VOID SHEET

TO: License Fee Management Branch

FROM: RIII - _____

SUBJECT: VOIDED APPLICATION

Control Number: 303280

Applicant: Ball Memorial Hospital

License Number: 13-00951-03

Docket Number: 030-01586

Date Voided: 1/22/98

Reason for Void: Licensee requires an extended period of time to respond to deficiencies noted during 1/22/98 phone conf.

Signature

1/22/98
Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

___ Refund Authorized and processed

✓ No Refund Due

___ Fee Exempt or Fee Not Required

Comments: _____

_____

_____

-og completed ✓

Processed by: SAC 1/27/98

ML
30
BT

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: C
Fee Category: 7C 2B
Exp. Date: 20040331
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: BALL MEMORIAL HOSPITAL INCORPORATED
Received Date: 971107
Doc' t No: 3001586
Control No.: 303280
License No.: 13-00951-03
Action Type: Amendment

52

2. FEE ATTACHED
Amount: 460
Check No.: 139333

3. COMMENTS

Signed D. Hersey
Date 11-12-97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered (√))

1. Fee Category and Amount: 7C 2B #460

2. Correct Fee Paid. Application may be processed for:
Amendment ✓
Renewal
License

3. OTHER

Signed SC
Date 11/14/97

RECEIVED
NOV 19 1997
REGION III

Log Nov 5 III
Remitter
Check No. 139333
Amount $460
Fee Category 7C 2B
Type of Fee AMD
Date Check Rec'd 11/14/97
Date Completed 11/14/97
By: SC

November 6, 1997

U. S Nuclear Regulatory Commission
Region #3
Materials Licensing Section
801 Waurenville Rd.
Lisle, Illinois 60532-4351

Re. An Amendment to Nuclear License #13-0-0951-03
Belonging to Ball Memorial Hospital Radiology Department
2401 West University Avenue
Muncie, Indiana 47303

Person to be Contacted: M.J. Ramsey, MS ABR
Radiation Safety Officer
Tel.# 765-747-4440

Dear Sirs:

We are requesting the following amendment to our license to permit the use of Ir-192 radioactive source in a High Dose Rate (HDR) Remote After-Loading Device.

Enclosed find a check in the amount of $460.00.

Sincerely,

Mary J. Ramsey

M.J. Ramsey, MS, ABR
Radiation Safety Officer

RECEIVED
NOV 07 1997
REGION III

Pm: 11-6-97

303280
NOV 07 1997

Amendment Request for Authorization to use Ir-192 in a High Dose Rate Remote After-Loading Device

The following information is supplied in order to get the necessary amendment in our Radioactive Materials License to permit the use of Ir-192 radioactive source in a High Dose Rate (HDR) Remote After-Loading Device.

I. Description of Device & Source

A. Source Description

1. Radionuclide: Ir-192

2. Manufacturer name and model number: Byk Mallinckrodt, Models CI L BV and MS-HDR, Petten, Holland

3. Maximum activity (in Curies)
   10 Ci in Afterloader; 12 Ci replacement source stored for decay to 10 Ci at facility

4. Number of sources: 2
   One source will reside in the HDR unit for treating patients. The second source will arrive a few days before the next source change. This replacement source will be surveyed with a calibrated survey meter and exposure rates will measured at the surface of the container and at a distance of 1 meter from the surface. Then this source container will be stored in the brachytherapy hot lab.

B. Device Description

1. Manufacturer's name: Nucletron Corporation
   Address: 7080 Columbia Gateway Drive
   Columbia, MD 21046-2133
   Telephone: 800-445-9295

2. Model name/number: microSelectron-HDR (080.000)

II. Intended Use

The Ir-192 in a High Dose Rate Remote After-Loading Device is to be used for interstitial, intracavitary and intraluminal treatment of cancer in humans. Intraluminal treatments will include multiple or single catheter endobronchial treatments of the lung.

III. Proposed Users

The use of this device will be restricted to those physician-users approved for use of 10CFR35.400 material under Ball Memorial Hospital NRC License # 13-00951-03.

A. Physicians

Both our physicians are approved for 10 CF 35.400 materials.

1. Full Name: Gregg A. Dickerson, M.D., DABR

2. Evidence of the Physician's license to practice medicine:
   Dr. Dickerson has an Indiana State License.

3. Evidence of Certification:
   Dr. Dickerson is Certified by the American Board of Radiology in Radiation Oncology.

4. Experience in Brachytherapy:
   Dr. Dickerson has several years of clinical experience in LDR brachytherapy, involving unsealed and sealed radioactive sources. He will participate in HDR training.

1. Full Name: A. Stephen Tilmans, M.D., DABR

2. Evidence of the Physician's license to practice medicine:
   Dr. Tilmans has an Indiana State License.

3. Evidence of Certification:
   Dr. Tilmans is Certified by the American Board of Radiology in Radiation Oncology.

4. Experience in Brachytherapy:
   Dr. Tilmans has several years of clinical experience in LDR brachytherapy, involving unsealed and sealed radioactive sources. He will participate in HDR training.

B. Physicists

1. Full Name: Mary Jo Ramsey

2. Certification: American Board of Radiology (Therapeutic Radiology)

3. Special Training in HDR treatment planning: Will attend the training given by the Nucletron Corporation both for the operation of the HDR remote after-loader and for using their brachytherapy treatment planning system.

1. Full Name: Alvis E. Foster

2. Certification: American Board of Radiology (Therapeutic Radiology)

3. Special Training in HDR treatment planning: Will attend the training given by the Nucletron Corporation both for the operation of the HDR after-loader and for using their brachytherapy treatment planning system.

C. Technician

The device operators will be radiation therapy technologists who will be provided with a device-specific training program by Nucletron personnel (as outlined in the attachment) both at the time of installation and then annually thereafter.

IV. Training for Individuals

1. All the personnel involved in the use of the HDR remote after-loading device will be required to attend and to complete the training provided by the Nucletron Service Corporation at our hospital prior to the use of this device for treating patients. The outline of the training is attached. This training will include the emergency source retraction procedure and participation in "dry-runs" of emergency procedures. Re-training sessions will be held at the hospital annually.

2. The name, affiliation, and qualifications of the instructor(s) conducting the training is attached.

3. Orientation training will be provided to ancillary staff (including nurses, technologists, security staff, custodians, etc.) who provide patient care during treatment or frequent areas where remote afterloading devices are stored or used. This training will meet the requirements of 10 CFR 19.12 and 10 CFR 35.410. Refresher training, as appropriate will be conducted at intervals not to exceed 12 months.

4. Records of the initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. Such records will include the names of the instructors, the names of attendees, and an outline of the topics discussed.

V. Facilities

A. Room Layout

A drawing of the room layout is attached.

B. Shielding Evaluations/Calculations

The details of the shielding calculation is attached and the expected exposure rate in each adjacent area of the room housing the after-loader is included in the calculation. Since the HDR unit will be placed in the Clinac 1800 vault, its walls and ceiling (concrete of density 147 lb/ft^3) designed to provide radiation protection against 18 MV photons will be sufficient to shield radiation exposures for the desired HDR workloads. It should be mentioned that access to the roof top is restricted and has no occupancy. The area above the Clinac 1800/HDR vault is fenced and locked and posted with "Radiation Area" signs. Notification of the Radiation Oncology Department is required prior to entry into this area.

The exposure rate in the unrestricted areas is < 2 mrem/wk or < 100 mrem/year.

C. Viewing System and Intercom

A CCTV with monitor at the operator's console will be used for continuous viewing of the patient during the treatment. A backup system is located at the Clinac 1800 console. An intercom system will be used to maintain communication with the patient during the entire treatment session. Its functionality will be checked during the HDR unit warm-up on each treatment day. A backup system is located at the Clinac 1800 console.

D. Security

1. The HDR unit will be located in the same vault as the Clinac 1800. The HDR unit will be secured in a locked cabinet when not in use. Access to the room will be restricted by the receptionist and the technologist in charge of the operation of the unit. Only authorized personnel will be allowed into the restricted area.

2. A door interlock switch is provided at the entrance to the treatment area. The door interlock will prevent the source from leaving the safe when the door is open. Any attempted entry into the room during the treatment will activate the door interlock and will cause the source to be withdrawn from the patient to the microselectron HDR safe. All attending personnel will remain at the HDR control console area during treatment.

