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U.S. NUCLEAR REGULATORY COMMISSION

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Amendment No. 12

JUN 12 1900

MATERIALS LICENSE - TELETHERAPY

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s), and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with application dated November 15, 1982
1. Veterans Administration Medical Center 130 West Kingsbridge Road 2. Bronx, New York 10468	3. License number 31-00636-02 is amended in its entirety to read as follows:
	4. Expiration date March 31, 1988
	5. Docket or Reference No. 030 00363

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Teletherapy sealed sources (Picker Corp. Model P3800A through P3802A or Advanced Medical Systems, Inc., Model AMS-3802)	A. 27,360 curies (2 sources of not more than 13,680 curies each)

9. Authorized use

A. One source to be used in a Picker Corporation Model 6376A teletherapy unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary to the replacement of the source in the teletherapy unit only.

CONDITIONS

10 Licensed material shall be used only at Veterans Administration Medical Center, Ground Floor, D-Building, Room GJ-3, 130 West Kingsbridge Road, Bronx, New York.

11 The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12 Licensed material shall be used by or under the supervision of Bernard Roswit, M.D.

13 Teletherapy facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.

14. A. Teletherapy sources shall be tested for leakage at intervals not to exceed six months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Commission. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the source shall not be used until tested for leakage.

B. The test shall be sufficiently sensitive to detect 0.05 microcurie of contamination on the test sample.

C. The test sample shall be taken from selected accessible surfaces of the teletherapy head. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cones or beam collimating device. The test sample shall be taken with the source in the "off" position.

D. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall promptly take action to prevent spread of contamination and shall file a report within five days of the test with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, describing the test results and the corrective action taken. A copy of such report shall also be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

15. Prior to initiation of a treatment program, each teletherapy unit shall be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to assure compliance with § 20.105(b) of 10 CFR 20, "Standards for Protection Against Radiation," as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with Condition No. 18.

16. A set of written emergency instructions shall be posted at the teletherapy machine control. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room.

17. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.

B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation off immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.

C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of any door interlock, the teletherapy machine control shall be locked in the "off" condition and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

18. Prior to initiation of a treatment program, and subsequent to each installation of a teletherapy source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The teletherapy source housing with the teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 millirems per hour and 2 millirems per hour, respectively.

(2) All areas adjacent to the treatment room with the teletherapy source in the "on" position. The survey, except for leakage, shall be performed with a phantom in the primary beam of radiation shall clearly establish:

(a) The radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter I, "Standards for Protection Against Radiation" (10 CFR 20).

18. (Continued)

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in § 20.105(b), 10 CFR 20.

(c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of

(i) Electrical interlocks on entrance doors to the teletherapy treatment room.

(ii) The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.

(iii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation; carriage or stand travel and operation of the beam "on-off" mechanism.)

(iv) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, not later than thirty (30) days following each installation of a teletherapy source. A copy of such report shall be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

19. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the teletherapy unit that could result in increased radiation levels in areas outside the teletherapy treatment room shall be evaluated by a radiation survey made in accordance with Condition 18, and reported to the Commission within thirty (30) days following completion of the changes(s).

B. Relocation of the teletherapy unit to a new facility is not permitted without prior approval of the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 18, and reported to the Commission within thirty (30) days after completion of the move.

20. SEE BELOW

21. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation, relocation or removal of teletherapy units containing sources.

B. Source exchange.

C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation level.

20. The licensee shall comply with the requirements in Section 35.21 through 35.27, inclusive, of Title 10, Chapter 1, Code of Feiderai Regulations, Part 35, "Medical Uses of Byproduct Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 31-00636-02

Docket or Reference number:

Amendment No. 12

CONDITIONS

22. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import the uranium contained as shielding material in the teletherapy units authorized by this license.

23. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

(a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

(b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

(c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

24. The Radiation Protection Officer for the activities authorized by this license is John Detko.

25. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in letter with enclosure dated June 23, 1981 signed by Cyprian B. Reid, RSO; letter dated August 20, 1981 signed by Cyprian B. Reid, RSO; application dated November 15, 1982 signed by Julius Wolf, M.D., Acting Director; and letter with enclosures dated February 17, 1983 signed by Julius Wolf, M.D., Acting Director. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 31 1983

By _____
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
Washington, D. C. 20555

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

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20); NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19); EMPLOYEE PROTECTION

WHAT IS THE NUCLEAR REGULATORY COMMISSION?

