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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, REVISION 1; STANDARD LICENSE CONDITIONS

Attached for your use is a revised, up-to-date list of Material License Standard Conditions (Enclosure 1). The previous list dated October 1983 is superseded and should be discarded.

The revised list does not include conditions which merely reference regulatory requirements. Seldom used and ambiguous conditions have been deleted.

Notes for guidance have been placed directly in the list of conditions. The use of the "authorized user" conditions is explained in the attached memorandum dated March 25, 1985 (Enclosure 2).

The use of standard conditions should not substitute for obtaining information from applicants and licensees. Effort should be made to obtain commitments from applicants and licensees about their programs to minimize the number of conditions which need to be put into licenses.

In order to maintain consistency throughout NRC, standard conditions should be used to the maximum extent possible. Therefore, proposed revisions to standard conditions or proposed special conditions should be coordinated through Headquarters prior to use.

Original Signed by
Richard E. Cunningham

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

Enclosures:
1. Standard Conditions
2. Memo to Mr. Stohr from Mr. Cunningham dated March 25, 1985

*See Previous Concurrence

*FCML	*FCML	*ELD	FCML*	FC	FC
NBassin/sc	JHickey	TDorian	VLMiler	DRChapell	RECunningham
11/19/85		11/ / 85	11/19/85	11/ /85	11/20/85

MATERIAL LICENSE STANDARD CONDITIONS

November 1985

PLACE OF USE

1. Licensed material shall be used only at _____.

2. Licensed material may be used at _____ and at temporary job sites of the licensee anywhere in the United States. (This condition would be used for Federal Agencies).

3. 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.

4. Licensed material may be stored at _____and may be used 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.

5. 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.

SUPERVISION-GENERAL

6. Licensed material shall be used by _____.

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

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

SUPERVISION-SPECIAL MEDICAL

Conditions 9. and 10. may be used on broad medical licenses or on specific licenses of limited scope when licensees are permitted to select their own users.

9. The use of licensed material in or on humans shall be by a physician as defined in Section 35.3(b) of 10 CFR Part 35.

10. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980, and as revised December 2, 1982 (47 FR 54376).

Condition 11. is for use on a teletherapy license when licensee is permitted to select its own users.

11. Licensed material shall be used by, or under the supervision of, physicians (as defined in Section 35.3(b) of 10 CFR Part 35) who are certified by the American Board of Radiology in Radiology or Therapeutic Radiology and who have been approved by _____.

Condition 12. is for use on private practice medical licenses and Condition 13. is for use on hospital licensees. These conditions are for use in lieu of Conditions 6. and 7. respectively, if the authorized users can be authorized to use some of the radioactive material/clinical procedures combinations listed on the license.

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

(NAME) (USES)

13. 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)

Condition 14. may be used under the "uses" column of Condition 12. or 13. if a proposed physician-user has no training and experience or a proposed physician-user with limited training and experience wants to perform a few procedures (In-vitro/In vivo studies) and does not wish to file Form NRC-482 or Form NRC-483.

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

SUPERVISION-NUCLEAR PHARMACY

The following Condition should be used together with Condition 7.

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

SUPERVISION-BROAD LICENSE

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

SUPERVISION-PORTABLE GAUGING DEVICES

17. Licensed material shall be used by, or under the supervision and in the physical presence of, _____ or individuals who have been trained as specified in application dated _____. The licensee shall maintain records of individuals designated as users.

LEAK TESTS

The following Conditions 18. through 23. apply to leak testing of sources except for civil defense, radiography, teletherapy, broad licensees, source fabricators, and some panoramic irradiators.

For licenses in which all sources need to be leak tested at 6 month intervals, use the following as the A. section of the condition.

18. A.(1) The source(s) specified in Item(s) 7._____ shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer 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.

For licenses in which all sources need to be tested at 3 year intervals, use the following as the A. section of the condition.

19. A.(1) The source(s) specified in Item(s) 7._____ shall be tested for leakage and/or contamination at intervals not to exceed 3 years. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer 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.

For licenses in which there is a mixture of six month and three year intervals, use the following as the A. section of the condition.

20. A.(1). The source(s) specified in Item(s) 7._____ shall be tested for leakage and/or contamination at intervals not to exceed 6 months and the source(s) specified in Items(s) 7._____ shall be tested for leakage and/or contamination at intervals not to exceed 3 years. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer 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.

For those licenses which provide for possession of fixed gauges which are not specified by model numbers and are manufactured by Kay Ray, Accuray, Ohmart, LFE, or Texas Nuclear, use the following as the A. section of the condition.

21. A. Sources contained in devices manufactured by_____ shall be tested for leakage and/or contamination at intervals not to exceed 6 months. The test may be conducted at 3 year intervals provided the sources have been authorized by the Commission (or an Agreement State) for a three year leak test interval. Any source which is received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

For licenses in which sources designed to emit alpha particles are authorized, use the following as the A. section of the condition.