3. If there is interruption of the interlock, the interlock must be reset before the afterloading device can be activated and treatment resumed.

4. If there is a malfunction of the interlock system the afterloading device will be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

5. The treatment door will be posted with a sign stating "CAUTION RADIOACTIVE MATERIAL," or the equivalent. There will be an independent radiation indicator which will produce a visible flashing light during treatment.

6. A Clinac 1800 therapy unit will be housed in the same room used for the HDR unit. Only one of the two devices will be operated at a time. This will be ensured by the use of a key-control device which will only activate one of the two devices at a time. The remote after-loading device or the therapy linac unit will be disabled when not in use by the above method

7. The operating console will be turned off and the operation key will be removed when the unit is not in use or unattended. The HDR after-loading unit will be placed in a locked cabinet in the treatment room when not in use. The keys to the HDR source unit and the console will be kept in a secured area accessible only to authorized personnel of the department.

E. Permanent Radiation Monitor

1. A radiation indicator will be permanently installed to ensure that the source is in the safe condition when not in use. The radiation monitor will provide visible notice of an afterloader device malfunction that results in an exposed or partially exposed source, and will be observable at the entrance to the room.

2. The radiation monitor will be equipped with a backup power supply separate from the power supply to the afterloader device.

3. The radiation monitor will be checked with a dedicated check source for proper operation each day before the afterloader device is used. A record of the radiation monitor check will be maintained for a period of three years. The operability check will be performed and documented as described in the Operating and Calibration Procedures.

4. If a radiation monitor is found inoperable, any individual entering the treatment room will use a survey instrument to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey instrument will be checked with a dedicated check source for proper operation at the beginning of each day of use.

F. Surveys

1. Surveys of radiation levels in adjacent areas outside the HDR treatment room and control console areas will be performed with a calibrated survey meter and documented after installation of the remote after-loading unit and source in the treatment facility, after every source change and when the device location changes from conditions existing during previous surveys. It will be confirmed that maximum radiation level at 10 cm from the nearest accessible surface surrounding the main source safe of HDR unit shall not exceed 1 mr/hr with the source in the shielded position. An annual survey will be made to verify continued adequacy of the shielding. A dedicated portable survey meter will be maintained for the HDR room survey as well patient's exit survey. This survey meter will be calibrated once every year. The records of these surveys will be maintained for the duration of the license.

2. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.

3. Radiation levels in unrestricted areas will not result in a dose to any member of the public in excess of the limits specified in 10 CFR 20.1301.

VI. Personnel Monitoring

All the personnel working with or near the HDR unit will be required to use the Film Badges as part of our general radiation monitoring program.

VII. Survey Instruments

A portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 mR per hour to 100 mR per hour and 1 mR per hour to 1000 mR per hour will be available to device operators and ancillary personnel at all times when an afterloading device is in use.

1. The survey instrument will be calibrated prior to first use, annually and following repair.

a. Will be calibrated on all scales with readings up to 1000 mR per hour with a radiation source.

b. Will be calibrated on two separate readings on each scale that must be calibrated.

c. Conspicuously noted on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration and the date of calibration.

2. A correction chart or graph shall be conspicuously attached to the instrument

3. Each survey instrument shall be checked for proper operation with a dedicated check source each day of use.

4. A record of each survey instrument calibration shall be retained for three years which will include a description of the calibration procedure and the date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicate by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

VIII. Operating Procedures

A. The licensee must provide a copy of operating procedures, which include, at a minimum the following commitments:

1. Copies of operating procedures will be provided to appropriate staff and one copy will be maintained at the HDR afterloader console. Operating procedures may be updated and revised without NRC approval provided that such revisions do not relax restrictiveness or degraded safety.

2. Operating procedures will include steps to ensure that the following requirements are met.

(a) A remote afterloading device and console will secured when unattended.

(b) Only the patient will be in the treatment room during the activation of the HDR afterloading device. If the patient is allowed visitors between treatment fractions, written procedures shall be established to insure the source is retracted into the shielded safe prior to permitting the entry of any visitor(s) into the room. The maximum number and length of visits will be charted.

(c) Treatment planning computer systems utilizing removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each floppy disk labeled with the corresponding patient's name and identification number. Such media may be reused, and (must be relabeled) in accordance with the manufacturer's instructions.

(d) Immediately after each use of HDR device, a survey of the device and patient will be performed to ensure that source has been returned to the fully shielded position. The survey shall include connectors and applicator apparatus, the full length of the catheter guide, and external surface of the device to ensure that the source is fully retracted. The patient shall be surveyed over the body surface near the treatment site prior to removing the patient from the treatment room. For surveys associated with the HDR treatments the calibrated survey meter capable of measuring rates of 1 - 1000 mR/hr will be used.

(e) A record of the survey described above will be maintained for a period of three years. This record will contain date of survey, ID of HDR model and serial number, ID and name of the patient, and ID of the instrument used to perform survey (make, model, and serial number), a representative background exposure rate, the survey results, and the initials of the individual performing the survey.

(f) A commitment from the licensee that if the survey specified in (d) indicates that the source is not fully retracted to a shielded position in the device, personnel will immediately implement licensee's applicable emergency procedures.

(g) A commitment from the licensee that it shall not conduct any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container, as determined by the RSO or medical physicist.

(h) During all patient treatments using an HDR remote afterloading device, both the authorized user and either the medical physicist or RSO must be physically present.

B. The licensee must confirm, that as minimum, the following safety checks will be performed that written, as well as verbal, instructions will be provided to individuals assigned to complete the checks. A copy of the checklist to perform these daily tests will be submitted for review.

1. At the beginning of each day of use, the following checks will be performed in accordance with the manufacturer's instructions:

(a) For dedicated treatment room, the permanent radiation monitor will be checked with a dedicated check source for proper operation.

(b) A dedicated CCTV to maintain constant observation of the patient will be checked to verify proper operation. Intercom systems installed in the HDR treatment room will be checked to verify proper operation.

(c) Treatment console operational check, test of all indicator lamps, other status and operational displays, and if appropriate, printer test.

(d) Source status indicators ("safe" or "unsafe"), including those which are integral to the afterloading device as well as any additional indicators installed at the treatment console or room entrance, will be checked using a dedicated source (the afterloading device may be used) to verify proper operation.

(e) Electrical interlocks installed at room entrance to a dedicated treatment room for HDR treatments will be tested for proper operation. Records of each test will be maintained for a period of three years and will include the date of the test, the results of the test, and the initials of the individual who performed the test.

(f) The mechanical integrity of all applicators, source guide tubes, and connectors to be used shall be determined by visual inspection and/or radiographs. The presence and placement of any internal shield and other essential internal components shall be determined.

(g) A record of these check will be maintained for a period of three years and will include the date of the check, the results of the check, and the initials of the individual who performed the check.

2. Prior to use, the following checks will be performed in accordance with the manufacturer's instructions within the proceeding 30 days:

(a) The HDR device will tested to determine to determine the accuracy of source positioning. Source positioning within the catheter tube should be within +/- 1 mm of the programmed position. A record of the test will be maintained and will include the date of the test, the programmed position, the actual position of the source following activation of the device, and initials of the individual who performed the test. This record may include the radiograph used to determine source position. If the source position tolerance above (+/- 1 mm) is exceeded, the authorized user and radiation safety officer or authorized medical physicist must be notified prior to performing patient treatment.

(b) Timer accuracy and linearity.

(c) For the HDR afterloading device using a cable/wire to transport the source, measurement of source guide tube to confirm the length to 1 mm accuracy.

(d) The backup battery for the remote afterloading device will be tested, in accordance with the manufacturer's instructions, to verify emergency source retraction capability upon power failure. At a minimum, this shall consist of function test with the AC power disconnected.

(e) A record of these checks will be maintained for a period of three years.

C. The licensee must develop and implement procedures governing calibration of the HDR afterloading device. At a minimum, the calibration procedure must address the following:

1. Calibration measurements of the HDR remote afterloading device source must be performed by the licensee's authorized physicist(s). The licensee should provide information about individual's experience in the use of dosimetry systems necessary to perform the calibration measurements. The licensee must confirm that the individual(s) performing calibration measurements will complete all measurements and calculations in accordance with the procedures established by the licensee's authorized physicist.

2. The method used to determine the exposure rate under specific criteria (i.e. distances used for the measurement, whether the measurement is an "in-air" measurement or done using a phantom, configuration of the chamber with respect to source guide tube and device, scatter factors used to compute the exposure rate, etc.

