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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

MAY 04 1993

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Docket No. 030-31765 - EA

Board Notification 93-10

MEMORANDUM FOR: Atomic Safety and Licensing Board
and All Interested Parties

FROM: John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: NEW INFORMATION POTENTIALLY RELEVANT TO LICENSING BOARD PROCEEDING IN THE MATTER OF ONCOLOGY SERVICES CORPORATION

In conformance with the Commission's policy on Board notifications, this memorandum calls attention to the staff's actions with respect to Oncology Services Corporation (OSC) during the period of March 15, 1993, through April 22, 1993. All of the staff's actions prior to March 15, 1993, were previously summarized in the staff's response of March 15, 1993, to the Board's Memorandum and Order (Requesting Additional Party Filings Addressing Issue of "Overriding Patient Need").

A meeting was held at Region I to discuss OSC's February 15, 1993, request for a general relaxation of the Order to permit resumption of licensed activities at the Greater Harrisburg and Pittsburgh Cancer Centers on March 23, 1993. The results of this meeting were summarized in a Region I management meeting report, sent to OSC on March 30, 1993. In the interim, OSC responded by letters, dated March 26, 1993, and April 8, 1993, addressing the concerns and deficiencies discussed during the meeting. The letter, dated April 8, 1993, from OSC completes the response to the staff's March 5, 1993, information request. Region I's determination of the acceptability of OSC's response, in a letter to OSC dated April 22, 1993, starts the estimated six week process for the staff to make a determination on OSC's February 15, 1993, relaxation request. Copies of all documents related to this meeting are enclosed (Enclosures 1, 2, 3 and 3a.)

In a letter, dated March 22, 1993, OSC requested relaxation of the Order, suspending license for performing a source exchange for their Omnitron 2000 remote afterloader located at their Greater Harrisburg Cancer Center. This relaxation was granted on April 2, 1993, by Region I staff. By letter, dated April 12, 1993, OSC informed Region I that the approved source exchange was scheduled for April 22, 1993 (Enclosures 4 - 8.) In addition, in a letter dated March 23, 1993, OSC requested relaxation of the Order to permit the treatment of six additional patients at their Greater Harrisburg Cancer Center facility. This relaxation request was granted by Region I staff on March 26, 1993 (Enclosures 9 and 10).

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On February 5, 1993, OSC submitted a request to Region I to amend their NRC license to change their Radiation Safety Officer from David E. Cunningham, Ph.D., to Bernard Rogers, M.D. This was followed by a March 31, 1993, letter requesting the deletion of mobile service and authorization for OSC personnel to perform source exchanges on their remote afterloading devices. On April 2, 1993, Region I issued Amendment No. 04 to OSC's license authorizing the requested changes (Enclosure 11 with attachments).

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:
1. RI ltr to OSC, dtd 03/30/93
   w/attached mtg summary
2. OSC ltr dtd 03/26/93
   w/2 attachments
3. Ltr fm OSC to RI dtd 4/8/93
3a. Ltr fm RI to OSC dtd 4/22/93
4. OSC request fr source exchange
   dtd 03/22/93
5. Ltr fm Dr. Unal on source
   exchange dtd 03/30/93
6. Ltr fm Dr. Unal on source
   exchange dtd 03/31/93
7. Relaxation fr source exchange
   dtd 4/2/93
8. Ltr fm OSC informing RI of
   scheduled source exchange
   dtd 04/12/93
9. OSC request to treat 6 new patients
   dtd 03/23/93
10. Relaxation for treating 6 patients
    dtd 03/26/93
11. Amend No. 04 to OSC license
    dtd 04/2/93 w/attachments

cc: Service List

Board Notification 93-10 dated May 4 , 1993

NRC Service List

J. Taylor, EDO
H. Thompson, DEDS
R. Bernero, NMSS
G. Arlotto, NMSS
W. Parler, OGC
L. Chandler, OGC
R. Cunningham, IMNS
J. Liberman, OE
T. Martin, RI
SECY (3)

SERVICE LIST

G. Paul Bollwerk, III, Chairman
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dr. Charles N. Kelber
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dr. Peter S. Lam
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Atomic Safety and Licensing Board
Panel (1)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Adjudicatory File (2)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Office of the Commission Appellate
Adjudication (1)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Office of the Secretary (2)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn.: Docketing and Service Section

