactive material crosses the placenta, or incorporates in the soft and skeletal tissues of the fetus. There is currently insufficient data to determine the degree that inorganic phosphorus is capable of crossing the placental barrier. Clearly, if a radionuclide is transplacental, the fetus is at risk of receiving significantly more exposure than that dose delivered to the mother's uterus.

Regulatory Guide 8.36 (Reference 3) establishes the estimation of fetal dose as 3.03E-3 rem/μCi of maternal intake. However, not clearly explained in Reference 1, the NIH fetal dose assessment appears to apply a fetal dose factor of 6.40E-3 rem/μCi of maternal intake, based on personal communication concerning a draft NUREG document. Using the value of 6.40E-03 rem/μCi the revised fetal dose based on the preliminary maternal intake estimate of 1000 μCi is 6.4 rem. The dose is 3 rem when based on the original Reg. Guide value. The lack of biokinetic data pertaining to phosphorus in the expectant mother however, results in a high degree of uncertainty in fetal dose projections.

It should be noted for comparison that the recommendations of the International Commission on Radiation Protection (ICRP) and NCRP which have been adopted in federal regulations by the NRC and DOE establish a fetal exposure limit of 0.5 rem over the entire gestation period which establishes a definable margin of safety with regard to fetal development. The estimated fetal dose in this case is a factor of 6 to 12 above this recommended limit and may likely be higher based on whether P-32 has the ability to cross the placental barrier. In addition, the level of fetal development at the time of the ingestion may also render the fetal dose estimate unreliably low.

5.0 INADEQUACY OF NIH CALCULATION OF INTERNAL DOSE

The National Institute of Health internal dose evaluation reported an effective dose equivalent of 4.17 rem (Reference 1). This is substantially less than the dose projection presented in this report of 9.2 rem. The issues discussed in the remainder of this section serve to explain this discrepancy.

5.1 Use of Early Bioassay Data

The dose estimate performed by the NIH included data obtained from the radioanalysis of urine excreted during the two days immediately following the intake. These data points were excluded from consideration for the purpose of this dose evaluation. The results from the analysis of these samples were considered unreliable for the following reasons:

- The urine samples collected during the first two days following the intake were collected as spot samples. Rather than collecting the entire urinary excretion compartment over a 24 hour period, a series of samples were collected at each voiding. This sampling program did not ensure collection of the entire integral excretion over the required 24 hour period. As a result, the value of this early data is significantly diminished.

- Review of the associated documentation indicate that large volumes of fluid were administered in an attempt to hasten elimination of the radioactive phosphorus. The apparent impact of this treatment is evaluated in Section 7.0 of this report. However, it must be noted that this greatly increased the urinary output during this time period. When a true 24 hour urine collection is not obtained, correction for the concentration measurement is required to account for this dilution. It appears that NIH did not properly perform this correction based on our review of Reference 1. This correction could have been accomplished through the measurement of specific gravity (S.G.) of the sample and comparing that to the average S.G. of urine which is 1.024 g/ml. Another method of correction involves the ratio of expected creatinine content verses the measured creatinine content in the urine (Reference 4). Since neither measurement was performed, the relationship between the measured radioactive concentration of these samples can not be related to the total 24 hour excretion.

- Generally, data from excreta collected close in time to the intake is of less value for the determination of internal dose (Reference 4). In part, this is due to the greater variability of the rate of excretion of radioactive material over the collection period of the sample. In other words, the difference in excretion rate from the beginning to the end of a 24 hour sample collected the day following an intake is much greater than that occurring during a 24 hour collection 30 days post intake. This increase in excretion variation substantially increases the error associated with the internal dose evaluation.

5.2 Duration of Excreta Sample Collection

The dose estimate in this report is based on the analysis of excretion collected over a significantly longer period of time than was the dose evaluation conducted by the NIH. This

allows for a more accurate determination of the actual excretion pattern occurring. The NIH dose evaluation was based solely on samples collected during the first month following the intake. However, urinary excretion patterns appear to deviate significantly from the norm and the NIH sampling program failed to compensate for this deviation in that complete 24 hour urine samples were not collected. Therefore, this represents a large potential for error to be introduced into the dose assessment. The preliminary dose evaluation in this report is based on the analysis of samples collected over a period from July 1 to August 23, 1995. The reason this estimate is still considered preliminary is that in vitro bioassay sampling should continue until no further useful information can be obtained from additional sampling. Sampling and analysis are continuing in this case and a final dose assessment will be performed upon the evaluation of pending analytical data.

5.3 Use of Fecal Analysis

The dose estimate performed by the NIH relied entirely on analysis of urine samples and was not confirmed through the analysis of fecal samples. The ICRP 30 model for inorganic phosphorus excretion predicts that 20% of ingested phosphorus will be excreted through the feces. The dose evaluation presented in this report used fecal samples collected over a three day period to confirm the intake assessment. A close agreement was observed with the urine data indicating a 1,100 μCi intake and the fecal data indicating a 1,000 μCi intake. NIH's failure to collect fecal samples precluded their identifying the discrepancy in dose estimation.

5.4 Mathematical Modeling of the Data

The NIH dose assessment evaluated the data using two mathematical models, the unweighted least squares fit (ULSF) method as outlined in NUREG/CR-4884 (Reference 5) and the weighted least squares fit (WLSF) method identified by Skrable et. al. (Reference 6). The later represents the method used by NIH to assign their final dose in this case. The weighted least squares fit method provides a simple methodology in which the sum of the measurements is equal to the sum of the expectation values. Although this method is acceptable when the actual excretion closely follows the anticipated model it can lead to a gross underestimation of the true error when the actual excretion varies from the model prediction (Reference 7). NIH did not use the most appropriate mathematical fit for the data.

The dose assessment presented in this report evaluated three mathematical models relative to the fit of the data, the Ratio of the Means (ROM), the Average of the Slopes (AOS) and the Un-weighted Least Squares Fit (ULSF). A determination of the mathematical fit of each data point was conducted for each of the three methods. This was accomplished by dividing the measured values by the value predicted by the model evaluated. The closer the result is to 1.0, the better the model fits the data. This method identified that the average of the slopes as the mathematical model that most closely fits the measured values. The average results for the ROM, AOS and ULSF methods were 1.56, 1.00, and 2.10, respectively. This data

is graphically represented in Attachment A.

6.0 EFFECTIVENESS OF MEDICAL INTERVENTION

From the review of Reference 1 and several news articles (References 9-11), it is understood that medical intervention was attempted following the detection of this intake.[1] It also is believed that these attempts were limited to the administration of large volumes of fluid in an attempt to accelerate the elimination of the radioactive phosphorus from Dr. Ma. Subsequent urinary collection reflects such attempts in that extraordinarily large renal output was observed over the days subsequent to the intake. The best evaluation of these dilute samples indicates that no discernable enhancement of phosphorus-32 elimination was evident. It is apparent from the urine data that the hydration therapy did not serve to accelerate the removal of P-32 from Dr. Ma's body. Therefore, this technique was ineffective in reducing the dose from the intake.

The National Council on Radiation Protection and Measurements (NCRP) Report 65 (Reference 12) details a case history of an accidental over administration of phosphorus-32 in which treatment was not begun until the 9th day following the incident. Intervention included large doses of phosphate by mouth daily as the buffered sodium salt, calcium given intravenously daily and 200 units of parathyroid extract I.M. every 6 hours. This treatment was continued over an 18 day period, and though started late, accomplished an estimated 38% reduction of radiation dose to the bone marrow. NCRP Report 65 (Reference 12) also presents recommendations for treatment of non-radioactive phosphorus ingestion to be considered in the treatment of accidental phosphorus-32 ingestion. Treatments recommended include gastric lavage with potassium permanganate or 3% hydrogen peroxide, Copper sulfate in a glass of water, or Mineral Oil to hasten elimination. Aluminum hydroxide gel or aluminum phosphate gel are also recommended to help prevent G.I. absorption.

As stated above, it does not appear from the data nor does the written record suggest that any of the above interventions were employed in the case of Dr. Ma's ingestion other than the forcing of fluids.

7.0 RADIOANALYSIS OF EXCRETA DATA

All data used for dosimetric evaluation in this report resulted from analyses performed at TMA/NORCAL in Richmond, California. This included eleven urine samples which were collected by the NIH and selected for reanalysis. This reanalysis was deemed necessary since evidence was not provided by NIH demonstrating that the original analyses had been

---

[1] That Dr. Ma received hydration therapy can only be deduced from Reference 1 in that daily urinary output exceeded the typical value by more than a factor of six over an 8 hour sample period.

conducted by a qualified bioassay laboratory practicing to the standard of care as established in draft ANSI N13.30 Standard (Reference 7) and operating under an acceptable quality assurance program. The absence of such assurances raised concerns as to the ability to validate the NIH bioassay analyses at a future date. The following lists some of the essential program elements that a laboratory must implement to ensure that data generated is accurate and defensible:

- Analyses must be performed in accordance with approved written procedures specific to the radioisotope and matrix of interest (i.e. P-32 in a urine matrix). Additionally, these procedures must be controlled documents.

- Procedures must allow for the separation of the analyte of interest from any interfering nuclide. (e.g., K-40 would interfere with the direct measurement of P-32 in urine.)

- Training must be conducted and documented for all technicians performing each phase of each analysis. This training must include initial qualification and annual requalification.

- All devices used to measure and weigh samples and reagents must be currently calibrated in the range in which they are used.

- All reagents utilized must be verified as acceptable under the quality program prior to use. Reagents must also be labeled with the appropriate expiration date.

- When appropriate, tracers must be used to accurately determine chemical yields.

- Adequate quality control samples must be analyzed with each set of samples to demonstrate the ANSI N13.30 performance requirements for precision have been met for that analysis.

- Adequate quality control samples must be analyzed with each set of samples to demonstrate the ANSI N13.30 performance requirements for bias have been met for that analysis.

- A program for the analysis of blind spikes, splits, and blanks must be implemented to ensure the quality of analytical results.

- All standards and standard solutions used must be directly traceable to the N.I.S.T. or an equivalent standards authority.

- Counting instruments utilized for the analysis of radiobioassay samples must be

calibrated for the analyte of interest in the geometry of interest.

- o Instrument operability must be verified prior to the conduct of radiobioassay analyses e.g., daily operability tests are performed and documented. Results of these verifications should be analyzed for the presence of any trends.

- o Documentation verifying and validating all computer codes and software used must be maintained.

The above programmatic items must be in place to ensure that any degradation in bioassay laboratory performance is recognized by the laboratory before adversely affected data would be reported. To date we have not been presented with evidence to confirm that any or all of the above controls were in place at NIH at the time of the sample analysis.

8.0 CONCLUSIONS

- The preliminary report from the MJW Corporation Inc. indicates that Dr. Ma's initial intake of phosphorous-32 was 1,000 μCi (microcuries), which results in a dose of 9.2 rem. This intake is almost two times the recommended annual limit on intake (ALI) for phosphorous-32 of 600 μCi for a non-pregnant occupationally exposed woman, and over 16 times the recommended gestational ALI of 60 μCi (0.5 rem) for an occupationally exposed pregnant woman.

- The dose to Dr. Ma's fetus is estimated at 6.4 rem, or a factor of 12 above the Nuclear Regulatory Commission's established fetal exposure limit of 0.5 rem for the entire gestation period.

- The medical intervention recommended by National Institutes of Health officials for Dr. Ma following discovery of her contamination appears to have had no effect in decreasing her internal phosphorous-32 contamination in any way.

- In July of 1995, NIH reported that it had calculated Dr. Ma's phosphorous-32 intake to be 200 to 300 μCi. In August of 1995, NIH changed that assessment to 500-600 μCi.

REFERENCES

1. Letter to Robert A. Zoon, RSO NIH, from Shawn W. Googins, Deputy RSO, NIH, dated 8/29/95; "Intake Estimate and Fetal dose Equivalent".

2. ICRP Publication 30, Limits for the Intake of Radionuclides by Workers, Annals of the ICRP 2 (3/4) 1979, et. seq., Pergamon Press.

3. U.S. Nuclear Regulatory Commission, Radiation Dose to the Embryo/Fetus, Regulatory Guide 8.36, July 1992.

4. National Council on Radiation Protection and Measurements, Report No. 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, 1987.

5. NUREG/CR-4884, 1987, Interpretation of Bioassay Measurements, Lessard E.T., et. al., Brookhaven National Laboratory, Upton, New York.

6. Skrable, K. W., et. al., Use of Multicompartment Models of Retention for Internally Deposited Radionuclides, in "Internal Radiation Dosimetry," Otto G. Rabe, ed., Health Physics Society Summer School, 1994.

7. Personal Communication with Dr. Ken Skrable, Skrable Enterprises, Inc., October 4, 1995.

8. American National Standards Institute, ANSI N13.30 (Draft), 1989, Performance Criteria for Radiobioassay.

9. The Washington Post, 26 at NIH Exposed to Radiation, p B1, July 18, 1995.

10. The Almanac, Radioactivity Found in NIH Water Cooler, p 6, July 19, 1995.

11. The Washington Gazette, NRC Boosts level of consumed toxins at NIH, p A-9, August 9, 1995.

12. (National Council on Radiation Protection and Measurements Report No. 65 "Management of Persons Accidentally Contaminated with Radionuclides" Section 6.10.)

EXHIBIT 5
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DCS No: 03001786950628
Date: July 3, 1995

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PN1-9525

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility:
Department of Health & Human Services
National Institutes of Health
Bethesda, Maryland 20892

Licensee Emergency Classification:
_____Notification of Unusual Event
_____Alert
_____Site Area Emergency
_____General Emergency
__X__ Not Applicable

Docket No.: 030-01786
License No.: 19-00296-10
Event No.: 29008
Event Location Code: MAT

SUBJECT: INTERNAL CONTAMINATION OF RESEARCHER

On June 30, 1995, at 8:00 a.m., the licensee's Radiation Safety Officer informed the NRC's inspector on-site performing a routine inspection that an incident involving internal contamination of a researcher had been reported to the radiation safety office at approximately 5:30 p.m. the previous evening.

The licensee identified the researcher as a 32 year old female who is in her fourth month of pregnancy but had not declared herself to be pregnant to the licensee.

The emergency response and follow-up by the licensee confirmed the existence of a detectable radioactivity burden, however it does not appear that an annual limit on intake was exceeded. The licensee identified the ingested isotope to be phosphorous-32 (P-32).

The incident is under investigation by the licensee. There are no adverse health consequences expected for the researcher or the fetus. The estimated ingestion is approximately 300 microcuries of P-32. The licensee believes that the event probably occurred around noon on Wednesday, June 28, 1995.

NRC managers and Commissioner's Assistants were briefed. Region I has dispatched an Augmented Inspection Team (AIT). An NRC medical consultant has been contacted and the licensee and the NRC are interacting with the Radiation Emergency Assistance Center/Training Site (REACTS) at Oak Ridge, Tennessee.

The State of Maryland has been informed.

The Region I Office of Public Affairs is prepared to respond to media inquiries.

This information is current as of 9:30 a.m., July 3, 1995.

EXHIBIT 5
PAGE 147 OF 296 PAGE(S)

Contact: Jenny M. Johansen (610)337-5304
Susan F. Shankman (610)337-5283

— Exhibit 7 —

A11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date: July 11, 1995

This copy with 6/30/95 Images
For Dr. Ma
AC 8/1/95

From: Acting Chief, Nuclear Medicine Department, CC

Subject: P-32 Contamination

To: Mr. Robert Zoon, Chief
Radiation Safety Branch

The subject, Wenli Ma, had an internal exposure to P-32. I was asked to image the subject to try to estimate the dose of P-32 in her body. This recommendation was made by Nuclear Regulatory Commission through Radiation Safety Branch. This study was performed in the Nuclear Medicine Department of the Clinical Center as a single subject exemption under compassionate use. The performance of the study was authorized by Dr. John Gallin, Director of the Clinical Center. Miss Ma was brought to the Nuclear Medicine Department accompanied by Mr. Mike Noska. After I discussed the imaging with her, she gave her verbal informed consent to undergo scanning. No sources of radioactivity were used to scan the patient, therefore she was not exposed to any additional radiation. It was indicated to both the subject as well as to radiation safety and NRC that because P-32 has no gamma radiation and only Beta radiation which is weak and not very well detected that the estimates obtained from our study would be only crude estimates.

The patient was imaged 6/30/95 at 17:41 hrs in our Biad dual headed gamma camera. The windows used were those recommended in the literature by Siegel et al. We used a medium energy collimator and used a 100 keV peak with a 50% window for imaging. Images were acquired in 256 by 256 matrix. Images were obtained of the skull, chest and upper abdomen, mid abdomen down to the lower thighs. The images had some overlap, which was small. No focal area of increased activity was noted in the midline of the abdomen in the image of the mid abdomen which had the uterus in the upper portion of our field of view.

In addition, a water-filled phantom with a circumference of 33 inches containing 132 µCi's of P-32 was also imaged. The imaging of the phantom was performed using the same parameters described for the subject. The circumference of 33 inches was equal to the circumference of the patient around the area of the breast. The circumference at the narrowest point which was the waist, was 26 inches. In addition to phantom and subject images, background images were also obtained. A second phantom containing 3.5 mCi of P-32 was imaged 7/7/95 at 16:28 hrs. The patient was studied a second time on 7/6/95 at 17:13 hrs.

In order to approximate the activity in the patient, the anterior and posterior images were summed and smooth for both subject, phantom, and background. The background was then subtracted from the patient images and the activity in the field of view was compared to that in the field of view for the phantom with 3.5 mCi.

The estimates from this were (Table 1) that the patient had a total of 862 μCi retained at the time of initial scanning. The most activity was estimated to be 409 μCi in the view of the chest and upper abdomen. The most intense activity was in the region of the liver (in the initial scan) The patient was counted at a distance of 5.1 meters using a probe count (NaI crystal) with a large open window. The 3.5 mCi phantom was also counted at this distance and the background subtracted counts and estimates of activity are given in Table 2.

These measurements were performed with the assistance of our physicist, Dr. Craig Barker.

A Carrasquillo

Jorge A. Carrasquillo, M.D.

lp

EXHIBIT 5

PAGE 149 OF 216 PAGE(S)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF PUBLIC AFFAIRS, REGION I
475 Allendale Road, King of Prussia, PA 19406
Tel. 610/337-5330

I-95-36 July 3, 1995
Contact: Victor Dricks

NRC SENDS AUGMENTED INSPECTION TEAM TO THE NATIONAL INSTITUTES OF HEALTH TO INVESTIGATE RADIOACTIVE CONTAMINATION OF PREGNANT RESEARCHER

KING OF PRUSSIA, PA -- The Nuclear Regulatory Commission staff has sent an Augmented Inspection Team (AIT) to the National Institutes of Health in Bethesda, Maryland, to investigate the circumstances surrounding the radioactive contamination of a pregnant research fellow.

The woman was taken to a Maryland hospital last Thursday night after her husband, who was working with her at NIH, detected the contamination during a routine check of their lab. She received intravenous hydration treatment to dilute the radioactive isotope found in urine in concentrations of about 16,000 disintegrations per minute per milliliter (dpm/ml) of urine. After hydration therapy the activity in the urine was significantly reduced and urine samples taken today indicate an activity of 2000 to 3000 dpm/ml. Hospital doctors who examined the woman do not believe the contamination will cause medical complications for the woman or her fetus. The woman is believed to have ingested about half of the annual dose limit of the radioactive isotope.

The circumstances surrounding the incident are under review by the licensee. Contamination was also found in front of a refrigerator in a room used for storage and eating of lunches in another area of the building on the same floor. Urine samples from the researcher's husband taken today found activity at least 10 times less than found in the researcher. The AIT is monitoring the licensee's activities and gathering independent data.

The general objectives of the AIT are to:

1. Conduct a thorough and systematic review of the circumstances surrounding the Department of Health and Human Services National Institutes of Health internal contamination reported to the NRC on June 30, 1995, including an incident chronology detailing the sequence of events associated with the contamination event.

2. Assess the safety significance of the event and communicate to Regional and Headquarters management the facts and safety concerns related to the event so that appropriate follow-up actions can be taken. Include an analysis of the actual and potential dose consequences.

3. Collect, analyze, and document factual information and evidence sufficient to determine the cause(s), conditions, and circumstances pertaining to the event.

4. Examine any procedural or management failures and identify associated root causes.

5. Prepare a report documenting the results of this review for the Regional Administrator within thirty days of the completion of the inspection.

In addition to the above, in coordination with the Office of Nuclear Material Safety and Safeguards, examine and assess the adequacy of the NRC procedures and processes for responding to on-going events including a medical emergency. Document any lessons learned and recommended changes in a separate document within sixty days of completion of the inspection.

The four-member team includes specialists in radiation safety and health physics from NRC's Region I office and NRC headquarters, as well as a medical consultant. The team will produce a written report that will be made public.

***

ORISE
OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION

(615) 576-3449
FAX: (615) 576-8673
Internet: stabinmc@orau.gov

July 5, 1995

Michael Noska
Department of Health and Human Services
National Institutes of Health
Radiation Safety
Bethesda, MD 20892

Dear Mike,

Enclosed is a very quick plot of the P-32 excretion data so far. It was a little difficult to get these right into the format needed to compare them to the NUREG/CR-4884 data for excretion of ingested P-32 as phosphate, so let me describe what I did and you tell me if you think that it is reasonable. I treated the data from 6/29 at 1900 to 6/30 at 1000 as the 24-hr excretion for day 2. I then took the data from 6/30 at 1300 to 6/30 at 1800, added a portion of the weekend sample, and called that the 24-hr excretion for day 3 (to go to 1100 hrs on 7/1). The portion was based only on hours, not volume, as we did not have that information. I then used the remaining data for the weekend and assumed that it was excreted evenly over days 4 and 5, as apparently no other estimate can be made from this pooled sample. The activity excretion pattern I used was thus:

Day	Activity (μCi)
2	14.5
3	4.4
4	4.95
5	4.95

Using these values with the NUREG/CR-4884 24-hr excretion numbers, and using the $r\ V \cdot E / r\ E^2$ method, I obtained an estimated intake of 265 μCi. Plotting the values in the table above as a fraction of this number, I obtained the numbers on the attached graph, and compared it to the NUREG function as shown.

We only have a little data at this point, and there is some uncertainty in the pooled weekend sample. But overall, the agreement with the ICRP model for phosphate is reasonable at present. We should certainly continue to study this pattern for several more days, trying to obtain and use true 24-hr samples where possible. We can also look at the nuclear medicine scan data and the whole body counts, when the calibrations have been completed, to check the agreement with the model as well. Please let me know what you think of this information and approach.

Sincerely,

Michael Stabin
Radiation Internal Dose
Information Center

enc: plot of excretion data

Exhibit 10

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DCS No: 03001786950628
Date: July 17, 1995

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNI-9525A

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility:
Department of Health & Human Services
National Institutes of Health
Bethesda, Maryland 20892

Licensee Emergency Classification:
_____Notification of Unusual Event
_____Alert
_____Site Area Emergency
_____General Emergency
__X__ Not Applicable

Docket No.: 030-01786
License No.: 19-00296-10
Event No.: 29008
Event Location Code: MAT

SUBJECT: INTERNAL CONTAMINATION OF RESEARCHER UPDATE

On July 14, 1995, at 3:15 p.m., the licensee's Radiation Safety Officer(RSO) informed the NRC Region I that a contaminated water cooler had been identified during the licensee's investigation of an incident involving internal contamination of a researcher that had been reported to the NRC on June 30, 1995.

The licensee stated that through urine bioassays their investigation has identified approximately 25 additional individuals who have low level internal phosphorus-32 (P-32) contamination. These individuals worked in the same building as the originally contaminated researcher. The licensee, in looking for a commonality for the source of contamination, surveyed all the water coolers and found radiation levels on the spigot and in the reservoir of one water cooler on the floor of the building where the individuals all work. The five gallon water bottle was removed from the water cooler and no detectable activity was found on the outside of the bottle or in the water within the bottle.

The RSO stated that the vendor supplying the water bottles for the cooler had picked up the empty bottles on July 13, 1995. In a telephone call with the vendor the RSO learned that the empty bottles were returned to the vendor's collection facility. Bottles picked up prior to July 13, 1995, were reshipped to the vendor's bottling facility. At the bottling facility the bottles are washed with hot soapy water, rinsed, and sterilized prior to being refilled with fresh water and recapped for later distribution. Analysis of wash water and samples of recycled full water bottles from the bottling facility showed no detectable activity in the wash water or filled water bottles. The empty bottles at the collection facility identified as coming from NIH were surveyed today and no contamination was identified. There are no adverse health consequences for members of the public from this event.

The licensee continues to investigate for possible sources of contamination.

NRC managers and Commissioner's Assistants have been briefed. Region I AIT will be on site to continue its evaluation of the event, July 17, 1995.

The State of Maryland and Region II have been informed. Region II contacted the Commonwealth of Virginia. Office of Public Affairs is prepared to respond to media inquiries.

EXHIBIT 5

This information is current as of 11:30 a.m., July 17, 1995

Contact: Jenny M. Johansen (610)337-5304 Susan F. Shankman (610)337-5283

The Washington Post

26 at NIH Exposed To Radiation

Sabotage Suspected At Bethesda Facility

By Brian Mooar
Washington Post Staff Writer

Federal authorities are investigating two apparent acts of radioactive sabotage in which a pregnant scientist and 25 co-workers unwittingly consumed contaminated food or water at the National Institutes of Health, officials said yesterday.

Officials at NIH in Bethesda said they found traces of a radioactive phosphorus isotope near a lunchroom refrigerator and in a nearby water cooler. The isotope is used in tests performed at the laboratory.

"It is under investigation, but the nature of what we know suggests that it was not accidental," said Anne Thomas, an NIH spokeswoman.

The scientist, who is about four months pregnant, received 200 to 300 microcuries, about half of the yearly allowable dose of radiation under federal guidelines, or the equivalent of about 10 chest X-rays. Thomas said the levels were not believed to pose a significant risk, although doctors recommend that pregnant women avoid exposure to radiation.

Investigators believe she may have eaten contaminated food from a lunchroom refrigerator June 28.

Friday, investigators determined that 25 other workers had been exposed to similar radiation by drinking water from a cooler. Officials said they received one-tenth or less of the yearly exposure limit.

An investigation into the contaminations is being conducted by NIH security officials, the Nuclear Regulatory Commission and the FBI. Special Agent Larry K. Foust, a spokesman for the FBI's Baltimore division, confirmed that agents from his office had traveled to the site to confer with security investigators.

The rare contaminations caused widespread concern at NIH, particularly in the offices where the incidents occurred: the fifth-floor west corridor of Building 37. The area mostly houses researchers from the National Cancer Institute.

NIH officials have been urging workers to bring their own water and drinks to work until the inquiry is concluded, and some employees were scanning food and drinks with Geiger counters yesterday as word about the latest contamination spread.

NIH officials met with about 100 scientists yesterday to try to provide information and allay fears.

RADIATION, From B1

"We're all upset, and we don't know what's going on," said a worker who spoke on the condition of anonymity. "We don't know who did it or why, and nobody wants to work in an environment where somebody's trying to poison you. Anybody could have come in contact with this."

The pregnant scientist discovered that she had been contaminated June 28 when her husband, also an NIH scientist, was sweeping the laboratory with a Geiger counter as part of a routine safety procedure, Thomas said. When the man ran the radiation counter near his wife, it jumped, and the woman was taken to a nearby medical facility for treatment.

"The woman underwent intravenous hydration treatment to dilute the radioactive isotope, and this hydration therapy significantly reduced the [radioactive] activity in the urine," Thomas said. "The doctors who examined her do not believe this will cause any long-term medical complications for her or her fetus."

About noon Friday, NIH workers found more material in a dispenser of bottled drinking water on the same floor. A short time later, workers throughout the building received an urgent notice telling them to contact a supervisor if they had drunk water from the cooler in the last month.

After urine tests, 25 workers were found to have been contaminated, Thomas said.

Thomas, who would not elaborate, said researchers who deal with the radioactive isotopes "have excellent surveillance and keep meticulous records, which is going to be a great help in this investigation. Everyone has been asked to be very vigilant and asked to fill out a questionnaire to help figure out when this might have occurred."

The isotope, P-32, generally is kept in locked containers, officials said.

Exhibit 12

EXHIBIT 5
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LAW OFFICES
BERNABEI & KATZ
1773 T STREET, N.W.
WASHINGTON, D.C. 20009

(202) 745-1942

TELECOPIER (202) 745-2627

LYNNE BERNABEI
DEBRA S. KATZ
AMY W. LUSTIG
MICHAEL C. SUBIT

By Telecopier
August 25, 1995

Patricia A. Kvochak, Esquire
Deputy NIH Legal Advisor
Office of the General Counsel
Public Health Division
National Institutes of Health
Building 31, Room 2B-50
Bethesda, MD 20892

RE: Radiation Contamination of Dr. Maryann Wenli Ma

Dear Ms. Kvochak:

I am writing to follow up on our conversation yesterday concerning the additional testing we have arranged be conducted on the specimens taken from Dr. Ma following detection of her contamination with Phosphorus 32 on June 29, 1995.

As you explained to me yesterday, and as Dr. Googins confirmed, Oak Ridge Institute for Science and Education ("ORISE") was sent four of the first fifteen specimens taken from Dr. Ma on June 29, and 30, 1995, to cross-check the analysis of the samples conducted by the Radiation Safety Branch of NIH. These samples were number 1, 14, 15, and the pooled sample. You will note that the samples which were analyzed were not taken from a full 24 hour period.

Nureg-CR-4884 of the Interpretation of the Bioassay Measurements (1987), promulgated by the Nuclear Regulatory Commission, requires that standard systemic excreta data be analyzed for a full 24 hour period following an internal contamination with radiation. The data analyzed by ORISE is not true 24 hour data, as required by the NRC.

Accordingly, our expert Dr. David Dooley has advised us that the information analyzed by ORISE is inadequate to have reached a proper, independent determination of Dr. Ma's level of internal contamination consistent with the requirements of Nureg-CR-4884. Furthermore, NIH has failed altogether to have any independent verification of the samples collected after July 1, 1995.

By this time I am sure that you are aware that NIH's Nuclear Medicine Department, under Dr. Jorge A. Carrasquillo's direction, estimated that Dr. Ma had a total of 862 uCi retained at the time of her initial scanning on June 30, 1995 -- two days after she ingested the radioactive materials -- and that substantial exposure is detected in the area in which the fetus is located. Given the significant discrepancies in the estimates, and in light of the obvious health implications to Dr. Ma in failing to have a properly verified dosage ascribed to her for the contamination, we have had sample numbers 1, 15, 16, 17, 20, 21, 22, 23, 24, 25, and the "3-10 pooled" sample sent to TMA/Norcal for independent analysis. I am advised that this is the minimal analysis that needs to be conducted to reach a scientifically valid verification of the analysis performed by the RSB.

I am writing to request that the National Institutes of Health agree to pay for this analysis. We, of course, will share all results with NIH. I understand that the likely cost of such analysis is $1,500 per specimen. This cost is obviously one which Dr. Ma is completely incapable of assuming without significant economic hardship, but is one which has been necessitated by virtue of the occupational injury she suffered at NIH.

Given the pendency of time since the samples were taken and the degradation to the specimens which has already occurred, your immediate response to this request is urgent. I would appreciate a response to this request by 5:00 p.m. today, if at all possible, so that I may direct the laboratory to proceed.

If NIH is unwilling to agree to this request, we will seek the NRC's assistance. Perhaps, if you deem it appropriate, you could help coordinate such efforts with the NRC.

I look forward to hearing from you and appreciate the all the cooperation you have provided to date.

Sincerely,

Debra S. Katz

cc: Judith Wolfer, Esquire
Dr. Maryann Ma
DSK:sp

EXHIBIT 5
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LAW OFFICES
BERNABEI & KATZ
1773 T STREET, N.W.
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LYNNE BERNABEI
DEBRA S. KATZ
AMY W. LUSTIG
MICHAEL C. SUBIT

Exhibit 14

By Telecopier
August 28, 1995

Charles W. Hehl, Director
Division of Radiation, Safety and Safeguards
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Radiation Contamination of Dr. Maryann Wenli Ma
National Institutes of Health License No. 19-00296

Dear Mr. Hehl:

Dr. Maryann Ma has retained the law firms of Bernabei & Katz and Vecchia & Wolfer to represent her with respect to her contamination with Phosphorus-32 on or around June 28, 1995, at the National Institutes of Health ("NIH").

Following the detection of Dr. Ma's contamination on June 29, 1995, the Radiation Safety Branch ("RSB") of NIH took and received from Holy Cross Hospital twenty-five samples, spanning the period of June 29, 1995 through July 27, 1995.

I understand that at the Nuclear Regulatory Commission's request, NIH sent the Oak Ridge Institute for Science and Education ("ORISE") four of the first fifteen specimens taken from Dr. Ma on June 29, and 30, 1995, to cross-check the analysis of the samples conducted by the RSB. These samples were numbers 1, 14, 15, and the "3-10 pooled" sample. You will note that none of the samples which were analyzed were taken from a full 24 hour period. Consequently, ORISE could not base its analysis on the actual volume excreted over time, which is critical for model interpretation.

NUREG/CR-4884, Interpretation of the Bioassay Measurements (1987), published by the Nuclear Regulatory Commission, recommends that standard systemic excreta data be analyzed for a full 24 hour period following an internal radiation contamination event. The data analyzed by ORISE to date has not included any

of the 24 hour data collected after July 1, 1995. These 24 hour samples should also be independently analyzed due to the serious nature of the exposure (estimated as high as 1.5 ALI), and the extenuating physical circumstances of the exposed individual (she was four months pregnant at the time of the initial intake.)

Accordingly, our expert Dr. David Dooley has advised us that the information analyzed by ORISE is inadequate to have reached a proper, independent determination of Dr. Ma's level of internal contamination consistent with the recommendations of NUREG/CR-4884 and those of NCRP 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition (1987). Furthermore, NIH has failed altogether to have any independent verification of the samples collected after July 1, 1995.

NIH's Nuclear Medicine Department, under Dr. Jorge A. Carrasquillo's direction, estimated that Dr. Ma had a total of 862 uCi retained at the time of her initial scanning on June 30, 1995 -- approximately two days after she ingested the radioactive materials -- and that substantial exposure is detected in the area in which the fetus is located as well as in the area of the liver. Given the significant discrepancies in the estimates, and in light of the obvious health implications to Dr. Ma in failing to have a properly verified dosage ascribed to her for the contamination, we have had sample numbers 1, 15, 16, 17, 20, 21, 22, 23, 24, 25, and the "3-10 pooled" sample sent to TMA/Norcal for independent analysis. I am advised that this is the minimal analysis that needs to be conducted to reach a scientifically valid verification of the analysis performed by the RSB.

I am writing to request that either the Nuclear Regulatory Commission agree to pay for this analysis or that it direct NIH to do so. We, of course, will share all results with the NRC and NIH. I understand that the likely cost of such analysis is approximately $1,500 per specimen. This cost is obviously one which Dr. Ma is completely incapable of assuming without significant economic hardship, but is one which has been necessitated by virtue of the occupational injury she suffered at NIH.

Given the pendency of time since the samples were taken and the degradation to the specimens which has already occurred, your immediate response to this request is urgent. I would appreciate a response to this request by close of business tomorrow, August 29, 1995. I made a similar request to NIH by letter dated August 25, 1995, which it has still not responded to.

I look forward to hearing from you.

Sincerely,

Debra S. Katz

cc: Judith Wolfer, Esquire
Dr. Maryann Ma
/am

EXHIBIT 5
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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

MEMORANDUM

National Institutes of Health
Bethesda, Maryland 20892

DATE: August 29, 1995

FROM: Deputy Radiation Safety Officer, NIH
Chief, Technical Services Sections, RSB, TSS

SUBJECT: Intake Estimate and Fetal Dose equivalent

TO: Robert A. Zoon, M.E., M.S.
Radiation Safety Officer, NIH

The final assessment of Dr. Ma's intake, effective dose equivalent and dose equivalent to the fetus has been completed. The data is as follows:

Unweighted: 300 μCi

Weighted: 500 μCi

Individual Effective Dose Equivalent: 4.17 rem.

Fetal Dose Equivalent: 3.2 rem(@500 μCi maternal intake).

Our assessment, and assignment of a 500 μCi intake, is consistent with the data and has been further verified by the use of the computer model INDOSE, (Skrable Enterprises, INC.), which arrives at estimates of 342, 363 and 573 μCi (weighted, unweighted and iterative weighted fit of the data, respectively). The INDOSE model data is contained in attachment 1. This is a revised INDOSE report (8-25-95), the previous report dated (8-15-95) assumed that several urine data points represented multiple day collections. The 8-25-95 report uses the single day collection period as appropriate.

The assignment of the effective dose equivalent for the individual based 10 CFR 20.1204 (h)(1) is 500/600 * 5 rem = 4.17 rem.

Shawn W. Googins, M.S., CHP

cc: M. Noska
M. Newman
S. Austin
K. Austin
D. Case

attachments

EXHIBIT 15

EXHIBIT 5
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Attachment 1
Data Considerations and Use

The urine samples were a combination of 24 hour collections and, particularly at earlier time points, spot samples. Table 1 (attached) shows the concentration of activity for each sample, the decay corrected activity and the total activity based on the volume of each sample. Decay corrections were carried out to conform with the model in NUREG/CR-4884 which is based on the ICRP 30 inorganic phosphate model (1,2). Activities were corrected from the time of counting to the sample collection time or the midpoint of the sampling time for 24 hour samples and are listed in Table 2.

The inorganic phosphate model is considered to be valid in this case given the analysis of the material found in the water cooler conducted by Dr. Michael Cashel, and information regarding metabolism of ^{32}P labeled compounds by Dr. Shelby Berger. Furthermore, the biological elimination of the material is consistent with the ICRP 30 model.

Table 2 shows the activities which have been assigned to each day for the purpose of calculation. The date of intake was assigned based on physical data (contaminated clothing) as Wednesday, June 28, 1995. The activity in Day 2 is a combination of samples 1-10 and the pooled sample shown in Table 1. Sample 1 volume was adjusted so that the sample was representative of urine activity excreted for the eight hour period from 11:00, 6/29 to 19:00, 6/29. The volume of this sample was assigned based on an estimated average daily urine output of 3200 ml for 8/24's of a day. The urine output volume (3200 ml) is representative of Dr.Ma's actual output as opposed to Reference Woman (1000 ml). Thus, the estimated activity for the first sample is 7.76 μCi and the total for Day 2 is 9.68 μCi.

Sample 15, a 24 hour collection, encompassed both Day 3 and 4 post ingestion and was adjusted with 17/24's of the activity being placed into Day 3 and 7/24's being scaled-up to represent Day 4. Sample volume for samples 18 and 19 were adjusted accordingly and comprised Day 9 activity. Sample 23 was collected only for 12 hours, this activity was adjusted to a 24 hour collection and represents the sample for Day 21. All remaining samples were used "as is" with their known volumes. The "f" values presented in Table 2 are Intake Retention Fractions taken from NUREG/CR-4884, page B-484.

Table 2 also shows two estimates of intake based on our data. The first estimate is the unweighted least squares fit (ULSF) recommended in NUREG/CR-4884 (page 22) for multiple samples. The estimated intake using this method was 300 μCi. The second estimate is based on a weighted least squares fit (WLSF) as recommended by Skrable et al (3). This estimate was 500 μCi. Fetal dose equivalent is based upon a draft NUREG document (4).

References:

1. NUREG/CR-4884, "Interpretation of Bioassay Results", BNL, Upton, NY, 1987.

2. ICRP Publication 30, "Limits for Intakes of Radionuclides by Workers", Pergamon Press, Oxford, 1979.

3. Skrable, KW, Chabot, GE, French, CS, La Bone, TR. Chapter 14, Use of Multi-Compartment Models of Retention for Internally Deposited Radionuclides, in "Internal Radiation Dosimetry", Otto G. Raabe, ed. Health Physics Society Summer School, 1994.