3. Record maintenance requirements, including a commitment to maintain a record of calibration measurements, and associated calculations for a period of three years. The records must include the manufacturer's name, model number, and serial number for both the afterloading device and source; the manufacturer's name, model number and serial number of the instrument used to measure the output of the afterloading device, the date that the calibration measurement was performed, and the name of the individual who performed the measurement. The record must also include the output of the device expressed in centigray (rads) per hour or, if appropriate, sieverts (rems) per hour and a comparison of manufacturer's ("expected") output value (corrected for decay).

A sample copy of calibration procedure and calculation sheet will be provided for review. The "expected" and measured source activity (output) should be within +/- 5 %. If the measured value differs by more than 5 % of the expected value, the licensee must commit to having the results reviewed by their RSO or medical physicist prior to performing further patient treatments.

4. A description of the dosimetry system which will be used to perform calibration measurements must be submitted with the procedures. The licensee must confirm that the dosimetry system (chamber, electrometer, etc.) will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have effected system calibration. The licensee should confirm that records of such calibration will be maintained for inspection.

5. The calibration measurements will be performed following installation of a new source before patient treatment is resumed, and recommended monthly thereafter.

6. The procedures must include a description of the method to be used to confirm source homogeneity of each source contained in the afterloading device. This will be done by autoradiography, following source replacement but prior to using the source for patient treatment.

IX. Tests and Calibrations

1. Timer accuracy will be verified at monthly intervals. The requirement for the timer accuracy will be such that the resulting error in the dose delivered must be less than or equal to 1 % of the prescribed dose.

Timer accuracy will be determined using the following method.

(i) A treatment time of 300 seconds in a single dwell position will be programmed.

(ii) After the start command is initiated from the console, the source travel will be visually monitored. The flashing yellow light on the console which indicates that the source is traveling to the dwell position will become steady or solid when the source reaches the designated position. At that instant, a stopwatch will be started to measure the time.

(iii) At the end of the programmed treatment time, the yellow light will begin flashing indicating movement of the source back into the shielded safe. When the light will start again flashing, the stopwatch will be stopped.

(iv) After the source returns to the safe, the computer printout, giving the source treatment time, will be compared with the time measured by the stopwatch, and the accuracy of the timer in the unit will be evaluated. The computer printout of the source treatment time shall be within 10% of the treatment time measured with the stopwatch. We will use 300 seconds of treatment time in the procedure in order to minimize the time delays in starting and in stopping the stopwatch.

2. The error in dose due to source travel time will be determined during the initial installation and semi-annually. Corrections in the dwell times will be made to take into account the travel time error for treatments where the travel time error could lead to an error of more than 1% of the prescribed dose. We will use the following procedure suggested by the manufacturer to determine the travel time error.

The microSelectron-HDR utilizes two independent timers to monitor source travel. The first timer starts the moment the radioactive source leaves the shielded enclosure to traverse to the first treatment position. The second timer is initiated upon arrival at the first of the sequential treatment positions. After the treatment is completed for a particular dwell position or channel the second timer stops when the source starts its travel period. The initial timer stops when the source is in the shielded safe. Printouts quantitate the time for which the source was out of the safe and the treatment time. Subtracting one from the other gives the travel time noted by the system. During Quality Assurance testing prior to initiating treatment, this travel time can be quantitated and used as reference. If travel time noted during a treatment exceeds by more than 10% the nominal travel time, Nucletron should be notified.

3. As mentioned in earlier, Source calibration will be performed at initial installation and after each source exchange. A HDR-1000 Plus Well Ionization Chamber calibrated by the University of Wisconsin Accredited Dosimetry Calibration Laboratory (ADCL) for Ir-192 source will be used for calibration. Our calibration procedure will be based on the methods described in the papers by S.J. Goetsch et al. (Medical Physics 18, 462-467 (1991), and Int. J. Radiat. Oncol. Biol. Phys. 24, 167-170 (1992)). Our chamber is calibrated specially for Ir-192 source by the ADCL, and the error in the calibration of the source activity is expected to be within 2 %. The results of these calibrations will be maintained for a period of three years. If the measured and expected activity (output) differs by more than 5 %, then the results will be reviewed by the RSO or radiation physicist prior to performing patient treatments.

A sample copy of the source calibration sheet and calibration procedure is attached.

X. Inventory

Physical inventories will be conducted quarterly and records of the inventories will be maintained in accordance with 10 CFR 35.59(g).

XI. Emergency Procedures

In case the Ir-192 source fails to retract into the shielded safe of the microSelectron-HDR after-loading unit, the steps outlined in the attached Emergency Procedures sheet will be followed step by step. Copies of the procedure (enclosed) will be provided to device operators, authorized user(s), and other personnel as necessary. In addition copies of this procedure will be posted inside the treatment room and near the control console. This sheet will contain the telephone numbers of the physicians, the Physicists, Radiation Safety Officer, and Nucletron and their local representative who will be contacted immediately in case of emergency. The emergency source recovery equipment include shielded storage containers, remote handling tool (long forceps , etc.), and supplies necessary to surgically remove applicators or sources from the patient, including scissors, and cable cutters.
This equipment will be located by the HDR unit in the treatment room.

In the situation where the source can be retracted without removing the applicator, the emergency procedures will be performed by the Physicist in charge of the treatment. If it would be necessary to remove the applicator containing the source, the emergency procedure will be carried out by the treating physician who will be assisted by the physicist to ensure that suitable precautions are taken to minimize the radiation exposure to the patient and personnel. An emergency HDR source container with sufficient shielding for 10 Ci Ir-192 source which can easily accommodate all the applicators to be used in the HDR brachytherapy will be permanently kept in the treatment room. All emergency manual source handling will be done using 30 cm long forceps.

While carrying out the emergency procedure, the first consideration will be given to minimizing the exposure to the patient.

After the patient is removed from the room, warning signs for **"No Entry"** will be posted on the door, and the area will be secured.

XII. Maintenance

A. The licensee must confirm that only personnel who are licensed by the Commission or an agreement state to perform such services will perform maintenance and repair on HDR afterloading device. Maintenance and repair includes installation, replacement, relocation or removal of the sealed source or an afterloading device that contains a sealed source. Maintenance and repair also means any adjustment involving any mechanism on the afterloading device, treatment console, or interlocks that could expose the source, reduce the shielding around the source, or affect the source drive controls.

The licensee must confirm that a record of maintenance and repair will be maintained for the duration that the device is in use and must include the date of repair, description of the nature of maintenance or repair, the name and signature of the individual who performed the repair, the NRC license number authorizing the individual to perform such repairs, and the signature of the individual who performed the repairs.

B. The licensee must confirm that the following requirements are met for inspection and service of remote afterloading devices.

1. The remote afterloading device will be fully inspected at intervals not to exceed one year, to ensure proper functioning of the source exposure mechanism. The scheduled service recommended by the manufacturer will performed in accordance with the manufacturer's instructions.

2. The inspection and service will only be performed by the manufacturer or other persons specifically licensed to do so by the Commission or an agreement state.

3. Records of inspections and service will be maintained for the duration of the license and will include the date of the inspection/service, the name of the individual who performed the inspection/service, the NRC license number authorizing the individual to perform inspection/service, a description of the nature of the inspection/service including a list of the components inspected and a list of components serviced or replaced, and the signature of the inspector.

XIII. Waste Disposal

Quarterly source changes will be performed by the authorized Nucletron/Oldelft engineer at regular intervals. Each source change report will be reviewed by one of the certified physicists before approval. This report contains manufacturer source calibration certificate, leak test and source survey data. The records of these reports will be maintained by the physicist in charge of HDR system. After each source change, the Nucletron/Oldelft engineer will place the old source in its shielded source container ready to be shipped to Nucletron for disposal. He will leave the completed paper work with the physicist who will call FedEx for source package pickup.

HEALTH and SAFETY PROCEDURES

SAFETY ANALYSIS SUMMARY

The microSelectron-HDR is designed as a fail-safe device, with the radiation source being withdrawn into the storage safe if any alarm or error condition arises. It is impossible to send out the radiation source unless an applicator is correctly connected and the check cable run has successfully occurred.

