January 27, 1997

Hubert J. Miller
Regional Administrator
NUCLEAR REGULATORY COMMISSION
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Demand for Information (12/31/96)

Dear Mr. Miller:

In part A of the Demand for Information dated December 31, 1996, you ask me to describe my involvement in Temple University's failure to perform monthly quality assurance checks of the high dose rate remote afterloader (HDR). You also ask me to state whether I disagree with any of the statements made in the Demand for Information.

HDR Quality Assurance

Beginning in September of 1994, I was employed by Salick Health Care, Inc., to serve as the Chief Medical Physicist, Department of Radiation Oncology at Temple University's Cancer Center. My responsibilities included:

(1) Performing or supervising the performance of quality assurance (QA) checks on all of the radiation therapy equipment;

(2) Verifying that patients were treated as their physicians prescribed by reviewing treatment plans, beam-on calculations, and treatment charts;

(3) Working with Temple's physicians to constantly monitor and improve the Quality Management Program; and,

(4) Coordinating with the Acting Radiation Safety Officer (RSO) to ensure that Temple complied with state and federal laws and regulations.

One of my assigned responsibilities, therefore, was to perform or supervise the performance of the QA checks of the HDR. When I assumed my duties at Temple, I was trained by the vendor on the use of the HDR. Temple's clinical use of the HDR resumed in November of 1994. I can only presume that as part of the vendor training, I learned that monthly HDR spot-checks were recommended as good standards of practice.

Until late 1996, I never recall being told that monthly HDR spot-checks were part of Temple's license conditions. At some point after I assumed my position, I was given a copy of Temple's license to read; however, I was never given a copy of the correspondence listed under Condition 32 of Temple's Material License. Although Condition 32 references documents that are incorporated in the license, they were not forwarded to me. Obviously, I wish that I had read these documents or asked someone to give me copies, but I did not do so. To benefit the QA program, I conducted an annual review of our radiation regulations and policies, yet I had no information to indicate that monthly HDR checks were part of our license conditions. The RSO and I regularly discussed QA issues and regulatory compliance. Perhaps he assumed I fully understood all the license conditions.

I do wish to add that both the RSO and I have trained radiation workers about NRC license conditions but, to the best of my knowledge, we have never included <u>any</u> of the correspondence referenced under Condition 32. For your reference, I have attached a copy of an April 17, 1995 memorandum from the acting RSO to the Chairperson of the Department of Radiation Oncology. The memorandum sets forth the selected license conditions relevant to users of licensed radioactive materials. This material makes no reference to the need to perform monthly spot-checks under the license.

In August of 1995, I began to use a form I designed to improve QA procedures so that I could better coordinate my activities with Temple's acting RSO. I have attached a copy of the form I designed. By memorandum dated August 7, 1995 (copy attached), I forwarded the new QA form to the RSO and requested any feedback he could give to improve QA. I also asked him to consider preparing "a standard form for you to send us when we are delinquent, and/or something (maybe quarterly) to let us know that you have received the information." The RSO never developed a feedback mechanism.

On one of these QA review forms I did point out that the monthly HDR spot-check for October of 1995 had not been performed.

I have attached a copy of the QA form dated 11/2/95. At the bottom of the form I wrote, "HDR monthly QA not done in October." Also, by memorandum dated February 2, 1996, I forwarded my monthly report for January and again indicated on the QA form, "[n]o HDR done in January." I never received any comments after sending these forms to the RSO and I eventually stopped sending them after July of 1996. I began sending the forms again in November of 1996.

In November of 1996, Temple received the NRC Inspection Report about the routine inspection conducted in September and October of 1996. I was given the assignment of researching whether any patients were treated within 30 days of the previous monthly HDR spot-check. By memorandum dated November 25, 1996 (copy attached), I gave Temple's acting RSO the results of my research. In that memorandum, I pointed out that my report to him for the month of October 1995 "indicates that we were aware the monthly spot-check had not been done." I also asked him to clarify whether we needed to do a monthly spot-check "if we are not treating patients." I went on to explain that I thought "we have careful, complete, accurate, and reasonable QA for the HDR, especially in the context of our light patient load. We attend to our equipment and try to comply with regulations." Even though the NRC Inspector possibly discussed this issue with me, I still did not fully appreciate that the HDR monthly spot-checks were required as a condition of the license.

Predecisional Enforcement Conference

I do not dispute any of the statements made in the Demand for Information about my answers to the questions directed to me at the predecisional enforcement conference on December 6, 1996. When I attended the conference, I did not completely understand the seriousness of the situation. The Chairperson of the Radiation Oncology Department had requested my attendance to support Temple, and I wish I had prepared myself better to answer the questions.