Kerry A. Kearney, Esq.
Counsel for Oncology Services Corp.
Reed Smith Shaw & McClay
P.O. Box 2009
Pittsburgh, PA 15230

Marcy L. Colkitt, Esq.
General Counsel
Oncology Services Corp
110 Regent Court, Suite 100
State College, PA 16801

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MAR 30 1993

Docket No. 030-31765 License No. 37-28540-01
EA No. 93-006

Oncology Services Corporation
ATTN: Douglas R. Colkitt, M.D.
President
110 Regent Court, Suite 100
State College, Pennsylvania 16801

Dear Dr. Colkitt:

SUBJECT: Management Meeting conducted March 23, 1993

This letter refers to the Management Meeting conducted at our Regional office in King of Prussia, Pennsylvania relative to our March 5, 1993, letter which outlined the deficiencies in your February 15, 1993, submittal. The meeting was attended by Dr. Bernard Rogers and other members of your staff and myself and other NRC staff members.

Although the meeting was productive and useful and enabled us to gain a better understanding of your completed and planned actions to address the identified deficiencies, your staff was unable to address certain major items in our March 5, 1993 letter. Of particular concern are: the lack of plans for establishing and implementing a corrective action system for identified audit findings; the lack of corporate expectations and Statement of Responsibility for the Radiation Safety Officer; and the lack of a Radiation Safety Committee Charter. Correction of these weaknesses in management oversight of your radiation safety program through the Radiation Safety Officer is essential to your long term ability to safely conduct HDR operations under your license, and to our approval of your February 15, 1993 request for relaxation of the Order at the Greater Harrisburg and Pittsburgh Cancer Centers.

At the end of the meeting, OSC representatives committed to provide the NRC with full and detailed clarification for all the issues raised in our March 5, 1993 letter. The licensee was reminded that the NRC staff would not be able to resume its detailed review of the licensee's February 15, 1993 request to relax the January 20, 1993 suspension order until the staff receives the licensee's response to the March 5, 1993 letter. The licensee stated that all requested information, including the response to the March 5, 1993 letter, would be submitted to the NRC staff to support a decision for the resumption of licensed activities at the Greater Harrisburg and Pittsburgh Cancer Centers.

Subsequent to the meeting, on March 26, 1993, the licensee submitted information in response to the March 5, 1993 letter. This information is currently under staff review.

In accordance with 10 CFR 2.790, a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

No reply to this letter is required. Your cooperation with us in this matter is appreciated.

Sincerely,

Richard W. Cooper, II, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Management Meeting Report

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

bcc:
Region I Docket Room (w/concurrences)
H. Thompson, DEDS
R. Bernero, NMSS
E. Jordan, AEOD
T. Martin, RI
W. Kane, RI
C. Paperiello, RIII
R. Cooper, RI
L. Spessard, AEOD
S. Shankman, RI
R. Bellamy, RI
B. Letts, RI
M. Shanbaky, RI
D. Holody, RI
T. Easlick, RI
K. Smith, RI
P. Nessen, RI
J. Glenn, NMSS
J. Lieberman, OE
R. Cunningham, NMSS
J. Moore, OGC
J. Goldberg, OGC
S. Lewis, OGC
K. Abraham, PAO
J. DelMedico, OE

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-31765/92-001

Docket No. 030-31765

License No. 37-28540-01 Priority 2 Category G

Licensee: Oncology Services Corporation
775 South Arlington Avenue
Harrisburg, Pennsylvania 17109

Facility Name: Oncology Services Corporation

Management Meeting Conducted At: King of Prussia, Pennsylvania

Management Meeting Conducted: March 23, 1993

Prepared By: M. Shanbaky 3/29/93
Mohamed Shanbaky, Chief Date
Medical Inspection Section

Approved By: Richard W. Cooper, II 3/29/93
Richard Cooper, II, Director Date
Division of Radiation Safety
and Safeguards

Meeting Summary: A Management Meeting was held at the NRC Region I Office in King of Prussia, Pennsylvania on March 23, 1993, to discuss NRC, Region I's March 5, 1993, letter outlining the deficiencies identified in Oncology Services Corporation's February 15, 1993, submittal.

