



**HOSPITAL
PAVIA**

José O. Morales, M.D. FACNP
DIRECTOR

DEPARTAMENTO DE MEDICINA NUCLEAR

March 12, 2001

Mr. Hector Bermúdez
USNRC Region 2

Dear Mr. Bermudez:

I am sending a copy of recent correspondence between Dr. Friger and I as chair of Radiation Safety.

According to Mr. Rios, the cases done recently have followed the "new" protocol. I am trying to impress on Dr. Friger that we have to follow strict protocol.

Saludos,

José O. Morales

Hospital Pavia

1462 Asia Street
Post Office Box 11137
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phone 809-727-6060
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March 9, 2001

Marangeli Friger, MD
PMB 126
138 S.W. 8th Street
Miami, Florida 33184

Dear Dr. Friger:

I have received your letter dated February 17th and postmarked February 23, 2001, regarding the Brachytherapy Program.

It is apparent to me that you do not have a clear understanding of my concerns and their impact on the conditions of our NRC License. Let me first tell you that I sympathize with your administrative difficulties in the purchasing of the 125I seeds. Rest assured that many of us go through these hassles almost on a daily basis. But this is not germane to the issue of compliance with the NRC requirements, which in a letter dated January 25, 2001, you stated that you would follow.

On Page QA-5 paragraph 3 of the Quality Assurance and Radiation Safety Program under "Seed Handling", it is clearly stated that the shipment received will be compared to "what the radiation oncologist ordered". Therefore, we need a copy of that order. Paragraph 3(m) of your letter states that you asked the Vitalife representative to fax to us a copy of the order. That, is not acceptable. We want you to fax to us the same completed form (copy enclosed for reference purposes) immediately after you fax Vitalife.

On October 16, 2000 you sent me a letter stating that you had hired Mr. Miguel Rios and specified a list of duties. After Pavia entered into a contract with Mr. Rios to be the Brachytherapy RSO you unilaterally cancelled the above contract, which is part of our new license amendment, without notifying me. Contrary to your opinion, Mr. Rios has a contract with Pavia even if not yet formalized in writing. One of the problems was that Mr. Rios had to change the wording of the contract when you decided not to employ him anymore. I had to contact Dr. Maestre who promptly understood the situation and it is my understanding that you have once more hired Mr. Rios. This is crucial because, once a patient is discharged from the Hospital, it is your responsibility to deal with any medical or radiation safety considerations and neither you or Dr. Martin can do that from Florida.

Regarding my two calls to you on February 13, 2001. You have always answered them promptly and this time you did not do so. In fact, you never did. Those calls dealt with the issue of the copy of the form for the seed(s) ordered by Dr. Martin.

Clearly understand that I am not questioning your professionalism or the treatment of your patients. However, if you do not follow the guidelines and protocols strictly as outlined, I will not hesitate to recommend to the Administration, that the Brachytherapy Program be terminated. Should I have to do that, I will also ask the Radiology Department Chair to suspend your privileges.

Sincerely,



**Chair, Radiation Safety Committee
Director, Nuclear Medicine**

Enclosures: 4

Copy to: Mr. José Cuevas, CEO, Pavía Health, Inc. with enclosures
Mr. Alfredo E. Volckers, Executive Vice President Pavía Hospital
Mr. Wilson Quiroga, Administrator Pavía-Hato Rey
Mr. Héctor Bermudez, NRC Region II with enclosures and Dr. Friger's letter
Dr. Reynold López, Associate Medical Director for Pavía-Hato Rey
Dr. Rafael Rodríguez, Medical Director
Dr. Manuel Pérez, Chair, Department of Radiology.

Centro de Braquiterapia Prostática

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February 17, 2001

Sent by certified mail

Dear Dr. José O. Morales
Chair, Radiation Safety Committee

The purpose of this letter is to respond a message you left me on my cellular voice mail on Tuesday 2/13/01 (at approximately 2:15 PM and 6:00 PM, when I was on the Airport on my way to PR). Your message stated that still Diana Sotomayor was not receiving the seed order information with enough time, and the "to you this was a violation of the protocol, and that since you were the Radiation Safety Committee Chair, you were going to recommend to stop the program", a message I could not understand, by its context and the way it was sent.

Let me try to explain to you again, that in order to plan this patients, a "mapping" is done, which is a special volumetric study of the prostate. These studies are done close to implant date to give accurate dose. If done too early, the dose can be too high, and this is unacceptable. To remind you these patients are receiving hormonal manipulation, and this will change the prostatic volume.

I would like to certify the following:

- 1- Pavía Hospital Hato Rey is the custodian of the records of all the patients of Brachytherapy as per protocol.
- 2- I have not in any way or matter violated the protocol of the program. All forms and QMP protocol has been followed.
- 3- There are certain administrative issues that are in conflict with the pathway we take to plan adequately this patients, but that does not mean in any way that I am violating the protocol. I will be more than happy to discuss these issues to find a solution, since they are only administrative. I would like to remind you a few issues that are important, to make you

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understand that I have no control on administrative issues, but that I am always available to try to find a solution.