22. A.(1) The source(s) specified in Item(s) 7._____ shall be tested for leakage and/or contamination at intervals not to exceed three months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within three months before the transfer 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.

NOTE: If there are both alpha sources and other sources provided for in a license, an appropriate combination of Conditions 17. through 21. should be used.

In combination with Conditions 18.A. through 21.A., the B.,C., and D. paragraph below complete the leak test condition. For irradiators other than wet storage, panoramic irradiators, substitute 0.05 microcurie for 0.005 microcurie. For wet storage, panoramic irradiators, see Condition 67.

23. B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region ___, _____, ATTN: Chief, Nuclear Material Safety and Safeguards Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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

OR

D. The licensee is authorized to collect leak test samples for analysis by_____ or tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

For broad licenses and for licenses which authorize fabrication of sources, use the following condition.

24. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before 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 materials 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 before any use or transfer to another person unless they have been leak tested within 6 months before 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 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 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. Records may be disposed of following Commission inspection.

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 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region __, _____, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, describing the equipment involved, the test results, and the corrective action taken.

"TIE DOWN"

25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A.

B. (Documents should be listed chronologically)

C.

GAS CHROMATOGRAPHS

The following Condition 26. is for use in licenses which include gas chromatographs containing Nickel-63.

26. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR 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.

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

28. 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.

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

CIVIL DEFENSE

30. 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 1 inch square, shall bear a conventional radiation symbol prescribed in Section 20.203(a) of 10 CFR 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 provided by the Federal Emergency Management Agency.

31. 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 6 months before transfer and found free of surface contamination. Thereafter, sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Records of leak tests shall be maintained by the licensee. Records may be disposed of following Commission inspection.

B. The test for leakage and/or contamination shall be capable of detecting the presence of 0.005 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 the date the leak test result is known shall notify the U. S. Nuclear Regulatory Commission, Region ___, _____. ATTN: Chief, Nuclear Material Safety and Safeguard Branch.

D. Leak tests of sealed sources in DCPA Sealed Source Sets shall be performed by the licensee in accordance with instructions contained in procedures provided by the Federal Emergency Management Agency.

INDUSTRIAL RADIOGRAPHY

32. 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 of 10 CFR Part 34:

RADIOGRAPHERS	RADIOGRAPHER'S ASSISTANTS

(For use if Radiographers and Radiographers' Assistants are specifically named and the licensee does not have an approved training program.)

33. A. Notwithstanding the periodic leak test required by Section 34.25(b) of 10 CFR Part 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 before use or transfer to another person.

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

(B. should be used only if the license provides for use of sources other than radiography sources, e.g., a source contained in an instrument calibrator.)

34. 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 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 this 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 of 10 CFR Part 34.

    (If a license provides only for iridium-192, delete cobalt-60.)

35. Pursuant to 10 CFR 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.

WELL-LOGGING

36. 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: IF FOUND - DANGER - RADIOACTIVE - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES.

FIXED GAUGES

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

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

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

NUCLEAR PHARMACIES

Nuclear pharmacies are not subject to 10 CFR Part 35.

40. 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.

41. 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.

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

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

TELETHERAPY

44. The following shall be performed only by persons specifically licensed 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.

45. A. Teletherapy sources shall be tested for leakage at intervals not to exceed 6 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 6 months before 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 immediately withdraw the source from use and take action to prevent spread of contamination. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulation Commission, Region __, _____, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch. The report shall specify the source involved, the test results, and corrective action taken.

46. Pursuant to 10 CFR 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 teletherapy units authorized by this license.

47. Before 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) of 10 CFR Part 20 as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with Condition ___. of this license.

48. 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.

49. 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 6 months. Records of test results shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

    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.

50. Before 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 1 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 of 10 CFR Part 20,

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b) of 10 CFR Part 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 U. S. Nuclear Regulatory Commission, Region ____, _____, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch not more than 30 days after each installation of a teletherapy source.

51. 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___., and reported to the Commission within 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___., and reported to the Commission within 30 days after completion of the move.

52. Notwithstanding other authorizations and requirements 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.

53. Notwithstanding the requirements of Section 35.26(a) of 10 CFR 35, the licensee is authorized to extend until _____ the time interval for inspection and servicing of its teletherapy unit.

54. Notwithstanding the requirements of Section 35.24 of 10 CFR Part 35 _____ may perform the duties of the qualified expert for those full-calibration and spot-check measurements specified in Section 35.21 and 35.22 of 10 CFR Part 35.

CARDIAC PACEMAKERS

55. 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.

56. The licensee shall report to the U. S. Nuclear Regulatory Commission, Region____, ATT: Chief, Nuclear Material Safety and Safeguards Branch, _____, within 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 30 days.

57. The licensee shall report to the U. S. Nuclear Regulatory Commission, Region____, ATT: Chief, Nuclear Material Safety and Safeguards Branch, _____, within 10 days of loss of contact with a nuclear pacemaker patient.

