

MOUNT AUBURN HOSPITAL

330 Mount Auburn Street Cambridge, Massachusetts 02238 Tel:: (617) 492-3500



November 27, 1989

U.S. Nuclear Regulatory Commission Region I Nuclear Material Section B 475 Allendale Road King of Prussia, PA 19406

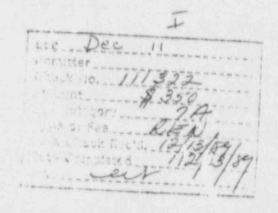
Gentlemen:

This letter and attachments constitute our request for renewal of the Teletherapy License No. 20-12063-02. The supporting information requested in Section 2 of Appendix L of the Teletherapy Guide and in Enclosure 1 to your Notice of Expiration dated September 1, 1989 is attached.

Sincerely.

Francis P. Lynch

President



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Established in 1871

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SUPPORTING INFORMATION FOR RENEWAL OF MATERIALS LICENSE NO. 20-12063-02

- a. This is an application for the renewal of materials license No. 20-12063-02.
- Mount Auburn Hospital Department of Radiology
- c. 330 Mount Auburn Street Cambridge, MA 02138
- d. Department of Radiology
 Mount Auburn Street
 Cambridge, MA 02138
 Department of Radiology
 Ground Floor
 Therapy Treatment Room
- e. Location of teletherapy unit is the same as that described in original license application dated April 2, 1979. No changes have been made that affect radiation levels in surrounding areas or that affect the patient viewing system. (See Survey Report dated November 26, 1986.)
- f. Electrical or mechanical stops that limit use of the primary beam of radiation are still installed and continue to operate as described in the last survey report of November 26, 1986 submitted to the NRC.
- g. Sealed Sources: (A) Cobalt-60

 Neutron Products, Inc.

 NPI No. 20-7000W; S/N T-841

 Maximum activity per source 7800 curies

 Maximum Number of sources two
 - (B) Uranium 238
 Neutron Products, Inc.
 No source model number
 Material used for trimmer bars, source
 shielding and source drawer. Maximum
 activity and number of sources not
 specified by manufacturer; maximum
 weight is specified as 80 lb (36.4 kg).

Teletherapy Unit: Atomic Energy of Canada Ltd. Theratron 80.

This unit is used for the treatment of humans.

h. Licensed material shall be used by, or under the supervision of, Chan Hyuk Choi, M.D.

- 1. The Radiation Safety Officer is Merrill Johnson, M.D.
- j. Item 8--Training for Individuals Working in or Frequenting Restricted Areas. We, Mount Auburn Hospital, Department of Radiology, shall follow the training program described in Appendix D of Draft Regulatory Guide FC 414-4.

Item 10.5--Operating Procedures (See attached Appendix).

Item 10.6--Emergency Procedures. We, Mount Auburn Hospital, Department of Radiology, will follow the emergency procedures described in Appendix I of Draft Regulatory Guide FC 414-4.

k. Item 10.1--Personnel Monitor Program. We, Mount Auburn Hospital, Department of Radiology, have a program which follows the criteria specified in Item 10.1.2 of Draft Regulatory Guide FC 414-4.

Item 10.2--Instrumentation. We, Mount Auburn Hospital, Department of Radiology, will have available for use from the time we begin operation the instrumentation specified in Item 10.2.2 of Draft Regulatory Guide FC 414-4.

Item 10.3--Calibration of Portable Survey Instruments. We, Mount Auburn Hospital, Department of Radiology, will calibrate our own survey instruments in accordance with written procedures that include as requirements the criteria described in Item 10.3.4 of Draft Regulatory Guide FC 414-4.

- There has been no change in the information previously submitted to NRC regarding other aspects of the radiation protection program or the teletherapy program.
- m. Radiation Safety Committee--The RSC's responsibilities, duties and meeting frequency will be as described in Appendix K of Draft Regulatory Guide FC 41404.
- n. We, Mount Auburn Hospital, Department of Radiology, have adopted the model ALARA program described in Appendix J of Draft Regulatory Guide FC 414-4.
- Survey report for source change performed on November 13, 1986 was submitted.
- p. We, Mourt Auburn Hospital, Department of Radiology, do not wish to make any other changes in the teletherapy program.