4. Mel Sikov, Pacific Northwest Laboratories, personal communication.

Attachment 2
Tables

Table 1

Urinary Excretion Data, P-32 Ingestion[1]

Wendi Ma

Sample #	Date/Time	dpm/ml	Decay Corr.[2]	uCi/ml	Vol. (ml)	Tot. Act. (uCi)
1	6/29, 19:00	16,089	16154	0.00728	1067	7.76
2	6/29, 22:00	947	951	0.00043	190	0.08
3	6/29, 22:54	3496	3586	0.00162	32	0.05
4	6/30, 1:30	2135	2179	0.00098	50	0.05
5	6/30, 2:30	1500	1527	0.00069	43	0.03
6	6/30, 3:30	1391	1414	0.00064	41	0.03
7	6/30, 4:00	1508	1532	0.00069	44	0.03
8	6/30, 4:50	4195	4253	0.00192	47	0.09
9	6/30, 8:00	3531	3557	0.00160	45	0.07
10	6/30, 10:00	7185	7208	0.00325	41	0.13
Remainder 3-10, pooled[3]		2011	2047	0.00106	1283	1.36
					Total[4]	1.92
11	6/30, 13:00	2496	2511	0.00113	187	0.21
12	6/30, 13:45	3317	3332	0.00150	115	0.17
13	6/30, 15:40	2436	2437	0.00110	229	0.25
14	6/30, 18:00	1294	1480	0.00067	239	0.16
15	6/30-7/1[5]	3200	3576	0.00161	7281	11.73
16	7/3-7/4[6]	1897	2060	0.00093	7242	6.72
17	7/5-7/6[7]	3718	3827	0.00172	2763	4.76
18	7/6, 17:00	5158	5440	0.00245	95	0.23
19	7/6, 18:30	5123	5387	0.00243	108	0.26
20	7/7-7/8[8]	3461	4247	0.00191	4875	9.35
21	7/11-7/12[9]	2448	2608	0.00117	3040	3.57
22	7/16-7/17[10]	777	939	0.00042	3526	1.41
23	7/19[11]	1450	1530	0.00069	2354	1.62
24	7/25-7/26[12]	1109	1238	0.00056	1704	0.95
25	7/26-7/27[13]	1471	1564	0.00070	1973	1.39

Notes:

[1] Assumed intake occured on 6/28/95 @~11:00

[2] These values are decay corrected from the time of analysis to the midpoint of the sampling period

[3] Individual samples were taken for timepoints shown in samples 3-10; remainder of volumes were pooled

[4] Total activity for 6/29, 22:54 - 6/30, 10:00

[5] Assume collection was from 6/30, 18:00 - 7/1, 18:00

[6] 11:00, 7/3 - 14:00, 7/4

[7] 16:00, 7/5 - 15:00, 7/6

[8] 19:00, 7/7 - 19:00, 7/8

[9] 19:00, 7/11 - 19:00, 7/12

[10] 7:00, 7/16 - 7:00, 7/17

[11] 7:00, 7/19 - 19:00, 7/19

[12-13] Sample times not given; assuming midpoint of sampling period is 7:00

EXHIBIT 5
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Table 2
Total Urine Activity and Estimates of Intake

Day		Activity (μCi)		f
2		9.68		0.0504
3		9.1		0.0273
4		11.73		0.0183
6		6.72		0.0109
8		4.76		0.00745
9		7.31		0.00637
10		9.33		0.00553
14		3.57		0.00413
19		1.41		0.00237
21		3.24		0.0019
28		0.95		0.00109
29		1.39		0.00098
Intake (ULSF) = $(\Sigma f_i * A_i)/\Sigma f_i^2$ = 300 μCi				
Intake (WLSF) = $\Sigma A_i/\Sigma f_i$ = 500 μCi				

EXHIBIT 5
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Attachment 3
INDOSE Evaluation

EXHIBIT 5
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25-AUG-95

SKRABLE ENTERPRISES, INC.

P-32 Unweighted

INTAKE EVALUATION

********** RADIONUCLIDE **********

P-32
PHYSICAL HALF-LIFE = 1.429E+001 DAYS

********** RESPIRATORY AND GI TRACT INPUT - DOSIMETRY INPUT **********

ACUTE INGESTION INTAKE

STANDARD ICRP 30 RESPIRATORY TRACT AND GI TRACT MODELS USED

WITH FRACTIONAL UPTAKE FROM GI TRACT (F1) = 8.000E-001
STOCHASTIC (INGESTION) ALI = 6.000E+002 uCi

********** SYSTEMIC EXCRETION **********

FRACTION OF SYSTEMIC EXCRETION THROUGH URINE = 0.80

********** PARAMETERS FOR SYSTEMIC MODEL **********

COMPARTMENT	COEFFICIENT	BIOLOGICAL HALF-LIFE (DAYS)
1	1.500E-001	5.000E-001
2	1.500E-001	2.000E+000
3	4.000E-001	1.900E+001
4	3.000E-001	1.500E+003

********** INTAKE ESTIMATE **********

INTAKE ESTIMATED FROM INCREMENTAL URINE DATA
ESTIMATE OF INTAKE FROM UNWEIGHTED FIT OF DATA = 3.417E+002 uCi
EXPERIMENTAL ERROR IN INTAKE ESTIMATE = 7.521E+001 uCi

********** DOSIMETRY RESULTS **********

FRACTION OF STOCHASTIC ALI = 5.7E-001
COMMITTED EFFECTIVE DOSE EQUIVALENT = 2.848E+000 rem

EXHIBIT 5
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SKRABLE ENTERPRISES, INC.

P-32 Unweighted

INTAKE ESTIMATED FROM STATISTICAL EVALUATION OF
P-32 INCREMENTAL URINE DATA

TIME POST INTAKE (DAYS)	URINE COLLECTION PERIOD (DAYS)	BIOASSAY MEASUREMENT (uCi)	ERROR MEASUREMENT (uCi)	RETENTION FRACTION	UNWEIGHTED-FIT EXPECTATION MEASUREMENT (uCi)
2.00	1.00	9.680E+000	3.111E+000	4.483E-002	1.532E+001
3.00	1.00	9.100E+000	3.017E+000	2.427E-002	8.295E+000
4.00	1.00	1.173E+001	3.425E+000	1.630E-002	5.569E+000
6.00	1.00	6.720E+000	2.592E+000	9.666E-003	3.303E+000
8.00	1.00	4.760E+000	2.182E+000	6.626E-003	2.264E+000
9.00	1.00	7.310E+000	2.704E+000	5.662E-003	1.935E+000
10.00	1.00	9.330E+000	3.055E+000	4.917E-003	1.680E+000
14.00	1.00	3.570E+000	1.889E+000	3.109E-003	1.062E+000
19.00	1.00	1.410E+000	1.187E+000	1.955E-003	6.680E-001
21.00	1.00	3.240E+000	1.800E+000	1.642E-003	5.613E-001
28.00	1.00	9.500E-001	9.747E-001	9.062E-004	3.097E-001
29.00	1.00	1.390E+000	1.179E+000	8.330E-004	2.846E-001

25-AUG-95

SKRABLE ENTERPRISES, INC.

P-32 Weighted

INTAKE EVALUATION

********** RADIONUCLIDE **********

P-32
PHYSICAL HALF-LIFE = 1.429E+001 DAYS

********** RESPIRATORY AND GI TRACT INPUT - DOSIMETRY INPUT **********

ACUTE INGESTION INTAKE

STANDARD ICRP 30 RESPIRATORY TRACT AND GI TRACT MODELS USED

WITH FRACTIONAL UPTAKE FROM GI TRACT (F1) = 8.000E-001
STOCHASTIC (INGESTION) ALI = 6.000E+002 uCi

********** SYSTEMIC EXCRETION **********

FRACTION OF SYSTEMIC EXCRETION THROUGH URINE = 0.80

********** PARAMETERS FOR SYSTEMIC MODEL **********

COMPARTMENT	COEFFICIENT	BIOLOGICAL HALF-LIFE (DAYS)
1	1.500E-001	5.000E-001
2	1.500E-001	2.000E+000
3	4.000E-001	1.900E+001
4	3.000E-001	1.500E+003

********** INTAKE ESTIMATE **********

INTAKE ESTIMATED FROM INCREMENTAL URINE DATA
ESTIMATE OF INTAKE FROM WEIGHTED FIT OF DATA = 3.628E+002 uCi
EXPERIMENTAL ERROR IN INTAKE ESTIMATE = 8.329E+001 uCi

********** DOSIMETRY RESULTS **********

FRACTION OF STOCHASTIC ALI = 6.0E-001
COMMITTED EFFECTIVE DOSE EQUIVALENT = 3.024E+000 rem

EXHIBIT 5
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SKRABLE ENTERPRISES, INC.

P-32 Weighted

INTAKE ESTIMATED FROM STATISTICAL EVALUATION OF
P-32 INCREMENTAL URINE DATA

TIME POST INTAKE (DAYS)	URINE COLLECTION PERIOD (DAYS)	BIOASSAY MEASUREMENT (uCi)	ERROR MEASUREMENT (uCi)	RETENTION FRACTION	WEIGHTED-FIT EXPECTATION MEASUREMENT (uCi)
2.00	1.00	9.680E+000	3.111E+000	4.483E-002	1.626E+001
3.00	1.00	9.100E+000	3.017E+000	2.427E-002	8.808E+000
4.00	1.00	1.173E+001	3.425E+000	1.630E-002	5.913E+000
6.00	1.00	6.720E+000	2.592E+000	9.666E-003	3.507E+000
8.00	1.00	4.760E+000	2.182E+000	6.626E-003	2.404E+000
9.00	1.00	7.310E+000	2.704E+000	5.662E-003	2.055E+000
10.00	1.00	9.330E+000	3.055E+000	4.917E-003	1.784E+000
14.00	1.00	3.570E+000	1.889E+000	3.109E-003	1.128E+000
19.00	1.00	1.410E+000	1.187E+000	1.955E-003	7.093E-001
21.00	1.00	3.240E+000	1.800E+000	1.643E-003	5.960E-001
26.00	1.00	9.500E-001	9.747E-001	9.062E-004	3.288E-001
29.00	1.00	1.390E+000	1.179E+000	8.330E-004	3.022E-001

25-AUG-95

SKRABLE ENTERPRISES, INC.

P-32 Iter. Weighted

INTAKE EVALUATION

********** RADIONUCLIDE **********

P-32
PHYSICAL HALF-LIFE = 1.429E+001 DAYS

********** RESPIRATORY AND GI TRACT INPUT - DOSIMETRY INPUT **********

ACUTE INGESTION INTAKE

STANDARD ICRP 30 RESPIRATORY TRACT AND GI TRACT MODELS USED

WITH FRACTIONAL UPTAKE FROM GI TRACT (F1) = 8.000E-001
STOCHASTIC (INGESTION) ALI = 6.000E+002 uCi

********** SYSTEMIC EXCRETION **********

FRACTION OF SYSTEMIC EXCRETION THROUGH URINE = 0.80

********** PARAMETERS FOR SYSTEMIC MODEL **********

COMPARTMENT	COEFFICIENT	BIOLOGICAL HALF-LIFE (DAYS)
1	1.500E-001	5.000E-001
2	1.500E-001	2.000E+000
3	4.000E-001	1.900E+001
4	3.000E-001	1.500E+003

********** INTAKE ESTIMATE **********

INTAKE ESTIMATED FROM INCREMENTAL URINE DATA
ESTIMATE OF INTAKE FROM ITERATIVE
WEIGHTED FIT OF DATA = 5.732E+002 uCi
EXPERIMENTAL ERROR IN INTAKE ESTIMATE = 1.354E+002 uCi

********** DOSIMETRY RESULTS **********

FRACTION OF STOCHASTIC ALI = 9.6E-001
COMMITTED EFFECTIVE DOSE EQUIVALENT = 4.776E+000 rem

SKRABLE ENTERPRISES, INC.

P-32 Iter. Weighted

INTAKE ESTIMATED FROM STATISTICAL EVALUATION OF
P-32 INCREMENTAL URINE DATA

TIME POST INTAKE (DAYS)	URINE COLLECTION PERIOD (DAYS)	BIOASSAY MEASUREMENT (uCi)	ERROR MEASUREMENT (uCi)	RETENTION FRACTION	ITERATIVE WEIGHTED-FIT EXPECTATION MEASUREMENT (uCi)
2.00	1.00	9.680E+000	3.111E+000	4.483E-002	2.569E+001
3.00	1.00	9.100E+000	3.017E+000	2.427E-002	1.391E+001
4.00	1.00	1.173E+001	3.425E+000	1.630E-002	9.341E+000
6.00	1.00	6.720E+000	2.592E+000	9.666E-003	5.540E+000
8.00	1.00	4.760E+000	2.182E+000	6.626E-003	3.798E+000
9.00	1.00	7.310E+000	2.704E+000	5.662E-003	3.245E+000
10.00	1.00	9.330E+000	3.055E+000	4.917E-003	2.818E+000
14.00	1.00	3.570E+000	1.889E+000	3.109E-003	1.782E+000
19.00	1.00	1.410E+000	1.187E+000	1.955E-003	1.120E+000
21.00	1.00	3.240E+000	1.800E+000	1.643E-003	9.416E-001
28.00	1.00	9.500E-001	9.747E-001	9.062E-004	5.194E-001
29.00	1.00	1.390E+000	1.179E+000	8.330E-004	4.774E-001

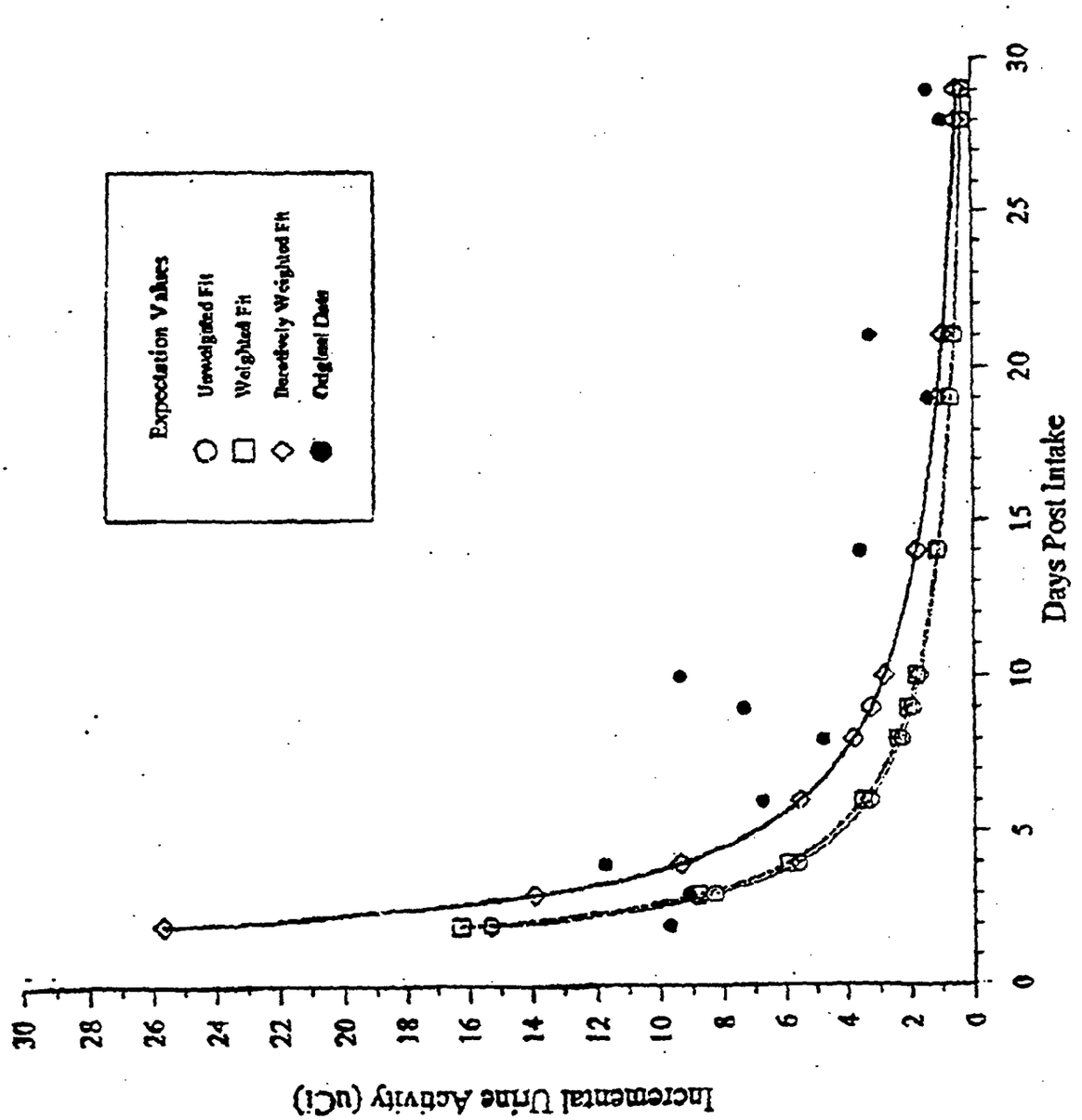

EXHIBIT 5
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

SEP 02 1995

August 30, 1995

Debra S. Katz, Esquire
Bernabei & Katz
1773 T Street, N.W.
Washington, D.C. 20009

RE: Radiation Contamination of Dr. Maryann Wenli Ma; National Institutes of Health License No. 19-00296-10

Dear Ms. Katz:

This letter responds to your August 28, 1995 letter. Your letter expressed concerns regarding the analyses of body fluid samples taken from your client, Dr. Maryann Ma, indicated that you sent certain samples to TMA/Norcal for an independent analysis, and requested that the Nuclear Regulatory Commission (NRC) pay for this independent analysis or direct the National Institutes of Health (NIH) to do so.

First, we would like to correct and clarify some of the information contained in your letter. The samples that were sent to the Oak Ridge Institute for Science and Education (ORISE) for analysis were sent by the NRC in order to confirm the isotopic analyses performed by the NIH Radiation Safety Branch (RSB). This work was performed by personnel in ORISE's Environmental Survey and Site Assessment Program (ESSAP) under a contract with the NRC. The four samples were from urine sample #1, urine sample #14, urine sample #15 which was a 24-hour sample collected between June 30 and July 1, and the blood sample provided by Dr. Ma on June 30, 1995 at the National Institutes of Health Occupational Medicine Section facility. ESSAP was only asked to confirm the isotopic analyses performed by the RSB, not to assess Dr. Ma's intake of phosphorus-32 (P-32).

NRC has contracted with ORISE's Radiation Internal Dosimetry Center (RIDIC) to perform: (1) an independent analysis of Dr. Ma's intake of P-32; (2) an assessment of Dr. Ma's internal dose from the P-32 intake; and (3) an assessment of the dose to Dr. Ma's fetus. Data from all 25 urine samples provided by Dr. Ma were provided to RIDIC to support these assessments. RIDIC provided us with their assessment on August 16, 1995, and currently is reviewing the assessment provided by the RSB on August 18, 1995. Once we have received RIDIC's final assessment, we intend to provide the RSB assessment and RIDIC's assessment to a third party for independent review. NRC currently is pursuing a contract to accomplish this review.

NRC will issue a report when our activities are complete. This report will include the results of this independent review.

EXHIBIT 16

EXHIBIT 5
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In your letter you stated your concern that NIH failed to have an independent verification of analyses performed on urine samples collected after July 1, 1995. NRC has confidence in NIH's ability to analyze these samples accurately. This confidence is based on the results of the previously discussed confirmatory analyses performed for NRC by ESSAP as well as confirmatory analyses of water samples from the contaminated water cooler which were performed by the NRC Region I laboratory. Nevertheless, in recognition of your concern, NRC has requested that NIH provide samples of urine provided by your client on July 1, July 6, July 12, and July 26, 1995. These additional samples will be analyzed in the NRC Region I laboratory within the next 7 days.

In light of the analyses that have been conducted and that are planned as noted above, the NRC finds it unnecessary to pay for the independent analysis that you requested TMA/Norcal to conduct.

Sincerely,

Charles W. Hehl, Director
Division of Radiation Safety
and Safeguards

NIH failed to lock up radioactive materials in '94

by Myra Monath Pariner
Staff Writer

Officials at the National Institutes of Health (NIH) in Bethesda failed to lock up some radioactive material for more than five weeks last summer because they were experimenting with a new, more liberal policy on handling the material.

They notified federal regulators that they were trying the new system by sending them a copy of their new policy. The agency was not penalized for straying from federal rules on radioactive safety, said Frank Ingram, a spokesman for the Nuclear Regulatory Commission (NRC).

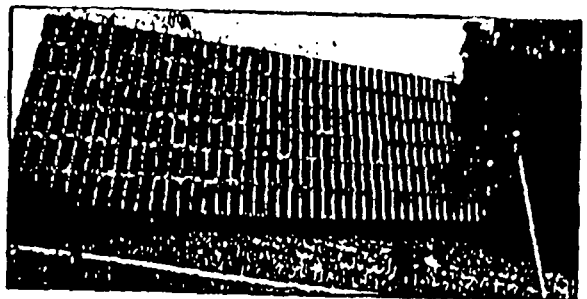
Although NIH dropped the experiment last July, NIH chief Harold Varmus began to push for a permanent rule change last summer so that researchers could stop locking up radioactive material above certain levels.

A tape of a Nov. 21, 1994 meeting with NRC and NIH officials shows an NRC official noting that NIH had written the commission to say it was deploying the new policy on its own. "You...tried this new security policy for about four to five weeks from the end of June 'til the conference," the NRC official said.

The purpose of the November meeting was to discuss a proposal made to the NRC by Varmus that NIH be granted a special exemption that would allow it to stop locking away radioactive material up to 10 times above levels now specified for lockup. He argued in a letter to the NRC that current regulations are "an impediment" to research. Late last month, without any public notice, NIH abruptly ended its effort to win the exemption.

The move came as a team of NRC investigators and officials from other agencies, including the Federal Bureau of Investigations (FBI), continued their criminal and safety probes of a June 29 incident in which NIH discovered that a pregnant scientist apparently had ingested 200 to 300 microcuries of radioactive phosphorus, which is within the federal safety limit for workplace exposure. Twenty-six others also have been found to be contaminated.

A top NRC investigator said this week that initial findings strongly suggest that the June 29 contamination was deliberate. The NRC will conclude its investigation in mid-August and issue a report 30 days later. Neither the NRC, the FBI nor NIH will comment on their investigations.



Building 37, on the NIH campus

The investigations are being conducted to find out how at the end of June a water cooler in Building 37 became contaminated with phosphorus 32, apparently leading to the contamination of NIH employees.

On NRC's orders, NIH has completed testing the urine of more than 622 workers who work in or who have visited Building 37, and will soon begin random testing of workers in other campus buildings.

Information about the 1994 period of experimentation — in which radioactive materials at levels 10 times above what must normally be locked away were allowed to be left unsecured — is mentioned in a tape of the November 1994 meeting at NRC's Rockville headquarters. NRC regulations say that NIH must lock up all radioactive materials above a certain level when not in use in laboratories.

A member of the North Bethesda Congress, a local citizens' group, copied the meeting and gave a copy to the *Gazette* last week. The tape shows some NRC officials apparently leaning toward granting NIH the special exemption.

Others from the NRC on the tape raised questions about the security not only of radioactive materials but of biohazards and toxic chemicals in NIH laboratories. Both NIH and NRC officials noted that NRC officials had been able to walk unchallenged into NIH labs at the spring 1994 inspection.

Ronald Bellamy, an NRC official who was at the November meeting, said the NRC will not comment on any questions related to the tape because there is no way to know whether it was doctored. Bellamy is chief of the Nuclear Materials Safety Branch of the NRC's region 1 in King of Prussia, Pa.

NIH spokesman Anne Thomas said NIH emphasizes "security at the local level where the materials are actually used" and will continue to do so. Thomas would not comment further on NIH's decision July 20 to drop its battle to loosen regulations for handling radioactivity. NRC official Bellamy said NIH has not informed the NRC in writing of the decision, although NRC officials expect such notification.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

OCT 31 1994

Mr. John McGraph
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: License No. 10-00296-10

Dear Mr. McGraph:

The recent NRC enforcement actions in the matter of security of small quantities of licensed radioactive materials at the NIH and other research institutions are potentially a serious impediment to the effective conduct of biomedical research. These actions are unnecessary, considering the activity levels of radioactive materials normally employed in biomedical labelling procedures. As you know, I have recently written to the Chairman of the Nuclear Regulatory Commission on behalf of the biomedical research community regarding these enforcement initiatives.

To resolve the concerns of both the NRC and the biomedical research community, I propose a reasonable threshold be placed on those activity levels that would demand the highest levels of security during use and storage. Regulations specifying these threshold values already exist for the posting of rooms and the labelling of specimens; we propose to extend these thresholds to the issue of security.

Hence, the NIH requests an amendment to License No. 10-00296-10 to establish and permanently implement the policy submitted as an Interim Security Policy (ISP) to the NRC for comment on June 3, 1994, in conformance with Action 5 in the Confirmatory Action Letter (CAL), number 1-94-006.

Enclosed for your review is our proposed security policy. It requires that any use of radioactive materials which exceeds ten times the activity listed in Appendix C of 10 CFR 20 *per container* must be afforded the most stringent security (i.e., under lock and key or direct oversight at all times). Activities *per container* at or below the threshold limit may be used in posted radioactive material use areas without the requirement for direct oversight or lock and key. We believe that approval of a reasonable exemption threshold is

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consistent with an approval already granted the NIH for corridor storage of radioactive materials and published NRC technical opinions on regulatory requirements for the storage and control of licensed material.

In support of the numerical criteria for these thresholds, we note the following regulatory thresholds, which are part of the revised 10 CFR 20: According to §20.1905(a), a licensee is not required to label containers holding licensed materials in quantities less than the quantities listed in Appendix C. Likewise, according to §20.1902(e), areas or rooms where licensed materials are used or stored are not required to be posted unless the amount of licensed materials exceeds ten times the quantity of such material specified in Appendix C. These thresholds, in the labeling and posting requirements, set precedents for the quantities of materials that require other regulatory precautions such as enhanced security.

Additional support for this concept would appear to be cited in the NRC publication NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20," which is a summary reflecting NRC staff decisions and technical opinions on aspects of the revised 10 CFR 20 regulatory requirements. Section 2.8, "Subpart I - Storage and Control of Licensed Materials," contains Question 129, which requests clarification of how the requirements of 10 CFR 20.1801 and 20.1802 will be imposed by the NRC. The question and NRC responses are listed in the following text:

"Question 129: 10 CFR 20.1801 and 20.1802 do not specify quantities of radioactive material below which unauthorized access to, unauthorized removal from, or the maintenance of constant surveillance over, are not required in controlled areas. Will these requirements be imposed (a) on all quantities of licensed material, however small and (b) on quantities that are exempt from labeling by 10 CFR 20.1905(a) and (b)?

Answer: (a) No. The requirements of 10 CFR 20.1801 and 20.1802 are not new; they are essentially the same as the requirements of 10 CFR 20.207(a) and 20.207(b) except that the revised Part 20 requirements apply to controlled areas as well as unrestricted areas. NRC will continue to enforce these requirements as it has in the past. (b) No. (References: 10 CFR 20.1801, 20.1802, 20.1905)"

The NRC answer to Question 129 clearly indicates the intention of the NRC to allow approval of a reasonable exemption threshold for security of radioactive materials in use within posted radioactive material laboratories.

During discussions between the NRC and NIH in 1978, agreement was reached that radioactive materials may be stored in corridors in unlocked refrigerators or freezers if the activity per container was within the limits specified in the regulations as exempt quantities. This has been incorporated within the NIH corridor policy and has been approved by the NRC in each NIH license renewal since this date.

It appears reasonable to allow a higher threshold for security inside a posted radioactive

material laboratory than in an unrestricted area such as a corridor. Our proposed threshold of activity per container, which will require the strictest security provisions, is ten times the activity listed in Appendix C of 10 CFR 20. This level, which we consider safe and reasonable, will not place an undue burden, inappropriate cost, or cause a negative impact on valuable biomedical research.

The NIH has operated a safe and responsible program for the use of radionuclides since the inception of its license. This has been done without requiring that all quantities of radionuclides, no matter how small, be either under surveillance or secured. Approval of the license amendment request will allow the NIH to continue program operation with greater security and without unnecessary expense and interference in the conduct of biomedical research.

We would appreciate your expeditious review and approval of this license amendment request. At this time, the NIH also requests an extension to the November 1, 1993 due date for the implementation of the permanent security policy, pending an NRC decision on this amendment request.

If you have any questions or need clarifications on this matter, please contact Mr. Ted W. Fowler, NIH Radiation Safety Officer, or Mr. Robert A. Zoon, Acting Chief of the NIH Radiation Safety Branch, at (301) 496-2254.

Sincerely,

Harold Varmus

Harold Varmus, M.D.
Director

Enclosure

cc: Dr. Selin, Chairman, Nuclear Regulatory Commission
Dr. Liotta, Chairman, Radiation Safety Committee, NIH
Dr. Wyatt, Assistant Director for Intramural Affairs, NIH
Mr. Ficca, Associate Director for Research Services, NIH
Dr. McKinney, Director, Division of Safety, NIH
Mr. Fowler, Radiation Safety Officer, NIH
Mr. Zoon, Acting Chief, Radiation Safety Branch, NIH

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National Institutes of Health
Security Policy for Radioactive Materials

Authorized Users are responsible for the security of all radioactive materials which they receive. The U.S. Nuclear Regulatory Commission (NRC) regulations from 10 CFR Part 20 Subpart I are as follows:

§ 20.1801 Security of stored material:

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

§ 20.1802 Control of material not in storage:

The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

To ensure proper security of radioactive materials, the following security policy is established:

1. Any radioactive material in use in a laboratory which exceeds ten times the activity levels of Appendix C of 10CFR20 per container must be attended or secured by locking the room when not attended.

   Containers of radioactive material exceeding ten times the activities in Appendix C of 10CFR20 stored in a room must be secured in locked cabinets, locked refrigerators, locked freezers or another similarly locked container unless the room is locked or occupied.

2. Radioactive materials stored in corridor refrigerators or freezers must be secured in accordance with the following:

   a. Containers of radioactive materials which exceed the activity quantities of Appendix C of 10CFR20 must be in locked storage.

   b. Containers of radioactive materials which are less than or equal to the Appendix C quantity may be stored without locking.

Implementation of this policy requires that the following procedures be observed:

- Radioactive materials delivered to Authorized Users must be immediately stored in a posted radioactive materials laboratory and secured against unauthorized removal from the place of storage.
- Radioactive materials being transported through unrestricted areas must be attended at all times.
- Persons who are unknown to the occupants of a radionuclide use area should never be permitted into the area without being requested for identification and admitted only with a legitimate reason for entry.

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The following exceptions are in place:

- Buildings or areas within buildings which have access control by card key or by use of security guards are not subject to the above room locking requirements.

- Radioactive waste must be collected and stored in a properly posted restricted area until pickup. Unoccupied labs will not be required to be locked due to the presence of only radioactive waste. However, we strongly recommend that lab staff make prompt requests to remove radioactive waste once containers are at recommended capacities.

- Radioactive materials use is not permitted in any corridor, except for counting samples in liquid scintillation counters and gamma counters. Corridor storage of materials is permitted in accordance with Instruction 2. above.

  Building 49 has an additional exemption for its equipment alcoves, separately communicated to its occupants.

Application of this policy and execution of these procedures are the responsibility of the designated Authorized User for the laboratory where the radioactive materials are used and the Authorized User who ordered the radioactive materials. Authorized Users will be held accountable for any violations and appropriate enforcement actions will be taken by the Radiation Safety Officer, NIH. Questions should be directed to the Radiation Safety Branch at 496-5774.

Security & Corridor Storage Limits for Common Biomedical Nuclides

	Security Limit[1] (μCi)	Corridor Storage Limit[2] (μCi)
Laboratory Nuclides:		
^{3}H	10000	1000
^{14}C	10000	1000
^{32}P	100	10
^{33}P	1000	100
^{35}S	1000	100
^{45}Ca	1000	100
^{51}Cr	10000	1000
^{125}I	10	1
^{131}I	10	1
Clinical Nuclides:		
^{18}F	10000	1000
^{67}Ga	1000	100
^{90}Y	100	10
^{99m}Tc	10000	1000
^{111}In	1000	100
^{201}Tl	10000	1000

[1] The **Security Limit** is the maximum amount of a nuclide per container (e.g. vial, tube or flask), that can be in use within a room or laboratory without requiring someone in attendance or without locking the room. These amounts are ten times the activity listed in Appendix C of 10CFR20.

Use of amoun above the limit require the enhanced security precautions of locked storag eas and locked rooms when the materials are in use but not attended.

[2] The **Corridor Storage Limit** is the maximum amount, per vial or sample, that may be stored in refrigerators, freezers or other storage located in corridors. The limit is the amount listed in Appendix C of 10CFR20.

For limits on nuclides not listed above call the Radiation Safety Branch (x65774).

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NATIONAL CANCER INSTITUTE
FREDERICK CANCER RESEARCH FACILITY
P.O. Box B, Frederick, Maryland 21701

March 11, 1987

Director
Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

SUBJECT: RESPONSE TO NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY (NRC INSPECTION NUMBER 86-01)

Dear Sir:

The enclosed report is submitted by Program Resources, Incorporated (PRI), in response to the provisions of 10 CFR 2.201 (reference Docket Number 30-19755, License Number 19-21091-01, EA 87-19, dated February 26, 1987). Please note that, in addition to this report, we have elected to pay the civil penalty recommended by the NRC. We also reaffirm our commitment to administer the license in accordance with all NRC regulations and feel that the actions taken as a result of the NRC report have greatly strengthened our ability to do so. We hope you will agree with this assessment.

Sincerely,

Raymond V. Gilden, Ph.D.
Director, Frederick Operations
Program Resources, Inc.
NCI-Frederick Cancer Research Facility

cc: Regional Administrator
U.S. Nuclear Regulatory Commission, Region I

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A. Violation

An overexposure to the left hand of a radiation worker in our Radiation Program #84-03, Room 122 of Building 539, NCI-FCRF, was recorded on the ring badge which was collected on September 4, 1986 and processed by Landauer Labs who notified the Radiation Protection Office of the result by phone on Friday, September 19, 1986. This overexposure occurred substantially as described in the report of inspection 86-01, 1-15-87 and the Notice of Violation, 2-27-87.

Cause

The immediate cause of the overexposure was because of the worker holding one or more 10 mCi vials of phosphorus-32 orthophosphate without shielding while opening the foil and septum covering. Upon investigation of the incident it was determined that the worker had not received training as specified in our Manual, Section IC2b, D2c, D2d, and 10 CFR 19.12, for the specific protocol in use or for handling high activity levels of high energy beta emitters.

In addition, the worker's prior experience was misrepresented on the Format for Training and Experience submitted to the Radiation Protection Office at the time of application for isotope use clearance. This form (Attachment A) indicates use of up to 250 mCi of sulfur-35 and 100 mCi of phosphorus-32 at two different institutions. Following the incident she told the NRC inspector that this was incorrect and that she had not handled more than 0.1 mCi of phosphorus-32 prior to work at NCI-FCRF.

Corrective Action Taken

The worker and the Principal Investigator were notified immediately of the ring badge result. The worker was prohibited from using any isotope until further investigation to determine the cause of the report.

On Monday morning September 22, 1986, the incident was reviewed with the Principal Investigator and the worker. It was determined that there was probable cause to assume that the reading represented a real exposure. Consequently, the worker was prohibited from using any high energy beta emitters which could increase her cumulative exposure for the next six months. (Attachment B).

Additional discussions with the Principal Investigator were focused on his obligations as the supervisor and trainer of his program. An attitude of increased awareness was taken and passed on in this program, as evidenced by meetings held with his laboratory workers (Attachments C & D).

The hazard of phosphorus-32 coupled with the level of use of this isotope at the NCI-FCRF was taken into consideration and additional safety information was distributed to all programs (Attachment E).

Corrective Action to be Taken

Protective equipment for handling high activity levels of all isotopes in current use at the FCRF is available from the Radiation Protection Office. Many programs with specific needs already have their own individual equipment. Users within Program 84-03 have been instructed on what equipment should have been used and it has been placed in their laboratory. Specifically, a lucite holder for the stock vial has been made. This allows the vial to be secured for manipulation while being shielded at the same time (Attachment F). A lucite box designed to hold and shield petrie dishes while cell labeling is in progress has been placed in the same laboratory.

Use of these protective devices was discussed in detail with a radiation worker in Program 84-03 prior to the overexposure incident; use of these devices would have prevented the incident.

The availability of such safety equipment has been made known to each program. Specifically, the lucite stock vial holder will be required for any program using 10 mCi vials of any form of phosphorus-32.

As part of a program to increase the level of training provided to all workers, video programs of proper technique for handling phosphorus-32 are being made for inclusion in the training given to all workers.

Compliance

Our license is currently in compliance with 10 CFR 20.101. The single overexposure reported in September 1986 is the first such reportable exposure in 14 years of operation at the NCI-FCRF. This was an isolated incident compounded by misrepresentation of past experience and lax supervision of a new protocol. With the increased training of Principal Investigators and workers already in place, such conditions should not be repeated.

B. Violation

A failure to adequately instruct and supervise a radiation worker, as required in the NCI-FCRF Radiation Manual section IC2b and 10 CFR 19.12 did occur in the NCI-FCRF Radiation Program 84-03.

Cause

The Principal Investigator of Program 84-03 failed to observe and train, as necessary, a professional employee whose actual training and experience with isotopes was not as represented to the NCI-FCRF Radiation Protection Officer (Attachment A, see above).

Corrective Action Taken

The Principal Investigator of Program 84-03 was instructed on all aspects of the duties and obligations of the position. The requirement for training on isotope and specific protocols in use in his own program was emphasized. Increased awareness and involvement in the management of his program is evidenced by the information distributed to his workers at instructional laboratory meetings (Attachments C & D).

Upon further investigation of the overexposure incident, the Radiation Safety Committee concluded that more than haste or oversight had contributed to the opportunity for the incident to occur. The absence of proper shielding devices, remote tools, and prior instruction caused the Radiation Safety Committee to impose a suspension on all use of phosphorus-32 orthophosphate, the isotope form and use which led to the problems (Attachment G). Resumption of experiments with orthophosphate in 10 mCi amounts and greater for cell labeling is contingent upon the establishment of acceptable training and supervisory procedures.

Corrective Action to be Taken

Meetings with all Principal Investigators will be held to review and clarify all duties and obligations of Principal Investigators within their programs. An agenda for these meetings has been developed by the Radiation Protection Office and the Radiation Safety Chairman and approved by the Radiation Safety Committee (Attachments H & I). Maintenance of programs in good standing, post April 15, 1987 is dependent on the Principal Investigator's attendance at one of these meetings. Groups shall not exceed twelve Principal Investigators, and will include appropriate administrative personnel to appraise them of facility and license obligations.

Future Principal Investigators for new programs shall receive similar materials, individually or in a group as appropriate, prior to being certified.

Compliance

All current programs shall have had the proposed training by April 15, 1987.

C1,a,b. Violation

a. During the month of August 1986, a radiation worker in Radiation Program 84-03 approved to work with 1 mCi of phosphorus-32 handled stock vials of 10 mCi of phosphorus-32 for experiments using up to 8 mCi of orthophosphate for cell labeling.

b. In July 1986, a radiation worker in Program 84-03 ordered and received 50 mCi of phosphorus-32 orthophosphate. Although the laboratory had an authorized inventory limit of 50 mCi for all forms of phosphorus-32, the original program application stated that the total inventory for orthophosphate would be limited to 20 mCi. This was a violation of the originally requested and approved program limits.

Cause

The Radiation Area Supervisor and the members of the laboratory program were not familiar with the inventory limits in the original program application; the Principal Investigator and Radiation Area Supervisor had failed to post or communicate this information.

Personnel were similarly unfamiliar with individual restrictions. Approval memos had not been discussed between the Principal Investigator and the new applicant.

Corrective Action Taken

Meetings with the Principal Investigator and the Radiation Area Supervisor have made them more acutely aware of the distinctions between individual and program limits and requirements. In subsequent meetings with the radiation workers, the Principal Investigator has communicated this information verbally and in writing to all (Attachment D).

A reevaluation of all personnel limits in Program 84-03 has been conducted and an update submitted to the Radiation Safety Office for approval (Attachment J).

A reduction in potential new isotope use has been effected by utilizing other qualified services for protein iodinations. This has eliminated the potential use of unbound iodine in this laboratory (Attachment K).

A notice reminding all Principal Investigators of their obligations and responsibilities under the NCI-FCRF license was issued to reinforce the above attitudes facility-wide. A signed copy has been received in acknowledgement from every Principal Investigator (Attachment L).

A Directorate within the NCI-FCRF which includes ten Radiation Programs has established a committee responsible for guidance and internal enforcement of radiation safety practices and policies (Attachments M & N). This committee has established strict policies for record keeping and has established enforcement procedures to be used for non-compliance. All policies of this committee are independent from and in addition to the NCI-FCRF Radiation Safety Committee. The activity of this committee is strong evidence of cooperation and recognition of responsibility from this Directorate.

Corrective Action to be Taken

The proposed meetings with Principal Investigators (see B above) will include a review of the duties of the Principal Investigator as a major focus of the agenda. This will concentrate on aspects of program limits, personal limits, and proper training and supervision (Attachment H). Attendance at these meetings is mandatory; Programs not represented by April 15, 1987 will be considered in suspension until training has been received.

The Training and Experience Form used by new laboratory personnel to apply for isotope use privileges has been modified to include a section for the applicant to identify the isotope clearance and use level being requested and signature lines for both the applicant and the Principal Investigator (Attachment O). This has been done for the applicant to verify the accuracy of the information presented and to ensure that the Principal Investigator is fully aware of the prior experience, and possible limitations, of the new applicant.

Compliance:

This license shall be in compliance with all aspects of the NCI-FCRF Manual, Section C or or before April 15, 1987.

C2. Violation

On December 17, 1986, a sink in room 31-16, Building 560, Radiation Program 81-09 was found to be contaminated. Upon analysis the contamination was confirmed to be iodine-125.

Cause

A radiation worker in Program 81-09 was found to have washed radioactive glassware in the sink and allowed the washings to go to the drain, rather than retaining them for separate disposal, as required. This individual had attended the bimonthly training session.

Corrective Actions Taken

The individual responsible for this violation was privately instructed on proper disposal techniques, and assigned an experienced technician to do radioisotope manipulations for him (Attachment P).

When a second incident of minor contamination on a bench was traced to the same individual, the Principal Investigator suspended him from all further radiation work (Attachment Q). This suspension was enforced without prior consultation with either the Radiation Protection Office or the Radiation Safety Committee, reflecting that the Principal Investigator was exerting strong internal control over his program.