58. 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.

MEDICAL

59. For a period not to exceed 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 Radiation Safety Committee, and

    B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

    The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

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

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

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

The following Conditions 63. and 64. should be used only if the license does not provide for use under Group VI of 10 CFR Part 35.

63 Needles or standard medical applicator cells containing cobalt 60 as wire shall not be opened by the licensee.

64. Patients containing cobalt 60, cesium 137 or iridium 192 implants shall remain hospitalized until a source count and surveys made with a 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 5 years from the time the implants are removed.

65. 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.

MOBILE NUCLEAR MEDICINE SERVICE LICENSES

Condition 66. should be placed on all mobile service licenses.

66. Upon the issuance by the Nuclear Regulatory Commission of a specific license to any institution specified in Condition ___, the licensee shall cease use of byproduct material on the premises of the institution.

GAMMA IRRADIATORS

For wet source-storage irradiators which have an ion exchange system for water cleanup, the following leak test condition is acceptable.

67. The ion exchange resin filter bed shall be monitored as specified in application dated _____. If any radioactivity above normal background is detected, the licensee shall determine if the radioactivity is due to a leaking source. Any source found to be leaking shall be removed from service. A report of a leaking source shall be made within 5 days of the date the leak test result is known to the U. S. Nuclear Regulatory Commission, Region __,_____, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch.

The following condition should be used only for panoramic irradiators. It should not be used for self-contained irradiators.

68. Before initiation of irradiator operations or after reloading of sources in the irradiator and before restart of the irradiator, a radiation survey shall be conducted to determine radiation levels around, above, and below the irradiator with the sources in the shielded position and in the exposed position. The results of the survey shall be sent to the U. S. Nuclear Regulatory Commission, Region ___, _____, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch not more than 30 days after the survey is conducted.

The following condition is appropriate for self-contained irradiators.

69. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

TRANSPORTATION

70. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

WASTE DISPOSAL

71. 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 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall 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. (C. should be deleted if generators are not in the license.)

72. Pursuant to Sections 20.106(b) and 20.302 of 10 CFR Part 20, the licensee is authorized to dispose of _____ by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 of 10 CFR Part 20 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 Part 20.

The last sentence of Condition 71., may be omitted or modified to apply to situations where the licensee packages its waste residues and transfers them to authorized recipients for disposal.

MISCELLANEOUS

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

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

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

76. Licensed material shall not be used in or on human beings.

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

78. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintain for 2 years from the date of each inventory.

79. Pursuant to Section 20.105(a) of 10 CFR Part 20, and in reliance on 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

Enclosure
PCW

MAR 25 1985

MEMORANDUM FOR: J. Philip Stohr, Director
Division of Radiation Safety and Safeguards
Region II

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

SUBJECT: INTERPRETATION OF "USED BY" AND "MEDICAL INSTITUTION" AS USED IN MATERIALS LICENSING

Thank you for your February 13, 1985 memorandum on this subject.

As you know, there are two authorized user conditions that are used most frequently on material licenses; Standard License Condition 6 that reads, "Licensed material shall be used by _____" and Standard License Condition 7 that reads, "Licensed material shall be used by, or under the supervision of, _____."

On the industrial side, Standard License Condition 6 is used rarely and indicates that only the individuals named in the condition may handle licensed material. Standard License Condition 7 is used more frequently and indicates that the named individuals may handle licensed materials themselves; other unnamed individuals (e.g., technicians) may also handle licensed material if the unnamed individuals are supervised by one of the named users.

On the medical side, the Commission has recognized that, in the practice of medicine, physicians use technologists and other paramedical personnel to perform some of the activities and manipulations involved in the medical use of isotopes and that, in these instances, the physician is still considered to be the user. Accordingly, Standard License Condition 6 permits named physicians to handle licensed material or to direct technologists or other paramedical personnel in their handling of licensed material. Standard License Condition 7 not only permits the same activities as those permitted by Standard License Condition 6, but also provides a mechanism whereby nonapproved physicians, under the supervision of a physician named on the license, may obtain basic and clinical radioisotope training and experience to enable them to qualify as authorized users.

Standard License Condition 6 is used on the so-called "private practice" licenses, i.e., those issued in the name of a physician or group of physicians pursuant to Section 35.12 of 10 CFR Part 35. Standard License Condition 7 is used on licenses issued to medical institutions pursuant to Section 35.11 of 10 CFR Part 35.

The interpretation of these two license conditions as they pertain to medical licensees has not been confined to "internal interpretive documents" as you suggest. Enclosures 1 and 2 and the discussion of Item 4 of Regulatory Guide 10.8 (Revision 1) discuss these issues, either directly or indirectly.

The term "medical institution" is not defined in 10 CFR Part 35 but, in the past, has been interpreted as an organization that provides medical, surgical or psychiatric treatment, nursing, food and lodging, etc., to ill or injured patients. These organizations are usually listed in the American Hospital Association Guide to the Health Care Field; a copy of this document should be available in each Region. Many medical institutions are accredited, but applicants for licenses issued pursuant to Section 35.11 need not show evidence of accreditation.