The transfer of the source into the applicator is initiated from the Control Unit outside of the shielded room and this can only occur when:

- the door is closed and
- the applicator is correctly connected and
- the dummy run checks the condition of the applicator and the complete microSelectron-HDR system

Note: One of the most critical factors in high dose rate brachytherapy is the correct position of the radioactive source. This system ensures an accuracy of ± 1 mm throughout the treatment.

The microSelectron-HDR has dual timers. One set of timers is started by the source leaving the safe of the treatment unit and the other is started by the arrival of the source in its correct position in the applicator. If there is a discrepancy of more than a few seconds between the two an alarm will sound and the source will be withdrawn.

If any alarm condition occurs, the source is withdrawn into the treatment unit safe and in certain cases, the emergency stop circuit will be activated and an LED will illuminate in the Control Area.

In the event of power failure, a backup battery in the treatment unit withdraws the source. In the event of complete failure of the system there is a hand crank which can withdraw the source in approximately 5 seconds.

Note: The check cable ensures that it is not possible to send out sources into the applicator unless the applicator is correctly connected.

SHIELDING

SHIELDING CALCULATIONS FOR 10 Ci HDR Ir-192 SOURCE TREATMENT ROOM

The microSelectron HDR remote after-loader unit will be installed in the existing vault designed for Clinac 1800 linac. The schematic drawing of the room is attached. The calculations are performed for the worst conditions, i.e. source in air, affixed to inner surface of the wall. The wall thickness is calculated to reduce the exposure on the outer surface to 0.2 mR/h. The survey will made upon completion of the installation to verify efficacy of the room shielding.

HDR Source Data:

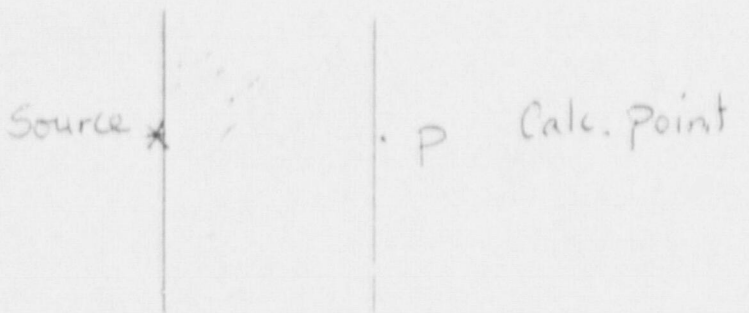
Radionuclide: Ir-192

Average Photon Energy: 370 KeV

Half Life: 74.2 days

Exposure rate constant, Γ: 4.69 R cm^2/ mCi-hr

Half value thickness (Concrete): 4.3 cm



$$X_p = \{4.69\ R\ cm^2/mCi\ hr\} \times \{10^4\ mCi\} \times \frac{1}{(76.2cm)^2}$$

$$= 8.077 \times 10^3\ R/hr$$

$$\text{Transmission: } T = \left[\frac{1}{2}\right]^n = \frac{0.2mR/h}{8.77x10^3 mR/h}$$

$$2^n = 40385$$

$$n \log 2 = \log 40385$$

$$n = 15.3 \quad \# \text{ of HVL's}$$

Wall thickness: $B = 15.3 \times 4.3 = 65.8\ cm = 2.16\ ft$

Since each wall of our vault is thicker than this value, the exposure rates outside the HDR treatment room will be lower than the tolerance limit of 0.2 mR/h.

SUMMARY OF HDR SHIELDING CALCULATION AND MEASUREMENTS
EXISTING VAULT ROOM

AREA	EXTRA SHIELD NEEDED	CALCULATED EXPOSURE RATE(*)	MEASURED EXPOSURE RATE(**)
WALL (1) CLINAC 2300 ROOM	NONE	0.2 $\frac{mR}{h}$ (*)	
WALL (2) CLINAC 2100C ROOM	NONE	0.2 $\frac{mR}{h}$ (*)	
WALL (3) : **NEW** CONTROL CONSOLE	NONE	0.2 $\frac{mR}{h}$ (*)	
WALL (4) SOUTH WALL (OUTSIDE)	NONE	0.2 $\frac{mR}{h}$ (*)	
WALL (5) NORTH WALL	NONE	0.2 $\frac{mR}{h}$ (*)	
VAULT DOOR	NONE	0.2 $\frac{mR}{h}$ (*)	

(*) Max "ON" time = 15 $\frac{min}{hour}$ = 0.25 hour. Calculated exposure rate after shielding barrier assumed to be 2 $\frac{mR}{wk}$ = 0.2 $\frac{mR}{h}$ (Workload assumed 2h/day, 10 h/week). If max. "ON" time is 0.25 h , the maximun dose a person may receive **in one hour** would be 0.2 $\frac{mR}{h}$ x 0.25 h = 0.05 mR

(**) Instrument used for survey: survey meter , Calibration date:
Measurements taken in the worst conditions: source in air, afixed to the surface of each wall.

UnRestricted Area
FENCED Area
No Occupancy on Ceiling : Restricted
UnRestricted Area
Including Ceiling = Concrete
ρ = 147 lb/ft³
CL 1800
LINEAR ACCELERATOR
HDR
Shielded Door
UnRestricted
HDR Console
Linac Console
Restricted
2100-C
LINEAR ACCELERATOR
Restricted
①
②
③
④
⑤

Dose Limits for Shielding Calculations
NCRP Repot 91

Occupational:
Controlled Area

	Annual	Weekly
	5 Rem (5000 mRem) (50 mSv)	0.1 Rem (100 mRem) (1 mSv)

Members of the General Public:
Non-controlled Area

	Annual	Weekly
(Infrequent Occupancy)	0.1 Rem (100 mRem)	2×10^{-3} Rem (2 mRem)
(Continuous Occupancy) ≤ 2 mRem/ hour	0.05 Rem 50 mRem	1×10^{-3} Rem 1 mRem

---

Embryo - Pregnant Woman

Total < 0.5 Rem (5 mSv) in 9 Months

≤ 0.05 Rem in One Month

DOSE TO EMBRYO/FETUS NOT TO EXCEED 0.5 REM

Units: Remember 1 Rem = 1 mSv

TRAINING

PERSONNEL TRAINING PROGRAM NUCLETRON HDR REMOTE AFTERLOADING DEVICE

I. SCHEDULE FOR TRAINING

Training will be provided:

A. Before an employee assumes duties with or in the immediate vicinity of the HDR device.
B. Annually at refresher training for all employees working with the HDR device.
C. Whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

II. DESCRIPTION OF THE TRAINING PROGRAM

Training will be sufficient to ensure that:

A. Individuals who work in or frequent restricted areas are instructed in the items specified in 10 CFR Part 19.12.
B. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.
C. Device operators are thoroughly familiar with the design and use of the HDR device and its operating and emergency procedures.

III. CONTENT OF THE TRAINING PROGRAM

A. Instruction for Authorized Users, Medical Physicists, and device operators will include:

1. Applications of high dose rate remote afterloading treatment.
2. The design, use, and function of the Nucletron microSelectron HDR device, including safety systems.
3. Operating and emergency procedures for the HDR device.
4. Radiation protection and instrumentation, including the use of personnel dosimeters, survey instruments, and area radiation monitors.
5. Pertinent terms and conditions of the NRC license, including procedures developed as a prerequisite for obtaining the license and commitments incorporated into the license by condition.
6. Procedures for shipping and receiving the Ir-192 source.
7. On-the-job ("hands-on") training in the actural operation of the HDR device under the direct supervision of an experienced device user. This will include the routine patient set-up and treatment as well as a dry run of the emergency procedures.

B. Instruction for ancillary staff will include:

1. Appropriate response to emergencies or unsafe conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material.
4. Radiological safety procedures appropriate to the duties of the employee.
5. Pertinent NRC regulations.
6. The obligations of all personnel to report unsafe conditions to the radiation safety officer.
7. The right of all personnel to be informed of radiation exposure and bioassay results.
8. The locations where the licensee has posted or made available notices, copies of regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR Part 19.

IV. QUALIFICATIONS OF TRAINING INSTRUCTORS

Instructors who will provide the required training for HDR device operators will be Authorized Users or medical physicists who have attended the microSelectron HDR customer training course given by Nucletron Service Corporation engineers.

V. RECORDS THAT DOCUMENT TRAINING

Records of initial and refresher training will be maintained for at least three years and will Include:

1. The name of the instructor who conducted the training.
2. The names of the individuals who received the training.
3. A list of the topics covered.
4. The date of the training session.