DETAILS

1.0 Attendees

Oncology Services Corporation:

Bernard Rogers, M.D., Medical Director of Brachytherapy Services
Robert Gallaghar, Health Physics Consultant
Sayed Mansour, Assistant President of Physics

NRC:

Richard Cooper, II, Director, Division of Radiation
Safety and Safeguards
Mohamed Shanbaky, Chief, Medical Inspection Section
Penny Nessen, Health Physicist, Medical Inspection Section
Tom Thompson, Health Physicist, Medical Licensing Section
Karla Smith, Regional Counsel
Robert Ayres, Nuclear Materials Safety and Safeguards, Headquarters

2.0 Summary

On March 23, 1993, representatives of Oncology Services Corporation (OSC) met with NRC representatives in the Region I Office at King of Prussia, Pennsylvania. In an opening statement, Mr. Richard W. Cooper, the Region I Director of the Division of Radiation Safety and Safeguards explained the purpose of the Management Meeting.

Mr. Robert Gallaghar, the licensee's health physics consultant provided opening remarks on the licensee's February 15, 1993, submittal.

Mr. Gallaghar discussed the licensee's audit and certification process for all OSC cancer treatment centers. He indicated that the audit process would continue for 12 months and audits of a facility would be performed at least annually. Mr. Gallaghar stated that the audit process would include unannounced and off-shift audits, interviews with staff, observations of staff, radiation measurements, and examination of equipment. Mr. Gallaghar also stated that the certification of a facility would not be granted or would be rescinded if the facility did not meet minimum requirements of the NRC regulations and license conditions. He also stated that the certification program that he was developing and implementing would, when attained by each Cancer Center, provide a level of

performance in excess of that provided by compliance with regulations. Mr. Gallaghar indicated that the Greater Pittsburgh Cancer Center and the Harrisburg Cancer Treatment Center are ready for certification pending the completion of a 30 day dosimetry study being performed in the surrounding areas of the Centers.

Mr. Cooper informed the licensee that the final audit reports to which the licensee committed in a Confirmatory Action Letter of December 14, 1992, and discussed in a January 27, 1993, Management Meeting, were not submitted by the licensee. The licensee committed to provide to NRC Region I the final audit report discussed in the January 27, 1993, meeting with a corrective action plan addressing identified weaknesses.

Mr. Cooper asked OSC representatives to clarify OSC's corrective action system for identified audit findings. OSC representatives stated that this area would be reviewed and OSC plans and procedures for developing and implementing a corrective action system would be provided in their written response to NRC's March 5, 1993, letter.

With regard to the statements of responsibilities for the Radiation Safety Officer (RSO), the Authorized User (AU), and the physicist, the licensee provided additional information. The licensee stated that they were unable to discuss the status of the statement of responsibility for the RSO and would forward this document to NRC Region I with their response to the March 5, 1993 deficiency letter. Further, the licensee indicated that the statement of responsibility of the AU would be updated to include his required presence at the high dose rate afterloader (HDR) treatment console during patient treatment, the responsibility for ensuring that hand held survey meter measurements are taken after patient treatment, and clarification on the delegation of authority process from the AU to other staff members. The licensee also discussed their requirement that the physicist be present at the HDR treatment console during patient treatment and committed to add this requirement to the statement of responsibility for the physicist.

With regard to the Radiation Safety Committee (RSC), the licensee was in the process of creating the RSC charter and documentation process but was unable to provide any proposed RSC charter. The licensee committed to forward this document to NRC Region I with their response to the March 5, 1993, deficiency letter.

With regard to the licensee's radiation safety training program, the licensee was unable to discuss in detail their radiation safety training procedures and committed to provide this information to NRC Region I with their response to the March 5, 1993, deficiency letter.

Dr. Rogers, the licensee's Medical Director of Brachytherapy and proposed RSO, discussed the licensee's emergency procedures. Dr. Rogers indicated that he will provide a video within the next two weeks to AU's that discusses the emergency procedures to be taken for each type of implant. Dr. Rogers indicated that no open ended catheters are used in implants, and stated that the method used to determine whether the source wire

is broken is by using a hand held survey meter and responding to the alarming of the primealert.