Appendix A of Regulatory Guide 10.8 encourages physicians to obtain their training in formal accredited residency programs, but does provide for training obtained in other types of programs within a medical institution. However, training must be obtained in an institutional nuclear medicine program (i.e., one licensed pursuant to Section 35.11) under the supervision or tutelage of one of the authorized physicians named as a user on the institution's license. Clinical training may not be obtained in a nuclear medicine program conducted under a so-called "private practice" license, because these licenses do not authorize the licensee to conduct such training programs; Standard License Condition 6 is used on these licenses.

Copies of this memorandum will be sent to each Region. We do not believe that a Policy and Guidance Directive is needed on the issues raised in your memorandum.

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

Enclosures:
1. 38 FR 6399
2. 50 FR 8136

cc: T. Martin, Region I
J. Glenn, Region I
J. Potter, Region II
J. Hind, Region III
B. Mallett, Region III
J. Everett, Region IV
R. Scarano, Region V
R. Thomas, Region V
D. Nussbaumer, State Agreements Program

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3/20/85	3/20/85	3/21/85	3/21/85	3/22/85	3/25/85

PART 35

HUMAN USES OF BYPRODUCT MATERIAL

PROPOSED RULE MAKING

38 FR 6399
Published 3/9/73
Comment Period expires 4/23/73

MEDICAL USES OF RADIOISOTOPES (BYPRODUCT MATERIAL)

User and Reporting Requirements

The Atomic Energy Commission has under consideration amendments to its regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," to: (1) Change the title of the part to "Medical Uses of Radioisotopes (Byproduct Material)," (2) specify certain responsibilities of physicians authorized to use radioisotopes for medical uses, (3) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, (4) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, (5) require reporting to the Commission of misadministrations of radioisotopes or radiation therefrom, and (6) require notification to the patient or a responsible relative of the patient of the misadministration of radioisotopes or radiation therefrom which could adversely affect the patient.

The title of 10 CFR Part 35 would be changed by the proposed rule to "Medical Uses of Radioisotopes (Byproduct Material)" to make the title more meaningful to users of radioactive material. If this rule is finally adopted, amendments to conform to this new title will be made to this and other parts of the Commission's regulations pertaining to byproduct material.

In its licensing of the medical uses of radioisotopes pursuant to 10 CFR Part 35, the Commission requires that the responsible user be a physician licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine. Physicians are authorized to use radioisotopes by a condition of specific or general licenses issued by the Commission. One of the following three standard conditions is included in each specific license issued for medical use of radioisotopes:

1. "Byproduct material shall be used by (a named physician)." This condition is used in licenses to physicians in private practice.

2. "Byproduct material shall be used by, or under the supervision of (one or more named physicians)." This condition is used in licenses issued to medical institutions which have medical isotopes committees to review all proposals for uses of isotopes within the institution. The named physicians are those designated on the application for license as having appropriate nuclear medicine training and experience with isotopes. The phrase "or under the supervision of" provides a means whereby nonapproved physicians under the supervision of a physician named on the license may obtain basic and clinical radioisotope training and experience to enable them to qualify as authorized users.

3. "A. Byproduct material shall be used by, or under the supervision of, individuals designated by the (name of institution's isotopes committee).

"B. The use of byproduct material in or on humans shall be by a physician." This condition is used in licenses issued to medical institutions—usually medical schools—whose isotopes committees have set up appropriate administrative procedures, and training and experience criteria, for the committee to approve individual users. This condition also allows other physicians to obtain training and experience under the supervision of a physician designated by the committee as an authorized user.

It is recognized by the Commission that physicians utilize technicians and other paramedical personnel to perform some of the activities and manipulations involved in the medical uses of radioisotopes. In such instances, the physician is still considered to be the user of the radioisotopes. The Commission has developed with the assistance of its Advisory Committee on the Medical Uses of Isotopes a list of responsibilities which shall not be delegated by authorized physician users of radioisotopes—except to other physicians who are under the supervision of authorized physicians—and a list of activities that may be delegated by physicians to technicians and other paramedical personnel. The proposed new § 35.32 would codify these nondelegable responsibilities and permissible delegations in the Commission's regulations. Section 35.32 would also require physicians to determine that technicians and other paramedical personnel are properly trained to perform the activities which are delegated to them. Certification in nuclear medical technology by either the American Registry of Radiologic Technologists or the Registry of Medical Technologists would be deemed to satisfy the requirement for such proper training; however, the Commission does not consider it necessary to require paramedical personnel who only assist physicians with simple manipulations or in programs of limited scope to be fully trained and certified technologists.

