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

OCT 20 1983

MEMORANDUM FOR: Regional Administrators

Branch Chiefs
Division of Fuel Cycle and
Material Safety

FROM: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

SUBJECT: POLICY AND GUIDANCE DIRECTIVE FC 83-20;
STANDARD LICENSE CONDITIONS

Attached for your use is a revised, up-to-date list of Material Licensing Standard Conditions (Enclosure 1). An explanation of the revisions is included as Enclosure 2. The previous list dated December, 1981, is superseded and should be discarded.

In order to maintain consistency throughout NRC, standard conditions should be used to the maximum extent possible. Any future revisions will be transmitted by memoranda as part of the FC Directive System. Therefore, proposed revisions to standard conditions or proposed special conditions should be coordinated through Headquarters prior to use.

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

Enclosure:
1. Material Licensing Standard Conditions
2. Explanation of Revisions

MATERIAL LICENSING BRANCH

STANDARD CONDITIONS

October, 1983

1.B. Licensed material shall be used only at _____.

1.C. The licensee shall notify _____ of each operation conducted under this license at a location other than that specified in Item 2 above when such operation continues for more than 60 days. The licensee also shall notify the aforementioned Regional Office upon cessation of such operation.

2.A. Licensed material may be used at _____ and at temporary job sites of the licensee anywhere in the United States.

2.B. Licensed material may be used at _____ and at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

3. Licensed material shall be used only at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

4. Licensed material may be used anywhere in _____.

. 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."

6.A. Licensed material shall be used by _____.

6.B. Licensed material listed in Item 6 above is authorized for use by the following individual(s) for the materials and uses indicated:

(NAME) (USES)

7.A. Licensed material shall be used by, or under the supervision of, _____.

7.B. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

7.C. (The following is used in conjunction with Standard Condition 7.A.:)

At least one individual named in Condition 12.A. shall be physically present at the authorized place of use whenever licensed material is being used.

8. Licensed material shall be used by, or under the supervision and in the physical presence of, _____.

9.A. Licensed material shall be used by, or under the supervision of, individuals designated by _____.

9.B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).

9.C. Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980.

9.D. The Radiation Protection Officer for the activities authorized by this license is _____.

CONDITIONS 10

The following condition is the leak test condition for BROAD LICENSES and for licenses to persons who fabricate sources.

10. A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region _____, _____ _____, describing the equipment involved, the test results, and the corrective action taken.

CONDITION 11.

The following condition is the leak test condition for neutron and beta-gamma sources only.

11. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 11.A.(3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region _____, _____ _____, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

Note: Blank in paragraph D may be filled in the "the licensee", the device manufacturer, the source manufacturer, etc., or omitted. Normally paragraph D or E, but not both, should be used.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

The following condition is the leak test condition for alpha, neutron, and beta-gamma sources.

12. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. In the absence of a certificate from a transferor, indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 12.A. (3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region _____, _____, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

Note: Blank in paragraph D may be filled in with "the licensee", the device manufacturer, the source manufacturer, etc., or omitted. Normally paragraph D or E, but not both, should be used.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

CONDITION 13.

This condition provides for leak test intervals of three years for certain specified equipment.

13. A. (1) Each sealed source shall be tested for leakage and/or contamination at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 13.A. (3) may be applied where, in the judgment of the technical reviewer, health and safety will not compromised.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with U. S. Nuclear Regulatory Commission, Region _____, _____, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

Note: Blank in paragraph D may be filled in with "the licensee", the device manufacturer, the source manufacturer, etc., or omitted. Normally paragraph D or E, but not both, should be used.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

14. Each sealed source containing licensed material to be used outside of a shielded exposure device shall bear a durable, legible, and visible tag permanently attached to the source. The tag shall be at least one (1) inch square, shall bear the conventional radiation symbol prescribed in Section 20.203(a), 10 CFR 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND. Repair or replacement of tags shall be accomplished by persons specifically licensed by the Commission or an Agreement State to perform this service.

15. Each sealed source containing licensed material to be used outside of a shielded exposure device shall bear a durable, legible, and visible tag permanently attached to the source. The tag shall be at least one (1) inch square, shall bear the conventional radiation symbol prescribed in Section 20.203(a), 10 CFR 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY MILITARY AUTHORITIES IF FOUND. Repair or replacement of tags shall be accomplished by persons specifically licensed by the Commission or an Agreement State to perform this service.

16. 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 _____. 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.

17. Pursuant to the Atomic Energy Act of 1954, as amended, and Title 10, Chapter 1, Code of Federal Regulations, Part 70, "Special Nuclear Material", the licensee is authorized to receive, possess, and use the special nuclear material resulting from the decay of _____. This license shall be deemed to contain the conditions specified in Section 70.32(a) of said regulations.

18. Sealed sources containing licensed material shall not be opened.

19. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

20. Sealed sources containing licensed material shall not be opened or removed from _____ by the licensee.

21. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.

    B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

22. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

23. A. Each chromatograph detector containing Nickel 63 shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a detector received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the surfaces of the device in which the foil is mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the foil from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region ____, _____ describing the equipment involved, the test results, and the corrective action taken.

Note: Blank in paragraph D may be filled in with "the licensee", the device manufacturer, the source manufacturer, etc., or omitted. Normally paragraph D or E, but not both, should be used.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

24. The licensee shall report by telephone within 24 hours to the nearest U. S. Nuclear Regulatory Commission Regional Office, loss or potential abandonment down-hole of any sealed source containing licensed material. In addition, a written report shall be submitted within 30 days for the lost or abandoned source which shall include information regarding isotope, amount, location, depth, method of immobilization, sealing, placarding, and notations to be placed in public records.

25. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

26. Experimental animals administered licensed materials or their products shall not be used for human consumption.

27. Licensed material shall not be used in or on human beings or in products distributed to the public.

28. A. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

Tritium Bioassays - Processors, Dial Painters, Etc.

B. (1) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 28 microcuries of tritium per liter when averaged over a calendar quarter.

(2) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 10 microcuries per liter, urinalysis may be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 10 microcuries per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

(3) A report of an average concentration in excess of the limit specified in B(1) above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the appropriate Regional Office. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentrations, and the corrective steps taken or planned to assure against a recurrence.

(4) Any single urinalysis which discloses a concentration of greater than 50 microcuries per liter shall be reported, in writing, within seven (7) days of the licensee's receipt of the results, to the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the U. S. Nuclear Regulatory Commission, Region _____, _____ _____.

Civil Defense

29. Each sealed source containing licensed material to be used outside of a shielded exposure device shall have a durable, legible, and visible tag permanently attached by a durable ring. The tag shall be at least one (1) inch square, shall bear a conventional radiation symbol prescribed in Section 20.203(a) of Part 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND.

Replacement of tags and rings shall be carried out by the licensee in accordance with instructions contained in MANUAL OF PROCEDURES FOR THE USE AND CONTROL OF THE OCD CD V-778 RADIATION TRAINING SOURCE SET, dated August 1975.

30. A. Licensed material contained in DCPA Sealed Source Sets shall be tested for external leakage and/or contamination upon receipt from another person, except when the licensee receives certification from the person that the sources had been tested within six (6) months prior to transfer and found free of surface contamination. Thereafter, sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. Records of leak test results shall be maintained by the licensee.

B. The test for leakage and/or contamination shall be capable of detecting the presence of 0.05 microcurie of radioactive material on the test sample.

C. If the test reveals any radioactive material, the licensee shall take immediate action to prevent spread of contamination and within five (5) days after completion of the test shall notify the U. S. Nuclear Regulatory Commission, Region _____.

D. Leak test of sealed sources in DCPA Sealed Source Sets shall be performed by the licensee in accordance with instructions contained in MANUAL OF PROCEDURES FOR THE USE AND CONTROL OF THE OCD CD V-778 RADIATION TRAINING SOURCE SET, dated August 1975.

31. Licensed material shall be stored _____ except for temporary storage at _____ locations where training courses are conducted.

32. BLANK
33. BLANK
34. BLANK

Radiography - Sealed Sources and Devices - Industrial

35. 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," Part 20, "Standards for Protection Against Radiation," and Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations."

36. The individuals listed below are the only persons authorized by this license to act as radiographers or radiographers' assistants as defined in Section 34.2, 10 CFR 34:

Radiographers	Radiographers' Assistants

37. A. Pursuant to Section 34.25, 10 CFR 34, the licensee is authorized to perform tests for leakage or contamination of the sealed sources authorized by this license in accordance with procedures contained in _____

B. Notwithstanding the periodic leak test required by Section 34.25(b), 10 CFR 34, such requirement does not apply to radiography sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

C. Sealed sources authorized for a use other than radiography shall be tested as radiography sources in accordance with Section 34.25 of 10 CFR 34.

38. The licensee is authorized to receive, possess, and use sealed sources of Iridium 192 or Cobalt 60 where the radioactivity exceeds the maximum amount of radioactivity specified in Item 8 of this license provided:

A. Such possession does not exceed the quantity per source specified in Item 8 by more than 20% for Iridium 192 or 10% for Cobalt 60;

B. Records of the licensee show that no more than the maximum amount of radioactivity per source specified in Item 8 of the license was ordered from the supplier or transferor of the byproduct material; and

C. The levels of radiation for radiographic exposure devices and storage containers do not exceed those specified in Section 34.21, 10 CFR 34.

39. This license does not authorize the commercial distribution of exempt quantities of licensed material pursuant to Section 30.18, 10 CFR 30, and Section 32.18, 10 CFR 32.

40. 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 up to 999 kilograms of uranium contained as shielding material in the radiography exposure devices and source changers authorized by this license.

41. 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.

42. Each source holder and logging tool containing radioac material shall bear a legible and visible marking. The marking shall bear the conventional radiation symbol and the following wording: DANGER - RADIOACTIVE - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES.

43. The licensee shall not transfer possession and/or control of materials or products containing licensed material as a contaminant except:

A. By transfer of waste to an authorized recipient;

B. By transfer to a specifically licensed recipient; or

C. As provided otherwise by specific condition of this license pursuant to the requirements of Section 32.11, 10 CFR 32.

44. Installation, relocation, removal from service, maintenance, repair, and initial radiation survey of devices containing licensed material and installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

45. Installation, relocation, removal from service, maintenance, repair, and initial radiation survey of _____ containing licensed material shall be performed only by _____ in accordance with _____, by the device manufacturer, or by other persons specifically authorized by the Commission or an Agreement State to perform such services. Installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by the device manufacturer or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

45. A. Installation, relocation, removal from service, and initial radiation survey of devices containing licensed material shall be performed only by _____ in accordance with _____, by the device manufacturer, or by other persons specifically authorized by the Commission or an Agreement State to perform such services. Maintenance and repair of devices, and installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by the device manufacturer or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

46. Maintenance, repair and initial radiation survey of devices containing licensed material and installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

46.A. Maintenance or repair of portable devices involving removal of the sealed sources from the devices or removal or dismantling of shielding may be performed by _____, the device manufacturer, or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

47. The licensee shall conduct a physical inventory every six (6) months to account for all _____ received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of licensed material, location of _____ and the date of the inventory.