Appendix: Operating Procedures

- 1. Receipt and Disposal of Radioactive Materials. Radioactive materials shal always be handled by licensed source handlers for receipt and disposal.
- 2. Use of the Teletherapy Unit. Only certified radiation therapy technologists and certified radiation therapists may operate the unit to treat patients. In addition, radiation therapy physicists perform monthly and annual checks on this unit. The unit may be operated in any gantry orientations provided the primary beam is intercepted by the beam stop. A 'search button' is installed in the treatment room. To turn the unit on, this button has to be pressed and the room door has to be closed within a preset time period ("30 sec). This therefore requires the operator to enter the room for a survey each and every time the unit is to be turned on. A daily check in accordance with section 35.615 is performed each day by the technologist before patients are treated.
- 3. Safety Device Checks. All safety devices are checked daily, monthly and annually. Any malfunctions are to be reported to a certified physicist and the use of the unit is to be discontinued until either the problem is corrected or a backup safety device is put into operation.
- 4. Personnel Dosimetry. All personnel who work full-time in the radiation area shall wear file badges. These are whole body film badges and should be worn at chest level. In the event that a person receives or suspects that he/she received a high exposure, the incident is to be report to the Radiation Safety Officer.
- 5. Procedure for Securing the Teletherapy Unit. When the unit is unattended, the unit is locked and the keys kept in a secured place.
- 6. Instrument Calibration and Checks. Calibration of instruments is carried out and/or supervised by certified physicists. Full calibration dosimetry system are calibrated by NBS or AAPM accredited calibration laboratory within the last twenty-four months. Spot check dosimetry systems are calibrated using the full calibration dosimetry system bi-annually. Beam-on monitor and survey meter are check daily with a 10 μ Ci Csl37 source. Survey meters are calibrated annually.
- 7. Full Calibration of Teletherapy Units. Full calibration is carried out at intervals not exceeding one year by certified physicists according to 35.632 using the instruments describe in Item 6 above.
- 8. Monthly Spot-check Measurements of Teletherpy Units. Spot checks are carried out once in each calendar month according to 35.634 using the instruments described in Item 6 above.

- 9. Leak Test. Leak test is performed biannually in accordance to Item 10.4 of Draft Regulatory Guide FC 414-4. See attached procedure.
- 10. Inspection and Servicing of the Teletherapy Unit. The unit shall be fully inspected and serviced during source change or at intervals not to exceed 5 years by licensed source handlers.
- 11. Limitations on Work Done on Teletherpy Unit. All work performed on the unit that involves the source, source drawer, shutter or other mechanism that could expose the source, reduce the shielding around the source or compromise the safety of the unit and result in increased radiation levels is carried out by a licensed source handler.
- 12. Survey Reports. A radiation survey shall be performed whenever a source is changed, changes are made to the treatment room shielding, the location of the unit within the room is changed or the use of the teletherapy unit is changed such that radiation levels outside the room is altered. A report of the survey shall be submitted to the NRC within 30 days following these changes.
- 13. Relocation of Teletherapy Unit. A relocation of the unit shall require an amendment to the license and also approval by the NRC.
- 14. Recordkeeping. The following records hall be maintain to comply with NRC regulations.
 - (1) Copies of the NRC licenses.
 - (ii) License applications.
 - (iii) Correspondence with the NRC in support of a license request.
 - (iv) Daily safety device checks.
 - (v) Daily beam-on monitor checks.
 - (vi) Survey instrument calibrations.
 - (vii) Calibrations of dosimetry systems.
 - (viii) Results of spot-checks and full calibrations.
 - (ix) Results of leak tests.
 - (x) Records of full inspections and servicing of unit.
 - (xi) Radiation survey reports.
 - (xii) Personnel dosimetry records.
 - (xiii) Records of training of new personnel and annual refresher training of personnel.
 - (xiv) Records of receipt and disposal of radioactive materials.
- 15. Emergency Procedures. Emergency procedures shall be posted in the vicinity of the teletherapy machine control. Refer to Item 10.6 of Draft Regulatory Guide FC 414-4.
- 16. Procedures for Notifying the Proper Persons in the Event of

an Accident or Unusual Occurrence. In the event of a teletherapy unit malfunction or therapy misadministration, this shall be reported to the appropriate individuals listed in the machine control area. This list includes the names, addresses and telephone numbers of the radiation safety officer, hospital administrator, teletherapy unit manufacturer, service representative and the NRC.

Item 10.4 Leak Test Program

The leak test procedure is performed by the Chief Nuclear Medicine Technologist under the supervision of the Radiation Safety Officer. Samples are taken using a cotton tipped applicator moistened with distilled water and are obtained by wiping the collimator blades nearest the source. Sampling is performed under the supervision of the therapy technologist and gloves are worn during the procedure. The sample is immediately placed in a plastic counting tube and the gloves are disposed of as contaminated trash.