Section 20.403 of 10 CFR Part 20 of the Commission's regulations requires licensees to notify the Commission of incidents involving the exposure of individuals to more than certain stated amounts of radiation, section 20.405(c) requires that any exposure of an individual to radiation which is required to be reported to the Commission shall also be reported to the individual. However, since § 20.107 of 10 CFR Part 20 provides that nothing in the regulations in that part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy, notifications have not been required of incidents involving the exposure of patients to radiation if the patient were receiving any intentional medical exposure. Although incidents involving medical exposures have not been required to be reported, 12 instances of misadministrations of radioactive materials involving 20 patients have been brought to the Commission's attention. Since these incidents have generally involved accidental or erroneous exposures of patients to radiation in amounts or forms other than intended, it does not appear appropriate to continue the past practice of not requiring reports of such misadministrations of radioactive materials to medical patients. The proposed new paragraphs (a) and (c) of § 35.33 would require licensees to report misadministrations of radiopharmaceuticals or radiation from byproduct material sources to the Commission. Paragraph (b) of § 35.33 would also require a notification to the patient or to a responsible relative of the patient of a misadministration which could cause a demonstrably adverse effect on the patient unless in the physician's professional judgment such notifi-

cation would be contrary to the best interests of the patient or a surviving relative of the patient. (In accordance with the Freedom of Information Act and 10 CFR Part 9 of the Commission's rules and regulations, copies of reports filed under these proposed rules, except for any details which would identify the patient, will be available for public inspection.)

Pursuant to the Atomic Energy Act of 1954, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 35 is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary of the Commission, U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Chief, Public Proceedings Staff by April 23, 1973. Copies of comments on the proposed amendments may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

1. The title of 10 CFR Part 35 is amended to read as follows: "Medical uses of radioisotopes (byproduct material)."

2. A new § 35.32 is added to 10 CFR Part 35 to read as follows:

§ 35.32 Conditions of licenses for medical uses of radioisotopes.

(a) The user of radioisotopes in or applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a general license or a specific license, including a specific license of broad scope, issued by the Commission (authorized physician).

(b) No authorized physician may delegate to persons who are not physicians under the supervision of the authorized physician, the following:

(1) The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources,

(2) The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered,

(3) The determination of the route of administration,

(4) The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(c) Subject to the provisions of paragraphs (b), (d), (e), (f), and (g) of this section, an authorized physician may permit technicians and other paramedical personnel to perform the following activities:

(1) Preparation and quality control testing of radiopharmaceuticals and sources of radiation,

(2) Measurement of radiopharmaceutical doses prior to administration.

(3) Use of appropriate instrumentation for the collection of data to be used by the physician,

(4) Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable Federal, State or local laws.

(d) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to paragraph (c) of this section shall:

(1) Prior to such permission, determine that such technicians and other paramedical personnel have been properly trained to perform their duties. This training shall include training in the following subjects, as applicable to the duties assigned:

(i) General characteristics of radiation and radioactive materials.

(ii) Physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used.

(iii) Mathematics and calculations basic to the use and measurement of radioactivity, including units of quantity of radioactivity (curies, millicuries, microcuries) and units of radiation dose and radiation exposure.

(iv) Use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments.

(v) Principles and practices of radiation protection.

(vi) Additional training in the above subjects, as appropriate, when new duties are added.

(2) Assure that such technicians and other paramedical personnel receive appropriate retraining in the subjects listed in paragraph (d)(1) of this section to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology.

(3) Keep records showing the bases for such determinations of proper training, and

(4) Retain responsibility as licensee or authorized user for the satisfactory performance of such activities.

(e) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists will be deemed to satisfy the training requirements of paragraph (d) (1) and (2) of this section.

(f) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training (including retraining as required to keep abreast of developments in technology) such personnel or for otherwise determining that such personnel are properly trained to perform their duties. With respect to licenses in effect on (effective date of rule), a licensee who is permitting or who desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section shall file the information required by this paragraph with the Director of Licensing, U.S. Atomic Energy Commission, Washington, D.C. 20545, with his next application for amendment or renewal of the license or within 1 year of (effective date of rule), whichever occurs first.

(g) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician (not necessarily a physician authorized by the Commission to be a user of radioisotopes) shall be immediately accessible.

3. A new § 35.33 is added to 10 CFR Part 35 to read as follows:

§ 35.33 Notifications and reports of misadministrations.

(a) Each licensee shall notify the Director of the appropriate Atomic Energy Commission Regulatory Operations Regional Office listed in Appendix D of 10 CFR Part 20 of the Commission's regulations by telephone and telegraph of any misadministration of radiopharmaceuticals or any misadministration of radiation from teletherapy and brachytherapy sources. This notification shall be made within 24 hours after such misadministration is known. For the purpose of the requirements of this section, misadministration is defined to include the administration of:

(1) A radiopharmaceutical, or radiation from a source other than the one intended,

(2) A radiopharmaceutical or radiation to the wrong patient, or

(3) A dose of a radiopharmaceutical, or exposure from a radiation source, outside of the intended dose range prescribed by the physician or by a route of administration other than that intended by the physician.