47.A. The licensee shall conduct a physical inventory every six (6) months to account for all _____ received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of _____ and the date of the inventory.

Note: Condition 47.A. may be used for fixed gauge licenses which do not specify model numbers. See also Condition Nos. 106 and 107.

48. Detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.

FOR PHARMACY LICENSES

49. A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

B. The licensee shall not distribute technetium-99m for human use if the technetium-99m contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains more than five (5) microcuries of molybdenum-99 per dose of technetium-99m at the expiration date and time shown on the package label. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Subitem E.1. above shall be maintained for three (3) years following the performance of the tests and the training of personnel.

FOR MEDICAL LICENSEES

50. A. Notwithstanding the requirements of Section 35.14(b) of Title 10, Code of Federal Regulations, Part 35, the licensee may possess and use any licensed material for which he was authorized and that was in his possession on January 13, 1975.

B. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

C. Licensed material of the types, quantities, and forms specified in Sections 35.31(a) of 10 CFR 35 and 31.11(a) of 10 CFR 31 to be used in accordance with the provisions of (a) and (c) of Section 35.31, 10 CFR 35 and paragraphs (a), (c), and (d) of Section 31.11, 10 CFR 31.

51. Needles or standard medical applicator cells containing Cobalt 60 as wire shall not be opened by the licensee unless specifically authorized by a condition in this license.

52. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.

53. Patients containing Iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.

54. Pursuant to Section 20.105(a) of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation," and in reliance of statements, procedures and representations made by the licensee in his _____, the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level	Unrestricted Area

55. Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.

56. Notwithstanding the labeling requirements of Section 20.203(f), 10 CFR Part 20, (or comparable Agreement State regulations) the licensee is authorized to receive, possess, and use licensed material received under the American College of Pathologists Nuclear Medicine Quality Control Program with labeling as proposed in letter dated _____

57. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients or otherwise in use.

58. The licensee shall not receive or transfer in any single transaction one (1) gram or more of plutonium 238 contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR 70.

59. The licensee shall report to the Material Licensing Branch, U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Washington, D. C. 20555, within twenty-four (24) hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within thirty (30) days.

60. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, within ten (10) days, loss of contact with a nuclear pacemaker patient.

61. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

62. 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.

63. A. Technetium-99m separated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and quantify molybdenum-99 activity prior to administration to patients.

    B. The licensee shall not administer technetium-99m to patients if the technetium-99m contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains more than five (5) microcuries of molybdenum-99 per dose of technetium-99m at time of administration. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

    C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

63. continued

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Subitem E.1. above shall be maintained for three (3) years following the performance of the tests and the training of personnel.

64. 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 levels.

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

66. 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, a source received from another person shall not be used until tested for leakage.

B. The tests 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.

66. 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 (5) 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 U. S. Nuclear Regulatory Commission, Region _____, _____ _____.

67. 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 ensure compliance with Section 20.105(b), Title 10, Part 20, Code of Federal Regulations, Chapter 1, "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.

68. 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.

69. 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 for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

70. 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:

(i) 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 milliroentgens per hour and 2 milliroentgens per hour, respectively.

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

(a) That 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 1, "Standards for Protection Against Radiation" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 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, U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, 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 U. S. Nuclear Regulatory Commission, Region _____
_____.

71. 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 change(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.

72. The licensee shall comply with the requirements in Sections 35.21 through 35.27, inclusive, of Title 10, Chapter 1, Code of Federal Regulations, Part 35, "Human Uses of Byproduct Material."

GAMMA IRRADIATORS

73. A. Each sealed source containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.05 microcurie of contamination on the test sample. The test samples shall be taken from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region _____, _____, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

Note: Blank in paragraph D may be filled in with "the licensee", the device manufacturer, the source manufacturer, etc. or omitted. Normally paragraphs D or E, but not both, should be used.

74. Written instructions _____ shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555.

75. The procedures contained in AECL's instruction manual for the "Gammacell _____" device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.

76. A. The licensee is authorized to relocate, store, and install source units containing material licensed above and to perform maintenance and repair of the units which do not involve exposure of sealed sources. Replacement and disposal of sealed sources containing licensed material shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services.

B. This license does not authorize repairs or alterations of the irradiator involving removal of shielding or access to the licensed material except as provided otherwise by specific condition of this license. Removal, replacement and disposal of sealed sources shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.

77. After installation of the irradiator and Cobalt 60 or Cesium 137 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report of the results of the surveys 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 installation of the source. A copy of such report shall also be sent to the U. S. Nuclear Regulatory Commission, Region____, _____.

78. After installation of the irradiator and Cesium 137 or Cobalt 60 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine radiation levels around, above, and below the irradiator with the source in the irradiate position and with the source in the shielded position. A detailed report of the results of the surveys 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 installation of the source. A copy of such report shall also be sent to the U. S. Nuclear Regulatory Commission, Region _____, _____ _____.

TRANSPORTATION

The following condition is to be used in licenses where the licensee (not a common or contract carrier under regulations published by the Department of Transportation or U. S. Post Office) wants coverage for transportation of radioisotopes because his transportation is by air other than civil aircraft.

79. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."

INCINERATION

The last sentence of this condition may be omitted or modified to apply to situations where the licensee packages his waste residues and transfers them to authorized recipients for disposal.

80. Pursuant to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

GENERAL LICENSE DISTRIBUTION - CERTAIN SEALED SOURCES AND DEVICES

81. DELETED

82. No generally licensed device shall be installed by the licensee in such a manner or in such a location that any person could receive more than 0.5 rem in a calendar year under ordinary circumstances of use.

83. The licensee shall furnish to each general licensee to whom he transfers a device pursuant to this license, a copy of Section 31.5, 10 CFR 31; Sections 30.34 and 30.51 through 30.63, 10 CFR 30; Sections 20.402 and 20.403, 10 CFR 20, and Appendix D, 10 CFR 20.

84. Tests of sealed sources for leakage or contamination shall be in accordance with the following:

A. The conditions of pertinent U. S. Nuclear Regulatory Commission and Agreement State licenses authorizing the customer's use and possession of the licensed material;

B. The procedures described in the application filed by _____ and dated _____;

C. The sealed source shall not be removed from the device. Tests shall be made with the sealed source in the shielded or off condition;

D. Prior to collection of test samples, the tester shall survey the area which he will occupy during the sample collection; and

E. A report of the results of each test shall be provided the customer in units of microcuries.

85. After installation by the licensee of each device distributed to persons generally licensed pursuant to Section 31.5 of 10 CFR, Part 31, the licensee shall conduct a radiation survey and shall assure that the levels of radiation do not exceed those specified in the license authorizing the manufacture or distribution of the installed gauge. The licensee shall furnish the general licensee a copy of the radiation survey report.

86. The handling of radioactive material under this license in the manufacture, installation, dismantling, relocation, and testing of devices shall be performed by _____.

87. The licensee shall test each device distributed under this license for leakage or contamination of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at the time of installation of the device.

88. A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the following or substantially similar statements:

1. "Receipt, possession, use and transfer of this device are subject to a general license or equivalent and regulations of the U. S. Nuclear Regulatory Commission or an Agreement State."
2. "Abandonment or disposal prohibited unless transferred to persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State."
3. "Operation prohibited if there is indication of failure of or damage to shielding, source containment or on-off mechanism."
4. "Installation, dismantling, relocation, maintenance, repair and testing involving the radioactive material, its shielding or containment shall be performed by persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State."
5. "The device shall be tested for radioactive leakage and proper functioning of on-off mechanism and indicator, if any, at installation, at source replacement, and thereafter at no longer than _____ intervals."
6. "Loss, theft, or transfer of this device and failure of or damage to the shielding, the source containment or the on-off mechanism must be reported to the U. S. Nuclear Regulatory Commission or an Agreement State."
7. "This label shall be maintained on the device in a legible condition."

B. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta or purple on a yellow background, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.

C. Each label required by this condition shall bear the statement, "Removal of this label is prohibited."

89. A. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, all transfers of devices distributed under this license to persons generally licensed under Section 31.5, 10 CFR 31. Such report shall identify each general licensee by name and address, the type of device transferred, the quantity and type of licensed material contained in the device, and the specific location where each device is installed. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which any such device is transferred to a generally licensed person.

B. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, all transfers of devices distributed under this license to persons generally licensed under Section 31.5, 10 CFR 31. Such report shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of licensed material contained in the device. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which any such device is transferred to a generally licensed person.

LEAK TESTS FOR PLUTONIUM SOURCES

90. A. Each encapsulated plutonium source designed for the purpose of emitting neutron or gamma radiation shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample shall be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable alpha contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired by a person appropriately licensed to make such repairs or to be disposed of in accordance with the Commission regulations. Within five (5) days after determining that any source has leaked, the licensee shall file a report with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, describing the source, the test results, the extent of contamination, the apparent or suspected cause of source failure, and the corrective action taken. A copy of the report shall be sent to the U. S. Nuclear Regulatory Commission, Region _____, _____ _____.

90. continued

D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six (6) months prior to the date of use or transfer.

E. Notwithstanding the other provisions of this leak test condition, leak tests are not required on pacemakers implanted in experimental animals provided that a leak test shall be performed immediately following removal of the pacemakers from the animal.

91. A. Each plutonium alpha source shall be tested for leakage at intervals not to exceed three (3) months. In the absence of a certificate from a transferor indicating that a test has been made within three (3) months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample shall be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable alpha contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired by a person appropriately licensed to make such repairs or to be disposed of in accordance with the Commission regulations. Within five (5) days after determining that any source has leaked, the licensee shall file a report with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, describing the source, the test results, the extent of contamination, the apparent or suspected cause of source failure, and the corrective action taken. A copy of the report shall be sent to the U. S. Nuclear Regulatory Commission, Region _____, _____ _____.

D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within three (3) months prior to the date of use or transfer.

92. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which the NRC has specifically approved for transport of plutonium by air.

93. The licensee shall file periodic reports as specified in Section 32._____ 10 CFR 32.

94. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.

B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.

95. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.

B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

96. Notwithstanding other authorizations and requirement of this license, the licensee shall have the cobalt 60 source described in Subitem 7._____. of this license removed from the teletherapy head and returned to the supplier if the radiation levels permitted by Condition _____ are exceeded.

97. Notwithstanding the requirements of 10 CFR 35.26(a), the licensee is authorized to extend until_____ the time interval for inspection and servicing of his teletherapy unit.

98. Notwithstanding the requirements of 10 CFR 35.24,_____ may perform the duties of the qualified expert for those full-calibration and spot-check measurements specified in 10 CFR 35.21 and 35.22.

99. Licensed material shall be used by, or under the supervision of, physicians (as defined in 10 CFR 35.3 (b)) who are certified by the American Board of Radiology in Radiology or Therapeutic Radiology and who have been approved by_____ .

100. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in _____.

101. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

102. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

103. Reagent kits may be redistributed to persons licensed pursuant to Section 35.14 and 35.100, 10 CFR 35, or under equivalent licenses of Agreement States, for Group III.

104. The licensee may use the Calicheck device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

105. The licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.

Note: Condition 106 may be used for licenses authorizing possession of Kay Ray, AccuRay, Ohmart, or LFE fixed gauges, where the model numbers are not specified. The blank should be filled in with the name of the manufacturer(s). See also Condition Nos. 47.A and 107.

106. For possession and use in _____ devices which have been evaluated and approved for licensing purposes and authorized for distribution under a license issued by the Nuclear Regulatory Commission or an Agreement State.

Note: Condition 107 may be used as a leak test condition covering a license authorizing a mixture of sealed sources in devices, some of which require six-month leak testing and some of which require three-year leak testing. See also Condition Nos. 106 and 47.A.

107. A. (1) Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months; except those sealed sources as specified by the manufacturer and specifically authorized by the Commission or an Agreement State may be leak tested at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with Region _____, U. S. Nuclear Regulatory Commission, _____, describing the equipment involved, the test results, and the corrective action taken.

(107 continued)

107. (continued)

Note: Blank in paragraph D may be filled in with "the licensee", the device manufacturer, the source manufacturer, etc., or omitted. Normally paragraph D or E, but not both, should be used.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

E. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's _____ for analysis by _____. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

108. This license does not authorize commercial distribution of licensed material.

109. This license does not authorize possession or use of licensed material.

110. This license does not authorize distribution to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35.

ENCLOSURE 2

EXPLANATION OF REVISIONS TO STANDARD CONDITIONS

1. Condition Nos. 106 (use condition), 47A (inventory condition), and 107 (leak test) are added for use in licenses authorizing Kay Ray, Accu Ray, Ohmart, and LFE fixed gauges where model numbers are not specified. These conditions have been used in licenses for over a year, but have never been incorporated into the Standard Conditions.

2. Leak test condition Nos. 11, 12, 13, 23, 73, and 107, paragraphs D and E, are modified to make it more clear who can collect and analyze leak test samples. In most cases, D or E should be used, but not both.

3. Condition Nos. 29 and 30 are modified to reference the current 1975 FEMA safety manual.

4. Condition Nos. 44 and 45 are modified to delete references to leak testing, to avoid conflicts with leak test conditions.

5. Condition Nos. 44 and 45 are modified to add "removal from service," to make it clear whether a licensee can remove a device from service.

6. Condition No. 45A is added as a modification to condition No. 45 for cases where a licensee is not authorized to perform maintenance and repair.

7. Condition No. 46A is added to cover maintenance and repair of portable gauges.

8. Condition No. 47 is modified to reference "licensed material," so it can be used for Part 40 and Part 70 licenses.

9. Conditions Nos. 72 and 97, applicable to teletherapy, are modified to make them consistent with new 10 CFR Section 35.26, published in 1983.

10. Condition Nos. 108 and 109 are added to prohibit commercial distribution, possession, or use of licensed material. These conditions are commonly used, but have never been incorporated into the Standard Conditions.

11. Note: A standard condition addressing protection of fixed gauges against environmental conditions is still under development.

12. Condition 110 makes clear that a distributor may not distribute to group medical licensees. (An "MD" license is required for this purpose.)

13. Note: References to Regional Offices of Inspection and Enforcement have been deleted from all license conditions. This is consistent with the fact that Regional Offices are no longer part of IE.

MATERIAL LICENSING BRANCH - STANDARD CONDITIONS

September, 1979

GENERAL

1.A. Licensed material shall be used only at the licensee's address stated in Item 2. above.

1.B. Licensed material shall be used only at _____.

1.C. The licensee shall notify (appropriate Regional Office of Inspection and Enforcement) of each operation conducted under this license at a location other than that specified in Item 2 above when such operation continues for more than 60 days. The licensee also shall notify the aforementioned Regional Office of Inspection and Enforcement upon cessation of such operation.

2.A. Licensed material may be used at _____ and at temporary job sites of the licensee anywhere in the United States.

2.B. Licensed material may be used at _____ and at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

3. Licensed material shall be used only at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

4. Licensed material may be used anywhere in _____.

5. 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."

6.A. Licensed material shall be used by _____.

6.B. Licensed material listed in Item 6 above is authorized for use by the following individual(s) for the materials and uses indicated:

(Name) (Uses)

7.A. Licensed material shall be used by, or under the supervision of, _____.

7.B. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

(Name) (Uses)

8. Licensed material shall be used by, or under the supervision and in the physical presence of, _____.

9.A. Licensed material shall be used by, or under the supervision of, individuals designated by _____.

9.B. The use of licensed material in or on humans shall be by a physician.

ALARA PROGRAM

(10) As low as reasonably achievable

and Model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (Rev. 1), "Guide for the Preparation of Applications for Medical Program," October 1980.

CONDITION 10.

The following condition is the leak test condition for broad licenses and for licenses to persons who fabricate sources.

10. A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 10.A(3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - (see list attached), describing the equipment involved, the test results, and the corrective action taken.

CONDITION 11

The following condition is the leak test condition for neutron and beta-gamma sources only. Section D., which specifies by whom the leak test shall be carried out, may be omitted where it is inappropriate.

11. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 11.A(3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached), describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

CONDITION 12

The following condition is the leak test condition for alpha, neutron, and beta-gamma sources. Section D., which specifies by whom the leak test shall be carried out, may be omitted where it is inappropriate.

12. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. In the absence of a certificate from a transferor, indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 12.A(3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, . . Region (type appropriate Regional Office of Inspection and Enforcement - see list attached), describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

CONDITION 13

This condition provides for leak test intervals of three years for certain specified equipment.

13. A. (1) _____ shall be tested for leakage and/or contamination at intervals not to exceed three years. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

The exception in 13.A.(3) may be applied where, in the judgment of the technical reviewer, health and safety will not be compromised.

(3) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached), describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

14. Each sealed source containing licensed material to be used outside of a shielded exposure device shall bear a durable, legible, and visible tag permanently attached to the source. The tag shall be at least one (1) inch square, shall bear the conventional radiation symbol prescribed in Section 20.203(a), 10 CFR 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND. Repair or replacement of tags shall be accomplished by persons specifically licensed by the Commission or an Agreement State to perform this service.

15. Each sealed source containing licensed material to be used outside of a shielded exposure device shall bear a durable, legible, and visible tag permanently attached to the source. The tag shall be at least one (1) inch square, shall bear the conventional radiation symbol prescribed in Section 20.203(a), 10 CFR 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY MILITARY AUTHORITIES IF FOUND. Repair or replacement of tags shall be accomplished by persons specifically licensed by the Commission or an Agreement State to perform this service.

16. 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 _____. 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.

17. Pursuant to the Atomic Energy Act of 1954, as amended, and Title 10, Chapter 1, Code of Federal Regulations, Part 70, "Domestic Licensing of Special Nuclear Material", the licensee is authorized to receive, possess, and use the special nuclear material resulting from the decay of _____. This license shall be deemed to contain the conditions specified in Section 70.32(a) of said regulations.

18. Sealed sources containing licensed material shall not be opened.

19. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

20. Sealed sources containing licensed material shall not be opened or removed from _____ by the licensee.

21. A. Detector cells containing titanium tritide foil shall only be used in conjunction with properly operating temperature control mechanisms which prevent foil temperatures from exceeding 225 degrees Centigrade.

    B. Detector cells containing scandium tritide foil shall only be used in conjunction with properly operating temperature control mechanisms which prevent foil temperatures from exceeding 325 degrees Centigrade.

22. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

23. A. Each chromatograph detector cell containing Nickel 63 shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, a detector cell received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the surfaces of the device in which the Nickel 63 is mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the detector cell from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached), describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

24. The licensee shall report by telephone within twenty-four (24) hours to the nearest U.S. Nuclear Regulatory Commission Office of Inspection and Enforcement, the loss or potential abandonment down-hole of any sealed source containing licensed material. In addition, a written report shall be submitted within thirty (30) days for the lost or abandoned source which shall include information regarding isotope, amount, location, depth, method of immobilization, sealing, placarding, and notations to be placed in public records.

25. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

26. Experimental animals administered licensed materials or their products shall not be used for human consumption.

27. Licensed material shall not be used in or on human beings or in products distributed to the public.

28. A. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

Tritium Bioassays - Processors, Dial Painters, Etc.

28. B. (1) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 28 microcuries of tritium per liter when averaged over a calendar quarter.

(2) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 10 microcuries per liter, urinalysis may be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 10 microcuries per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

(3) A report of an average concentration in excess of the limit specified in B(1) above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Regional Office of of Inspection and Enforcement. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentrations, and the corrective steps taken or planned to assure against a recurrence.

(4) Any single urinalysis which discloses a concentration of greater than 50 microcuries per liter shall be reported, in writing, within seven (7) days of the licensee's receipt of the results, to the Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

Civil Defense

29. Each sealed source containing licensed material to be used outside of a shielded exposure device shall have a durable, legible, and visible tag permanently attached by a durable ring. The tag shall be at least one (1) inch square, shall bear a conventional radiation symbol prescribed in Section 20.203(a) of Part 20, and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND.

    Replacement of tags and rings shall be carried out by the licensee in accordance with instructions contained in PROCEDURES AND REGULATIONS FOR THE CARE AND USE OF THE OCD CD V-778 RADIATION TRAINING SOURCE SET, dated February 1967.