The sample is counted in NaI (T1) well crystal connected to a single channel analyzer. Counter efficiency for Cobalt 60 is determined at least semi-annually using a Co-60 calibrated reference standard purchased from DuPont. Results are calculated as follows:

Net Sample Counts per Minute (cpm) = Sample Counts - Background counting time

Decays per minute (dpm) = Net Sample Counts counter efficiency

Microcuries (ACi) = Decays per Minute 2.22 x 106 dpm/ACi

Example Calculation:

Sample Counts 500
Background 200
Count Time 100 Minutes
Counter Efficiency 0.02 (2%)

(500 - 200) - 100 = 3cpm

3cpm - 0.02 = 150 dpm

150 dpm ÷ 2.220 x 106 = 6.7 x 10-5 ACI

Result = 0.000067 MC1 = < 0.001 MC1

The leak-test procedure is performed by the Chief Nuclear Medicine Technologist, Dean DeMaster. He holds a Master's Degree in chemistry, has twenty years experience in Nuclear Medicine technology, and holds APRT (NM) and NMTCB certification. All results are checked and verified by the Radiation Safety Officer.

Leak-test records are maintained for at least two years after each test and include the source identity (manufacturer's name, model number and serial number) the measured activity of the sample, the test date, and the name of the person who performed the test.

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| 030-15175 | | P/GEOF |
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| ADDRESS JOHNSON MARKET STREET | | Appendix A Appendix 8 |
| INSPECTION REPORT NO. 90-001 | | Appendix C |
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| 330 mg aulum Street | | |
| Cambridge Mossochusetts 02138 | | |
| LICENSEE CONTACT: Mexilla Johnson | M.O. Teleph | ione No: 617-492-3500 |
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| 20-12003-02 | CATEGORY G 3 | PRIORITY: 2 |
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| SUMMARY OF FINDINGS AND | ACTION | |
| MO NONCOMPLIANCE, CLEAR 591 ISSUED | | ACTION ON PREVIOUS NONCOMPLIANCE. |
| NO NONCOMPLIANCE, LETTER | | APPENDIX B |
| MONCOMPLIANCE, APPENDIX A | | MONCOMPLIANCE, 591 ISSUED |
| | | SUPPLEMENTAL INFO, APPENDIX C |
| RECOMMENDATIONS | | |
| SEE BASIS IN APPEND | IX C | |
| CHANGE CATEGORY TO: | | |
| NEXT INSPECTION DATE: 10/91 | | CHANGE PRIORITY TO: |
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| Merill C. Johnson M. D. R. | | |
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| Joseph J. Long Ph.D., M | ideal Ptys | night |
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| Kathy Sur Cas NMT | | THE PERSON NAMED OF THE PE |
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| REGION 1 | Form 198-E.2 82) | | |
|-----------|---------------------|------------------------------|-------|
| | REPORT 90-01 | MANUFACTOR | |
| | A-4 | AREAS INSPECTED AND FINDINGS | 78720 |
| Licensee: | Mr. Chilm | License No: | |

| Licer | see: Mr. Chilum | License No: | Amendment No: |
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| | INSPECTION ITEM | CRITERIA | FINDING |
| Romatte | Organization Management organization? Radiation protection organization Patient load? NOTES & REMARKS: L. Oncolony now has made in 1250 house That only a out of load eatings. Law Appe. | or cout of moss well as media granted 6/7/90 for groups merrill of De moster is his | the state of the s |
| 2. | Training and Instructions to Emp Training program, scope and freq retraining? Required tests administered, sco factory? Instructions to workers? NOTES & REMARKS: | uency, Lic Cond | is cartified KTT Training By Moss Harrand. |
| 3. | Radiation Protection Procedures Operating and emergency procedure interlock failure, handling maduring operations? 5-year maintenance? due 9 Emergency Procedures posted? Radiation room monitor mounted, Tested? Survey meter used who NOTES & REMARKS: Juney retained. 1/89. Chacket when the content of t | Lic Cond 20 functions Lic Cond 16 Rozan operable? Order n inoperable? | interlocke testal and tioning appropriately. monitor operate an and D.C. 14, "Cutie Pie", calib. wed, will be required |

Page _____ of ____ Medical - Teletherapy

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| | AREAS IN | NSPECTED AND FINDINGS | |
| ce | nsee: Mr aulenn | License No: | Amendment No: |
| | INSPECTION ITEM | CRITERIA | FINDING |
| 4. | Materials, Facilities and Instruments | | |
| | Teletherapy unit location, interlock system operational, required tests? (every 6 months, records) | Lic Cond 10, 17, 19 | Vesta conducted more wantly than required |
| | Access controls, posting of areas & rooms? | 20.203 | as required |
| | Survey instruments & dosimeters operable, properly calibraled? | Lic Cond Su | they instrument roady comera provides to ing system |
| | Patient viewing system? | Lic Cond 13 TU | comera providen po |
| | NOTES & REMARKS: | Union | ing system |
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| 5. | Personnel Protection - External | | |
| 5. | Personnel Protection - External Personnel monitoring control; minimize exposures, control of accumulated dose? | | |
| | Personnel monitoring control: minimize | | |
| 5. | Personnel monitoring control; minimize exposures, control of accumulated dose? Surveys conducted following last source change? Sent to NRC? Adequate? | | |
| 5. | Personnel monitoring control; minimize exposures, control of accumulated dose? Surveys conducted following last source change? Sent to NRC? Adequate? Levels in unrestricted areas? N/I | 20.101, 20.102, 20.202 20.201 Lic Cond 18 | |
| 5. | Personnel monitoring control; minimize exposures, control of accumulated dose? Surveys conducted following last source change? Sent to NRC? Adequate? Levels in unrestricted areas? N/I | 20.101, 20.102, 20.202 20.201 L1c Cond 18 | Personnel budged by many Hanaral pot source change 9 |

Performed by authorized persons & methods:

Performed at 6-mont' (or other) inter 17

Records maintained; reports submittew of leaking sources; corrective action taken?