The Nuclear Regulatory Commission is an independent Federal regulatory agency responsible for licensing and inspecting nuclear power plants and other commercial uses of radioactive materials.

WHAT DOES THE NRC DO?

The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation and that nuclear facilities including power plants are constructed to high quality standards and operated in a safe manner. The NRC does this by establishing requirements in Title 10 of the Code of Federal Regulations (10 CFR) and in licenses issued to [illegible]

WHAT RESPONSIBILITIES DOES MY EMPLOYER HAVE?

Any company that [illegible] licensed by the NRC [illegible] the NRC's requirements [illegible] violates NRC requirements, [illegible] fined or have its license modified, suspended or revoked.

Your employer must tell you which NRC radiation requirements apply to your work and must post NRC Notices of Violation involving radiological working conditions.

WHAT IS MY RESPONSIBILITY?

For your own protection and the protection of your co-workers, you should know how NRC requirements relate to your work and should obey them. If you observe violations of the requirements, you should report them.

HOW DO I REPORT VIOLATIONS?

If you believe that violations of NRC rules or of the terms of the license have occurred, you should report them immediately to your supervisor. If you believe that adequate corrective action is not being taken, you may report this to an NRC inspector or the nearest NRC Regional Office.

WHAT IF I WORK IN A RADIATION AREA?

If you work with radioactive materials or in a radiation (controlled) area, the amount of radiation exposure that you may legally receive is limited by the NRC. The limits on your exposure are contained in sections 20.101, 20.103, and 20.104 of Title 10 of the Code of Federal Regulations (10 CFR 20). While these are the maximum allowable limits, your employer should also keep your radiation exposure as far below these limits as is "reasonably achievable."

MAY I GET A RECORD OF MY RADIATION EXPOSURE?

Yes. Your employer is required to tell you, in writing, if you receive any radiation exposure above the limits set in the NRC regulations or your employer's license. In addition, if your job involves radiation, you may request from your employer a record of your annual radiation exposure and a written report of your total exposure when you leave your job.

HOW ARE VIOLATIONS OF NRC REQUIREMENTS IDENTIFIED?

NRC conducts regular inspections at licensed facilities to assure compliance with NRC requirements. In addition, your employer and site contractors conduct their own inspections to assure compliance. All inspectors are protected by Federal law. Interference with them may result in criminal prosecution by a Federal attorney.

MAY I TALK WITH AN NRC INSPECTOR?

Yes. Your employer may not prevent you from talking with an NRC inspector and you may talk privately with an inspector and request that your identity remain confidential.

MAY I REQUEST AN INSPECTION?

If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the nearest NRC Regional Office and must describe the alleged violation in detail. It must be signed by you or your representative.

HOW DO I CONTACT THE NRC?

Notify an NRC inspector on-site or call the nearest NRC Regional office listed. NRC inspectors want to talk to you if you are worried about radiation safety or other aspects of licensed activities, such as the quality of construction or operations at your plant.

CAN I BE FIRED FOR TALKING TO THE NRC?

No. Federal law prohibits an employer from firing or otherwise discriminating against a worker for bringing safety concerns to the attention of the NRC. You may not be fired or discriminated against because you:

- ask the NRC to enforce its rules against your employer;
- testify in an NRC proceeding;
- provide information or are about to provide information to the NRC about violations of requirements;
- are about to ask for or testify, help, or take part in an NRC proceeding.

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

No employer may fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the NRC.

HOW AM I PROTECTED FROM DISCRIMINATION?

If you believe that you have been discriminated against for bringing safety concerns to the NRC, you may file a complaint with the U.S. Department of Labor. Your complaint must describe the firing or discrimination and must be filed within 30 days of the occurrence.