Corrective Action to be Taken

The training session currently offered for all new radiation workers is to be modified in several ways to improve the information provided and increase the total coverage of personnel.

The current bimonthly course presents approximately 5 hours of instruction on radiation physics, 2 hours on general radiation safety principles, and 1 hour of NCI-FCRF policy instruction, which includes discussion of required record keeping and instruction on proper waste handling procedures (Attachment R).

The proposed course outline will continue the bimonthly presentation of radiation physics and general radiation safety principles. However, the time allotted to this course will be one full day, 8 hours. This will allow additional instruction in principles of radiation safety to be developed.

In alternating months the Radiation Protection Office will present a 4 hour course of safety training and policies and procedures (Attachment S). The safety content of this portion will be developed from video tapes already available, and video demonstrations of specific experimental design as typically encountered at FCRF. Additionally, more time will be allotted to the specific policies at NCI-FCRF.

Attendance requirements will be changed to correct a previous loophole which allowed some personnel to miss the instruction on policies and procedures as applied at FCRF. The Introduction to Radiation Physics will be required of all new radiation workers unless they can demonstrate that they have taken the equivalent course at NIH. The course at NIH was developed by Dr. W. Schadt who is the consultant instructor for our course of identical content. The Introduction to Radiation Practices at FCRF will be required of all new personnel, regardless of prior work experience. This change will ensure that all personnel are presented material on both safety and local policy.

Foreign language translations of the general rules for isotope handling at the NCI-FCRF have been prepared and distributed in French, Italian, German, Spanish, Japanese, and Chinese (Attachment T). We feel that this is a unique and highly effective way to assure that the numerous Visiting Scientists at the NCI-FCRF are fully cognizant of all radiation safety policies and requirements. These were completed and distributed in October, 1986.

Compliance

All radiation programs and workers are expected to be in compliance with all requirements of the NCI-FCRF policy at the current time. Modifications to the training program are scheduled to be effective by May 1987.

C3. Violation

On or about August 30, 1985, the NCI-FCRF Radiation Protection Office was notified that 5 mCi of chromium-51 belonging to our license had been found in a Uniformed Services University laboratory. No transfer papers had been processed. Upon investigation it was determined that the isotope was on the inventory of our program 81-09; the Principal Investigator admitted that he had transported the isotope and failed to notify the Radiation Protection Office prior to the transfer.

Cause

The NCI investigator was collaborating with a scientist at the Uniformed Services University and attempted to provide reagent to complete work in a short time frame on a weekend. He was aware that proper procedures were not being followed, but intended to follow up when there was more time.

Corrective Action Taken

The Principal Investigator of 81-09 was counseled at length about the serious implications of any violation of NCI-FCRF or NRC regulations by the Director of Operations, Director of Safety, and the General Manager. The isotope in question was actually logged off the laboratory inventory, the material was packaged safely and properly, and the Principal Investigator cooperated in every way to resolve problems created. If our Radiation Protection Office would have been notified as required this would have been a legal transfer. At the time, these mitigating factors caused no action to be taken against the radiation program.

Memoranda of suspension of worker privileges (Attachments P & Q) issued by the Principal Investigator of program 81-09 provide clear evidence that he is now taking an active and serious role in the oversight of the radiation safety aspects of his program.

Corrective Action to be Taken

Since this incident, the Radiation Safety Committee has voted to temporarily suspend any program and its Principal Investigator for any similar violation. The terms of such a suspension shall be determined by the circumstances.

Future training sessions with radiation workers and Principal Investigators shall emphasize adherence to all regulations, without exception. Due to the presence of numerous government investigators on our license, and our proximity to the National Institutes of Health, Bethesda, MD, special emphasis will be placed upon strict adherence to proper transfer procedures.

Compliance

All programs are currently in compliance for proper transfer procedures, and strict enforcement will be administered to maintain total compliance.

General Surveillance

The following actions have either been taken, or will be instituted shortly, to increase and improve the surveillance of all aspects of radiation program operations.

1) The Format for Training and Experience form used to amend personnel to a radiation program has been modified (Attachment O) to provide for signature verification of the submission by both the applicant and the Principal Investigator. This has been done to prevent a recurrence of the misrepresentation of experience which occurred in conjunction with the incident cited in sections B and C1a of the Notice of Violation.

2) The letter of approval for new personnel shall be routed through the Principal Investigator rather than directly to the new applicant. This, in conjunction with (1) above is being done to address issues noted primarily in sections C1a and C1b of the Notice of Violation. These two steps should serve to increase the Principal Investigator's awareness of the qualifications and limitations of each new worker.

3) New training materials are being developed which will be used in expanded Introduction and Training Sessions to provide more basic safety information prior to specific training in individual laboratories. The new materials will include video tape enactments of experimental situations and techniques likely to be encountered in typical laboratories here. These materials are intended to broaden the basic safety training an individual receives from the Radiation Protection Office, and will be aimed to help workers identify a potentially dangerous situation before harm occurs. These steps are being taken to improve deficiencies which resulted in items A and B of the Notice of Violation.

4) An independent consultant will be contracted to perform periodic reviews of the radiation safety programs under this license. These audits will be for the purpose of assisting the individual programs and the Radiation Safety Committee in determining where potential shortcomings may exist. The use of the consultant will not replace any functions or responsibilities of the Radiation Protection Office or individual Principal Investigators. The Radiation Safety Committee felt that an outside consultant could be more objective and candid in evaluating our programs, could provide a professional perspective gained from experience with other institutions, and would be more thorough than an internal committee operating with less time and experience for this type of function.

All recommendations from such audits will be reviewed by the Principal Investigator of the individual program, and by the Radiation Safety Committee as a whole. Any modifications to program structure will be done by the Principal Investigator. Any disciplinary action, if deemed necessary, would be decided and imposed by the Radiation Safety Committee.

5) The Radiation Safety Committee will meet quarterly, rather than semi-annually as at present, to maintain a more current awareness of all aspects of the current radiologic programs. Monthly written reports are currently circulated to all members for this same purpose. Additional information will be included as available and when appropriate. We have already increased inventory monitoring by including the monthly inventory status of each program with this report. As additional information is computerized, it will be utilized where appropriate.

6) Frequent and open communications between the Program Directors at NCI-Frederick Cancer Research Facility have emphasized the importance and commitment to Radiation Safety (Attachments U, V, and W). These messages have been promulgated in writing and in numerous meetings with laboratory and section heads. There can be no doubt in any investigator's mind that all levels of management at the NCI-Frederick Cancer Research Facility are concerned about radiation policy and will accept no excuses or make exceptions in the effort to achieve a hazard free work environment.

U. S. NUCLEAR REGULATORY COMMISSION

REGION I

Report No. 030-01786

Docket No. 19-00296-10 Priority I Category GI Program Code 2110

Licensee: Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20014

Facility Name: National Institutes of Health

Inspection At: Bethesda, Rockville and Baltimore, Maryland

Inspection Conducted: July 8 - 12, 1991

Inspectors: William E Davidson 8-14-91
Will Davidson, Health Physicist date

Cheryl A Trottier for F-14-91
John McGrath, Senior Health Physicist date

Cheryl A Trottier for 8-14-91
Teresa Hall Darden, Senior Health Physicist date

Approved by: Cheryl A Trottier for 8-14-91
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Section A

Inspection Summary: Routine announced inspection on July 8 - 12, 1991 (Report No. 030-01786/91-001)

Areas Inspected: Organization and staffing; licensee's actions on previous inspection findings; incidents/ notifications; training; procurement and inventory controls; materials receipt and distribution; radioactive waste management; leak tests; facilities; radiotherapy; personnel exposure; instrument calibration: airborne effluents and radioactive waste management.

Results: One violation was identified - failure to maintain constant surveillance of radioactive materials in the nuclear pharmacy (Section 11.2).

Details

1.0 Persons Contacted

*Lynn Jenkins, Acting Chief, Clinical Center Unit
*Ted W. Fowler, Deputy Radiation Safety Officer
*Robert A. Zoon, Chief, Data & Analytical Service
*Nancy Newman, Assistant Chief, Radiation Safety Operations Section
*Wm. J. Walker, Radiation Safety Officer (RSO)
*Tara Barkley, Health Physicist
*Lisa L. Coronado, Health Physicist
*Katharine McLellan, Health Physicist
*Ivan Wallace, Health Physicist
*Kelly Austin, Health Physicist
*Bruce Smith, Assistant Chief, Support Services Unit
*Kathleen Dolce, Health Physicist
*Richard J. Kagan, Health Physicist
*William Holcomb, Radiation Safety Training Officer
P. Boon Choch, Member, Radiation Safety Committee
*Israel Putnam, Chief, Materials Control Unit, Radiation Safety Branch
*Jorge A. Carroquillo, Deputy Chief Department of Nuclear Medicine and Member, Radiation Safety Committee
*Adel Baryoun, Health Physicist
Mark Potman, Radiopharmacist
Pat Henney, Lead Technician, Nuclear Medicine
Craig Cochron, Nurse
Cheryl Burns, Technician, Radiation Service Organization, Inc.
*Sean Austin, Radioactive Waste Project Officer
Other managerial, research, and radiation safety personnel, including contractors, were contacted during this inspection.

2.0 Scope of the Inspection

This inspection was an examination of activities conducted under a medical research, diagnosis and therapy license of broad scope. During the course of the inspection, the inspectors observed operations of the Radiation Safety Branch (RSB) in Building 21, radiopharmacy operations in Building 10, the Nuclear Medicine Department, approximately 30 research laboratories in Buildings 10, 14, 21 and 37, research laboratories at the licensee's facility in Rockville, Maryland, and at the Baltimore, Maryland Gerontology Center. The inspectors observed use and storage of radioactive materials, interviewed personnel, examined records and performed measurements for radiation exposure and contamination throughout the facilities.

3.0 Organization and Staffing

The Radiation Safety Branch (RSB) is comprised of 33 professional, technical, and support staff members, supplemented by a number of full-time contractor personnel. The Chief of the Radiation Safety Branch also serves as the licensee's Radiation Safety Officer (RSO). The RSO has authority to suspend authorized users when violations of procedures, National Institutes of Health (NIH) policy, NRC regulations, or license conditions occur.

The NIH Radiation Safety Committee is appointed by the Director of NIH. The major classes of users of radioactive materials and radiation sources are represented. Representatives from nursing services and NIH management are also included in NIH Radiation Safety Committee membership.

The inspectors reviewed the Radiation Safety Committee (RSC) meeting minutes for the past year and determined that the RSC has carried out its functions as described in the Radiation Safety Guide. The Radiation Safety Committee minutes thoroughly discussed incidents of radiological concern which occurred at NIH during the period reviewed. Further, all reviews, approvals, or denials of human use protocols continue to be performed by the RSC. The RSC also concurred in the RSO's nonhuman use authorizations.

No violations were identified.

4.0 Licensee's Actions on Previous Inspection Findings

The inspectors reviewed the actions taken by the licensee to correct and prevent recurrence of the violation identified during the inspection of the licensee's program on June 11 - 13, 1990, as documented in the Nuclear Regulatory Commission's (NRC) letter dated August 23, 1990.

(Closed). Failure to accurately estimate radioactive material in the solid waste.

The inspector observed that the licensee instituted a waste tagging system which requires that all authorized users note on the tag, the isotopic contents and activities in the container. A carbon copy of the tag is forwarded to data processing to update the database for inventory control.

5.0 Incidents/Notifications

The inspector reviewed incidents identified and documented by the RSB since the 90-001 Inspection. The events described in these documents included spills, unauthorized removal of trash by housekeeping and other personnel, security breaches involving radioactive materials, unauthorized removal, possession and use of radioactive material, improper transfer of radioactive material, fire in a lab which contained radioactive material, loss and recoveries of licensed material, personnel contaminations and bagged waste which triggered the radiation alarm at the incinerator. The inspector noted that responses by the RSB to incidents were immediate. Reviews of the events were comprehensive and included evaluations of causes, effects, corrective and preventive actions. Notifications, when required, were made to the NRC. Disciplinary measures were taken in accordance with Radiation Safety Policy and were supported by management. The inspector noted that the Radiation Safety Disciplinary Policy regarding misadministrations has been considered harsh by some and has been a topic of discussion at Radiation Safety Committee Meetings. This was described in the minutes of the Radiation Safety Committee and verified by the RSO. The disciplinary policies have been supported by NIH management.

6.0 Training

The adequacy of the authorized user and supervisor training was determined by discussions with licensee representatives and interviews with users. These discussions indicated that all handlers of radioactive materials are required to attend a one day training course conducted by the RSB. All users and ancillary personnel are required to take refresher training annually. The RSB also provided training to contract personnel. Authorized users (those specifically licensed thru the Radiation Safety Committee in conjunction with the Radiation Safety Branch) are required to take a two week training course offered by the RSB. According to RSB personnel, prior to 1989, the two week radiation safety training courses were offered to authorized user candidates twice a year.

Since 1989, as a result of decreased authorized user candidate interest, cost constraints and staffing limitations, the schedule for this training has been decreased to once a year. It was offered April 3 thru April 24, 1989; September 17 thru October 4, 1990 and is scheduled to be held September 4, thru September 20, 1991. If an individual misses the annual authorized user training course and desires to become an authorized user, he or she is permitted to work under the license of an authorized user until the scheduled training is received. If an individual does not follow this procedure, permission is not granted to work with radioactive materials as an independent authorized user. Through discussion with the RSB staff, the RSO, and individual workers, the inspectors determined that individuals were aware of the NIH radiation safety training guidelines, and had received individual or authorized user training, and that refresher training had been performed as required.

No violations were identified.

7.0 Procurement and Inventory Controls

According to RSB personnel, most radioactive materials are ordered by individual users through a system of blanket purchase agreements with major suppliers. Each institute at NIH has its own procurement office. Larger orders or special items (anything over $2500) are procured through a written requisition process. Such orders must be approved by the RSO. There are generally no direct deliveries to investigators with the exception of a large item, such as an irradiator. Also, the Gerontology Research Center in Baltimore receives material directly.

The inspector observed that NIH had a computerized inventory control system. Information on each incoming shipment of radioactive material was entered into the database daily as the material was received in Building 21. NIH prepared monthly reports which noted the total inventory for each major isotope. The reports used the previous month's total, adding in the monthly receipts and subtracting the total monthly activity disposed including the shipped waste, the liquid wastes disposed of through the sanitary sewer and the solid waste incinerated. The computer program used to generate the report incorporates radioactive decay. Authorized users were responsible for maintaining a record of the receipt, utilization and disposal of radioactive materials used under their authorization using NIH Form 88-16 " Isotope Receipt, Utilization and Disposal Record." A binder was provided by the RSB to maintain these records. During the inspection, all of the labs visited by the inspectors had appropriately completed 88-16 Forms.

No violations were identified.

8.0 Receipt and Distribution of Radioactive Material

All radioactive materials shipments are received by the Radiation Safety Branch in Building 21. Most shipments are received during normal working hours. Occasionally shipments arrive during the weekend. Security personnel escort the carrier to Building 21 where the package is left in a secure area until radiation safety staff can process it. Packages are normally surveyed in accordarce with 10 CFR 20.205. The inspector observed that surveys were performed on the exterior package surface and information on the shipping papers was matched with the purchase order information. The packages were opened in a fume hood and wipes were performed on the inner packages. Package data was entered and verified on a computer terminal.

Also, the inspector observed that external radiation surveys at the package surface and at one meter were performed on packages containing greater than Type A quantities. Contamination surveys were also performed when required pursuant to 10 CFR 20.205. The shipping papers were reviewed to assure that information from the purchase order matched the information on the NIH Form 88-1 "Request for Purchase and Use of Radioactive Materials." If an 88-1 was not received from the authorized user, the package was held in the RSB until the appropriate information was received. The material was also held when there were noted discrepancies between the shipping papers and the 88-1 which could not be resolved by phone. The computer was used to log information on each shipment into the RSB database which enabled the licensee to maintain a fairly accurate materials inventory. The database was also used to verify that the user was authorized for the material ordered.

The inspector also observed that packages were opened in a hood and each inner package was swiped for contamination. There was a GM meter and a scintillation counter in the hood for analyzing wipes for gamma and high energy beta emitters. The licensee stated that for low energy beta emitters the wipes are sent to the lab for counting. Routinely, if no contamination is found, each order is repackaged and prepared for delivery to the authorized user. Packages sometimes contain multiple orders. Actual delivery is routinely performed by a contractor, Radiation Service Organization, Inc. (RSOI). RSOI personnel have been instructed to obtain the signature of an individual user upon delivery.

The inspector noted that all personnel who worked in the materials receipt area were monitored with whole body and wrist film badges as well as a ring TLD. The individual performing package wipes in the fume hood was observed to be wearing ring and wrist badges on the right hand facing outward. During observation of the operation, it was noted that the individual held each package with his left hand and using forceps, wiped each package with his right hand. It was recommended by the inspector that the badges be worn on the left hand facing inward.

No violations were identified.

9.0 Radioactive Waste Program

From records review and observation, the inspector determined that all radioactive waste was processed through the Radiation Safety Branch in Building 21. Work was carried out by the licensee's contractor, RSOI. During the last inspection, it was noted that contrary to procedures, the data collection mechanism to generate estimates of solid radioactive wastes did not incorporate specific data sheets from each user. Consequently, the estimate of radioactive material in the solid waste was grossly inaccurate in that disposal estimations often exceeded materials receipts. To address this deficiency, the licensee instituted a waste tagging system which required each authorized user to tag all liquid and solid waste containers prior to pick-up by RSOI. RSOI staff was instructed to pick up only waste that was tagged. The inspector noted that the information on

the tag included the name of the authorized investigator, room number, type of container (e.g. 5 gallon carboy), isotopes activities and date of pick-up. One copy of the tag is routinely forwarded to data processing to update the database for inventory purposes.

9.1 Liquid Waste

The inspector observed that liquid waste was collected by the licensee's contractor and transferred to Building 21 in 2 or 5 gallon carboys. Each carboy was tested for Ph. Liquid with a Ph below 3 or above 10 was appropriately treated. An aliquot was taken and counted to determine the concentration of radioactive material in each carboy. The volume in the carboy was estimated and the total activity determined. This activity was compared to the activity listed on the tag by the user. The inspector noted that since the activity listed by the authorized users was only an estimate, the activity of the sample sometimes differed. Routinely, when the difference is significant, it is discussed with the authorized user by RSB personnel. From review of licensee records, procedures and personnel interviews, the inspector determined that the licensee is authorized to dispose of 8 curies of licensed material each year to the sanitary sewer system. In calculating disposal limits the licensee used an amount of 32 millicuries for each work day and assumed 250 work days per year. Approximately 15-25 carboys of liquid waste were handled daily. When the total activity for all the carboys was less than 32 millicuries, the liquid was disposed of down the sewer. When the activity was greater than 32 millicuries, selected carboys (such as those with significant amounts of P-32) were held for decay, while the liquid from the remaining carboys (with activity less than 32 millicuries) was released to the sanitary sewer. Larger amounts of liquid waste were kept in nine storage tanks. In 1990, the licensee disposed of 5926 millicuries of liquid waste. So far in 1991, the licensee had disposed of 3047 millicuries of liquid waste. Records show that releases to the sanitary sewer system were less than 1% of MPC averaged over one month. Also the records indicated that the licensee was comparing releases to Table II values rather than Table I as specified in 10 CFR 20.303.

Liquid scintillation vials are handled separately. Vials containing only hydrogen 3 (H-3) or carbon 14 (C-14) below the limits of 10 CFR 20.306 are placed in a separate drum for shipment to Quadrex, a commercial disposal company. Vials with shorter lived licensed materials such as P-32 are normally held for decay.

9.2 Solid Waste

The inspector observed that solid waste was collected from individual users in plastic bags by RSOI and brought to Building 21 for processing. When the waste was off loaded from the trucks it was placed in 55 gallon drums. The waste was then compacted in one of two waste compactors. The licensee indicated that they try to achieve a 2-to-1 compacting ratio. The waste tags for each bag of waste were kept to identify the waste compacted in each drum. Licensee procedures required that drums be sealed when filled, labeled and prepared for shipment to Chem-Nuclear, another disposal company. The inspector also noted that appropriate protective clothing was worn and breathing zone air samples were collected in the vicinity of the compactors. A review of the records of these samples indicated no measurable airborne contamination levels. The licensee's contractor also performs daily radiation and contamination surveys of the area. In response to the inspector's inquiry concerning floor contamination surveys around the two compactors, RSOI personnel surveyed the floor with a GM meter with a pancake probe and detected some contamination. A resurvey performed after efforts to decontaminate the area showed that contamination still remained. At this point, RSOI staff roped off the area and performed a more detailed wipe survey of the area to determine the nature of the contamination. During this procedure the RSOI staff was observed to put on protective booties. The inspector recommended to RSB staff that because of the potential for increased floor contamination the wearing of protective booties during the compacting operation might be a desirable practice. The RSB staff agreed that this would be appropriate and indicated that they intended to review the waste area to determine if more effective controls could reduce the possibility of floor contamination.

9.3 Incineration

It was noted by the inspector that NIH had three incinerators on site routinely used for the destruction of pathological waste. However, the RSB also utilizes the incinerators for the disposal of some radioactive wastes. To assure that releases from the incinerators remained below regulatory limits, NIH limits the amount of radioactive waste sent to the incinerators. This limitation is based on the maximum activity per isotope that may be incinerated per day such that the 24-hour average concentration in the gaseous effluent will not exceed MPC. This assumes that all of the activity goes up the stack. A review of records indicated that the maximum daily concentration for the most common isotope, H-3, was about 7% of MPC. Also, it was noted that the licensees estimate of annual airflow was based on the flow from the two older incinerators. The newer incinerator No. 3 has a greatly increased airflow. Therefore, the inspector determined that actual emissions were probably much less than indicated. The licensee representative stated that they intend to provide additional information to the NRC concerning the increased air flow to modify their current incineration activities.

As a result of a previous inspection, NIH committed to installing an automatic alarm system for detecting radioactivity in medical pathological waste boxes which could inadvertently be sent to the incinerators. The inspector observed that this system consisted of a Victoreen GammaGuard area monitor with two GM detectors mounted on the incinerator feed conveyor belt so that each box can be monitored on two sides. The detectors are set to alarm at the detection of a 1 millicurie cesium-137 source. This setting also ensures the detection of significant levels of other nuclides with medium to high energy gamma emissions. During the inspection, the detectors were tested by the NIH staff using a 100 microcurie cesium-137 source. The alarm functioned properly.

No violations were identified.

10.0 Sealed Source Inventory and Leak Tests

The inspectors reviewed the licensee's records of sealed source inventory and leak tests. Inventories and leak tests are required to be performed once every six months. All results of leak tests were within license limits, and the tests were performed within the required time interval.

No violations were identified.

11.0 Tour of Facilities

11.1 Research Laboratories

The inspectors visited approximately 30 research laboratories and performed inspections which included independent measurements, review of laboratory records, and discussions with individual and authorized users. The lab visits were conducted in the presence of RSB staff members assigned to the specific laboratories. The inspectors determined that all authorized users were aware of their responsibilities and were adhering to policies and procedures stated in the NIH Radiation Safety Guide, various commitments made by the licensee to the NRC, and NRC regulations. The inspectors noted the following: radioactive materials were properly labelled; laboratories were posted as required; the required dosimetry and protective clothing were worn; logs of material used were maintained; no evidence of eating, drinking or smoking was observed in the laboratories; and monthly surveys were properly documented. In addition, the users who were interviewed indicated that they had received the required licensee radiation safety training and appeared to be familiar with the requirements of the licensee's radiation safety program.

No violations were identified.

11.2 Radiopharmacies

There are two radiopharmacies on the NIH campus, each responsible for different types of radiopharmaceutical preparations. The radiopharmacy in Building 21 is primarily responsible for monoclonal antibody labeling and dose preparation, and preparation of non-routine radiopharmaceuticals. The radiopharmacy in Building 10 is primarily responsible for radiopharmaceutical doses containing technetium-99m, and cyclotron produced radioisotope preparations, as well as other radiopharmaceuticals and radioisotopes routinely used in nuclear medicine. The Radiopharmacy in Building 21 was closed during the week of the inspection because the radiopharmacist normally in Building 10 was on vacation and the radiopharmacist from Building 21 was his replacement.

The inspectors interviewed the radiopharmacist and observed his work in progress including the elution of the technetium-99m generator. The inspectors reviewed records of surveys and dose calibrator constancy, linearity, geometry and accuracy tests.

The inspectors noted that there were three doors. One opens to a hallway in the Nuclear Medicine Department. However, this door remains locked at all times. Another door opens to the receptionist area. The third door has two parts and opens to the Nuclear Medicine Department. The top part of this door is normally open and the bottom part has a bench top which is kept closed. The inspectors observed that the radiopharmacist prepared the doses, and then placed them in lead boxes on the bench top with a copy of the dose calibrator print-out which noted the activity contained in the syringe. The Nuclear Medicine technologists or physicians then removed the lead boxes from the bench top for patient injections. When asked by the inspector about the bench top distribution during his absence, the radiopharmacist stated that he normally left the top half of the door open when he left the department for lunch and that the bottom door was kept closed but not locked.

During the radiopharmacist's lunch break the inspectors returned to the radiopharmacy and found three lead boxes containing licensed material on the door bench top. They were unchallenged by any licensee personnel as they entered the area. The inspectors noted that there were no other personnel in the area at the time to maintain constant surveillance or direct control over the radioactive material.

Failure to secure licensed material or maintain surveillance in an area to which access is not controlled by the licensee is an apparent violation of the requirements of 10 CFR 20.207.

11.3 Nuclear Medicine Department

The inspectors reviewed procedures, records of surveys, interviewed several technologists in the Nuclear Medicine Department and determined the following: during normal working hours, the radiopharmacists prepared and assayed all radiopharmaceutical doses for patient administration. The nuclear medicine technologists become involved in radiopharmaceutical dose preparation and assay only on weekends. The nuclear medicine technologist had the option on weekends to elute the technetium-99m generator or to order bulk technetium. Review of assay records indicated that prepared doses were assayed prior to administration in accordance with the procedures submitted with the license application. Further, the dose calibrator constancy was checked daily, as required.

No violations were identified.

12.0 Radiotherapy

12.1 Radiopharmaceutical Therapy

Two rooms are routinely used for radiopharmaceutical iodine therapy. The licensee told the inspector that the rooms were not surveyed and decontaminated after each therapy patient. Since the rooms are usually used for therapy patients, the area Health Physicist only surveys and decontaminates after every two therapy patients. The licensee also stated that when it's determined that the room is to be released to a non-therapy patient, it is decontaminated and surveyed before the non-therapy patient is allowed to occupy the room.

The inspector explained to the RSB staff that even though a safety evaluation was performed to determine the significance of the hazard associated with placing pharmaceutical therapy patients in the room prior to decontamination 10 CFR 35.315(a)(7) requires that the room not be reassigned until the removable contamination is less than 200 disintegrations per minute per 100 square centimeters (dpm/100cm^2). There is no explicit exclusion for therapy patients. The inspector then suggested to the licensee that they submit their proposal for exception to the Regulations regarding decontamination of dedicated radiopharmaceutical therapy patient rooms prior to release for use by another patient. The RSO stated that they intend to apply for relief through an amendment in the near future. The inspector stated that resolution of this issue will be reviewed during the next inspection.

The inspector observed an iodine-131 therapy procedure and noted that the area health physicist performed the appropriate dose rate measurements and used good ALARA techniques during the procedure.

12.2 Brachytherapy

The licensee told the inspector that brachytherapy was rarely performed. However, the number of brachytherapy procedures is expected to increase in the future due to the arrival of a new physician. The inspector found, by looking at the source log, that only one brachytherapy procedure had been performed within the last year. The inspector verified that the brachytherapy sources were leak tested and included in the inventory checks as required.

Two adjacent patient rooms have been designed to be used for brachytherapy procedures. There is mobile lead shielding in both rooms available for staff and visitors to use when in the room.

No violations were identified.

13.0 Personnel Exposure Monitoring

13.1 External Dosimety

The licensee's dosimetry records indicated that NIH provided film badge monitoring to over 6,000 individuals. RSB representatives stated that all individuals working with gamma emitters, X-ray producing machines, and penetrating beta emitters were required to wear film badge dosimeters. In addition, film badges were routinely issued to other workers when dosimetry was requested.

The licensee also provided extremity monitoring to users handling over 500 microcuries of phosphorus-32 in stock solutions and individuals using millicurie quantities of gamma-emmiting nuclides.

Exposure history of individuals was stored in database files. The inspectors reviewed selected exposure records and noted that dose information was easily retrieved and maintained up to date.

The inspector also noted that appropriate minor and major investigations were conducted by the area health physicist on individuals exceeding ALARA levels. The inspector examined quarterly and annual film badge summaries and determined that no exposures in excess of regulatory limits had occurred within the last year.

No violations were identified.

13.2 Internal Dosimetry

13.2.1 Air Sampling Program

The inspector reviewed selected records of room, breathing zone, and hood air analysis. The licensee utilized activated charcoal to sample for iodines. Breathing zone samples were analyzed by the health physics staff after each iodination. The inspector noted that the collection efficiency of the charcoal medium was measured weekly and was consistently greater than 99%.

The records reviewed indicated that measured room air concentrations had not exceeded the regulatory limit for airborne concentrations in restricted areas for any nuclide during the monitoring period.

No violations were identified.

13.2.2 Bioassay Program

From records review and personnel interviews, the inspectors observed that the licensee's bioassay program included urinalysis, thyroid and whole body counting. Individuals who used greater than ten millicuries of iodine-125 and/or 100 millicuries of tritium as well as all personnel involved in the receipt, prepackaging or waste processing of these isotopes were required to have a bioassay performed within 7 days of use or processing.

Individuals performing iodinations are tracked on the computer to ensure that thyroid uptake counts are completed at the required frequency. For individuals using a cumulative quantity of iodine exceeding 10 millicuries in a calendar quarter, a thyroid uptake count must be performed by the end of the quarter. There are less than 5 users of tritium in quantities greater than 100 millicuries.

The inspector found that the RSB staff investigates any unusual exposures as well as all exposures greater than 10% of the maximum permissible body burden or critical organ burden. The inspector found that there were no exposures which exceeded regulatory limits within the past 12 months.

No violations were identified.

14.0 Airborne Effluents from Hoods

The license stated that the major portion of the iodinations and other activities involving radioiodines are performed in the facilities of Building 21. Iodination enclosures with a charcoal filtration system were used in hoods which also had charcoal filtration. Continuous effluent air sampling was used in hoods in Building 21 and other high use hoods. Effluent iodine samples were collected on charcoal cartridges and tritium oxide was collected on selica gel for appropriate analysis. Weekly efficiency tests showed the charcoal filter to have a collection efficiency consistently of greater than 99%.

The inspector examined selected records of airborne effluent monitoring for the last year. The inspector noted that several hoods in Building 21 had effluents measuring at or above the MPC levels in air for iodine-125 on some weekly samples. However, the inspector's review did not indicate any instance in which any hood approached the 10 CFR 20, Appendix B release limits when averaged over the year.

No violations were identified.

15.0 Calibration of Radiation Survey Instrumentation

The licensee's radiation survey instruments used to measure dose rates are calibrated by RSOI. The inspector verified that these calibrations were done annually as required. Radiation survey instruments used to measure contamination (such as those used by researchers) were routinely calibrated on site by RSOI. The inspector observed the field calibration of a radiation survey meter performed by an RSOI employee. A field calibration includes calibrating the count rate of each scale of the meter with an electronic meter and determining detector efficiency with a standard source.

No violation was identified.

16.0 Exit Interview

At the conclusion of the inspection, the inspectors met with the individuals identified in paragraph 1 of this report and discussed the scope and finding of the inspection.

U. S. NUCLEAR REGULATORY COMMISSION

REGION I

Report No. 030-01786/92-001

Docket No. 030-01786

License No. 19-00296-10 Priority 1 Category G1 Program Code 02110

Licensee: Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20892

Facility Name: National Institutes of Health

Inspection At: Bethesda and Rockville, Maryland

Inspection Conducted: July 20-24, 1992

Inspectors:

Keith D. Brown, Ph.D., Health Physicist — 9/14/92 Date Signed

James P. Dwyer, Senior Health Physicist — 9/11/92 Date Signed

Penny A. Nessen, Health Physicist — 9/11/92 Date Signed

Approved by:

Mohamed M. Shanbaky, Ph.D., Chief
Medical Inspection Section — 9/14/92 Date Signed

Inspection Summary: Routine, unannounced inspection conducted from July 20-24, 1992 (Report No. 030-01786/92-001)

Areas Inspected: Organization and staffing; licensee's actions on previous inspection findings; incidents/notifications; annual review; training; procurement and inventory controls; receipt and distribution of radioactive materials; radioactive waste management; sealed source inventories and leak tests; facilities; radiotherapy; personnel exposure monitoring; airborne effluent; and instrument calibration.

Results: One violation was identified: failure to perform an adequate survey of a radiopharmacist to assure compliance with the regulatory limit for exposure of the skin (Section 5.0).

DETAILS

1.0 Persons Contacted

*William J. Walker, Ph.D., Radiation Safety Officer (RSO) & Chief of the Radiation Safety Branch (RSB)
*Ted W. Fowler, Deputy RSO & Chief of the Radiation Safety Operations Section (RSOS)
*Robert A. Zoon, Deputy Chief, RSB
Nancy Newman, Assistant Chief, RSOS, RSB
*Roger N. Broseus, Ph.D., Assistant to the Chief, RSB
*Tara Barkley, Health Physicist, RSB
*Lisa Coronado, Health Physicist, RSB
*Katharine McLellan, Health Physicist, RSB
*Kelly Austin, Health Physicist, RSB
*C. Bruce Smith, Ph.D., Acting Chief, Data and Analytical Services Section, DASS, RSB
*William F. Holcomb, Radiation Safety Training Officer, RSB
*Israel Putnam, Chief, Materials Control Unit, DASS, RSB
*Jorge A. Carrasquillo, M.D., Deputy Chief, Department of Nuclear Medicine
*Adel M. Baryoun, Health Physicist, RSB
*Sean Austin, Radioactive Waste Service Project Officer, RSB
*Philip S. Chen, Jr., Ph.D., Associate Director for Intramural Affairs
*Jacob Robbins, M.D., Chairman, Radiation Safety Committee (RSC)
*Richard G. Wyatt, Assistant Director for Intramural Affairs & Member, RSC
*Robert W. McKinney, Ph.D., Director, Division of Safety
*P. Boon Chock, Ph.D., Member, RSC
*Lynn Jenkins, Unit Leader, Clinical Center Unit, RSOS, RSB
*Jan Van de Geijn, Ph.D., Head, Section of Physics, National Cancer Institute
*Ronald Neumann, M.D., Chief, Department of Nuclear Medicine
*Robert Leedham, Jr., Nuclear Pharmacist, Department of Nuclear Medicine
*Richard Fejka, Nuclear Pharmacist, Department of Nuclear Medicine
*Shawn Googins, Acting Assistant Chief, DASS, RSB
*Beth Reed, Physical Science Technician, RSB
*Carol DeWeese, Health Physicist, RSB
*Cathy Ribaudo, Health Physicist, RSB
*George O. Redmond, Physical Science Technician, RSB

Other managerial, research and radiation safety personnel, including contractors, were contacted during this inspection.

*Denoted attendance at exit meeting

2.0 Scope of the Inspection

This inspection was an examination of activities conducted under a medical research, diagnosis and therapy license of broad scope. During the course of the inspection, the inspectors observed operations of the Radiation Safety Branch (RSB) in Building 21, radiopharmacy operations in Buildings 10 and 21, the Department of Nuclear Medicine, approximately 100 research laboratories in Buildings 4, 6, 10, 14, 18T, 21, 29A, 30, 36 and 37, and research laboratories at the licensee's facility in Rockville, Maryland. The inspectors observed the use and storage of radioactive materials, interviewed personnel, examined records, and performed measurements for radiation exposure and contamination throughout the facilities.

3.0 Organization and Staffing

The RSB is comprised of 33 professional, technical, and support staff members, supplemented by a number of full-time technical contractor personnel. The RSB currently has two positions open that are effected by a hiring freeze. The RSB plans to reevaluate its staffing needs since two new research buildings are being added to the National Institutes of Health (NIH) license. The Chief of the RSB also serves as the licensee's Radiation Safety Officer (RSO). The RSO has authority to suspend an authorized user when violations of procedures, NIH policy, NRC regulations, or license conditions occur.

The NIH Radiation Safety Committee (RSC) is appointed by the Director of NIH. The major classes of users of radioactive materials and radiation sources are represented. Representatives from nursing services and NIH management are included in the RSC membership.

The inspector reviewed the RSC meeting minutes for the past year and determined that the RSC has carried out its functions as described in the Radiation Safety Guide. The RSC meeting minutes indicated that the RSC thoroughly discussed incidents of radiological concern which occurred at NIH during the period reviewed. Further, all reviews, approvals, or denials of human use protocols continue to be performed by the RSC. The RSC also concurred in the RSO's nonhuman use authorizations.

4.0 Licensee's Actions on Previous Inspection Findings

The inspector reviewed the actions taken by the licensee to correct and prevent recurrence of the violation identified during the inspection of the licensee's program from July 8 to 12, 1991, as documented in the NRC's letter dated August 20, 1991.

(Closed). Failure to maintain constant surveillance of radioactive materials in the nuclear pharmacy.

The inspector observed that the licensee instituted a procedure to lock the nuclear pharmacy and secure all licensed material while the pharmacist was away or a nuclear medicine technologist was not in attendance. All radioactive material use areas inspected were secure on the dates of the inspection.

5.0 Incidents/Notifications

The inspector reviewed incidents identified and documented by the RSB since the 91-001 Inspection. The events described in these documents included: spills; unauthorized removal of trash by housekeeping and other personnel; improper transfer of radioactive material; unauthorized removal, possession, and use of radioactive material; losses and recoveries of licensed material; personnel contaminations; and radiation alarms at the incinerator triggered by bagged waste. The inspector noted that, in general, responses by the RSB to incidents were immediate, comprehensive and included evaluations of causes, effects, and corrective and preventive actions. Disciplinary measures were taken in accordance with Radiation Safety Policy and were supported by management.

During a review of operations in the Building 21 radiopharmacy, the inspector determined that a spill of approximately 8 millicuries (mCi) of lutetium-177 had occurred on June 16, 1992, which resulted in the contamination of the radiopharmacy and radiopharmacist. The Radiopharmacist stated that on the morning of June 16, 1992, he was working alone in the pharmacy preparing to label a monoclonal antibody with approximately 47 mCi of lutetium-177. At approximately 6:45 a.m., the Radiopharmacist attempted to vent the sealed vial containing the lutetium-177 liquid using a small gauge needle and one milliliter syringe. Pressure within the vial forced the plunger out of the syringe and allowed the radioactive liquid to escape the vial. The lutetium-177 liquid was sprayed up toward the pharmacy ceiling. The Radiopharmacist said that air supply vents in the ceiling directed the lutetium-177 "mist" back toward the work bench. The Radiopharmacist stated that because he was working behind an L-block and wearing protective clothing and safety glasses, the only area of his body to receive contamination was his forehead near the hair line. The Radiopharmacist said that he changed his protective clothing but continued with the monoclonal antibody labeling because he believed that he needed help with the decontamination of his forehead and because of time constraints on the monoclonal antibody labeling.

According to a memorandum describing the incident which was written by the area Health Physicist on July 13, 1992, the RSB was notified of the spill by the Radiopharmacist at approximately 8:00 a.m. on June 16, 1992. The area Health Physicist stated that upon her arrival at Building 21 at 8:15 a.m., she surveyed the Radiopharmacist with a pancake Geiger-Muller (GM) probe and found count rates in excess of 500,000 counts per minute (cpm) on his forehead. The area Health Physicist indicated that 500,000 cpm was the maximum on scale reading for the survey instrument. Surveys made of the L-block and areas around the L-block also indicated count rates in excess of 500,000 cpm. The area Health Physicist stated that the Radiopharmacist's shoes were contaminated and count rates on the floors in the pharmacy ranged from 2500 cpm to in excess of 500,000 cpm. Localized contamination in the range of 300 cpm to 8000 cpm was detected in the adjoining hall and adjacent laboratory. The inspector determined that at least one wipe test for removable contamination was taken from the L-block. The area Health Physicist stated that an analysis of this wipe indicated removable lutetium-177 contamination of 40,000 disintegrations per minute per 100 square centimeters (dpm/100cm^2).

The area Health Physicist stated in her memorandum that the Radiopharmacist began decontaminating his forehead but after one hour of repeated cleaning, 4000 cpm of contamination remained in his hair. The Radiopharmacist elected to remove the contaminated hair. A whole body count and urine bioassay were performed and indicated no detectable internal contamination or remaining external skin contamination. Difficulties were encountered in decontaminating the facilities and repeated decontamination attempts were performed. The licensee was eventually successful in decontaminating the affected areas.

The licensee stated that, based on the results of the urine bioassay and whole body counts and the level of removable contamination on the L-block as indicated by the wipe test, they concluded that the incident would not result in an overexposure to the skin of the Radiopharmacist and that the incident was not reportable to the NRC. Therefore, no immediate dose assessment was performed. The licensee said that their intent was to perform the dose assessment when time permitted. The previously mentioned memorandum from the area Health Physicist was written on July 13, 1992. This memorandum included corrective and preventative actions taken as a result of the incident.