30. A. Licensed material contained in DCPA Sealed Source Sets shall be tested for external leakage and/or contamination upon receipt from another person, except when the licensee receives certification from the person that the sources had been tested within six (6) months prior to transfer and found free of surface contamination. Thereafter, sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. Records of leak test results shall be maintained by the licensee.

    B. The test for leakage and/or contamination shall be capable of detecting the presence of 0.05 microcurie of radioactive material on the test sample.

    C. If the test reveals any radioactive material, the licensee shall take immediate action to prevent spread of contamination and within five (5) days after completion of the test shall notify the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

    D. Leak test of sealed sources in DCPA Sealed Source Sets shall be performed by the licensee in accordance with instructions contained in PROCEDURES AND REGULATIONS FOR THE CARE AND USE OF THE OCD CD V-778 RADIATION TRAINING SOURCE SET, dated February 1967.

31. Licensed material shall be stored _____ except for temporary storage at locations where training courses are conducted.

32. (Blank)

33. (Blank)

34. (Blank)

Radiography - Sealed Sources and Devices - Industrial

35. 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," Part 20, "Standards for Protection Against Radiation," and Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations."

36. The individuals listed below are the only persons authorized by this license to act as radiographers or radiographers' assistants as defined in Section 34.2, 10 CFR 34:

Radiographers	Radiographers' Assistants

37. A. Pursuant to Section 34.25, 10 CFR 34, the licensee is authorized to perform tests for leakage or contamination of the sealed sources authorized by this license in accordance with procedures contained in _____.

B. Notwithstanding the periodic leak test required by Section 34.25(b), 10 CFR 34, such requirement does not apply to radiography sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

C. Sealed sources authorized for a use other than radiography shall be tested as radiography sources in accordance with Section 34.25 of 10 CFR 34.

38. The licensee is authorized to receive, possess, and use sealed sources of Iridium 192 or Cobalt 60 where the radioactivity exceeds the maximum amount of radioactivity specified in Item 8 of this license provided:

A. Such possession does not exceed the quantity per source specified in Item 8 by more than 20% for Iridium 192 or 10% for Cobalt 60;

B. Records of the licensee show that no more than the maximum amount of radioactivity per source specified in Item 8 of the license was ordered from the supplier or transferor of the byproduct material; and

C. The levels of radiation for radiographic exposure devices and storage containers do not exceed those specified in Section 34.21, 10 CFR 34.

39. This license does not authorize the commercial distribution of licensed material to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30.

40. 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 up to 999 kilograms of uranium contained as shielding material in the radiography exposure devices and source changers authorized by this license.

41. 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.

42. Each source holder and logging tool containing radioactive material shall bear a legible and visible marking. The marking shall bear the conventional radiation symbol and the following wording: DANGER - RADIOACTIVE - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES.

43. The licensee shall not transfer possession and/or control of materials or products containing licensed material as a contaminant except:

    A. By transfer of waste to an authorized recipient;

    B. By transfer to a specifically licensed recipient; or

    C. As provided otherwise by specific condition of this license pursuant to the requirements of Section 32.11, 10 CFR 32.

44. Installation, relocation, maintenance, repair, and initial radiation survey of devices containing licensed material and leak testing, installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

45. Installation, initial radiation survey of devices, relocation, maintenance, repair, and removal from service of the devices containing licensed material and installation, replacement, and disposal of sealed sources containing licensed material used in the devices shall be performed only by _____ _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

46. Maintenance, repair and initial radiation survey of devices containing licensed material and leak testing, installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

47. The licensee shall conduct a physical inventory every six (6) months to account for all _____ received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources, and the date of the inventory.

48. Detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.

49. (For Pharmacy Licenses)

A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

B. The licensee shall not distribute for human use technetium-99m that, at the expiration date and time shown on the package label, contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or more than five (5) microcuries of molybdenum-99 per dose of technetium-99m. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Subitem E.1. above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

50. A. Notwithstanding the requirements of Section 35.14(b) of Title 10, Code of Federal Regulations, Part 35, the licensee may possess and use any licensed material for which he was authorized and that was in his possession on January 13, 1975.

B. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

C. Licensed material of the types, quantities, and forms specified in Sections 35.31(a) of 10 CFR 35 and 31.11(a) of 10 CFR 31 may also be used by _____ in accordance with the provisions of paragraphs (a) and (c) of Section 35.31, 10 CFR 35 and paragraphs (a), (c), and (d) of Section 31.11, 10 CFR 31.

51. Needles or standard medical applicator cells containing Cobalt 60 as wire shall not be opened by the licensee unless specifically authorized by a condition in this license.

52. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.

53. Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less.

54. Pursuant to Section 20.105(a) of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation," and in reliance of statements, procedures and representations made by the licensee in his _____, the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level	Unrestricted Area

55. Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug, and Cosmetic Act.

56. Notwithstanding the labeling requirements of Section 20.203(f), 10 CFR Part 20, (or comparable Agreement State regulations) the licensee is authorized to receive, possess, and use licensed material received under the American College of Pathologists Nuclear Medicine Quality Control Program with labeling as proposed in letter dated _____.

57. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients or otherwise in use.

58. The licensee shall not receive or transfer in any single transaction one (1) gram or more of plutonium 238 contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR 70.

59. The licensee shall report to the Material Licensing Branch, U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Washington, D. C. 20555, within twenty-four (24) hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within thirty (30) days.

60. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, within ten (10) days, loss of contact with a nuclear pacemaker patient.

61. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

62. 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.

63. A. Technetium-99m separated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and quantify molybdenum-99 activity prior to administration to patients.

    B. The licensee shall not administer to patients technetium-99m containing more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or more than five (5) microcuries of molybdenum-99 per dose of technetium-99m at time of administration. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

63. C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Subitem E.1. above shall be maintained for two (2) years following the performance of the tests and the training of personnel.

Teletherapy

64. 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 levels.

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

66. 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, a source received from another person shall not be used until tested for leakage.

B. The tests 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 (5) 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 U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

67. 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 ensure compliance with Section 20.105(b), Title 10, Part 20, Code of Federal Regulations, Chapter 1, "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.

68. 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.

69. 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 for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

70. 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:

(i) 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 milliroentgens per hour and 2 milliroentgens per hour, respectively.

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

(a) That 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 1, "Standards for Protection Against Radiation) (10 CFR 20).

70. continued

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 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, U. S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, 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 U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

71. 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 change(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.

72. Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the U. S. Nuclear Regulatory Commission or an Agreement State, and a report of the inspection and servicing must be kept on file for review by the Commission's Office of Inspection and Enforcement.

Gamma Irradiators

73. A. Each sealed source containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.05 microcurie of contamination on the test sample. The test samples shall be taken from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached), describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

74. Written instructions _____, shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555.

75. The procedures contained in AECL's instruction manual for the "Gammacell _____" device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.

76. A. The licensee is authorized to relocate, store, and install source units containing material licensed above and to perform maintenance and repair of the units which do not involve exposure of sealed sources. Replacement and disposal of sealed sources containing licensed material shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services.

B. This license does not authorize repairs or alterations of the irradiator involving removal of shielding or access to the licensed material except as provided otherwise by specific condition of this license. Removal, replacement and disposal of sealed sources shall be performed only by _____ or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.

77. After installation of the irradiator and Cobalt 60 or Cesium 137 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report of the results of the surveys 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 installation of the source. A copy of such report shall also be sent to the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

78. After installation of the irradiator and Cesium 137 or Cobalt 60 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine radiation levels around, above, and below the irradiator with the source in the irradiate position and with the source in the shielded position. A detailed report of the results of the surveys 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 installation of the source. A copy of such report shall also be sent to the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - see list attached).

TRANSPORTATION

The following condition is to be used in licenses where the licensee (not a common or contract carrier under regulations published by the Department of Transportation or U. S. Post Office) wants coverage for transportation of radioisotopes because his transportation does not occur in interstate or foreign commerce or the transportation is by air other than civil aircraft.

79. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."

INCINERATION

The last sentence of this condition may be omitted or modified to apply to situations where the licensee packages his waste residues and transfers them to authorized recipients for disposal.

80. Pursuant to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

GENERAL LICENSE DISTRIBUTION - CERTAIN SEALED SOURCES AND DEVICES

81. (Previous Condition 81. no longer in use.)

82. No generally licensed device shall be installed by the licensee in such a manner or in such a location that any person could receive more than 0.5 rem in a calendar year under ordinary circumstances of use.

83. The licensee shall furnish to each general licensee to whom he transfers a device pursuant to this license, a copy of Section 31.5, 10 CFR 31; Sections 30.34 and 30.51 through 30.63, 10 CFR 30; Sections 20.402 and 20.403, 10 CFR 20, and Appendix D., 10 CFR 20.

84. Tests of sealed sources for leakage or contamination shall be in accordance with the following:

A. The conditions of pertinent U. S. Nuclear Regulatory Commission and Agreement State licenses authorizing the customer's use and possession of the licensed material;

B. The procedures described in the application filed by _____ and dated _____;

C. The sealed source shall not be removed from the device. Tests shall be made with the sealed source in the shielded or off condition;

D. Prior to collection of test samples, the tester shall survey the area which he will occupy during the sample collection; and

E. A report of the results of each test shall be provided the customer in units of microcuries.

85. After installation by the licensee of each device distributed to persons generally licensed pursuant to Section 31.5 of 10 CFR, Part 31, the licensee shall conduct a radiation survey and shall assure that the levels of radiation do not exceed those specified in the license authorizing the manufacture or distribution of the installed gauge. The licensee shall furnish the general licensee a copy of the radiation survey report.

86. The handling of radioactive material under this license in the manufacture, installation, dismantling, relocation, and testing of devices shall be performed by _____.

87. The licensee shall test each device distributed under this license for leakage or contamination of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at the time of installation of the device.

88. A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the following or substantially similar statements:

1. "Receipt, possession, use and transfer of this device are subject to a general license or equivalent and regulations of the U. S. Nuclear Regulatory Commission or an Agreement State."

2. "Abandonment or disposal prohibited unless transferred to persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State."

3. "Operation prohibited if there is indication of failure of or damage to shielding, source containment or on-off mechanism."

4. "Installation, dismantling, relocation, maintenance, repair and testing involving the radioactive material, its shielding or containment shall be performed by persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State."

5. "Device shall be tested for radioactive leakage and proper functioning of on-off mechanism and indicator, if any, at installation, at source replacement, and thereafter at no longer than _____ _____ .intervals."