With regard to the license amendment submitted by the licensee to change the RSO, Dr. Rogers discussed his desire to change the previously suggested frequency of visits to each of the two facilities from one day every week to once every two weeks, and committed to provide NRC Region I with a written statement estimating the percentage of his time that will be spent on radiation safety duties while at the facilities and the subject matter of the RSO inspections. Also, the licensee was unable to provide criteria for determining when Mr. Gallaghar's services for augmenting and training the RSO would no longer be needed and agreed to provide this information at a later date.

Finally, Mr. Cooper discussed the licensee's request to limit the location of use to the Harrisburg and Pittsburgh facilities. Mr. Cooper informed the licensee that the other four facilities cannot be deleted from the license until either the other four facilities are decommissioned or applications are received and processed to independently license the other four facilities.

The licensee committed to provide a written response to NRC Region I addressing all of the items listed in the March 5, 1993, deficiency letter and discussed in this Management Meeting.

Mr. Cooper reminded the licensee that until the NRC receives a docketed, written response to the March 5, 1993, letter that addresses each of the deficiencies therein and provides clarification as discussed at this meeting, the NRC is unable to act on the licensee's February 15, 1993, request for relaxation of the Order for the Greater Harrisburg and Pittsburgh Cancer Centers. The licensee was also reminded that the NRC would have to evaluate the submittal and independently inspect each facility before it would consider relaxation of the Order.

Mr. Cooper thanked the licensee for the information provided and the meeting was then adjourned.

ONCOLOGY SERVICES CORPORATION

110 Regent Court • Suite 100 • State College, PA • 16801 814-238-0375 • 800-628-9076 • Fax: 814-238-8069

March 26, 1993

Via Telecopy

U.S. Nuclear Regulatory Commission
Region I
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

ATTN: RICHARD W. COOPER, II, DIRECTOR
MOHAMED M. SHANBAKY, PH.D., SECTION CHIEF

RE: License No. 37-28540-01, Docket No. 030-31765
Mail Control No. 117698

Dear Mr. Cooper and Dr. Shanbaky:

As a result of the March 23, 1993 meeting between you and other members of your staff and Bernard Rogers, M.D., Sayed Mansour and our consultant, Robert G. Gallaghar, CHP of Applied Health Physics, Inc., it is my understanding that you will expedite our request dated February 16, 1993 for an amendment of our license to change the designated Radiation Safety Officer (RSO) from David E. Cunningham, Ph.D., CHP to Bernard Rogers, M.D. based upon the following facts:

1) Dr. Rogers will devote substantial professional efforts to the organization and operation of our radiation safety program at Harrisburg and Pittsburgh.

2) The quality of Dr. Rogers professional services as RSO is more important than the frequency of his visits to NRC licensed facilities. However, during a transitional period of 10 weeks, Dr. Rogers will be auditing the High Dose Radiation (HDR) operations at the Pittsburgh and Harrisburg facilities on a bi-weekly basis, assisted by Mr. Gallaghar, Mr. Mansour and possible others.

3) Dr. Rogers work as RSO will implement the recommendations resulting from Applied Health Physics' (AHP) audits of the radiological operations specified in our Operating Procedures Manual (OPM). OSC's OPM will be reviewed quarterly by AHP and/or the RSO with annual re-authorization to include all revisions and updates as approved by the RSO. The RSO will see that the NRC as well as other regulatory agencies are informed of amendments and additions to the OPM in a timely manner.

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4) Enclosed as Attachment 1 is a copy of the OSC RSO Job Description.

The following concern the number of hours and specific services that are being provided by Applied Health Physics (AHP) under Mr. Gallaghar's direction:

* Our contractual commitment for a 12 month period has been prepaid for 500 hours of professional services plus associated expenses by AHP.

* AHP's initial assignment calls for a comprehensive audit of radiological safety and regulatory compliance.

* AHP has completed their audits of OSC's Pittsburgh and Harrisburg facilities. Mr. Gallaghar is in the process of completing his reports and intends to provide us with certification of both centers on or before April 15, 1993.

* Attachment 2 herein contains an outline of the specific items and documentation reviewed in a typical audit of OSC by AHP. At this time we do not have a specific criteria, other than the quality of AHP's services for determining when their support is no longer required.

Please contact me directly if you require additional information relative to lifting the suspension order as to the Pittsburgh and Harrisburg facilities. It is my understanding that this process can be completed within a few business days. I can be reached today at 814-238-0375.