- a) On letter dated 1/22/01 I am notified the program was to restart , and patients were scheduled in OR for Jan. 31, Feb. 1-2, 2001. My physicist had worked an approximate time of 32 hours to complete adequately the pre plan and isodose curves on the 8 patients that were posted for the following week (all this professional fee is paid by me).
- b) On Friday morning (1/26/01) I am notified by Diana Sotomayor that "somebody" in the Hospital gave order that they were not going to give a check for that COD order that Pharmalogic (the seed vendor), always required COD payment, because of Pavía's credit history with Pharmalogic.
- c) I spoke with another vendor, Vitalife, and negotiated with them a better price for seeds for Pavia, as well as to get credit for Pavía. I helped solve this situation, because it is important to understand we are treating patients and we all are liable, and can't solve all the situations by cancelling the procedures.
- d) Because of differences in dosimetry factors (that I understand Diana Sotomayor and other personnel doesn't understand), she wanted me to give immediately the # seeds and strength for Mentor seeds, when this information is not transferable.
- e) I did not have time to change all the work done, so Steve Martin, my physicist, and I tried to negotiate with Imagyn (the company that Pharmalogic represents in Puerto Rico), to accept a post dated check that Pavia was willing to give to pay for the seeds.
- f) On Monday, Jan. 29, 2001, I was told by company representatives (Pharmalogic), that they were going to accept the check.
- g) Diana Sotomayor was notified of every change and of every negotiation.
- h) On Tuesday 1/30/01, I flew to PR, in the afternoon (day before the implants).
- i) At 10 PM, 1/30/01, I was notified that the company did not send the seeds, because of Pharmalogic's payment history with Imagyn, and because Pharmalogic stated that if the check from Pavia bounced they were not responsible for paying the seeds. At 11 PM we had to call

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- each patient to cancel the cases for 1/31/01 (as you can see I can prove these are administrative issues).
- j) On the morning of 1/31/01, finally Imagyn accepted the postdated check and the sources were available for Thursday and Friday, but 2 cases could not be done, because OR could not schedule them so fast, (and that is understandable), so I had to come the following week to implant the patients or Pavia, would have lost the money, because sources have to be paid even if not used.
 - k) To help out again, I had to spend on another trip to PR for my physicist and I, to cooperate with administrative issues.
 - l) In order to give the ordering information to Diana (Nuclear Medicine), the plan has to be done, mappings on our patients are very recent to give adequate dose (not more or less if this plan is done too early).
 - m) I asked Vitalife representative (Diana Torres), to fax the order to Diana Sotomayor immediately after they receive the order, that is no earlier than three working days before implant date, so Diana can get the PO number. With all these administrative problems, the program administratively may not look perfect, but I am always willing to communicate with you and find solutions.
 - n) We will not order any seeds other than from Mentor (Vitalife), only one case that was done on 2/16/01 used Imagyn seeds, and it will not happen again, unless Pavia administration finalizes and agrees to contracting also other vendors.
- 4- The protocol has been followed. Administrative issues are not clinical issues, and since the Hospital has difficulties, I will be willing to help. But my main purpose is to give treatment of excellence and quality to the patients, the dosage that they need, for my patient's diagnosis of cancer that is a catastrophic disease.
- 5- Since we understand the importance of following the protocol and guidelines, I would like to clarify that I just knew, on 2/13/01, as per Mr. Miguel Rios, that his contract got lost, and that he has not been paid since December, 2000. If the RSO of the program has no contract with Pavia and is not being paid, I suppose technically is not an employee of Pavia. He is the RSO for Brachytherapy, he is in the license and as per

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protocol, we have to comply. So on that day I had to call Mr. Cuevas office to find out how could we expedite this paperwork, because if Mr. Rios is not employed and paid by Pavia, besides being on the NRC license only, this is a clear violation of the protocol.

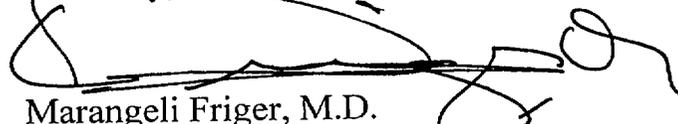
- 6- As of today, I can tell you that Mr. Rios and Pavia are working to expedite his contract and pay. As you can see I have done nothing else but try to help in every way I can for the success of the program in every way.

I hope that this letter will help to clarify the difficult issues I had to deal with, but I would like to make you understand and to remind you, what you always tell me, that we are human beings, I am treating human beings.

Let me remind you that it took two years of my life to develop and start this program, that the cost to Pavia has been insignificant, when compared to the real cost if they had to pay for all the technical and professional components involved. If I have been available in the past to go to meet with you only, at a cost to me of \$800.00, I would have done the same to clarify this issue and to find a solution to it. I am in the best disposition to meet with you and all other parties involved, to find a solution to this administrative issue, in my next trip to P.R., because as professionals I believe every administrative issue can be resolved.