6. "Loss, theft, or transfer of this device and failure of or damage to the shielding, the source containment or the on-off mechanism must be reported to the U. S. Nuclear Regulatory Commission or an Agreement State."

B. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta or purple on a yellow background, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.

C. Each label required by this condition shall bear the statement, "Removal of this label is prohibited."

89. A. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, all transfers of devices distributed under this license to persons generally licensed under Section 31.5, 10 CFR 31. Such report shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of licensed material contained in the device, and the specific location where each device is installed. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which any such device is transferred to a generally licensed person.

B. The licensee shall report to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, all transfers of devices distributed under this license to persons generally licensed under Section 31.5, 10 CFR 31. Such report shall identify each general licensee by name and address, the type of device transferred, and the quantity and type of licensed material contained in the device. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which any such device is transferred to a generally licensed person.

LEAK TESTS FOR PLUTONIUM SOURCES

90. A. Each encapsulated plutonium source designed for the purpose of emitting neutron or gamma radiation shall be tested for leakage at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample shall be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable alpha contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired by a person appropriately licensed to make such repairs or to be disposed of in accordance with the Commission regulations. Within five (5) days after determining that any source has leaked, the licensee shall file a report with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, describing the source, the test results, the extent of contamination, the apparent or suspected cause of source failure, and the corrective action taken. A copy of the report shall be sent to the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - (see list attached).

D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six (6) months prior to the date of use or transfer.

90. continued

E. Notwithstanding the other provisions of this leak test condition, leak tests are not required on pacemakers implanted in experimental animals provided that a leak test shall be performed immediately following removal of the pacemakers from the animal.

91. A. Each plutonium alpha source shall be tested for leakage at intervals not to exceed three (3) months. In the absence of a certificate from a transferor indicating that a test has been made within three (3) months prior to the transfer a sealed source received from another person shall not be put into use until tested.

B. The test shall be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample shall be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable alpha contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired by a person appropriately licensed to make such repairs or to be disposed of in accordance with the Commission regulations. Within five (5) days after determining that any source has leaked, the licensee shall file a report with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, describing the source, the test results, the extent of contamination, the apparent or suspected cause of source failure, and the corrective action taken. A copy of the report shall be sent to the U. S. Nuclear Regulatory Commission, Region (type appropriate Regional Office of Inspection and Enforcement - (see list attached).

D. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within three (3) months prior to the date of use or transfer.

92. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which the NRC has specifically approved for transport of plutonium by air.

93. The licensee shall file an annual report as specified in Section 32._____, 10 CFR Part 32.

"The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided: 6 11 81

A. Effected radioactive waste shall be held for decay a minimum of ten (10) half-lives.

B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to bakground levels prior to disposal."

94. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor. 1 23 81

B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.

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Region II	Regional Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 101 Marietta Street, Suite 3100 Atlanta, Georgia 30303
Region III	Regional Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 799 Roosevelt Road Glen Ellyn, Illinois 60137
Region IV	Regional Office of Inspection and Enforcemnt U. S. Nuclear Regulatory Commission 611 Ryan Plaza Drive, Suite 1000 Arlington, Texas 76012
Region V	Regional Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 1990 N. California Blvd., Suite 202 Walnut Creek, California 94596

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American Association of Physicists in Medicine

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OFFICE OF THE SECRETARY
DOCKETING & SERVICE BRANCH

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November 5, 1981

(15)

-35
(46 FR 43846)

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Chief, Docketing & Service Branch

Dear Sir:

Reference is made to 10CFR 35.23 (a) of the U.S. Nuclear Regulatory Commission Rules and Regulations which states that "Full calibration measurements required by para. 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration."

The National Bureau of Standards (NBS) and the accredited Regional Calibration Laboratories (RCLs) are able to calibrate a limited number of instruments each year. With the advent of the referenced NRC regulation the waiting period for instrument calibration has increased and at present is about six months. It is probable that the waiting period will become longer as more instruments are due for calibrations.

In order to aleviate this situation, the American Association of Physicists in Medicine (AAPM) recommends a longer interval between calibrations, provided that suitable dosimetry system verification checks are carried out as outlined in the attached Appendix. Specifically, the AAPM recommends the following to the NRC:

1. Grant variances to licensed teletherapy users who are not able to have instruments calibrated within the two year period.

2. Modify the referenced regulation 10CFR 35.23 (a) and regulation 35.25 (a), as outlined in the attached Appendix, in accordance with the "Expedited Procedure for Handling Certain Petitions for Rulemaking" published in 46FR35486 relative to 10CFR 2.802 (e).

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Should you so desire, representatives of the AAPM will be pleased to meet with appropriate NRC staff to discuss this petition.

Sincerely yours,

Colin G. Orton, Ph.D.
President

CGO/lk

Enclosures

American Association of Physicists in Medicine

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Appendix & Suggested Amendment of 10CFR 35.23 (a) and 35.25 (a)

Para 35.23 (a):

Full calibration measurements required by para 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards (NBS) or by a Regional Calibration Laboratory (RCL) accredited by the American Association of Physicists in Medicine (AAPM). The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration. As an alternative, the dosimetry system shall be calibrated every four years; an independent cobalt-60 intercomparison shall be made midway (± 6 months) in the period; and suitable records shall be kept to prove constancy of the dosimetry system.

Independent cobalt-60 intercomparisons shall be sponsored by a professional organization, such as a chapter of the AAPM, the Radiological Physics Center (RPC), or a regional Center for Radiological Physics (CRP). Such intercomparisons shall not provide a calibration factor for the dosimetry system but will provide a check to determine that the existing calibration factor is valid. If such a dosimetry system intercomparison demonstrates that the calibration factor appears to have changed by more than 2%, then the dosimetry system shall be recalibrated at the NBS or an RCL.

Constancy of dosimetry system performance shall be verified before and after calibration by the NBS or an RCL, before and after a dosimetry system intercomparison, and at least quarterly thereafter, or prior to the use of a dosimetry system if the interval is greater. A cobalt-60 teletherapy source, with a jig for positive positioning of the ionization chamber, or a shielded Strontium-90 or other long-lived radioactive source, may be used for such constancy checks.* The time of irradiation shall be long compared to the time required to start and stop an irradiation. Corrections shall be made for radioactive source decay, and ambient temperature and pressure;

*A compact constancy checker shall not be used for dosimetry system intercomparisons.

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attention shall be paid to possible errors in source or chamber positioning, collimator geometry, and timers. For field instruments changes or fluctuations of ± 1% are normal.

Records of (1) full calibration measurements under para 35.21 and (2) dosimetry system intercomparisons using Co-60, and (3) constancy checks of the dosimetry system used to make these measurements under para 35.23, shall be preserved for at least five years after completion of the full calibration.

Rationale:

The AAPM considers it essential to maintain high standards of calibration for dosimetry systems used in the calibration of teletherapy units. Since the capacity of the NBS and RCLs is limited, an alternative method has been suggested to maintain these high standards while reducing the load on the calibration laboratories. Members of the AAPM are almost invariably the physicists responsible for the calibration of teletherapy units.

The specific issues involved are the need to insure high accuracy in the calibration of teletherapy units and, within the capabilities of the calibration laboratories, to assure that dosimetry systems provide this accuracy. The recommendations made above are to change the requirement for dosimetry system calibrations every two years by the NBS or an RCL, to an alternative of requiring a calibration every four years with a dosimetry system intercomparison midway in the period and constancy checks throughout the four year period. The current rule could result in the use of a defective dosimetry system for a period as long as two years if, for example, it was damaged in transit or an error was made in the calibration. It is difficult, on short notice, to collect data showing that instrument calibrations stay constant over periods of many years. A number of qualified physicists who calibrate instruments and machines, believe that an initial calibration with proper constancy checks and dosimetry system intercomparisons would provide a better way to assure proper dosimetry system accuracy, than a new calibration every two years. Rationale for a longer period between calibrations was included in the IAEA "Manual of Dosimetry in Radiotherapy" in 1970. A recent publication by Karzmark (1980) reported on constancy checks and intercomparisons for periods up to 14 years. For integrated

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dose data, the average standard deviation for six field instruments was 0.79%. Shalek et al (1981) reported on intercomparisons and calibrations with several different dosimetry systems. The results presented indicated that reliability of the dosimetry system or chamber calibration factor provided by the NBS or an RCL was unrelated to the number of years since calibration. The current rule is unduly burdensome because the calibration facilities of the NBS and RCLs are limited and at present there is a backlog of about six months.

REFERENCES

Massey, John B., IAEA Technical Report No. 110, "Manual of Dosimetry in Radiotherapy", p. 26, 1970.

Karzmark, C.J., "Concerning radiotherapy standard dose meter calibration" Med. Phys. 7, 574-5, 1980.

Shalek, R.J., Humphries, L.J. and Hanson, W.F., "The American Association of Physicists in Medicine Regional Calibration Laboratory System", Proceedings of a Meeting on Traceability for Ionizing Radiation Measurements, NBS Special Publication 609, in press, 1981.

MANUAL OF DOSIMETRY IN RADIOTHERAPY

A practical guide for testing and calibrating equipment used in external beam treatments

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published on behalf of the
International Atomic Energy Agency,
the World Health Organization
and the
Pan American Health Organization

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 1970

slightly lower standard of accuracy, the calibration services of the secondary standardizing laboratories are to be regarded as those which will be used by most radiotherapy centres and are of adequate accuracy. The accuracy of a calibration obtained by the technique of section 3.5.6 or, particularly, by a postal dose intercomparison service is very dependent on the experience of the workers and the amount of effort expended. Although of great value on many occasions, these latter methods should be used only to obtain temporary calibration factors pending a calibration by a standardizing laboratory.

3.3.3.2. Frequency of calibration

It is desirable that the dosemeter should be calibrated by the standardizing laboratory at intervals of about two or three years. This is particularly necessary for radiation qualities of less than 3 mm Cu HVT where changes in the chamber which are not detected by radioactive check (section 3.5.2) can affect the calibration. For ^{60}Co calibrations the interval may be longer if the radioactive check shows no significant change.

In the intervals between calibrations tests (which are detailed in section 3.5) must be performed to confirm that no gross change in sensitivity and therefore in calibration factor (K_E) is occurring. In this connection regular radioactive standard checks (section 3.5.2) are imperative. If any of the tests raise doubts, a calibration may have to be repeated before the two-yearly period is over.