Frankly, I do not recall exactly what I said, although I know I left the NRC representatives and my Temple colleagues with the impression that I was either inept or a willful rule breaker. I do recall that I said I knew monthly HDR spot-checks were required, and that I had made the decision to postpone the monthly checks on certain occasions. As I have discussed above, when I made the decision to postpone the checks or when I realized after the fact that they had not been performed, it was with the understanding that the checks were part of Temple's QA program, as opposed to a condition of Temple's license.

There is one other impression I may have given at the conference that I must correct. I am very concerned that Mr. Hale and Dr. Shanbaky concluded from my answers that I allowed patients to be treated on a machine that had not been calibrated. I can assure you that we never treated a patient without calibrating the HDR's source and checking the timer linearity. Our experience has shown the absolute necessity for checking the source strengths before treating a patient. We do not rely on the manufacturer's source strength specifications. Further, on each day a patient was scheduled for treatment, we completed the extensive QA procedure attached. We have never treated a patient without completing the quarterly and daily checks.

Adherence to NRC Requirements

In part B of the Demand for Information, you ask me to state why the NRC should have confidence that I will adhere to NRC requirements, and refrain from any willful violations of the requirements. I can assure you that I now fully understand all of the conditions of Temple's license, and I know I must adhere to them. At some point following the predecisional enforcement conference, I asked Temple's acting RSO to give me copies of the correspondence listed by date under License Condition 32. As you can see from the attached memorandum dated December 26, 1996, I advised the Chairman of Temple's Radiation Oncology Department "[b]ecause of license conditions, we do quarterly checks monthly. . . . It has only recently come to my attention that I do not have a complete record of the conditions of our license. Kurt [Temple's acting RSO at the time] will be giving that to me today."

Subsequently, the RSO gave me a copy of the March 1994 correspondence where Temple indicated that the HDR's calibration would be performed by an authorized physicist following "the installation of a new source, before treatment was resumed, and monthly thereafter." I can assure you that it has been made very clear to me that we have made a licensing commitment to perform a monthly HDR spot-check.

My concern about compliance has extended to the entire Departmental Quality Management Program. I have openly encouraged an independent review of my QMP, and I will carefully review the suggestions that we receive. In addition, I have asked the members of my staff to analyze our existing procedures so that we can improve them further. This significant feedback will help me to assure full compliance with all rules and regulations.

Disciplinary and Corrective Actions

I have been severely disciplined for my role in contributing to the failure to perform the HDR monthly spot-checks. By letter dated December 16, 1996, I received a written reprimand from my employer, stating there was no excuse for my failure to perform monthly calibrations of the HDR unit. My employer told me that further disciplinary action may be taken if the results of the independent audits recommend such action. On January 14, 1997, Temple suspended me from all clinical activities, until the NRC completed its investigation of me and until independent audits of my work were completed. I initially asked Temple to conduct these audits to review my physics program and to mend the breach in confidence.

In order that Temple can guarantee that all past activities have been reviewed and that all future conditions will be conducted as pledged under the license, Temple has implemented the following procedures:

(1) No patients will be scheduled on the afternoon of the first Wednesday of each month so that monthly QA can be performed on the Cobalt teletherapy unit and the HDR unit;

(2) Selected personnel, including the Chairman of the Radiation Oncology Department, the RSO, the Chief Medical Physicist, and the Chief Radiation Therapist will meet on the second Wednesday of each month to review the monthly QA results;

(3) The RSO will review all policies and procedures within the Department of Radiation Oncology for strict compliance with Temple's licensed activities;

(4) QA forms have been revised to ensure that HDR monthly spot-checks are a highly visible, significant component of both quality assurance and pretreatment procedures; and,

(5) A regular monthly report of all NRC related QA activities will be sent to the Vice President of the Health Science Center.

In spite of my suspension, Temple authorities have permitted me to continue to monitor and contribute to peer group discussions of quality assurance improvements. I am also allowed to discuss

the QA programs I set up with the auditors who are reviewing my performance. Management's decision to let me assume a role that helps me improve and learn from my experience has been a source of encouragement through my personal ordeal. Because I am still allowed to associate with and confer with my peers, I believe I have come to a quicker understanding of how meticulous my performance standards must be if I am to have a future at Temple.

Future Role in NRC Licensed Activities

In part C of the Demand for Information, you ask me to state why I should not be barred from any further involvement in NRC licensed activities. I hope that you believe me when I say I did not willfully engage in any deliberate misconduct. I consider Temple's commitment to the NRC through the conditions of its license to be my own commitment. I certainly have learned an important lesson from this experience. In the future, I will ask what is legally expected of me and make sure that I personally read and understand all materials that are essential to the performance of Temple's licensed activities. I will not wait for other individuals to provide me with these materials.