Send complaints to:

Office of the Administrator
Wage and Hour Division
Employment Standards Administration
U.S. Department of Labor
Room S3502
200 Constitution Avenue, N.W.
Washington, D.C. 20210

or any local office of the Department of Labor, Wage and Hour Division. Check your telephone directory under U.S. Government listings.

WHAT CAN THE LABOR DEPARTMENT DO?

The Department of Labor will notify the employer that a complaint has been filed and will investigate the case.

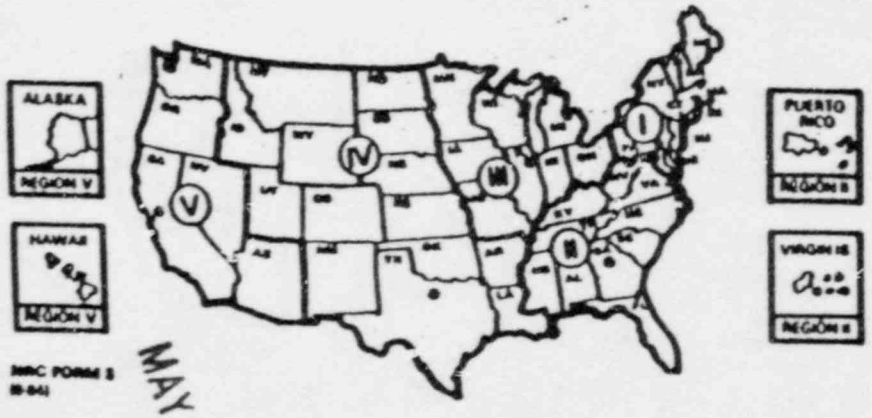
If the Department of Labor finds that your employer has unlawfully discriminated against you, it may order you to be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination.

WHAT WILL THE NRC DO?

The NRC may assist the Department of Labor in its investigation. NRC may conduct its own investigation where necessary to determine whether unlawful discrimination has prevented the free flow of information to the Commission. Also, if the NRC or Department of Labor finds that unlawful discrimination has occurred, the NRC may issue a Notice of Violation to your employer, impose a fine, or suspend, modify, or revoke your employer's NRC license.

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICE LOCATIONS

A representative of the Nuclear Regulatory Commission can be contacted at the following addresses and telephone numbers. The Regional Office will accept collect telephone calls from employees who wish to register complaints or concerns about radiological working conditions or other matters regarding compliance with Commission rules and regulations.



Regional Offices

REGION	ADDRESS	TELEPHONE
I	U.S. Nuclear Regulatory Commission Region I 631 Park Avenue King of Prussia, PA 19406	215 337-5000
II	U.S. Nuclear Regulatory Commission Region II 101 Marietta St., N.W., Suite 2900 Atlanta, GA 30323	404 221-4503
III	U.S. Nuclear Regulatory Commission Region III 799 Roosevelt Road Glen Ellyn, IL 60137	312 790-5600
IV	U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 1000 Arlington, TX 76011	817 860-8100
V	U.S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596	415 943-3700

NRC FORM 3
(5-84)

MAY 12 1987

PART 19

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec.

Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 931, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282); sec. 201, 88 Stat. 1242, as amended by Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5841). Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 19.11(a), (c), (d), and (e) and 19.12 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 19.13 and 19.14(a) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

40 FR 8774

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities, and options available to such individuals in connection with Commission inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder regarding radiological working conditions.

47 FR 57446

§ 19.2 Scope.

The regulations in this part appy to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in Parts 30 through 35,40,60,61,70 or 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter.

38 FR 22217

§ 19.3 Definitions.

As used in this part:

(a) "Act" means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto;

(b) "Commission" means the United States Nuclear Regulatory Commission;

(c) "Worker" means an individual engaged in activities licensed by the Commission and controlled by a licensee, but does not include the licensee.

47 FR 57446

(d) "License" means a license issued under the regulations in Parts 30 through 35,40,60,61,70 or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter and licenses to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter. "Licensee" means the holder of such a license.

38 FR 22217

(e) "Restricted area" means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

§ 19.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

40 FR 8774

§ 19.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications, reports, and applications may be delivered in person at the Commission's offices at 1717 H Street, NW., Washington, D.C.; or at 7920 Norfolk Avenue, Bethesda, Maryland.

