FEB - 2 1995

Ruth Blodgett
Senior Vice President
Berkshire Medical Center
725 North Street
Pittsfield, Massachusetts 01201

SUBJECT: ROUTINE INSPECTION NO. 030-00245/94-001 and 030-01942/94-001

Dear Ms. Blodgett:

This letter refers to your December 9, 1994 correspondence, in response to our November 16, 1994 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

No reply to this letter is required. Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:
John R. McGrath

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Docket Nos. 030-01942
030-00245

License Nos. 20-12009-01
20-12009-03

cc:
Commonwealth of Massachusetts

Distribution:
Public w/encl
Nuclear Safety Information Center (NSIC) w/encl
Region I Docket Room (w/concurrences) w/encl

DOCUMENT NAME: S:\PENDING\BERKS.RL

OFFICE	DRSS/RI	DRSS/RI	DRSS/RI	DRSS/RI
NAME	ICzerwinskyj/amw	JMcGrath		
DATE	02/01/95	02/2/95	02/ /95	02/ /95

RETURN ORIGINAL TO REGION I

OFFICIAL RECORD COPY

IE 07

Berkshire
Medical Center
BERKSHIRE HEALTH SYSTEMS

725 North Street
Pittsfield, MA 01201
(413) 447-2000

December 9, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Gentlemen:

Subject: Reply to a Notice of Violation
Docket No. 030-00245 License No. 20-12009-01
030-01942 20-12009-03

This is in response to your letter of November 16, 1994, regarding the notice of violations as a result of your routine inspection conducted on October 5 and 6, 1994.

Item A. Failure to conduct a formal annual review of the Radiation Safety Program.

On September 1, 1994, the RSO submitted the annual briefing to management. A copy of this briefing is appended as ATTA. The report contains the radiation safety program audit performed by our consultant William A. Roventine on October 26, 1993. His report includes an annual review of the radiation safety program dated October 19, 1993. Since the review was done less than eleven months ago, the RSO thought it could be performed again after September without violating our licenses condition. On October 18, 1994, the RSO conducted a formal annual review of the radiation safety program. A copy of the review is appended as ATT A1. In the future, the annual review will be performed before submitting the annual briefing to management.

Item B. Failure to use a radiation detection system having its lower limit of detection higher than 200 disintegrations per minute.

We have used the Sigma 420 gamma camera for counting wipe samples. In order to achieve the maximal sensitivity the camera must be operated with the collimator removed and with the window positioned at the most prominent photopeak of the pulse height spectrum of iodine 131. With this setup, on April 4, 1994 a sample of 40 nanocuries of iodine 131 was recorded 31, 980 counts in five minutes. 200 disintegrations per minute would require about 80 counts per five minutes. This level of contamination appears to be detectable. Since the camera is primarily used for clinical imaging and only limited time is available for radiation safety use, we would like to obtain a system which is in full compliance with the regulatory requirements. We are in the process of procuring a CAPRAC wipe test counter. As soon as we receive it, all wipe tests requiring to detect less than 200 disintegrations per minute will be done with this

Berkshire
Medical Center
BERKSHIRE HEALTH SYSTEMS

725 North Street
Pittsfield, MA 01201
(413) 447-2000

counter.

Item C. Failure to provide training for Nuclear Medicine Staff.

The corrective actions have been taken to provide inservice education to the Nuclear Medicine Staff. On October 14,1994, the staff participated in a videotaped program written by John W. Duley. The program entitled Radiation Protection Standards contains the new 10 CFR Part 20. The record of training is appended as ATT C1. Besides the new 10 CFR Part 20, the Nuclear Medicine Staff have received the following radiation safety inservice educations:

On February 10, 1994, the instruction was given by the RSO on the revised quality management program. The record of the training is appended as ATT C2.

On December 7, 1993, training on QMP was conducted by the RSO. The record of training is appended as ATT C3.

On December 13, 1993, a videotaped program was displayed to all Nuclear Medicine Staff. The program entitled Hospital Radiation Protection Practices provides general hospital employees with a basic understanding of radiation. Topics include natural background radiation, hospital radiation sources, biological effects of ionizing radiation, the general principles of radiation protection in a hospital setting, radiation safety requirements in the Cobalt 60 teletherapy as well as Nuclear Medicine Department and nursing care requirements for iodine 131 therapy patients. The record of this presentation is appended as ATT C4.

Please let me know if you have any questions regarding this matter.

Enclosures.

Sincerely,

Ruey R. Wu, Ph.D.
Radiation Safety Officer

Berkshire
Medical Center
BERKSHIRE HEALTH SYSTEMS

725 North Street
Pittsfield, MA 01201
(413) 447-2000

cc: Ruth Blodgett
Senior Vice President
Ambulatory Care

Joseph Levine, M.D.
Chairman of Radiation Safety Committee

Steve Bennett
Administrative Director of Radiology

ATT A

BERKSHIRE MEDICAL CENTER

ANNUAL BRIEFING TO MANAGEMENT

THE RADIATION SAFETY PROGRAM

Submitted by: Ruey R. Wu

Ruey R. Wu, Ph.D.
Radiation Safety Officer

Date: September 1, 1994

The radiation safety activity at Berkshire Medical Center during the last twelve months can be summarized as follows:

1. On June 29 and 30, 1993, NRC conducted a routine safety inspection and resulted in enforcement actions against Berkshire Medical Center. The enforcement actions include issuance of a notice of a series violations, an imposition of a civil penalty, and an enforcement conference held at NRC Region I office.

2. In response to the enforcement actions imposed by NRC, a consulting physicist, Mr. William Roventine, was hired to conduct a comprehensive review and audit on our radiation safety program. He submitted his report of the audit on October 26, 1993. A copy of the report is appended as ATT 1.

3. The Radiation Safety Committee held several special meetings from November 15, 1993, through December 13, 1993, to discuss the radiation safety issues recommended in the radiation safety audit and to formulate the strategy of implementing the radiation safety program.

4. During the routine Radiation Safety Committee meeting held on April 27, 1994, the Radiation Safety Officer submitted the report of radiation safety compliance achieved. A copy of the compliance list is appended as ATT 2.

5. On May 24, 1994, a mock NRC inspection was conducted by Gerry Cryan and Steve Bennett. It was concluded that the overall readiness of Berkshire Medical Center appears to be in good shape for the upcoming NRC inspection. A copy of the report is appended as ATT 3.

6. On June 15, 1994, a routine safety inspection was conducted by a NRC staff. The inspection had emphasized in the radiation safety program related to the teletherapy license and had also examined the corrective actions for some violations cited in the previous inspection. In the meeting of discussing findings held by the inspector with Mr. Thomas Romeo and other members of our staff at the conclusion of the inspection, the inspector stated that no specific violations had been found. However, he claimed that he might come back in the near future to examine other areas not covered in this inspection, while collecting some information of corrective actions that had already been taken. As of today, we have not received the letter from NRC regarding this inspection. It is advised that all staff should make a great effort continuing to keep full compliance of the radiation safety program.

7. The annual summary of the occupational radiation dose record of all radiation workers for the 1993 calendar year is appended as ATT 4. One recorded 295 mrems which is the highest dose among 174 workers. Records for the rest of the group are 10 received dose between 100 and 249 mrems, 37 between 1 and 99 mrems, and 126 in the zero rem category. The average occupational exposure

of our personnel is well below that of other hospitals reported in the issue of August 1994 HPS Newsletters.