On July 23, 1992, the licensee performed an assessment of the dose to the skin of the Radiopharmacist using the Varskin program. Because of similarities in beta and gamma energies between lutetium-177 and iodine-131, and because lutetium-177 was not included in the Varskin library, the assessment was performed using factors developed for iodine-131. The inspector determined that this assumption was appropriate and conservative. From their assessment the licensee estimated that the Radiopharmacist received a radiation exposure of 60 millirems to the skin on his forehead. The inspector determined that this dose assessment was inadequate for several reasons which are discussed in the following paragraphs.

In performing the dose assessment, the licensee assumed that the total activity on the Radiopharmacist's skin was 40,000 dpm. This assumption was based on the removable contamination found on the wipe test of the L-block. The inspector determined that this assumption was not appropriate because it assumes 100 percent efficiency of the wipe test for removing all of the contamination present. Based on the apparent difficulty encountered in decontaminating the floors and other surfaces in the pharmacy, it seems likely that the actual contamination on the skin could have been several times greater than that detected by the wipe test. The inspector noted that a commonly assumed efficiency of the wipe test for removing the activity present of 10 percent would result in an estimated skin contamination of 400,000 dpm, a contamination level more consistent with the greater than 500,000 cpm reading measured by the area Health Physicist. Additional questions regarding the actual skin contamination activity are raised in that the wipe sample was taken from the L-block and not the Radiopharmacist's forehead. The licensee acknowledged that the wipe test taken on the L-block might not be an accurate representation of the contamination on the Radiopharmacist's forehead but stated that they did not want to delay decontamination of the Radiopharmacist. The inspector agreed that the licensee should not unnecessarily delay decontamination of personnel, however, the Radiopharmacist had already been contaminated for approximately 90 minutes. Valuable information regarding the quantity and distribution of the activity on the Radiopharmacist's forehead could have been gathered concurrent with the decontamination without any appreciable increase in time or exposure.

For purposes of dose assessment, the licensee also assumed that the skin contamination was uniformly spread over 100 square centimeters (cm^2). The licensee stated that this assumption was based on guidance found in NRC Regulatory Guide 8.23, Table 2, entitled "Recommended Action Levels for Removable Surface Contamination in Medical Institutions". The inspector noted that Table 2 provides recommended action levels for removable surface contamination but does not provide guidance for determining skin dose from contamination. The International Commission on Radiological Protection (ICRP) in Publication No. 26 (1977) recommends that for routine monitoring of skin exposure, it is adequate to regard the contamination as being averaged over an area of 100 cm^2 however, in accident

situations, an estimate should be made of the average dose equivalent over 1 cm^2 in the region of the highest dose equivalent and this dose equivalent should be compared with the dose equivalent limit in 10 CFR 20.101. The licensee did not evaluate the area and uniformity of the radiopharmacist's skin contamination. The inspector determined that the licensee's assumption that the skin contamination was uniformly spread over 100 cm^2 was inappropriate without specific evidence to support this assumption. The incident events supported a discrete contamination of a limited area of the skin with high specific activity droplets of lutetium-177.

For purposes of dose assessment, the licensee also assumed that the skin contamination existed for a period of one hour. The source of this information is unknown. Based on the interview conducted by the inspector with the Radiopharmacist, the contamination existed for one and one half hours before decontamination began and complete decontamination was not achieved for an additional hour.

10 CFR 20.201(b) requires that each licensee perform surveys necessary to assure compliance with 10 CFR Part 20. 10 CFR 20.101(a) restricts the occupational radiation exposure to the skin of the whole body to 7.5 rems per calendar quarter. The inspector concluded that the licensee did not adequately evaluate the exposure to the skin of the forehead of the Radiopharmacist due to the lutetium-177 contamination incident. Failure to perform a survey to assure compliance with 10 CFR 20.101 radiation exposure limits is an apparent violation of 10 CFR 20.201(b).

6.0 Annual Review

The RSB program was reviewed by the Radiation Safety Committee on April 17, 1992 and a formal report documenting the review presented at the April 30, 1992 RSC meeting. The review included discussions of the following:

- 85 minor exposure investigations (125 to 370 millirem per quarter whole body, 750 to 2240 millirem per quarter skin, or 1875 to 5620 millirem per quarter extremity) conducted in 1991.
- 19 major exposure investigations (exposures greater than the above amounts) conducted in 1991, with no reportable overexposures.
- 7,000 badged individuals
- Average personnel exposures for 1991
- Previous NRC Inspection
- Decay in storage increase to include isotopes with half lives of up to 100 days
- Addition of a Cesium-137 Gammacell irradiator
- Increase in the licensed limit for americium-241 to 29 millicuries
- Diagnostic misadministration that occurred in March 1991 and reviewed during the 1991 NRC Inspection

- Quality Management Program implementation
- 24 suspensions of authorized users, and 2 suspensions of individual users, primarily for failure to attend refresher training
- Contingency plan for storage of waste
- Addition of a new waste compactor
- Refresher training on waste minimization
- Use of radioactive waste pickup receipt tag
- 300 training sessions given in 1991 for 7,000 researchers, patient-care personnel, animal handlers, housekeepers, maintenance, and building engineers
- Management Improvement Plan to evaluate training
- Cyclotron use
- 1,400 urine, thyroid, and whole body bioassays performed in 1991 with four percent confirming minor burdens
- 32 iodine-131 oral therapies, 3 iodine-131 monoclonal therapies, 2 iridium-192 therapies, and 1 cesium-137 therapy performed in 1991
- 36,024 packages containing radioactive material received in 1991
- Computer system to track hot lab users who need bioassays
- Planned conversion (10-1-92) to centralized processing of package orders
- RSB Internal Program Improvement Plan
- Revision of the Radiation Safety Manual by the end of 1992
- Clear inspection by the American Association for Lab Animal Care
- 59 research protocols reviewed in 1991
- 7800 lab inspections conducted by the contractor Radiation Safety Organization, Inc. (RSOI) and 2000 RSB lab inspections in 1991
- 1772 drums of radioactive waste shipped in 1991
- 151,551 liters of liquid radioactive waste disposed of in 1991
- 3,732 boxes incinerated in 1991
- Monthly Public Health Service radiation safety seminars

The inspector concluded that the annual review was comprehensive and identified the licensee's future goals.

7.0 Training

The adequacy of the authorized user and supervisor training was determined by discussions with licensee representatives and interviews with users. These discussions indicated that all handlers of radioactive materials are required to attend a one day training course conducted by the RSB. All users and ancillary personnel are required to take refresher training annually. The RSB also provided training to contract personnel. Authorized users (those specifically licensed through the RSC in conjunction with the RSB) are required to take a two week training course offered by the RSB. If an individual misses the annual authorized user training course and desires to become an authorized user, he or she is permitted to work under the license

of an authorized user until the scheduled training is received. If an individual does not follow this procedure, permission is not granted to work with radioactive materials as an independent authorized user. Through discussion with the RSB staff, RSO, and individual workers, the inspectors determined that individuals were aware of the NIH radiation safety training guidelines, they had received individual or authorized user training, and that refresher training had been performed as required.

8.0 Procurement and Inventory Controls

According to RSB personnel, most radioactive materials are ordered by individual users through a system of blanket purchase agreements with major suppliers. Each institute at NIH has its own procurement office. Larger radioactive material orders or special items (anything over $2,500) are procured through a written requisition process. Such orders must be approved by the RSO. As discussed in Section 6.0, the licensee plans to move towards centralized processing of package orders on October 1, 1992. There are generally no direct deliveries to investigators with the exception of a large item, such as an irradiator. Gerontology Research Center (GRC) in Baltimore receives material directly.

The inspector observed that NIH had a computerized inventory control system. Information on each incoming shipment of radioactive material was entered into the database daily as the material was received in Building 21. NIH prepared monthly reports which noted the total inventory for each major isotope. The reports used the previous month's total, adding in the monthly receipts and subtracting the total monthly activity disposed including the shipped waste, the liquid wastes disposed through the sanitary sewer and the solid waste incinerated. The computer program used to generate the report incorporates radioactive decay. Authorized users were responsible for maintaining a record of the receipt, utilization, and disposal of radioactive materials used under their authorization using NIH Form 88-16 "Isotope Receipt, Utilization and Disposal Records." A binder was provided by the RSB to maintain these records. During the inspection, all of the labs visited by the inspectors had appropriately completed NIH Form 88-16.

9.0 Receipt and Distribution of Radioactive Material

With the exception of the GRC, all radioactive materials shipments are received by the Radiation Safety Branch in Building 21. Most shipments are received during normal working hours. Occasionally shipments arrive during the weekend. For the weekend deliveries, security personnel escort the carrier to Building 21 where the package is left in a secure area until radiation safety staff can process the package.

The inspector observed that external radiation surveys at the package surface and at one meter were performed on packages containing greater than Type A quantities, contamination surveys were performed when required pursuant to 10 CFR 20.205, and shipping papers were reviewed to assure that information from the purchase order matched the information on the NIH Form 88-1 "Request for Purchase and Use of Radioactive Materials." If an NIH Form 88-1 was not received from the authorized user, the package was held in the RSB until the appropriate information was received. The material was also held when discrepancies were noted between the shipping papers and the NIH Form 88-1 which could not be resolved by phone. The computer was used to log information on each shipment into the RSB database which enabled the licensee to maintain a fairly accurate materials inventory. The database was also used to verify that the user was authorized for the material ordered.

10.0 Radioactive Waste Management

The volume of radioactive waste generated by this licensee is large. The licensee reported that last year it shipped 965 drums of radioactive waste for burial in a low-level radioactive waste disposal site, and it expects to ship 750 drums this year. In addition to the transfer of radioactive waste to a disposal site, the licensee also disposes of material through incineration, through the sanitary sewer system, and, to some extent, through decay-in-storage.

The licensee's procedures specify that radioactive waste from the hospital and the research laboratories are picked up by the contractor, RSOI, and taken to Building 21 for further processing. Authorized users are required to tag each container of waste, be it liquid waste or solid waste, with a label specifying the isotopes in the waste and the activity of each. If the waste is not properly tagged, RSOI personnel are instructed not to pick it up. All waste containers which the inspector observed in the waste processing area of Building 21 were properly labeled.

10.1 Liquid Waste

Liquid waste is received in Building 21 Waste Processing Area in 2 gallon or 5 gallon carboys or in other sealed containers. RSOI personnel explained that, although all containers are tagged with the user's estimate of the contents, an aliquot is taken from each for analysis as to the exact types and quantities of radioactive material. If the analysis differs significantly from the tag, the contents are reanalyzed, and if the second analysis still differs from the tag, the authorized user is notified of the need to more accurately tag the contents. The results of the analysis are then entered into the computer so that the amount of liquid radioactive waste can be tracked.

With the exception of a few containers which contain high activities of long-lived material, each container is adjusted to a pH between 3 and 10 and then either disposed directly to the sewer system or poured into a drain which leads to nine holding tanks. The flow into a particular tank is controlled by valves at the top of each tank. At any given time, one holding tank is receiving waste containing, primarily, isotopes with half-lives less than thirty days and another is receiving waste containing, primarily, isotopes with half-lives between thirty days and one hundred days. The waste handling personnel stated that the contents of the full tanks are held to reduce the activity of the short-lived isotopes through decay. A valve at the bottom of each tank allows the tank to be released to the sanitary sewer system when decay is deemed adequate. Another valve, just before the sewer system and a recirculation pump, guards against accidental releases. It should be noted that the holding tanks are not, strictly speaking, a decay-in-storage system. The isotopes decayed in the tanks are not released as nonradioactive; rather, the decay of these isotopes is used to ensure releases into the sanitary sewer system in a given year are in compliance with the license condition limiting the released amount.

Containers which contain very high activities of long-lived material are solidified and disposed of by transfer as solid waste. As reported by RSOI personnel, all containers which have been emptied are washed and, if there are no detectable radiation levels due to residue in a given container, the container is put back into service.

The licensee's procedures for handling of liquid waste appear adequate to ensure public health and safety. Decaying liquid waste to the extent feasible is a good way to put the ALARA principle into practice.

10.2 Solid Waste

Solid waste is received in Building 21 Waste Processing Area in plastic bags which are contained in 55 gallon drums. Some of the waste is then repackaged in "burn boxes" and sent to the incinerator. Other waste is transferred to a barrel in one of the licensee's compactor units where it is compacted by about a factor of three. A small amount of waste, primarily that resulting from iodine thyroid ablation therapies, is packaged for decay-in-storage.

In a previous inspection, the NRC had expressed concern about contamination on the floor of the Building 21 Waste Processing Area. At that time, the contaminated area was not restricted in any way .. The inspector observed RSOI personnel unloading the plastic bags from the drums in which they are received. The unloading was performed in the area adjacent to the

compactors. The RSOI personnel said that this area is roped off because the process of unloading the barrels frequently results in contamination on the floor. The personnel were observed to wear protective booties in the roped-off area which were removed upon leaving the area.

The licensee segregated the bags of waste received into those to be incinerated and those to be compacted. As each bag of solid waste was unloaded from the barrel, the tags on the bags were removed and one copy separated to be sent to data entry. If the bag contained only tritium and carbon-14, or if the quantities of other isotopes were deemed small enough, the bag was placed in a "burn box" to be sent to the incinerator. Otherwise it was put in one of the compactors and an identifying number on the barrel in the compactor was written on all copies of the tag for tracking purposes. The tags from all bags going into a given barrel of compacted waste were taped to the top of that barrel once the barrel was sealed.

The licensee requires its authorized users to package used liquid scintillation vials separately from other solid waste. RSOI personnel reported that these vials are put into 55 gallon drums without any analysis of the quantity or type of material on the vial. Once the drums are full, RSOI transfers them to Quadrex, a licensed recipient, for ultimate disposal.

The inspector did not find any deficiencies in the licensee's solid waste disposal program. The licensee, however, could considerably reduce the volume of waste sent for burial in low level radioactive waste sites by segregating radioactive waste containing short-lived isotopes from that containing long lived isotopes, and disposing of the former through decay-in-storage.

10.3 Incineration

NIH operates three incinerators which are primarily used to incinerate pathological waste but which are approved for incineration of low-level radioactive waste. Two of the incinerators are older and, according to the licensee, have flow rates of 5500 cubic feet per minute (ft^3/minute) each, while the newer incinerator has a flow rate of 13000 ft^3/minute. The licensee indicated that, on most occasions, the newer incinerator and one of the older incinerators are in operation. The licensee stated that solid waste containing tritium, carbon-14, and, on occasion, small activities of other radioactive isotopes is routinely transferred from the waste collection facility in Building

21 for incineration. Material is transferred between the waste collection facility and the incineration facility once each day, and the transferred material is immediately burned. Records indicate that the effluent from the incineration of the material is less that ten percent of the maximum permissible concentration (MPC) prescribed by 10 CFR Part 20, Appendix B, Table II, when averaged over one year.

Review of records of analysis of incineration ash frequently show that, in addition to the radioisotopes present due to material transferred from Building 21 and accounted for in those transfer records, small amounts of iodine-131 and gallium-67 are sometimes present in the ash. The inspector noted that these isotopes are apparently getting into the incinerators in infectious waste transferred directly from the hospital. The licensee has taken various actions in attempting to keep this side stream radioactive waste under control. Hospital personnel who are expected to encounter these types of waste are reportedly trained to segregate them as radioactive waste. Alarming radiation detectors are mounted on the conveyers which carry boxes into the incinerators to detect any box which has readily detectable radiation emanating from it so that incinerator personnel can prevent it from being burned.

The exact activity in these wastes would be expected to be highly variable, and thus probably cannot be accurately quantified. In an attempt to characterize this problem, the licensee stationed RSB personnel at the incinerator for a short period. These individuals performed careful surveys of the contents of all boxes arriving in the incinerator waste stream. Based on the results of these surveys, the licensee believes that the quantity of iodine-131 arriving in the nonradioactive waste stream is much less than would cause them to exceed the limits in 10 CFR 20.106(a) at the stack exit. Gallium-67 is accelerator produced, thus not under NRC jurisdiction. Probable concentrations of Gallium-67 in any occupied area, however, are believed to be well below the concentrations in 10 CFR 20.106(a) for beta-gamma emitting nuclides. Calculations performed by the licensee using the Industrial Source Complex meteorological model, an EPA screening model, show that the expected effluent concentration at any accessible point is approximately 10^{-4} times the concentration at the stack exit or less.

The licensee also checks for airborne contaminants using environmental monitoring stations located at various points on the NIH campus. Samples from these stations are collected once a week and the identity and quantity of gamma emitting nuclides on the filters are determined using an intrinsic germanium detector. The energy calibration of this crystal is checked daily using a National Institute of Standards and Technology (NIST) traceable mixed gamma source. The lower limits of detection for the radionuclides in the counting system's gamma-ray library are also checked each day of use. The

records reviewed by the inspector indicated that none of these monitors detected any appreciable concentration of iodine-131 or gallium-67, although several monitors on the roofs of buildings did detect iodine-125 in concentrations up to 3.5×10^{-14} microcuries per cubic centimeter (μCi/cc), presumably from iodination hood effluents.

The licensee does not perform any direct measurement of radionuclides in the stack effluent at present. Previous attempts to place monitors directly in the stack have not been successful due to the inability of the selected probes to withstand the temperatures in the stacks during temperature excursions. The licensee stated that it is actively pursuing the acquisition of a stack monitoring system capable of operating in the stack environment.

Each of the incinerator stacks is equipped with a scrubber system. After the pH of the scrubber water is adjusted, the water is released into the sanitary sewer system. To monitor for radionuclides being released, samples of the water in the scrubber system are continuously collected in a five gallon container, which the licensee analyzes using a liquid scintillation counting system. The inspector reviewed the analysis records of scrubber water and noted that, other than tritium, no isotopes were detected. The records reviewed indicated that the concentration of tritium in the scrubber water was never above 3.9×10^{-4} μCi/ml. The maximum concentration allowed to be released to unrestricted areas is 3×10^{-3} μCi/ml, so it is permissible to release the scrubber water directly to the sanitary sewer system, as is done. The licensee's sewer disposal records did not indicate whether the discharge from the incinerator scrubber system is included in its total of material released to the sanitary sewer system. This will be reviewed at the next inspection.

Condition 24 of License No. 19-00296-10 permits the licensee to dispose of ash from the incinerator as ordinary waste so long as the concentrations of licensed material appearing in the ash do not exceed the numerical concentrations specified in Appendix B, Table II, Column 2, 10 CFR Part 20, in microcuries per gram. To ensure that the concentration of licensed material is below the allowable limits, the licensee samples ash from each of the dumpsters which collect the ash. In each dumpster, the licensee uses a scoop mounted on a long pole to take five grab samples. This procedure was approved in the last license renewal based on data submitted by the licensee showing that activity in such samples could be reasonably expected to be within two standard deviations of activities obtained in samples taken more uniformly throughout the dumpsters. The ash samples are analyzed for gamma emitting radionuclides using an intrinsic germanium detector. The licensee does not perform any analysis for pure beta emitting nuclides due to the difficulty of performing analysis of ash samples using liquid scintillation counting. The licensee is, however, exploring techniques so that liquid

scintillation counting can be used for analysis of pure beta-emitting nuclides in the ash. At present, the licensee assumes that all the tritium, carbon-14, and sulfur-35 goes into the airborne effluent.

The inspector reviewed records of analysis of incinerator ash and noted that approximately 30% of the samples contained quantities of radioisotopes above the minimum detectable activity for the isotopes, which were typically 1×10^{-7} microcuries (μCi) or less per liter of ash. The most common isotope detected was gallium-67, followed by iodine-131. In one case, when the sample contained 1.07 times the concentration of gallium-67 which could be released, the record indicated that the dumpster was held for over a week and recounted before disposal.

The primary method used by the licensee to control the concentration of isotopes in the incinerator effluent is through control of radioactive waste sent to the incinerator from Building 21. This method is clearly not perfect, as is made apparent by the periodic appearance of iodine-131 and gallium-67 in the incinerator ash. Data from air sampling stations on the NIH campus, however, indicate that concentrations on isotopes in occupied areas are below maximum permissible concentrations. Still, it would be better to have more direct measurement of the stack effluent as could be obtained through in-stack monitoring, and the licensee is encouraged to pursue a system capable of such monitoring.

11.0 Sealed Source Inventories and Leak Tests

The inspectors reviewed the licensee's records of sealed source inventory and leak tests. Inventories and leak tests are required to be performed once every six months. All results of leak tests were within license limits, and the tests were performed within the required time interval.

12.0 Facilities

12.1 Research Laboratories

The licensee has approximately 2700 labs with 800 authorized users. The inspectors visited approximately 100 research laboratories and performed inspections which included independent measurements, review of laboratory records, and discussions with individual and authorized users. The inspector was present during a contractor audit of a laboratory and determined that the audit was comprehensive and effective in identifying deficiencies and obtaining immediate corrective actions. The inspector learned from discussions with

RSB staff that contractor reports of lab audits were presented for their review and additional action if necessary. The inspector determined that all authorized users were aware of their responsibilities and were adhering to policies and procedures stated in the NIH Radiation Safety Guide, various commitments made by the licensee to the NRC, and NRC regulations. The inspector noted the following: radioactive materials were properly secured and labeled; laboratories were posted as required; the required dosimetry and protective clothing were worn; logs of material used were maintained; no evidence of eating, drinking or smoking was observed in the laboratories; and monthly surveys were properly documented. In addition, the users who were interviewed indicated that they had received the required radiation safety training and appeared to be familiar with the requirements of the licensee's radiation safety program.

12.2 Radiopharmacies

NIH oversees the operation of three radiopharmacies. The Clinical Center radiopharmacy is used for the routine preparation of common diagnostic and therapeutic radiopharmaceuticals used in clinical nuclear medicine. A second radiopharmacy is located in Building 21 and is used for the preparation of radiolabeled monoclonal antibodies for patient therapies and monoclonal antibody research. A third radiopharmacy is located in the Clinical Center's Cyclotron Facility and is used for preparation for short-lived positron emitting (accelerator produced) radiopharmaceuticals used in positron emission tomography (PET) research. The PET radiopharmacy was not reviewed during this inspection.

NIH has three full-time radiopharmacists, one is currently on a leave of absence. The radiopharmacists assigned to the Building 21 and PET pharmacies provide coverage for the radiopharmacist assigned to the Clinical pharmacy. The inspector interviewed two of the radiopharmacists and observed their work in progress, including the elution of a technetium-99m generator. The inspector reviewed records of surveys and of dose calibrator constancy, linearity, geometry, and accuracy tests.

The inspector determined that the radiopharmacies were adequately equipped and were staffed by highly proficient pharmacists who were knowledgeable of, and compliant with, applicable NRC regulations.

12.3 Nuclear Medicine Department

The inspector reviewed procedures and records of surveys, and interviewed several technologists in the Nuclear Medicine Department. The inspector determined that during normal working hours, the radiopharmacists prepared and assayed all radiopharmaceutical doses for patient administration. The nuclear medicine technologists become involved in radiopharmaceutical dose preparation and assay only on weekends and after normal hours. Review of assay records indicated that prepared doses were assayed prior to administration in accordance with the procedures submitted with the license application. Further, the dose calibrator was checked daily for constancy, as required.

The inspector noted that doses are drawn in labeled, shielded syringes and placed by the pharmacist with the prescription in a shielded metal carrying case. When requested by the Nuclear Medicine Technologist (NMT), the pharmacist places the dose on a counter built into the lower section of the pharmacy's "Dutch" door. The inspector noted that the pharmacist's desk was located directly adjacent to the door and that the pharmacist maintained surveillance over the dose until picked up by the NMT. The pharmacist also stated that the pharmacy door is closed and locked during his absence with entry possible by using a key pad lock. The inspector determined that the pharmacist and NMTs provided adequate security during use of the licensed material.

Doses are administered by the NMTs in two administration rooms located adjacent to the pharmacy. The inspector noted that the NMT reviewed the prescription and identified the patient by name and birth date prior to administration.

The Department of Nuclear Medicine currently has seven full time certified NMTs. NMTs are required to attend the NIH one day radiation safety training and annual refresher training, as well as annual specialized training provided by the radiopharmacist.

The inspector determined that the Department of Nuclear Medicine was adequately equipped, well managed, and was staffed by knowledgeable and proficient technologists.

13.0 Radiotherapy

13.1 Radiopharmaceutical Therapy

Four rooms are available for radiopharmaceutical iodine therapy. The rooms are prepared for the patient by the RSB health physicist responsible for the area. The health physicist is also responsible for administration of the iodine capsules to the patient.

The inspector witnessed the administration of a 300 millicurie iodine-131 dose and determined that the licensee utilized good ALARA techniques during the procedure. Patient and room area surveys, as well as surveys in adjacent areas above, below, and around the patient's room were conducted. The health physicist measured approximately 2 milliroentgens per hour in the unoccupied patient room adjacent to the therapy room, posted the room as a radiation area, and closed the room to patient use. The inspector determined from interviews with the nursing staff that they were well instructed in the precautions necessary during radioiodine therapy. The licensee's procedures permit entry into the patient room only by nursing staff and then only to draw blood samples, administer medication, or respond to an emergency. During these entries the member of the nursing staff is required to wear an assigned film badge, a disposable protective coat, and shoe covers.

The inspector determined that prior to release of the room for unrestricted use the health physicist cleans and decontaminates the room to less than 200 dpm/100cm^2, a procedure estimated by the licensee to require 12 to 16 person hours of work. For this reason, if a therapy room will be assigned to another radioiodine therapy patient, the licensee cleans the room and performs a general area survey for gross contamination but does not decontaminate the room to the levels required in 10 CFR 35.315(a)(7). This procedure and the need for an exception to the regulation was identified during the 91-001 inspection. The inspector noted that the licensee had requested an exception to the regulation on May 15, 1992 and that a technical assistance request was forwarded to the Chief of the Medical, Academic, and Commercial Use Safety Branch by Region I on May 26, 1992. The inspector stated that, until the request for exemption to the regulation is resolved, the licensee would have to comply with the regulations or submit some therapy room release criteria which would be acceptable to the NRC on an interim basis.

On July 30, 1992, the licensee verbally committed to decontaminating patient therapy rooms prior to release to another therapy patient to 22,000 dpm/100 cm^2 of removable contamination and to locking the therapy room between therapy patients. This matter will remain unresolved pending the NRC issuance of the license amendment.

The inspector determined that the licensee's radiopharmaceutical therapy program was well managed by the clinical staff and that the Radiation Safety Branch provided effective oversight sufficient to assure public health and safety.

13.2 Brachytherapy

The licensee told the inspector that brachytherapy was rarely performed, however, the number of brachytherapy procedures is expected to increase in the future due to the arrival of a new physician. The inspector found, by reviewing the source log, that only two brachytherapy procedures had been performed within the last year. The inspector verified that the brachytherapy sources were leak tested and inventory checks were performed as required. The inspector determined that brachytherapy sources were stored in a locked, lead lined safe in a locked closet inside of a linear accelerator therapy room and that only the RSB has keys to the safe. Surveys of the storage areas were performed as required.

Two adjacent patient rooms have been designed to be used for brachytherapy procedures. There is mobile lead shielding in both rooms available for staff and visitors to use when in the room. The inspectors determined that surveys of the room and adjacent areas were performed for each patient and required surveys and inventories were performed immediately following removal of the sources from the patient.

The inspector determined that the licensee's brachytherapy program was well managed by the clinical staff and that the Radiation Safety Branch provided effective oversight sufficient to assure public health and safety.

14.0 Personnel Exposure Monitoring

14.1 External Dosimetry

The licensee's dosimetry records indicated that NIH provided film badge monitoring to over 7,000 individuals. RSB representatives stated that all individuals working with gamma emitters, x-ray producing machines, and

penetrating beta emitters were required to wear film badge dosimeters. In addition, film badges were routinely issued to other workers when dosimetry was requested. The licensee also provided extremity monitoring to users handling over 500 microcuries of phosphorus-32 in stock solutions and individuals using millicurie quantities of gamma-emitting nuclides. Exposure histories of individuals were stored in database files. The inspector reviewed selected exposure records and noted that dose information was easily retrieved and maintained up to date. The inspector also noted that appropriate minor and major investigations were conducted by the area health physicist on individuals exceeding ALARA levels. The inspector examined quarterly and annual film badge summaries and determined that no exposures in excess of regulatory limits had occurred within the last year.

The inspector discussed the procedure for lost or unreturned badges with the licensee. The licensee stated that approximately 100 badges are unreturned or lost each month and that an investigation and subsequent addition of dose estimations to the personnel dosimetry record are made only if the individual is in a high use category (i.e., Radiation Safety, Nuclear Medicine).

14.2 Internal Dosimetry

14.2.1 Air Sampling program

The inspector reviewed selected records (1991-1992) of room, breathing zone, and hood air analyses. The licensee utilized activated charcoal to sample for iodine and silica gel traps to sample for tritium. The records reviewed indicated that measured room air concentrations had not exceeded the regulatory limit for airborne concentrations in restricted areas for any nuclide during the monitoring period.

14.2.2 Bioassay Program

From records review and personnel interviews, the inspectors found that the licensee's bioassay program included urinalysis, thyroid counting, and whole body counting. Individuals who used greater than ten millicuries of iodine-125, ten millicuries of iodine-131, and/or 100 millicuries of tritium as well as all personnel involved in the receipt, prepackaging, or waste processing of these isotopes were required to have a bioassay performed within 7 days of use or processing. Personnel involved with iodine-131 therapies of greater than 30 millicuries were required to have a bioassay performed within 72 hours of

dose preparation or administration.

Individuals performing iodinations are tracked on the computer to ensure that thyroid uptake counts are completed at the required frequency. For individuals using a cumulative quantity of iodine exceeding 10 millicuries in a calendar quarter a thyroid uptake count must be performed by the end of the quarter. Tritium bioassays for the quarter are handled similarly, though there are very few of these since there are less than 5 users of tritium in quantities greater than 100 millicuries.

The inspector found that the RSB staff investigated any unusual exposures as well as all exposures greater than 10% of the maximum permissible body burden or critical organ burden. The inspector found that there were no exposures which exceeded regulatory limits within the past 12 months.

15.0 Airborne Effluent

The licensee stated that the majority of the iodinations and other activities involving radioiodine are performed in the facilities of Building 21. Iodination enclosures with a charcoal filtration system were used in hoods which also had charcoal filtration. Silica gel was used to sample effluents from hoods in which tritium was used. Continuous effluent air sampling was used in hoods in Building 21 and other high use hoods.

The inspector examined selected records of airborne effluent monitoring for the last year. The inspector noted that several hoods in Building 21 had effluent which occasionally measured at or above the MPC levels for iodine-125 on the weekly samples. However, the inspector's review did not indicate any instance in which any hood approached the 10 CFR 20, Appendix B release limits when averaged over the year.

16.0 Instrument Calibration

The licensee's radiation survey instruments used to measure dose rates are calibrated by RSOI. The inspector verified that the calibrations were performed annually as required. Radiation survey instruments used to measure contamination (such as those used by researchers) were routinely calibrated on site by RSOI during periodic

radiation safety audits of individual laboratories. The inspector observed the field calibration of a radiation survey meter performed by an RSOI employee. A field calibration included calibrating the count rate of each scale of the meter with an electronic meter and determining detector efficiency with a standard source.

17.0 Exit Interview

At the conclusion of the inspection, the inspectors met with the individuals identified in paragraph 1 of this report and discussed the scope and finding of the inspection.

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01786/93-001 License No. 19-00296-10

EA No. 93-009

Docket No. 030-01786 Priority 1 Category G1 Program Code 02110

Licensee: Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20892

Facility Name: National Institutes of Health

Inspection at: Bethesda, Maryland

Inspection Date: January 13, 1993

Inspector: Richard W. McKinley — 1-29-93
Richard McKinley, Health Physicist — Date

Inspector: Sattar Lodhi — 1-25-93
Sattar Lodhi, Ph.D., Health Physicist — Date

Approved by: for — 1/25/93
Mohamed Shanbaky, Ph.D., Chief — Date
Medical Inspection Section

Inspection Summary: Special announced inspection conducted on January 13, 1993 (Report No. 030-01876/93-001)

Areas Inspected: Review of circumstances surrounding the incident that resulted in an extremity overexposure. The inspection also included interviews with the personnel involved in the incident.

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Results: Four apparent violations were identified: (1) extremity exposure in excess of regulatory limit (Section 6); (2) failure to ensure that radiation safety activities are performed in accordance with approved procedures (Section 5); (3) failure to supply personnel monitoring equipment to an individual who is likely to receive a dose in excess of 25% of 10 CFR 20.101(a) values (Section 5); and (4) failure to notify an individual of exposure to radiation (Section 6).

DETAILS

1. Persons Contacted:

William J. Walker, Ph.D., Radiation Safety Officer (RSO)
*Robert A. Zoon, Deputy Branch Chief, Radiation Safety Branch
*Ted W. Fowler, Chief, Radiation Safety Operations Section and Deputy Radiation Safety Officer
*Roger W. Broseus, Ph.D., Assistant to Chief, Radiation Safety Branch
*Adel Baryoun, Area Health Physicist, Radiation Safety Branch
Nancy Newman, Assistant Section Chief, Radiation Safety Operations Section
Lynn Jenkins, Supervisor, Clinical Center Staff, Radiation Safety Branch
Harry L. Malech, M.D., Authorized User
Phillip Murphy, Authorized User
Steven Wieland, Supervised User
Sunil Ahuja, Supervised User

*Present at Exit Conference

2. Scope of Operations:

The National Institutes of Health are authorized to use byproduct material for medical research, diagnosis and radiation therapy under an NRC broad scope license No. 19-00296-10 issued to the Department of Health and Human Services. Many individuals are involved in the activities conducted under this license including approximately 850 authorized users and over 3500 supervised users of radioactive material. The activities conducted under the NRC license are regulated by the Radiation Safety Branch (RSB) which is comprised of 34 staff members including 24 health physicists. The chief of RSB also serves as the licensee's Radiation Safety Officer (RSO). The RSB has the responsibility of ensuring that licensed material is used safely and in accordance with various regulatory requirements. The RSO has the authority to suspend the authorization of a user when violations of procedures, NIH policy, NRC regulations, or license conditions occur.

3. Notification of Incident:

On December 17, 1992 the licensee notified the NRC Region I Office by mail that an incident involving an extremity exposure in excess of the regulatory limit had occurred at its facility. The licensed material involved was phosphorus-32. The event occurred before lunch (around noon) on November 17, 1992 and was identified

by the licensee at approximately 5:00 p.m. on November 18, 1992. The licensee stated in its notification that the incident occurred when an individual contaminated his hands while assisting in the clean up of a phosphorus-32 spill. The contamination was localized near the tip of the left index finger and remained undetected for about 30 hours. The licensee estimated that the quantity of radioactivity on the contaminated finger was 1.5 microcuries at the time of contamination and that the highest radiation dose to one square centimeter (cm^2) area of the skin of the finger was 24.9 rem. The licensee also estimated that the radiation dose averaged over the contaminated area of the finger was 23.5 rem per cm^2. The NRC's evaluation of licensee's assessment is discussed in Section 6 of this report.

4. Chronology of Events:

- On November 17, 1992, at approximately 11:30 a.m., an individual (Researcher A) working with a vial containing radioactive adenosinetriphosphate (ATP) was unable to close the container vial and asked a second individual (Researcher B) for assistance.

- Researcher B noticed wet spots on the absorbent pad behind the plexiglass shield and also noticed some wetness on the container vial.

- Researcher B surveyed the area with a radiation detecting survey meter and found the wet spots to be radioactive.

- Researcher B helped in the clean up of the work area including the disposition of the contaminated pad, the vial, and the used pairs of protective gloves. The disposed vial still contained some radioactive ATP.

- Researcher B surveyed the cleaned areas for radioactive contamination but did not survey his body and his hands as required by the licensee's procedures. Researcher A surveyed his hands after clean up and did not find any contamination on his hands.

- On November 18, 1992, at approximately 5:00 p.m., Researcher B detected radioactive contamination on his hand and notified his supervisor.

- On November 18, 1992, at approximately 6:30 p.m., the supervisor notified the RSB and requested assistance.

- The RSB personnel measured a contact count rate of 400,000 counts per minute on Researcher B's finger. The licensee determined that this count rate was equivalent to 0.644 microcuries of phosphorus-32. Most of the contamination was localized in a 7.5 cm^2 area near the tip of the index finger. Minor contamination of Researcher B's thumb, his shoestring and the zipper of his trousers was also detected. At that time a urine sample was collected from Researcher B.

- On the evening of November 18, 1992, Researcher B surveyed his automobile and home and found minor contamination on the steering wheel of his automobile and a door knob that he had repaired during the evening of November 17, 1992.

- On November 19, 1992, Researcher B's urine sample was analyzed for radioactive contamination and no detectable radioactivity was found in the sample. The radioactivity on the contaminated finger was measured again at 1:00 p.m. and was determined to be 0.056 microcurie.

- On November 23, 1992, at 10:15 a.m., the radioactivity on the contaminated finger was again measured and was found to be 0.008 microcurie.

- On November 30, 1992, at 11:30 a.m., the residual contamination on the finger was measured to be 0.00056 microcurie.

- On December 16, 1992, the licensee mailed the notification of the incident to the Region I Office.

5. Review of Incident:

An announced special inspection was conducted on January 13, 1993. This inspection was limited to a review of the activities and circumstances surrounding the incident. The inspector conducted interviews with the licensee's staff, including those individuals directly involved in the incident. The inspector also inspected the laboratory where the incident occurred. The licensee explained the circumstances that led to the incident and summarized the subsequent follow up conducted by the RSB personnel.

The incident occurred on November 17, 1992 at approximately 11:30 a.m. when a researcher (Researcher A) was unable to properly close a vial containing phosphorus-32 in the form of liquid adenosinetriphosphate (ATP). Researcher A stated that he had not used such a vial previously and was not fully familiar with its opening and closing mechanism. He sought assistance from a second individual (Researcher B) who was also working in the same laboratory at that time. Researcher B noticed a

few wet spots on the absorbent pad in the work area under the plexiglass shield and some wetness on the sides of the vial. Researcher B conducted a survey of the work area and determined that the absorbent pad was contaminated with radioactive material. The contamination was, however, limited to the areas where the wet spots were located. Researchers A and B both performed the clean up of the contaminated area. Researchers A and B stated that they were wearing protective gloves while working in the area and during the decontamination procedure. Researchers A and B discarded the contaminated absorbent pad, the vial that still contained the remaining radioactive material, and their protective gloves following the clean up of the area. Researcher B conducted a radiation survey of the area after the clean up and found no detectable contamination in the area. Researcher A stated that he performed surveys of his body and hands to ensure that there was no contamination of his body parts or clothing. Researcher B stated that he did not perform a survey of his body, hands or clothing following the clean up.

The licensee requires users to survey their laboratories and themselves for contamination on a daily basis when radioactive materials have been used. This requirement is described in item 10.13.2 of the licensee's application for license renewal dated July 28, 1986. In addition, Item 3 of the licensee's Procedure For Spill Clean Up requires that individuals monitor themselves for contamination and decontaminate immediately if any contamination is found. The inspector determined that Researcher B did not follow the licensee's procedure for performing personal contamination surveys. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are performed in accordance with approved procedures.

Failure of the licensee to ensure that radiation safety activities are performed in accordance with approved procedures is an apparent violation of 10 CFR 35.21(a).

Researcher B detected radioactive contamination on his left index finger at about 5:00 p.m. on November 18, 1992 while working with another radioactive probe and realized that this contamination occurred on the previous day while he assisted his colleague in the clean up of the radioactive ATP spill. A radiation survey of the affected finger with a pancake Geiger-Mueller (GM) detector indicated readings of 250,000 counts per minute. The radioactive material appeared to have become bonded to the skin of the finger because the affected finger could not be decontaminated in spite of very aggressive efforts. The RSB was notified of this incident at about 6:30 p.m. and a health physicist went to the laboratory to investigate the incident. Researcher B's affected finger had become reddened as a result of decontamination efforts and further efforts at decontamination were abandoned because of the possibility of a break in the skin. The health physicist measured the activity on the affected area of the finger with a pancake probe GM detector and noted count rates as high as 400,000 counts per minute. The licensee determined that the efficiency of the GM pancake probe for detecting phosphorus-32 was 28%. The

health physicist also determined that the contamination was limited to a 7.5 cm^2 area of the finger. Minor contaminations of Researcher B's left thumb (about 1000 counts per minute), shoelace and the zipper on his trousers were also detected by the RSB health physicist. Some contamination (about 50 to 100 counts per minute above background level) was also found on the steering wheel of Researcher B's automobile and a door knob at his house. These objects (shoelace, the zipper, steering wheel and the door knob) were decontaminated. The assessment by the RSB of the radioactivity on the finger and the resulting radiation dose to the finger are described in Section 6 of this report.

Researcher A stated that he has been working in the laboratory with radioactive material since the middle of September, 1992, on a part time basis (three days a week) under the supervision of an authorized user. Researcher A stated that his prior experience working with radioactive material was over 10 years ago but that he was given instructions on how to use radioactive material by his supervisor and he observed his supervisor use radioactive material during the month of September, 1992.