49 FR 19623

§ 19.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0044.

(b) The approved information collection requirements contained in this part appear in § 19.13.

49 FR 19623

36 FR 22217

§ 19.11 Posting of notices to workers.

(a) Each licensee shall post current copies of the following documents: (1) The regulations in this part and in Part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to licensed activities; (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee.

(b) If posting of a document specified in paragraph (a) (1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

47 FR 30452

(c) Each licensee and applicant shall post Form NRC-3, (Revision 8–82 or later) "Notice to Employees," as required by Parts 30, 40, 50, 60, 70, 72, and 150 of this chapter.

NOTE: Copies of Form NRC-3 may be obtained by writing to the Director of the appropriate U.S. Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix "D", Part 20 of this chapter, or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

38 FR 22217

(d) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Commission documents posted pursuant to paragraph (a)(4) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

§ 19.12 Instructions to workers.

All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated

PART 20

STANDARDS FOR PROTECTION AGAINST RADIATION

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); secs. 201, as amended, 202, 206, Pub. L. 93-438, 88 Stat. 1242, 1244, 1246, Pub. L. 94-79, 89 Stat. 413 (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended, (42 U.S.C. 2273), §§ 20.101, 20.102, 20.103(a) (b), and (f), 20.104 (a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.206, 20.207, 20.301, 20.303, 20.304 and 20.305 are issued under sec. 161b, 68 Stat 948, as amended, (42 U.S.C. 2201(b)); and §§ 20.102, 20.103(a), 20.401–20.407, 20.408(b) and 20.409 are issued under sec. 161o, 68 Stat. 950, as amended, (42 U.S.C. 2201(o)).

GENERAL PROVISIONS

§ 20.1 Purpose.

(a) The regulations in this part establish standards for protection against radiation hazards arising out of activities under licenses issued by the Nuclear Regulatory Commission and are issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974. [40 FR 8774]

(b) The use of radioactive material or other sources of radiation not licensed by the Commission is not subject to the regulations in this part. However, it is the purpose of the regulations in this part to control the possession, use, and transfer of licensed material by any licensee in such a manner that the total dose to an individual (including exposures to licensed and unlicensed radioactive material and to other unlicensed sources of radiation, whether in the possession of the licensee or any other person, but not including exposures to radiation from natural background sources or medical diagnosis and therapy) does not exceed the standards of radiation protection prescribed in the regulations in this part. [44 FR 32352] [40 FR 8774]

(c) In accordance with recommendations of the Federal Radiation Council, approved by the President, persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest. [40 FR 58847]

§ 20.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed pursuant to the regulations in Parts 30 through 35, 40, 60, 61, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter. [47 FR 57446]

§ 20.3 Definitions.

(a) As used in this part:

(1) "Act" means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto;

(2) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases;

(3) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; [40 FR 8774]

(4) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No licensee shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year. [40 FR 42587]

EXPOSURE GUIDELINES

External Exposure — 100 mR/week

(based on 40 hr work week)

Internal Exposure — 40 mpc-hrs in any 7 consecutive days

(based on not exceeding 520 mpc-hrs in a calendard quarter)

Stay-time

The maximum time allowed in a restricted area such that neither of the exposure guidelines are exceeded.

Calculations

Stay-time (external exposure)

$$\frac{100\ \text{mR} - \text{accumulative exposure for the week}}{\text{work area exposure rate}}$$

Example:

Accumulative exposure for the week = 25 mR
Work area exposure rate = 50 mR/hr

$$ST_{(EE)} = \frac{100\ \text{mR} - 25\ \text{mR}}{50\ \text{mR/hr}}$$

$$= \frac{75\ \text{mR}}{50\ \text{mR/hr}}$$

$$= 1.5\ \text{hr}$$

Stay-time* (internal exposure)

*Assuming start of day 7

$$\frac{\text{40 mpc-hrs - total mpc-hrs during last 6 consecutive days}}{\text{measured number of mpc's in work area}}$$

Example:

Total mpc-hrs during last 6 days = 20 mpc-hrs
Airborne activity in work area = 1.8×10^{-8} uC/ml

$$ST_{(IE)} = \frac{\text{40 mpc-hrs - 20 mpc-hrs}}{\frac{1.8 \times 10^{-8} \text{ uC/ml}}{9 \times 10^{-9} \text{ uC/ml/mpc}}}$$

$$= \frac{\text{20 mpc-hrs}}{\text{2 mpc's}}$$

$$= \text{10 hrs}$$

AMS BIOASSAY PROGRAM

A. Purpose

The bioassay program at the London Road Facility of Advanced Medical Systems provides internal monitoring dosimetry for individuals frequenting areas where there may exist a potential for internal contamination. This program also provides information to the Radiation Safety Officer in determining the adequacy of current procedural and engineering controls used in limiting internal contamination and in assessing the magnitude and significance of an intake of radioactivity.

B. References

10 CFR 20	"Standards for Protection Against Radiation"
U.S. NRC Regulatory Guide 8.11	"Applications of Bioassay for Uranium"
U.S. NRC Regulatory Guide 8.26	"Application of Bioassay for Fission and Activation Products"
ANSI N343-1978	"American National Standard for Internal Dosimetry for Mixed Fission and Activation Products"

C. Source of Internal Contamination

The primary source of potential internal contamination of individuals frequenting designated bioassay areas at the London Road Facility is a non-transportable (insoluble) form of cobalt-60. This form of loose contamination is generated by the oxidation of metallic ^{60}Co used in the fabrication of sealed sources.

D. Bioassay Areas

The following areas are designated BIOASSAY AREAS at the London Road facility of Advanced Medical Systems, Inc.

1. Hot Cell

2. Decontamination Room

3. Isotope Shop Area

4. Waste Storage and Packaging Area

5. Equipment Room

6. Any other area where respiratory protection is required or where the operation performed therein creates the potential for internal contamination of personnel as defined by the Radiation Safety Officer, i.e., waste packaging, a changing of air filters.

E. Internal Exposure Controls

The primary method used for control of internal exposures are the air monitoring and respiratory protection programs. These programs are designed to ensure that individuals are not exposed to concentrations in excess of the limits specified in 10 CFR 20.103. Accordingly, the basic criteria for limiting internal depositions is for any individual not to exceed a weekly exposure of 40 MPC-Hours.

The bioassay monitoring program is used in conjunction with the internal exposure control program. Data from bioassay monitoring is used as follows:

1. To verify that the air monitoring and respiratory protection programs are sufficiently effective in limiting internal exposure to less than 40 MPC-Hr/week and less than 520 MPC-Hr/quarter.

2. To determine the location and amount of internal deposition.

3. To provide information, if necessary, for determining the dose received to the critical organ.

4. To determine the applicability of work restrictions.

F. Body Burden and Critical Organ Assumptions

The air concentration limits given for insoluble ^{60}Co in Appendix B, Table I, Column 1 of 10 CFR 20 are based upon limiting the total dose to the critical organ to less than 15 rem in a year. Due to the avid retention of oxides of ^{60}Co in the lungs, the lungs are considered the critical organ for the body burden limit.

The correlation between the inhalation limits of 10 CFR 20.103 and the Maximum Permissible Body Burden by bioassay monitoring is given by the following:

Assumptions:

Maximum Permissible Concentration in Air (MPC_a)
for insoluble $^{60}Co = 9 \times 10^{-9}$ uCi/ml

Quarterly Quantity Limit = 9×10^{-9} uCi/ml $\times 6.3 \times 10^{8} = 5.67$ uCi

The fraction of the Quarterly Quantity Limit retained in the lungs is .12 or in units of radioactivity, .68 uCi.

Based on these assumptions, the relationship between bioassay results and MPC-Hr is that an exposure of 40 MPC-Hr will result in a body burden with the lung as the critical organ of 52 nCi (nanocuries).

Internal exposures by ingestion or injection shall be evaluated on a case by case basis and included in determining whether the limitation of 10 CFR 20.103 has been exceeded.