E. The new standards for protection against radiation in 10 CFR 20 became effective on January 1, 1994. One of the most important changes is the way of specifying the occupational dose limits. The total effective dose equivalent (TEDE) is used and is limited to 5 rems per annum for adults. The total effective dose equivalent is the sum of the deep-dose equivalent and the committed effective dose equivalent. In response to these changes, the new ALARA quarterly investigational levels have been established. The new ALARA quarterly investigational levels and the definition of the total effective dose equivalent are appended as ATT 5.

BERKSHIRE MEDICAL CENTER

RADIATION SAFETY PROGRAM

AUDIT

Date submitted: 26 October 1993

Performed by: William A. Roventine

William A. Roventine, M.Sc.
Certified Radiological Physicist

A. INTRODUCTION

A comprehensive audit of the BMC Radiation Safety Program, operating under NRC license No. 20-12009-01, was conducted throughout the month of September and through the beginning of October 1993 with the assistance of the Radiation Safety Officer and other staff members. The attached Radiation Safety Compliance checklist shows the various program components evaluated and the general compliance status of each. In addition, radiation safety activities in the brachytherapy and Pathology Department (limited review) were also evaluated. Listed below are specific detailed findings and recommendations. These have been classified into three categories. Primary Findings and Recommendations include items associated with moderate to significant compliance issues or have the potential for escalating into such issues. Secondary Findings and Recommendations include items associated with minor compliance issues. Suggestions and Recommendations include items which are not associated with specific non-compliance findings, but are intended to strengthen the various radiation safety program components to minimize the probability of future compliance issues. The numerical order of items within each of these three groupings is not intended to imply any increasing or decreasing level of importance or severity.

B. PRIMARY FINDINGS AND RECOMMENDATIONS

1. Each department appears to be responsible for arranging and documenting the required (10CFR 19.12) periodic radiation safety training. These are generally presented using a video format and do not usually involve the participation of the Radiation Safety Officer or designee to answer questions. The Radiation Safety Officer should be more directly involved with the various radiation safety training sessions for radiation workers and support personnel. Centralized records of training documentation and attendance should be maintained by the RSO. These should include the date presented, a description or outline of topics covered, and names of attendees and instructor. The present video format should be supplemented with a question and answer segment and review of facility specific procedures where appropriate. In particular, more extensive radiation safety inservice should be provided for the Nuclear Medicine and Pathology areas at this time.

2. Current written procedures for ordering radioactive material only address material used in Nuclear Medicine and Brachytherapy, not the Pathology area. Formal procedures for ordering and approving requests for radioactive material for use in areas outside Nuclear Medicine and Radiation Therapy should be developed and implemented to ensure proper control and compliance with license conditions.

3. The ALARA program requires that management conduct a formal annual review of the radiation safety program, including ALARA considerations. This is usually done in conjunction with the Radiation Safety Committee's annual review of the program. As cited in the recent NRC inspection report, this was not performed during the

past year. Presently, this independent audit of the BMC radiation safety program is intended to facilitate the current review of the program by the Radiation Safety Committee. Management needs to ensure that future annual reviews are conducted by the Radiation Safety Committee. This should be facilitated by the RSO's annual audit and include a review of current policies and procedures, as well as any incidents or problems associated with the program during the past year. The Committee's review should be documented in the minutes, including any recommendations for changes or areas of future concern. At management's discretion, program review by an independent consultant may also be included.

4. Radiation safety operating procedures as submitted to NRC and modified in associated correspondence are available, but not easily referenced because they are distributed among several files and documents. These various procedures should be consolidated and assembled into a formal Radiation Safety Office Policy and Procedure Manual to facilitate easy reference and review.

5. There appears to be no general written procedure for storage and inventory of radioactive material (10CFR 35.21). Such a procedure needs to be developed and implemented.

6. The RSO is required to brief management annually on the byproduct material program. As noted in the recent NRC inspection report, this had not been done in the past year. This has been addressed currently by the presentation of a special management inservice on 8-31-93 and by briefing management on the results of this audit on 10-26-93. In the future, the RSO needs to brief management annually on the scope of the byproduct material program. This briefing should include a summary of the types of use, number of authorized users, activity levels of radioisotopes received and used, volume of diagnostic and therapeutic procedures performed, any misadministrations or recordable events significant radiation problems encountered during the past year, and any significant changes in radiation safety policies or regulatory requirements. A record of these annual management briefings should be included in the Radiation Safety Committee minutes. I suggest these management briefings be routinely scheduled for the same month each year.

7. An annual written audit of the radiation safety program by the RSO was not conducted in the past year as cited in the recent NRC inspection report. The RSO needs to conduct such an audit annually and report the findings to the Radiation Safety Committee to facilitate their annual review of the program. The NRC compliance checklist utilized in this independent audit should be used as a guide for future audits by the RSO.

8. The present Radiation Safety Committee charter does not specify quorum requirements. The committee membership does not appear to include a research representative. The Committee should formally adopt the model Radiation Safety Committee charter and appoint a research representative to the Committee.

9. The written dose calibrator procedure for routine checks of constancy, linearity, accuracy, and geometry currently in the Nuclear Medicine policy manual is not sufficiently detailed and needs to be revised to conform with the model procedure adopted by BMC. The daily constancy check needs to be performed on all clinical settings routinely used, including both manual and push button settings, as appropriate. The constancy check should be performed prior to each days assay of patient doses, including weekends and holidays. In addition, the dose calibrator HV (test) setting should be checked and the value recorded as part of the daily constancy check. The detector bias battery should be replaced when the HV value drops below 130 volts. The Nuclear Medicine staff have been instructed to use this procedure.

10. All survey meters have been calibrated within the past year. However, the direct reading pocket dosimeters have not been calibrated since 1991. These dosimeters need to be calibrated annually and should be checked for accuracy, linearity, and leakage.

11. Presently, there is no survey meter available in Pathology for routine monitoring. Consideration should be given to the acquisition of another survey meter for assignment to the Pathology Department.

12. When assaying patient diagnostic doses in the dose calibrator, technologists should record the actual value displayed in the utilization log, rather than rounding off to the prescribed dose value. The dose record should also include the initials of the technologist performing the assay.

13. As previously mentioned in the QMP annual review, Nuclear Medicine technologists should assay I-131 therapy doses in a consistent manner. The therapy dose should be assayed by measuring the initial activity and the activity remaining in the vial after administration. The administered dose is the difference between these two values. The prescribed dose of I-131 should also be listed in the utilization log for each therapy patient.

14. Although regulations do not require assay of beta emitters, routine assay of P-32 therapy doses in the dose calibrator is recommended.

15. Presently leak testing of sealed sources is performed by wiping all sources with the same single wipe and submitting it to Siemens for assay as coming from a Cs-137 source. This could result in cross contamination of sources and failure of Siemens to assay wipe for lower energy sources. Separate wipes should be used for wiping each source and the source properly identified. Brachy sources stored in safe drawers may be wiped in small groups of similar sources and source strengths if necessary for ALARA considerations. The model leak test procedure should be adopted or used as a guide for development of a written policy for proper leak testing procedure.

16. All sealed sources, not just brachy sources, at BMC need to be inventoried quarterly regardless of their activity. The quarterly inventory documentation should also include model, serial number, and

activity of each source as well as the source storage location. A spread sheet type of inventory form can be used to facilitate these quarterly inventories. Such inventories should be conducted in Nuclear Medicine and other hospital areas where sealed sources are stored.

