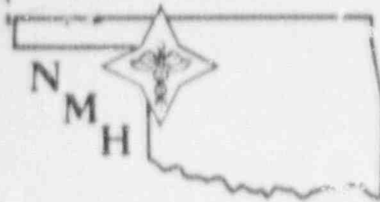

NEWMAN MEMORIAL HOSPITAL

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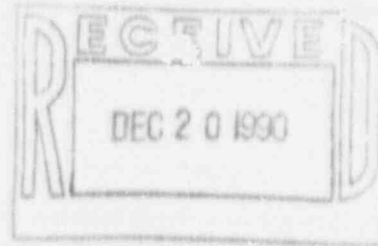

December 14, 1990

Charles Cain, Chief
Nuclear Material and Safeguards Inspection Section
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, Texas 76011

Dear Mr. Cain:

Enclosed for your records and review is a copy of the transcript from the November 14th meeting held in Arlington. We hope that you find this transcription understandable and conclusive as to the content of the meeting on that day. I believe that at this time this completes our submissions to you pending any future submissions regarding compliance and reinstitution of the Nuclear Medicine Service at the appropriate time.

Respectfully,

Gary W. Mitchell, M.S.,
Interim Administrator

GWM/saw

enclosure

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DRAFT

NRC CONFERENCE IN ARLINGTON, TEXAS
NOVEMBER 14, 1990

Let me begin by, before we get into a discussion on the individual violations that are identified in the inspection report, and basically give you our history of Newman and our concerns and hopefully today we can focus on the broader issue on how we get to the end of the tunnel and the light at the end of the tunnel. First of all let me say that I recognize there have been changes since the previous inspections and we recognize that you have to have some time to implement corrective actions. Unfortunately this event occurred possibly in that interim time period. We conducted two inspections last year at Newman and found a number of violations. Those violations, in and of themselves were not significant, but grouped together indicated to us a lack of management oversite. Quite candidly, the enforcement conference that was conducted also gave us concern because of the apparent failure to be able to address the corrective actions that were necessary to correct the violations and we had to conduct another inspection to ensure those corrective actions were in place. Currently that enforcement action, as you know, is still under review of our headquarters staff. What I hope we can do today since we do have a dilemma here because of the previous history, because of the unfortunate timing of this issue, is to hopefully pass you the ball and give you a chance to assure us what you are doing to provide the adequate oversite at Newman Hospital. While we will talk about each individual violation, that is the more over

riding concern. We'll briefly go over the violations, but what we really hope to hear from you is things that you are putting into place and have put in place to provide the oversite that is needed, I guess with that you would like to add anything, I will go ahead and turn the meeting over to Chuck.

What I will do at this point is I want to go through the violations with you and even though we have given you the inspection report, you have had a chance to read that, I want to go through those again and give you an opportunity to respond to each one of them in terms of what your understanding of the violation is and perhaps what corrective action you may have taken, if any, or any other discussion that feel is necessary for each one. I am not going to read it in a great deal of detail, I just want to overview the issue with you for each one. First violation had to do with the fact that, and by the way I may not be giving these to you in order in which they appear in the inspection report. I am giving them to you more in terms of order of severity, if you will, in our eyes. First violation has to do with the fact that there was transfer of a radioactive material, radiopharmaceutical, to a patient, someone who was not authorized, not licensed by NRC to possess radio active material. That is very distinctly stated that is what that violation is about. Do you have any questions in regard to that or can you give us any information in terms of corrective action? Dr. Mitchell- Do you want us to answer those now or do you want to go

through all of them? They are pretty much singular category so - Chuck - Just let me go through all of them. Dr. Mitchell - I think that would be more effective. Chuck - Along the way, if you want to interject any comments on that particular issue, feel free to do so. Second one had to do with the fact that, part 35 of our regulations, specified that any radiopharmaceuticals can only be distributed to hospitals by entities that are licensed for distribution of those materials and so what was happening in this situation was that Newman was in fact serving as a radiopharmaceutical distributor by supplying those materials to the hospital in Woodward. The third violation, in a word, had to do with supervision of the, in this case, I guess it was a X-Ray technologist serving as also a Nuclear Medicine tech, in that the technologist was not instructed in the principals of radiation safety regard the use of materials as evidenced of the violation that was found subsequent to the event and he improperly prepared the radiopharmaceutical for transfer and then of course he was also involved in the transfer of that material to an unauthorized recipient, that being the patient. The fourth violation involves failure of the technologist to wear a finger osimeter when he worked with the generator and with the prepared dose. Dr. Mitchell - Which technologist was this and was that that evening? Chuck - yes that was the x-ray tech. Dr. Mitchell - OK. Chuck - By the way, that violation stems, the ones previously stems from the regulations themselves. This one that I just identified stems from