Thank you.

Very truly yours,

Douglas R. Colkitt, M.D.

DRC/amh

Attachments

ONCOLOGY SERVICES CORPORATION

RADIATION SAFETY OFFICER

POSITION TITLE - Radiation Safety Officer (RSO)

POSITION PURPOSE

Satisfies all regulatory requirements as set forth in Title 10 CFR 35.21; NCRP Report No. 59, Section 2.1; and NCRP Report No. 105, Section 5.3 (see references 1, 2 & 3). Implements corporate radiation safety and regulatory compliance policy and procedures. Instructs and oversees commitments to controlling radiation risks to levels that are as low as reasonably achievable (ALARA).

RESPONSIBLE TO/ACCOUNTABILITY

The Radiation Safety Officer (RSO) reports directly to the Chief Executive Officer (CEO) of the corporation.

PRINCIPAL DUTIES AND RESPONSIBILITIES

The RSO reviews training, documentation, exposure investigations, adherence to written operating procedures manual (OPM); use, calibration, repair, maintenance of radiation instrument and alarms; verifies receipts, transfer, and distribution of licensed radioactive materials as well as the maintenance, calibration and authorize usage of radiation producing equipment.
The RSO is responsible for selection, training and supervision of an assistant RSO who will be capable of assuming and effectively performing the RSO's duties in the absence of the RSO.
Responsible for application, modification, renewal of all corporate licenses, registrations, permits, and certificates associated or required for the use of radioactive material and/or radiation producing devices. The RSO may approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of the CEO.

Investigates, identifies and reports apparent deficiencies as well as the progress of implementation of all of corporate policies, regulatory compliance, adherence to OPM requirements, practices and procedures. Recommends and institutes remedial actions as necessary to control unnecessary risks to corporate regulatory compliance, credibility and responsibility.
Assists and evaluates the selection, quality assurance, installation acceptance testing, calibration maintenance and deposition of radiation producing equipment.
Provides professional guidance to OSC personnel responsible for design, construction, modification of cancer centers relative to radiation shielding specifications and testing.

Assumes responsibility for acquiring and adapting as necessary changes in regulatory requirements, applicable radiation safety criteria. Disseminates this information throughout the corporation to other professionals who might be interested or impacted by such changes in policies, procedures or enforcement practices.

Enhances professional growth and competency through active participation in educational programs, seminars, workshops, and conferences needed to keep abreast of the safe and effective use of radiation to treat cancer.
Perform such other duties and assignments as may be directed or required.

KNOWLEDGE, SKILLS, EXPERIENCE REQUIRED

Advanced academic degree (ScD; Ph.D., MS in health physics, radiological physics and/or current certification by the American Board of Health Physics (comprehensive practice): The American Board of Radiology (radiation therapy). The RSO may be a physician or other individual qualified by virtue of applicable training and experience as an RSO. At least 5 years of acceptable service at a medical institution wherein the individual was named RSO in the institution's license.

Detailed Outline of Applied Health Physics for Performing

a

Radiological Safety Audit of Oncology Services Corporation

INTRODUCTION

Name and Address of OSC Cancer Center
Department
Name and Title of User Visited
Description of Licenses, Registrations
Type and Date of Visit
Name(s) of All Personnel Making Survey
Distribution of Report of This Survey/Audit and Follow-Up

I. ADMINISTRATIVE CONTROL

- A. Program & Policy Statement by CEO
- B. Organization
  - 1. Designation of Responsibility
    - a. RSO - Qualifications
    - b. Radiation Safety Committee
      - (1) members
      - (2) chairman
      - (3) functions
  - 2. Authority of RSO (Radiological Safety Officer)
    - a. Control Routine Operation
    - b. Cope with Emergency Condition
- C. Written Administrative (Radiological Protection) Procedures (Instructions)
  - 1. Details Covered
    - a. Responsibility of Material
    - b. Responsibility For Decisions Concerning Radiation Protection
  - 2. Responsible Person for Changes Therein
  - 3. Instruction of Personnel
    - a. Area Designations (labels, radiation levels, rules, roping off, etc.)
    - b. Handling of Material
      - (1) techniques
      - (2) security
      - (3) storage
      - (4) disposal
      - (5) leak testing
    - c. Monitoring Procedures