NOTES & REMARKS:

LIT performed by lienace Fast let on 2/7 and 7/26/90. Records reviewed are adequate

AREAS INSPECTED AND FINDINGS

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| en en | INSPECTION ITEM | CRITERIA | FINDING |
| 7. | Notifications and Reports | | |
| | To individuals? | 19.13 N/I | The state of the s |
| | Overexposures, excessive levels, incidents? | 20.403, 20.405 Mone | |
| | Personnel exposures and monitoring, termination reports? | 20.407, 20.408 N/I | |
| | Theft or loss of licensed material: | 20.402 mone | |
| | Misadministrations? | 35.41 - 35.45 none | |
| | NOTES & REMARKS: | | |
| 8. | Annual Calibration | | |
| | At required intervals? Yex | 35.21 (a) Yout and | tel on 11/16/89 |
| | Include all required tests? Yas | 35.21 (b) | mer on 11/16/87 |
| | Properly calibrated dosimetry system? You | | -lagar 0/10/00 |
| | Performed by a qualified expert? | 35.21 (e), 35.24 Keithle | Lang suforma full calid |
| | Decay corrections for interval not exceeding 1 month? | 35.21 (d) you | tany suforma full colid |
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| 9. | Spot Check Measurements | | |
| | At required intervals? | 35.22 (a) Muni | the charles sentones |
| | Include all required tests? Zea | 35.22 (b) ly | my several true! |
| | Performed by qualified expert or reviewed by qualified expert within 15 days? | 35.22 (c), 35.24 John | dante and fached |
| | Properly calibrated dosimetry system? | 35.23 (b) | against withen 150 |
| | Records available? | 35.25 Cennus | tolandy system uses |
| | NOTES & REMARKS: Remaind spot | here for pain | of 12/21/84 to 10/18/90 |
| 0. | Posting of Notices | | |
| | Part 20, license & documents, procedures, Londice of violations? | | The state of the s |
| | NRC-3? NOTES & REMARKS: | 19.11 (c) | a poetinga conjecte. |
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| AREAS | INSPECTED AND FINDINGS | - Medical - Teletherapy |
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| censee: Mr. aulum | License No: | Amendment No: |
| INSPECTION ITEM | CRITERIA | FINDING |
| 11. Other License Conditions | | - N/A |
| NOTES & REMARKS: | | |
| 12. Confirmatory Measurements Output check? Confirmation of condition 18 survey? NOTES & REMARKS: | | _N/A |
| IRC Instrument: | Calibration Due Date | e: |
| 3. Independent Inspection Effort | | -N/A |
| NOTES & REMARKS: | | |

REGION I Form 198-E

(July 82) INSPECTION REPORT NUMBER 90-001 APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS Licensee Mr aulun License No: Identification and summary of action taken Status Failure rohave andayy re, Report No: 89-001 Typs n/c: VIOL Describe: Oh RSC / Action taken: Rep named, however attended only 2 out CLOSED last 5 neetings Report No: _____ Describe: _____ OPEN Action taken: CLGSED Report No: Type n/c: Describe: OPEN Action taken: CLOSED Action taken: OPEN CLOSED Type n/c: ______Describe Report No: Action taken: OPEN CLOSED

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| Page | - | 20 | | |
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APPENDIX C - SUPPLEMENTARY INFORMATION

| L10 | cens | ee: M+. Aulum | License No: |
|-----|------|---|--------------------------|
| (|) | Uncorrected/repeated noncompliance | () Unresolved items |
| (|) | Unusual occurrence, conditions, etc | (x) Inspector's comments |
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() besit for thenge of telegory or refority

Or. Choi named a oncology rep. on KSC, however he has attended only 2 out of the last 5 meetings. Recommended naming a new rep. or encourage more frequent attendance. Violation of 89-001 remains open.

RSC meetings:

-9/29/90 Choi absent

-0/7/90 Choi absent

-0/7/90 Choi present

-12/8/89 Choi present

-9/29/89 Choi present

Department had to patients on this day and only one technician. Physician not on premies on day of inspecton but could be reached by phone. Seems like heavy workload for one individual.