your application dated January 1987 where there was a commitment to use extremity osimeters when the generator was eluted and a dose prepared. The fifth violation again is back to the regulations, part 35 requires that the licensee prepare a reagent kit in accordance with the manufacturers instructions with the brochure that accompanies the reagent kit. There has been added to that regulation recently the provision that the license be made a part of those instructions provided that the licensee has a written directive from an authorized user physician that directs a specific departure with a particular patient and for that particular radiopharmaceutical. But our findings were in this case was that the technologist did not have departure instructions, yet he did depart from those brochure instructions in that he reconstituted I believe the entire kit, whereas, he used the entire contents of the kit for the patient, rather following the instructions which indicate that only 50 millicuries of technecium should be used and the recommended number of particles for single injections should be between 200 and 700 valences instead he reconstituted the kit with 5 millicuries and injected our estimated 3 to 6 million particles per single injection. The sixth violation has to do with the regulation in part 35.21 which identified specific duties of the Radiation Safety Officer. It requires that the licensee ensures that radiation safety activities be performed in accordance with approved procedures and regulatory requirements and they be operational with the licensee materials program and in

addition there is a lengthy list of specific duties of the RSO in that regulation and the findings of our inspection were that some of those responsibilities had been fulfilled as a result of this incident as evidenced again by the violations that identified that we are remunerating now. The seventh and last of the violations actually has four parts and these are all violations of the department of transportation regulations. NRC has really incorporated by eference the regulations in title 49 of the DOT regulations and we inspect those routinely in the course of our inspections and we found that the package that was given to the patient for transfer to the other hospital was not certified as a Type A package which is defined in the regulations for containing radio active material. It was not properly labeled in accordance with the DOT regulations, there were no shipping papers prepared for that transfer and lastly it was found to have Beta Gamma contaminatio in excess of DOT limits on the package. That is a brief run down of the violations and perhaps now give you an opportunity to respond to those.

Dr. Mitchell - the improper transfer of licensed material, unauthorized distribution of radiopharmaceuticals, inadequate supervision I think speaks for itself. I have no defense. It was a situation I did not anticipate arising. We are going to take steps to try to correct those problems. I will go over those steps with you if that is what I am supposed to do at this point. Is

that correct? Chuck - yes. Dr. Mitchell - I was asked by Mr. Shain with the departure of Dr. Naumoff, if I would serve as Radiation Safety Officer for their Nuclear Medicine program until such time as they were able to get a Radiologist or a Nuclear Medicine Physician on board or a closer proximity than I was located. I certainly realize this a difficult task, certainly a challenge perhaps maybe it can't be done, but I felt strong enough about it that an attempt should be made. My first concern was to try to re-evaluate the ten previous violations that had been stated to ensure myself that these violations were corrected and to set up something to keep them from being renewed or at least not repeated. That occupied my two visits to Shattuck, one with the Radiation Safety Committee, which was reorganized at your request. All members of that Radiation Safety Committee were there, there was still some question about personnel monitoring, they were trying to get some information from the people who ran the Film Badge service. They had not gotten that yet. I was not happy at the time of the Radiation Safety Committee meeting with the records and the way they were being kept. At the Radiation Safety Committee meeting I suggested we get an outside Radiation Physicist to come in as a consultant, primarily to make sure that the type of records that were being kept were those that would assure proper quality control of that area of Nuclear Medicine. That we would not inadvertently overdose a patient, that we would follow certain standards and procedures and protocol, particularly in

reconstitution of isotopes. Ten citations, really occupy my time, this instant was precipitated by something I could not in my wildest dreams have foreseen to have happen. That is a physician come down and intimidates an x-ray technician, who knows where the laboratory is, apparently knew where the key was, and thought he knew enough about Nuclear Medicine that he could perform the test. This supposedly was a life threatening situation for the patient, and the physician was most adamant that this be done, and I think he has a responsibility to the patient because as you well know pulmonary emboli is a life threatening situation. The x-ray tech under those pressure type circumstances yielded his better judgment and tried to accommodate the referring physician. He is not trained to do this in any way, shape or form, he didn't know who to call, he didn't call anybody at Newman Memorial who was on board, I was on call that Friday night and available had anybody tried to call me. I was not contacted until the next morning by Dr. Ficken, and when I got that I started trying to get a hold of people in Shattuck and that didn't work to well on Saturday morning anyway. We did get around to at least notifying Nuclear Regulatory Commission what had transpired the night before. My records indicate that you inspected in January 25 & 26, May 10 and June 14. Is that not correct? Lady - That is correct, the June 14 inspection is one that Mr. Beatry? (cannot understand) Dr. Mitchell - Oh, OK. As I said, in my wildest dreams, I wouldn't have conceived this type of problem happening. Every possible