3.4. SPECIAL REQUIREMENTS FOR LOW-VOLTAGE X-RAYS (GRENZ RAYS)

It has already been commented that it is important to choose an ionization chamber that is suitable for the quality range of interest. This is particularly so for low-voltage X-rays. The normal type of thimble chamber is acceptable down to about 1 mm Al HVT but below this the wall thickness needs to be very small in order to be sure that the chamber is measuring the radiation properly. For this range of quality – the so-called Grenz-ray range – it is usual to use a parallel plate chamber with a very thin front wall or even no wall at all.

The calibration of such a chamber also calls for special care and it should be done at approximately the same exposure rate as that to be measured since it is difficult to achieve full saturation at the high dose rates encountered.

3.5. CARE AND MAINTENANCE OF THE DOSEMETER

The instructions given in the manufacturer's handbook accompanying the dosemeter should be studied and followed. The user must check that the instrument is behaving in a sensible manner. Dosemeters, although moderately rugged, are sensitive scientific instruments and should be treated as such. In the event of any misbehaviour, no attempt should be made to dismantle the instrument (especially the chamber) and to attempt a repair unless the user is sure of his competence. It is preferable to

Concerning radiotherapy standard dose meter calibration

One suggested[1] and one existing[2] guideline in the control of radiation for radiotherapy treatment require that measurement of the output of the therapy beam shall be performed with a measurement instrument, the calibration of which is directly traceable to national standards of exposure or absorbed dose and which shall have been calibrated within the preceding two years. The two year requirement is appropriate in many circumstances. However, in some circumstances, it may be unnecessarily short and hence, add to inconvenience and patient care costs.

A method which provides frequent, local calibration constancy checks may well be preferable to a mandatory but less frequent and more inconvenient assessment as provided by distant calibration facilities. Certainly, where obvious damage has occurred, such as from dropping a chamber, immediate recalibration is warranted. The presence of significant electrical leakage in the secondary standard dose meter is cause for investigation, repair and possible recalibration. A sudden, inexplicable calibration factor shift for a treatment unit should make the calibration dosemeter suspect.

Less frequent calibration is appropriate where some redundant method of assuring constancy of ionization chamber response is provided. One redundant method would be to have two or more completely independent ionization chamber systems. Another method is to assess chamber response constancy by using a long-lived isotopic standard in repeatable geometry. We have done this for a number of Victoreen, Baldwin Farmer, and Farmer ionization chambers, using a 2 milligram, shielded radium source[3] having a fixed cylindrical geometry. Closely fitting, cylindrical Lucite sleeves are placed between the chamber and source to ensure geometrical repeatability for these constancy checks. It is important to note that such close-geometry measurements are valid for constancy checks, but it is inappropriate to intercompare chambers with such a source, since significant inaccuracies could result.

TABLE I. Summary-ionization chambers: constancy measurements with radium sources.

Dose meter chamber model(s) and usage	Serial chamber	No. descr.	Scale reading		Dates of data	No. data points	Mean value	Percent standard deviation
Victoreen model 570	#900	100 R red	Integrated	100 R	1967-80	37	7.08	0.47%
type 121 chambers	#477	100 R blue	dose	100 R	1967-80	37	7.19	0.63%
secondary standard Keithley 602, serial #47024A			(Coulombs)					
farmer type 2505/3	#3439	Labeled	inte-	3×10^{-7}	1977-80	4	1.23	1.68%
(carbon) chamber		red	grated	3×10^{-8}	1977-80	4	1.25	0.45%
secondary standard			dose	3×10^{-9}	1977-80	4	1.24	0.58%
Victoreen model 570 type 121 chambers	#454	100 R red	Inte- grated	100 R	1967-79	30	6.44	0.72%
field instrument	#10051	100 R blue	dose	100 R	1974-80	15	6.76	0.90%
D & K #1 dose meter			Dose	1000 R	1969-80	7	5.86	4.05%
baldwin farmer	#616905	—	rate	100 R	1969-80	6	5.90	0.88%
model F chamber				10 R	1969-80	9	5.60	0.76%
field instrument			inte-	1000 I	1969-80	10	5.73	0.96%
			grated	100 I	1969-80	25	5.68	0.95%
			dose	10 I	1969-80	11	5.62	0.91%
D & K #2 dose meter			Dose	1000 R	1969-76	5	5.98	3.81%
baldwin farmer	#8080514	—	rate	100 R	1969-77	8	5.88	3.06%
model F chamber				10 R	1969-77	10	5.99	3.06%
field instrument			Inte-	1000 I	1975-80	10	5.67	0.86%
			grated	100 I	1975-80	25	5.69	0.67%
			dose	10 I	1975-80	10	5.62	1.20%
D & K #2			Inte-	1000 I	1977-80	7	5.59	0.77%
farmer type 2505/3	#1741	—	grated	100 I	1977-80	7	5.57	0.62%
(carbon) chamber			dose	10 I	1977-80	7	5.55	0.97
field instrument								
Keithley 602,			(coulombs	3×10^{-7}	1977-80	4	1.202	0.59%
serial #47013A				3×10^{-8}	1977-80	4	1.215	0.36%
farmer type 2505/3	#3399	Labeled	Integ	3×10^{-9}	1977-80	4	1.197	0.52%
(carbon) chamber		blue	dose					
field instrument								

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575

Table I summarizes our constancy measurements for nine ionization chambers using the 2 mg Ra source for periods of time extending to 14 years. The standard deviation for the three secondary ionization standard chambers listed is 0.68%, a value well within the ±2% accuracy associated with our national laboratory standardization. If our experience is relevant, then the two year requirement would appear too restrictive for some circumstances. Where redundant methods are available, a longer interval appears warranted, coupled with prompt recalibration if sudden changes occur.

We have had experience with six field instrument ionization chambers which are intercompared with our secondary standard instruments for various quality radiations in appropriate geometries (see Table 1). Here, the average of the standard deviations using the 2 mg Ra source is 1.07% if we include both dose and dose rate data for the two D & K instruments.[4] If only integrated dose data are included, the average standard deviation is reduced to 0.79%, a value close to that of our secondary standard dose meters.

We suggest that the views and experience of a wider constituency be sought on the question of calibration frequency. At current prices, calibration services typically vary in cost from $300 to $1000 depending on their extent. Hence, if the interval between calibrations could be extended to four or five years, a significant cost saving would accrue, and instruments would be less frequently subject to damage during transit. It would seem appropriate, in this event, to require that suitable constancy assurance procedures be carried out at defined times during the interim. However, the two year requirement could remain an option.

Acknowledgment: We are indebted to Dr. L. J. Humphries and Dr. R. Loevinger for helpful discussions.

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THE AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE'S REGIONAL CALIBRATION LABORATORY SYSTEM

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Three Regional Calibration Laboratories have been established primarily for the dissemination of national radiation standards for radiation therapy. The National Bureau of Standards together with the regional laboratories have a calibration capacity in rough equilibrium with the demand. However, if all instrument users had field instruments calibrated regularly the demand might exceed present calibration capacity. Various data are adduced to demonstrate that commercially available field instruments can maintain calibrations for periods longer than the generally recommended 2 year interval.

Introduction

It is estimated that there are 1322 radiation therapy facilities in the United States and that a minimum of 1057 field instruments require calibration in order to service these facilities [1]. At present the National Bureau of Standards calibrates less than 100 field instruments per year. In order to close the gap between need and calibration capacity, it was suggested that secondary radiation standardizing laboratories be established just as secondary laboratories exist for the dissemination of electrical and other standards. Robert Loevinger of the National Bureau of Standards recommended that the American Association of Physicists in Medicine (AAPM) become the accrediting agency for the establishment of Regional Calibration Laboratories (RCL) [2]. The AAPM accepted the suggestion in 1970 and appointed Task Group #3 of the Radiation Therapy Committee to establish criteria for the initiation and operation of the laboratories, to review applications for laboratory accreditation, to select laboratories and to continue in the supervision of the laboratories.

To date, three Regional Calibration Laboratories have been accredited by the AAPM. These facilities are located at Memorial Sloan-Kettering Cancer Center (MSK) in New York, The University of Texas System Cancer Center M. D. Anderson Hospital and Tumor Institute (MDA) in Houston, and Victoreen Instrument Division (VIC) in Cleveland. It has been recommended that at least one additional RCL be established at a distance from the other laboratories [1].

In the discussion here, some of the requirements and capabilities of the regional laboratories will be considered together with an indication of the quality assurance procedures between the National Bureau of Standards and the regional laboratories. The distribution of work load between the laboratories and the types of instruments now used as field instruments will be discussed. In addition, the frequency of calibration of field instruments used for the calibration of radiation therapy machines will be considered from the view of what is occurring and what may be required for the satisfactory use of the instruments.

The information derives from Task Group #3 reports, from a Report of the Committee on Radiation Calibration Needs in Therapy of the American Association of Physicists in Medicine (L. Lanzl, Chairman) [1], from the operating experience of the M. D. Anderson RCL, and from data collected by the Radiological Physics Center (RPC). The latter organization reviews radiation measurements and calculations relating to radiation therapy at institutions participating in interinstitutional clincial trials and thus has the opportunity for observing the operation of field instruments by the user.

Requirements For and Operation of Regional Calibration Laboratories

The specific requirements for operation of an RCL are presently being reviewed by a subcommittee of Task Group #3 [3]. It is likely that the RCLs will be required to provide instrument calibrations that agree with the national standards to within the limits specified in Table I. These overall requirements will replace present specific requirements upon various steps in the calibration process. In this paper only instruments for the calibration of therapy machines will be considered.