17. The model procedure for periodic surveys, which BMC has adopted, requires external surveys and contamination checks be performed in radiopharmaceutical waste storage areas on a weekly basis. I-131 and P-32 therapy waste is routinely stored in the brachy room. However, this area is only surveyed quarterly and not checked for contamination. The required weekly surveys and contamination checks should be implemented and properly documented.

18. Records of surveys and contamination checks should be reviewed by the RSO on a monthly basis to comply with the model procedure for periodic surveys adopted by BMC. This may be accomplished by site visits to each area or having copies of the surveys forwarded to the RSO for review.

19. Presently there is about two years worth of I-131 and P-32 therapy waste surrounding the brachy storage safe in the brachy room with no apparent log or inventory of this waste. This waste should be relocated to an isolated section of the brachy room and waste which has decayed to background discarded. The remaining waste should be inventoried and a waste log established and maintained which includes the isotope and activity, date placed in storage, final disposal and survey results, and initials of person performing survey or disposal, etc.

20. Pathology RIA, "in-vivo", and research radioactive waste is presently stored for decay in a basement storage area. It is not clear, at this time, if any of the RIA waste comes under the general license exemption and if it is segregated from the other waste. The physical conditions of this storage area are not conducive to proper waste management. Periodic monitoring of the area is not evident and a description of the area does not appear in the current license application. This waste needs to be relocated to a more suitable storage location. In the interim, this waste needs to be characterized and properly segregated for decay. Waste that has decayed to background (greater than 10 half-lifes) or can be disposed of as general license waste should be removed and properly disposed of. A proper waste log should be established and periodic surveys and contamination checks instituted. The location and description of this (preferably relocated) waste storage area needs to be submitted to NRC as an amendment to update our license application.

21. I-131 therapy doses greater than 30 mCi should be administered by the authorized user rather than the technologist. The RSO should be present during administration to survey the areas adjacent to the patient's hospital room.

22. Presently, there is no written protocol for P-32 therapy

administration. A written protocol needs to be developed and implemented to address proper procedure and radiation safety considerations, including radiation safety instruction of the patient, the use of beta-syringe shields, eye protection, contamination control, etc.

23. The location of activities involving RIA, "in-vivo" assays, and research (using S-35 and P-32) in the Pathology department and a description of the associated facilities does not appear to have been included in the current license application. The license should be amended to reflect the use of material in the Pathology department.

24. If RIA is performed under the specific license, rather than a general license, I-125 and Co-57 waste needs to be segregated to facilitate storage for decay. Under such circumstances, BMC should consider applying for a general license to avoid the waste disposal requirements of the specific license.

25. The "in-vivo" work such as Schilling and Blood Volume tests in Pathology needs to be evaluated with regard to radiation safety compliance and any necessary corrective actions implemented. Waste from these procedures needs to be treated as specific license waste.

26. The research use of P-32 and S-35 in Pathology needs further evaluation with regard to radiation safety compliance. Periodic surveys and contamination checks need to be implemented if not currently performed, and a beta shield needs to be installed over the hot sink.

C. SECONDARY FINDINGS AND RECOMMENDATIONS

1. Copies of required NRC regulations, license and license conditions are available. However, neither they nor a notice of their availability are posted. The following notice of availability should be added to all posted NRC-3 forms:

> "Copies of NRC regulations, license, license conditions, and operating procedures are available for review in the Radiation Safety Office."

2. Radiation safety orientation for support personnel should be scheduled for Security and Environmental Services prior to the end of the year.

3. Periodic surveys conducted in unrestricted areas (e.g. corridors, exam rooms, bathrooms, offices, etc.) need to be formally documented.

4. There has been a change in the film badge vendor since the current NRC license application was submitted. This needs to be reflected in a ministerial change to the personnel monitoring program.

5. Nuclear Medicine's written policy for the opening and monitoring of radioactive material packages needs to be modified to include trigger

levels for external monitoring and to specify monitoring at both surface and 3 feet to comply with the model procedure which BMC has adopted.

6. Maximum discharge limits should be established for the sink disposal of radioactive material in the Pathology area (e.g. S-35, P-32, Cr-51, etc.).

7. Staff should be informed of the key elements of the ALARA program as part of their periodic radiation safety training and published copies of the program should be available for review.

8. The Radiation Safety Committee minutes should specifically indicate approval, not just review, of the prior minutes and should always specify what action is taken on requests considered by the Committee.

9. The dose calibrator annual accuracy report should include the serial number of each reference source used. Geometry checks should be performed for both vial and syringe configurations. All reports need to be initialed by the RSO.

10. Leak test reports should include the serial number, isotope, and activity of each source tested and need to be initialed by the RSO.

11. Daily external surveys in Nuclear Medicine should be taken at the end, rather than at the beginning of each day and should include additional areas in the scan room as well as the stress testing room. Trigger levels should be assigned and indicated for each location.

12. Weekly contamination checks in Nuclear Medicine should consist of more than two wipes and should be performed in the afternoon rather than early morning. Several additional areas of potential contamination in the hot lab, scan room, and stress testing room should be wiped. Wipes should be counted with an end-window GM survey meter or well type scintillation detector, rather than with the gamma camera.

13. Quarterly surveys of the brachy room should include measurements in the adjacent unrestricted and restricted areas and should be documented on a standard survey form and include a diagram showing measurement locations and actual mr/hr values along with the other required data.

14. Nuclear Medicine's written waste disposal policy needs revision to include the model procedure for return of generators to the manufacturer. The name or the initials of the individual performing the final waste disposal should be indicated in the waste records.

15. Therapy patients discharged with permanent implants or internal doses should be given a written form containing a brief description of the therapy and information on how to contact the RSO or Nuclear Medicine and instructed to show this to their physician should the patient require subsequent medical care or hospitalization.

16. Nursing radiation safety inservice for brachytherapy procedures should be given at least annually by the RSO in the future and proper documentation of training maintained.

17. RIA work areas should be placarded and demarcated from non-radioactive work areas. Basic contamination control measures should be employed with contamination checks performed monthly.

D. SUGGESTIONS AND RECOMMENDATIONS

1. The subscription to 10CFR and periodic supplements to maintain abreast of current and proposed NRC regulations has apparently lapsed for the past two years due to lack of funding. This subscription should be reactivated and maintained on an on-going basis.

2. NRC communications (e.g. regulatory guides, information bulletins, correspondence, etc.) appears to filter down from the Director's office through several management levels before reaching the RSO, and occasionally is directed to other individuals. Administration should take measures to ensure that NRC communications are promptly directed to the RSO to assure timely response and information update. Other individuals in the communication chain may be copied or subsequently informed by the RSO as appropriate.

3. Copies of the monthly film badge reports for each program area should be posted in the respective departments each month so that radiation workers are made aware of their monthly exposure. Currently, they are only posted in Radiology.

4. Presently additions and deletions to the film badge service are made directly with the vendor by both the RSO and Radiology personnel. The RSO should exercise centralized control over the addition or deletion of individuals to the personnel monitoring service.

5. The film badge exchange frequency should be changed from biweekly to monthly as recommended by the RSO. This is a more appropriate frequency and should reduce handling time and cost. This change should be reflected in a ministerial change to the personnel monitoring program.

6. Decisions on changes in film badge vendor should not be made unilaterally solely on economic criteria. The Radiation Safety Committee, along with the RSO, have responsibility for providing this service and selecting an appropriate vendors based upon a number of considerations.