violation that could occur, did occur under these circumstances. Somebody who had absolutely no business going into the laboratory, did. So what are we going to do about it? OK, because of the ten prior violations I was in the process of redoing the policy and procedure manual for Newman Memorial Hospital. Also because I am "an absentee type RSO" I have to rely on other people, and I was trying to outline in my procedure and policy manual what steps we could take in order to make up for the absentee deficiency of being fairly remote. I would certainly appreciate any help or suggestions that you all might have to offer on that matter. I have consulted three other Radiation Safety Officers in trying to tackle come of these problems. Mr. Mike Morris, Vernon Ficken and Max Quiby? They are not the easiest people to find and contact a lot of time and they are not very speedy with their consults, but we have gotten some feed back from Mr. Morris, we have also had considerable help from Max Quiby. At the Radiation Safety Committee meeting as I mentioned, I wanted Mr. Quiby to go out there unannounced and examine all of the physical area, the hot lab, how the security was set up, what the bookkeeping, how it was being done, would it in his estimation meet the requirements for Nuclear Regulatory Commission? Not only that but something that would make sense to me, so that I could answer your questions should there be any problem arise. It was my understanding that Max had not yet been able to get out there to make that. There was some hesitancy on the part of the Administration to pay his fee at

that time. Newman Memorial Hospital is an acute care hospital in Northwest Oklahoma. It has been out there since the Comanches left the country and it has been a land mark. The entire community of Shattuck, Oklahoma depends upon that hospital, the entire economy base is based upon that hospital and they are in a great deal of trouble right now, financial trouble. I felt like that if it is going to remain an acute care hospital, they need Nuclear Medicine. That is just part of taking care of pati[illegible] example of that, a patient comes in, I don't care whether they are young or old or whatever, if they are bed ridden they are at risk for a pulmonary embolism. More die in hospitals of pulmonary emboli's than practically any other disorder. Simply because they are immobilized. Pulmonary emboli is very difficult to diagnose, it may have classic symptoms it may have no symptoms. As a matter of fact a lung scan doesn't always answer the question. It is not very sensitive and certainly not very specific, but it is the best we have. Short of pulmonary angiology. I have visited with members of the medical staff and have outlined the program. Number one, we will have a list of all of the Nuclear Medicine procedures, in the second column, we will have a list of those clinical situations in which that examination is indicated. No Nuclear Medicine tests will be performed without either laboratory documentation or clinical history provided. We have established an algorithm for patients suspected of pulmonary embolis. If Nuclear Medicine is not available within the next twelve hours after the

diagnosis is suspected, the patient either, 1) if they are to sick to be transported, we immediately transferred to the Intensive Care Unit and Heparinization started. When lung scans become available twenty-four to forty eight hours later, then it can be performed and the therapy can be altered or discontinued, whatever is appropriate in the clinical situation. If the patient is not critically ill, and it is going to be less th[illegible]lve hours before a Nuclear Medicine scan can be performed, the patient should be admitted and heparinized for a very short period of time, which carry a very low morbidity number. If at that time, twenty four hours, a lung scan can be performed then a determination can be made whether the therapy is appropriate or whether it can be discontinued. If the patient to sick to transfer, we have to take care of him anyway, we can't, we are stuck with what we've got. If the patient is not critically ill, but still they feel clinically there is a very good likelihood there is a pulmonary embolis, the patient will be transported, and I am going to insist they be transported by ambulance or helicopter to a facility prepared to take care of them. In my policy and procedure manual I am going to point out to the medical staff also that Nuclear Medicine at Newman Memorial Hospital is not going to be a seven day a week, twenty-four hour a day service. It can't be because we have one Nuclear Med tech and he does sleep. So they are going to have to fit this around his schedule, because he has to have time off. Starting a program of inservice education for the medical staff about the

services that are available for, I hope will be available, in Nuclear Medicine to facilitate their care of the patient. Also going to inform them of the obvious limitations of these procedures and make sure nothing inappropriate is ordered. Nuclear Medicine at Newman Memorial Hospital is grossly under utilized, particularly for an acute care hospital and one that sees a lot of elderly patients with Neoplasm, looking for metastatic disease of liver and bone. I hope to correct that by talking and educating the medical staff. I think, I have talked with Gary and I feel like we need one key, maybe two keys to the Nuclear Medicine laboratory. One is carried by the Nuclear Med tech, one by the Administrator and that area be totally secured so that this incident cannot happen again, that is the only way I can guarantee that it won't happen again is to lock it up. Either the Nuclear Medicine tech or the administrator will have to be on call when isotopes are delivered and be put in a proper safe place, lock and key until they can be surveyed and marked or whatever needs to be done. There are other steps that I have not really decided that we should try to do, but one of them that was suggested would be to allow Mr. Dancer to take a course, I believe it is forty hours in length, in order to become a qualified Radiation Safety Officer, so he would be on site. Hopefully as Newman Memorial Hospital in Shattuck is able to attract additional physicians, the service will increase, we certainly need to consider training a back up technologist and this also can be done in order that we constitute the seven day, twenty-