(b) (1) Whenever a misadministration of a radiopharmaceutical or radiation from a teletherapy or brachytherapy source could cause a demonstrably adverse effect on the patient to whom it was administered, the licensee or the authorized physician shall promptly notify the patient or a responsible relative of the patient of the misadministration unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient.

(2) If death occurs after a judgment is made by the physician that notification to the patient or a responsible relative of the patient of the misadministration would be contrary to the best interests of the patient and the misadministration may have been a contributory cause of the death, the licensee or the authorized physician shall notify a responsible relative of the patient of the misadministration unless the physician makes an additional determination that such notification would be contrary to the best interests of a surviving relative of the patient.

(c) In addition to the notification required by paragraph (a) of this section, each licensee shall make a report in writing within 30 days to the Director of Regulatory Operations, U.S. Atomic Energy Commission, Washington, D.C. 20545, with a copy to the Director of the appropriate Regulatory Operations Regional Office specified in Appendix D of 10 CFR Part 20, of each misadministration. The report required under this paragraph need not include the name of the

patient but shall describe the nature, extent, and cause of the misadministration and the corrective steps taken or planned to assure against a recurrence. If the misadministration could cause a demonstrably adverse effect on the patient or if death occurs and the misadministration may have been a contributory cause of the death, the report shall either confirm that the patient or a responsible relative of the patient has been notified of the misadministration as required by paragraph (c) (1) and (2) of this section or shall state that notification was not given because in the physician's judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. If the patient or relative is not notified, the physician shall confirm that this decision was reviewed by a local Ethics Committee or an equivalent group of peers and shall state whether or not the committee or group concurred with the decision.

(d) Any notification or report filed with the Commission pursuant to paragraphs (a) and (c) of this section shall be prepared so that any details which would identify the patient will be stated in a separate part of the notification or report.

40 FR 8832
Published 3/3/75
Comment Period expires 5/2/75
(extended to 5/19/75)

Reports to the Commission Concerning Defects and Noncompliance

See Part 21 Proposed Rule Making.

40 FR 20110
Published 5/8/75
Comment Period extended to 5/19/75

Reports to the Commission Concerning Defects and Noncompliance; Proposed Requirements; Extension of Comment Period

See Part 21 Proposed Rule Making.

42 FR 12185
Published 3/3/77
Comment Period expires 4/18/77

[10 CFR Part 35]

HUMAN USES OF BYPRODUCT MATERIAL

Specific Licenses to Individual Physicians and Institutions

Following its organization under the Energy Reorganization Act of 1974 (Pub. L. 93-438), the Nuclear Regulatory Commission (NRC) has stated its intention of reviewing those of its regulations and procedures pertaining to the licensing and regulation of nuclear facilities and materials that were originally promulgated by the Atomic Energy Commission, with a view to considering what changes should be made.

Summary. The Nuclear Regulatory Commission has under consideration an amendment to its regulations in 10 CFR Part 35, "Human Uses of Byproduct Material." The amendment would require a medical institution to be licensed for byproduct material used in the institution, rather than the individual physician using the byproduct material. This would be accomplished by limiting the granting of individual physician licenses under § 35.12 to a physician or group of physicians in private practice in an office outside the institution. (In order not to impede the delivery of nuclear medicine services at small medical institutions or clinics, an exception would be made for private practice in an institution or clinic to allow a physician(s) to bring byproduct material into a hospital (1) to administer radiopharmaceuticals to a patient for therapeutic or diagnostic purposes, (2) to perform diagnostic studies on patients to whom a radiopharmaceutical has been administered or (3) perform in vitro diagnostic studies. The physician(s) would be required to remove from the premises, when he (they) depart(s), all byproduct materials except those remaining in the patient. As provided in § 30.34(c), the licensee shall confine his possession and use to the locations and purposes authorized in the license.)

Institutions and Individual Practice. "The Manual on Radition Protection in Hospitals and General Practice," published by the World Health Organization (1974) in cooperation with the International Labor Organization and the International Atomic Energy Agency, offers the following guidance:

> Responsibility for radiation protection affects all members of the administrative system, from the employing authority to the individual carrying out a radiological procedure. The authority in charge of any establishment is ultimately responsible for the protection of all staff, patients, and members of the public who may come within range of any radiation from its equipment.

In context, this statement is used to encourage management to designate a person in each department concerned with ionizing radiations to take care of day-to-day protection measures; however, the admonition for management responsibility and involvement in radiation safety is regarded here as the goal for medical use and other radiation safety programs.