7. Presently all radioactive material shipments are delivered to Nuclear Medicine where they log in and monitor their packages, while transferring others to the respective departments for subsequent log in and monitoring. This system sometimes results in packages for other departments not being monitored and does not facilitate tracking

of packages. The receipt, including logging-in and monitoring, of all radioactive material packages should be centralized in Nuclear Medicine.

8. Presently Nuclear Medicine wipe tests the outer carton and inner container of all packages which they monitor and open. Wipe tests are not required for each package received unless they exceed Type A quantity limits. Rarely are these quantities received. When such wipe tests are necessary, they can more easily be performed using an end window GM detector or well counter, rather than the gamma camera procedure presently employed.

9. An expanded description of the RSO's responsibilities, including a generalized list of duties, should be developed and incorporated as part of the radiation safety program documentation. An example of such a listing is attached as guidance.

10. The RSO should review the Nuclear Medicine department safety records and procedures on a quarterly basis and report findings to the Radiation Safety Committee using a format comparable to the sample Quarterly Review form attached. This not only keeps the RSO and Committee abreast of activities in Nuclear Medicine, but satisfies the JCAH requirements for a quarterly audit or review of the Nuclear Medicine area by the medical physicist.

11. The RSO should audit the Pathology Department radioactive material activities semi-annually (i.e. mid-year and at the time of the annual audit) to monitor compliance with radiation safety procedures and to offer guidance as required.

12. The Cs-137, rather than the Co-57, reference source should be used for the dose calibrator daily constancy check to minimize radioactive decay variations. The daily constancy log should include the dose calibrator model and serial number.

13. A Calicheck device should be purchased to facilitate the quarterly linearity check of the dose calibrator and such tests should be analyzed by the technologist to provide a prompt determination of compliance. Results should still be reviewed and approved by the RSO.

14. Consideration should be given to assaying leak test wipes "in-house" using a scintillation well detector (Nuclear Medicine) rather than sending them out to Siemens so that the results are more readily available.

15. Consideration should be given to adopting the model Xenon-trap testing procedure which would allow for monthly testing, rather than after each use.

16. Radiation safety instruction of hospitalized radiopharmaceutical therapy and brachytherapy patients is required, before authorizing release, to provide guidance to keep radiation exposure to household

members and the public ALARA. Currently, this instruction is provided by staff other than the RSO. The RSO should assume responsibility for this instruction and document same in the patient chart and therapy physics record.

17. Hyperthyroid therapy patients should be given radiation safety instruction by the technologist or individual administering the therapy and standard written precautions.

18. Since I-131 therapies involving hospitalized patients are infrequent, consideration should be given to briefing the nursing staff before each patient therapy to review the appropriate procedures. This need not be done on each shift if the inserviced shift transfers information to the other shifts and written nursing instructions are readily available for each shift to refer to.

19. Consideration should be given to the eventual development of a formal BMC Radiation Safety Manual which can be distributed to users and staff as required.

20. Consideration should be given to the need to amend the possession limits of radioisotopes used in the research area to facilitate future expansion of activities in this area and to accommodate the long range storage of accumulated waste.

21. Depending upon how future physics staffing evolves, consideration should be given to the designation of an assistant Radiation Safety Officer and/or a radiation safety consultant to the Radiation Safety Committee to assist the RSO and Committee in accomplishing its radiation safety program tasks and responsibilities.

NRC RADIATION SAFETY COMPLIANCE CHECKLIST

LOCATION: BMC DATE: 10-19-93

I. 10 CFR Part 19

Part 19.11 Posting Documents

19/94 No NRC Part 19
19/94 No NRC Part 20
19/94 No NRC License and Conditions
4/94 No Notice of availability of above
Yes Form NRC-3 (map)
Note: Operating Procedures
Notice of Violations + Response Posted

Part 19.12 Training

Yes Rad Saf Training conducted (Decentralized)
✓ Date (s) 4/8/93, 4/27/93, 11/92
Some Training Documented
4 Total Nuclear Med Staff
2 Number trained
Note: No Security training documentation
Environmental Services Due November

Part 19.13 Exposure Reports

Yes Exposure reports posted
Yes Staff knows how to get information
Note: Reports posted in Radiology only
Annual + Termination Reports

II. 10 CFR PART 20

OK Highest annual dose 680 mREM
OK Highest quarterly dose 245 mREM
Note: _____

Part 20.105 Levels in Unrestricted Areas

✓ Surveys conducted in unrestricted areas
✓ Highest level in unrestricted areas < 2 mR/hr
Note: Not Formally documented

Part 20.202 Personnel Monitoring

Yes Staff assigned and wear body badges
Yes Ring badges for staff preparing, administering
Note: New service Vendor

Part 20.203 Caution Signs, Labels

OK "Radiation Area" (>5mr/hr. or 100 mr/5 days)
OK "Caution, Radioactive Materials" on all use, storage areas
OK Containers labeled w/symbol
Note: _____

Part 20.205 Receiving, Opening Packages

Yes Packages promptly delivered
Yes Exterior of package inspected
Yes Survey at 1 meter (<10mr/hr)
Yes Survey at surface (<100 mr/hr)
Yes Wipe test of surface (<0.01 uCi)
Yes Survey container before discarding
See Above Written procedure for receiving
Yes Instructions to Supply, Police, MAS
Note: Only Nuc Med. has written procedure

Part 20.303 Disposal by Release to Sewer

Yes Written procedure established
✓ User has determined daily effluent rate
✓ Calculated average monthly concentration
Yes Keeps log of sewer diapsoia quantities.. type.

III. 10 CFR Part 35

Part 35.20 ALARA
Yes Written program exists
— No Program is published (License typ. only)
Yes NM staff aware of ALARA
3/31/93 No Written ALARA review (audit)
Note: NRC cited for no annual audit

Part 35.21 Radiation Safety Officer
Yes RSO same as license
Yes RSO duties, authority defined
2-1/94 ✓ RSO has written policy/procedures for: (Not Consolidated)
Yes Byproduct material purchase
Yes Receiving, delivery
Yes After hours delivery, MAS, Security
Yes Opening packages
12/29/93 ✓ Storage and inventory of materials (Nuc. Med. Only) storage only
Yes Safe use, general instruction
Yes Emergency procedures, spill, loss
Yes Periodic surveys
Yes Checks of survey instruments
Yes Disposal of byproducts material
Yes Training, NM, Supply, Bldg Mgmt, etc.
Yes RSO has file system for records, reports
3/31/93 No RSO briefs management; Date: _____
Yes Establish ALARA investigation levels
Level-I 125 Level-II 395
✓ Note: No detailed list of RSO duties
3/2/94 No generic policy for storage/inventory
No annual audit by RSO

Part 35.22 Radiation Safety Committee
Yes Committee established by Hospital Memo and:
Yes Includes Nuclear Medicine representative
12/29/93 No Research representative
Yes Radiology/radiation oncology representative
Yes Nursing representative
Yes Radiation Safety Officer
Yes Management representative
Yes Committee meets quarterly
Yes Quorum (1/2 membership) including RSO, management representative (since NRC inspection)
Yes Minutes kept
Yes Minutes include: date, members present, absent
Yes Summary of deliberations
Yes Recommended actions (See notes)
Yes Numerical results of ballots (when less than unanimous)
Yes ALARA reports are reviewed by committee
1/26/93 No Annual documented review of Rad Safe program
Note: Medical staff/administrative Committee

Part 35.23 Authority and Responsibility
Yes Management delegation of authority to RSO