four hour coverage that is necessary. I also would encourage administration to consider spot checks by a RSO from other institutions in the area to make sure there are not things that we are obviously overlooking. As you well know, I am a primary user and not a RSO per sae and this physics is very difficult for me, but I really believe Newman Memorial needs Nuclear Medicine service and these are the things I feel, I hope can bring it under compliance, and prevent the unfortunate thing that happened. Incidentally, that technician was disciplined for that, we instituted things immediately to try to correct that so that it won't happen again. I really think that had I lived there, had been next door, that thing would have happened anyway, I not so sure that being there with a baseball bat would have prevented it unless I was physically there and you know that Friday night in Oklahoma is Football night. Gary - We as administration support Dr. Mitchell's outline and share all of his concerns, that we regret the timing of the incident, I think it is most unfortunate and we don't contest the fact that it did not happen, it certainly did. Very unfortunate. I believe that Newman did in good faith contact the Nuclear Regulatory Commission to discuss this matter, to bring it to their attention, it was obvious that something had gone awry and in light of all of those factors, the most recent occurrences at our hospital are that the Board of Trustees met in a

special meeting Monday evening to authorize a letter that we sent down here indicating our desire, at this point in time, to get all of our program in place, we will prohibit the conduct of any surveys or scans, Nuclear services until we do get this done. We do not wish to discontinue the service or surrender the license. We do wish to retain that, we want to provide the service, our physicians do feel it is a very viable and necessary service. We as management, and obviously from the description of the plan that Dr. Mitchell has, we have grave concerns and we have to take and get a handle on. I can't tell you that, I wasn't involved in the previous incident, I wasn't even involved in this one, I only heard about it on the side, but we're going to get this thing right or we are not going to do it. That is the only bottom line, and I have written down ten things that we agree with Dr. Mitchell that we need some additional outside, unbiased reviews to enhance our capabilities. Indeed the technician was reprimanded and disciplined over the matter, why in the world he chose to make that decision, who knows. He just felt that he had to. I think that our program needs a complete review that Dr. Mitchell & I will certainly work to do. This has the highest level of attention, not only of myself but Dr. Mitchell, Brian Dancer, in the Radiology area and our Board of Directors and our Medical Staff. We can't go any further than that. I want to assure you that when I had a full Board meeting Monday night, every member was there, they are very

concerned, they want this thing resolved and they want it resolved properly, within all regulations and with all things done correctly. It is a learning experience for me, we will have a lot of work to do, and we do hope, I emphasize as Dr. Mitchell did, that we can learn things from here today that will give us the proper perspectives that we can go back and accomplish. That is what we are going to do. We see this as a continuing transition of our abilities to adapt to our changing environment in our institution. Our medical staff is changing, we're changing, the Board is changing, everyone working toward this. Why in the world it happened, I can't tell you. Chuck - How long do you anticipate suspending activities in your Nuclear Medicine program? Gary - At this juncture it's, we are going to work on this immediately, first of all, but in terms of getting back on board, I think we are looking at mid to late January as an initial projection. Dr. Mitchell - I don't see why we can't go ahead and continue on unless - Lady - that was going to be a portion of a question that I had, from your apparent proposed corrective actions, it appears as though you are working to implement that might address some of these concerns immediately and you're position appears to conflict with that slightly, that you want to terminate activities intermittently. Have you reached a decision on that? Gary - I think that it only conflicts in the sense that I'm much more conservative and may not have the best of appreciation of how this will work and Dr. Mitchell has much better impression of that. I

don't see a conflict there, I'm just being very conservative and trying to get that accomplished. Charles L. - I think that the key to this is that this time we want to make sure rather than to say we are going to do this, policy and procedures are being written and presented to the Board as opposed to saying we are going to do those that after this conference we feel we need a full time RSO, and we are looking at the availability of a full time radiology there, but if we are going to have to train Brian Dancer to be an RSO, we don't know when the course is offered, but part of this is dependent on the feed back we get from you to, but the Board suspended it and the Board is the only group that can put this back in place and I assure this time they want to see it in writing and know that all of these things are in place and that the things that Dr. Mitchell has recommended have been done. Like the independent survey, we ought to have that done before we get back into it again, and that can be done I think on a short basis. The main thing is that we have this in place, in writing and tell the Board this is not going to happen again. I think we have a credibility gap here that we need to cover that before we ask. Chuck - Let me ask, have you researched or is it, I don't, my question is with Brian Dancer, is that the only thing that he lacks from being a qualified RSO. Dr. Mitchell - he just needs to take the necessary 40 hours course. Chuck - The regulation requires that he have 200 hours of training in various subjects that are identified in the regulations, will the completion of that 40 hour training course