9.0 CUSTOMER TRAINING - MICROSELECTRON-HDR

I. Teaching Aids Required:

1. microSelectron-HDR Installed System
2. microSelectron-HDR User Manual
3. Note Pads and Pens
4. Applicators & Accessories
5. Source container and Dummy Source
6. Survey Meter provided by customer

II. Introduction to microSelectron-HDR

1. What is Remote Afterloading Brachytherapy (30 minutes)

a) radiation protection
b) treatment control
c) short treatment times

2. Applications of microSelectron-HDR (30 minutes)

a) Bronchus
b) Interstitial
c) Intracavitary
d) Intraoperative

3. Demonstration of Applicators and Accessories (30 minutes)

a) Bronchus
b) GYN
c) Esophagus
d) Interstitial

III. General Information microSelectron-HDR

1. Specifications (30 minutes)

a) Source
b) Radiation protection
c) Power requirements
d) Number of channels
e) Moving and handling

2. Equipment Operation (1 hour)

a) Explanation of Console
b) Explanation of Treatment Unit
c) Programming Mode

d) Treatment mode
   i) Start
   ii) Interrupt
   iii) Emergency Stop
   iv) alarm and error codes

e) Demonstration (30 minutes)
f) Student practice (estimated 1½ hours - varies with number of students)

IV. Isotope (^{192}Ir) Shipping and Receiving (30 minutes)

1. Delivery

a) Unpacking
b) Acceptance into Inventory
c) Calibration Data
d) Installation by engineers
   (Discussion Only)

2. Shipping

a) Release from Inventory
b) Packing
c) Shipping Documents
d) Measurement of Transport Index (TI)

V. Questions and Answers

Note 1: this training course is given by Nucletron Corporation engineers and is included in the purchase price of the unit. Annual re-training is available to all customers as part of the Nucletron Service Agreement.

Note 2: facility radiation protection requirements and record keeping will be discussed by the licensee's R.S.O. or designated deputy.

Agenda

Customer Training Agenda for the microSelectron HDR Version 2

05/21/97
12:00 PM to 3:45 PM
Facility Name and Address

Instructor:

Site Physicist/RSO:

Please have available: microSelectron Version 2 User's Manual, Emergency Procedures Card, Applicators & Accessories, System Log Book

Agenda Topics

12:00-12:45 PM **Functions of the Treatment Control Station**

A. Detection of Correct User Information
   1. Serial Number
   2. Source Calibration Data

B. Self Test Dialog Window
   1. Discussion of Internal Checks TCS Performs
   2. Failure of the Self Test
   3. Running the Self Test from the Maintenance Option

C. System
   1. New Password
   2. Settings
   3. System Overview

D. Maintenance
   1. Self Test
   2. Source Exchange
   3. Source Calibration
   4. Check Cable Exchange
E. Database Menu
   1. Applicators
   2. Staff Members
   3. Groups
   4. Messages
   5. Backup and Restore
F. Reports
   1. Standards
   2. Message Logbook
   3. Texts for Reporting
G. Help
   1. Contents
   2. About microSelectron

12:45-1:30 PM **Treatment Session**

A. Explanation of the Patient Data Panel
B. Explanation of the Session Plan Panel
C. Programming the Treatment Data
   1. Via Keyboard
   2. Using Standard Modes
   3. Importing from PLATO/NPS
      a. Explanation of Import Plato Plan Dialog Box
      b. Associated Source Strength
D. Sample Treatment Administered Using Dummy Source

1:30-2:15 PM	**Treatment Control Panel** A. Treatment Control Panel Interface to Treatment Unit 1. Transfer of Data from Treatment Control Station to Treatment Unit 2. Status Messages/Event Log 3. Emergency Stops B. Explanation of Key Operated Switches 1. Standby/Operation 2. Override Switch 3. Reset Switch C. Explanation of System Status Indicators 1. Interrupt 2. Alarm 3. Engaged 4. Action 5. Out of Safe 6. Radiation D. Source Location 1. Out of Safe 2. In Safe E. Power Status 1. Power Present 2. Power Fail
2:15-3:00 PM	**Treatment Unit** A. Handling 1. Telescope Up/Down Switch 2. Wheel Locks 3. Access to Top Panel B. Power Requirements 1. Dedicated Power Outlet 2. Power Conditioner 3. Power Switch Location C. Treatment Unit Radiation Detector

D. Motors

1. Source Cable Stepper Motor
2. Check Cable Stepper Motor
3. Indexer Stepper Motor
4. DC Emergency Stop Motor

E. Source Head Lock Mechanism

F. Applicators and Accessories

1. Connections of Applicators/Accessories to:
   a. Transfer Tubes
   b. Adapters
   c. Treatment Unit

PLEASE HAVE ALL STAFF WHO WILL BE INVOLVED WITH ANY ASPECT OF A TREATMENT AVAILABLE FOR THE EMERGENCY PROCEDURES TRAINING.

3:00-3:45 PM

Emergency Procedures

A. Radiation Indicators/Detectors

1. Independent Facility Installed Radiation Detector
2. Treatment Control Panel Radiation Indicator(s)
3. Facility Installed "Radiation-in-Use" Light
4. Facility Owned Radiation Survey Meter

B. Emergency Stops

1. Master Emergency Stop Switch
2. Auxillary Emergency Stop Switch(es)
3. Treatment Unit Emergency Stop Switch

C. Hand Cranks

1. Gold (Source Cable) Hand Crank
2. Black (Check Cable) Hand Crank

D. Removal of Applicator(s) from Patient

E. Storage of Applicator(s) in Emergency Container

F. Survey of Patient

G. Whom to Contact

9.1 VI. Ancillary Staff Training microSelectron-HDR

1. What HDR unit looks like and what it is used for.

2. Location of HDR Device and Console

   a) Device posses Radioactive Source
   b) Safety Instructions about entrance into Room
      (what to look for, who to ask, prior to entrance

3. Basic Radiation Safety Techniques

   a) Time, Distance and Shielding
   b) Use of whole body radiation badges
      (if issued film badge)
   c) Survey Meter use (if applicable)

4. Awareness of Safety Devices and Locations

   a) Locations and understanding of caution signs and
      devices
   b) Awareness and understanding of
      Applicators/Connectors/Tubing, etc.
   c) What to look for in the event of emergency

5. Who to Contact in Event of Emergency

   a) Radiation Safety Officer (RSO)
   b) Authorized Users (M.D.'s and Physicists)

6. Care of Patient Receiving Treatment

Nucletron

IV – C
DRAFT

microSelectron HDR Emergency Procedures
Training Outline

1. Standard treatment starts and interrupts
   a) Explain proper treatment start (room cleared except for patient, door closed)
   b) Explain proper treatment interrupt and restart

2. Door switch functionality.
   a) Door interlock functionality (Linac-m/HDR)
   b) DOES functionality

3. Emergency Stop functionality
   a) E-stop switch location
   b) Master E-stop reset function

4. Radiation Indication Verification
   a) Radiation in use light
   b) Room monitor (Prime Alert)

5. Entering treatment room
   a) Staff required to handle emergency
   b) Calibrated Survey instrument turned on

6. Hand crank functionality
   a) Hatch cover accessibility
   b) Crank clutch functionality (indrive only)
   c) Test cranks for each user

7. Emergency / Service Container
   a) Placement near indexer
   b) Container usage

8. Applicator Removal
   a) Applicator construction (closed ended for containment vessel)
   b) Applicator removal from patient
   c) Applicator placement in Emergency container

9. Patient and Staff egress from treatment room
   a) Patient Radiation Survey

10. Room security
    a) Close and lock door
    b) Post "No Entry" sign
    c) Post guard

11. Notification
    a) Notify facility RSO
    b) Notifying Nucletron
        i) Regular hours
        ii) After hours

12. Developing site specific Emergency Procedures
    a) Encourage staff to develop specific procedures to suit their needs

13.

nucletron®
service corporation

NUCLETRON TRAINING SEMINAR

Institution: _____

City, State, Zip: _____

1. **Teaching Aids Used**
   - User's Manual _____
   - Applicators & Accessories _____
   - Source Container & Dummy Sources _____
   - Other _____

2. **Topics Covered**
   - Explanation of Remote Afterloading _____
   - Explanation of Radiation Protection _____

Applications
- Bronchus _____
- Interstitial _____
- Intracavitary _____
- Intraoperative _____