4. Written Emergency Procedures
   a. Control Measures
      (1) emergency equipment
      (2) radiation ins uments standby in safe area
      (3) decontamination equipment
   b. Liaison With Local Fire Department

D. Experience and Training of Personnel
   1. Choice of Personnel
      a. Education
      b. Experience
   2. Training Program
      a. Details Covered
      b. Frequency and Length

E. Procurement Control
   1. Responsibility
   2. System
   3. Method of Maintaining and Auditing Possession Limit

F. Decontamination and Decommissioning
   a. Review Written Plan Filed With Regulatory Agency
      (1) Decommissioning Funding Plan
      (2) Financial Assurance Mechanisms
      (3) Administration's Notification System
      (4) Instructions to RSO
   b. Evaluate Adequacy of Funding & Protocols

II. <u>RADIOACTIVE MATERIAL USED AND/OR INDUCED (Intentionally or Inadvertently)*</u>

A. Material On Hand
   1. Types
   2. Quantities
   3. Forms
      a. Sealed Sources
         (1) capsule
            (a) model
            (b) identification
            (c) tag
         (2) leak test
      b. Other

B. Calibration Procedures
   1. Instrumentation
      a. Method
      b. Frequency

C. Uses
   1. Human
      a. Research
      b. Routine
         (1) diagnostic
         (2) therapeutic
      c. Sterilization Method Used

D. Disposal
   1. Method of Disposal
      a. Site
      b. Control
   2. Quantity
      a. Amount of Effluent
      b. Concentration
      c. Accumulation

*See Table I - "Examples of Accelerator Produced Radioactivity"

III. FACILITIES AND EQUIPMENT

A. Laboratory or Radiation Room
   1. Location
      a. Surrounding Areas
      b. Control
         (1) interlocks
         (2) barriers
         (3) marked or roped off areas - roof top
         (4) segregation
   2. Ventilation - Mold Room re: Pb., Cd.
      a. General Air Flow
      b. Hoods and Dry Boxes
         (1) air flow
            (a) measures (75 to 100 cfm)
            (b) design (turbulence)
         (2) exhaust
            (a) location of blower
            (b) filters
            (c) length and location of stack
            (d) concentrations released
         (3) surfaces
         (4) shielding
         (5) location of control
   3. Surfaces
      a. Floor
      b. Walls
      c. Ceiling
      d. Sink
         (1) drain
         (2) segregation
      e. Bench Tops
      f. Secondary Contamination Control
         (1) trays
         (2) diaper paper

B. Radiation Producing Equipment (Accelerator)
   1. Type and Operating Characteristics (Power Levels Peak; Routine)
      a. Particles Accelerated, Energies
      b. Radiation - Primary Beam, MEV
      c. Beam Orientations & Alignment Practices
      d. Duration (Pulse Rate)

2. Targets
    a. Types
    b. Access & Transfer Methods
    c. Maintenance & Repair
3. Operating Procedures
    a. Routine
    b. Authorize Deviations
    c. Problem Identification and Safeguard Analysis
    d. Independent Audit by CHP
    e. Visitor/Contractor Access Control
4. Future Changes
    a. Location
    b. Operations
    c. Safety Procedures

C. Shielding
1. Portable and Semi-Portable
    a. Security (stability)
    b. Used Properly
    c. Design
        (1) material
        (2) thickness
        (3) floor loading
    d. Fire Resistance
    e. Radiation Levels Verified
    Transmission/Activation
    f. Labels, Warning; Re: Access,
    Radiation Control
2. Fixed
    (see above)

D. Equipment; Radiological Safety
1. Tongs for emergency source recovery
2. Fire, Smoke Detection & Automatic Suppression
3. Waste Containers - Pb. Cd.
    a. Labels
    b. Contamination Control

E. Instrumentation, Radiation, Fixed, Alarms, Portable
1. Measurement
2. Survey
    a. Low Level
    b. High Level
    c. Calibration
    d. Operation Alarms, Warnings
    e. Air and Water Sampling - Re. Pb.
3. Personnel Monitoring
    a. Film Badge/TLD
        (1) operation
        (2) readings
4. Leak Test
    a. Method
    b. Handling Facilities
    c. Counter
5. Location
    a. Utility
    b. Availability in Emergency