With this goal in mind, the Commission is proposing a rule change that would, in effect, require a medical institution, now operating a nuclear medicine program under an individual physician license, to be licensed as an institution under § 35.11 at the time of expiration of the individual physician license obtained under § 35.12. In order for a physician to continue to practice nuclear medicine in a medical institution he would have to be named on the institution's license by the time his individual physician license expires. At the expiration of the individual physican license, the Commission would not renew authorization for practice within a medical institution. Medical institutions which already hold an institution license would be encouraged to add the names of individual physicians to their institution license immediately, rather than wait until the physician's individual license expires. The proposed rule change, in effect, provides that institutional licenses and individual physician licenses are mutually exclusive.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendment to 10 CFR Part 35 is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendment should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by April 18, 1977. Copies of comments may be examined in the NRC Public Document Room at 1717 H Street, NW., Washington, D.C.

§ 35.12 is revised to read as follows:

§ 35.12 Specific licenses to individual physicians for human use of byproduct material.

(a) An application by an individual physician or group of physicians for a specific license for human use of byproduct material will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(3) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of such experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of such experience.)

(b) The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use byproduct material on the premises of a medical institution unless:

(1) The use of byproduct material is limited to:

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered; or

Federal Register
Vol. 50, No. 40
Thursday, February 28, 1985

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-5]

Nuclear Radiation Consultants; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is denying a petition for rulemaking submitted by Nuclear Radiation Consultants. The petition requested that NRC regulations be amended to permit any health professional to obtain a license to use the dual photon spine scanner, also known as a bone mineral analyzer, which utilizes radioactive gadolinium-153. Current NRC regulations require that a person must be a physician in order to obtain a license for human use of sources and devices containing byproduct material.

FOR FURTHER INFORMATION CONTACT: Judith Foulke, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 427-4563.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is denying a petition for rulemaking dated January 19, 1984, submitted by Nuclear Radiation Consultants. A notice of filing of the petition was published in the Federal Register on March 8, 1984 (49 FR 8621), and public comment was invited.

Twenty-seven comment letters were received and all of the commenters opposed adoption of the petition. Copies of the petition and public comments are available for inspection and may be copied for a fee at the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

Background

The petitioner, Nuclear Radiation Consultants, requested the NRC to amend its regulations governing the human use of byproduct material to permit any health professional with appropriate training and experience to obtain a license to use a specific medical diagnostic device containing the radioactive isotope Gd-153. This device is the dual photon spine scanner, which is also known as a bone mineral analyzer. By measuring the transmission of radiation through the spinal bones, the condition of the skeleton can be assessed.

As described in the Commission's February 9, 1979 policy statement, "Regulation of the Medical Uses of Radioisotopes" (44 FR 8242):

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Use of Isotopes.

An NRC license for the medical use of radioisotopes is not a license to practice medicine. It has a different purpose, namely, assuring the safe handling and use of radioisotopes. To the extent that it affects the practice of medicine, it does so no more than necessary to protect public health and safety. However, under the Commission's regulations in 10 CFR Part 35, a physician must be licensed by a State to practice medicine prior to receiving an NRC license. NRC's license involving irradiation of humans is restricted to State-licensed physicians because of the need for the requisite competence to practice medicine that is demonstrated by a license from a State.

As is the case with X-ray machines and other diagnostic equipment, the actual measurements may be made on the patient by paramedical personnel. These technicians and technologists are trained in the use of the specific devices by their physician-supervisor in addition to their formal schooling and are supervised by the physician who is responsible for care of the patients. NRC has recognized this situation from the beginning and discusses the permissible scope of activities for a technician in section 4 of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs."

NRC has provided an exemption from its requirements that only physicians can obtain a license for human use of byproduct material by allowing podiatrists and dentists to be licensed to use the lixiscope, a device similar to an X-ray machine. The rationale for this exemption was based on the fact that these professionals must also be licensed by a State to treat specific portions of the human body.

Issues Raised by Commenters

Among the concerns expressed by the commenters was the potential for erroneous interpretation of the results. These commenters pointed out that complications due to coexistent osteoarthritic or post-surgical changes in the spine may lead to failure to diagnose the serious medical condition of osteoporosis or to initiation of therapy with possibly harmful agents such as estrogens for patients not in need of it. As is true for all areas of clinical medicine, diagnostic results must be interpreted only by individuals who understand the primary and coexistent medical problems of the patient. In addition, allowing non-physicians to be licensed to use the bone mineral analyzer could lead to unnecessary radiation exposure since tests would be more likely to be performed on individuals not needing them. This would be contrary to the Commission's policy that all radiation exposures should be balanced by a concomitant benefit.

Commenters also noted that, while under optimal conditions the doses to the patient and the operator resulting from the use of a bone mineral analyzers are acceptably small, situations can arise which present significant radiation safety hazards. Improper positioning of the patient or failure of the device to move as programmed can result in overexposure of the patient. Instances were cited where the gadolinium source was found to contain another radionuclide, which produced a much higher dose rate, or was leaking, which produced transferable contamination. While these occurrences are rare, they do demonstrate that the bone mineral

petitioner claimed.

NRC Responses to Issues Raised in Petition

Issue 1: The petitioner claims "The e of this device cannot reasonably be nsidered the practice of medicine because it is solely a diagnostic tool."