If the NRC allows me to remain and if Temple still trusts me, I would like to continue my work in the Radiation Oncology Department. Over the years, I have gained a good deal of training through positions I held at the Naval Research Laboratory, the University of California at Los Angeles, and the University of Pennsylvania. My work at UCLA gave me an opportunity to learn first hand the mechanical intricacies of cancer treating equipment, and I have had an opportunity to review many different types of radiation safety programs. I sincerely have tried to establish a model QA program for Temple based upon the highest industry standards. I also have worked hard to give feedback to and to develop rapport with Temple's RSO -- both the acting RSO and the newly appointed RSO. As a member of the Radiation Protection Committee, I have worked to improve the details of Temple's QMP.

In my opinion, quality management requires continuity, a time to assess, a time to plan, and a time to improve. During my two years at Temple, I have assimilated a significant amount of data critical to Radiation Oncology's effective operation. I believe I can still constructively share this knowledge with my colleagues and staff and I would greatly appreciate being able to continue to help plan and develop Temple's QA program. I sincerely hope that this letter conveys my respect for regulatory issues, my commitment to meet and exceed the regulatory standards, and my ongoing concern for providing the best standard of care for the Department's patients.

In closing, I would like to state that I appreciate the opportunity the NRC has given me to provide this additional information. Should an NRC representative wish to ask me additional questions, I would be glad to cooperate to the best of my ability. Please contact my attorney, Jane G. Penny at Killian & Gephart, Harrisburg, Pennsylvania, (717) 232-1851, so that we can respond promptly to your inquiry.

Respectfully submitted,

Lee T. Myers

Lee T. Myers

LTM/bj

Enclosures

VERIFICATION

I, Lee T. Myers, Ph.D., being duly sworn, verify that the statements of fact set forth in the attached Answer to Demand for Information are true and correct to the best of my knowledge, information, and belief.

Lee T. Myers

Lee T. Myers, Ph.D.

Sworn to and subscribed
before me this 27th day of
January, 1997.

Ann Marie Bonawitz

Notary Public

NOTARIAL SEAL
ANN MARIE BONAWITZ, Notary Public
City of Harrisburg, Dauphin County
My Commission Expires Dec. 9, 1999

TEMPLE UNIVERSITY
A Commonwealth University

Environmental Health and Safety

3223 N. Broad Street (600-00)
Philadelphia, Pennsylvania 19140
(215) 707-2520
Fax: (215) 707-1600

Apr 1 1995

APR 17 1995

MEMORANDUM

TO: Dr. Patrick Thomas
Chairperson, Department of Radiation Oncology

FROM: Kurt Bodison
Acting Radiation Safety Officer

SUBJECT: QMP and NRC License Conditions

DATE: April 17, 1995

Please distribute copies of Temple University's Quality Management Program and NRC License conditions to each member of your staff who work with or around licensed radioactive materials (physicians, technologists, physics staff, nurses and residents).

These materials should also be a part of any initial or refresher training that you provide to your staff dealing with the use of licensed radioactive materials, particularly that training that is provided to residents.

I would also like to set up some mechanism to ensure that Environmental Health and Safety is notified of any training sessions that your department conducts that include discussion of radiation safety issues.

Thank you for your assistance in this matter.

KB:kb
Enclosures

To Lee Myers.
Should not this training be done by your section in conjunction with Kurt?

cc: Dr. Lee T. Myers, Chief Medical Physicist
Dr. Glenda Smith, Chairperson, Quality Improvement Committee
Elizabeth Palacio, Chief Technologist

EXHIBIT 1

TEMPLE UNIVERSITY QUALITY MANAGEMENT PROGRAM

Purpose: The Temple University Quality Management Program has been established to provide a high degree of confidence that byproduct radioactive material or radiation from byproduct radioactive material will be administered as directed by the appropriate Nuclear Medicine or Radiation Oncology physician. Temple's policies and procedures regarding the administration of radiation to humans, are intended to satisfy the elements of a Quality Management Program (QMP) as mandated by the United States Nuclear Regulatory Commission (NRC).

Scope: The Quality Management Program applies to the Department of Diagnostic Imaging, Nuclear Medicine Division, and to the Department of Radiation Oncology - Salik Health Care, Inc., Temple University Cancer Center.