Table I

Proposed Criteria for Calibration Agreement Between an RCL and NBS

	^{60}Co	X ray
Reference-class instruments suitable for calibration of other instruments to a precision of 0.1%	±0.5%	±1.0%
Field-class instruments suitable for therapy beam calibration	±1.0%	±2.0%
Field-class instruments suitable for diagnostic x-ray calibration	±5.0%	±5.0%
Field-class instruments suitable for health physics survey measurements	±10%	±10%

Table II

Secondary Standard Instrumentation at the MDA RCL

Exposure Standards: (NBS calibration biennially)
- Shonka-Wyckoff, 3.6cc, 0.25mm AE wall
- Exradin Model A-3, 3.6cc, 2.54mm AE wall
- Victoreen Model 415A, 2cc, 2mil mylar window
- Nuclear Enterprises Model 2561 (NPL Secondary Standard), 0.3cc, 0.5mm graphite wall

Capacitance Standards: (NBS traceable calibration biennially)
- General Radio Type 1404-A, 1000 pF
- General Radio Type 1404-B, 100 pF

Voltage Standards: (*NBS traceable calibration biennially)
- Keithley Model 240A, Regulated HV supply, 0 to 1.2kV
- *Data Precision Model 3500, 5½ digit, DMM
- Data Precision Model 245, 4½ digit, DMM
- *Eppley Model 100, Standard Cell

Other RCL Instruments:
- Keithley Model 602 electrometers
- Keithley Model 261 picoampere source
- Taylor Model 6204M aneroid barometer
- Fisher Model 15-041A thermometer, 1 to 51°C, 0.1°C/div.
- Aluminized-mylar transmission monitor chamber

Table III

Radiation Beam Qualities Available at NBS and the RCLs (1980)

Lab	^{60}Co	X Ray (HVL/kV)	*Filt.
NBS	Yes	0.03-2.78mm Al/10-100 kVcp	L
		1.6mm Al-3.2mm Cu/60-250 kVcp	M
		4.2mm Al-5.2mm Cu/50-250 kVcp	H
MDA	Yes	0.07-2.4mm Al/20-100 kVp	L
		2.0mm Al-3.0mm Cu/75-250 kVp	M
MSK	Yes	0.03-1.95mm Al/10- 60 kVp	L
		3.0mm Al-2.1mm Cu/60-250 kVcp	M
VIC	Yes	0.9-1.6mm Al/50- 75 kVp	L
		2.8mm Al-3.2mm Cu/60-250 kVcp	M

* Filtration: Light, L; Moderate, M; Heavy, H

NBS also calibrates at ^{137}Cs energy

Table IV

RCL Measurement Assurance Tests by NBS

		Medium Energy X Ray[b] Deviation[a]			^{60}Co
Year	RCL	Mean	σ[c]	Max	Deviation[a]
1976	MDA	-1	3	- 4	-3
	MSK	+2	1	+ 4	-1
	VIC	-7	2	-11	+1
1977	MDA	-5	--	- 5	-1
	MSK	-3	--	- 3	+3
	VIC	+2	3	+ 8	+2
1978	MDA	-4	5	-11	+2
	MSK	-2	1	- 4	0
	VIC	+3	2	+ 6	+1
1979	MDA	-5	2	- 8	+2
	MSK	+2	4	+ 9	-1
	VIC	-6	4	-12	-4

(a) Deviation: Parts per thousand [(RCL/NBS)-1] x 1000

(b) 60-250kV; 1.86mm Al to 3.2mm Cu HVLs

(c) One standard deviation

Intercomparison Instrument

1976: Shonka 3cm³ ion chamber
1977: Victoreen 2cm³ 4158 chamber
1978: NBL Dosemeter and Farmer Chamber
1979: PTW 1cm³ 30-349 chamber

In Table II, the equipment employed at the MDA RCL is listed. This equipment is commercially available and for the most part capable of performing with a reproducibility of 0.1%. The range of beam qualities available for calibration at NBS and at each RCL are shown in Table III.

The ionization chambers maintained as secondary standards by an RCL are calibrated at NBS at least biennially for each calibration energy offered by an RCL. Other instruments such as standard capacitor, standard voltage cell, barometer, thermomether and voltmeter have calibrations documented as traceable to NBS. In addition NBS circulates a chamber or dosimeter system with undisclosed calibration annually to each RCL for calibration. The results from four years of these measurement assurance tests are shown in Table IV. In each year the calibration at cobalt-60 and the mean of the calibrations in the x-ray range were within the criteria defined in Table I. In two isoloated x-ray cases, the deviation from the national standard exceeded the 1% proposed for reference-class instruments, however, the worst case was only 1.2%.

Table V shows the distribution of instrument calibrations among the various laboratories. Data comes from two sources, the questionnaries circulated by the Lanzl committee [1] and from RCL records. 80% of the responders to the Lanzl committee questionnaire had calibrations from NBS or an RCL. Although the word *regional* appears in the name of the secondary laboratories, instruments come for calibration to the RCLs from distant parts of the country and some foreign countries.

Table V

Laboratory of Last Calibration and RCL Workload

Laboratory	Respondents(a) %	#Instruments(b) 7/78 - 6/79
NBS	19	—
MDA RCL	24	102
MSK RCL	21	65
VIC RCL	16	75
Manufacturer or other	20	—

(a) Number of respondents to this question was 520; number of radiotherapy centers is approximately 1,322.[1]

(b) From RCL reports

Directly Traceable to NBS

The first definition of *directly traceable* appeared in the 1971 protocol of the AAPM Scientific Committee on Radiation Dosimetry (SCRAD) [4] as follows, "for the purposes of this protocol, an instrument with a calibration factor directly traceable to the National Bureau of Standards has been calibrated either at NBS or against a reference instrument which has itself been calibrated at NBS." Robert Loevinger of NBS has proposed that the definition of *directly traceable* be tightened as follows [5]. *A field instrument with a calibration factor directly traceable to the National Bureau of Standards has been calibrated against the national standard maintained at NBS or against a secondary standard maintained at a Regional Calibration Laboratory.* Implicit in this definition is the recognition that a *secondary standard* is more than a reference-class instrument calibrated at NBS because of the quality assurance requirements placed upon an RCL by the AAPM.

The Frequency of Calibration of Field Instruments

The Nuclear Regulatory Commission requires that licencees of cobalt-60 teletherapy units perform calibrations with dosimetry systems calibrated by NBS or an RCL within the previous two years [6]. Some states and other agencies require annual recalibration. A time period of two years between calibrations of field instruments accords reasonably well with current practices as shown in Table VI.

Table VI

Frequency of securing a calibration

From Lanzl Report		From MDA RCL Data	
Time (years)(a)	Frequency %	Time (years)(b)	Frequency %
<1	3	0.5	9
1	33	1	29
2	30	1.5	32
3	13	2	18
4	7	2.5	4
5	4	3	4
6	4	3.5	3
7	2	4	1
8	2		
>8	3		
Average time:	2.5 year		1.5 year
Mean time :	1.5 year		1.2 year

a) Time since last calibration

b) Time between calibrations by an institution

The median time indicated by respondents to the Lanzl questionnaire [1] or users of the MDA RCL is approximately 1.5 years. Despite the agreement between the practices of users and the federal regulation, the frequency of calibration necessary for field instruments is worth consideration. Information to be addressed here suggests that the time period between the calibrations of field instruments could be longer than two years if suitable other tests upon the instrument are performed by the user.

During visits to institutions to review measurements and calculations relating to radiation therapy, the RPC usually makes an intercomparison in air in a ^{60}Co beam between the institution's field instrument and the RPC instrument. Since September, 1970 the RPC instrument consisted of one of several Farmer chambers and a Keithley 602 electrometer. As an indication of RPC precision, seventy-five constancy checks over a three-year period using the RPC field instrument showed a standard deviation of 0.4% for individual measurements, with a maximum deviation of 1%, where ^{60}Co irradiator or a commercial ^{90}Sr checker was the radiation source [7]. In some intercomparisons prior to September 1970, the RPC used a Farmer Secondary Standard model 2502 electrometer and chamber that showed a standard deviation of 0.7% for individual measurements in 17 measurements over a two-year period [7].

In Figure 1 a bar graph indicates the types of chambers the institutions visited by the RPC employed during various two-year intervals from 1968 to 1979. It is clear that Farmer-type chambers are being used more and that Victoreen R-Meters are being used less as time passes. However, the stability of the various instruments in holding their calibration appears to be comparable as is shown in Table VII. Here RPC intercomparisons with instruments which had calibrations from NBS or an RCL show no great difference according to instrument type. The lapsed time between the calibration of the instrument and the intercomparison with RPC was a median 13 months for Victoreen R-Meters and 10 months for Farmer type instruments. In tables which follow, no distinction is made between different types of instruments.

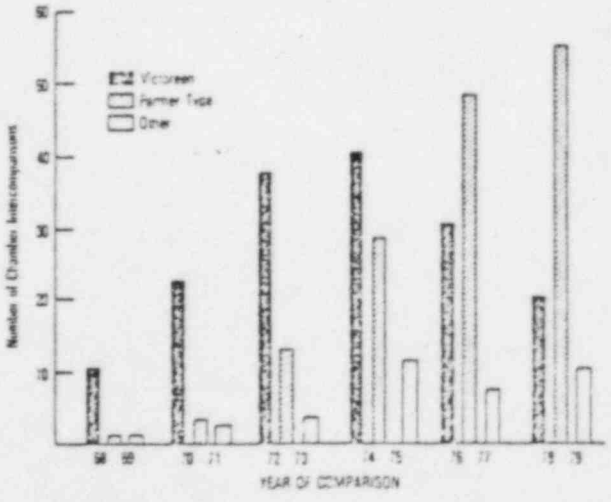

Figure 1: Number of chamber intercomparisons performed by the RPC, by year, for Victoreen R-Meters, Farmer type chambers and for other chambers.

In Table VIII, the results of RPC intercomparisons are shown according to calibration source before 1976 and after 1976. It is clear that prior to 1976 instruments which were calibrated by a manufacturer or had an uncertain calibration history (other) were suspect; after 1976 few instruments with suspect calibrations were found regardless of the method of calibration; however, there are not enough manufacturer or other calibrations after 1976 to demonstrate a conclusive improvement. It is noteworthy that field instruments intercompared with other instruments which were calibrated at NBS or an RCL appear to have calibration factors which are not significantly less reliable than those calibrated by NBS or an RCL. Many of these instruments were an institution's instrument for everyday use which has been compared to the institution's standard instrument calibrated at NBS or an RCL. Prior to about 1976, intercomparison with the institution's chamber was usually made only when the RPC differed by more than 2% in the calibration of a therapy machine. After that time intercomparisons were made whenever the institution's instrument was available during review visits. Thus some bias in the direction of causing the earlier data to appear less consistent has been introduced by RPC procedures.

Table VII

Intercomparison of the RPC instrument with instruments calibrated at NBS or an RCL, distinguishing the type of instrument (1968 - 1980)

Instrument	Number of Intercomparisons	Mean RPC/Inst	σ[a]	>3%[b]
Victoreen R Meters	57	1.000	0.014	1
Farmer-type chambers	56	1.000	0.009	0
Other	10	1.016	0.033	1

a) One standard deviation

b) Number of chambers whose factor differed from the RPC by more than 3%

Properly maintained therapy field instruments appear to maintain their calibration factors over long periods of time. The time since instrument calibration does not seem to play a role in the reliability of the chamber calibration factor as seen in RPC intercomparisons in Table IX. These instruments were calibrated at NBS or an RCL and thus started with a calibration directly traceable to NBS.