fulfill that 200 hour requirement. Dr. Mitchell - It is my understanding that it will, I can't guarantee that, but I understand that it will. Charles - Our impression was that he had 150 or so that we thought qualifi nim for that and all that he needed was the other, but again, we don't know all of the answers to that. Gary - Do you have an answer? Lady - There are also some further requirements in regards to experience in RSO related factors and the regulations speak of one year of experience in that regard, if he is not already certified in the medical process. So you may want to closely examine his background in experience to see if it meets or would fulfill that criteria as you are all aware, Newman Memorial had previously submitted an amendment request, which was later withdrawn, regarding appointing Mr. Dancer as the RSO. We were not provided with that type of information at the time so the information that we have on hand would be insufficient for us to tell you right now if he could meet their criteria on that. Chuck - They are all identified by the way his 35.900's for regulations. It is a short paragraph that 35.900 lists the qualifications of a Radiation Safety Officer. Mr. Mitchell - If I could make a point, I am a little concerned with your concern, we are only throwing this out for open and frank discussion. I don't want to feel, nor do I think you are trying to tell me, that you can't do this. We need to know if we have options or not, then we can make sure we comply with it. As Dr. Mitchell said, we can't guarantee you today that that is what the situation is, but before

we would ever submit that to be a possibility we will make sure he is in compliance with those regulations. We appreciate the advice, but at the same time I am feeling that maybe you think we should not pursue this. Woman - No, we are just bringing this to your attention. Charles L - I think the other thing, Dr. Mitchell has been a good friend to the hospital, we don't want to put him in a spot. He has been trying to give us some help. Dr. Mitchell - I just don't know where it is. Chuck - What is the status today of the program? Mr. Mitchell - It has been suspended, inactive. Charles - We don't want to get back until we know everything has been done, that Dr. Mitchell is saying needs to be done. Chuck - Certainly that is an aggressive action on your part, and indicates the type of corrective actions, whether or not that was what we were looking for. Could you send me a letter, today or when you get back, confirming this fact. Gary Mitchell - There should be, we did a Fax a letter late Monday night, but with the holiday, the original should be here today. Chuck - OK, this gives the reason we are asking for further clarification is that the letter we received spoke of the fact they you were, you used the word proposed, that directed by the identifying of our problems, we propose that the hospital, to comply with the regulations we take the following steps. It left some question in our minds, after we got to questioning it, whether a suspension was in fact in effort or not. Gary - It is in effect and I think the best resolution would be to send you a copy of the resolution that the Board looked

at. Chuck - Alright. Charles - I think that our Medical Staff certainly wants to do this, we just want to make sure this doesn't get put back in, this service, until the Board removes the suspension. We are comfortable with this, it is something that we have done. Chuck - You are going to send another letter. Gary M. - Yes, I will follow up with that, with the actual wording of the resolution that the Board passed. Chuck - OK - I would put in as much detail in the letter, to give the flavor of what you are doing on your own initiative. One thing I would also ask you, the reason I was asking about the RSO was I was saying if it was only a 40 hour course, since we don't have the information, would you go back and research, would you look to see how close Mr. Dancer is and perhaps you could send that information to us also. Could you expand a little bit on what it is that will allow you to go back to the Board with some confidence and tell the Board you are prepared to resume conducting a Nuclear Medicine Program. In the bigger picture of the sense not necessarily the individual things that you are planning to do, but what it is going to take to give you that confidence. Charles - I think part of it is what we need to do with a little bit of help from you on what we need, whether we need a full time or whether the present method of having Dr. Mitchell and whether he is willing to cover this, under those circumstances. We know that all of the things that he has recommended that we do are already in place, not in progress. He said we needed someone to come down and survey the department, that should be done, so