I. Nuclear Medicine Administrations

^{125}I and/or ^{131}I > 30 microcuries	**Therapeutic Administration Other Than ^{125}I and/or ^{131}I**
1. Written Directive: The "Radiopharmaceutical Therapy Order Form" must be completed, signed and dated by the physician prior to administration.	1. Written Directive: See item 1 for ^{125}I and/or ^{131}I > 30 uCi.
a) If a delay in treatment in order to provide a written revision to the "Radiopharmaceutical Therapy Order Form" would jeopardize a patient's health, an oral revision may be given, and must be documented immediately in the treatment record. A revised form must be signed and dated by the physician authorized user or a physician under his/her supervision within 48 hours of the oral revision.	a) See item 1.a. for ^{125}I and/or ^{131}I > 30 uCi.
b) If a delay in treatment in order to complete the "Radiopharmaceutical Therapy Order Form" would jeopardize a patient's health, an oral directive may be given, and must be documented immediately in the treatment record, and the "Radiopharmaceutical Therapy Order Form" must be prepared within 24 hours of the oral directive.	b) See item 1.b. for ^{125}I and/or ^{131}I > 30 uCi.
c) All revisions to the "Radiopharmaceutical Therapy Order Form" must be signed and dated by the physician authorized user or his/her designee. All revisions are to be made prior to the administration of the radiopharmaceutical dosage.	c) See item 1.c.for ^{125}I and/or ^{131}I > 30 uCi.
d) If the "Radiopharmaceutical Therapy Order Form" is incomplete, vague or unclear, the technologist should immediately notify the chief technologist and/or the physician authorized user.	d) See item 1.d. for ^{125}I and/or ^{131}I > 30 uCi.

^{125}I and/or ^{131}I > 30 microcuries	**Therapeutic Administration Other Than ^{125}I and/or ^{131}I**
2. Patient Identification: Part A - Patient Verification, of the "Treatment/Dose Verification Form" must be completed, including the signatures of both the physician and technologist who confirm the identity of the patient to be treated.	2. Patient Identification: See item 2. for ^{125}I and/or ^{131}I > 30 uCi.
3. Dosage Verification: Part C - Radiopharmaceutical Verification, of the "Treatment/Dose Verification Form" must be completed, including the signatures of the physician and technologist who verify the dosage as measured to be within 10% of the dosage prescribed.	3. Dosage Verification: Part C - Radiopharmaceutical Verification, of the "Treatment /Dose Verification Form" must be completed, including the signatures of both the physician and technologist who verify that the dosage shown on the label of the unit dose container is in agreement with the dosage prescribed.

II. Radiation Oncology Implants

Brachytherapy

1. Written Directive: The Pre-plan section of the "Brachytherapy Authorization Form" must be completed, signed and dated by the physician prior to implantation. The Final Plan section of this form must be completed by the physician after implantation but prior to the completion of the procedure.

   a) If a delay in treatment in order to provide a written revision to the "Brachytherapy Authorization Form" would jeopardize a patient's health, an oral revision may be given, and must be documented immediately in the treatment record. A revised form must be signed and dated by the staff radiation oncologist or his/her designee within 48 hours.

   b) If a delay in treatment in order to complete the "Brachytherapy Authorization Form" would jeopardize a patient's health, an oral directive may be given, and must be documented immediately in the treatment record, and the "Brachytherapy Authorization Form" must be completed within 24 hours of the oral directive.

   c) All revisions to the "Brachytherapy Authorization Form" must be signed and dated by the staff radiation oncologist or his/her designee. All revisions in dose or dose fractionation are to be made prior to the treatment with the revision.

   d) If the "Brachytherapy Authorization Form" is vague or unclear, inconsistent with the treatment plan, or inconsistent with the capabilities of the equipment, the technologist should immediately notify (a) the chief technologist, (b) physics or dosimetry staff, and (c) the staff radiation oncologist.

2. Patient Identification: Prior to administration, the identity of the patient will be verified as the individual named on the "Brachytherapy Authorization Form" by (1) verbally ascertaining and confirming the patient's name, and either (2) use of the patient's Hospital ID, or (3) use of a photograph of the patient.