The inspector determined from discussion with the RSB staff that the authorized user did not register Researcher A with the RSB as a new radiation worker prior to allowing him to work with radioactive material. Because Researcher A was not registered with the RSB, no personnel dosimetry was provided to Researcher A. 10 CFR 20.202(a)(1) requires that each licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in excess of 25% of the applicable value specified in paragraph (a) of 10 CFR 20.101. The inspector determined that Researcher A's use of up to one millicurie quantities of phosphorus-32 could result in his receiving a dose in excess of 25% of the values for extremity and skin exposures specified in 10 CFR 20.101(a). This determination is supported by the fact that Researcher B received an apparent extremity exposure in excess of the 10 CFR 20.101(a) value while assisting Researcher A. The inspector also noted that the licensee's own policy requires that all individuals working with high energy beta emitters and gamma emitters wear a whole body film badge and that persons working with greater than 0.5 millicurie quantities of phosphorus-32 use a wrist or finger monitor. The licensee's policy requires that these monitors be acquired before first use.

Failure of the licensee to supply appropriate personnel monitoring equipment to each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in excess of 25% of the applicable value specified in paragraph (a) of 10 CFR 20.101 is an apparent violation of 10 CFR 20.202(a)(1).

6. Licensee Assessment:

The supervisor of the individual notified the RSB of the incident at approximately 6:30 p.m. A health physicist from the RSB responded, performed a radiation survey of Researcher B's affected finger, and noted a count rate of 400,000 counts per minute. The RSB health physicist confirmed that the contaminant on Researcher B's finger tip was phosphorus-32 by covering the detector window with a foil to block the beta particles. By using a crude collimator in front of the detector window, the health physicist determined that the contamination was limited to a 7.5 cm^2 area near the tip of the index finger of Researcher B's left hand. The health physicist stated that his measurements of the radioactivity on Researcher B's finger indicated that the contamination was uniformly distributed over the 7.5 cm^2 area and the measured activity of phosphorus-32 on the finger was 0.644 microcuries. Some minor contamination was also found on the tip of the left thumb. Efforts to decontaminate the finger were minimally effective in removing the contamination as the contaminant had become bonded to the skin of the finger.

Researcher B expressed concern that some radioactive material may have been ingested by him because of his habit of biting his fingernails. The RSB health physicist collected his urine sample on November 18, 1992 at approximately 7:00 p.m. This sample was analyzed for radioactivity in the morning on November 19, 1992 and no detectable radioactivity was found in the sample. The licensee ruled out the possibility of any significant intake of radioactive material by Researcher B based on the results of the urine bioassay.

The activity on the finger was monitored periodically as a function of elapsed time until the residual activity on the finger was reduced to 0.00056 microcurie at 11:30 a.m. on November 30, 1992. From these data the licensee estimated that the initial activity on the finger at the time of the incident (11:30 a.m. on November 17, 1992) was 1.5 microcurie. The licensee also used these data in the Mathematical Modeling System computer code (MLAB) to calculate the cumulated activity. These calculations gave an estimated cumulated activity of 40.5 microcurie-hour.

RSB personnel described the methods that were used to estimate the initial activity on the finger and the resulting radiation dose. The licensee stated that because guidelines for determining the radiation dose for regulatory compliance were not available, the radiation dose to the extremity of the individual was determined in three different ways. The licensee used the VARSKIN computer code in assessing the skin dose. The cumulated activity of 40.5 microcurie-hour was used in these calculations and the radiation dose to the skin was calculated at basal layer (at a depth of 0.042 cm). Based on the results of these calculations, the licensee estimated that the maximum radiation dose to one cm^2 area of the finger was 24.9 rem, while the radiation dose per cm^2 averaged over the area of contamination (7.5 cm^2) was 23.5 rem. The licensee stated that they faced a similar situation during the last NRC inspection that

was conducted from July 20 to 24, 1992, when they were cited for not performing an adequate evaluation of a skin exposure which had resulted from a contamination incident. The licensee stated that, in their response to the Notice of Violation, they had provided a basis for retraction or downgrade of the violation but that the NRC had not yet responded. The inspector stated that assumptions for regulatory purposes concerning tissue depth determinations are provided in the Instructions for Preparation of NRC Form 5 (Item 5) and that these instructions are regulatory requirements. The inspector also stated that in such cases the dose to the skin is assessed at a depth of 7 mg/cm^2 in the tissue and is averaged over the contaminated area rather than over the entire organ and that an area of one cm^2 has been established for calculating skin dose for comparison with the dose limit for the hands.

10 CFR 20.401(a) requires, in part, that a licensee maintain records showing the radiation exposures of all individual for whom personnel monitoring is required and that these records be in accordance with the instructions contained in Form NRC-5. A calculation of the radiation dose made on the basis of the regulatory guidelines by the inspector resulted in an average radiation dose of 48 rem to one cm^2 area of the skin. However, the inspector determined that the licensee responded properly to the contamination incident and made an effort to evaluate the radiation dose to the skin in accordance with its understanding of the regulatory requirements.

10 CFR 20.101(a) states, in part, that no licensee use licensed material in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter a total occupational dose to the hands and forearms in excess of 18.75 rem.

Failure to keep an occupational dose to a worker within the regulatory limit is an apparent violation of 10 CFR 20.101(a).

10 CFR 20.409(b) requires, in part, that a licensee reporting to the Commission pursuant to 10 CFR 20.405 also notify the individual no later than the transmittal to the Commission in accordance with the provisions of 10 CFR 19.13(a). 10 CFR 19.13(a) requires, in part, that each notification be in writing and also contain the statement "This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference". During the January 13, 1993 inspection, the licensee stated that although the contaminated individual was aware of the exposure, a written notification to the individual in accordance with the requirements of 10 CFR 20.409(b) had not been made.

Failure to notify the exposed individual in a timely manner is an apparent violation of 10 CFR 20.409(b).

7. Corrective and Preventive Actions:

The licensee provided the required radiation safety training to Researcher A on January 7, 1993 and the appropriate personnel monitoring equipment was provided to the individual on November 19, 1992. Warnings were also issued to the authorized users under whose supervision this individual was working. The RSB has the authority to suspend the authorization of any user if serious violations of the regulations, policies and procedures occur under his supervision. In this particular instance, however, warnings of possible suspension were issued to the involved authorized users.

8. Exit:

The inspector met with the individuals identified in Section 1 and discussed the scope and findings of the inspection.

North Bethesda Congress of Citizens' Associations, Inc.
c/o 9928 Brixton Lane
Bethesda, MD 20817
Phone: (301) 469-7790 ext 77

December 2, 1993

Docket No. 030-01786

Mr. James M. Taylor
Executive Director for Operations
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: Request for Action Pursuant to 10 CFR § 2.206

Dear Mr. Taylor:

This letter transmits our request for action pursuant to Section 2.206 of Title 10 of the Code of Federal Regulations (10 CFR § 2.206). Specifically, we request that the U. S. Nuclear Regulatory Commission (NRC) suspend License Condition 24, of the National Institutes of Health (NIH) Materials License, No. 19-00296-10, pending resolution of two regulatory issues. License Condition 24 authorizes NIH to dispose of licensed materials by incineration.

The basis for our request is contained in the attachment to this letter. In brief, our concerns are (1) no environmental report or environmental assessment has been compl.. ed regarding the incineration of radioactive waste on NIH's Bethesda campus; and (2) there may be less than adequate monitoring to ensure that radioactive effluent releases are within regulatory limits.

Additionally, with respect to this docket, we request a copy of the NRC environmental assessments and/or safety evaluations that provide the bases for (1) an exception from 10 CFR § 20.303(d) limits regarding radioactive material discharges into sanitary sewer systems (License Condition 21); and (2) approval of the construction and operation of a low level radioactive waste storage facility at NIH's Poolesville campus (License Condition 28). We have been unable to identify these bases documents as they do not accompany the corresponding license amendments.

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We request that a copy of future correspondence between your agency and NIH regarding these matters be forwarded to our attention. In advance, thank you for your consideration of this request.

Sincerely,

Arlene S. Allen,
President

Attachment: as discussed

cc: Rep. C. Morella
(MD) Sen. H. Denis
S. Ficca, NIH
T. Martin, NRC Region I

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Action Requested Under 10 CFR § 2.206

Pursuant to 10 CFR § 2.206, the North Bethesda Congress[1] requests that License Condition No. 24 to the materials license for the National Institutes of Health (NIH), License No. 19-00296-10, be suspended pending resolution of the issues discussed herein. License Condition 24 states, in part, that:

> "Pursuant to Sections 20.106(b) and 20.302 of 10 CFR Part 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20."

Basis for the Request

1. Possible Noncompliance With Environmental Regulations

NIH, to our knowledge, has not completed and submitted to the U. S. Nuclear Regulatory Commission (NRC) an environmental report regarding the radiological releases from their incinerators at the Bethesda campus. Moreover, the NRC has not issued an environmental assessment or impact statement regarding the NIH radiological emissions, as far as we have been able to determine.

The National Environmental Policy Act (NEPA) of 1969, as amended, provides the legal basis for the requirement to perform environmental impact statements. This law is implemented by specific agency regulations such as 40 CFR Part 1500 for the Environmental Protection Agency (EPA) and 10 CFR Part 51 for NRC. Within the broad spectrum of NRC actions subject to Part 51, only those types of actions which have been determined by rule to be categorical exclusions [i.e., those discussed in 10 CFR § 51.22(c) and (d)] are excluded from the NEPA process. The remaining actions are subject to NEPA review, requiring either an environmental impact statement or an environmental assessment leading in turn to a finding of no significant impact or to a decision to prepare an environmental impact statement.[2]

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1. The North Bethesda Congress is a neighborhood association that represents residents living in the Bethesda, Maryland area. The North Bethesda Congress serves as an umbrella organization with representatives from various other citizen's associations throughout the Bethesda area participating as members. Several weeks ago, it came to the group's attention that the three incinerators located on the NIH Bethesda campus were authorized to burn medical and radiological waste. Given the proximity of the incinerators to nearby neighborhoods, a research effort was initiated by the group to determine the licensing basis for the incinerators.
2. Refer to Statements of Considerations for final rulemaking regarding NRC environmental regulations, 49 FR 9352.

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The criteria for categorical exclusion as defined in the NRC's regulations, while including issuance and amendment of material licenses for certain activities [10 CFR § 51.22(c)(14)], does not include the disposal of radioactive waste by incineration. Disposal via this mechanism requires specific and separate approval by the NRC under 10 CFR § 20.302, and constitutes a licensing action that is not within the scope of a routine Part 35 license.[3] This type of action is, therefore, subject to the NEPA process.

10 CFR § 51.60(b)(2), requires a materials licensee to prepare an environmental report for amendments to its license that would "authorize or result in...(ii) a significant change in the types of effluents [or], (iii) a significant increase in the amounts of effluents..." License Condition 24 authorizes NIH to incinerate its radioactive waste and release up to several curies per year of various radioactive effluents (refer to Table 1) as a direct result of this incineration.[4] We have been unable to identify an environmental report for this activity (i.e., a report containing the information required by 10 CFR § 51.45) in any license amendment request including the most recent license renewal application. Furthermore, no NRC safety evaluation or environmental assessment, the latter of which we believe is required by 10 CFR § 51.21, have been identified for this activity. Prior to NRC approval of License Condition 24, NIH was not permitted to incinerate radioactive material onsite and, therefore, this action constituted a "significant change" in the type and "significant increase" in the amount of radioactive effluents being released to the environment.

As discussed in NRC inspection report No. 030-01786/88-001, Attachment 8, radiological releases from the incinerators are capable of exceeding regulatory limits and we believe that the total radiological emissions from NIH (including those from Building 21 hoods) are sufficient to warrant environmental analysis.

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3. In the Statement of Considerations accompanying the newly revised 10 CFR Part 20, the NRC stated (56 FR 2338) that "The requirement for prior NRC approval of incineration remains in the amendments to Part 20 in this final rule because the acceptability of incineration as a disposal option, except for exempted quantities of radioactive materials, must be determined on a site specific basis considering: (1) incinerator design, (2) the variable isotopic composition and activity of the material to be burned, and (3) potential human exposure to effluents, which may require special calculational methods because of complex meteorologic conditions and other factors." In making this statement, the NRC rejected the notion that disposal of radioactive waste by incineration is simply just another form of general effluent release.

4. These activity limits were derived using the maximum airflow capacity of all three incinerators and may be increased as incinerators with larger airflows are used to burn the waste. It should be noted also that NIH has stated in correspondence to the NRC that normally only two incinerators are operating at any one time and there are no restrictions placed on NIH to prohibit burning all the waste in one incinerator. Thus, with only one or two incinerators operating, the annual limits listed in Table 1 are not valid since they would result in actual concentrations exceeding required levels.

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Furthermore, we believe that the volume of radiological waste incinerated will increase over the next few years up to the limits imposed by the license as new incinerators are built[5] and other low level radioactive waste disposal methods cease to be available.

We view the generation of an environmental report and corresponding assessment as an important decision-making process as it would, in part, evaluate the total impact of NIH radiological emissions on the surrounding neighborhoods as well as consider reasonable alternatives to certain activities such as incineration, as required by NEPA.

We conclude, therefore, that continued burning of radioactive and potentially contaminated medical/pathological waste in the NIH incinerators without a complete environmental report and accompanying assessment may be in noncompliance with NRC's environmental regulations.

2. Questionable Methodology for Determining Radioactive Effluent Releases

To date, as far as we are able to determine, no continuous stack monitoring for radioactive airborne effluents exists at the NIH incinerator stacks.

In 1986, NIH was cited for its failure to adequately monitor radioactive effluents from its incinerator stacks. Problems in this area continued through the end of 1988, as documented in an NRC inspection report (No. 030-01786/88-001).[6] The problems apparently resulted from two main factors: (1) the lack of direct stack monitoring instrumentation; and (2) the failure to intercept contaminated medical waste prior to it being fed into the incinerator. In January 1989, a Management Meeting was held between NRC staff and NIH officials to discuss the issues and proposed corrective actions. At the conclusion of the meeting, it was agreed that the resolution of the problem would encompass three corrective actions (refer NRC meeting summary dated January 24, 1989):

(1) Restrict the incinerator influent and sample/survey packages going to the incinerators, using a statistical model, to demonstrate compliance;

(2) Sample the stack effluent with a composite air sampler/conditioner; and

(3) Validate the location of environmental sampling stations using existing technology, EPA dispersion models and available meteorological data.

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5. Refer to a letter from W. Walker, NIH to the NRC, Region I, dated February 24, 1992.

6. It was in this inspection report that the NRC documented (in Attachment 8) its conclusion that NIH exceeded its yearly radioactive effluent release limit to unrestricted areas for 1987.

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In follow-up letters to the NRC, it appeared that NIH committed to install instrumentation that would continuously monitor incineration effluents. However, as described in the NRC's most recent inspection report of the incinerators (dated September 16, 1992) NIH had still not installed this direct effluent monitoring instrumentation at the incinerator stack.

In an effort to prevent contaminated medical waste from entering the incinerator, NIH has installed a box monitoring system. According to NIH and NRC records, this monitoring system is sensitive enough to detect a 1 mCi Cs-137 source. Boxes that contain sources with higher levels of radioactive contamination will presumably set off an alarm and the box can be prevented from entering the incinerator. It remains unclear (1) how these detectors identify boxes that contain low energy gamma and beta emitters (such as iodine-125 and tritium) and (2) what assumptions are used when determining the total radioactive effluents released from the incinerators to account for the contribution from the medical waste boxes that are burned in the incinerator which could have radioactive contamination up to the detection threshold of 1 mCi.

Small amounts of iodine continue to be identified in the incinerator ash (according to the 1992 NRC inspection report) indicating that contaminated medical waste is still getting into the incinerators. This is of concern because after considering a reasonable partition factor, even small amounts of activity in the ashes when compounded by the large volume of waste burned can translate into effluent releases that, when combined with other known releases, approach or exceed effluent release limits to unrestricted areas. Additionally, radionuclide releases from other sources, such as Building 21, do not appear to be routinely considered in conjunction with incinerator radionuclide releases when computing the overall facility release totals to unrestricted areas.

NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," states, in part, that (page 8.37-4):

> "Licensees must perform surveys and monitoring...that may be necessary to determine whether radioactive levels and effluents meet the licensee's established ALARA goals."
>
> "When practicable, release of airborne radioactive effluents should be from monitored release points to ensure that the magnitude of such effluents is known with a sufficient degree of confidence to estimate public exposure."
>
> "Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities."

10 CFR § 20.106, specifies that the concentration limits in Appendix B, Table II (of Part 20) apply where the material leaves the stack and enters the unrestricted area. Given

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the inaccurate methods used to detect contaminated medical waste at the inlet to incinerators, and with no provisions for continuous stack monitoring as specified in ANSI N13.1, it is unclear how compliance with Part 20 limits can be assured. We recognize that NIH has implemented an environmental monitoring program. However, as discussed in ANSI N13.1, the interpretation of atmospheric samples is subject to large uncertainties due to meteorological variables. This approach may only be useful in reinforcing the validity of effluent monitoring, but not useful in providing the primary method of compliance verification.

In conclusion, it is unclear how the methods currently used by NIH to assess radioactive effluent releases at the incinerators satisfy regulatory requirements and provide adequate accuracy and assurance that release limits are being met.

Table 1

Activity Limits for Radioactive Effluents from NIH Incinerators

Nuclide	Annual Limit (mCi)
H-3	5,540
C-14	2,770
P-32	55.4
S-35	249.3
Ca-45	27.7
Cr-51	2,216
Mn-54	27.2
Zn-65	55.4
Se-75	110.8
Y-90	83.1
Tc-99m	13,850
I-125	2.2
I-131	2.8
Tl-201	831

Note: Information in the table was obtained from a letter from W. Walker, NIH to NRC dated August 11, 1992, as part of a license amendment request (for Amendment No. 68).

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APR 26 1994

Docket No. 030-06922 License No. 19-00296-12

Department of Health & Human Services
National Institutes of Health
ATTN: William J. Walker, Ph.D.
Radiation Safety Officer
Bethesda, Maryland 20892

Dear Dr. Walker:

Subject: Routine Inspection No. 030-06922/93-002

This letter refers to your December 21, 1993 correspondence, in response to our November 22, 1993 letter. We have reviewed the information contained in your response concerning the failure of the National Institutes of Health (NIH) to notify the Nuclear Regulatory Commission (NRC) of an irradiator failure in accordance with 10 CFR 21.21(c)(3)(i).

Your response has not changed our view that the interlock failure created a substantial safety hazard as defined by 10 CFR 21.3(m) for two reasons. First, you have not demonstrated that the interlock failure could not have resulted in a condition where the source could have been moved such that the shield no longer protected the operator from the source and second, you have not adequately demonstrated that the interlock failure could not have occurred while the source shield carriage was away from the bottom shield, thus dropping the source down towards the floor. In addition, we believe that the radiation alarm and the survey meter you described in your response do not replace the engineered safety function of the interlocks. Your staff's quick response to the alarm and the relatively shielded position of the source prevented a substantial exposure from occurring during the events of September 24, 1993. However, we believe that a substantial safety hazard existed, although only for a short period of time.

In addition, we have evaluated your comment that a failure of a one-of-a-kind device is not reportable under 10 CFR 21. If a licensee discovers a deviation or a failure to comply in a basic component, or part thereof, the licensee must evaluate the deviation or failure to comply in accordance with 10 CFR 21.21 to identify defects and failures to comply that may involve substantial safety hazards. The purpose is to identify a reportable defect or failure to comply that could create a substantial safety hazard were it to remain uncorrected. In all cases, if, based on an evaluation, a deviation is determined to be a defect as defined in Part 21, a notification must be made to the NRC, regardless of whether one-of-a kind or generic implications are involved. Part 21 regulations implement Section 206 of the Energy Reorganization Act of 1974, as amended, which requires that all licensees, as well as non-

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licensees which supply basic components to licensees, report defects that could create a substantial safety hazard. There is no exception for components which are not common to those in other units. Therefore, Section 21.21 requires that the appropriate individuals or organizations adopt procedures to ensure that all deviations and/or failures to comply are evaluated.

One of the reasons that the NRC requires these reports is to obtain information which often forms the basis for generic communications (in one-of-a-kind design cases such as this one, a generic communication might be appropriate to alert other irradiators who use an interlock design of their own that similar problems may be possible with their designs). In addition, the reports contribute to the overall improved safety of the nuclear industry ensuring that (1) the NRC is aware of the nature of the defect or deviation; (2) the supplier is identified; and (3) the licensee has taken or will take corrective actions regarding the defect or deviation.

You have not provided justification for withdrawal of the violation, and the violation stands. You are required to respond within 30 days of the date of this letter with the information requested in the Notice of Violation attached to our November 22, 1993 letter.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Charles W. Hehl

Charles W. Hehl, Director
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Maryland

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bcc:
Region I Docket Room (w/concurrences)
D. Holody
K. Smith
S. Shankman

DRSS:RI	DRSS:RI	DRSS:RI	ORA:RI	DRSS:RI	DRSS:RI
Kirkwood/gc	Pasciak	Bellamy	Smith	Hehl	Holody
2/28/94	3/2/94	3/2/94	4/4/94	4/1/94	4/ /94

U.S. NUCLEAR REGULATORY COMMISSION
REGION I
INSPECTION REPORT

Combined Report Nos. 030-01786/94-001
030-17872/94-001

Docket Nos. 030-01786
030-17872

License No. 19-00296-10 Priority 1 Category G1 Program Code 02110
License No. 19-00296-20 Priority 3 Category E Program Code 03511

Licensee: Department of Health and Human Service
National Institutes of Health
Bethesda, Maryland 20892

Facility Name: National Institutes of Health (NIH)

Inspection At: Bethesda, Rockville, Poolesville, and Baltimore, Maryland

Inspection Conducted: April 4-8, & 20 and May 9-13, 1994

Inspectors:

Richard McKinley, Health Physicist — 6/29/94 date

Ihor Czerwinskyj, Health Physicist — 6/24/94 date

Eric Reber, Health Physicist — 6/28/94 date

Judith Joustra, Senior Health Physicist — 7/1/94 date

Sami Sherbini, Health Physicist — 7/1/94 date

Teresa Hall Darden, Senior Health Physicist — 6/27/94 date

Approved by:

Jenny Johansen, Chief
Medical Inspection Section — 7/1/94 date

Inspection Summary: Routine, unannounced inspection conducted from April 4-8 and 20, 1994 and May 9-13, 1994 (Report Nos. 030-01786/94-001 and 030-17872/94-001)

Areas Inspected: Corrective actions; organization/management oversight; incidents; training; quality management implementation; dosimetry; nuclear medicine; radiation therapy; tour of facilities; monthly radiation surveys; waste processing and storage; instrument calibration; sealed source inventories and leak tests; inventory and control of radioactive material; package receipt and distribution; and Gammacell 40 Irradiators.

Results: Four apparent violations were identified for License No. 19-00296-10: 1) failure to perform an adequate survey (Section 12.f); failure to survey (Section 4.c); 2) failure to provide security of radioactive materials, (Section 10.a); and 3) failure to refrain from eating and drinking in a restricted area, (Section 10.a). Also, two licensee identified violations were identified, however they meet the criteria for non-cited violations: 1) unauthorized user of phosphorus-32 (Section 4.c); and 2) failure to survey packages containing radioactive material (Section 8). No violations were identified for License No. 19-00296-20.

DETAILS

1. Persons Contacted

*+ Roger W. Brosuis, Asst. to Chief, Radiation Safety Branch (RSB); Exec. Sec. Radiation Safety Committee (RSC)
*+ William Walker, Branch Chief and Radiation Safety Officer (RSO)
*+ Robert Zoon, Deputy Chief, RSB
* Bruce Smith, Asst. to Chief, RSB; Information Management
*+ Sean Austin, Chief, Rad. Materials Control Section, RSB
*+ Nancy Newman, Chief, Radiation Safety Operations Section, RSB
*+ Mike Noska, Health Physicist
*+ Beth Reed, Health Physics Technician
*+ Cathy Ribaudo, Health Physicist
*+ Katharine McLellan, Health Physicist
*+ Israel Putnam, Chief, Materials Acquisition Unit
*+ Shawn Googins, Asst. Chief, TSS, Chief Rad., RSB
*+ Ted W. Fowler, Deputy Radiation Safety Officer, NIH and Chief, Technical Services Section, RSB
* Adel M. Baryoun, Area Health Physicist (AHP)
*+ Ivan G. Wallace, AHP
*+ Lynn E. Jenkins, Assistant Chief, RSOS, RSB
*+ William F. Holcomb, Training Program Manager, RSB
* Robert W. McKinney, Director, Division of Safety
* Chang H. Paik, Nuclear Medicine Dept.
*+ George O. Redmond, Health Physicist
* Kenneth W. Fiester, Health Physics Technician
*+ Virginia Sheldon, Physical Science Technician
*+ Steve Ficca, Assoc. Director, Per. Services
* Richard Fejka, Chief, Clinical Radiopharmacy
* James C. Reynolds, Chief, Clinical Studies Section, NMD
* Kim Suhar, Intern, Clinical Radiopharmacy
* Mary Pettiford, Supervisory Technologist, NMD
*+ Jacob Robbins, Chairman, RSC
*+ Philip S. Chen, Jr., Associate Director for Intramural Affairs
* Mark Rotman, Chief, Radiolabeling Unit, DNM
* Ray Johnson, C.H.P., CSI - Survey Contractor
Richard Kagan, H.P.
John Kusiak, Ph.D., Researcher
Nikka Hollbrook, Ph.D., Researcher
Vince Burton, H.P. (CSI Contractor)
Steve Tilden, Instrument Calibration Tech. (CSI Contractor)
Teressa Russ, R.N., Floor Nurse, LDR Afterloader
Alan Epstein, M.D., Oncologist
Eva Horak, Tech. (Animal Lab)
Robert Nicholson, Foreman (Incinerator)
Jan Van de Geijn, Ph.D., Physicist
+ Kelly Austin, Health Physicist

Other management, research, RSB and contract personnel were contacted during this inspection.

* Denotes attendance at the April 8, 1994 Exit Meeting
+ Denotes attendance at the May 13, 1994 Exit Meeting

2. Scope of Inspection

This inspection was an examination of activities conducted under a license of broad scope which authorizes medical research, diagnostic nuclear medicine and radiation oncology, and an examination of activities conducted under a separate specific license which authorizes the operation of irradiators. The inspection included observations by the inspectors, review of records, interviews with licensee personnel and contractors, and the performance of measurements for radiation exposure and contamination, including analysis of incinerator ash samples. The inspectors observed operations in the RSB; various buildings that are located on the NIH main campus; the Gerontology Research Center in Baltimore, Maryland; the Poolesville, Maryland Research Building which includes the Interim Waste Storage Facility; and the nuclear medicine, radiation therapy, clinical laboratory and radiopharmacy operations. An examination of the licensee's corrective actions for previously identified violations was also performed. NRC inspectors were accompanied by two Maryland State inspectors on April 4 - 8, 1994.

3. Review of Corrective Action

(Closed) Violation, Special Inspection Report No. 030-01786/93-001. Failure to limit exposure to the extremity of an individual to 18.75 Rem in a calendar quarter.

The inspector found that corrective action to limit extremity exposure was adequate and the methodology to assess exposure in accordance with NRC Form 5 was implemented.

(Open) Violation, Special Inspection Report No. 030-01786/93-001. Failure of an individual to survey daily for contamination when radioactive materials have been used.

The inspector found that the licensee had implemented corrective action to ensure that radiation workers are knowledgeable of the necessity to perform surveys of the area and themselves upon completion of working with radioactive materials. Training on adequate survey procedures was performed and users also were issued information packets on surveys.

However, an incident, identified in August 1993, which caused wide spread contamination occurred because an unauthorized individual using phosphorus-32 (P-32) did not perform a survey either during or upon completion of work with P-32 probes as required. Therefore, the performance of daily surveys will be reviewed during future inspections.

(Closed) Violation, Special Inspection Report No. 030-01786/93-001. Failure to supply appropriate personnel monitoring equipment to a researcher working with P-32 in quantities greater than 0.5 millicurie who was likely to receive greater than 25 percent of the maximum permissible dose in a calendar quarter.

The inspector noted that the licensee's corrective action to ensure that this violation does not recur included a policy that all authorized users certify that newly assigned persons using radioactive material (RAM) under their authorization are registered with the RSB for personnel monitoring and training and that appropriate dosimetry badges are obtained for the individuals.

4. Organization/Management Oversight

a. Radiation Safety Committee (RSC)

The RSC has technical oversight of the RSB. Members of the RSC are appointed by the Director of NIH. The Radioactive Drug Research Committee also reports to the RSC. A representative sample of the minutes of the RSC meetings was reviewed by the inspector. The inspector noted that usually the RSC meets monthly even though the requirement is quarterly. Representation by each major class of users of radioactive materials as well as Administration and Nursing are documented in the RSC meeting minutes. Review of the minutes indicated that the RSC has extensive discussions concerning: State versus Federal authority; NRC licensing, inspection and enforcement actions; regulatory interpretations; specific incidents and events involving radioactive material; and the development of policies and guidance relevant to the use of, and possible exposure to, radioactive materials such as guidance for declared pregnant workers. As Low As Reasonably Achievable (ALARA) investigations, disciplinary measures, waste processing and storage, protocols and authorizations as well as training policies and procedures are also discussed.

b. Radiation Safety Branch (RSB)

The Radiation Safety Officer (RSO) is also the Branch Chief of the RSB. Administratively, the RSO reports to the Director of the Division of Safety, and technically, he reports to the RSC.

The RSB staffing plan indicates that there are 35 full time positions. Three positions are unfilled and currently there is a job freeze. The RSB also has a number of contract personnel who perform surveys, deliver packages and process waste. Currently, there are three sections in the RSB, namely, Operations, Radioactive Materials Control, and Technical Services. The RSO stated that the Radioactive Materials Control Section is new and was established to provide oversight and control for radioactive waste and receipt and distribution packages.

Area Health Physicists (AHP's) are assigned responsibility for specific portions of the NIH campus. To ensure that all areas have continued coverage, AHP's are also assigned back-up responsibility to areas other than their main area of responsibility. The AHP follows-up on deficiencies that are identified during surveys/audits (e.g. visiting the laboratory and/or sending a warning memo). If significant findings, such as large areas of contamination or skin exposure, are identified by the contractor during surveys/audits, the AHP is notified immediately. The AHP follow-ups are documented on the same form as the original survey/audit. The inspector reviewed selected records of follow-ups performed from January 1993 to the present. For most of the follow-ups performed during the past several months, the actions documented by the AHP's were appropriate and timely (e.g. sending a warning memo to an Authorized User (AU) within a week of receiving a survey/audit finding that monthly surveys were not documented). However, several follow-ups performed recently were a result of surveys/audits which were performed approximately one year ago. In these cases the initial survey/audit findings were minor contamination (e.g. 1,500 counts per minute of contamination on a pipette tip rack which was measured with a Geiger-Muller counter with a pancake type probe) and/or monthly surveys not being performed. In all of the cases noted, the documentation of the initial survey/audit indicated that the contamination was labeled and/or removed, and a responsible individual was informed of its presence. Therefore, the health and safety significance of the delayed follow-up was minor. The RSO stated that the RSB is trying to improve the timeliness of follow-ups. The licensee has established a computer tracking system which the RSO reviews monthly. The tracking system identifies the following information: 1) The AU, 2) location of use, 3) HP area, 4) survey identification number, 5) survey date, 6) receipt date. The licensee has also created a schedule of deadlines "RSOS Deadlines" which are required to be met. Follow-ups which are considered significant (major) are to be completed in two weeks. Follow-ups which are considered not significant (minor) are to be addressed in one month. Deficiencies in surveys (Item 49 on the original survey/audit form) noted by the contractor require the AU to respond to a memo sent by the AHP. If the AU does not respond, a memo with the RSO's signature is sent to the AU. The AU has ten days to respond. If a response is not received, the AU's authorization is suspended. This step-by-step procedure has been designated by the licensee as the "Three Strikes" Policy.

In a discussion between the inspector and the AHP supervisor concerning documentation of follow-up reports, the AHP supervisor stated that she occasionally edits the documentation of follow-ups that are submitted for her approval. She stated that she edited documentation when comments by the AHP were, in her view, inappropriate and/or unnecessary. For example, she stated that she had deleted statements by an AHP concerning the fact that it had been greater than 10 half-lives since radioactive contamination was identified, and therefore, following up on the contamination would be a moot point. The inspector noted that the date of the initial survey and the follow-up were clearly designated on all survey/audit forms that were reviewed during the inspection. Also, she stated that she never deleted information

that would make the record incomplete or inaccurate. The inspector's review of records found no evidence or indication that information was changed or deleted inappropriately.

The RSB also gives technical support to researchers that includes assistance in developing protocols. The submission of a protocol is required when AU's wish to perform human-use experiments and non-human-use experiments involving "protocol" quantities of radioactive materials (e.g. use of greater than 10 millicuries of P-32 or the performance of iodinations). This assistance may take the form of developing and/or writing procedures in cooperation with the researcher which reflect RSB policy.

Annual audits of the Radiation Safety Program are performed by the RSB. The inspector reviewed the audits for 1992 and 1993 and found them to be comprehensive and objective in the evaluation of radiation safety and associated events.

c. Review of Incidents

The Incident File was reviewed by the inspector. The inspector noted that the file contained documentation of incidents that had occurred from July 1992 through March 1994. The documents described spills, contaminations, unauthorized waste pickups, temporary loss of control of radioactive material, illness of a waste processor associated with odorous radioactive waste and unauthorized use of radioactive material and irradiators.

The inspector observed that once the RSB was notified, response was generally timely and comprehensive. Corrective actions were implemented and disciplinary measures were enforced unilaterally. The inspector noted that a P-32 contamination incident which occurred in August 1993 was missing the supporting documentation which referenced the details of the incident. A facsimile of the requested documentation was provided to the inspector on April 20, 1994. The inspector noted that the contamination resulted from an unauthorized P-32 user's failure to perform a survey at the conclusion of work with P-32 probes on August 24, 1993. The contamination was undetected until August 27, 1993, when floor contamination was detected as result of a cursory survey that was performed with a Geiger-Mueller (GM) counter when water was observed on the laboratory floor. The water had apparently leaked from a distilled water apparatus. Dry floor areas were also surveyed and contamination was noted. The RSB was notified and health physicists (HPs) responded. A review of the associated documentation indicated that the actions taken by the RSB were aggressive, comprehensive and timely. HPs identified that widespread contamination had occurred and included area floors, corridors, offices, labs, workers shoes, public rest rooms, parking lot, driveway gravel, an automobile and two residences. No skin contamination was identified. A bioassay was performed on the original unauthorized user and no uptake was noted.

Disciplinary measures were instituted against those involved, in that, the authorization permits for the AU, under whom the original unauthorized P-32 user worked, as well for the AU, who originally possessed the P-32, were suspended. The licensee also distributed information to radiation workers referencing similar events involving other licensees which had resulted in NRC escalated enforcement action.

The licensee determined that this incident was not immediately reportable to the NRC because it did not meet the reporting criteria described in 10 CFR 30.50. This decision was based on the following: The Oral Ingestion ALI for P-32 is 600 μCi (Appendix B, Table 1, Column 1 of 10 CFR 20.1001-20.2401) and assuming that if an ALI were applied to the general public, under the current 10 CFR Part 20 Regulations, 1/10 of the occupational ALI would be 60 μCi. The maximum level of contamination found in an unrestricted area was 20,000 cpm gross counts that was measured with a GM survey instrument with an efficiency of 31% which is approximately .0291 μCi P-32. Consequently, the contamination was well below 60 μCi and a member of the general public could not have received a dose in excess of 500 millirem under superseded 10 CFR Part 20 or 100 millirem under current 10 CFR Part 20.

The criteria in 10 CFR 30.50 (b)(1)(i), (ii), and (iii) were reviewed and it was determined that a 24 hour report was not necessary because:

i. The unplanned contamination event did not require that access be restricted for more than 24 hours. The corridor involved in the spill was closed for a total of 4 hours until the areas could be cleaned and smeared.

   Access to the room (B1B43) was not restricted because of a radiation hazard caused by the P-32 spill. Exposure limits were not a concern and the amount of contamination on the floor did not pose a health hazard. The room remained open throughout the spill; however, until the floor could be completely decontaminated, shoe covers were required to protect individual's shoes from becoming contaminated and then cross contaminating the cleaned areas.

ii. In reviewing Appendix B of 10 CFR 20.1001-20.2401, the lowest annual limit of intake for P-32 is the oral ingestion limit of 6E+2 μCi and 5 times the lowest limit is 3 mCi of P-32. Assuming a worst case scenario such that all 240 μCi of P-32 manipulated by the user were spilled, we are well below the limit.

iii. Access to the area was not restricted except for the 4 hours for decontamination and verification.

After review of the licensee's documentation of this incident, the inspector determined that a violation of Condition 31 of License No. 19-00296-10, which references user criteria for radioisotopes, had occurred. The licensee's standard procedure for P-32 use authorization was circumvented. However, the violation was identified by the licensee; and was not a willful violation or a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation. Therefore, the inspector determined that in accordance with 10 CFR 2, Appendix C, that this is a non-cited violation based on the following; 1) it was licensee identified; 2) the activity of the isotope involved indicated that this event was not critical, but warranted more than minor concern; 3) normally, this violation is classified as a Severity Level IV violation; 4) the event was not required to be reported; and 5) the licensee's corrective action was decisive and comprehensive in that the authorization to work with isotopes, was suspended for those individuals involved. Also, the licensee stated that the survey requirement would be stressed at future training sessions.

Therefore, a Notice of Violation is not being issued for this incident. However, a Notice of Violation is being issued for the failure to perform a daily survey in accordance with Condition 31 of License No. 19-00296-10, which references Section 10.13.2 of the application dated July 28, 1986. This section requires, in part, that users survey their laboratories and themselves for contamination on a daily basis when radioactive materials have been used. This is a repeat of a violation that was identified in January 1993 when an individual also failed to perform a survey of the laboratory and himself when working with P-32 and resulted in some skin contamination to himself.

Failure of the user of radioactive materials to survey both the laboratory of use and herself for radiation contamination on a daily basis when using radioactive material is an apparent violation of Condition 31 of License No.19-00296-10.

The inspector toured the site of the NIH custom built cobalt-60 (Co-60) irradiator that failed in early 1993. The irradiator failure was due to the inability of the carriage lock rod to fit into the control box when the locking mechanism became stuck in the locked position. This failure was identified to the NRC by the licensee. The licensee was issued a Notice of Violation based on 10 CFR 21, with respect to manufacturer defects. The Co-60 irradiator is located in Room B2B56 in Building 10. The inspector interviewed the AHP, and examined representative records pertaining to the irradiator. The inspector determined that the irradiator was last used on March 22, 1993. During the September 24, 1993 quarterly inventory check, the technologist discovered that both of the irradiator's interlocks had failed. The Co-60 source, (approximately 86 curies on February 25, 1994) was in the shielded position. The licensee has decided to permanently discontinue the use of this unit. The unit was made inoperative by securing it with a heavy chain and padlocks in two locations, making it impossible to expose the source. The chains and padlocks and general condition of the unit are checked weekly by an HP. The

inspector examined the records of the weekly checks and found that the checks were performed as required.

The inspector learned that funds have been appropriated to permanently remove the defective irradiator by transferring the unit to an authorized recipient. The AHP stated that it was expected that the unit will be disposed of in approximately two months.

On February 2, 1994, P-32 contamination averaging approximately 1,000 dpm/100cm^2 was discovered on several drawers and a floor area of approximately 50 ft.^{2} in Building 49, Room 4B80. The contamination was discovered during a daily survey of the laboratory. Laboratory personnel decontaminated the affected area and a member of the RSB, with the help of the AU responsible for the laboratory, investigated the cause of the contamination and monitored the clean-up. A laboratory worker stated that a survey that would have detected the contamination was performed in the area of the contamination the day before the contamination was discovered. Therefore, it is somewhat likely that the contamination occurred overnight. Laboratory personnel stated that the specific cause of the contamination was never determined with certainty; however, one AU responsible for the laboratory stated that he theorized that someone from another laboratory caused the contamination when working in the laboratory on the evening of February 1, 1994.

At the time of the contamination incident, workers from other laboratories routinely used Room 4B80 when working with P-32. In respc :e to the contamination incident, the AU held a meeting with all individuals on the floor that work with radioactive materials to ask if anyone had contaminate ' the laboratory or used the laboratory on the evening of February 1, 1994. The AU stated that no one claimed responsibility for the spill or stated that they had worked in the laboratory on that evening. As a result of the contamination incident, the AU instituted a new policy whereby only individuals assigned to Room 4B80 could use radioactive material in that room. Survey procedures employed by laboratory personnel were reviewed by the inspector. Individuals who worked in the laboratory stated that currently, and at the time of the discovery of the contamination, surveys of their work area are/were performed with a Geiger-Muller survey meter before, during and after use of radioactive materials (the minimum requirement is a daily survey). Monthly wipe surveys for radioactive contamination are required, but laboratory personnel stated that they decided to perform them weekly because of the amount of radioactive materials used in the laboratory. Records of weekly surveys performed from October 29, 1993 to the present were reviewed by the inspector. The records indicated that decontamination and resurvey were performed when appropriate. Laboratory personnel stated that they have kept records of daily surveys since the contamination was discovered on February 2, 1994 to document when surveys were performed. The inspector noted that the laboratory personnel were knowledgeable and concerned about radiation safety procedures. The effort that the individuals are

willing to expend in identifying radiation hazards was illustrated by the fact that they occasionally make radiographs of contaminated areas to pinpoint the exact location of the contamination.