that he is comfortable. I think we have to make him comfortable as RSO. That we have done the things that he has recommended. Dr. Mitchell - I think we can figure out some way in which, at least on a temporary basis, an absentee type RSO can function properly and fill the necessary requirements then I think we can reinstitute activity, I think we need to do that as soon as possible if we are going to stay in the business. That is why I am looking for help from you, what else I need to do. I personally obviously can't be out there full time nor would I, as I said before, prevent what happened. Chuck - Let me ask, more importantly, the previous issues that you looked at, do you feel that they up to this point did you have those resolved or are you also taking. Dr. Mitchell - At the last Radiation Safety Committee meeting, I have gone through every one of the ten violations, that is I had some concerns about it that is why I wanted somebody outside to come in and look, to have a little greater expertise in some of these areas that I possess. I understand the clinical end of it, I don't fully understand fully some of the regulatory requirements, I don't fully understand some of the physics involved. That is why I felt rather uncomfortable about it and wanted somebody else there to at least tell me they are on track. The other thing is that as an absentee RSO, so to speak, I was going to implement a plan which if a Nuclear Medicine request for study did not fit the criteria for clinical conditions that were appropriate, that the Nuclear Med tech notify me by telephone, I in turn call the referring physician

and discuss the case with him, discuss the merits of if this is indeed what he wants done or not. I think that can be done very easily and that would give the type of supervision that would be required.I'm unfortunately in a position where I am available, I would like not to be, but I am. Lady - I have a couple of questions regarding some of your corrective actions, that you had just outlined for us, you indicated that you believed the physician had intimidated the technologist that evening into doing that test. Has there been any further discussion with the referring physician to stop doing this in regard to that. Dr. Mitchell - Yes. Lady - Maybe you can elaborate on that. Dr. Mitchell - I talked directly with Dr. Flaherty about the situation and explained to him the, intimidation is probably not the correct word, here you have a physician in the community that is deeply concerned about the health of another individual and he really needed to know in his own mind whether or not this patient had a pulmonary emboli or not, he suspected it clinically, and he is concerned and he's upset, and that whole atmosphere for any one of us would become one of certain amount of intimidation, he didn't double up his fist or take a baseball bat and say "you will do this", it was not that type of intimidation, just the fact that the referring physician was viably and sincerely concerned about the well being of his patient.

The other end of this equation is the one that really, from a clinical, medical, legal stand point, blow my mind. That is that patient walked in to the Woodward Emergency Room and based on clinical findings no further investigation of a pulmonary emboli was carried out. 80% of the pulmonary embolis patients are a symptomatic. You don't make that diagnosis on clinical grounds. You suspect it, but you damn sure don't rule it out. That I know is not in your jurisdiction, but - Lady - You have apparently had discussions in regards to if a referring physician at Newman has a problem with trying to get or coordinate an examination before referring, do they not contact you or is there anything of that nature. Dr. Mitchell - The mechanism is, that if a Nuclear Medicine study is ordered, and it does not fit some prescribed clinical situations, then the technician calls me and I call the referring physician. Lady - Let me pose another questions based on your, would that have prevented this, because didn't the diagnostic evidence actually support doing a lung scan, an emergency lung scan? Dr. Mitchell - If they have of got in touch with me, they never would have gone througn the fiasco of trying to put something on a bottle and giving it to a patient and putting him in a private car and driving 35 miles down the road. If the patient is sick enough he should be transported in an ambulance and that institution should care for him not to have the examination done and brought back. That has been discussed. Lady - As long as you feel you have met those measures in case the physician runs into

similarly circumstances. Dr. Mitchell - Yes, and I hope that once we get up to steam again a similar situation those people will not do anything until they contact me, and if they can't contact me they are not going to do anything. Gary Mitchell - I have had the opportunity to visit with the physicians too and they are gravely concerned. They understand the remedial actions. The things we are proposing to do and I think the other thing is as Dr. Mitchell said, maybe that word intimidation is not the right one, but we can't live the telephone call that was received and the feeling that the technician may have taken from the way the physician was doing, recognize that it was 5:00 o'clock in the afternoon on a Friday when most of us are thinking about leaving or away from work. It was probably some anticipation going on, there are just numerous human factors that I think we are all trying to understand, and I think we do understand, but we don't know exactly what the way it was inferred to that technician. Lady - I was not left with the impression during the inspection that it was real intimidation. Gary Mitchell - I think you have to understand though that, we are a small community, the physicians are highly regarded, we do our very best to comply with their wishes within regulations, rules and policies. In this case, we tried to do that with a technician that did not fully understand what should have been done. Charles - I'm not sure the doctor understood the technician didn't know what he was doing. Gary - That is also true. Charles - He didn't realize the difference between somebody