G. Work Restrictions

Work restrictions shall be implemented by the Radiation Safety Officer in accordance with the following:

1. Access to bioassay areas for individuals with an apparent body burden $\geq$52 nCi is forbidden.

2. Access to bioassay areas for individuals required to have SPECIAL bioassay monitoring is forbidden, pending the results of the monitoring and evaluation by the Radiation Safety Officer.

These restrictions are necessary to minimize the potential for any individual to exceed the applicable exposure limits.

The Radiation Safety Officer shall also enforce such restrictions as necessary on individuals and operations to ensure that internal exposure and dose are limited in accordance with the principles of ALARA.

H. Bioassay Frequency

The bioassay program at Advanced Medical Systems incorporates the following monitoring frequencies:

MINIMUM

All facility personnel who routinely enter bioassay areas for routine operation or maintenance are to be bioassayed according to the following schedule:

1. A "baseline" analysis at the time of assignment to the London Road facility. A review of this analysis and the individuals previous occupational exposure shall be made by the Radiation Safety Officer prior to initial entry into any bioassay area;

2. Annually for extended employment at the London Road Facility;

3. Prior to employment termination; or

4. Post-operational (within one month of last assignment in bioassay area).

SPECIAL

Special bioassays shall be performed when the Radiation Safety Officer determines that conditions exist such that significant internal exposure may have occurred. Such conditions include:

1. Nasal-swab results exceeding 10,000 dpm.

   NOTE: Although positive results from a nasal swab are a good indication of possible internal contamination; negative results should never be used as the only criteria for not performing in-vivo bioassays.

2. An internal exposure in excess of 40 MPC-Hr in seven consecutive days. MPC-Hr shall be determined by using air sampling data in accordance with the applicable procedures in the Isotope Facility Safety Procedures Manual.

3. Any accidental exposure whether real or suspected.

Should special bioassays be required, an operational and procedural review of the incident shall be conducted by the Radiation Safety Officer to assure against recurrence.

ROUTINE

Routine bioassay evaluations shall be performed to ensure that the air monitoring and respiratory protection programs at the London Road Facility are sufficiently effective in controlling internal exposures.

The following schedule shall be used for routine bioassay monitoring of individuals frequenting the designated bioassay areas.

FREQUENCY FOR ROUTINE BIOASSAYS BASED ON AIRBORNE CONCENTRATIONS

AIR SAMPLE RESULTS IN DESIGNATED BIOASSAY AREAS (uCi/ml)	BIOASSAY FREQUENCY (BIOASSAYS/YR EQUALLY SPACED)
0 < QA < 1/10 MPC and 0 < M < 1/4 MPC	Minimum
0 < QA < 1/10 MPC	
1/4 MPC < M < 1 MPC	2
1 MPC < M < 10 MPC	2
M > 10 MPC	4
1/10 MPC < QA < 1/4 MPC	
0 < M < 1 MPC	2
1 MPC < M < 10 MPC	4
M > 10 MPC	4
1/4 MPC < QA < 1/2 MPC	
0 < M < 1 MPC	4
1 MPC < M < 10 MPC	4
M > 10 MPC	12
1/2 MPC < QA < 1 MPC	
0 < M < 10 MPC	12
M > 10 MPC	12

MPC = 9×10^{-9} uCi/ml

Where:

QA = Most Recent Quarterly average of air concentration in a designated bioassay area

M = Maximum concentration used in the calculation of the quarterly average

The action based upon routine bioassay includes the following:

Individual Bioassay Results	Action
≤ 5.2 nCi	None
> 5.2 nCi and < 52 nCi	If the results of the bioassay are unexpected for the established exposure controls and exposure period, perform the following: 1. Compare MPC-Hr estimation from air monitoring data to confirm results. 2. Identify the probable cause and correct or initiate additional control measures. 3. Determine whether others could have been exposed and perform bioassay measurements if indicated.
≥ 52 nCi and ≤ 535 nCi	Perform 1, 2, and 3 above and 4. Apply applicable work restrictions 5. Determine whether the 40 MPC-Hr/week control measure has been exceeded for the exposure period. If the 40 MPC-Hr/week control measure has been exceeded review the air monitoring program to determine why air samples are not representative and make necessary corrections. 6. Take corrective actions necessary to prevent recurrence and to ensure the 520 MPC-Hr quarterly exposure limit is not exceeded (712 nCi).