High Dose Rate Remote Afterloading (HDR)

1. Written Directive: The "HDR Written Directive Form" must be completed, dated and signed by an authorized user prior to the administration of any brachytherapy dose from the HDR.

   a) If a delay in treatment in order to provide a written revision to the "HDR Written Directive Form" would jeopardize a patient's health, an oral revision may be given, and must be documented immediately in the treatment record. A revised form must be dated and signed by the staff radiation oncologist or his/her designee within 48 hours.

   b) If a delay in treatment in order to complete the "HDR Written Directive Form" would jeopardize a patient's health, an oral directive may be given, and must be documented immediately in the treatment record, and the "HDR Written Directive Form" must be completed within 24 hours of the oral directive.

   c) All revisions to the "HDR Written Directive Form" must be signed and dated by the staff radiation oncologist or his/her designee. All revisions in dose or dose fractionation are to be made prior to the treatment with the revision.

   d) If the "HDR Written Directive Form" is vague or unclear, inconsistent with the treatment plan, or inconsistent with the capabilities of the equipment, the technologist should immediately notify (a) the chief technologist, (b) physics or dosimetry staff, and (c) the staff radiation oncologist.

2. Patient Identification: Prior to administration, identity of the patient will be verified as the individual named on the "HDR Written Directive Form" by (1) verbally ascertaining and confirming the patient's name, and either (2) use of the patient's Hospital ID, or (3) use of a photograph of the patient.

3. Dosage Verification: The person administering the brachytherapy treatment will be responsible for assuring that the prescribed radionuclide, treatment site, and total dose are in accordance with the "Brachytherapy Authorization Form" and the treatment plan.

3. Dosage Verification: The person administering the brachytherapy treatment will be responsible for assuring that the prescribed radionuclide, treatment site, and total dose are in accordance with the "HDR Written Directive Form" and the treatment plan.

Teletherapy

1. Written Directive: The "Treatment Plan General Orders Form" must be completed, signed and dated by the staff radiation oncologist prior to administration.

   a) If a delay in treatment in order to provide a written revision to the "Treatment Plan General Orders Form" would jeopardize a patient's health, an oral revision may be given, and must be documented immediately in the treatment record. A revised "Treatment Plan General Orders Form" must be signed and dated by the staff radiation oncologist or his/her designee within 48 hours.

   b) If a delay in treatment in order to complete the "Treatment Plan General Orders Form" would jeopardize a patient's health, an oral directive may be given, and must be documented immediately in the treatment record. The "Treatment Plan General Orders Form" must be completed within 24 hours of the oral directive.

   c) All revisions to the "Treatment Plan General Orders Form" must be signed and dated by the staff radiation oncologist or his/her designee. All revisions in dose or dose fractionation are to be made prior to the treatment with the revision.

   d) If the "Treatment Plan General Orders Form" is vague or unclear, inconsistent with the treatment plan, or inconsistent with the capabilities of the equipment, the technologist should immediately notify (a) the chief technologist, (b) physics or dosimetry staff, and (c) the staff radiation oncologist.

2. Patient Identification: Prior to administration, the identity of the patient will be verified as the individual named on the "Treatment Plan General Orders Form" by verbally ascertaining and confirming the patient's name, and the use of a photograph of the patient, which also shows the treatment field.

3. Dosage Verification: The technologist administering the treatment is responsible for assuring that the patient, the treatment site, the cumulative dose, and the dose fraction are in agreement with the "Treatment Plan General Orders Form" and the treatment plan.

4. Calculation Review:

   a) Isodose Plans - all isodose plans will be checked by performing a hand calculation to verify the results. Preferably this will be done by a member of the physics staff who did not originally generate the plan. All plans should be signed by the initial person generating the plan, the person checking the plan, and the physician, prior to its use for patient treatment.

   b) Other Calculations - all calculations relating to target dose, beam-on-time, and doses to various sites of interest, whether performed by hand or by computer, will be checked by a hand calculation by a person, preferably a member of the physics staff, who did not perform the original calculation. Calculations will be checked prior to being used for patient treatment. Doses and beam-on-times will be recorded and totaled to the nearest rad (cGy) or timer setting, respectively.

   c) Thermoluminescent Dosimetry - a physicist will verify the interpretation of all TLD results.

5. Chart Review: The physics staff and the Chief Technologist will review the patient's treatment charts following the first treatment with a new or modified field and/or no later than weekly thereafter, and following the patient's final treatment. Chart review will include verification that beam-on-times and doses are being recorded and totaled correctly, verification that the course of treatment is adhering to the physician's prescription, and assurance that the methods of treatment are physically compatible with the prescribed course of treatment and the way it is being recorded in the patient's chart.

III. Radiation Safety Department

1. A representative sample of patient administrations shall be evaluated by the Radiation Safety Department on an annual basis.

2. All recordable events as defined by the NRC will be investigated and evaluated by within 30 days of the discovery of the event. The records of the investigation shall be kept by the Radiation Safety Department for at least 3 years.

3. All misadministrations as defined by the NRC will be investigated and evaluated, including the proper notifications, reports and record keeping requirements, as specified in 10 CFR 35.33.