Applicators & Accessories
- Bronchus _____
- GYN _____
- Esophagus _____
- Interstitial _____
- Other _____

Equipment Operation
- Treatment Unit _____
- Handling _____
- Power Requirements _____
- Console _____
- Treatment _____
- Start _____
- Interrupt _____
- Emergency Stop _____
- Alarm & Error Codes _____

Radioactive Source: _____
isotope

Receiving
- Unpacking _____
- Acceptance _____
- Calibration _____
- Installation _____

Shipping
- Release _____
- Packing _____
- Documents _____
- Measurements _____

Emergency Procedures _____

All areas marked were covered during training

_____ Instructor

_____ Title

_____ Date

_____ Department Head

_____ Title

_____ Date

*List of all attendees accompanies this form

nucletron®

NUCLETRON CORPORATION
7080 COLUMBIA GATEWAY DRIVE
COLUMBIA, MD 21046-2119
TELEPHONE: (410) 312-4100
TOLL FREE: 1-800-336-2249
CANADA TOLL FREE: 1-800-465-2249
FAX: (410) 312-4196

NUCLETRON TRAINING SEMINAR
ATTENDANCE REGISTRATION

Hospital _____ Date _____

Course _____

Instructor _____

NAME	DEPARTMENT	TITLE	SIGNATURE

I certify that the above individuals have been instructed in Equipment Operation, Safety Precautions and Emergency Procedures in accordance with Nucletron Corporation Training Standards.

Instructor Signature _____

Instructor Title _____

Date _____

7.5 Qualifications of Engineers and Training Personnel

RADIATION SOURCE LOADING FOR MICROSELECTRON-HDR

The personnel listed below have been trained in the installation of the microSelectron Remote Afterloading equipment and the loading of the radiation sources into the storage safe of the microSelectron-HDR from the transport container. (listed below).

Person	Years Experience	Experience and Training
A. ten Brinke	10	International Service Manager of Nucletron Engineering B.V., responsible for worldwide warranty and service of the 200+ Selectron systems. He has installed over 100 systems. Training "Ionizing Radiation" Level B (handling of Encapsulated Radioactive Sources-IVBS Rotterdam).
C. Mellink	10	Trained by Nucletron, Engineering B.V. (L. van Zwol and F. Hermanus). Has carried out installations in USA, Canada, China, Europe.
O. Dionne	1	Nucletron Corporation Radiation Safety Officer
C. Jones	8	Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
H. Archibald	8	West Coast Service Manager. Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources
B. Loudy	7	" "
C. Scott	7	" "

Person	Years Experience	Experience and Training (June, 1996)
J. Cowan	5	East Coast Service Manager. Trained by Nucletron Corporation on operation, service and safety of the machine and sources.
P. Koonce	5	Trained by Nucletron Corporation on operation, service and safety of the machine and sources.
D. Glessner	5	" "
L. Vincent	4	" "
C. Tow	4	" "
Mark Irvin	3	" "
C. Hicks	3	" "
K. Ertugrul	2	" "
C. Valentine	1	" "
M. Cerniack	1	" "

NUCLETRON CORPORATION

By: Ovila J. Dionne, Jr.

Ovila J. Dionne, Jr. Radiation Safety Officer

Nucletron

This certifies that

Hal Archibald

has successfully completed our course on

microSelectron High Dose Rate Version 2

given the 14th through the 18th day of July, 1997

at Nucletron Corporation
Columbia, MD

Alan Taylor
Technical Support Specialist

 7080 Columbia Gateway Drive Columbia, MD 21046-2133

Nucletron

This certifies that

David Kuligowski

has successfully completed the

microSelectron HDR Training Course

given the 27th through the 31st days of January, 1997

at Nucletron Corporation
Columbia, MD

Chuck Tow

Chuck Tow
Instructor, Technical Support

Nucletron

This certifies that

Dave Kuligowski

has successfully completed our course on

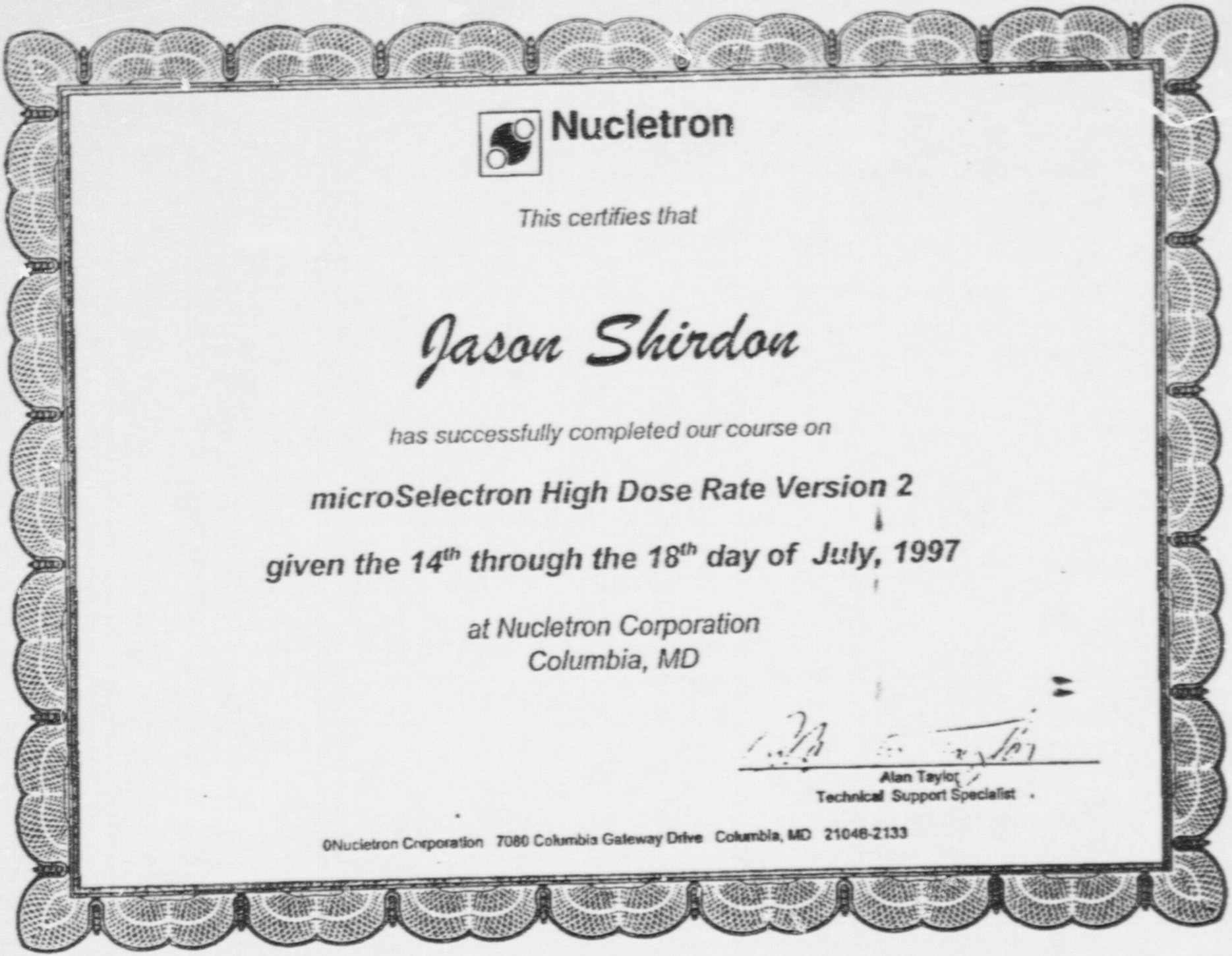
microSelectron High Dose Rate Version 2

given the 14th through the 18th day of July, 1997

at Nucletron Corpcration
Columbia, MD

Alan Taylor
Technical Support Specialist

©Nucletron Corporation 7080 Columbia Gateway Drive Columbia, MD 21046-2133



Nucletron

This certifies that

Jason Shirdon

has successfully completed our course on

microSelectron High Dose Rate Version 2

given the 14th through the 18th day of July, 1997

at Nucletron Corporation
Columbia, MD

Alan Taylor
Technical Support Specialist

ONucletron Corporation 7080 Columbia Gateway Drive Columbia, MD 21046-2133

Nucletron

Training Certificate

given to:

Alan G. Taylor

for having completed the following training course:

Radiation Safety Procedures for Source Handlers

Course Date: December 12, 1996

Ralph Shuping

Ralph Shuping, Sc.D.
Instructor/ Regulatory Affairs Manager

Ovila J. Dionne, Jr.,
Radiation Safety Officer

Nucletron

TRAINING CERTIFICATE

given to

Mr Alan G. Taylor

for attending the following

microSelectron-HDR Version 2 Technical Training
for Field Service Trainers

19 97

course date

December 9-12,1996

Nucletron B.V.
Veenendaal
The Netherlands

C.R. Hermanus
Technical Support Manager

OPERATING PROCEDURES

MICROSELECTRON HDR WARMUP CHECK LIST

DEPARTMENT OF RADIATION ONCOLOGY
BALL MEMORIAL HOSPITAL

I. SOURCE LOCATION

POSITION: 1. EXPECTED _____ MEASURED _____

2. EXPECTED _____ MEASURED _____

3. EXPECTED _____ MEASURED _____

FOR THIS TEST, A KODAK XV FILM AND THE NUCLETRON SOURCE POSITION CHECK RULER SHOULD BE USED. AT THE END OF THE TEST, THE READING FROM THE WHITE ROD WILL INDICATE 6.5 mm FARTHER THAN THE POSITION EXPECTED.