Response 1: As pointed out in several comment letters received from professional medical societies, diagnosing disease has always been an integral part of the practice of medicine. Consequently, use of diagnostic tools on humans definitely falls within the definition of the practice of medicine.

Issue 2: The petitioner claims "It is unreasonable to believe only physicians are capable of using bone mineral analyzers without risk to public health and safety. NRC is aware that nuclear medicine technologists with one year training past secondary school routinely administer intravenously substantial doses of radiopharmaceuticals. NRC is aware these materials deliver far greater radiation doses than the 10–20 mrem dose to a limited anatomical area resulting from use of the bone analyzer."

Response 2: We agree that other individuals such as medical technologists can operate this device safely. However, NRC does not license technologists because responsibility for patient care is vested in a named individual licensed to practice medicine y a State. In this regard, the magnitude of the radiation dose is not the issue of concern. As noted above, the delegation of operation of devices to paramedical personnel with the proper training and under the supervision of a licensed physician is acceptable.

Issue 3: The petitioner claims ". . . there are individuals trained in radiation physics and health physics who are often the very instructors in the subjects required by NRC in the directive noted above."

Response 3: We agree that there are other individuals who meet the training criteria as far as radiation physics and health physics are concerned. However, these individuals are not licensed by a State to practice medicine.

Issue 4: The petitioner claims that NRC's licensing policy is "de facto antitrust in that it blocks entry of individuals with pertinent and equal training and experience from becoming licensed users."

Response 4: We assume from the latter part of the sentence that the petitioner meant to say that NRC was contributing to establishment of a monopoly (not "antitrust"). If this were the case, it would be an indirect onsequence of NRC's carrying out its public health and safety.

Issue 5: The petitioner claims that NRC's licensing policy for the human use of byproduct materials is contrary to the Regulatory Flexibility Act.

Response 5: NRC Policy Directive FC–83–24, "Licensing the Lixiscope and Bone Mineral Analyzer for Human Use," contary to what the petitioner asserts, is not in conflict with the intent of Congress as spelled out in the Regulatory Flexibility Act. First of all, the Regulatory Flexibility Act, 5 U.S.C. 601–612, is only applicable to agency rulemakings on which public comment is required by section 533(b) of the Administrative Procedure Act or any other law. Second, the Regulatory Flexibility Act establishes a *procedure* for evaluating the effect of agency regulations on small entities. All agencies, as part of the rulemaking process, must prepare a regulatory flexibility analysis for any rule that has a significant economic impact on a substantial number of small entities. The analysis must, among other things, discuss how a rule will affect small entities, describe significant alternatives that would minimize any significant economic impact of the rule on small entities, and explain why each one of such alternatives was rejected. The intent of the Act is to require government agencies to review proposed rules to ensure that, while accomplishing their intended purpose, they do not unduly affect the ability of small entities to carry out their activities. Contrary to the implications of the petitioner's letter, the Act does not require the agency to make the accommodation of any and all small business interests its paramount concern at the expense of the agency's other satutory resonsibilities. To the countrary, Section 606 of the Regulatory Flexibility Act states that the requirement to analyze the economic impact of agency regulations to determine their impact upon small entities does not alter in any manner the standards otherwise applicable by law to agency action.

Issue 6: The petitioner claims that NRC's policy is ". . . inconsistent with the mandate of NRC to encourage safe uses of radioactivity."

Response 6: NRC's mandate is to assure the safety of workers and the public. NRC has never had any mandate to encourage the use of radioactive materials. In fact, one of the reasons why the Atomic Energy Commission was divided into two agencies (NRC and ERDA, now DOE) was to separate the regulatory and promotional activities materials.

Conclusion

A bone mineral analyzer is used only as a means of obtaining information on a patient's skeletal status in order to diagnose diseases such as osteoporosis. Diagnosing diseases has always been construed by all levels of government as an integral part of the practice of medicine. Consequently, NRC has always issued licenses involving human use of byproduct material only to licensed physicians (or to podiatrists or dentists for limited use of the Lixiscope) because only they are authorized to practice medicine and possess the demonstrated competence to practice medicine, as evidenced by their State license. The petitioner's statements do not provide adequate justification for changing this policy.

Dated at Bethesda, Maryland, this 1st day of February, 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85–CE–5–AD]

Airworthiness Directives; Cessna 206, P206, U206, 207 and 210 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This Notice proposes to adopt a new Airworthiness Directive (AD) applicable to Cessna 206, P206, U206, 207 and 210 Series Airplanes, which would require inspection, repair and/or modification of the engine induction airbox installation. Loss of engine power has resulted from pieces of the lower forward induction airbox separating from the botton of the duct and being ingested by the engine. This action will preclude engine power loss caused by induction airbox failures.

DATES: Comments must be received on or before April 5, 1985.

ADDRESS: Send comments on the proposal in duplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 85–CE–5–