FOLLOW-UP

If the bioassay results indicate an apparent body burden in excess of 100 nCi in an exposure period of 13 weeks, follow-up bioassays shall be performed on a biweekly basis until the body burden is less than 5.2 nCi or until the effective half-life has been determined. Data from follow-up bioassays shall be used by the Radiation Safety Officer for the following:

1. To verify the location and amount of the deposition.

2. To determine whether the deposition was from other than inhalation

3. To estimate the internal dose resulting from the internal deposition.

I. Type and Source of Bioassay Monitoring

Advanced Medical System's London Road Facility shall use in-vivo monitoring for its bioassay program. Whole body counting shall be obtained through the services of a private or commercial whole body counting facility.

At this time, AMS utilizes the services at the Department of Physics at the University of Toronto. The Cleveland Electric Illuminating Company (Perry Nuclear Power Plant) has also agreed to provide whole body counting for AMS personnel.

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PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL ★ ★

GENERAL PROVISIONS

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RECORDS, INSPECTIONS, TESTS, AND REPORTS

30.51 Records.
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ENFORCEMENT

30.61 Modification and revocation of licenses.
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SCHEDULES

30.70 Schedule A—exempt concentrations.
30.71 Schedule B.

52 FR 1292 ➢ Authority: Sections 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 30.3, 30.34 (b) and (c), 30.41 (a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.36, 30.51, 30.52, 30.55, and 30.56 (b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

52 FR 1292

§ 30.1 Purpose and scope.

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by section 81 of the Act.

43 FR 6915

§ 30.2 Resolution of conflict.

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

30 FR 8185

§ 30.3 Activities requiring license.

Except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in this chapter.

43 FR 6915

§ 30.4 Definitions.

As used in this part and Parts 31 through 35 of this chapter:

(a) "Act" means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

36 FR 1466

(a-1) "Department" and "Department of Energy" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

45 FR 14199

(b) Terms defined in section 11 of the Act shall have the same meaning when used in the regulations in this part and Parts 31 through 35 to the extent such terms are not specifically defined in this part;

43 FR 6915

(c) "Agreement State" means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. "Non-agreement State" means any other State;

40 FR 8774

(d) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(e) "Commission" means the Nuclear Regulatory Commission and its duly authorized representatives;

(f) "Curie" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

(g) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

30 FR 8185

(h) "Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

51 FR 36932

(i) "License", except where otherwise specified means a license for byproduct material issued pursuant to the regulations in this part and Parts 31 through 35 of this chapter;

43 FR 6915

PERSONAL EXPOSURE REDUCTION METHODS

Time Distance Shielding

Time - less time spent near source,
less radiation exposure received

The radiation dose is directly proportional to time in radiation field.

Distance - the further from source,
the less exposure received

The radiation dose is inversely proportional to the square of the distance from the source.

Shielding - use of shielding reduces radiation exposure

half-value layer (HVL) - The amount of shielding required to reduce the beam intensity by 1/2.

Half Value Layers

Shield Material	Co-60 HVL (Inches)	Cs-137 HVL (Inches)
Concrete	2.7	1.9
Lead	0.49	0.26
Uranium	0.26	-

$$DR_{FINAL} = DR_{INITIAL} \times \frac{1}{2^n}$$

Where:

n = the number of HVL's

Advanced Medical Systems
Radiation Work Permit

1. Purpose

This purpose of this procedure is to set forth the instructions needed to prepare and use radiation work permits. Radiation work permits are an integral part of Advanced Medical's ALARA program.

2. Responsibilities

2.1 All employees are responsible for ensuring that entries in the radiological controlled areas of the facility are in accordance with the applicable radiation work permit.

2.2 The Radiation Safety Officer or designate is responsible for ensuring that all radiation work permits are prepared in accordance with this procedure.

3. Instructions

3.1 Types of RWPs

3.1.1 Job Specific RWP - This type RWP is to be used for all entries into high radiation areas that have accessible radiation levels greater than 500 mR/hr as measured 18 inches from the source, for all entries into contaminated areas that exceed 5000 dpm/100 centimeters square, and for all work in radiation controlled areas that involves radioactive materials. These RWPs will be prepared for each job and will be terminated immediately following completion of work, but no later than one week after the start of work.