II. RADIATION SAFETY CHECKS

1. TV MONITOR FUNCTION _____
2. INTERCOM FUNCTION _____
3. CHANNEL CHECK _____
4. EMERGENCY SWITCH _____
5. INTERRUPT KEY _____
6. DOOR INTERLOCK _____
7. ROOM RADIATION MONITOR _____
8. ROOM RADIATION MONITOR TEST WITH CHECK SOURCE _____
9. HDR SOURCE ACTIVITY VERIFIED FROM DECAY TABLE: _____

III. COMMENTS: All QA checks are in compliance.

_____

_____

_____

PERFORMED BY: _____

DATE: _____

MEDICAL PHYSICIST: _____

Revised/June 1997

Summary of Measurement Procedures:

1. Allow the HDR-1000 chamber to equilibrate to ambient temperature and pressure.

2. Connect HDR-1000 chamber to an electrometer and apply 300 V bias voltage.

3. Connect a catheter, such as the endobronchial. French 6 blue catheter to HDR irradiator.

4. Align the punch mark on the well insert with the punch mark on the body of the chamber. (See Figure 1).

5. Loosen thumbscrew, move slotted washer so that catheter can be inserted through center. Insert catheter end to bottom of chamber source tube.

6. Gently slide slotted washer against catheter. Be careful not to kink or pinch catheter with washer. Insure that source will be able to move freely within the catheter. Tighten thumbscrew. Note: Tape may also be useful in securing the catheter in the desired position.

7. Set HDR irradiator to locate source at most sensitive point on the axis; usually 51 to 53 mm from bottom of source tube. Check the calibration report for this distance. Note: it is good practice to verify this most sensitive spot periodically by measuring the ionization current versus distance from the bottom of the source tube.

8. After performing all manufacturer recommended safety procedures for the HDR irradiator, run the ^{192}Ir source to the radiation sensitive axial point of the chamber for a minimum of 20 sec for current measurement or for a reproducible set time (1 min) for charge measurement. If the charge mode is used, remember to account for the transit time error of the source.

9. Read and record the measured current or charge.

10. Use correction factor for temperature/pressure, electrometer correction factor and calibration factor given by the Accredited Dosimetry Calibration Laboratory to calculate the activity of the source. As any physicist is aware the following equation can be used (for example if the activity is desired, the calibration factor for the activity from the calibration report would be used for C)

$$A = RxFxExC$$

where:

A = the Activity of the source in Bq or Ci depending which calibration factor is used
R = the reading in A (if current scale) or in C/s (if charge scale measured for a set time)
F = the temperature and pressure correction factor
E = the correction factor for the electrometer scale
C = the HDR-1000 calibration factor (in this case the activity calibration factor)
Note that A can be divided by A_{ion} if desired to correct for recombination effects.

MICROSELECTRON HDR SOURCE CALIBRATION

DATE OF CALIBRATION: _____ TIME: _____ PHYSICIST: _____

NUCLETRON ENGINEER: _____

MANUFACTURER QUOTED SOURCE ACTIVITY: _____ Ci on _____
Date/Time

INSTRUMENTS USED:

ELECTROMETER: **CDX-2000A** S/N **B9700210**
CALIBRATION FACTOR OF ELECTROMETER: **(C.E.)** _____

CHAMBER: **HDR-1000 Plus** **A970132** OTHER: _____
CHAMBER CALIBRATION FACTORS **(Cal. FOR HDR-1000 Plus):**

Air Kerma Strength C.F.:	4.664×10^{5} Gy m^2 h^{-1} A^{-1}
Exposure Rate C.F.:	5.318×10^{7} R m^2 h^{-1} A^{-1}
Activity C.F.:	4.281 GBq nA^{-1} or
	1.157×10^{-3} Ci A^{-1}

$$\Gamma = 4.66 \frac{R}{h} \frac{cm^2}{mCi} \qquad A = \frac{Xd^2}{\Gamma}$$

CHAMBER CALIBRATION DATE: _____
BAROMETER: _____ PRESSURE: _____
THERMOMETER: _____ TEMPERATURE: _____
Cal: _____

MAXIMUM READING SEARCH

Time (sec)	Position	Electrometer reading

READINGS AT POSITION OF MAXIMUM

Time (sec)	Electrometer reading
Average:	

$$A = R\left(\frac{273.2 + T}{295.2} * \frac{760}{P}\right) * C.E. * Cal.$$

= _____

= Ci

COMPARISON WITH MANUFACTURER CALIBRATION

BMI	MALLINCKRODT	Δ%
Ci	Ci	

9.2

microSelectron-HDR
Relocation Procedure
Treatment Unit/Treatment Control Unit

1. Lower head to transport position (run elevator motor in the downward direction until the motor stops).

2. Make sure the left hand key switch is in the off position.

3. Check the key on the treatment unit that locks the source in the safe(in the locked position).

4. Survey head of TU for verification of "source in safe" condition. Hand held survey meter to accompany unit during transport.

5. Disconnect TU data cable from wall box. This is accomplished by unscrewing the ribbed ring on the CPC connector (the connector will disengage while the ring is being turned).

6. Turn power off to unit (switch located on the base of the TU).

7. Unplug the power cable from the power conditioner and along with the data cable, secure them to the TU.

8. Disconnect the TCU data cable from the rear of the unit as per step #5.

9. Transport the TU, TCU and power conditioner to the room in which it is to be relocated.

10. Upon arrival in new location plug TU power cord into the on line power conditioner.

11. Turn on the power to the TU and check that the audible "power off" stops beeping.

12. Reconnect TU data cable to the wall box taking precautions to align the pins so as to not damage the pins.

13. Reconnect the TCU data cable.

14. Re-survey the head of the TU to verify the "source safe" condition.

15. Unlock source lock on head of TU

16. On the TCU, turn the left hand keyswitch to prepare and verify a normal "initialization" occurs.

17. Run a complete Q/A process on the system to verify correct function of all systems ie. door interlock, "E" stop boxes, source transport and source position verification.

18. Complete all required documentation.

EMERGENCY PROCEDURES

EMERGENCY PROCEDURES

FOR

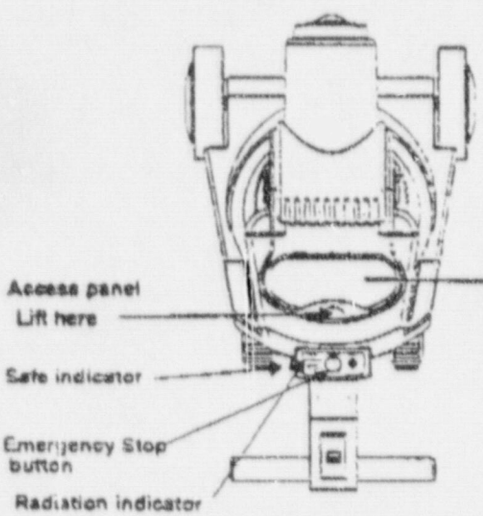
microSelectron-HDR

IF THE SOURCE FAILS TO RETURN TO THE SAFE

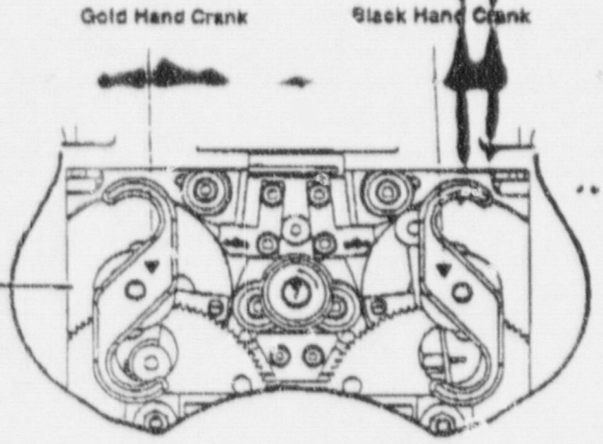
1. Depress RED EMERGENCY STOP BUTTON on emergency stop button on the treatment control panel. If the source retracts, go to step 7, otherwise step 2.