4. The number of cases audited during Radiation Safety's periodic review will be doubled for each recordable event uncovered, and all cases will be audited if a misadministration is uncovered during this review.

5. The policies and procedures included in Temple University's Quality Management Program will be reevaluated after each annual review by both the Radiation Protection Committee and the Salik Health Care, Inc. Quality Improvement Committee to determine the effectiveness of the program, and to make any changes deemed necessary. A record of this review shall be kept by the Radiation Safety Department for at least 3 years.

6. Modifications to the QMP shall be submitted to the NRC within 30 days after the modification has been made.

7. The Training and Information Department of the Temple University Environmental Health and Safety Office will annually coordinate training and/or instruction of supervised individuals in the details of Temple's written Quality Management Program.

THE TEMPLE UNIVERSITY
CANCER CENTER

Memorandum

Date: 7 August 1995

To: Kurt Bodison, RSO

From: Lee T. Myers

Subject: Regular Monthly Reports

Here is the monthly report for July. Because of AAPM meeting, the review was a little late, but still done in a timely fashion. The review process has been very helpful. We are improving the organization of our documentation, reviewing and formalizing the existing procedures, and attempting to add important new QA procedures. As always, we would welcome your input, especially with respect to improving the procedures for the regular QA of radiation sources.

Let me know if you would like any other information included on this form, such as training for new employees, number of reported variances, or whatever. We can provide more detail or less, as you prefer. After using this standard form for a few months, we will go to computer generated reports. We will also have regular monthly and daily QA reports automatically generated, which we can provide to you if you wish.

As we discussed, we need a mechanism to close the loop. A standard form for you to send to us when we are delinquent, and/or something (maybe quarterly) to let us know that you have received the information.

EXHIBIT 2

3322 NORTH BROAD STREET, P.O. BOX 38346, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092
A SALICK HEALTH CARE AFFILIATE

THE TEMPLE UNIVERSITY CANCER CENTER

Physics Monthly QA Review Form

(rev. 1::form=radQAmo.doc)

Date of Review: 8/7/95 for month of 7/95

1. Simulator

mechanical checks	✓
safety checks	✓
image quality	✓
review of daily checks	✓

X-ray calibrated 7/14/95 by Bald

2. Cobalt-60

Decayed output: 79.3 cGy/min Measured output: 79.9 cGy/min

timer linearity	✓ *
mechanical checks	✓
safety checks	✓
review weekly congruence films	✓
review daily checks	✓

3. Clinac-1800

Output Spotchecks

6X	1.01	18X	1.006 **
6e	0.99	9e	0.99
12e	1.017	16e	1.023
20e	1.006		

safety checks	✓
mechanical checks	✓
review daily checks	✓

4. HDR-Ir192

Decayed output: 7.75 Ci Measured output: 8.077 Ci

timer linearity	✓
mechanical checks	✓
safety checks	✓
applicator inspection	✓
review daily checks	✓

5. Annual and Quarterly Checks on Schedule

Simulator	✓	Cobalt	✓ ***	Linac	✓
HDR	✓	brachy	✓	equipment	✓

6. Comments

*timer linearity was not measured over full range in July.
**Needed adjustment on 7/13/95
*** Cobalt Annuals currently in progress

Reviewed by Gail T. Myers

3322 NORTH BROAD STREET, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092
AN AFFILIATE OF SALICK HEALTH CARE, INC.

THE TEMPLE UNIVERSITY CANCER CENTER

Physics Monthly QA Review Form

(rev. 1::form=radQAmo.doc)

Date of Review: 11/2/95 for month of October

1. Simulator

mechanical checks	✓
safety checks	✓
image quality	✓
review of daily checks	✓

2. Cobalt-60

Decayed output: 76.8 cGy/min Measured output: 78.18 cGy/min

timer linearity	✓
mechanical checks	✓
safety checks	✓
review weekly congruence films	✓
review daily checks	✓

3. Clinac-1800

Output Spotchecks

6X	1.015	18X	0.991
6e	1.014	9e	0.991
12e	1.021	16e	0.996
20e	1.015		

safety checks	✓
mechanical checks	✓
review daily checks	✓ *

4. HDR-Ir192 ***

Decayed output: 5.58 Measured output: —

timer linearity	—
mechanical checks	✓
safety checks	✓
applicator inspection	✓
review daily checks	✓

5. Annual and Quarterly Checks on Schedule

Simulator	✓	Cobalt	✓	Linac	**
HDR	✓	brachy	✓	equipment	✓

6. Comments

* baseline values need to be adjusted.
** Linac Annual overdue
*** HDR monthly QA not done in October.