Part 35.25 Supervision/Instruction
✓ Workers instructed in rad safety
✓ Audits of use and records of use
Note: _____

Part 35.27 Visiting Users
Yes Licensee has visiting users (60 day)
Yes Visitors have prior written permission
Yes Licensee has copy of visitors' license
Note: Teletherapy — clarified with last NRC inspection

Part 35.33 Misadministrations
1 Number of misadministrations in 2 years Corrective
Yes actions implemented
Note: Teletherapy

Part 35.49 Suppliers
Yes Isotopes only from licensed suppliers
Yes Reagents only from licensed suppliers
Note: _____

Part 35.50 Dose Calibrators
Yes Daily constancy check
10/12/93 No Performed on all clinical settings
— No Performed on call-back (STAT) studies
Yes Annual accuracy check;
Yes Using at least two sources
Yes NBS traceable, ± 5%
Yes Average 3 readings for each source
Yes Compute % difference
Yes Permanent record of test
Yes Linearity test performed quarterly;
✓ From highest patient dosage 150 mCi } Since NRC inspection
✓ To less than 10 uCi
Yes Geometry test, one time or after repair
Yes Has the DC been repaired or adjusted? Battery Replaced
Yes If yes, were accuracy, linearity, geometry repeated?
— No Were geometry or linearity errors > 10%?
— If yes is there a correction chart?
— No Were accuracy or constancy errors > 10%?
— If yes, was the instrument repaired?
2/2/94 No Constancy records include model, serial no. of DC, I check source, date, activity measure, initials.
7/26/93 No Accuracy records include model and serial number of calculated activities, measured activities, % differenc signature of RSO
9/15/93 No Geometry records include model and serial numoer o configuration of sources (vial, syringe), activity of e volume measured, date, signature of RSO
Note: Nuc Med written procedure insufficient to comply with model procedure — needs revisio

Part 35.51 Survey Instruments
3 Number of instruments available
Yes Each calibrated within last 12 mo.
Yes Calibration record for each
Yes Record includes description of calibration source
Yes Two points on each range calibrated
Yes Check (constancy) source available
Yes Level of check source marked on meter scale
Yes Check source measured with each use
Note: Pocket Dosimeters – not calibrated since 1991

Part 35.53 Measurement of Doses
Yes Records of dose measurements including:
Yes Name or abbreviation of radiopharmaceutical
Yes Lot number of radiopharmaceutical
Yes Expiration date of radiopharmaceutical
Yes Name of radionuclide
Yes Patient name
— Patient SSN
9/23/93 No Prescribed dose (Not listed for I-131 therapy)
10/29/93 No Actual (measured) dose Recording of prescribed dose value.
Yes Date and time of measurement
10/29/93 No Initials of individual who made record
P-32 therapy doses not assayed
Note: Dispositte prescribed doses in procedure manual

Part 35.57 Calibration and Reference Sources
4 Number of calibration sources available
✓ 37Co Activity: 5.6 mCi Calib. Date: 2/10/92
✓ 133Ba Activity 0.265 mCi Calib. Date: 7/19/89
✓ 137Cs Activity: 0.205 mCi Calib. Date: 5/2/89
✓ 60Co Activity: 0.050 mCi Calib. Date: 5/12/89
No Flood Activity: ____ mCi Calib. Date: ____
____ Other Activity: ____ mCi Calib. Date: ____
Note: Uses liquid Tc source for spect studies

Part 35.59 Testing of Calibration Sources
Yes Leak Test on all calibration sources every 6 months.
Yes Test records available and include:
7/9/93 No Model & serial no. of source tested
Yes Name of radionuclide in source (see note)
Yes Activity of sources (see Note)
Yes Measured activity in uCi ea test sample
Yes Date of test
7/19/93 No Written description of test procedure
7/19/93 No Signed by RSO
No Any leakage detected? [See 35.59(e)]
7/29/93 Not All Quarterly Inventory of calibration sources (only Brachy)
7/19/93 No Inventory record includes model & serial no.
Yes Identity of radionuclide
7/19/93 No Activity of radionuclide
Yes Location of each source
Yes Inventory signed by RSO
Yes Sealed source storage survey at least quarterly

Part 35.60 Syringe Shields and Labels
Yes Radiation Shields available for syringes
Yes Syringes labeled w/radiopharmaceutical name
Yes Syringes labeled with patient name or procedure
Yes Syringe shields available for prep and injection
Note: _____

Part 35.61 Vial Shield and Labels
Yes Stock radiopharmceutical vials in shields
Yes Vial shields labeled
Yes Label identifies contents (Color code)
Note: _____

Part 35.70 Survey & Contamination Checks
Yes Preparation and use areas surveyed daily
1/11/94 Yes Storage areas surveyed at least weekly (Nuc Med Only)
✓ Waste storage areas surveyed at least weekly (Nuc. Med only)
Yes Survey instrument will measure 0.1 mrem/hr
2/15/94 No Trigger levels for RSO notification established
Yes Weekly wipe test of prep, use and storage areas
Yes Test will detect 2000 dpm contamination
Yes Trigger levels for RSO notification established
Yes Written survey & wipe records maintained and:
Yes Survey & wipes dated
2/8/94 Not All Plan of each area surveyed in records
Yes Detected dose rate in several areas
Yes Dose rate in mr/hr (Nuc. Med. Only)
Yes Contamination wipe results in dpm/100 cm
Yes Record of instrument used for survey or wipe
Yes Initials of individual who performed survey/wipe
Note: Brachy + Path Waste Areas Not surveyed as waste storage area

Part 35.75 Release of Patients Containing Activity
63 Patients treated w/radiopharmaceuticals (Last Year)
0 No. of treatments w/activity > 30mCi
10/27/93 Not Survey or calculations of release date/time
Note: _____

Part 35.90 Storage of Volatiles and Gases
Yes 131I in unit doses or ___ multi-doses
Yes 133Xe in unit doses or ___ multi-doses
Yes Fume hood storage for gases/volatiles
Yes Fume hood flow (velocity) calibrated annually
Note: Except as noted in NRC inspection report

Part 35.92 Decay in Storage

Yes Waste is segrated according to half-life
Yes Waste stored for 10 half-lives (or amendment)
Yes Waste surveyed in low bkg area before disposal
Yes Labels obliterated
No Generator columns separated and surveyed Ref. to Manual
Yes Written disposal records kept including:
Yes Date of disposal
Yes Date material was placed in decay storage } see note
Yes Radionuclide contents of waste
1/11/94 ✓ Survey instrument used (only one)
Yes Background radiation level
Yes Radiation level at surface of waste package
3/12/93 No Name of individual who performed disposal

Note: No log of therapy waste
Path Waste Area - See Report
Nuc. Med. Proced - Needs Revision

Part 35.100-300 Scope of Services

50 Performs uptake, dilution excretion exams
3000 Performs imaging examinations:

Volume:		
	Bone Imaging	1500 per yr
	Gated Cardiac	100
	Heart Perfusion	150
	Renal	100
	Liver/Spleen	100

kits only Prepares radiopharmaceuticals in-house
Yes Uses commercial radiopharmacy
Yes Performs radiopharmaceutical therapy
✓ Type:
✓ Hyperthyroidism
✓ Thyroid CA
Colloidal P-32
✓ Soluble
Other
No Uses IND or NDA radiopharmaceuticals

Note:

Part 35.204 99Mo Concentration

Yes 99Mo concentration measured in each eluent
Yes Daily record of generator 99mTc elution including:
Yes Activity of 99TC in mCi
Yes Activity of 99Mo in uCi
Yes Ratio of Mo/Tc in uCi/mCi (<0.15)
Yes Date and time of measurement
Yes Initials of person performing measurement

Note: Model procedure adopted

Part 35.205 Control of Aerosols and Gases

2 Number of ventilation studies/~~week~~ month
20 Maximum activity/patient (mCi)
✓ Room volume 3944 ft3 (42c)
✓ Ventilation rate 2000 ft3/min (300c)
✓ Ventilation operated 168 hrs/week
Yes Room under negative pressure
Yes Uses Xe charcoal trap
Yes Calculation of inside concentration
Yes Calculation of concentration in unrestricted area
Yes Calculation of spill clearance time
Yes Spill clearance time and safety procedure posted
8/25/93 Seattle Xe trap tested each month
Yes Ventilation rates measured every 6 months (since HVAC inspection)

Note: Trap tested after each procedure

Part 35.220 Survey Instruments

Yes Portable instrument, Range 0.1-100 mr/hr
Yes Portable instrument, Range 1 - 1000 mr/hr

Note: No Survey Meter in Path. Dept.

Part 35.310 Safety Instruction for Therapy (Radiopharmaceuticals)

Yes Safety instruction for all persons providing care (I-131 only)
Yes Instruction includes patient control
Yes Visitor control
Yes Contamination control
Yes Waste control
Yes Procedure for RSO notification
4/4/94 No Record of persons receiving instruction
Yes Patients provided with private room
Yes Patient room has private bath
Yes Room doors posted "Radioactive Materials"
Yes Length of visiting times posted
Yes Visitors under 18 individually approved
Yes Area survey after dose administered (w/ adjacent areas)
Yes Survey records kept including:
Yes Date and time of survey
Yes Plan or list of areas survey
Yes Measured dose rate at several points
10/25/93 Yes Survey instrument used
No Initials of person performing survey
Yes Materials removed from room surveyed
10/25/93 No Counseling to patient before discharge (w/ty by RSO)
Yes Survey room & bath before reassignment
Yes Document removable act. <200 dpm/100cm2
Yes Thyroid bioassay of each staff person involved
Yes Written record of bioassay, including:
Yes Name of staff member
Yes Thyroid burden,
7/1/94 No Initials of person performing bioassay

Note: Bioassay performed with γ-camera
No P-32 Protocol

William A. Reventure
Signature

MEMO TO: Members of the Radiation Safety Committee

FROM: Gerard E. Cryan, M.Sc.

SUBJECT: NRC Audit

DATE: May 26, 1994

This is to inform you that on Tuesday, the 24th of May, 1994, a mock NRC inspection was conducted by myself and Steve Bennett to assess the state of compliance of Berkshire Medical Center. I am pleased to say that we are in very good shape for our upcoming NRC inspection. The following is a breakdown by department of recommendations/suggestions to further improve our readiness.

LAB

Overall excellent state of compliance.

Should be provided with written procedure for receiving/opening of packages.

Should be provided with written procedure in the event trigger levels are reached.

Need to place Radiation warning signs at eye level and on fume hood.

Radioactive waste storage needs to be addressed. Volume should be condensed; a written procedure for disposal and a new storage site acquired.

Housekeeping needs inservice as to proper handling of radioactive waste containers in the Lab.

NRC Doc. should be posted in Lab (19,20).

Lab personnel need Radiation Safety training inservice.

NUCLEAR MEDICINE DEPARTMENT

This is where the majority of byproduct work is done and as such poses the greatest concern. Due to the installation of our new gamma camera the overall appearance of this department is poor at best. Several questionable violations were present.

Food - coffee cups were in various places throughout the room and in close proximity to the hot lab.

NUCLEAR MEDICINE LAB: (CONT.)

Poor use of protective clothing, i.e., gloves worn by technician while working in hot lab but with short sleeve shirt.

Some records/log books hard to understand. (New forms have been received so this should no longer be a concern).

Survey meter not properly noted in log books. (Need manufacture, model number, serial number, date of calibration).

Most disturbing hot lab door open while no one working inside. This door should be closed at all times when not in use.

RADIATION THERAPY/RSO

Overall in good shape. Copies of all documents available but could improve accessability. Would suggest dedicated file cabinet for this material.

AIARA - written program exists but should be distributed to all departments not just in RSO records.

Written procedures for spill/contamination events should be available to all departments.

IDENTITY of RSO should be made aware to all hospital employees and should be listed in phone book along with Dr. Fireside/Dr. May Day. Also on doors to cesium vault and waste storage sites.

Radiation Safety training inservice program needs to be addressed in almost every case. When an employee was asked when they received their last training, their response was either they had none or I do not remember. This is a serious problem. I would suggest that this topic be added to the manditory classes required by all employees.

Finally the RSO has still not received fume hood flow report from maintenance department. He has requested it again but is still waiting.

In summary, the overall readiness of this facility appears to be in good shape for the upcoming NRC inspection. However, priority should be placed on completing the above items. I would suggest that each department conduct its own review in the very near future to assure that these items are completed as well as to assure no others exist.

CC: Dr. Brown
Dr. Poutasse
Dr. Spatz,Spec. Chem.
Dan Geibel, N.Med.
K.Thornton, RN,Rad.Onc.
S.Bennett,Adm.Dir.Rad.
T. Romeo,V.P.,Prof. Serv.
Dr. F.Peter Rentz
Dr. Levine
Dr. Shickmanter
Dr. Wu, Rad.Onc.
Dr. Sheridan, Chrmn.,Rad.Onc.
Dr. R. Intres

RADIATION DETECTION COMPANY
NVLAP*
482 Wolfe Road • P.O. Box 1414 • Sunnyvale, California 94088 • (408) 735-8700

April 26, 1994

Berkshire Medical Center
Attn: Dr. Wu
725 North Street
Pittsfield, Ma 01201

Account # 20334-02 through 07
Summary Report for all groups

Dear Dr. Wu:

The following is the deep whole body (penetrating radiation) categorized summary report for Berkshire personnel receiving radiation exposure results during calendar year 1993.

Rem Category	Number of Berkshire Personnel
0.000	126
0.001 - 0.099	37
0.100 - 0.249	10
0.250 - 0.499	1
0.500 - 0.749	0
0.750 - 0.999	0
1.000 - 1.999	0
2.000 - 2.999	0
3.000 - 3.999	0
4.000 - 4.999	0
5.000 - 5.999	0
6.000 - 6.999	0
7.000 - 7.999	0
8.000 - 8.999	0
9.000 - 9.999	0
10.000 -10.999	0
11.000 -11.999	0
12.000 plus	0
Total	174

Very truly yours,

RADIATION DETECTION COMPANY

Richard H. Holden

Richard H. Holden
President

ATT 5

Quarterly investigational levels (mrems)

Annual limits	Level I	Level II
1. Total effective dose equivalent(TEDE): 5 rems	125	375
2. Lens of the eye: 15 rems	375	1,125
3. Any individual organ or tissue other than the eye: 50 rems ($H_d + H_{T,50}$)	1,250	3,750
4. The skin or any extremity: 50 rems	1,250	3,750

Total Effective Dose Equivalent (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Deep-dose equivalent (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during th