The inspector reviewed the licensee's skin dose calculations performed in connection with an incident involving a researcher using iodine-labeled compounds. The incident occurred on January 11, 1993 during injection of a mouse with the labeled compounds. The 1 ml syringe in use at the time contained 0.2 ml solution with a total activity of 20 μCi, of which 15 μCi were I-131 and 5 μCi were I-125. According to the researcher, some of the solution in the syringe sprayed on her face during injection, but it is not clear why this occurred. She was wearing safety glasses, and so none of the activity reached the eyes. It was later determined that the contamination was confined mainly to parts of the hair and a small area of the skin on the forehead. No other contamination was found.

The researcher immediately surveyed the affected areas with a sodium iodide (NaI) probe and, about one half hour later, washed her hair and forehead. A survey with the same instrument after washing showed no change in activity, suggesting that the contaminant had by that time probably been incorporated into the skin and hair. The skin and hair were washed again later the same day, and a thyroid scan was performed the following day. The scan showed a thyroid activity of 0.57 nCi of I-131. A scan of the forehead area was also performed at that time, and showed 42.5 nCi I-131 and 11.72 nCi I-125. The licensee stated that the scans of the forehead area were only to support survey data and determine isotopic composition, and not for activity determination, because the counter was not calibrated for such an application. A survey at that time using a NaI instrument showed 300 cpm on the forehead and 900 cpm on the hair. Following several further attempts to wash the hair and face, as well as trimming parts of the hair that were suspected of being contaminated, the readings over the contaminated areas were reduced to background. These background readings were reached about midday on January 14, 1993, about 76 hours after the contamination occurred.

The licensee first performed a worst case dose assessment by attempting to estimate the volume of liquid that was sprayed from the syringe onto the forehead and calculating the dose using a skin thickness of 4 mg/cm^2 and a contamination area of 1 cm^2. Using an exposure time of 30 minutes, this calculation yielded a skin dose of 4.6 rem. The licensee considered this approach overly conservative and unreliable because it is difficult to estimate the volume of the very small quantity of liquid that was sprayed from the syringe. Due to the high specific activity of the liquid, small changes in this volume would have a large effect on the calculated dose. In addition, this method did not make use of the available survey data. In their modified method, the licensee attempted to estimate the extent of the contamination using the various survey instrument readings taken during decontamination. These attempts yielded a skin dose of about 20 mrem for an exposure duration of 30 minutes, using 4 mg/cm^2 for the skin thickness and a contamination area of 1 cm^2.

The inspector reviewed the licensee's assumptions and calculations and determined that, although some of the assumptions were difficult to justify rigorously, they seemed reasonable in view of the available measurements. The inspector stated, however, that an exposure profile is needed before the dose calculations can be completed. That profile provides an estimate of the level of contamination as a function of time from the time the contamination occurred to the time a background reading was achieved. The dose received at each contamination level must be estimated, and the components added to provide an estimate of the total dose resulting from the incident. According to the data, the duration between the occurrence of contamination and complete decontamination was in excess of 70 hours. The final dose to the skin of the forehead is therefore expected to be substantially higher than the 20 mrem estimated by the licensee on the basis of a 30 minute exposure duration. The licensee stated that they would repeat the calculations using an accurate exposure profile, a contamination area of 1 cm^2, and a skin thickness of 7 mg/cm^2. In a telephone conversation on June 7, 1994, with Eric H. Reber of our staff, Ted Fowler stated that NIH's revised estimate of the dose equivalent to the skin is 600 millirem. The 7 mg/cm^2 skin thickness must be used when showing compliance with NRC skin dose limits. The dose resulting from intake of iodine was estimated to be very small, of the order of a few mrem to the thyroid, based on the thyroid scan data. The NRC determined that a dose equivalent of 600 millirem is an acceptable number to enter into the contaminated person's exposure records.

No safety concerns or violations of NRC requirements were identified.

An incident relative to the Selectron Low Dose Remote (LDR) Afterloader is described in Section 9.b (Brachytherapy).

5. Training

The Radiation Safety Training Manager described the training program at NIH.

He stated that all researchers, including contractors who work with radioactive materials are required to attend the basic one-day, "Radiation Safety in the Laboratory" course. This course is used to give training required by 10 CFR 19.12.

Since the HPs work with radioactive materials, all HPs are also required to attend and successfully complete the "Padiation Safety in the Laboratory" course. HPs take additional courses, including the "Radiation Safety for Authorized Users" (a two-week course). Successful completion of the "Radiation Safety for Authorized Users" course by HPs is expected. A test is given at the completion of the "Radiation Safety for Authorized Users," course. This course, however, is not required for HPs, in order to meet NRC training requirements of 10 CFR 19.12.

Annual radiation safety refresher training is also required for all HPs and individuals that use radioactive materials. The RSO stated that individuals who do not attend annual refresher training are suspended from receiving and using radioactive materials, and their supervisors are notified. The refresher training of one researcher was reviewed. The researcher attended refresher training on November 14, 1991. He did not attend refresher training in 1992 and his authorization to use licensed radioactive materials was suspended on January 4, 1993 in accordance with the RSB's procedure.

The Radiation Safety Training Manager also stated that specialized training is given to animal handlers, cardiac and critical care nursing staff, as well as other ancillary personnel such as housekeeping and security personnel.

RSB has established an internal policy whereby AU's identify individuals who need training and will be working under their authorization. Through discussions with staff and various users, the inspector noted that training was conducted as required.

The Nursing Training Office identifies the nursing staff who are required to take radiation safety training. Nurses who are involved with therapeutic procedures receive training prior to working with therapy patients. Training is offered once a month as well as prior to a specific therapeutic patient procedure. A member of the RSB provides training to the nursing staff. The HP and the Training Officer meet and create a course agenda. There are also licensee generated pamphlets which contain instructions for nurses regarding therapeutic procedures. Instructions to nurses who are involved with brachytherapy patient care contain information regarding the licensee's emergency procedures. These procedures include steps to be taken if a therapy source becomes dislodged. The procedure requires that the source be placed in a secure and shielded location.

49 CFR 172.702 requires, in part, that individuals who prepare shipments of radioactive materials and/or sign radioactive material shipping manifests receive training in Department of Transportation regulations and safety training (hereafter referred to as DOT training). Members of the NIH staff that are involved with the preparation of shipments of radioactive materials attended a DOT training course that was held at the NIH campus on October 12, 13, and 14, 1993. One member of the RSB who was involved in the preparation of radioactive waste shipments was not given full credit for the course because she was absent from some of the sessions due to illness. A member of the RSB that supervises radioactive waste shipping personnel stated that he provided DOT training to this individual that was commensurate with her job duties, however this training was not documented. He stated that he felt that she had received adequate training because, when asked, she had no questions regarding her involvement with radioactive material shipments. He stated that he was satisfied with her preparation of radioactive waste shipments, including the safety precautions that she had taken. This individual was not contacted during the inspection, however, none of the waste shipments for which she signed the manifest, was rejected by the receiver of the shipment.

No safety concerns or violations of regulatory requirements were identified.

6. Quality Management Program Implementation

The inspector reviewed the implementation of the licensee's Quality Management Program (QMP). Training on the QMP was given in January, June, and December 1992, and November 1993. The annual QMP audits for 1992 and 1993 were reviewed along with a representative sample of patient treatment records subject to the QMP. The inspector noted that for 1992, the audit identified the following: zero misadministrations occurred; six instances when the AU did not verify that the dose calibrator slip was checked; and one instance when the AU had left the patient identification section blank. The inspector noted that the 1993 QMP audit identified that out of 153 administrations, 93 Written Directives (WD's) were reviewed by the RSB. Zero misadministrations occurred; one WD was not signed by the AU; one WD was not dated prior to patient dosing as required; and there were nine instances where the route of administration was not identified. The findings of the audits and the use of WD's were discussed with RSB staff. The inspector clarified that an adequate or acceptable WD must have all components required in 10 CFR 35.2 prior to dose administration with changes only as permitted in 10 CFR Part 35.

Also reviewed in the audit was the LDR Afterloader. Four patients were treated with the LDR. The audit indicated that WD's were used as required. One failure of the LDR unit was identified when the device failed to expose the source properly due to a moisture lock. No misadministration occurred as a result of this failure. The LDR unit was repaired and placed back in operation.

No safety concerns or violations of NRC requirements were identified.

7. Dosimetry

a. Film Badges

The inspector reviewed selected exposure histories of individuals who exceeded the ALARA level I limits from the licensee's data base. The information was easily retrievable and current. The licensee had conducted investigations of these exposures as warranted. Quarterly and annual summaries were examined. Except for an extremity exposure that exceeded regulatory limits and was the subject of Enforcement Conference 93-002 in February 1993, no exposures above regulatory limits were identified.

b. Bioassays

From records review and personnel interviews, the inspector noted that the licensee's bioassay program included urinalysis, thyroid uptake counting, and whole body counting. Individuals who used quantities of iodine-125 (I-125) or iodine-131

(I-131) greater than 10 millicuries were required to have a bioassay within seven days of use. Personnel involved in administering doses of I-131 greater than 30 millicuries were required to have a bioassay performed within 72 hours of dose preparation or administration. Representative records from July 1992 to April 1994 were reviewed and no significant uptakes were indicated. The inspector noted that during the first calendar quarter of 1994, 46 urinalyses, 86 thyroid scans, and 2 whole body scans were performed. The inspector found that the calculated organ doses from thyroid scan data were well below regulatory limits in 10 CFR Part 20 effective January 1994.

No safety concerns or violations of regulatory requirements were identified.

8. Nuclear Medicine

The inspector reviewed procedures and records of surveys, interviewed technologists, observed operations and conducted surveys in the Nuclear Medicine Department (NMD). The inspector determined that during normal working hours the radiopharmacist prepared and assayed all radiopharmaceutical doses for patient administration, while nuclear medicine technologists performed these tasks after normal hours and on weekends. The inspector observed prepared doses being assayed prior to administration in accordance with the procedures submitted with the license application. The inspector also observed the dose calibrator being checked for constancy. These observations and a review of records indicated that dose assays and constancy checks were performed as required. An instrument survey of the department revealed no unusual radiation levels.

In 1990, the NIH established a ministerial change regarding the linearity check for the dose calibrator in Building 21. The licensee decided to perform the linearity check in accordance with instruction provided by a manufacturer of a shield/sleeve ("Calicheck") method. The licensee identified an instance during 1993 in which the radiopharmacist did not exactly follow the "Calicheck" method. The radiopharmacist performed the check by decaying the isotope over a three day period rather than aliquot various amounts of activity from the source vial in order to obtain a lower activity range to complete the check. The licensee acknowledged this variation in procedure and determined that it did not negatively impact the calibration procedure. Licensee staff and the RSO determined that to aliquot part of the radioactive material in order to complete the linearity check in one day was not consistent with the ALARA concept. The shield/sleeve method requires manipulation of the source vial which could increase exposure. Therefore, subsequent linearity checks have been completed over a three day period. The decay methodology is a procedure that is acceptable to the NRC.

The inspector observed doses being drawn in labeled, shielded syringes by the nuclear pharmacist and placed in metal cases. The cases were placed upon a shelf of the lower half of a "Dutch" door where they were picked up by technologists. The inspector checked at various times during the day and noted that the door was under surveillance. The nuclear pharmacist stated that the door was always locked when the pharmacy was unattended.

The inspector noted that doses were administered by technologists in two administration rooms adjacent to the pharmacy. Patients were identified by at least two methods. All diagnostic iodine doses were required to be administered by an AU. Written directives were prepared for doses greater than 30 microcuries of iodine-131 or -125 as iodide.

The inspector reviewed memoranda relating to the delivery of packages containing radioactive material to the NMD. A memorandum dated September 19, 1990, permits the delivery of packages directly to the NMD if arrival is outside normal hours. The agreement is contingent upon following specified procedures. The inspector was informed that the Supervising Technologist of the NMD had recently requested that deliveries of radioactive material directly to the NMD during normal work hours also be permitted. This request was denied in a memorandum dated March 31, 1994, from the RSO to the NMD Chief. Cited as the reason for the denial was a memorandum dated March 25, 1994, from the Chief, Materials Acquisition Unit to the pertinent AHP detailing seventeen violations of NIH procedures which had been noted during an RSB audit of the previous six months of package deliveries to NMD. The inspector noted that most of the licensee-identified violations were for recordkeeping requirements. However, the inspector observed that some package surveys were not performed as required, which is a violation of 10 CFR 20.1906 (formerly 10 CFR 20.205).

10 CFR Part 2, Appendix C, Section G states, in part, that the NRC may refrain from issuing a notice of violation for a violation described in an inspection report if that violation meets the following criteria: a) It is normally classified at a Severity Level IV or V; b) it was reported if required; c) it was or will be corrected including measures to prevent recurrence, within a reasonable time; and d). it was not a willful violation or a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

In the situation described above, the licensee met the criteria described above in the following way: a) this event was identified by the licensee, and a record was maintained in the licensee's incident file; b) the amount of radioactive material and the radioisotope involved indicated that this event was not critical, but warranted more than minor concern; hence, a Severity Level IV violation; c) this event was not required to be reported; and d) the licensee has or will implement the following:

i. the Chief, NMD, has been required to submit to the RSB documentation of the steps he will develop and implement to correct the violations and prevent their recurrence.

ii. the RSB will more closely monitor documentation of future after hours shipments to the NMD.

iii. the NMD has been required to notify the RSB within 24 hours of placing and receiving an after hours shipment. Notification must include Form NIH 88-1 "Request for Purchase and Use of Radioactive Material" and a Radioactive Shipment Report.

Therefore, a Notice of Violation is not being issued for this incident.

No safety concerns or other violations of NRC requirements were identified.

9. Radiation Therapy

a. Radiopharmaceutical Therapy

Room No. 8S263 in Building 10, is dedicated for radiopharmaceutical iodine therapy use, either conventional or experimental. The iodine therapy use load has decreased in recent months, from approximately three patient treatments each month to about one patient treatment each month. The room is prepared for the patient by the RSB responsible AHP. The AHP also administers the iodine capsules to the patient under the supervision of an AU.

AHP's are given on-the-job training before they are authorized to administer I-131 therapy patient doses. After the patient receives the therapeutic I-131 dose the AHP is required to perform an area survey. This survey includes the hallway outside the patient's room, adjacent rooms as well as the rooms above and below the patient's room. The licensee's area survey procedure, which is incorporated in their NRC license, includes a provision that if a particular area cannot be surveyed, the AHP may document a reading which was obtained during a similar patient treatment using the same activity.

A review of records showed that appropriate surveys were done of the patient, patient's room, and surrounding areas. The room was properly posted and the adjacent room was restricted from patient use if dose rates were too high. The inspector interviewed three nurses and found that they were instructed in the precautions necessary for radioiodine therapy. Only nurses are permitted to enter the patient's room. During these entries they are required to wear an assigned film badge, a disposable protective coat, and shoe covers.

At the time of the inspection, room 8S263 was locked and empty. The inspector observed that plastic-backed paper covered the floor and other surfaces. All waste had been removed and sent to Building 21. A notice was posted on the door indicating that the room was still contaminated and was restricted from use until the next therapy patient in accordance with Condition 31 of License No. 19-00296-10 The inspector determined from survey records that contamination was less than 2200 dpm/100cm^2. This is in accordance with Amendment No. 65 to License No. 19-00296-10 issued in response to an exception requested by NIH on May 15, 1992.

b. Brachytherapy

NIH emphasizes research activities, therefore, relatively few routine brachytherapy procedures are performed. Through records review and discussions with RSB staff, the inspector determined that during 1993, five cesium-137 (Cs-137) conventional brachytherapy implants were performed. One implant using iridium-192 ribbons was performed in 1994. In addition, 4 patients were treated by LDR remote brachytherapy procedures. The inspector verified that brachytherapy sources were leak tested and that sealed source inventory was performed as required. All procedures (conventional brachytherapy, and LDR brachytherapy) were performed in the same dedicated and shielded room. Records review indicated that room surveys, surveys of all adjacent areas and surveys of each patient were performed following the source removal. Records also indicated that the required inventories were conducted before and after each procedure. The highest exposure rate in non-restricted areas, was 0.4 mR/hr for any of the above procedures.

Discussions with RSB staff and review of records revealed that in 1993 NIH began using the Nucletron MicroSelectron LDR remote brachytherapy afterloader. Four patients were treated during 1993. Each treatment consisted of two fractions. Nucletron provided training to all personnel involved with the afterloader before the first patient therapy. The Cs-137 sources for the afterloader were assayed in the dose calibrator prior to the first patient use. The inspector observed that there was a "Primalert 10" radiation monitor in the dedicated therapy room. The unit was equipped with a main treatment computer, and a remote control unit located at the nurse's station.

One incident was recorded during 1993 with respect to the LDR afterloader. Following a source retraction, the sources failed to leave the mobile storage container. The inspector interviewed the nurse on duty at the time of the incident and the LDR physicist, and learned that an alarm had sounded at the nurse's station. The nurse checked the patient's room and by observing the console indicators, as well as the "Primalert," she determined that the sources were not in the patient, but in the shielded device. Immediate action by the nurse failed to restart the treatment. As previously instructed, the nurse notified the AHP assigned to the LDR, who also was unsuccessful in attempts to get the sources out of the shielded container. The AHP then notified Nucletron. Nucletron arrived and determined that the malfunction was caused by a moisture problem in the LDR afterloader air compressor. The problem was repaired by an authorized individual. The therapy treatment, which had been interrupted, was reinitiated 24 hours after the LDR failed.

No safety concerns or violations of regulatory requirements were identified.

10. Tour Of Facilities

a. Main Campus

The inspector accompanied a contractor technician during the performance of surveys/audits of research laboratories. The inspector questioned the technician about the daily routine used in conducting room surveys and in-laboratory instrument calibration. The technician informed the inspector that each of the three field technicians survey/audit between 14-16 labs each day. A fourth contract individual is the supervisor who gives assignments and does the paper work. The inspector observed the technician performing a lab survey and noted that the surveys for ambient radiation exposure and removable contamination were comprehensive and thorough. The inspector observed that the technician used a "Survey Report Form" to record the laboratory inspection. The inspector also noted that the technician was not checking the laboratories for security of radioactive materials. The technician stated that they consider the whole floor as "sec red area" and do not routinely check for security of radioactive materials. The nspector also noted that the "Survey Report Form" did not have as a compliance item "Security" of RAM. Except for the failure to observe and/or enforce security, the inspector observed that the contractor's survey was of sufficient depth to determine the individual lab's compliance with NIH requirements for radiation safety in the laboratory.

The inspector, unaccompanied by licensee personnel, also visited some labs in the 8B and 8C corridors of Building No. 10. The inspector was unchallenged as he gained access to research labs in the area. There was an open connection to clinics and hospital areas and members of the general public could easily gain access to the laboratories that contained radioactive materials. The inspector's observations follow:

Room 8C-214 was found to be unlocked and unattended. There was a 1 millicurie container of Ca-45 in an unlocked refrigerator.

Room 8C-218 was found to be unlocked and unattended. There was a radioimmunoassay kit and (2) two containers from Amersham containing radioactive material in the refrigerator.

Room 8N-210 was found to be unlocked and unattended. P-32 was stored in three lead containers behind a Lucite Shield on the bench top.

Room 8B-17 was found to be unlocked and unattended. Numerous lead containers with radioactive material were found in an unlocked, small refrigerator.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Failure of the licensee to secure from unauthorized removal or access licensed materials is an apparent violation of 10 CFR 20.1801.

The inspector observed a researcher drinking coffee in room 8B08, a room posted as "Radiation Area" and containing various radioactive materials. Several empty coffee cups were observed by the inspector in the waste basket, in the same laboratory.

Attachment 10 D of the Application dated July 28, 1986, titled General Requirements for NIH Radionuclide Laboratories, and the 04/93 Edition, states that "Eating, Drinking, and Smoking are not permitted in rooms posted for the use or storage of Radionuclide use."

Failure of a researcher to refrain from drinking of coffee in a room posted for use and storage of radioactive materials is an apparent violation of NIH General Requirements and of Condition No. 31 of License No. 19-00296-10.

The inspector toured several floors in Building 10 including, but not limited to, the entrance to the Operating Room, Intensive Care Unit, Clinical Pathology Department Laboratory (Clin-Path), 8th Floor (I-131 therapy patient room) and 9 North. A number of medical pathological waste (MPW) boxes were found in the hallways. These boxes were not marked as containing radioactive material, however, the inspector surveyed each box. The survey results were consistent with area background readings. No radioactive material was identified in the MPW boxes observed by the inspector. MPW boxes labeled with "Caution Radioactive Material" (CRAM) were observed by the inspector in laboratories which were authorized to use licensed RAM.

The Clin-Path laboratory at NIH has established a Policy for handling, disposing and shipping radioactive specimens. This policy was approved November 3, 1993. The policy requires that specimens received in the laboratory be checked with a rate meter. If the specimen exceeds 350 counts per minute, a yellow radioactive sticker is to be placed on the specimen container, if it is not already labeled. Patient specimens which are to be shipped from Clin-Path to an outside laboratory are shipped in accordance with 49 CFR 173.421 for excepted radioactive material Limited Quantity N.O.S. UN2910. The package in which the specimen is placed must be measured on the exterior surface at contact, using a G.M. detector. The exposure rate is not to exceed 0.5 mR/hr. A number of other conditions must be met or otherwise the package must be shipped through RSB in Building 21. Individuals questioned by the inspector during the tour did not identify any shipments of radioactive material from Clin-Path to contractor laboratories that were not processed in accordance with the above mentioned policy. In addition, a representative from the State of Maryland, Radiation Control Program contacted a laboratory in Maryland who is contracted by NIH to analyzed specimens. The laboratory representative stated that they receive only a few specimens containing small amounts of radioactivity and did not recall ever having received radioactive material other than what they expected to receive.

The inspector toured the Clin-Path laboratory and observed the required instrumentation necessary to comply with the NIH policy. The instruments were both calibrated and operable.

b. Satellite Facilities

i. Poolesville

The inspector visited the NIH Animal Center at Poolesville, Maryland. Radioactive material use occurs in a small group of research laboratories and the animal care facility. The inspector toured seven laboratories, all of which used hydrogen-3 or carbon-14 in microcurie amounts. Through personnel interviews, the inspector determined that AU's and radiation workers were aware of their responsibilities and were adhering to policies and procedures stated in the NIH Radiation Safety Guide, license conditions and NRC regulations. The inspector observed the following: radioactive materials were properly secured and labeled; laboratories were posted as required; protective clothing was worn; materials receipt, use, and disposal logs were maintained; and monthly surveys were documented. Users indicated that they had received the required radiation safety training. Two animal handlers said that they had received additional RSB training with respect to handling animals, padding cages and removing contaminated padding for waste disposal as well as disposal of carcasses.

The inspector also visited the Interim Waste Storage Facility. The facility is a 60' x 100' warehouse and is enclosed by a wire mesh fence. Environmental TLD's are posted at four locations along the fence. Entrance to the facility from the main road is restricted by a locked gate with a security station, and another locked gate at the driveway. The building itself is metal with a concrete floor and a key lock to the only entrance outside the gate. Security officers check the building each shift. The facility is located within a locked fenced area. The main door to the building was locked and posted as required. All doors to the building are connected to an alarm system. During the inspection, the inspector opened one of the doors to the facility from inside the facility. When the inspector left the facility, the HP locked the main door and set the alarm. Once outside the facility, the inspector attempted to open the same door that had been opened while inside the facility. The door opened and the alarm sounded. It was determined that when this door is opened from the inside, the lock must be reset or the door will remain unlocked. A member of NIH Security arrived at the facility, within five minutes of activating the alarm. Drainage is away from the building in all directions, and the floor-wall interface is checked by the AHP for signs of water damage. The inspector saw no signs of water damage. Ventilation is through six outlets along the centerline of the ceiling.

On April 5, 1994, there were 334 barrels of waste in the facility. By May 13, 1994, the licensee had shipped out approximately 150 drums. Radioactive waste barrels were stacked in rows on wooden pallets, one layer high. The barrels were labeled with dose rates at contact and 1 meter, an identification number, weight, and the physical form of the waste. All waste was in dry, solid form. On the radioactive material label was noted the names of the isotopes, activities in millicuries, radioactive LSA designation, process date, and "decay to" date. The AHP stated that a complete meter and wipe survey of each barrel is performed upon each delivery to the facility Shipment records as well as survey records were maintained in a log book which remains inside the facility. The inspector measured dose rates in most of the facility. Most readings were at or near background levels with a maximum reading of 0.5 mR/hr which was at contact with one barrel.

The inspector verified that the Poolesville Interim Waste Storage Facility was in accordance with the criteria described in the license.

No safety concerns or violations of regulatory requirements were identified.

ii. Gerontology Center

The inspector accompanied one of the licensee's technicians on a visit to the Gerontology Research Center in Baltimore, Maryland. The inspector reviewed representative records and interviewed the AHP and technologist, several researchers and their technologists. The inspector determined that 90 labs, with 25 AU's and 214 radiation workers, use radioactive material at the Center. All of the radioactive material is used in research. A contractor routinely conducts periodic surveys of all labs using RAM. The AHP performs follow-up when necessary. Radioactive material is ordered by and delivered to the Gerontology Center. No sewer disposal of waste is permitted. The Gerontology Center generates approximately 150 drums (55 gallon) of radioactive waste each year.

The inspector visited two research labs at the Center and found that all of the required records of inventory, use, surveys, personnel exposure and disposal were in order.

No safety concerns or violations of regulatory requirements were identified.

11. Monthly Radiation Surveys

AU's whose authorization includes unsealed radioactive material are required to assure that monthly surveys of removable contamination and radiation levels are performed, and records kept during months in which radioactive materials were used.

Documentation of monthly surveys was reviewed during routine contractor audits/surveys. Records of 100 audits/surveys performed from January 1, 1993 to the present were reviewed by the inspector. The records indicated that monthly survey records were not available and/or not performed in 8 of 100 laboratories. The AHP explained that unavailable records do not necessarily indicate that a survey was not performed when it should have been, in that radioactive materials may not have been used during the months in question. However, the audit records indicated that a responsible RSB member was informed of the deficiency and that a warning memo was sent to the responsible AU by a member of the RSB.

The inspector reviewed the documentation of monthly surveys in Room 2D 05 in Building 37. Computer records indicated that the responsible AU last ordered radioactive material in 1988. Also, the biologist in charge of performing surveys stated that it has been a number of years since the AU ordered radioactive materials. Therefore, during the past several years, it was only required that laboratory personnel record that no radioactive material was used during the previous month in lieu of a radiation survey. Records were reviewed by the inspector which verified that radioactive material was not used from January 1992 to the present. All records appeared complete except that documentation was missing for a period from May 1993 through December 1993. The biologist in charge of maintaining records stated that he did not maintain records during this period because he was absent due to illness. He also stated that the AU in charge of the laboratory had informed the RSB of the circumstances associated with the lack of records maintenance during this period.

A licensee representative stated that AUs sometimes provide copies of survey records to the RSB when survey records could not be located during audits. She also stated that it is acceptable for them to document the fact that radioactive material was not used during a specified time period in response to this audit finding. She further stated that it is unacceptable to generate surveys after the fact for months in which radioactive materials were used. The RSB member, in charge of contractors who perform routine audits/surveys, stated that contractors were informed that they should not instruct researchers to generate surveys for months in which radioactive materials were used after the fact. The same RSB member informed the inspectors that the RSB permits AU's to generate a statement which indicates that no radioactive material has been used during a specific time period after the fact. She also stated that she knew of no instances when researchers generated monthly survey records after the fact. During review of records and interviews with personnel, there were no indications that monthly survey records had been generated after the fact.

NIH maintains an environmental air sampling program for iodination hoods. Vacuum pumps are used to continuously draw air through charcoal filters that are located in air ducts associated with radiation hoods. The charcoal filters are samples at least monthly. The inspector reviewed sample results for four hoods. Sampling is performed in order to determine the concentration of I-125 and I-131 in microcuries per cubic centimeter (cc) released, as well as, the percent of maximum permissible concentration

(MPC). The information reviewed by the inspector included results from 1992 and 1993. The largest recorded concentration of I-125 was 4.59 E-12 microcuries per cc (6% MPC) on May 6, 1993. The largest concentration of I-131 was 2.47 E-12 microcuries per cc (2% MPC) on September 3, 1992. These results were obtained from duct locations 10, 37-1.

The iodination hoods are equipped with 12" by 12" charcoal filters. The change-out rate for a filter is based on the frequency of use of I-125 and I-131, the activity used and the monthly environmental air sample results.

No safety concerns or violations of regulatory requirements were identified.

12. Waste Management

a. Waste Generation

There are approximately 3000 laboratories located in over 50 buildings in the NIH Bethesda campus. A large number of these laboratories use radioactive materials in their research work, and therefore produce radioactive wastes such as contaminated reagents, cell cultures, compounds tagged with radioactive tracers, contaminated laboratory equipment such as bottles, syringes, and liquid scintillation vials, and contaminated animals and animal organs and tissues. Radioactive material is also used in the clinical center in the diagnosis and treatment of patients, and the wastes produced there include disposable clothing, bedding, surgical and autopsy equipment, organs and tissues, blood and other biological samples. Radioactive waste is also produced in several off-campus locations in the Rockville area and at the Poolesville Animal Facility in Poolesville, Maryland.

A large number of different radionuclides are used at NIH, but most of these are used in relatively small amounts. A few, however, are used in relatively large quantities because of their utility in research and patient applications, and the amounts of these radionuclides received at NIH in 1993 are shown below.

Radioactive Materials Received in 1993, Curie (Ci)

H-3	12.9
P-32	24.3
S-35	16.1
Cr-51	4.4
I-131	5.9
I-125	4.3
C-14	0.2

In addition, 330 Ci of Mo-99 and 17.4 Ci of Tc-99m were also received. The above table of receipts gives only a partial view of the magnitude of the potential for waste generation, since there is also an inventory of radioactive materials on campus that is not reflected in the table. The inventory at the end of 1993 of the isotopes listed above is shown in the table below.

Inventory at the end of 1993, Ci

H-3	25.2
P-32	0.6
S-35	3.7
Cr-51	0.4
I-131	0.03
I-125	0.8

Of the seven radionuclides shown in these tables, four are pure beta emitting radionuclides (H-3, C-14, P-32, S-35). According to the licensee's records, these four radionuclides made up nearly 90% of the activity disposed of in wastes in 1993. Radionuclides that do not emit photons, or those that emit only low energy photons, cannot be detected by surveys of the external surfaces of the waste containers. A possible exception to this rule may be P-32, whose energetic beta radiation produces x-rays that may be detected by surveys outside the container. However, measurable intensities of x-rays will be produced only in the presence of large quantities of P-32, and such quantities are not usually present in the waste.

b. Waste Collection

Several classes of waste are generated on the NIH campus. These include ordinary trash, such as office wastes; chemical wastes, which include used and unused chemical reagents, solvents, etc; radioactive waste, which includes any wastes contaminated with radioactive material, such as glass, paper, cloth, laboratory equipment, etc.; mixed waste, which is waste that contains hazardous chemicals, as well as, radioactive materials; medical pathological waste (MPW), which is waste that is contaminated with potentially infectious agents, such as surgical equipment, syringes, blood samples, organs and tissues, bedding material, etc.; and MPW contaminated with radioactive or other hazardous materials. These wastes may be in solid or liquid form, and if in the solid form, may also be wet. Other relatively minor types of waste are also generated. Most waste on campus is handled by contractors, and each class of waste is handled by a different group of waste disposal personnel. A summary description of the manner in which wastes are handled on campus is provided below.

Ordinary trash is picked up by housekeeping at the points of generation and packaged for shipment to a local disposal facility, usually a landfill. About 35 tons per day of trash is shipped off campus each day. The waste is surveyed at the landfill to ensure that radioactive material was not inadvertently disposed of in the waste. Chemical wastes, usually in liquid form, are picked up by a chemical waste contractor. They are placed by the waste generator in the original reagent bottles or in specially designed containers supplied by the waste contractor upon request. The containers are appropriately labeled by the generator and picked up within a day or two of a pickup request from the generator. All forms of radioactive waste are picked up by the radioactive waste contractor within one or two days following a pickup request from the generator. Mixed waste, usually in liquid form, is placed in special mixed waste containers and is picked up by a team of chemical and radioactive waste contractors. MPW is placed in special, double lined, cardboard boxes approximately 24" x 15" x 15". The empty boxes, which typically weigh about 40 pounds when full, are placed in convenient locations near the points of waste generation and are labeled with the building and room number in which they are located. When full, the boxes are sealed and picked up by housekeeping and placed on a loading dock in the building in which the waste was generated. A truck delivers the waste boxes to Building 11, which contains the incineration facility. However, if the MPW is radioactive or contains hazardous chemicals, it is picked up by the radioactive waste or chemical waste contractors from the point of generation. All radioactive, chemical, and mixed wastes are taken to Building 21 for processing and disposal. Building 21 is located on campus and houses the chemical and radioactive waste processing facilities, some laboratories, and the NIH RSB staff and facilities.

Waste generators are provided with a waste disposal guide in the form of a calendar that may be hung on a wall for reference. The guide classifies wastes by category. A section is devoted to each category of waste, and describes the types of wastes that fall in that category, the methods to be used to dispose of the waste, the types of containers to be used, the required labeling, and the telephone numbers to call to obtain waste disposal containers, to seek advice or guidance, or to request a waste pickup. The guide was found to be well designed and comprehensive, and provides clear, easy to follow guidance on disposal of all forms of waste. This guidance supplements training that is provided to all users of radioactive material. The licensee stated that the emphasis in waste management training and instruction to users is to minimize the generation of waste and to segregate wastes by category as much as possible. In the case of radioactive wastes, the waste generators are also required to segregate the wastes by half-life. This segregation of wastes helps the licensee take advantage of the decay of short-lived activity to reduce the quantity of radioactive waste to be disposed of, and also helps minimize the generation of mixed wastes, which present exceptionally difficult disposal problems.

c. Waste Disposal Routes

The ultimate disposal of the wastes depends on the nature of the hazardous materials contained in the waste. Wherever possible, attempts are made to condition the waste in such a manner that it may be disposed of as ordinary waste, since this manner of disposal is the least hazardous and the least costly. Wastes containing short-lived radioactive material is held for decay, and is then disposed of as ordinary trash if solid or in the sewer if liquid. Mixed wastes containing short-lived radioactive material are held for decay, and at the end of that period become chemical wastes and are handled accordingly. Mixed wastes are much more difficult to dispose of than chemical or radioactive wastes, and many mixed wastes do not have a disposal outlet.

Solid wastes that contain high concentrations of long-lived radioactive materials are placed in 55-gallons drums, compacted, and shipped for disposal in a licensed waste disposal facility or stored in the interim radioactive waste storage facility at Poolesville pending ultimate disposal. Some solid waste is also shipped for supercompaction off-site before disposal. Waste disposal costs are accessed on a volume basis, and compaction is used to reduce disposal costs. Liquid waste containing high concentrations of long-lived radioactive materials is stabilized by solidification, packed in 55-gallon drums, and disposed of in the same manner as packaged solid waste.

Wastes containing low levels of long-lived radioactivity or short-lived radioactivity of any level are handled in a different manner. Solid wastes that contain low levels of long-lived activity are incinerated or packaged for off-site disposal. Those with short-lived activity are decayed for an appropriate period of time and disposed of as ordinary trash. Radioactive wastes may be incinerated on-site in one of the three campus incinerators or sent off-site to an incineration facility in Tennessee that is authorized to incinerate radioactive materials. Liquid wastes that contain low levels of long-lived radioactive materials are disposed of in the sewers, and those containing short-lived activity are placed in storage tanks for decay and then released to the sewers. Storage of wastes contaminated with short-lived isotopes takes advantage of radioactive decay to decrease the amount of radioactivity released to the environment. Storage of long-lived isotopes does not yield a significant benefit.

Mixed wastes may be treated chemically to convert them to a form that may be released, disposed of in licensed mixed waste disposal sites, or packaged and stored indefinitely on-site. The licensee estimates that approximately half of the mixed waste generated on campus does not have a waste disposal outlet and must be stored indefinitely on-site. About five drums of mixed waste with no disposal outlet are generated per month, and the current inventory of drums in storage is approximately 150. MPW with no radioactive contamination is sent directly from the collection point to the incinerators, either on-site or at a local off-site incineration facility licensed to incinerate medical wastes. If the MPW is contaminated with radioactive materials, it is taken to Building 21 for characterization, documentation, and possible

decay, and then incinerated on-site because the local off-site incinerator is not licensed to incinerate radioactive materials. Ash generated by the on-site incinerators is surveyed for radioactivity and then released for disposal at a local landfill if it meets release criteria. If the release criteria are not met, the ash is held for decay until it meets the criteria, then re-surveyed and released. Ash that does not meet these release criteria is packaged and stored in the interim storage facility at Poolesville. Ash generated in the local off-site incinerator does not contain radioactive material and is disposed of to a local landfill. Ash generated by incineration at the Oak Ridge, Tennessee incinerator is radioactive and is packaged and sent to South Carolina for disposal in a licensed burial facility.

The waste management program on campus is designed so that all hazardous wastes are disposed of by waste management contractors. Waste generators are not permitted to dispose of their wastes in any manner other than that authorized by the appropriate responsible group that handles each type of waste. Users of radioactive material are not authorized to dispose of their contaminated liquid wastes in the sewer or to dispose of their contaminated solid wastes as ordinary trash. The licensee stated that occasional mistakes occur and that the researchers will usually report these errors so that corrective actions may be taken. If contaminated liquid is accidentally disposed of in the sink, the sink is decontaminated and the amount disposed of is accounted for in the total activity permitted to be released to the sewer. Contaminated solid waste that is accidentally placed in ordinary trash receptacles or in MPW boxes is retrieved by tracing the path of the waste and retrieving the waste container. The licensee stated that this type of mistake does happen occasionally but not frequently, and the mistake is often quickly corrected. The licensee stated that the surveys performed by contractors, although not capable of identifying all infringements of waste management policy, do help in identifying unauthorized disposal.

d. Disposal of Liquid Wastes to the Sewer

According to Condition 23 of NRC License No. 19-00296-10, NIH is permitted to dispose into the sewer system eight Ci per year of licensed and other radioactive material, provided that the provisions of 10 CFR Part 20 pertaining to sewer disposal (Section 20.303(a), (b), and (c)) are met. This license condition both raises the sewer disposal limit specified in 10 CFR Part 20 from 7 Ci/yr to 8 Ci/yr and also changes the mix of radioactive material from the Part 20 requirement of 5 Ci/yr H-3, 1 Ci/yr C-14, and 1 Ci/yr all other radionuclides to any mix that the licensee chooses to use. The licensee stated that this condition was requested to provide greater waste disposal flexibility in view of the large number of different radionuclides used on campus and the changing nature of this mix of radionuclides depending on changes in ongoing research.

Aqueous liquid wastes contaminated with radioactive materials are placed by the waste generator in plastic containers, called carboys, and labeled with a radioactive materials label. Carboys are usually of five gallon capacity, but smaller and larger containers are sometimes used. A Radioactive Waste Pickup Receipt is also attached to the carboy and is filled out by the waste generator. Information entered on the receipt includes the name, building and room number of the investigator, the isotopes contained in the waste, and the estimated activity of each isotope listed. The receipt is signed by the waste generator and by the radioactive waste technician who picks up the waste. Solvents and hazardous chemicals contaminated with radioactive materials are treated in a manner similar, but the liquid is placed in special 5-gallon mixed waste containers. These containers have thicker walls than the carboys used for aqueous wastes, and are more resistant to chemicals. In addition to the radioactive waste tag, a chemical waste tag is also attached to identify the nature of the chemicals in the container.

All liquid wastes contaminated with radioactive materials are taken to Building 21 where the information on the waste tags is tabulated. The waste is then classified according to activity level and type of radioisotope. Liquid samples are taken from each waste container and analyzed for radioactive content by the waste management contractor, and the results of the analysis are also tabulated. Researchers are notified if the analysis shows activities that are substantially different from those listed on the waste receipt. The results of these analyses, rather than the information on the waste receipts, are used in demonstrating compliance with waste release limits.

Liquids containing long-lived activity in high concentrations are stabilized and packaged for burial at a licensed facility. Liquids with low levels of long-lived activity are disposed of to the sewer. Liquids with short-lived activity are stored in one of nine 2250-gallon tanks where the liquid is held for decay before release to the sewers. Samples are taken from the tanks and analyzed before each batch is released to the sewer. An administrative limit of 15 mCi is placed by the licensee on the daily activity released to the sewer. This is equivalent to approximately 5.5 Ci per year assuming daily disposal, and is substantially below the 8 Ci annual limit imposed by the NRC license. The administrative limit may be exceeded only after authorization by the licensee's waste manager. The licensee stated that there are no authorized release pathways to the sewer other than through Building 21, except for some inadvertent releases of small amounts in laboratory sinks by researchers. The licensee stated that they do not have an estimate of the magnitude of this release pathway but believe it to be negligible based on their experience. They stated that most researchers are well trained and take great care in the manner in which they dispose of their wastes. There was no documentation or studies to substantiate these statements, but reviews of other aspects of the program suggest that there are no inconsistencies.