Further data on long term stability of instruments comes from the MDA RCL. Table X shows data on 5 chambers which have been calibrated by MDA RCL 3 times or more since 1976. The checks indicate the year of initial calibration and the values are the ratio of the calibration factor determined in subsequent calibrations relative to that determined in the original calibration. The maximum deviation seen in the calibrations was 0.3%.

Forty-two other chambers were calibrated twice by MDA RCL since 1976. The time interval between calibrations varied from one to three years. The results are shown in Figure 2. The mean ratio between the new and original cali-

Table VIII

Intercomparison of the RPC instrument with institution's instruments calibrated by various laboratories

Calibration Source	Number of Intercomparisons	Mean RPC/Inst.	σ(a)	Number >3%(b)
Instruments calibrated before 1976				
NBS	29	1.001	0.017	1
RCL	35	1.003	0.020	1
Compared to chamber calibrated at NBS or RCL	20	1.005	0.01?	0
Chamber manufacturer	44	1.016	0.030	13
Other	25	1.009	0.031	6
Instruments calibrated in 1976 or later				
NBS	9	1.000	0.009	0
RCL	40	0.999	0.011	0
Compared to chamber calibrated at NBS or RCL	24	0.998	0.018	1
Chamber Manufacturer	4	1.017	0.053	1
Other	5	1.005	0.014	0

a) One standard deviation.

b) Number of instruments with calibration factor differing from the RPC by more than 3%

Table IX

Intercomparison of the RPC instrument with institution's instrument as a function of the time since instrument was calibrated at NBS or an RCL

Time since calibration (months)	Number of Intercomparisons	Mean RPC/inst.	σ(a)	Number >3%
0 - 12	60	1.003	0.018	2
13 - 24	29	0.997	0.010	0
25 - 36	10	0.996	0.008	0
37 - 48	10	1.008	0.016	0
49 - 60	1	0.990		0
>60	3	0.993	0.021	0

a) One standard deviation.

b) Number of instruments with calibration factor differing from RPC by more than 3%.

Table X

Repeated Calibrations by MDA RCL (new calibration factor)/(original calibration factor)

Dosimeter	'76	'77	'78	'79	'80
K-F	✓	.999	.999	.999	1.000
K-F	✓		1.000		0.999
K-F	✓		1.000		1.002
F		✓		0.999	1.002
Vict R	✓		0.999		1.000

K-F - Farmer 0.6 cc graphite chamber with Keithley model 602 or 616 electrometer

F - Farmer 0.6 cc graphite chamber

Vict R - Victoreen model 131 chamber with model 570 electrometer

bration factors was 1.002 with a standard deviation of 0.3%. A maximum deviation of 0.7% was seen in three chambers. There was no difference between the results for Victoreen R-Meters and Farmer type instruments.

The MDA RCL data indicate that instrumerts are even more stable and reliable than indicated by the RPC data above. These differences stem from several factors including: the RPC data are from field intercomaprisons with field instruments, the institution may be using the instrument in a different manner from that employed by the calibrating laboratory, or the instrument may have been modified since calibration. Although the data indicate good long term stability, there are two 0.6cc Farmer chambers (with nylon thimbles), belonging to the authors, each of which have experienced unexplained changes in calibration of 1 to 2%.

Discussion of the Time Between Calibrations of Field Instruments

If NBS and each RCL presently in operation were to calibrate 85 instruments per year, the 1057 instruments requiring calibration [1] could on the average be calibrated every 3.1 years. If another RCL was activated the average time between calibrations could be 2.5 years. However, there are a number of calibrations required following repair of instruments or purchase of new instruments. The fact that the average time between calibrations by an institution at the MDA RCL is 1.5 years suggests that some institutions or individuals may be overly conscientious in calibration of instruments while others allow longer periods of time between calibrations of their instruments.

From the instrument user's view, an instrument calibration is essential if he feels uncertain about his current calibration. However, if the user is confident of his instrument calibration, a recalibration according to a time schedule is usually not welcome, since there is risk to the instrument in transport and the absence of the instrument may be a serious inconvenience. In addition, the cost of calibration is sometimes a problem.

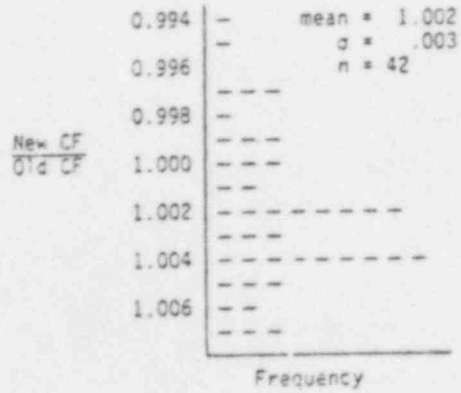

Figure 2: Histogram of the ratio of the calibration factor assigned by the MDA RCL on a subsequent calibration, relative to that assigned when the chamber had been previously calibrated by MDA RCL one to three years earlier.

Techniques Available to Assure Reliability of Assigned Calibration Factors

Since therapy field instruments appear to maintain their calibration factors over extended periods of time, the instrument user can maintain confidence in his instrument calibration through periodic constancy checks. Grant, et al. [7] discuss the use of a cobalt-60 therapy unit or a strontium-90 constancy check source device to perform routine checks on the performance of the instrument. Both techniques appear comparable. The ^{90}Sr data are reproduced in Figure 3, showing all checks to be within ± 1% of the mean.

Another important constancy check procedure is an intercomparison with instruments from other institutions that have chambers calibrated by NBS or an RCL. Table XI shows the results of intercomparisons carried out in conjunction with meetings of Southwest, Midwest and Missouri Valley chapters of the AAPM [8, 9, 10]. These intercomaprisons uncovered erroneous factors on two chambers whose factors were from questionable sources, and verified suspected problems with two RCL calibrated chambers. Periodic intercomparisons of several chamber electrometer systems (last 5 lines of Table XI) again demonstrate the long term stability of these dosimetry system.

It is important to remember that any calibration laboratory can provide an erroneous calibration factor and that instruments may

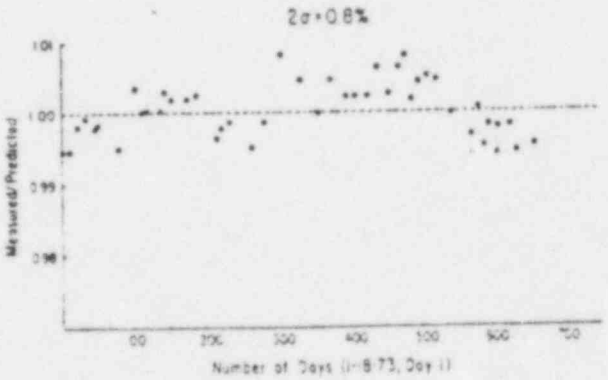

Figure 3: Constancy check of an NBS Farmer-Keithley dosimetry system over a 2½ month period using a ^{90}Sr constancy check device. From Grant et al. [7].

undergo change during transport. A physicist should therefore challenge, in every way possible, any calibration factor obtained from NBS and an RCL. These challenges can include; comparing the new factor with the old factor, a constancy check on the instrument before and after calibration, and intercomparison with other instruments calibrated at NBS or an RCL.

Conclusions and Recommendations

The Regional Calibration Laboratories appear to be sucessfully filling an important need in the radiological community. The users of therapy field instruments who respond to questionnaires and have their instruments calibrated regularly have calibrations at a mean interval of about 1.5 years. However, from an estimate of potential users and the current capacity of NBS and 3 RCLs it is suggested that only one calibration every three years would be possible for each user if all of the instruments were calibrated at the same interval.

Data from various sources support the conclusion that commerical field instruments are capable of maintaining their calibrations for many years. It is suggested here that there be a reconsideration of the time interval between calibration required by federal or state policy. If a user who has a calibration factor directly traceable to NBS verifies the constancy of this instrument monthly by measurements on a cobalt-60 irradiator or strontium-90 constancy checker and if he verifies the instrument constancy at least every two years by an intercomparison with other instruments with calibrations directly traceable to NBS, it should be possible to space calibrations at NBS or an RCL to periods of 3 to 5 years. The user would always use the factor assigned by NBS or an RCL and employ the monthly constancy checks and biennial intercomparison checks as indications for recalibration of his instrument when consistent discrepancies of 2% are found in the checks. This suggestion seems warranted by the performance characteristics of the available instruments if coupled with reliable checks and adequate documentation.

Table XI

Intercomparison of Chambers with a Reference Chamber that had been Recently Calibrated by NBS or an RCL[a]

Time Since Last Calibration (Months)	Type of Dosimeter	Calibrated by	Calibration Factor Institution/ Reference
40	F-K	RCL	1.000
38	Vict R	RCL	1.001
36	Vict R	?	1.042[b]
34	Cap	RCL	1.001
31	Vict R	RCL	0.981[c]
25	F-K	RCL	0.998
21	Vict R	RCL	0.996
18	F-Cap	RCL	0.980[c]
15	F-K	RCL	0.993
7	Vict R	RCL	0.997
1	Cap	RCL	1.003
1	F-K	RCL	0.994
?	EG&G-K	?	1.027[b]
?	F-K	Inter-comparison	0.994
4			0.998[d]
14	F-K	Inter-comparison	0.998
20			1.000
19			0.994[d]
33	F-K	Inter-comparison	0.993

F-K, Farmer 0.6cc chamber with Keithley model 602 or 616 electrometer
Vict R; Victoreen model 621 or 131 chamber with model 570 electrometer
Cap; Capintec model 192 chamber with model 192a electrometer
EG&G; EG&G model 586 A chamber

a) Data from various regional chapters of the AAPM [7,8,9].
b) The chamber factor in use for these two chambers was of unknown or questionable origin.
c) Problem with the correction factor was suspected by the institution.
d) The same institution on several occasions.

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AGENDA

January 21, 1982

NRC Willste Bldg

NRC-NBS discussion of AAPM petition to amend 10 CFR 35.23(a) on calibration requirements for teletherapy licensees.

- Introductions
- Conference-call phone connections to NRC consultants:

  Dr. Peter Almond - M.D.Anderson, Houston

  Dr. Edward Webster - Mass. General Hosp., Boston
- Dosimetry system calibration backlog
- AAPM recommendations for:
  - Longer interval between full calibrations
  - Dosimetry system verification
  - Suggested method of intercomparisons
  - Other methods
  - Constancy checks
- Discussion