trained in Nuclear Medicine is just a technician. Dr. Mitchell - Being a radiologist and dealing with Neurosurgeons, cardiac surgeons, the atmosphere can be intimidating I guarantee you. Lady - You also outlined a number in algorithms that you have developed, that you can implement in your procedures that would help make decisions regarding what to do with patients and I presume that those are particular not only to routine cases but emergency cases as well. Dr. Mitchell - Yes. Lady - Now you emphasized the lung scan, is that the only emergency exam that you would anticipate conducting at your hospital or do you need to address . Dr. Mitchell - That is all that would be available at Newman, yes. They don't do any cardiac studies. Lady - I guess my question was if you should expand that to involve all parts of the whole. Dr. Mitchell - If we do a procedure, it will be expanded. Particularly if it fall in the emergency category. Lady - I guess the other question that I had, if you do determine that you are unable to get a full time authori.ed user physician to serve as RSO, how do you plan to ensure that you meet the review requirements under the provisions of supervision in the regulations. Have you proposed any changes to your current review frequency or methods, or. Dr. Mitchell - Do you mean as far as keeping abreast of the current federal regulations. Lady - Well actually reviewing what is going on in the day to day operations of the program. Dr. Mitchell - One is involved with the final interpretation, I think that in a way serves as an audit, because I have the clinical history, the dosage

given the patient, I can tell if it is clinically indicated or not, as far as the day to day operations, I think I would have to rely on Mr. Dancer's honesty and proper record keeping as far as making sure that the kits are reconstructed in the proper way, that that which is not used is disposed of properly and I think in most instances, most RSO do have to depend on other people for the day to day monitoring and surveying. I would and can certainly pay more visits than just quarterly. Just exactly the number and the timing I don't know, because my schedule is not that flexible. If you have any suggestions in that area, I would be delighted to hear it. Chuck - Let me address that a little further, because I sense that is a question that you raised earlier in our discussing about the whole issue of supervision and management of the program. Let me try to characterize NRC's view of what constitutes supervision, to attempt to answer that perceived question. The regulations 35.25 and that there was a lot of introspection in the agency about how to write that regulation when it was developed back in 1986 and 1987. A lot of it was a draft regulation, promulgated and a lot of comments particularly on that issue on supervision. In fact, the original regulation had some very descriptive requirements such as making sure an RSO in a supervisory position be within one hours notice. Being able to be reached within one hour to respond. However, NRC eventually decided that those kind of requirements perhaps didn't get us to where we really wanted to go. We wanted a regulation that left it pretty much up to you as to how to assure

that proper supervision had occurred. Recognizing that you and only you know the talents and capabilities of the people that you supervise. Some of those people may require a great deal of close supervision, others may be trained and qualified where you can give them quite a long leash, if ;ou will, and so we have really put the issue in a great extent back in your ap. It is more of a results oriented view on supervision and if you go back and read our statements of consideration that were published in regard to that proposed and how we finally developed it, you can read that. Anyway, so that is the best answer we can give to you on the question on how much supervision is adequate. The bottom line is the correct amount is the amount that gives the effective results. WE will leave that to you to determine how much is effective, recognizing that you are remote from the hospital, that may be alright depending upon the personnel that you have available locally in Shattuck and how the procedures are set up and the effectiveness of the program to deal with circumstances as they arise. Only you can ultimately know that, you better than we can. Chuck - Any other questions? Joe, Janet do you all have any questions? Joe - I do have one that I would like to address to Mr. Gary Mitchell, it concerns the original notice of violation that was sent to the hospital on July 25, 1990, I understand that he wasn't the administrator at the time, but the notice seems to present a sort of a two part problem, the first was probably lack of adequate attention to the compliance on the part of the

Radiation Safety Officer and the second was the lack of management attention to compliance and compliance activity at the level of management above RSO and I was wondering what plan the licensee has at the present time to get ahold of that second issue, which is what tools are management going to use to be certain that whoever ends up being RSO is doing a good job and is fulfilling his or hers responsibility to compliance with NRC requirements? Gary - I wish I was more knowledgeable about some of the specifics of a lot of the background, so if you will bear with me a little bit. I think first of all getting a working knowledge of what the basic requirements that are written by your agency will be the first and foremost area. We have to make sure we comply there. Once we understand that basis that we just have to simply go back there and periodically make an effort to go back and scrutinize those with the manager on site and stay in close consultation with the physicians, both at our site and with Dr. Mitchell to review that material. I think we would also be looking at the possibility of enhancing the visits if possible and that would provide us with additional scrutiny and oversite. Man - What visits were you referring to to enhancing. Gary - Possibly Dr. Mitchell, depending on who scheduled. Chuck - Just let me inject one other question. You've mentioned that several other individuals, consultants if you will, have been and I think will be involved, you mentioned Max Quiby and Mike Morris and Vernon Ficken, what is the extent of their continuing involvement going to be in the future, or do you