2. Enter the treatment room.

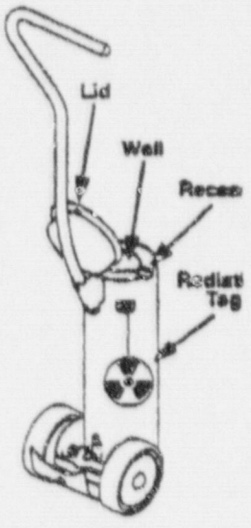
   - Lift the access panel on top of the treatment unit to access the GOLD hand crank. Turn it in the direction of the arrows (on the hand crank) until it blocks.
   - If the source retracts, go to step 7, otherwise step 3.



Access Panel Location



Gold Hand Crank Location



Emergency Container

3. Check the patient for radiation. If detected, remove the applicator from the patient, ensuring that radiation is confined to the applicator. Open the lid of the Emergency Container. Insert the applicator containing the source into the well, using long forceps. Guide the transfer tube through the recess at the container edge. Close the lid. Leave the radiation warning tag hanging outside the container, to indicate it contains radioactive material.

4. IMMEDIATELY assist the patient from the room.

5. Ensure that the applicator and source are safely stored inside the emergency container.

6. Leave the room. Close the door. Mark it NO ENTRY.

7. Retain the treatment data printout and contact the following:

Physicist:	Tel.....
Doctor:	Tel. .....
Nucletron-Oldelft Representative:	Tel. .....

The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

DRAFT

A significant safety risk of High Dose Rate remote afterloading brachytherapy procedures is the loss of the source outside of the shielded safe of the device. This risk is virtually eliminated in the Nucletron MHDR by both source and afterloader design as well as certification of source integrity to more than 20,000 transfers. The design includes a highly accurate measuring mechanism that the length of the source and cable every time the source is advanced from the shielded safe retraction, the length is verified. If a discrepancy exists an Error Code is generated and operator. Due to the high intensity of radiation emitted by this source proper precautions must be taken for any actions related to retrieval of a disconnected source including removal of applicators and catheters from patients and recovery of the source into a shielded storage container. In keeping the ALARA principle, all source recovery efforts should be conducted using time, distance, shielding with appropriate film dosimetry of the effected staff and estimated radiation dosage to the patient.

An unshielded source is considered to be an encapsulated source that has either detached from its driving cable or has not been positioned appropriately either within the shielded safe of the unit, or the shielded transport container. This condition will be apparent if the independent Radiation Monitor is activated when the unit has retracted the source cable.

If a source is determined to be in an unshielded condition, ascertain if it is detached from its drive cable. Review the Error Codes listing in the MHDR User's Manual for appropriate Error Codes for this condition. If the source cable drum is not fully against the mechanical stop and radiation is still present in the room, follow the posted Emergency Procedures titled **"If the Source fails to Return to the Safe"**. These procedures describe the use of the Emergency Stop button located at the Treatment Unit, and the use of the GOLD hand crank to manually retract the source into the shielded safe of the unit. If the source cable drum is fully against the mechanical stop and radiation is still present in the room, use of a survey meter can determine if the capsule is detached and its approximate location.

If during a patient treatment, the above Emergency Procedures fail to position the source in a shielded location, the following Emergency Procedures should be followed explicitly.

ENDOBRONCHIAL - ESOPHAGEAL TREATMENT

1. Ascertain the channel number currently being treated when the Error Code is generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000R/hr) and confirm that there is radiation in or near the patient's body.

3. Rapidly and smoothly remove the applicator from the patient's body maintaining its connection to the afterloading device.

4. A shielded emergency container should be available for insertion of the removed applicator.

5. After the applicator has been removed, survey the patient with the hand held survey meter to confirm that the source has indeed been removed from the patient.

INTRACAVITARY APPLICATORS

1. Ascertain the channel number currently being treated when the Error Code is generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (>1000R/hr) and confirm that there is radiation in or near the patient's body.

3. Rapidly disassemble the applicator and remove any packing material. The applicator components should be removed in the reverse order of insertion.

4. Rapidly and smoothly remove the applicator from the patient's body maintaining its connection to the afterloading device.

5. A shielded emergency container should be available for insertion of the removed applicator.

6. After the applicator has been removed, survey the patient with the hand held survey meter to confirm that the source has indeed been removed from the patient.

INTERSTITIAL IMPLANTS - FLEXIBLE

1. Ascertain the channel number currently being treated when the Error Code is generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (> 1000R/hr) and confirm that there is radiation in or near the patient's body.

3. Using a suture removal kit, sever any sutures that are retaining the implant tubes to the patient. If the distal end of the implant tube is protruding from the patient's skin and secured with a button, remove the button from the tube without severing the tube.

4. Have available sterile drapings to cover the wound left by the applicator removal.

5. A shielded emergency container should be available for insertion of the removed applicator.

6. After the applicator has been removed, survey the patient with the hand held survey meter to confirm that the source has indeed been removed from the patient.

INTERSTITIAL IMPLANTS - RIGID

1. Ascertain the channel number currently being treated when the Error Code is generated using the print out.

2. Enter the room with a hand held survey meter at its highest setting (> 1000R/hr) and confirm that there is radiation in or near the patient's body.

3. Using the appropriate tool, loosen the needle clamp on the effected needle and withdraw it from the template or fixing mechanism.

4. A shielded emergency container should be available for insertion of the removed applicator.

5. After the applicator has been removed, survey the patient with the hand held survey meter to confirm that the source has indeed been removed from the patient.

Unshielded source not within the patient's body.

If after following the posted Emergency Procedures and the source is not returned to the shielded safe, or contained in the Emergency Container, the following procedure shall be followed contain the radiation emitted by an unshielded source.

1. Remove the patient from the treatment room.

2. Survey the patient to determine if radiation is present.

3. Park the unit in a corner of the shielded room with the indexer facing the corner. The emergency storage container should be adjacent to the unit and contain as much of the applicator/treatment tube as possible.

4. Evacuate and lock the room against ingress.

5. Notify the hospital R.S.O.; Nucletron Corporation R.S.O.; and the appropriate Agreement State or NRC Regional Office

DISPOSAL

Nucletron

Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133
410-312-4100
Fax 410-312-4199
http://www.nucletron.com

To whom it may concern:

The following information summarizes the Nucletron source procurement, delivery and spent source disposal procedures.

Nucletron Corporation is responsible for ordering and delivering Ir-192 sources to clinical sites requiring initial or replacement sources. Sources are ordered from and returned to the manufacturer, Mallinckrodt Medical in Petten, The Netherlands Sources are fabricated with activities exceeding 10 Ci and delivered to the customer with activities of approximately 10 Ci for installation in the machine at 10 Ci or less. If the site's radioactive material license permits, the source may be shipped to the site for storage for decay to 10 Ci. Nucletron personnel are responsible for initial installation of the Ir-192 source in the mHDR, and thereafter for the removal of the depleted source and installation of the replacement source at the clinical site. Nucletron is the party responsible for transportation of the source to and from the clinical site and is responsible for arranging for transportation of the fresh source to the clinical site and for transportation of the depleted source to the manufacturer, Mallinckrodt Medical in Petten, The Netherlands. Mallinckrodt Medical has a license (# AI/C/VCR/KEW96/3519S) to manufacture and dispose of Ir-192 sources issued by the government of The Netherlands. This license is cited in the attached letter from Mallinckrodt.

Ralph Shuping, Sc.D.
Regulatory Affairs Manager