IV. PRECAUTIONARY PROCEDURES

A. Medical Control
   1. Physical Examinations
      a. Pre-employment
         (1) blood count
         (2) general
         (3) radiation exposure history (occupational/therapeutic)
         (4) written approval by M.D. (fit for radiation work)
      b. Routine
         (1) blood count
         (2) general
         (3) frequency
      c. Emergency
   2. Overexposures
      a. Magnitude
      b. Written Explanation and Investigation
      c. Corrective Action

B. Radiological Survey Procedures
   1. Air
   2. Surface and Personnel - HDR & Linac

C. Personnel Radiation Monitoring
   1. Type
      a. Film Badge
         (1) name of supplier - TLD
         (2) number
         (3) frequency
         (4) overexposure notification procedure
      b. Pocket Chambers
   2. Records
      a. Individual
      b. Totalized
      c. Notification
      d. Investigation of Overexposure
   3. Contamination Monitoring of Personnel - Pb. Cd.
      a. Routine
      b. Recorded
      c. Procedure Required

D. Controlled Areas
   1. Radiation Levels
      a. High Radiation Area
         (1) control alarm
         (2) temporary
      b. Radiation Area
      c. Airborne Radioactivity
      d. Containers
      e. Disposal Area
   2. Radiation Warning

E. Uncontrolled Areas
   1. Radiation Levels
      a. Peak
      b. Integrated
   2. Signs, Signals, Labels
   3. Occupancy

V. RECORDS

A. Personnel Monitoring
B. Surveys
   1. Area
   2. Leak Tests
C. Receipt and Transfer
D. Disposal
E. Accidents, Over-Exposure
   1. Commission Notified
   2. Insurance Carrier Notified
   3. Investigation Protocol Verified

VI. COMPLIANCE WITH REGULATIONS

A. Information on Applications, Form 313
   1. Instrumentation
   2. Facilities
   3. Equipment
   4. Procedures (last review/revision dates)
B. Special Conditions
   1. Radiation Surveys
   2. Written Procedures
   3. Detailed Drawings
   4. Tags, Warnings; Safety Lockout for Repair
C. Possession Limit Verified by Physical Audit
D. Location of Material
E. Use and User Authorization Verified
F. Instruction of Personnel Documented
G. Exposure of Personnel Posted
H. Export/Import Compliance
I. Radioactive Waste Management Records

VII. HAZARDOUS CONDITIONS

A. Radiation Levels
   1. On-site Verification Timely/Adequate.
      (a) restricted areas
      (b) non-restricted areas

DOCUMENTATION AUDIT

The following documents are relative to regulatory compliance and radiological safety and will be included in audits of Oncology Services operations by Certified Health Physicists from Applied Health Physics, Inc.

(1) Teletherapy Treatment Manual

(2) HDR Source Data: Acceptance Testing and Original Radiation Surveys

(3) HDR License and NRC Regulations - NRC Inspection reports and correspondence

(4) QA for simulators - RP's notes and surveys

(5) Calibration - Radiation Source

(6) Calibration survey meters and alarm systems

(7) State Regulation - copies of registrations, inspection reports, correspondence file

(8) HDR Transport (shipping & receiving, leak test, survey documentation)

(9) Chambers (Calibration Record)

(10) HDR Patient Treatment Planning - dose verification (computer vs. manual calculation)

(11) HDR Patient Treatment Record II - Patient identification, technician/RP's notes - M.D. prescription.

(12) Applicator List - inventory

(13) Weekly Physics QA (LINAC) 1993 & 1992 - RP's check/survey after any repair

(14) Annual Report (LINAC); Verification, survey

(15) Weekly Physics QA (1992 & 1993) for HDR

(16) Physics Report Commissioning (HBG) 1987

(17) Electrometer (Calibration)

(18) HBG QA & Physics Reports Annual & Monthly

(19) Radiation Safety Meeting Log - Committee Credentials

(20) HDR Manual

(21) HDR Training Sessions Log

(22) Service Log LINAC

(23) Operation Manual of EXL-8 HBG

(24) All documentation of all radiological safety & regulatory compliance training provided to OSC employees.

(25) OSHA compliance - MSDS log,
*training ("right to know") Pb/Cd

(26) Personnel Roster with Job Descriptions