Reviewed by [signature]

EXHIBIT 3

3322 NORTH BROAD STREET, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092

THE TEMPLE UNIVERSITY CANCER CENTER

MEMORANDUM

Date: 2 February 1996

To: Kurt Bodison, RSO

CC: Patrick Thomas, M.B., B.S.

From: Lee T. Myers, Ph.D.

Subject: Cobalt-60 Annual Calibration

This memo is to inform you that we have completed our annual Cobalt-60 calibration. The machine was calibrated using the TG-21 protocol and found to agree with the calculated decay output to within 2%. We measured timer linearity out to 10 minutes and found it to be excellent. In addition, we checked output factors, attenuation factors, and beam symmetry. We did mechanical checks on the gantry and collimator as well as the regular safety checks. In spite of its age, the Cobalt unit is functioning well.

The Cobalt annual is included as a comment in my monthly report for January. I have also attached a copy of our QA schedule for all of our equipment. It is included so that you can review it when you receive my monthly reports. The daily schedules are not included, just the monthly, quarterly, and annual activities. Although there is no key, I think the markings should be evident. If you have any questions, please give me a call.

Thank you for your continued support.

LTM/ltm

Attachments: January QA report

QA memo and shedule for 1996

EXHIBIT 4

3322 NORTH BROAD STREET, P.O. BOX 38346, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092

A SALICK HEALTH CARE AFFILIATE

THE TEMPLE UNIVERSITY CANCER CENTER

Physics Monthly QA Review Form

(rev. 1::form=radQAmo.doc)

Date of Review: 2-2-96 for month of JANUARY 1996.

1. Simulator

mechanical checks	✓
safety checks	✓
image quality	–
review of daily checks	✓

2. Cobalt-60

Decayed output: 74.47 Measured output: 73.4

timer linearity	✓
mechanical checks	✓
safety checks	✓
review weekly congruence films	✓
review daily checks	✓

3. Clinac-1800

Output Spotchecks

6X	101.3	18X	101.5
6e	99.1	9e	98.2
12e	100.0	16e	100.1
20e	101.5		

safety checks	✓
mechanical checks	✓
review daily checks	✓

4. HDR-Ir192

Decayed output: Measured output:

timer linearity	
mechanical checks	
safety checks	
applicator inspection	
review daily checks	

NO HDR done in JANUARY

5. Annual and Quarterly Checks on Schedule

Simulator	✓	Cobalt	✓	Linac	✓
HDR	✓	brachy	✓	equipment	✓

6. Comments

COBALT ANNUAL CALIBRATION COMPLETED.

Reviewed by Lee T. Myers

3322 NORTH BROAD STREET, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092
AN AFFILIATE OF SALICK HEALTH CARE, INC.

THE TEMPLE UNIVERSITY CANCER CENTER

HDR Daily QA Checklist

(revised 20 Dec 1996 :: file=hdrfm4.doc)

Today's Date:_____

Date of last monthly spotcheck:_____

1. Unlock source, inspect room, and all applicators to be used.	
2. Using survey meter, record exposure rate on side of HDR housing.	mR/hr
3. Using simulator, film 6F bronchial catheter (XV film, 100 kVp, 600 mAs) with dummies.	
4. Without moving catheter relative to film, remove dummies, and attach catheter to HDR.	
5. Check TV monitor and audio channels.	
6. Select standard 99, switch rt key to autoradiograph mode (run for 0.1 s).	
7. Check film for congruence.	
8. Switch back to normal mode and run standard 99.	
9. Check source indicator lights and source status indicators	
10. Check interrupt.	
11. Read radiation level with source out from radiation exit port monitor.	mR/hr
12. Check door interlock.	
13. Check emergency off at HDR unit.	
14. Check emergency off on wall in room.	
15. Check emergency off at console.	
16. Daily activity decayed from last calibration.	Ci
17. Daily activity from HDR console.	Ci
18. Generate test program card from treatment planning, and load.	
19. Planning, HDR, and decayed activities agree.	
20. Run test program. Dwell times agree with computer plan.	
21. Check emergency cart (forceps, cutter, suture removal).	
22. Check printer paper at console.	
23. Notify RSO of patient treatment times	

QA done by:_____ Time:_____

EXHIBIT 5

3322 NORTH BROAD STREET, P.O. BOX 38346, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092

THE TEMPLE UNIVERSITY CANCER CENTER

Memorandum

Date: 26 December 1996

To: Patrick Thomas, M.B.,B.S.
Chairman, Radiation Oncology

From: Lee T. Myers, Ph.D.
Chief Physicist

Subject: Physics Quality Assurance Schedules in Radiation Oncology

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Here are the QA schedules that you requested. They are tables taken from the Task Group 40 report on Comprehensive Quality Assurance in Radiation Oncology developed by the American Association of Physicists in Medicine. In terms of NRC equipment, we are fully TG-40 compliant. Because of license conditions, we do quarterly checks monthly. The recommended weekly checks are done before each treatment.