3.1.2 Extended RWP - This type of RWP is to be used for all entries into the controlled areas that do not require a job specific RWP. This type RWP may also be used for repetitive jobs involving small quantities of radioactive materials and low radiation exposures when the hazard have been clearly defined by historical data. These RWPs will be terminated at six month intervals or sooner if radiological conditions change such that additional controls are needed.

3.2 Initiating a Radiation Work Permit

3.2.1 Any employee wishing to enter the radiologically controlled areas of the facility should ensure that the entry is covered by a current RWP. If not, the employee can initiate an RWP by filling out the "Description and Location of Work" section on the RWP form and present the form to the Radiation Safety Officer or his designate for completion.

3.2.2 The Radiation Safety Officer or his designate will complete the RWP form, including the ALARA review, and activate the permit by signing and dating the form. Each RWP will be consecutively numbered and entered in the RWP Log.

3.2.3 Each person who enters a controlled area under an RWP must read and sign the RWP form. Each person signing an RWP acknowledges that he/she has read and understands the RWP requirements and precautions.

3.3 Use of a Radiation Work Permit

3.3.1 Prior to entering a radiologically controlled area, workers shall:

- read and understand the RWP.

when appropriate, receive a prejob briefing from the Radiation Safety Officer or his/her designate.

- obtain radiation safety job coverage if required.

- ensure that sufficient exposure is available for the job.

- ensure they have met all the necessary precautions and have obtained the needed protective clothing and devices for the job.

3.3.2 <u>During work, workers shall:</u>

- periodically read their self-reading dosimeter unless exposure is being tracked by timekeeping methods.

- wear protective clothing and devices properly.

- maintain exposures ALARA.

- stop work and exit the area if radiological conditions change significantly from those outlined in the RWP.

3.3.3 <u>When exiting the area/job site, workers shall:</u>

- leave the area in a clean and unlittered condition by removing all tools and materials from the job site.

- use proper techniques to minimize the spread of contamination, including proper removal of protective clothing and proper use of step-off pads.

- perform a whole body frisk for personal contamination, paying particular attention to those areas of the body that could most likely become contaminated (hands, feet, face, knees, etc.).

- report any personal contamination or unusal exposures to the Radiation Safety Officer or his designate.

3.3.4 RWPs will be terminated by the Radiation Safety Officer:

- upon completion of work.
- upon expiration of the RWP.
- if the scope of work has significantly changed.

Advanced Medical Systems
Radiation Work Permit

Permit No._____
Expiration Date_____

☐ Job Specific
☐ Extended

Description and Location of Work. _____

Survey Information:

General Area Dose Rates (mR/hr)_____
Maximum Accessible Dose Rates (mR/hr) _____
Removable Contamination levels (dpm/100 cm^2)_____
Air Sample Results (µCi/ml) (prejob)_____(during work)_____

ALARA Review:

Estimated Total Dose (person-rems)_____ Actual Total Dose (person-rems)_____
☐ Prejob Briefing ☐ Postjob Briefing Review Performed By:_____
Dose Reduction Techniques to be Employed: _____

Protective Equipment and Precautions:

☐ TLD/Film Badge ☐ Finger Ring ☐ Pocket Dosimeter(0-0.2R) ☐ Pocket dosimeter(0-1 R)
☐ Pocket Dosimeter (0-5R) ☐ Coveralls ☐ Labcoat ☐ Hood ☐ Rubber Gloves ☐ Booties
☐ Rubbers ☐ Respirator(full-face) ☐ Taped Seams ☐ Radiation Safety Coverage ☐ Air Sample

Other precautions and special instructions:

Persons Performing Work:

Name	Available Dose	Dose Received	Signature

Signing this document means that the worker has read and understands this radiation work permit.

Authorized Signature _____ Date _____

Terminated By_____ Date _____

Advanced Medical Systems
RWP Log

RWP No.	Date Activated	Expiration Date	Job Description