know at this point in time? How they might be involved? Dr. Mitchell - I think that as long as I am involved that Mr. Quiby will be involved. The others I can't really speak for, I think Vernon is considered contract Physicist, so I can consult him, but Mr. Quiby is in my back pocket, I know where he is.He is taking a renewed interest in this business. Chuck - I think Mr. Mitchell your perception is really right on the point, that one of the important things to do first hand is to have someone being fully aware of all the requirements in the license itself, which primarily include the commitments that were made in the license application and then also part 35 of our regulations. I would say that if an individual has studied through both of those documents he ought to be pretty knowledgeable on that subject of the requirements and have a viable program. Gary (NRC) - Bill has asked me to summarize our enforcement policy for you at this time. None of you were here for the last conference we had with NMH, still I will do it once again. The policy is published in Title 10 of the Code of Federal Regulations in part 2, it is published as appendix C. I have given you a couple of copies of it, if you've not read it before I really encourage you to read it at some point in time when you have the opportunity. It's purpose quite simply is to promote compliance NRC regulations that we deem, (end of tape, missed some) It is designed to give licensees a break, if they are in fact managing their programs effectively and identifying non compliance within their programs and correcting

that non compliance on their own without benefit NRC's periodic inspections. On the other hand there are negative incentives in the policy to bring about lasting corrective actions that the NRC is finding and discovering these problems in it's inspections and believes that licensees need some sort of additional incentives to implement lasting corrective actions. Among the tools the policy gives us for accomplishing this is monetary civil penalties, as you know, and orders of various types, orders to modify licenses, orders to suspend licenses in some cases, and ultimately order to revoke NRC licenses. We select the right tool based on our consideration of the significance of the violations that have occurred, and based on all of the other information that we gain by performing inspections and conducting conferences such as this. Our policy provides that violations are normally classified by severity, severity level 1 thru 5, with one being the most significant and 5 being the least significant. We will base our enforcement action on that, on the assigned severity level to the violations and we may do that either individually or we may consider the violations if they are closely related or have resulted from the same cause, we may consider them collectively and assign a singular severity level to a collection of violations. We will get together after this meeting among ourselves to discuss exactly what violations be believe occurred, how significant those violations are, either collectively or individually, and then discuss what sort of enforcement action the agency ought to

consi r as a result of that. I assure you we will take into serious consideration your actions to put your program on hold and we will consider that as a very positive step taken by the hospital in approaching these matters and trying to resolve NRC's concerns as well as your own about your program. In any event, we will inform your hospital in writing once we have made up our mind what action ought to be taken and if we propose any sort of escalating enforcement action by that I mean a monetary civil penalty or order of some kind. We normally accompany that with a news announcement, that is made available in the area. I think you know that from recent experience at Newman. We will explain in our letter to you exactly what your options are in terms in responding to whatever actions we suggest. It takes some time depending on the complexity of the issues, nature of the issues, it could be anywhere from a couple of week to several weeks before you hear from us. Dr. Mitchell - If we feel confident after a certain period of time, that the prior ten violations have been adequately corrected and that this situation has at least been to the best of our ability, been corrected so that we can monitor and so forth, what are the necessary steps if you decide to take the program off the "on hold" status and put it back in the works. Chuck - Write us a letter, assure yourselves that you ready to proceed with activities, license activities. Man - I guess we should also mention that we have pending with you some business on the previous portion of the problems. I guess you have that correspondence. Dr. Mitchell -

Yes. Man - OK. We owe you I guess at this point, a response to a letter that we received I guess a couple of months ago, that was responding to those ten violations. We will be in contact with you on that in the future. Gary - I only hope that the, it is very apparent and be taken in strong consideration in finalizing your enforcement, that we are extremely serious, and we have taken extremely aggressively measure to preclude this occurrence from ever happening again. We just hope that you will look upon those with leniency in your consideration. Chuck - Let me again thank you for coming down here today, I am sure you read the previous transcripts, you had no idea of what to expect, what you were coming into, but I have to admit we had a very difficult time to employ our message at the last conference and I believe this time certainly you have taken the responsibility and have told us what you are going to do. I assure you we will look very heavily at that aspect and take that in to very strong consideration when we consider action regarding this last issue. I urge you to take this opportunity to review all areas that you yourself admit that you are not comfortable with, Dr. Mitchell, and make sure you are starting off on a clean foot whenever you get ready to restart, as I said, if you can document in that letter to us today, that this has been suspended and whenever you are ready to restart follow that up in writing I would appreciate that. I do appreciate that you are taking this problem seriously, I think that was the problem that existed in the past, that it is being resolved and certainly

that is the type of action that we are looking for. I have no other comments. Gary M - I have one small question - are we in any violation by not, we have the license but we are not going to perform tests, are we in any violation or do we need to do any formality with you at this point? Chuck - The only formality that you have to fill with us is to write us a letter notifying us that you are suspending activities and the date that you did suspend activities and I would urge you to take that opportunity when you reply to explicitly state the extensiveness of the review and the actions that you are taking and have taken before you restart. Anything else. Joe - Janet - Joe, no Bill not at this time thank you. Thank you.