To assure compliance, we have revised several of our existing QA forms. First, the monthly QA review form has been revised to include the dates of each monthly check,as well as the last annual check (see enclosure). This review form will be signed by the department chair and the radiation safety officer. Second, the monthly QA Checklist has been revised (see enclosure) to include (1)a check for the length of the guide tubes and (2)direction to attach the date of the last monthly spot-check to the HDR console. Finally, the daily QA checklist will include the date of the last monthly spot-check (see enclosure).

For your review, I have also included the portions of 10 CFR 35 that are relevant to radiation oncology, sections on sealed sources and teletherapy. Understand that there are sections of Part 19 and Part 20 that we need to satisfy, but these are not directly related to machine QA. Cobalt teletherapy and use of sealed sources are primarily regulated by specific regulations in Title 10. The HDR remote afterloader is primarily regulated by the conditions of our license. It has only recently come to my attention that I do not have a complete record of the conditions of our license. Kurt will be giving that to me today. I will provide you with a summary of the relevant QA issues that are included there.

As always, we are open to feedback and continuous quality improvement. Please let me know if you need any additional information or have any other suggestions for further improvement of our program.

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xc: Ladawna Adams, M.S.N.
Robert Scanlon, D. Ed.

EXHIBIT 6

3322 NORTH BROAD STREET, P.O. BOX 38946, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092
A SALICK HEALTH CARE AFFILIATE

THE TEMPLE UNIVERSITY CANCER CENTER

Memorandum

Date: 25 November 1996

To: Kurt Bodison, RSO

From: Lee T. Myers, Ph.D.

Subject: NRC Concerns over Radiation Oncology QA activities

The NRC was concerned that the January, 1995 annual calibration for the Cobalt unit was not complete. It left out checks of output over the range of field sizes currently used. As you know, our more recent annual calibrations were considered sufficient. Field size dependence was measured. The January, 1995 calibration was done during a previous site visit, when it was discovered that an annual calibration had not been done during the previous year. We were cited for two deficiencies. My notes indicated that initially we needed to extend the range of linearity checks for the treatment timer. After we did that, the inspector indicated that we needed to do an annual calibration. We calibrated the machine output for a standard 10x10 field, but did not check output versus field size. Although I have nothing in my notes about any discussions relating to the need to measure field size dependence, we were making every effort to comply with NRC regulations. I remember asking the inspector if he wanted to review our calibration before he left. He said that it would be reviewed during the next visit.

The second concern was about monthly spot-checks for the HDR not being complete. In particular, no monthly checks were done from April 25 to July 1, 1995, from September 9 to November 6, 1995, and from June 10, 1996 to October 11, 1996. The May, 1995 calibration was not done. The single patient treated in May, started treatment on May 17, before the scheduled time for the monthly spot-check. One patient was treated in early June, and the new source was installed at the end of the month.. The new source was calibrated in July, prior to use for any patients. Four patients were treated during the month of October, 1995. My report to you for that month indicates that we were aware that the monthly spot-check had not been done. This was the month when we were dealing with the report of a misadministration to the NRC. Physics was very busy dealing with this issue with minimal staff. During the last time frame, very few patients were treated. The last patient in this time interval started treatment on July 10, 1996. No patients were treated from July 12, 1996 until October 14, 1996. A monthly spot-check was done on October 11, 1996. It is my understanding that we do not need to do a monthly spot-check if we are not treating patients. If this is not the case, I need clarification. I believe we have careful, complete, accurate, and reasonable QA for the HDR, especially in the context of our light patient load. We attend to our equipment and try to comply with regulations. As always, we respond to feedback and guidance from the regulatory agencies.

We seem to have stopped the monthly QA reports to radiation safety. I would like to resume that, hoping that we can establish a more effective feed back loop. If you have the information on hand, you can effectively respond to questions from the NRC. I certainly would appreciate a reminder from radiation safety that my monthly report is due. Let me know if you need any more information.

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xc: Patrick Thomas, M.B.,B.S.
Ladawna Adams, M.S.N.
Robert Scanlon, Ed. D.

EXHIBIT 7

3322 NORTH BROAD STREET, P.O. BOX 38346, PHILADELPHIA, PA 19140 (215) 707-4000 FAX (215) 707-8092
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