I like what I do, I practice Radiation Oncology because of vocation. At the beginning of every program "Administrative Issues" do not run always smoothly, but I will do my best to help administration to run it as smoothly as I can.

Sincerely,



Marangeli Friger, M.D.
Radiation Oncology/Brachytherapy

Cc: Sr. Jose Cuevas, President
Alfredo Volckers, Executive Vice President

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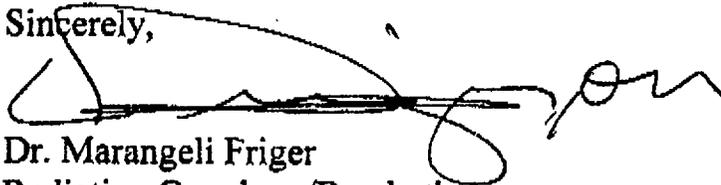
1/25/01

Dr. José O. Morales
Chair, Radiation Safety Committee
Hospital Pavía
Santurce, Puerto Rico

Dear Dr. Morales:

This letter is to confirm that I will follow the guidelines of the QMP and QA Program for the procedure of Brachytherapy of the Prostate at Pavia Hospital. I would like to assure that all the forms stated that need to be completely followed and signed before and after each procedure will be available at the Operation Room before each procedure is done.

Sincerely,



Dr. Marangeli Friger
Radiation Oncology/Brachytherapy

SEED HANDLING

- Receiving ^{125}I Seeds

The Department Policy for Receiving Radioactive Shipments, will be followed.

- Opening the Radioactive Shipment of ^{125}I .

1. Record survey meter measurements taken at 1 meter (3 ft.) and on the surface in the receiving section of the log book before opening the container. If the 1 meter measurement exceeds 10 mrem/hr or the surface measurement exceeds 200 mrem/hr, notify physicist or RSO immediately. The physicist or RSO will notify the final carrier, and the regional NRC office.
2. Using an alcohol wipe, perform a wipe test on the outer surface of the box in accordance with written department policy. Ensure any removable activity is less than 0.005 microcurie (5 nanocuries). If this value is exceeded, notify the Physicist or RSO immediately. The Physicist or RSO will notify the final carrier, and the regional NRC office. Follow existing hospital policy for containing spilled radioactive materials.
3. Read the Packing List and Bill of Lading. Make sure the ^{125}I that is received is what the radiation oncologist ordered. Multiply the strength of the seeds by the decay factor pertinent to the day of the procedure. Day 0 is the shipping day. The apparent activity will usually be listed on the packing list, usually in the description of the contents. Remember that the declared activity on the bill of lading is the actual contained activity, not the apparent activity!!
4. Open the box
5. In the "Receiving Log for I-125", record the patient's name, date, and radioactive material supplier, purchase order number, the shipping container number, total activity in mCi, the number of seeds, the strength per seed in mCi, and the initials of the person who surveyed the container.
6. Make a copy of the Bill of Landing for the brachytherapy chart.
7. Keep the return shipping papers in the "Receiving Log for I-125" until ready for use.
8. Ensure that there are the correct number of small lead containers (if you ordered a calibrated seed, there should be a second vial marked "CALIBRATED").
9. Leave the lead containers and the Bill of Landing in the shipping container. Do not remove the ^{125}I seeds from their lead container.

Marangeli Friger, M.D.
Radiation Oncology/Brachytherapy/Radiosurgery
Centro de Braquiterapia Prostática
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10/16/00

Dr. José Morales
Director Departamento
Medicina Nuclear
Hospital Pavia
Santurce, P.R.

Dear Dr. Morales:

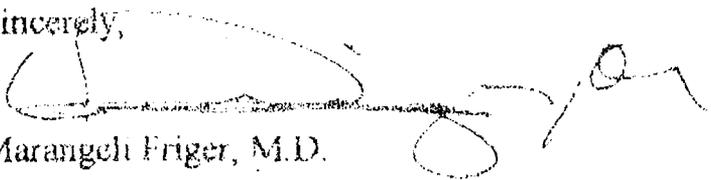
This letter is to notify that Mr. Miguel Ríos, will be hired by me, as part of the Brachytherapy Center with the following duties:

- 1- Review all brachytherapy charts following the QMP for Low Dose Rate Implants, to assure the quality is maintained.
- 2- Make sure all the forms required by the QMP are kept in good standing, in the charts.
- 3- To be involved in the process of source calibration.
- 4- To be my representative in the meeting of Radiation Safety Committee, if I can not attend.
- 5- To be accessible, if there is any emergency related to the Brachytherapy Service
- 6- To notify me immediately, if there is any emergency with any of my patients.

If there are any questions, please call me anytime at the following number: pager 1-800-983-7555.

Thank you for your attention in this matter.

Sincerely,


Marangeli Friger, M.D.