According to the licensee's records, releases to the sanitary sewer during 1993 included the following main radioisotopes.

Sanitary Sewer Releases During 1993 in mCi

H-3	3032
C-14	32
S-35	1496
P-32	190
Cr-51	238
I-125	145
Total	5204

Releases of other radioisotopes were very small compared with those listed above. The activity released represents 65% of the allowable activity limit permitted for sewer releases by the NRC license. This activity also represents approximately 44% of the total activity disposed of in radioactive wastes of all types during 1993, the remaining activity being disposed of by incineration or shipment off-site. The 1993 sewer release level is comparable to that for the previous years, which were approximately 6.3 Ci, 6.6 Ci, and 5.9 Ci for 1990, 1991, and 1992, respectively.

A review of the physical plant, equipment, and records showed that the licensee, through their contractor, implements an effective liquid waste management program. Records reviewed were complete and well maintained, and indicated that sewer disposals were made in accordance with regulatory requirements and good practice. However, the following areas for improvement were identified in this part of the program.

Official records for the daily activity disposed to the sewer are not maintained, but records of daily disposals are kept by the contractor in computer files. The licensee stated that the contractor provides them with weekly summaries of disposal activities, and these weekly totals are monitored to ensure compliance with the limit on the annual activity released. Although it may be difficult to verify the data in the weekly reports or trace errors without official records of daily disposals, especially if the contractor's files containing this data are not verified and stored, no regulatory limits were exceeded.

The licensee also did not maintain records of average daily and monthly concentrations of discharged materials. In addition to the limit on the annual activity disposed to the sewer, the license requires that the daily and monthly activities released be controlled so that the average concentrations when diluted by the average daily and monthly quantity of sewage released into the sewer by the licensee, will result in concentrations that do not exceed the values listed in 10 CFR Part 20, Appendix B, Table I, Column II. The licensee stated that, because of the very large volume of water discharged to the sewer each day by NIH, namely 5.5 X 10^6ml/day it is not possible to exceed the specified concentrations given the

amounts of radioactive materials handled on campus. The inspector verified this statement for the principal isotopes disposed of in liquid wastes. The daily administrative limit on sewer discharges of 15 mCi, when diluted by the daily flow of sewer water, yields concentrations that are lower than the limit for the most restrictive radioisotope listed in the table above. It was therefore concluded that the licensee's practice is justified. The inspector stated that this practice should be reevaluated if the waste disposal patterns change substantially.

Analyses of samples taken from storage tanks and carboys are used as the basis for showing compliance with the sewer release limits. However, the nine tanks used to store liquid waste prior to batch release to the sewer do not have the capability for mixing the stored water prior to sampling to ensure a representative sampling. To overcome this limitation, the licensee uses a device called a COLIWSA tube that is designed to sample liquids that may have stratified during storage. This device is used to collect a 10 liter sample from each tank for analysis before batch release. Although this method may be adequate for its intended purpose, which is to sample stratified liquids, it is not clear that it would be adequate for sampling liquids that may contain matter that could settle to the bottom of the tank, such as cell cultures or other matter that may contain most of the radioactivity in the liquid. The licensee stated that they believed the COLIWSA is capable of accurately sampling in such situations as well as in cases of stratification. Carboys are sampled using a hollow glass tube of about 5 mm internal diameter. The tube is inserted slowly into the carboy and a 10-20 ml sample is drawn as the tube moves deeper into the liquid. The method was devised by the contractor and appears to be a reasonable method for use in such situations. However, it was not reviewed and formally approved by the licensee as adequate for their purposes. The licensee stated that they will attempt to verify the methods or select more appropriate ones. This item will be reviewed during the next inspection.

The revised 10 CFR Part 20 requires that liquids disposed to the sewer contain only soluble materials, or soluble or dispersible biological material. The licensee stated that they do not verify solubility before disposal to the sewer because most of the radioisotopes used on campus are purchased in soluble chemical form. The inspector inquired as to whether this has actually been verified, but the licensee stated that it has not. In addition, the inspector stated that the chemical forms of these liquids may change during research and become insoluble by the time they are disposed of as waste. During inspection of the waste facilities, the inspector noted that the waste contractor was performing solubility checks on samples being prepared for disposal. The method used consists of diluting a 1 ml waste sample with 5 ml water and stirring for 5 minutes. The sample is allowed to settle for about an hour then examined visually for stratification or settling. If neither is observed, the sample is judged to meet the solubility criteria. The inspector stated that this method may not meet the NRC's acceptable methods for determining solubility, as described in NRC Information Notice 94-07, Solubility Criteria For Liquid Effluent Releases To Sanitary Sewerage Under The Revised 10 CFR Part 20. The inspector stated that the licensee is not required to use the methods described in the Information Notice, but should be able to justify use of any method chosen to

show compliance with regulatory requirements. The licensee stated that they will review their methods to ensure that they meet regulatory requirements.

Daily quality control (QC) measurements in the form of background and source checks are performed by the contractor on the liquid scintillation and gamma counters used in the waste analysis laboratory. However, although the results of these tests are recorded on forms provided for this purpose, there were no entries made to indicate the acceptability of the results, nor were there clearly specified numerical acceptance criteria for these tests. The licensee stated that they use two standard deviations from the mean established at the time of calibration to define acceptance limits for the QC measurements. The licensee also stated that the laboratory supervisor, who conducts these tests, is able to review the data and recognize readings that are not within tolerance. Discussions with the laboratory supervisor showed that he was well aware of the capabilities and limitations of his analytical equipment and the approximate readings that would be considered acceptable in QC measurements. A review of the data by the inspector showed that the readings were probably acceptable. However, such scrutiny of the data, without the use of numerical acceptance criteria, is subject to error and cannot be considered an adequate quality control practice. In addition, although the contractor's procedures require daily plots of the data on quality control charts, no active quality control charts are maintained. The licensee stated that the computer produces monthly printouts of quality control charts for the previous month. A review of recent computer-generated charts showed that the data for previous months were indeed within acceptable limits. However, the inspector stated that retrospective quality control charts cannot be considered part of the daily quality control procedures. It was not known at the time of the inspection whether the computer program that produces these charts would also provide a real time message in case a QC reading was out of tolerance. The licensee stated that they will make the necessary adjustments to the QC program.

Instrument calibrations are performed using sources traceable to the National Institutes for Science and Technology (NIST). Split samples are also periodically counted by both the contractor and the licensee as part of the quality assurance program for the laboratory. However, the licensee does not participate in any outside round-robin type of quality assurance measurements.

In general, the licensee provides minimal ongoing quality assurance oversight of the contractor's analytical laboratory, and is generally not familiar with the technical details of the analytical part of the contractor's waste operation. The licensee does, however, conduct periodic inspections of the contractor's operations. These inspections are limited mainly to reviews of contamination control practices and general housekeeping.

Each liquid waste container received at the waste processing facility in Building 21 is associated with two sets of data on radioactivity content: those provided by the waste generator and recorded on the waste receipt tag, and those obtained by the waste contractor from analyses of the contents of the containers. The licensee uses the latter values to demonstrate compliance with sewer release limits because these are deemed more reliable. However, except in very unusual circumstances, the data supplied by the waste generator is not used for any purpose. The unusual circumstances include large discrepancies between the activity levels recorded by the generator and those measured by the contractor, or significant discrepancies in the mix of radioisotopes present in the waste. In such cases, the waste generator is contacted to discuss the discrepancies. A review by the inspector of approximately 250 randomly selected waste receipt tags and their corresponding analysis data showed that approximately 60% of the waste generators over-reported the activity in their waste, while 30% under-reported the activity. The mix of radioisotopes reported present in the waste was usually, although not always, accurate. The total activity calculated from the data reported on the tags by the waste generators was found to correspond closely to the activity calculated using laboratory analysis data. This suggests that the over- and under-reporting tended to balance out, but it was not clear whether the sample selected was sufficiently representative. The inspector stated that the licensee does not provide sufficient quality assurance monitoring of the data provided to them by the waste generators, and therefore does not provide sufficient feedback to the generators in an attempt to maintain a high level of accuracy in the reported data. This may not seem to be an important factor in the case of liquid waste since laboratory analysis data is available. However, it is important in the case of solid wastes, where such analyses are generally not available, as is discussed in Section 12.e below.

e. Waste disposal by Incineration

Three waste incinerators located in the Bethesda campus are used by the licensee for incineration of solid wastes, mostly MPW. Two of the incinerators are of older design, the third being of more recent design and higher capacity than the older units. The incinerators are located in Building 11, which is the building housing many of the campus utilities such as boilers and heating units. Each incinerator is provided with a stack that is about 85 ft. above the closest ground level. The incinerators are operated by the Division of Engineering Services, with oversight provided by the RSB and the Environmental Protection Branch. MPW is incinerated because incineration is an effective method of destroying any pathogens that may be contained in these wastes, and also because biological and pathogenic waste cannot be disposed of in disposal sites such as landfills.

Sealed MPW boxes, labeled by point of origin, are delivered by truck to the incinerator loading dock in Building 11. The boxes are placed on a conveyor belt that takes them to be scanned, one at a time, by two radiation detectors positioned on either side of the belt. Each detector consists of a 3" x 1" sodium iodide (NaI) scintillation detector mounted in a shielded box with an acrylic window. The

detectors face each other and are approximately 60 cm apart. Each box stops in front of the detectors for 5 seconds before moving on to the next stage, which is either delivery to one of the incinerators or delivery to a second loading dock for shipment to an off-site incineration facility. According to the licensee's records, of the approximately 50,000 MPW boxes monitored during the four-month period prior to the inspection, approximately 60% of the boxes were shipped off-site and the rest were incinerated on-site. Ash from the incinerators is placed in dumpsters in preparation for shipment to a local landfill. The ash in a full dumpster is sampled by drawing a composite sample made up of ash taken from several depths in the dumpster.

Observation of the operation of the incineration facility during this inspection showed that activities were conducted in a well organized manner. The daily source check of the radiation detectors on the conveyor was observed, and the source check did alarm the radiation monitor at the indicated setpoint. A record of the daily source checks was maintained and was found to be complete. The check source is in the form of an MPW box with several Cs-137 sources embedded in the box. The total activity of these sources was estimated by the licensee to be about 4 μCi, but no record of the actual activity was available for review. The background reading for the monitors was observed to be about 0.5 μR/hr, and the alarm was set at 1 μR/hr. One MPW box alarmed the monitor during observation of the operation of the system and was removed from the belt. Such boxes are taken back to the generator to investigate the cause of the alarm. The radiation monitors were installed in late 1993 and, according to the licensees records, since that time 0.4% of the approximately 50,000 MPW boxes surveyed (186 boxes) alarmed the monitors. Over 90% of these boxes were believed to have come from the patient care facilities (some of these boxes were not labeled), the rest coming from the research laboratories. Gamma analyses of these boxes indicated the presence of Ga-67, Tc-99m, In-111, I-125, I-131, and Tl-201, which are isotopes used mostly in patient diagnostic tests.

A review of the licensee's records for incineration of radioactive waste showed them to be complete and well maintained. According to these records, the following activities were incinerated on-site during 1993.

Radioactive Waste Incineration During 1993 in mCi

H-3	385
C-14	135
S-35	49
P-32	10
Cr-51	18
Total	606

The licensee's records show that the activity incinerated during 1993 was substantially lower than that during the previous two years. No reason was provided for the change.

Review of the licensee's incineration operation showed that the RSB conducted proper surveys of wastes going to the incinerator, kept accurate and well organized records of wastes sent to the incinerator, and properly investigated unauthorized incineration of wastes when detected. Condition 27 of License No. 19-00296-10 permits incineration of licensed material provided the daily average concentrations of radioactive materials in the gaseous effluent from the incinerators do not exceed the concentrations listed in 10 CFR Part 20, Appendix B, Table II. The licensee is also committed to comply with the As Low As Reasonable Achievable (ALARA) requirement of 10 CFR Part 20 by maintaining the annual average concentrations below 10% of these limits. Based on these concentration limits, the licensee developed two activities, called Q values, for each of the radionuclides expected to be incinerated. One set of Q values gives the total activity of each radionuclide that may be incinerated alone each day without exceeding the license condition. The other set gives the corresponding annual quantities. If more than one radioisotope is to be incinerated at any given time, the rule of fractions described in 10 CFR Part 20, Appendix B, is used. The same method is used for the annual limits. The daily activity sent to the incinerator is controlled using a quantity defined by the licensee as a waste unit. Each container to be incinerated is assigned a waste unit, which is the sum of the activities of each of the isotopes in the box divided by the corresponding daily Q value. Each waste box is prominently labeled with its contents in waste units. The number of boxes sent for incineration on any day is limited so that the sum of waste units for all the boxes incinerated on that day does not exceed unity. This assures compliance with the daily release limits. A running total of the activity incinerated to date is also maintained to ensure that the annual limit is not exceeded. The licensee did not maintain daily records of the waste units incinerated, but the running totals showed that incineration was being conducted in accordance with license conditions.

The following areas for improvement were identified during reviews of the part of the program devoted to incineration of wastes.

The licensee has not characterized the capabilities and limitations of the radiation detectors installed to monitor MPW boxes before incineration. It is clear that these monitors alarm when the MPW contains 4 μCi of Cs-137, but the capabilities and detection limits for the other radionuclides that may be in these boxes has not been established. Some of the gamma emitting radioisotopes frequently found in the wastes generated on campus either emit very low energy photons (e.g. I-125) or low abundance higher energy photons (e.g. Cr-51). It is not clear how well the radiation monitors would be able to detect such activities. The inspector stated that it is difficult to assess the degree to which these monitors satisfy their intended function without such a characterization. The licensee stated that they do not have the technical data that would permit such an assessment of capabilities, but they will contact the manufacturer to obtain the data.

Records show that approximately 97% of the activity sent for incineration in 1993 was made up of the pure beta emitting radioisotopes H-3, C-14, S-35, and P-32. Pure beta emitting radioisotopes (with the exception of large quantities of P-32 which may produce bremsstrahlung radiation that can be detected by external monitoring) cannot be detected by surveys of the outside of the waste containers, nor would they be detectable by surveys of the contents of the containers if the containers were opened. The activities would have to be measured by complex sampling and analyses of the waste. In addition, much of the waste that is incinerated consists of MPW, which may contain infectious pathogens, and is therefore hazardous to open. In view of these difficulties, and also the fact that the effluents from the incinerators are not monitored for radioactive materials, the amount of radioactive material incinerated is estimated from the data provided by the waste generator. This data is augmented with radiation surveys if photon emitters are present in the waste. In addition, there are also no estimates of the number of MPW boxes that may contain unauthorized and undetectable radioactivity. These difficulties are to a large extent unavoidable because of the nature of the waste and the nature of the emissions from the contaminants. However, a review of the licensee's program showed that the licensee did not provide any means to spot check the waste generator's data, nor did the licensee maintain a quality assurance program, or other means, to estimate the reliability of the data supplied by the waste generators and to provide a measure of confidence in the data used to show compliance with license conditions. Several possibilities exist, such as use of the data available from the liquid waste pathway (as discussed in Section 12.d above), as well as data available from ash analyses (see Secuon 12.f below). Other possibilities might be found on careful consideration of the situation. The licensee stated that they will review this issue and take action as appropriate.

At the time this inspection started, the two older incinerators had been taken out of service permanently. The third incinerator was taken out of service during the inspection.

f. Ash Disposal

Ash from the incinerators is disposed of at a local landfill following analysis for radioactive content. Condition 27 of the License No. 19-00296-10 permits disposal of the ash as ordinary waste provided the concentrations of licensed material in the ash do not exceed the concentrations (in terms of μCi/g) specified for water in 10 CFR Part 20, Appendix B, Table II. The licensee's ash disposal records show that 1824 tons of MPW was incinerated during 1993, of which approximately 20 tons was known to contain radioactive material. The licensee estimated that the total weight of ash resulting from this incineration is approximately 20% of the weight of the MPW, or approximately 365 tons of ash shipped to the landfill. Each ash shipment is analyzed by the RSB to ensure that the ash meets license conditions before it is released. Ash shipments that do not meet these conditions are held for

decay and re-analyzed prior to release. Ash that cannot be decayed because of the presence of long-lived activity is packaged and stored at the Poolesville interim storage facility. A review of ash analysis records for 1993 showed that about 5 ash shipments were held for decay during that year. No ash was packaged for storage during that period.

The ash disposal program was found to be operated in accordance with the license requirements. However, the following areas for improvement were identified.

A review of the results of ash sample analyses during the period 1990-1994 showed that a large fraction of these samples contained radioactive materials, usually Cr-51, and occasionally Ga-67, I-125 and I-131. The concentrations of these radionuclides in the ash released for disposal were found to be well within those provided in the license condition for ash release. The activities of these four radioisotopes reported by the licensee to have been incinerated during 1993 are shown below.

Activities Incinerated During 1993, mCi

Cr-51	17.5
Ga-67	1.8
I-125	0.3
I-131	0.2

The licensee does not attempt to correlate the activity found in the ash to that reported incinerated. In an attempt to determine if the reported ash activities were at the level to be expected based on the reported activity incinerated, the inspector calculated the average annual concentration of these radionuclides for ash disposed during 1993, and the results were as follows:

Cr-51	5.4×10^{-5} μCi/g
Ga-67	2.4×10^{-4} μCi/g
I-125	1.3×10^{-6} μCi/g
I-131	1.3×10^{-7} μCi/g

Based on the licensee's estimates, approximately 365 tons of ash was shipped off-site for disposal. Using this weight of ash and the calculated average concentrations, good agreement was found in the case of Cr-51 and Ga-67 between the incinerated activity based on ash analyses and that reported to have been incinerated. Assuming that all the Cr-51 and Ga-67 remain in the ash, this result suggests that there was probably little unauthorized incineration of wastes containing these radionuclides. This is only a tentative conclusion, however, and supporting data, such as the accuracy of the weight estimate for the ash and the portioning of the activities between ash and air effluent, are needed. The analyses for the iodines, however, did not yield similar agreement, possibly because a substantial fraction of the iodines leave the incinerators via the stack as air effluent and only a small fraction remains

in the ash. Tests to measure this fraction, known as the partition coefficient were conducted by the licensee for I-125, and the results indicated that about 4% of the iodines remain in the ash. Using this value for the partition coefficient, it was found that the amount of iodine that may have been released in effluents in 1993 exceeded the annual limit for I-125 based on the ALARA commitment incorporated in the license, namely to keep the annual average concentration in the effluent below 10% of the values in 10 CFR Appendix B, Table II. A review of the data for ash disposal during 1990 through 1992 and in 1994 did not reveal other similar situations. The above analysis is a crude estimate of the activity released in the air, and must be considered as semi-quantitative because it is based on a rough estimate of the weight of ash disposed of during that year. The result is also very sensitive to the value of the partition coefficient chosen for the analysis, which could vary depending on the chemical form of the iodines in the waste as well as the operating conditions within the incinerator at the time of incineration. Nevertheless, such analysis could serve as an additional quality control measure to monitor incineration activities, to detect incineration of unauthorized activities, and to provide confidence in the licensee's effluent release estimates. As noted above, the ash data indicates that there is some question regarding the amount of I-125 actually incinerated during 1993. It also indicates that the amount of I-125 incinerated during that year may have been substantially above the 0.3 mCi recorded in the licensee's documents, making it difficult to determine the licensee's compliance staus in this area.

The licensee's failure to use the available data to verify compliance with the applicable limits in their license is considered a failure to perform an adequate survey in the area of incinerator effluents. This is a violation of the requirements of 10 CFR 20.201 (30-01786/94-01).

The licensee performs direct analyses of the ash only for photon-emitting radionuclides. The licensee stated that, due to the physical and chemical characteristics of the ash, the liquid scintillation counting technique for beta analysis is difficult to apply to routine ash analysis because it produces unreliable results. Instead, the licensee uses an indirect method known as Toxicity Characteristic Leaching Procedure (TCLP). This method is recommended by the Environmental Protection Agency (EPA) in 40 CFR 261 in the context of analysis for landfill disposal of toxic wastes. The procedure, which is a chemical extraction procedure, attempts to simulate the acidic leaching conditions in a landfill environment to determine the concentrations of hazardous chemicals in the leachate produced in the landfill. Extraction is done using an acetic acid solution at a pH of about 4.2 and the extracted solution is counted on a liquid scintillation counter. The licensee started TCLP analysis in late 1993, and a review of the data showed that only two samples showed traces of C-14 or S-35, which are difficult to separate by liquid scintillation counting. No other radionuclides were detected, and most sample analyses did not show the presence of any radioactivity. The method was submitted to the NRC by the licensee for approval and was incorporated into the NIH license.

However, the relevant quantity to show compliance with the ash release limits is the activity in the ash, not the activity that can leach out of the ash at the landfill. The licensee has not attempted to characterize the method to demonstrate that the activity remaining in a typical ash sample after performing a gamma analysis and application of the TCLP method is small and would not affect compliance with release limits. This is expected to be the case, however, on theoretical grounds since the pure beta emitting radioisotopes that contribute the most activity to the wastes, namely H-3, C-14, and S-35, are normally converted to the oxides of the elements during

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incineration and are released in gaseous form via the stack rather than remaining in the ash.

An ash sample was obtained by the inspector during this inspection, and subsequently split into three samples. One sample was retained by the licensee for analysis, another was provided to the State of Maryland, and the third was analyzed by NRC. The results of the analyses of all three samples agreed within the expected range of experimental uncertainty. They showed about $4.2 \times 10^{-4} \mu Ci/gm$ of Cr^{51} and $4.9 \times 10^{-4} \mu Ci/gm$ of C^{14}. No comparison with TCLP analysis of the samples was available. The C^{14} concentration is about 15% of the applicable release limit for the ash, and the concentration of Cr^{51} relative to its release limit was much lower. The significance of the presence of the observed level of C^{14} in the ash was not clear at the time of the inspection, particularly in view of the assumption made above, namely that most of the C^{14} would be expected to be released in the incinerator effluents. Further evaluation would have to be made upon restart of incineration.

A review of the ash analysis data and the calculations to demonstrate compliance with license conditions during the past several years showed that the licensee was using the concentration values in Appendix B, Table II, of 10 CFR Part 20 for the insoluble forms of several of the radionuclides found in the ash, including I-125 and I-131. The allowable concentrations for the insoluble compounds of these isotopes are generally much higher than those for the soluble compounds. This practice appeared to be inconsistent with the practice employed in determining compliance with the air effluent limits, in which case the licensee used the most restrictive concentration for each of the radionuclides released. The licensee stated that they had conducted solubility tests on the ash and had demonstrated that the isotopes in question were insoluble when found in the ash. The test consisted of mixing an ash sample in water and letting the mixture stand for a week. The liquid was then analyzed to determine if any activity was transferred from the ash to the water. None was found. The licensee stated that this conclusion is further supported by the fact that these isotopes were not found in samples obtained by the TCLP procedure. This policy was not documented in the licensee's documents reviewed during this inspection. The use of the limits for the insoluble forms of the isotopes was incorporated into a computer program that was used in data analysis. The program automatically calculated the activity of each isotope identified in the analysis in terms of the fraction of the applicable limit. This software was changed recently and the new software does not calculate these fractions. The licensee therefore calculated these numbers manually, and it was noticed during review of the recent analysis results that the manual calculations were being made using the most conservative limits for each isotope. When questioned by the inspector regarding this apparent change in policy, the licensee stated that this was an inadvertent change but that it is a more conservative practice. However, they have not decided whether to adopt this as the revised policy or return to the previous practice.

g. Environmental Monitoring Stations

Seven environmental monitoring stations are used by the licensee to monitor the concentrations of iodine in the air on the NIH campus. Each station is equipped with a sampler consisting of an iodine cartridge holder with a prefilter attached and an air pump to draw ambient air through the sampler. The air flow rate is maintained at 2 cubic feet per minute. The sampler is operated continuously for a period of one week and is then replaced with a fresh cartridge. The old cartridge is taken to the Building 21 laboratory for evaluation on a high resolution gamma analysis system. The lower limit of detection for this system for this application was estimated by the licensee to be about 1×10^{-15} μCi/ml. The inspector accompanied a licensee representative to inspect one of these stations.

The licensee stated that the locations of the station were selected using several criteria, including the locations of the nearest inhabitants to the incinerators and the locations of the maximum expected concentrations of iodine. The latter was determined on the basis of computer analysis of effluent dispersion patterns around the incinerators using wind rose data from Dulles and National airports. The computer analyses were performed for several pollutants in addition to radioactive materials.

A review of the results of the gamma analyses of the environmental cartridges obtained during 1993 and 1994 showed that three of the cartridges showed some I-125 activity during 1993, and one during 1994 showed I-131. The activities were all of the order of 1×10^{-14} to 1×10^{-15} μCi/ml. In two of these cases, a recount of the sample for a longer time interval showed no measurable activity. In both of these cases, the concentration obtained on the first count was very close to the counting system's detection limit. The first positive result may have been due to software misidentification of iodine peaks. There may also have been some loss of iodine from the cartridge between the first and second counts.

The licensee stated that the data from cartridge analysis show that the dose rates at the locations of the monitoring stations are significantly below regulatory limits. The most restrictive limit for I-125 in effluent provided in 10 CFR Part 20 Appendix B, Table 2 is 3×10^{-10} μCi/ml, and therefore concentrations of the 1×10^{-14} μCi/ml are several orders of magnitude lower than those specified in the limits. The resulting doses would be proportionately lower than the applicable regulatory limits. However, since the license conditions on incinerator effluents apply to concentrations at the point of release rather than at the monitoring stations, use of monitoring station results to demonstrate compliance cannot be made directly. Such use requires correlation of the monitoring results with effluent release concentrations using dispersion calculations. The licensee has performed such calculations, but the data provided during the inspection could not be used to make these correlations for a number of reasons. Although dilution factors were calculated by the licensee for a number of distances and directions from the stacks, the factors were annual averages

rather than weekly averages. Annual average dilutions for a particular monitoring location could be significantly lower or higher than dilutions over shorter periods of time depending on the details of the wind rose. Data were not available to determine whether typical wind shifts during a period of one week are similar to those that occur over a period of a year. In addition, it is not clear whether wind rose data (diagram that shows for a particular place the frequency and intensity of wind from different directions) from area airports can be used with any degree of accuracy to model the dispersion patterns on the NIH campus, with its complex of many buildings of many different heights. Additional work is required if the monitoring station data is to be used to correlate to effluent data. This is not a required license condition, and the results of such an analysis would only place bounds on such a correlation but would not be expected to provide accurate results. The conclusion that may be drawn from the monitoring station data is that the doses from radioiodines at these locations are substantially lower than the regulatory limits for exposure to these airborne radionuclides. It should be noted that iodine activity detected by these stations need not necessarily have originated in the incinerators, but may have been emitted from various buildings where iodine is used in research and patient diagnosis and treatment.

In addition to the above analyses, the licensee also ran EPA's COMPLY computer code to demonstrate compliance with EPA's 40 CFR Part 61, Subpart I standards. The calculations included environmental releases from all sources on campus, which includes the incinerator as well as other buildings where radioactive material is used and from which radioactive material may be released to the atmosphere. The calculations include exposure from all relevant exposure pathways such as inhalation, consumption of contaminated vegetables, meat, milk, etc. At the computer code's Level 4 analysis, which the most detailed level of analysis, the effective dose equivalent for 1993 was 1.5 mrem/yr from all radionuclides and 0.5 mrem/yr from iodine. The Subpart I standards require emissions be restricted to dose levels of 10 mrem/yr from all radionuclides and 3 mrem/yr from iodine.

An inspector also accompanied an AHP to one of seven air sampling stations which are located on roofs of various NIH buildings around the incinerator. The sampling station consisted of a locked, louvered enclosure on a building roof. Inside was a high volume air pump drawing a continuous sample of air through a filter and a charcoal cartridge.

No safety concerns or violations of regulatory requirements were identified.

13. Instrument Calibration

The licensee's radiation survey instruments used to measure dose rates are calibrated by a NIH contractor. At the time of the inspection NIH had ten Bicron RSO-5, and one Victoreen 450P ionization chambers. The inspector determined that all were calibrated annually, as required. Radiation survey instruments used to measure contamination were routinely calibrated by the survey contractor while conducting quarterly or semiannual surveys of the laboratories.

The inspector observed that a field calibration of a survey instrument by the survey contractor technician was performed in accordance with the license requirements. The "high voltage" was checked with a volt meter; next the technician checked and adjusted two points on each scale using a "Crystal Controlled Varipulser". Lastly, the technician established the efficiency of the meter for P-32 and I-125 using Sr-90 and I-129 sources.

No safety concerns or violations of regulatory requirements were identified.

14. Sealed Source Inventory And Leak Tests

The inspector reviewed the licensee's records of sealed source inventory and leak tests. Inventories were performed quarterly and leak tests were performed once every six months. Leak tests were performed during June and December of 1993. All results of leak tests were within regulatory limits, and the tests were performed within the required time intervals. The sealed source inventory records were signed by the RSO. The RSO indicated his preference to delegate the authority to sign individual leak test and inventory records to the RSB staff AHP's assigned responsibility for each of the campus areas. However, the inspector clarified to the RSO that the regulations require that leak test and inventory records must be signed by the RSO unless the licensee has applied for and received an exception to the regulations by license amendment.

No safety concerns or violations of regulatory requirements were identified.

15. Inventory And Control of Radioactive Material

According to RSB personnel, most radioactive materials are ordered by individual users through a system of blanket purchase agreements with major suppliers. Each institute at NIH has its own procurement office. Larger radioactive material orders or special items (anything over $2,500) are procured through a written requisition process. Such orders must be approved by the RSO. The RSO stated, that in the future, the RSB will order, as well as receive packages of radioactive material.

The inspector observed that NIH had a computerized inventory control system. Information on each incoming shipment of radioactive material was entered into the database daily as the material was received in Building 21. NIH prepared monthly reports which noted the total inventory for each major isotope. The reports used the previous month's total, adding in the monthly receipts and subtracting the total monthly activity disposed including the shipped waste, the liquid wastes disposed through the sanitary sewer and the solid waste incinerated. The computer program used to generate the report incorporates radioactive decay. Authorized users were responsible for maintaining a record of the receipt, utilization, and disposal of radioactive materials used under their authorization using NIH Form 88-16 "Isotope Receipt, Utilization and

Disposal Records." A binder was provided by the RSB to maintain these records. During the inspection, all of the labs visited by the inspectors had appropriately completed NIH Form 88-16.

A specific license (such as NIH's broad scope license) is required to possess or use certain licensed material. A licensee representative stated that, to the best of his knowledge, NIH has never possessed or used licensed material without the required license. All records that were reviewed indicated that, during the previous twelve months, NIH did not receive any licensed material requiring a specific license that was not listed on one of their licenses. The specific instance of the receipt of actinium-225/bismuth-213 generators was reviewed. Amendment No. 70 to License No. 19-00296-10, which authorizes NIH to possess and use actinium-225/bismuth-213 generators, was issued on March 23, 1993. Computerized receipt records maintained by the RSB indicated that a generator was not received until April 1, 1993. The receipt of the generator was also confirmed by review of records maintained by the researcher that requested that the RSB amend NIH's license. Therefore, NIH's license was amended before the generator arrived.

No safety concerns or violations of regulatory requirements were identified.

16. Package Receipts And Distribution

The inspector noted that except for the Gerontology Research Center and the temporary exception of the NMD, all radioactive materials shipments are received by the RSB in Building 21. Most shipments are received during normal working hours. Occasionally shipments arrive during the weekend. For the weekend deliveries, security personnel escort the carrier to Building 21 where the packages are left in a secure area until RSB staff can process the packages.

The inspector determined through discussion with the AHP and records review that approximately 35,000 packages of radioactive material are received at NIH annually. The inspector also observed that external radiation surveys at the package surface and at one meter were performed on packages containing greater than Type A quantities, contamination surveys were performed when required pursuant to 10 CFR 20.1906, and shipping papers were reviewed to assure that information from the purchase order matched the information on the NIH Form 88-1 "Request for Purchase and Use of Radioactive Materials." If an NIH Form 88-1 signed by an AU was not received by the RSB, the package was held by the RSB until the appropriate information was received. The material was also held when discrepancies were noted between the shipping papers and the NIH Form 88-1 that could not be resolved by phone. Information on each shipment was logged into the RSB database which enabled the licensee to maintain a fairly accurate materials inventory. The database was also used to verify that the user was authorized for the material received. Currently, there is ongoing construction of a new area for package receipts and distribution.

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The ordering of licensed materials by one researcher who, for a time, was not under the supervision of an AU and not an AU himself was reviewed by the inspector. The researcher was using licensed material under the supervision of an authorized user until May 25, 1993, when his name was removed from the list of people that were authorized to use licensed material under the AU. At that time, the researcher submitted an application to become an AU and was approved as an authorized user for non-human uses of licensed material (the researcher was already an AU for human uses of licensed material) on June 14, 1993. During the period which the researcher was not under the supervision of an AU, and not an AU himself, computer records maintained by the RSB indicate that no licensed material was delivered to him.

Also, approximately five individuals in Building 49 were interviewed by the inspector with respect to the ordering/receipt process. They stated that they would coordinate the ordering of non-routine radioactive material, such as an irradiator with the RSB. The individuals also stated that they knew of no unauthorized irradiators or other unauthorized radioactive material in the building. The inspector looked in several laboratories and no irradiators or unauthorized radioactive material were found.

No safety concerns or violations of regulatory requirements were identified.

17. Gammacell 40 Irradiator

A Nordion International, Gammacell 40 self-shielded irradiator containing 2,882 curies of cesium-137 is located in Building 10A. The irradiator is used for irradiating small animals such as mice and cell cultures. The primary responsibility for this irradiator, and all other irradiators on the NIH campus, lies with its custodian. Irradiator custodians are responsible for, among other things, training individuals that use the irradiators, keeping records of this training, limiting access to the irradiator to only those individuals that have received the training, and meeting other regulatory requirements that apply to their particular irradiator. To be named an irradiator custodian, candidates normally, unless an exception is granted by the RSC, complete the AU training course, receive specific training regarding operation of the specific irradiator, and must be approved by the RSC. The office of the current custodian for the Gammacell 40 is located in another building on the NIH campus. The Program Coordinator for Building 10A has applied to the RSB to be the custodian for the irradiator in Building 10A.

The irradiator is located in a room that is locked unless the irradiator is in use. The keys to the room and the irradiator are controlled by an administrative assistant. She stated that she has a list of persons who are authorized to use the irradiator and an individual must be on the list before she relinquishes the keys to them. A sign-out log for the keys is maintained. The inspector compared all the names of individuals who signed out the keys from October 10, 1993 to the present as well as names of individuals

who signed out the keys on selected dates from May 25, 1993 to October 10, 1993 with those on the authorized user list. No individuals signed out the keys who were not on the authorized user list for the entries reviewed.

No safety concerns or violations of regulatory requirements were identified.

18. Exit Interview

At the conclusion of the inspection on April 8, 1994, the inspectors met with the individuals identified in Section 1 of this report and discussed the scope and initial findings of the inspection. The inspectors informed the licensee that the inspection findings were not closed because some information had not yet been reviewed. On April 20, 1994, additional information was requested and provided to the inspectors by the licensee via facsimile. The findings are noted in this report. Another exit interview was held on May 13, 1994, at the conclusion of the inspection. The inspectors met with the individuals identified in Section I of this report. The scope and findings of the inspection were discussed.

19. Confirmatory Action Letter (CAL)

Subsequent to the inspection, a CAL was issued on May 5, 1994, with respect to several areas in which violations of security and control of radioactive materials were identified during the inspection. The CAL reiterated the NRC understanding of licensee actions to address and correct the violations. Licensee actions taken or planned by the noted dates follow:

1. May 4, 1994 - RSO to meet with and inform the RSC of the immediate action required to secure from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas, and control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; and discuss the commitments made to the NRC.

2. May 6, 1994 - RSC/RSO to inform all users to secure from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas, and control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

3. May 6, 1994 - RSO to require that all surveys performed by staff and contractor personnel include a review of security and control of licensed material. Non-conformance to be immediately reported to RSO for appropriate corrective action.

4. May 6, 1994 - RSO to assure that for all future training of new users and retraining of current users, emphasis is placed on security and control of licensed materials as stated in 10 CFR 20.1801 and 20.1802.

5. Within 30 days - Licensee to establish a written Interim Security Policy for all licensed material to ensure that licensed material is either secured or under constant surveillance. The effectiveness of the practiced interim policy will be evaluated and modified as necessary. Within 180 days, the permanent security policy will be placed in effect, it will include the necessary modifications.

The actions taken in response to the CAL will be inspected during future inspections.

20. Licensee Response to CAL

On May 18, 1994, a facsimile of the licensee's response to the CAL was received in the Region I Office. The letter, signed by the NIH Assistant Director for Intramural Affairs, stated that they had completed the required first four actions in the CAL. On June 3, 1994, another facsimile was received in Region I. This letter was also signed by the NIH Assistant Director for Intramural Affairs and stated that they were reporting completion of Item 5 of the CAL. The letter also indicated that the action specified in this letter would be fully implemented on June 20, 1994, pending comments from the NRC.

EXHIBIT 6

An interview was conducted with John Weinstein, M.D., Ph.D. on July 28, 1995. The interview began at 11:30am and was conducted by Jim Dwyer, Susan Shankman, and Donna-Beth Howe.

Susan Shankman explained the purpose of the Augmented Inspection Team. Dr. Weinstein denied any involvement with the cause of the event and said that the allegation caused him to delay talking to NRC. Dr. Weinstein said that he wanted to make sure that it was okay for him to talk to the team now. He was assured that it was. Susan Shankman told Dr. Weinstein that the team was looking into the health and safety issues of the incident and that the criminal investigators were charged with determining who was responsible and why it was done.

Dr. Weinstein said that he began working at NIH in 1973 and has been with the National Cancer Institute since 1975. Dr. Weinstein provided a copy of his curriculum vitae. Dr. Weinstein said that he worked in Building 10 until late 1992 and then moved to Building 37. Dr. Weinstein recalled that he used I-131, I-125, In-111, Tc-99m, and bismuth while working in Building 10 and used P-32, P-33, small amounts of H-3, and briefly used S-35 in Building 37. Dr. Weinstein explained that he has no permanent staff but has individuals working in his laboratory for 2 to 5 years. Dr. Weinstein said that he has responsibility for only one laboratory (5D18) but that a few months ago he was given additional space in laboratory 5D21. Dr. Weinstein said that Dr. Bonner has responsibility for laboratory 5D21. Jim Dwyer asked Dr. Weinstein if he was collaborating with, or doing research in, any other laboratories, on or off the NIH campus or license. Dr. Weinstein stated that he only worked at NIH and his collaborations were limited to computers, mathematics and writing papers, not hands on use of radioactive materials. Dr. Weinstein said that his laboratory is working on generating and pulling together structures of chemicals and target structures and that this information is applied to find chemicals that can be used to treat AIDS and cancer.

Dr. Weinstein said that at the end of June 1995 his staff consisted of the following individuals:

Joseph Casciari - A chemical engineer who worked on thymidine uptake in DNA ladder technique studies. Dr. Weinstein said that Casciari may have used some tritium but more than likely did not. Dr. Weinstein said that Casciari may have done some work with Dr. Pommier using P-32. Casciari currently works in 5D18.

Drs. Zheng and MA - Dr. Weinstein said that they began working at NIH in August 1994 but did not use radioactive materials for a while because their experiments required alot of preplanning. Dr. Weinstein said that Drs. Zheng and Ma used P-32 during the last quarter of 1994 but doesn't believe that they used P-32 after this. Dr. Weinstein said that Drs. Zheng and Ma used S-35 for a while until he

learned about contamination problems with S-35. Dr. Weinstein said that Drs. Zheng and Ma then began using P-33. Dr. Weinstein suggested that he was not the best source of information regarding the specific use of radioactive materials by Drs. Zheng and Ma and suggested that we rely on receipt records. Jim Dwyer advised Dr. Weinstein that receipt records indicated use of P-32 by Drs. Zheng and Ma in February 1995 and that survey reports for April and May 1995 indicated use of P-32 in the previous month. Dr. Weinstein said that he believed the survey reports were inaccurate. Dr. Weinstein said that in general he keeps up with what people are doing but does not have a formal schedule to discuss their work and projects. Dr. Weinstein said that he encouraged Drs. Zheng and Ma to take the radiation safety course. Drs. Zheng and Ma worked in laboratory 5D18.

Mark Waltham - A post doctoral fellow who works in room 5D21. Dr. Weinstein said that Waltham does not use radiolabeled phosphorus but does use some C-14 labeled proteins. Dr. Weinstein said that Waltham began work in his group in October 1994.

Quang Li - A resident alien from China who works with Dr. Waltham in laboratory 5D21.

Yi Fang - Dr. Weinstein said that Fang is a pure theoretician who does computer chemistry, no hands on use of radioactive materials. Dr. Weinstein said that Fang works in laboratory 5D18.

Timothy Myers - Dr. Weinstein said that Myers has been with him for three years and that he only does computer chemistry. Dr. Weinstein said that Myers spends most of his time in the Executive Plaza North Building.

[redacted] Dr. Weinstein said that [redacted] is a [redacted] student who only does computer work. Dr. Weinstein said that [redacted] works in laboratory 5D18.

Charles Perry - Dr. Weinstein said that Perry is a teacher from the District of Columbia. Dr. Weinstein said that Perry works with Quang Li and does not use radioactive materials.