NRC RADIATION SAFETY COMPLIANCE CHECKLIST

LOCATION: BMC DATE: 10/18/94

I. 10 CFR Part 19

Part 19.11 Posting Documents
Yes NRC Part 19
Yes NRC Part 20
Yes NRC License and Conditions
Yes Notice of availability of above
Yes Form NRC-3 (map)
Note: _____

Part 19.12 Training
Yes Rad Saf Training conducted
OK Date (s) 12/13/93, 2/16/94, 10/26/94, 1/3/94
Yes Training Documented
4 Total Nuclear Med Staff
4 Number trained
Note: _____

Part 19.13 Exposure Reports
Yes Exposure reports posted
Yes Staff knows how to get information
Note: _____

II. 10 CFR PART 20

OK Highest annual dose 295 mREM
OK Highest quarterly dose 170 mREM
Note: _____

Part 20.105 Levels in Unrestricted Areas
Yes Surveys conducted in unrestricted areas
OK Highest level in unrestricted areas <2 mR/hr
Note: _____

Part 20.202 Personnel Monitoring
Yes Staff assigned and wear body badges
Yes Ring badges for staff preparing, administering
Note: _____

Part 20.203 Caution Signs, Labels
OK "Radiation Area" (>5mr/hr. or 100 mr/5 days)
OK "Caution, Radioactive Materials" on all use, storage areas
OK Containers labeled w/symbol
Note: _____

Part 20.205 Receiving, Opening Packages
Yes Packages promptly delivered
Yes Exterior of package inspected
Yes Survey at 1 meter (<10m/hr)
Yes Survey at surface (<100 mr/hr)
Yes Wipe test of surface (<0.01 uCi)
Yes Survey container before discarding
Yes Written procedure for receiving
Yes Instructions to Supply, Police, MAS
Note: _____

Part 20.303 Disposal by Release to Sewer
Yes Written procedure established
Yes User has determined daily effluent rate
Yes Calculated average monthly concentration
Yes Keeps log of sewer diapsoia quantities.. type.

III. 10 CFR Part 35

Part 35.21 ALARA
Yes Written program exists
yes Program is published
Yes NM staff aware of ALARA
yes Written ALARA review (audit)
Note: _____

Part 35.21 Radiation Safety Officer
Yes RSO same as license
yes RSO duties, authority defined
yes RSO has written policy/procedures for:
yes Byproduct material purchase
yes Receiving, delivery
yes After hours delivery, MAS, Security
yes Opening packages
yes Storage and inventory of materials
yes Safe use, general instruction
yes Emergency procedures, spill, loss
yes Periodic surveys
yes Checks of survey instruments
yes Disposal of byproducts material
yes Training, NM, Supply, Bldg Mgmt, etc.
yes RSO has file system for records, reports
yes RSO briefs management; Date: 9-1-94
yes Establish ALARA investigation levels
Level-I 125 Level-II 375
Note: _____

Part 35.22 Radiation Safety Committee
Yes Committee established by Hospital Memo and:
yes Includes Nuclear Medicine representative
yes Research representative
yes Radiology/radiation oncology representative
yes Nursing representative
yes Radiation Safety Officer
yes Management representative
yes Committee meets quarterly
yes Quorum (1/2 membership) including RSO, management representative
Yes Minutes kept
yes Minutes include: date, members present, absent
Yes Summary of deliberations
yes Recommended actions
yes Numerical results of ballots (when less than Unanimous)
yes ALARA reports are reviewed by committee
yes Annual documented review of Rad Safe program

Note: _____

Part 35.23 Authority and Responsibility
Yes Management delegation of authority to RSO
yes Written management charge to Committee and RSO
Note: _____

Part 35.25 Supervision/Instruction
yes Workers instructed in rad safety
Yes Audits of use and records of use
Note: _____

Part 35.27 Visiting Users
yes Licensee has visiting users (60 day)
yes Visitors have prior written permission
yes Licensee has copy of visitors' license
Note: _____

Part 35.33 Misadministrations
0 Number of misadministrations in 2 years Corrective actions implemented
Note: No recordable events.

Part 35.49 Suppliers
Yes Isotopes only from licensed suppliers
Yes Reagents only from licensed suppliers
Note: _____

Part 35.50 Dose Calibrators
Yes Daily constancy check
Yes Performed on all clinical settings
NO Performed on call-back (STAT) studies
Yes Annual accuracy check:
yes Using at least two sources
Yes NBS traceable, ± 5%
Yes Average 3 readings for each source
yes Compute % difference
Yes Permanent record of test
yes Linearity test performed quarterly:
yes From highest patient dosage 150 mCi
Yes To less than 10 uCi
yes Geometry test, one time or after repair
Yes Has the DC been repaired or adjusted? Battery replaced
yes If yes, were accuracy, linearity, geometry repeated?
No Were geometry or linearity errors > 10%?
~ If yes is there a correction chart?
NO Were accuracy or constancy errors > 10%?
~ If yes, was the instrument repaired?
yes Constancy records include model, serial no. of DC, I check source, date, activity measure, initials.
Yes Accuracy records include model and serial number of calculated activities, measured activities, % differenc signature of RSO.
Yes Geometry records include model and serial number of configuration of sources (vial, syringe), activity of e volume measured, date, signature of RSO
Note: _____

Part 35.51 Survey Instruments
4 Number of instruments available
Yes Each calibrated within last 12 mo.
Yes Calibration record for each
Yes Record includes description of calibration source
Yes Two points on each range calibrated
* Yes Check (constancy) source available
Yes Level of check source marked on meter scale
Yes Check source measured with each use
Note: * except the one for pathology lab.

Part 35.53 Measurement of Doses
Yes Records of dose measurements including:
Yes Name or abbreviation of radiopharmaceutical
Yes Lot number of radiopharmaceutical
Yes Expiration date of radiopharmaceutical
Yes Name of radionuclide
Yes Patient name
— Patient SSN
Yes Prescribed dose
Yes Actual (measured) dose
Yes Date and time of measurement
Yes Initials of individual who made record

Note:

rt 35.57 Calibration and Reference Sources
4 Number of calibration sources available
✓ 57Co Activity: 5.4 mCi Calib. Date: 8/30/93
✓ 133Ba Activity: 0.265 mCi Calib. Date: 2/10/92
✓ 137Cs Activity: 0.268 mCi Calib. Date: 5/17/99
✓ 60Co Activity: 0.250 mCi Calib. Date: 5/17/99
NO Flood Activity: ____mCi Calib. Date: ____
____ Other Activity: ____mCi Calib. Date: ____
Note: Uses liquid flood source for Spect studies

Part 35.59 Testing of Calibration Sources
Yes Leak Test on all calibration sources every 6 months.
Yes Test records available and include:
Yes Model & serial no. of source tested
Yes Name of radionuclide in source
Yes Activity of sources
Yes Measured activity in uCi ea test sample
Yes Date of test
Yes Written description of test procedure
NO Signed by RSO
NO Any leakage detected? [See 35.59(e)]
Yes Quarterly Inventory of calibration sources
Yes Inventory record includes model & serial no.
Yes Identity of radionuclide
Yes Activity of radionuclide
Yes Location of each source
Yes Inventory signed by RSO
Yes Sealed source storage survey at least quarterly
Note: Written description of test procedure provided by Siemens Health Physics Services

Part 35.60 Syringe Shields and Labels
Yes Radiation Shields available for syringes
Yes Syringes labeled w/radiopharmaceutical name
Yes Syringes labeled with patient name or procedure
Yes Syringe shields available for prep and injection
Note:

Part 35.61 Vial Shield and Labels
Yes Stock radiopharmceutical vials in shields
Yes Vial shields labeled
Yes Label identifies contents (color code)
Note:

Part 35.70 Survey & Contamination Checks
Yes Preparation and use areas surveyed daily
Yes Storage areas surveyed at least weekly
Yes Waste storage areas surveyed at least weekly
Yes Survey instrument will measure 0.1 mrem/hr
Yes Trigger levels for RSO notification established
Yes Weekly wipe test of prep, use and storage areas
Yes Test will detect 2000 dpm contamination
Yes Trigger levels for RSO notification established
Yes Written survey & wipe records maintained and:
Yes Survey & wipes dated
Yes Plan of each area surveyed in records
Yes Detected dose rate in several areas
Yes Dose rate in mr/hr
Yes Contamination wipe results in dpm/100 cm
Yes Record of instrument used for survey or wipe
Yes Initials of individual who performed survey/wipe
Note:

Part 35.75 Release of Patients Containing Activity
71 Patients treated w/radiopharmaceuticals
4 No. of treatments w/activity > 30mCi
Yes Survey or calculations of release date/time
Note:

Part 35.90 Storage of Volatiles and Gases
Yes 131I in unit doses or ___multi-doses
Yes 133Xe in unit doses or ___multi-doses
Yes Fume hood storage for gases/volatiles
Yes Fume hood flow (velocity) calibrated annually
Note:

Part 35.92 Decay in Storage

Yes Waste is segrated according to half-life
Yes Waste stored for 10 half-lives (or amendment)
Yes Waste surveyed in low bkg area before disposal
Yes Labels obliterated
No Generator columns separated and surveyed Ref. to Manuf.
Yes Written disposal records kept including:
Yes Date of disposal
Yes Date material was placed in decay storage
Yes Radionuclide contents of waste
Yes Survey instrument used
Yes Background radiation level
Yes Radiation level at surface of waste package
Yes Name of individual who performed disposal

Note: _____

Part 35.100-300 Scope of Services

50 Performs uptake, dilution excretion exams
1318 Performs imaging examinations:

Volume: Bone Imaging 1000 per yr
Gated Cardiac 80
Heart Perfusion 140
Renal 65
Liver/Spleen 33

Yes Prepares radiopharmaceuticals in-house
Yes Uses commercial radiopharmacy
Yes Performs radiopharmaceutical therapy
✓ Type:
✓ Hyperthyroidism
✓ Thyroid CA
____ Colloidal P-32
____ Soluble
____ Other____
NO Uses IND or NDA radiopharmaceuticals

Note: _____

Part 35.204 99Mo Concentration

Yes 99Mo concentration measured in each eluent
Yes Daily record of generator 99mTc elution including:
Yes Activity of 99TC in mCi
Yes Activity of 99Mo in uCi
Yes Ratio of Mo/Tc in uCi/mCi (<0.15)
Yes Date and time of measurement
Yes Initials of person performing measurement

Note: _____

Part 35.205 Control of Aerosols and Gases

1-2 Number of ventilation studies/week
20 Maximum activity/patient
✓ Room volume 3984 ft3
✓ Ventilation rate 2000 ft3/min (3000)
✓ Ventilation operated 168 hrs/week
Yes Room under negative pressure
Yes Uses Xe charcoal trap
Yes Calculation of inside concentration
Yes Calculation of concentration in unrestricted area
Yes Calculation of spill clearance time
Yes Spill clearance time and safety procedure posted
See note Xe trap tested each month
Yes Ventilation rates measured every 6 months

Note: Trap tested after each procedure.

Part 35.220 Survey Instruments

Yes Portable instrument, Range 0.1-100 mr/hr
Yes Portable instrument, Range 1 - 1000 mr/hr

Note: _____

Part 35.310 Safety Instruction for Therapy (I-131)

Yes Safety instruction for all persons providing care
Yes Instruction includes patient control
Yes Visitor control
Yes Contamination control
Yes Waste control
Yes Procedure for RSO notification
Yes Record of persons receiving instruction
Yes Patients provided with private room
Yes Patient room has private bath
Yes Room doors posted "Radioactive Materials"
Yes Length of visiting times posted
Yes Visitors under 18 individually approved
Yes Area survey after dose administered
Yes Survey records kept including:
Yes Date and time of survey
Yes Plan or list of areas survey
Yes Measured dose rate at several points
Yes Survey instrument used
Yes Initials of person performing survey
Yes Materials removed from room surveyed
Yes Counseling to patient before discharge
Yes Survey room & bath before reassignment
Yes Document removable act. <200 dpm/100cm2
Yes Thyroid bioassay of each staff person involved
Yes Written record of bioassay, including:
Yes Name of staff member
Yes Thyroid burden.
Yes Initials of person performing bioassay

Note: _____

Rueq R Wu
Signature

Name: Rueq R Wu, Ph.D.

Title: RSO

ATT C 1

BERKSHIRE MEDICAL CENTER

RADIATION SAFETY INSERVICE EDUCATION

"The New Radiation Protection Standards"

	Signature of Participant	Date	
1.	Daniel Geibel	10/14/94	HEC
2.	Christina D. Hoosick	10/14/94	HEC
3.	Michael Sandrini	10/14/94	HEC
4.	William Ross	10-18-94	R
5.	Karen Thornton	10-18-94	R
6.	Edward J Paskey	10/18/94	R
7.	Diane Boyer	10/18/94	R
8.	[illegible]	10/18/94	R
9.	[illegible]	10/19/94	R
10.	Cheryl A. [illegible]	10/19/94	R
11.	Mildred Brewer	10-26-94	R
12.			

Questions and Answers: Gerry Cryan, M.S. Physicist
Ruey Wu, Ph.D., RSO

A Videotaped Program

ATT C2

BERKSHIRE MEDICAL CENTER

RADIATION SAFETY INSERVICE EDUCATION

"REVISED QUALITY MANAGEMENT PROGRAM"

	Signature of Participant	Date
1.	Gerard E Curyan	2-10-94
2.	David Bedard	2/11/94
3.	Cheryl A Bean	2-11-94
4.	Mildred Brewer	2-11-94
5.	Cary D. Jones	2-11-94
6.	Rosemary Donegan	2-11-94
7.	Diane Boyer	2-11-94
8.	Michael Sirkin	2/14/94
9.	[illegible]	2/22/94
10.	Wilma Ron	2-23-94

ATTC3

BERKSHIRE MEDICAL CENTER

RADIATION SAFETY INSERVICE EDUCATION

"QUALITY MANAGEMENT PROGRAM"

	Signature of Participant	Date
1.	Daniel Dalel	12/1/93
2.	Michael D Sarkisian	12/1/93
3.	Gary D Lavari	12-7-93
4.	William Kon	12-7-93
5.	Diane Boyer	12-7-93
6.	Mildred Brewer	12-7-93
7.	Christine A. Hancock	12-7-93
8.	Cheryl A Bean	12-10-93

ATTC4

NUCLEAR MEDICINE DEPARTMENT

RADIATION SAFETY INSERVICE EDUCATION

"HOSPITAL RADIATION PROTECTION PRACTICES"

Signature of Participant	Date
1. Darpine Zeolan	12/13/93
2. Michael Mueller	12/13/93
3. Christina D. Hornsick	12/13/93
4. [illegible]	12-13-93
5. Debbie Baker	12/13/93
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
16.	
17.	
18.	
19.	
20.	