In response to questions about how his staff received radioactive materials Dr. Weinstein said that all purchases had to be approved by him. Dr. Weinstein said that he did not ask his researchers to account for their time and acknowledged that, while he didn't think it was happening, it would be possible for one of his researchers to do collaborative research with another group without his being aware of it. Dr. Weinstein indicated that today there is much more concern over radiation safety than the old days and that applies to other safety concerns too.

In response to questions about how his staff handled radioactive waste, Dr. Weinstein said that the laboratory was equipped with two step cans and a large carboy. Dr. Weinstein explained that they usually do polymer chain reaction (PCR) experiments which do not involve large volumes of radioactive material. Dr. Weinstein said that the materials from the PCR experiments are run on gels and this produces much larger liquid volumes.

Dr. Weinstein was asked about his delegation of radiation safety oversight to Dr. Zheng. Dr. Weinstein said that Dr. Zheng was given this responsibility in March 1995 by virtue of the fact that he and Dr. Ma were the largest users of radioactive materials in the lab. Dr. Weinstein said that Dr. Zheng was required to perform a monthly survey and submit the survey results to the Radiation Safety Office. Dr. Weinstein said that Dr. Casciari had this responsibility prior to Dr. Zheng and that Dr. Waltham is responsible for the monthly surveys now that Dr. zheng is on administrative leave.

Dr. Weinstein thought Drs. Zheng and Ma had a healthy respect for radiation and were more careful than the average researcher. Dr. Weinstein said that he had heard that Dr. Zheng routinely did surveys in the laboratory even though he did not use radioactive material each day but that he never personally witnessed these surveys.

Dr. Weinstein said that when Dr. Ma told him she was pregnant, he called Radiation Safety for more information. Dr. Weinstein said that Radiation Safety provided him with information about declaration of pregnancy and that he explained it to Drs. Ma and Zheng. Dr. Weinstein said that he explained that declaration of pregnancy was voluntary. He indicated that Drs. Zheng and Ma decided she would do the non-radioactive parts of the experiments and he would do the radioactive components. Dr. Weinstein did not know when Dr. Ma stopped using radioactive materials.

Dr. Weinstein said that Drs. Zheng and Ma were concerned that they did not have the number of publications that some of their fellow researchers had in the more active research areas. Dr. Weinstein said that Drs. Zheng and Ma had received some promising experimental results and wanted to publish the results. Dr. Weinstein said that he, Dr. Kohn, and Dr. Fornace reviewed Dr. Zheng and Ma's work and told them that they needed to reproduce the results. Dr. Weinstein said that, during the week prior to the incident, Drs. Zheng and Ma tried to reproduce the experimental result and failed. Dr. Weinstein said that on Sunday, June 25th, he met with Drs. Zheng and Ma in the laboratory to discuss their experimental problems and to help them to get over the hump. Dr. Weinstein said that Drs. Zheng and Ma had come in to the lab to do experiments and that they may have used radioactive material, he did not know. Dr. Weinstein said that he agreed to submit their paper while they completed their experiments.

Dr. Weinstein said that he was out of the laboratory for part of the day Monday (6/26) and Tuesday (6/27), trying to get the paper submitted for publication. Dr. Weinstein reported seeing Drs. Zheng and Ma in the library on Monday or Tuesday. Dr. Weinstein believes that they did some experiments early in the week. Dr. Weinstein said that he was out of the laboratory most of Wednesday working on the submittal. Dr. Weinstein said that he was around the laboratory most of the day Thursday but was busy working towards a publication deadline and a deadline to submit funding requests. Dr. Weinstein said that he remembers that Drs. Zheng and Ma were working on an experiment. Dr. Ma was trying to finish up the experiment but he did not know if radioactivity was being used. Dr. Weinstein also remembers that he saw Dr. Ma sitting at the table in the hall outside of his lab. Dr. Weinstein said that he didn't know if Dr. Ma was eating or not.

Dr. Weinstein was asked about Zheng and Ma's eating habits. Dr. Weinstein indicated that he was not aware of their eating habits but knew that they sometimes brought in food and drink.

Dr. Weinstein indicated that at about 5:45pm he was in his office talking to someone (he does not remember if it was in person or on the telephone) when Dr. Zheng came to his office and said Dr. Ma was radioactive. Dr. Weinstein said that Dr. Zheng used the word "injected" but he later understood that Dr. Zheng meant "ingested". Dr. Zheng demonstrated to Dr. weinstein that Dr. Ma had a lot of counts. The ambulance arrived shortly after that and since the medical situation appeared to be taken care of, Dr Weinstein called radiation safety, speaking to Nancy Newman at about 6:00pm. Dr. Weinstein said that it was his understanding that Newman notified Bob Zoon and Shawn Googins. Dr. Weinstein said that meanwhile, the paramedics were on the phone with Suburban and Holy Cross Hospitals to see where to send her.

Dr. Weinstein said that Beth Reed and George Redmond arrived from the Radiation Safety Office and started to check Dr. Ma. Dr. Weinstein said that he and Dr. Zheng helped by counting smears using equipment on the floor.

Dr. Weinstein said that Dr. Zheng told him there was contamination in the conference room/library refrigerator. Dr. Weinstein said that he went to the conference room and saw 2 bags in the refrigerator (one white and one blue) and thought they were contaminated. Later he was shown that the carpet was contaminated. Drs. Li and Waltham were there during this time. He had Drs. Li and Waltham check each other and the laboratory with the geiger counter. They did not do swabs.

By then the ambulance people were just "tiding up the paper work". Dr. Zheng was upset about why they had not taken Dr. Ma to the hospital and Weinstein was also upset that things were not moving faster to get her to the hospital. He thought it was after 8:00 when they left for the hospital.

About 1 to 1.5 hours after they left he checked his office, laboratory, soft drink cans up on things in the hall, and found three mugs and cups on the table in hall. The cup with the tube was contaminated so he called Bob Zoon. Zoon said to put it in a plastic bag. It was suggested that his laboratory be closed up in addition to the library.

Dr. Weinstein said that he was concerned that he would not be able to get into his office for several days and he had some paperwork that had to be completed so he moved these papers into Dr. Kohn's office, next to the library. Dr. Weinstein said that he left to go to the hospital arriving after 11:15. Dr. Weinstein did not remember anyone surveying the water cooler. Dr. Weinstein said that people were coming and going on the floor. In addition to Drs. Zheng, Ma, Waltham, and Li, he remembers seeing a white haired police officer, Rabinovitz, Yi Fan, another chinese post Doc, and another post Doc with long hair and a mustache.

Dr. Weinstein reported that he left the hospital sometime after 1:00 a.m. and thinks he went straight home but is not absolutely sure. He said that he may have returned to the laboratory before going home. Dr. Weinstein does not know if Dr. Zheng or Dr. Ma have been back to the laboratory since the incident was discovered.

Dr. Weinstein said that the library/conference room is on the same key as the laboratory. Dr. Weinstein said that he knew about the contaminated paper bag in the conference room because radiation safety showed him the bag and demonstrated that the contamination was inside of the bag.

Dr. Weinstein said that he did not know how Ma's ingestion could have happened and did not offer any speculations. He said that he never had anything to do with the water cooler. He never drank water at the office, only sodas. He thinks the RSO expressed how unusual it was so he knew the water cooler was not an accident. He thought perhaps it might have been a random attack at the chinese because of friction between Taiwan and the People's Republic of China.

He met Dr. Zheng in China when he was there giving a lecture. He was impressed when Dr. Zheng asked him a question in the discussion period and later approached him with other comments. It was unusual for the chinese to ask questions and the questions indicated Zheng's knowledge and interest. He worked to get both Drs. Zheng and Ma out of China to work in his laboratory.

The interview ended at approximately 2:00pm.

EXHIBIT 7

Confidential, Prepared for my attorney only (1)

Notes on radiation incident of Thursday, 6/29/95
John N. Weinstein

Most times are approximate, since this appeared at the time to be a medical problem only, and I was not paying close attention to the time.

At approx. 5:45 p.m., I was in my office, which adjoins the laboratory area of room 5D-18. Dr. Zheng came to tell me that Dr. Ma had "injected" (he meant "ingested") radioisotope and that they had called the NIH emergency number for an ambulance. I believe he then demonstrated by passing a Geiger counter over her. I seem to recall that she was standing in the area between their desks and their work bench. I remember being skeptical at first about the idea that the contamination was internal. However, as Dr. Zheng pointed out, the radiation was over her whole body but most prominent over head and feet, not clothing.

Two NIH fire personnel, male and female (? names), arrived. They asked Dr. Zheng and Dr. Ma what had happened, took Dr. Ma's pulse and blood pressure, etc. I phoned Radiation Safety shortly before 6 p.m., first speaking with what sounded like a young woman. They located Mr. Shawn Googins to speak with me on the phone, and then Mr. Robert Zoon. Throughout the evening, I had a considerable number of phone conversations with one or the other. Not having any prior knowledge of them, I cannot recall which I was speaking with for many of those calls.

At about 6:30 or 6:45 p.m., Ms. Beth Reed and Mr. George Redmond (from Radiation Safety) arrived. They joined the two fire personnel in medical questions and in trying to assess the source and type of radiation. The radiation did not appear to be on Dr. Ma's clothes (confirmed after she changed into what looked like hospital greys). Swabs of her hands and face (taken by one of the Radiation Technologists and counted on our scintillation counter by Dr. Zheng, at my direction) showed little or no radiation. At approximately 7:30 pm, to the best of my recollection, Dr. Ma provided a urine sample. The sample was found by Geiger counter to be quite radioactive. Radiation spectra later run in Bldg 21 identified the isotope as 32-P. I don't recall whether the urine sample was also counted in our scintillation counter in Bldg 37.

At some point during or after the examinations, I remember Dr. Ma being seated at the workbench with a pipettor, saying in response to a question that she was trying to finish her experiment. At other times, I believe she complained of pain in the right flank (as she had on that and previous days) and of being tired.

Mr. Redmond surveyed Dr. Ma and Dr. Zheng's laboratory work space and desk areas with his counter (Geiger or NaI detector?). He found no radiation there or in other places that he inspected in the laboratory.

At some point I believe that Dr. Zheng told me there was contamination in the food refrigerator in Rm 5C-25 (the library). I went with Geiger counter and confirmed it. I don't recall the time, but it was probably at something like 8 p.m. There appeared to be radiation around the front lip of the brown refrigerator near the door and a lesser amount near the front lip of the white refrigerator next to it. I removed a blue bag from the brown refrigerator and initially thought it was radioactive. However, that was probably due to contamination on the carpet under where I had placed it because it did not appear significantly radioactive when I moved it farther away from the refrigerator, on the floor. I did not open that bag or a white one that was next to it in the brown refrigerator and that I similarly found not to be significantly radioactive. I replaced the bags in the refrigerator where I had found them.

Confidential, prepared for my attorney only. (2)

At some point, I asked Dr. Mark Waltham and Dr. Guang Li (postdoctoral fellows in my group) to survey themselves and their laboratory (diagonally across the hall from 5D-18) with a Geiger counter. They did and found no contamination.

At some point, Mr. Redmond also surveyed the conference room and said that the major radiation contamination was on the carpet directly in front of the brown refrigerator, not in the refrigerator itself. I believe he also found lesser amounts of radiation on the carpet elsewhere in the room.

For a considerable portion of the time after his arrival, the male emergency worker was on the telephone at Dr. Ma's desk speaking with his home office, with Suburban Hospital, and with Holy Cross Hospital (I don't know if he was speaking with other places as well). There was apparently concern as to the best place to take her and also the radiation safety aspect for personnel and patients where she would be taken.

At some point, I'm not sure of the time, I suggested that we should push fluids to keep Dr. Ma hydrated until she went to the hospital. Either Dr. Goggins or Dr. Zoon recommended the same over the phone. I urged a number of times that Dr. Ma do that, asking Dr. Zheng what Dr. Ma liked to drink that we could get her. Dr. Zheng appeared to be focused on getting her to the hospital. After a number of urgings, they agreed she should take some water and, to the best of my recollection, she had at least one cup (I don't know the source).

Dr. Ma was taken on a stretcher to Holy Cross hospital, and Dr. Zheng apparently rode with her in the ambulance.

After finding contamination in the library, Mr. Redmond called his superiors and I believe was told to restrict access to the library. I don't recall the time, but I found a roll of white tape and paper and remember watching him tape up the door, then post a sign on it. I recall suggesting that he write that no one could enter, rather than just that entry was "restricted."

At approximately 9:45 p.m. I surveyed my office, other parts of the laboratory, and the hallway with a Geiger counter. Since we then knew that the radiation had been ingested, I remember holding the counter over a number of empty soft drink cans set out for recycling, and over any other containers. The only radiation found was in a mostly white mug containing a 50-ml orange-top centrifuge tube. This mug was located between two other cups on a brown table to the right of the door to room 5D-18. To the best of my recollection, the counter I was using registered a quite high count rate when held directly over the centrifuge tube but not much if off to the side (as though the ceramic effectively blocked the radiation. Without touching the cup or tube, I phoned Mr. Zoon (who was either at home or in Bldg 21, I don't remember which). He suggested that I "secure" the mug in a plastic bag (using gloves). I did that and put it on the floor inside of room 5D-18 with a post-it note of explanation. I do not recall removing the tube from the mug but remember looking down into the mug and thinking there was some fluid in the bottom of the tube. After removal of that mug, the Geiger counter registered no more radioactivity on or around the table. I don't recall taking readings further to the West along the hallway after finding the mug.

At about the same time, Mr. Zoon phoned and asked (at the suggestion of Dr. McKinney, head of Occupational Medicine, he said) that that 5D-18 be closed and access restricted. I asked if that was something that he should do, rather than just me. He said it was o.k. for me to do it, that there was nothing more to do that night. I asked if it would be o.k. to

Confident. 1. (3)
Prepared for my attorney only.

take papers from my office that I needed to work on, and he said it would be. He said that they would be talking with the police first thing in the morning and also come by to investigate themselves.

Shortly before that time, Dr. Yi Fan (a postdoctoral fellow in our group) had arrived at the laboratory to work on her computer, along with a postdoctoral fellow from another laboratory. I told her they would have to leave, and they did. I brought two garbage cans (a small one and a large one into 5D-18 from the hall outside the door) and put post-it notes on them as well. They appeared to contain little or no radioactivity by Geiger counter. I then locked the door of 5D-18, put white tape over the edges of the door in a number of places, and attached a sign saying that no one could enter. I also stretched tape over the area of the hall table and chairs, with a sign saying not to touch.

I don't recall all of the people who might have been around in the late afternoon or early evening. As of about 10 - 10:30 p.m. those I saw included Dr. Fan, the postdoctoral fellow with her, a policeman whose name I don't recall, a postdoctoral fellow from another laboratory with blond-brown hair and a moustache, and Dr. Marco Rabinowitz, who was apparently packing up his laboratory.

From the laboratory's office (adjacent to the library), I phoned Suburban and Holy Cross Hospitals to see where Dr. Ma had been taken. Establishing that it was Holy Cross, I drove there, arriving at what I would guess at 11:15 p.m. Dr. Ma was in the emergency room with i.v. fluids running. She told me that Dr. Zheng had gone back to NIH with Mr. Zoon to pick up his (Dr. Zheng's car) and bring it to the hospital. I spoke with Dr. White, who was handling the case and with Dr. Ma, then went to the waiting room so that Dr. Ma could rest. Dr. Zheng returned at what I would estimate as 12:15 a.m. (having gotten lost since he had never driven to the hospital before). After attempts at reassurance, I left at what I recall as about 12:45 a.m. to return home.

EXHIBIT 8

REPORT OF INTERVIEW
WITH
[redacted]

On July 17, 1995 [redacted] student, was personally interviewed by Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Investigator Gerard Kenna. The interview was conducted at approximately 4:15 p.m. on a picnic bench outside and between buildings 35 and 37 at the National Institutes of Health (NIH). Present during the interview was [redacted] mother; no other persons were present. The purpose of the interview was to determine [redacted] knowledge of the contamination incident at NIH in which Wenli MA (Maryann) was contaminated with radioactive phorphorus-32 (P-32). In addition, [redacted] was interviewed regarding his knowledge of the P-32 contamination of the water cooler on the 5th floor of Building 37. [redacted] provided the following information in response to questions.

He resides at [redacted] and is a student attending [redacted] His date of birth is [redacted] he does not recall his Social Security Number. He has been a volunteer student worker at NIH since June 19, 1995. He is supervised by John WEINSTEIN and works in WEINSTEIN's laboratory.

On June 29, 1995, at about 6:00 p.m., he was working with Dr. Weinstein in the corner of the laboratory when Dr. Wenling ZHENG (Bill) interrupted WEINSTEIN and said, "something terrible has happened to Maryann [Wenli MA], but if you are busy [referring to Weinstein] you can look at it later." [redacted] said that ZHENG explained to Weinstein that MA was internally contaminated. During the aforementioned conversation, MA indicated and said that she had to finish her experiment. [redacted] was not aware if MA ever finished her experiment. ZHENG began showing WEINSTEIN the contamination by having MA take off her laboratory coat. [redacted] said that at about that time he departed the laboratory and went home.

[redacted] could provide no other pertinent information regarding the contamination incident at NIH in which Wenli MA was contaminated with P-32. In addition, he could provide no pertinent information regarding the P-32 contamination of the 5th floor water cooler.

The interview was completed at approximately 4:45 p.m.

This interview was reported on July 18, 1995.

Reported by:

Gerard Kenna, Investigator
Office of Investigations
Field Office, Region I

[redacted]
Case No. 1-95-033A

EXHIBIT 8
PAGE 1 OF 1 PAGE(S)

EXHIBIT 9

INTERVIEW REPORT
OF
SUMPTER EMBREY III

On October 25, 1995, Sumpter EMBREY III, Structural Firefighter/Emergency Medical Technician at the National Institutes of Health (NIH), was personally interviewed by Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Investigator Gerard Kenna and NIH Police Detective Jody LUKE. The interview was conducted at EMBREY's work station located at NIH. The interview started at approximately 10:15 a.m. and no other persons were present. The interview was conducted to determine EMBREY's knowledge of the contamination incident at NIH in which Wenli MA was contaminated with phosphorus-32 (P-32). EMBREY provided the following information in response to questions:

He resides at [redacted] and he has been employed at NIH since December 1979. His telephone number at work is 301-496-2372. His date of birth is [redacted] and his Social Security Number is [redacted] He graduated in [redacted] from Walter Johnson High School, Bethesda, MD. He attended Montgomery County Junior College, Tacomma Park, MD, during the summer and fall of [redacted] His current supervisor is Acting Chief Gary HESS.

After reviewing the attached timed computer records, EMBREY stated that just a few minutes prior to 5:58 p.m. on June 29, 1995, he received an emergency services telephone call (telephone number 116) from Wenling ZHENG regarding a possible radiation contamination incident at Building 37, 5th floor, Room 5D18. EMBREY stated that ZHENG spoke with an thick oriental accent and was difficult to understand. However, ZHENG stated something to the effect that his wife (MA) was contaminated with P-32. According to EMBREY, ZHENG stated that MA injected or ingested P-32. He said that he knew the radioisotope was P-32 prior to his departure from the fire station and did not discover the identity of the radioisotope at a later time. According to EMBREY, ZHENG definitely said that his wife was contaminated with P-32 during the initial telephone call. He took notes of the conversation which have since been destroyed. EMBREY stated the telephone call with ZHENG was brief and after the call he immediately informed his supervisor, Lt. Raymond POOLE, of the contents of the telephone call. NIH Fire Department documents that were created following the incident are appended.

At approximately 5:58 p.m. EMBREY departed the fire station in Ambulance 519, with Firefighter Wanda SHORT. At approximately 6:00 p.m. he arrived at the side entrance of Building 37. He and SHORT responded to room 5D18 which was a laboratory. When he arrived, John WEINSTEIN, Wenling ZHENG, and MA were present in the laboratory. He said he considered the atmosphere in the laboratory as "confusing." He said that it was his concern that MA was either internally or externally contaminated with P-32. ZHENG surveyed MA with a geiger counter which reflected radiation over her entire body. MA did not know the source of her contamination. Both ZHENG and WEINSTEIN wanted MA transported immediately to the hospital for treatment. He and SHORT took MA's vital signs and he was told that MA was 20 weeks pregnant. EMBREY was told by WEINSTEIN that the NIH Radiation Safety Branch (RSB) was notified of the incident. EMBREY also notified the RSB, he thinks by the NIH radio system,

and they were slow in responding to the scene. It was his understanding that RSB personnel first responded to the Occupational Medical Services Department (OMS) at the NIH hospital.

Beth REED and George REDMOND, RSB Health Physicists, eventually responded to the scene and made efforts to determine whether MA's contamination was internal or external. REED also spent time on the telephone advising her supervisors of the circumstances of the contamination. EMBREY recalls sending SHORT to the ambulance to retrieve items that were needed, to include "scrubs" for MA to wear. MA had to disrobe so that her clothing could be surveyed for radiation contamination. EMBREY said that SHORT accompanied MA into the ladies room during efforts to determine whether she was externally or internally contaminated. He recalled MA stating that she had recently showered before coming to work. Although he could not remember who said the refrigerator was contaminated, RSB personnel responded to a room that had a refrigerator. He said that he did not go to the area where the refrigerator was located, but remained with MA.

EMBREY said that he spent most of his time on the telephone advising and consulting with Lt. POOLE, Dr. STRANSBURY at OMS, and Dr. STRAUSS at Suburban General Hospital, on the circumstances surrounding MA's contamination. Suburban General Hospital, Bethesda, MD, is where most of the NIH emergency medical cases are taken because the hospital is close to the NIH facility. Usually consultations are made with the OMS at NIH before patients are transported to Suburban General or any other hospital. In his telephone conversations with Dr. STRAUSS, STRAUSS suggested that MA be transported to Holy Cross Hospital in Silver Spring, MD, because Suburban General Hospital did not have a medical unit for the care of pregnant patients. EMBREY said that he and STRAUSS agreed that MA should be transported to Holy Cross Hospital.

At approximately 7:58 p.m., EMBREY, along with SHORT and ZHENG, took the gurney containing MA to Ambulance 519. Ambulance 519 broke down at Building 37, and EMBREY called for a backup ambulance to be dispatched to Building 37. Bethesda Chevy Chase (BCC), a Montgomery County, MD, ambulance service in Bethesda, MD, responded with Ambulance Medic 10. The Ambulance Medic 10 personnel were dispatched at approximately 8:02 p.m. and were enroute to Building 37 at approximately 8:03 p.m. The Ambulance Medic 10 crew arrived at approximately 8:09 p.m., and at approximately 8:16 p.m., departed from Building 37 enroute to Holy Cross Hospital. EMBREY said that he travelled with Ambulance Medic 10 and SHORT remained with Ambulance 519. Shortly after arriving at Holy Cross Hospital, he returned to NIH and documented the incident.

EMBREY was questioned regarding his documentation of the incident and could offer no explanation as to why he wrote "P-32 P-33" on one form. Although he did not write the appended narrative of the incident, he agrees with the facts contained in the document.

The interview was terminated at approximately 11:15 a.m.

This interview was reported on October 25, 1995.

Reported by:

Gerard Kenna, Investigator
Office of Investigations
Field Office, Region I

Attachments:
As Stated

EXHIBIT 9
PAGE 3 OF 13 PAGE(S)

SCREEN

SCREEN MESSAGE

TIME	CC	INC#	REMARKS
175905	C		AVAIL ON RADIO
175905	D	043883	NIH HOSPITAL @8000 R
175909	E	043883	NIH HOSPITAL @8000 R
[illegible]	E	043883	NIH HOSPITAL @8000 R
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	D	043883	NIH HOSPITAL @8000 R
[illegible]	AR		AVAIL ON RADIO
[illegible]	C		AVAIL ON RADIO

TIME	CC	INC#	REMARKS
204325	AR		AVAIL ON RADIO
205216	AR		AVAIL ON RADIO
211559	C		AVAIL ON RADIO
----------			CLOSE ----------
054316	D	044073	[redacted]
054712	E	044073	
055045	A	044073	
055528	C	044073	

195503	AR		AVAIL ON RADIO
200253	D		AVAIL ON RADIO
200253	D	043883	NIH HOSPITAL @8000 R
200253	E	043883	NIH HOSPITAL @8000 R
200309	E	043883	NIH HOSPITAL @8000 R
200940	A	043883	NIH HOSPITAL @8000 R
201517	EA	043883	M10 HOP TA 2015
202403	AA	043883	AT HOSPITAL
203315	C	043883	NIH HOSPITAL @8000 R
FLM M10			
FLM 2151 050752			
FOL 94062274			
FLM M10 052955			

055825	AR		AVAIL ON RADIO
060210	C		AVAIL ON RADIO
130715	AR		AVAIL ON RADIO
142813	C		AVAIL ON RADIO
153836	D	044011	BEECHBANK RD / CAPIT
153759	E	044011	BEECHBANK RD / CAPIT
154248	C	044011	BEECHBANK RD / CAPIT
154250	AR		AVAIL ON RADIO
154705	C		AVAIL ON RADIO

CLEAR [illegible] APPLY ASTERISK
SCREEN [illegible] SINGLE MESSAGE

EXHIBIT 9
PAGE 4 OF 13 PAGE(S)

Call Type IP/ALS.. D H F T O DISPLAY CAL: Incident No 95043587
INJURED PERSON - ALS
Loc WIH HOSPITAL 99000 ROCKVILLE PIK. .... City MCC.

Name DO BI..... Contact? .
Add ..... Phone# ...-.... Area Code ...
Rmks INJECTED CHEMICAL IN HERSELF IN ROOM SD18, BLDG 37_ AB18, EB11, &....
HME1 ARE RESPONDING_ MEDIC 10 IS DUE_ M10 HOH TO 2018.....
Rmks Lg MI Grn P Pd Blond, Sts Brn, Ce Gl Fr .. .. F# ..... Ea .....

P ..... Ac 175722 Da 175805 En 175809 Pr 1800-2 Wf ..... Fo ..... Cl 121121
Drive 2121985 Tel-Id WILE.. Disp-Id FOBE.. Alarm Lv .. Radio Chg ....
Disp Code 21.. Rmks 3:133617..... .....
Unit Log 481F M10 EB11 HME1 M10

CLEAR SCREEN

PRINT SCREEN RETRIEVE MESSAGE

EXHIBIT 9
PAGE 5 OF 13 PAGE(S)

INCIDENT UNIT HISTORY FOR: 8E043887
DATE: 062985 CALLTYPE: IP/ALS

UNIT	TIME	CC	REMARKS	UNIT	TIME	CC	REMARKS
AE19	175805	D	NIH HOSPITAL @9000 R	A11	200855	EU	NIH HOSPITAL @9000 R
M10	175805	D	NIH HOSPITAL @9000 R	A11	200253	EK	NIH HOSPITAL @9000 R
ES11	175805	D	NIH HOSPITAL @9000 R	M10	200253	D	NIH HOSPITAL @9000 R
HM51	175905	D	NIH HOSPITAL @9000 R	M10	200253	E	NIH HOSPITAL @9000 R
M10	175905	E	NIH HOSPITAL @9000 R	M10	200309	E	NIH HOSPITAL @9000 R
AE19	175919	E	NIH HOSPITAL @9000 R	M10	200340	R	NIH HOSPITAL @9000 R
M10	175919	E	NIH HOSPITAL @9000 R	M10	201517	EH	M10 RCH TO 2016
ES11	175919	E	NIH HOSPITAL @9000 R	M10	202422	AH	AT HOSPITAL
HM51	175919	E	NIH HOSPITAL @9000 R	M10	204318	C	NIH HOSPITAL @9000 R
AE19	180401	A	NIH HOSPITAL @9000 R	ES11	212121	C	NIH HOSPITAL @9000 R
ES11	180401	A	NIH HOSPITAL @9000 R	HM51	212121	C	NIH HOSPITAL @9000 R
HM51	180401	A	NIH HOSPITAL @9000 R				
M10	180744	A	NIH HOSPITAL @9000 R				
M10	180709	C	NIH HOSPITAL @9000 R				
AE19	180744	C	NIH HOSPITAL @9000 R				

F1=H F2=
F3=M F4=E
F5=D F6=S
F7=U F8=
F9=

CLEAR SCREEN | PRINT SCREEN | RETRIEVE MESSAGE

EXHIBIT 9
PAGE 6 OF 13 PAGE(S)

Incident report # 698

Building 37 Room 5D18

At 1755 a call was received at the fire station requesting assistance for a patient that had ingested radioactive P-32. Ambulance 519 responded, arrived on the scene and found a 32 year old female who said she had been contaminated with a radioactive P-32. Her husband surveyed the patient with a geiger counter in the presence of the ambulance crew and confirmed that her entire body was contaminated. Firefighter Embrey conducted an interview and determined that she was 16 to 20 weeks pregnant. She advised she did not know how she had become contaminated. Vital signs were taken and were within normal limits. Firefighter Embrey called the station, advised Lieutenant Poole of the situation and requested Radiation Safety respond to the scene. Firefighter Embrey then called OMS and consulted with Dr. Stansbury, who advised the ambulance crew remain on the scene and continue to monitor the patient until Radiation Safety staff arrived.

Radiation Safety staff arrived on the scene and checked the patient for contamination. They advised she was contaminated and requested she remove her clothing and be checked again. A scrub suit was provided by the ambulance crew for her. After this was done she was checked again contamination was found. A urinalysis was conducted by Radiation Safety and it also showed contamination. Radiation Safety advised she had probably ingested the material; however, she could be safely transported to the hospital.

Firefighter Embrey again called OMS and advised them of the situation. The discission was made to contact Suburban Hospital for further consultation. Fire fighter Embrey contacted Dr. Strauss at Suburban and advise them of the problem. Suburban Hospital advised Firefighter Embrey that since the patient was pregnant she should be transported to Holy Cross for further treatment.

Ambulance 519 was having some mechanical problems, therefore Medic 10 was requested from Montgomery County. Medic 10's crew was advised of the patients condition and agreed to transport her to Holy Cross. Firefighter Embrey accompanied the patient to the hospital with Medic 10. Radiation Safety advised they would follow up and the call was cleared.

MONTGOMERY COUNTY EMERGENCY MEDICAL SERVICES
EMERGENCY MEDICAL INCIDENT REPORT

STA. RUN NO.	INCIDENT NO.	S	DATE	OUT	ON SCENE	DPT.	ARV HOSP.	IN SERV.	RTN STA.
3286	439 83		01 29 95						

INC TYPE	DISTRICT	ADDRESS - LOCATION
34	51	9000 Rockville Pike

ASSIGN STA.	UNIT	RESP. FROM	DISP.	STAFFING LEVEL
R1	M10	85	1 = ISWR; 22 = NO SERV.; 33 = SERV. RENDERED; 44 = SERV. REF.; TRANS STA. NO. 11	EMT-A 0; CRT 1; EMT-P 1

UNIT OPERATION: ☐ 1 = NONE ☐ 3 = OTHER ☒ 5 = MEDIC ☐ 4 = FIRST AID/REQ ☐ 6 = MED. AMB. — 9

PERSONNEL ON UNIT	PD	VOL	AT SC.	PD	VOL	AT STA.	PD	VOL
	2	0		02	00		00	00

PUPILS: ☐ 1 = EQUAL ☐ 3 = NEG RL ☐ 5 = NO RESPONSE ☐ 2 = DILATE ☐ 4 = NEG LL ☐ 6 = CONSTRICTED

PATIENT PRIORITY

COMA SCALE: EYE ___ MOT ___ VRB ___

MOISTURE: ☐ NORM ☐ DRY ☐ DIAPHORETIC

CAP REFILL: ☐ < 2 SEC ☐ > 2 SEC

COLOR: ☐ NORM ☐ PALE ☐ CYAN ☐ FLUSHED

TEMP: ☐ NORM ☐ WARM ☐ HOT ☐ COLD

LUNG SOUNDS: ☐ CLEAR ☐ RALES ☐ WHEEZES

ALLERGIES

CHIEF COMPLAINT, SYMPTOMS, TIME OF ONSET: Poss. Suicide By O.D.

HISTORY, ROUTINE MEDS

PATIENT'S PHY.

RECEIVING PHY. SIGN.

ATTENDANT'S SIGN.

TREATMENT BEFORE ARRIVAL

VIAL OF LIFE IN USE: ☐ 1 = YES ☐ 2 = NO

CPR START: P.T.A. ☐ 1 = NONE ☐ 2 = LAY ☐ 3 = F/R ☐ 4 = PD — IV ATTS ___ IV SUC ___

F.C.R. FILED ☐ 1 = YES ☐ 2 = NO

TIME	PUL	RES	B/P	TREATMENT	PM #	PRO	PM #	PRO
				A579 Placed				
ECG				M10				
TIME	PUL	RES	B/P	I.S.W.R.				
ECG								
TIME	PUL	RES	B/P					
ECG				UNR				
TIME	PUL	RES	B/P					
ECG								
TIME	PUL	RES	B/P					
ECG								

AGE	SEX	AFFECTED PART	NATURE	RESUSCITATION ATTEMPT	DISP

TYPE OF CALL	TRANS (R) (E) (N)	CONSULT HOSP.	RECEIVE HOSP.	REASON	CONSULT ☐ 9 = NONE ☐ 2 = PP ☐ 1 = EMS ☐ 3 = MED

NAME

ADDRESS

EXHIBIT 9

EMERGENCY MEDICAL INCIDENT REPORT

Row	Field	Value
A	STA. RUN NO.	698
A	INCIDENT NO.	43983
A	DATE	062995
A	OUT	1758
A	ON SCENE	1800
A	DPT.	
A	ARV HOSP.	
A	IN SERV.	1958
A	RTN STA.	
B	INC TYPE	35
B	DISTRICT	51
B	ADDRESS - LOCATION	900 Rockville Pk
C	ASSIGN STA.	51
C	UNIT	A519
C	RESP. FROM	51
C	DISP.	☐ 11 = ISWR ☐ 22 = NO SERV. ☑ 33 = SERV. RENO. ☐ 44 = SERV. REF. ☐ TRANS STA. NO. — 33
C	STAFFING LEVEL	EMT-A 2, CRT 0, EMT-P 0
D	UNIT OPERATION	☐ 1 = NONE ☑ 4 = FIRST AID/RES ☐ 7 = OTHER ☐ 8 = MED. AMB. ☐ 9 = MEDIC — 4
D	PERSONNEL ON UNIT	PD 2, VOL 0
D	AT SC.	PD 00, VOL 00
D	AT STA.	PD 06, VOL 00
E	PUPILS	☑ 1 = EQUAL ☐ 2 = DILATE ☐ 3 = REG RL ☐ 4 = REG LL ☐ 5 = NO RESPONSE ☐ 6 = CONSTRICTED
E	PATIENT PRIORITY	2
E	COMA SCALE	EYE 4, MOT 6, VER 5
E	MOISTURE	☐ NORM ☐ DRY ☐ DIAPHORETIC
E	CAP REFILL	☐ < 2 SEC ☐ > 2 SEC
F	COLOR	☐ NORM ☑ PALE ☐ CYAN ☐ FLUSHED
F	TEMP	☑ NORM ☐ HOT ☐ WARM ☐ COLD
F	LUNG SOUNDS	☐ CLEAR ☐ RALES ☐ WHEEZES
F	ALLERGIES	None
G	CHIEF COMPLAINT, SYMPTOMS, TIME OF ONSET	Radiated c̄ P32 P33 Pain Ⓡ Side — 6
G	HISTORY, ROUTINE MEDS	No Hx No Meds
G	PATIENT'S PHY.	
G	RECEIVING PHY. SIGN.	[signature]
G	ATTENDANT'S SIGN.	[signature]
H	TREATMENT BEFORE ARRIVAL	None
H	VIAL OF LIFE IN USE	☐ 1 = YES ☐ 2 = NO — 1
H	CPR START: P.T.A.	☐ 1 = NONE ☐ 2 = LAY ☐ 3 = F/R ☐ 4 = PD
H	IV ATTS / IV SUC	
I	F.C.R. FILED	☐ 1 = YES ☐ 2 = NO
J	TIME / PUL / RES / B/P	B/P 110/070
L	AGE	032
L	SEX	F
L	AFFECTED PART	99
L	NATURE	120
L	RESUSCITATION ATTEMPT	
L	OIOP	See Medic 10's Report — 8
M	TYPE OF CALL	02
M	TRANS (R) (E) (N)	E
M	CONSULT HOSP.	
M	RECEIVE HOSP.	
M	REASON	
M	CONSULT	☐ 0 = NONE ☐ 1 = EMSI ☐ 2 = PP ☐ 3 = MED
N	NAME	Wen li Ma
O	ADDRESS	1001 Rockville Pk 1740 Rockville MD 20852

TREATMENT / PM # / PRO: (blank)

EXHIBIT 9

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EMS-100 REV. (1/88)

STATION COPY

6-29-95

LT Park	0700	0700	SC	
Tech Boswell	0700	0700	DIESEL	
FF Embrey	0700	0700	EMT	
FF Lewis	0700	0700	DRIESEL	24 O/T
FF Shock	0700	0700	DRIESEL	Watch
FF BEDE	0700	0700	DRIESEL	
FF Mattingly	SIL	SIL		24 SIL
FF STAMPFER	ALL	ALL		24 ALL

0700 PLATOON #1 Relieved Platoon #2 OF ALL

0705 APPARATUS CHECK

0801 Electric Shop working Bldg #4

0820 Co-51 to Bldg #10/13th FL on FAD 4951

0832 IN Service me# 43858 FALSE/ACCIDENTAL

0830 Shift meeting with MR. SHAFF

0853 Electric Shop working Bldg #12

0854 Electric Shop working Bldg #10B1 LR-6 Back 0913

1045 E-51 to Bldg #10/3N105 For the mercy Shot

1115 IN Service me# NA HAZ/CONS

1201 A-519 to Bldg #108/CONS For the IP

1250 IN Service me# 43961 Amb/Rescue

1220 Su-51 to Bldg #10/B2A30 For the Chem. clear

1230 IN Service me# NA Good Inter

1300 Drill with Rescue #1 ACD TRAINING

1758 A-519 to Bldg #37/5D18 For the ~~Elev~~ I.P.

1958 IN Service me# 43983 Amb/Rescue

2000 A-519 OOS Due to ~~BAT~~ DEAD BATTERY

2030 All watch Duties Complete

2030 All outside Apparatus Secure

EXHIBIT 9
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EMERGENCY INCIDENT REPORT

Date:	Report Number	Mont Cnty.#
6-29-95	698	413483

INSTITUTE: OD DIVISION/PROGRAM: DS

Branch/Laboratory: OMS Section MM

Type Of Incident	Man Hours	Time Out	Time In
AMBULANCE + RESCUE	4 HR	1758	1958

Building	Floor	Location:
37	5	D 18

Incident Reported By:	Call Back Number	How Reported F/A ?	Occupied as (Lab, Etc.)
DR. WENLI	6-9572	116	LAB

Description of incident:
Report of one with Chem. exp P-32

Cause:
Unknown

Remarks:
Fire department responded found 32 y/o F hit by unknown objects injected an unknown quantity of P-32. Vitals Stable. Patient checked by Radiation Safety. Contact = Dr. Steinberg + Dr. Steagall at Sub.

Property Damage: Patient transported to Holy Cross via MICU-16

MM

9427488

Vehicle Information: Year: _____ Make: _____ Model: _____

VA# _____ State: _____ NIH Decal# _____

Signature OIC: FIE Embrey

WAS THE 100 PAGED ? Y (N)

CHEMICAL SUIT & BOOTS LOGED IN BOOK ? Y (N)

EXHIBIT 9

PAGE 11 OF 13 PAGE(S)

EMERGENCY INCIDENT REPORT	Date: 6/28/96	Report Number 006	Host Cnty.# 43883

INSTITUTE: [redacted] DIVISION/PROGRAM: DE

Branch/Laboratory: [redacted]	Section

Type Of Incident	[redacted] Hours	Time Out	Time In
Ambulance Rescue	4 Hr.	1758	1958

Building	Floor	Location:
37	5	Room: 5D18

Incident Reported By:	Call Back Number	How Reported F/A ?	Occupied as (Lab, Etc.)
Dr. Wenli	6-9672	116	Laboratory

Description of incident:

[redacted] me with radiation exposure. (P-32)

Cause:

N/A

Remarks:

SEE ATTACHED SHEET.

Property Damage:

None to government property.

Vehicle Information: Year: Make: Model:

Tag# State: NIH Decal#

OIC: F/F Embrey

WAS THE 100 PAGED ?
Y N

CHEMICAL SUITE & BOOTS LOGGED IN BOOK ?
Y N

EXHIBIT 9
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PLATOON #1	PLATOON #2	UNITS ON CALL	
A/C HESS	A/C LENOX	E-511	E-512
LT. POOLE	LT. WALKER	~~A-519~~	C-51
TECH. BOSWELL	TECH. MATTINGLY	MCB-51	HAZMAT 51
F/F EMBREY	F/F BRENNAN	SUPPORT UNIT 51	
F/F LEWIS	F/F DONALDSON	MUTUAL AID ASSISTANCE	
F/F MATTINGLY	F/F PYLES	[illegible]	
F/F STAMPHER	F/F GIBSON		
F/F SHORT	F/F MAY		
F/F REDE	F/F BARNETT		
INSP. DAVIS	INSP. WALTHER		
	INSP. REILLY		

REMARKS

EXHIBIT 9

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