

(SP-98-031, April 1998, Technical, Standard License Conditions)  
DATED: APRIL 17, 1998

SIGNED BY: RICHARD L. BANGART FOR  
PAUL H. LOHAUS

ALL AGREEMENT STATES  
OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-98-031)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....XX

DRAFT-UPDATE OF  
STANDARD LICENSE  
CONDITIONS

OTHER INFORMATION.....

Supplementary information: Enclosed for your review and comment is draft copy of updated standard license conditions. The update was prepared based on NRC staff review of 10 CFR, Generic Technical Assistance Requests (TARs), Policy and Guidance Directives, NUREG 1556 volumes, and the current standard license conditions. Please provide any comments on the draft directly to Patricia K. Holahan, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards by May 15, 1998. Ms. Holahan can be reached at (301) 415-8125 or by Fax at (301) 415-5369. For any further information, the OSP contact is listed below:

CONTACT:	KEVIN HSUEH
TELEPHONE:	(301) 415-2598
FAX:	(301) 415-3502
INTERNET:	KPH@NRC.GOV

Paul H. Lohaus, Deputy Director  
Office of State Programs

Enclosure:  
As stated

# DRAFT FOR COMMENT

- Rules:
1. New Conditions added are in italics.
  2. Changes in 1993 conditions are in strikeover-~~bbb~~ and added words in *italics*.
  3. Part of conditions needing OMB clearance are redlined.
  4. License conditions granting exemptions per P&GD 1-26 that regions can use without NMSS consultation are added in the subject area and are in *italics*.
  5. Each area should have at least two reserved condition numbers; therefore license conditions will have the new and old number assigned to help in review against the June 1993 edition of the standard license condition.

~~Revised June 1993~~ CT 1997 DEC 1997

## STANDARD LICENSE CONDITIONS

### PLACE OF USE

1. Licensed material ~~shall~~ *may* be used only at the licensee's facilities located at \_\_\_\_\_
2. Licensed material may be used *or stored* at the licensee's facilities located at \_\_\_\_\_ and at temporary job sites of the licensee anywhere in the United States.  
**[Reviewer Note: This condition should only be used for Federal Agencies.]**
3. Licensed material may be used *and stored* at the licensee's facilities located 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 the licensee's facilities located 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~~ *may* 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.
6. ~~The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: 1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and 2) the U.S. Nuclear Regulatory Commission, Region \_\_\_\_\_, ATTN: Chief, \_\_\_\_\_, has been notified in writing that activities authorized by the license will be initiated.~~  
(RESERVED)  
**[NOTE: The above condition is removed by the withdrawal of P&GD 92-04 on 7/10/97]**

07. (RESERVED)  
*In accordance with the requirements set forth in 10 CFR 30.36(b d ), 40.42(d) and 70.38(d), the licensee shall promptly notify the U.S. Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.*  
**[NOTE: New condition in accordance with P&GD 92-04 will be kept and used on all new licenses where the new applicant does not have other current licenses. Used on example license in NUREG 1556, Volume 1., May 1997.]**

8. (RESERVED)

9. RESERVED)

SUPERVISION - GENERAL

10. 8: Licensed material shall be used by, or under the supervision of, \_\_\_\_.

11. 9: Licensed material shall be used by, or under the supervision and in the physical presence of, \_\_\_\_\_.

12. 10: Licensed material shall be used only by \_\_\_\_\_.

13. 11: Licensed material shall be used by, or under the supervision of, individuals who satisfy the requirements of 10 CFR 33.15.

14. 12: (RESERVED)

15. 13: (RESERVED)

SUPERVISION - LIMITED MEDICAL

16. 14: Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
-------------------------	-------------------------

SUPERVISION - BROAD MEDICAL

17. 15: The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

18. 16: ~~Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 Part CFR 35 Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee's shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.~~

*Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee.*

**[Reviewer Note: Conditions 15 17 and 16 18 are used together. Modification from RI]**

19.  
17: Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee.

20.  
18: (RESERVED)

*The licensee's Radiation Safety Committee may approve medical physicists for their HDR brachytherapy program. Authorizations are limited to naming those physicist as who meet the requirements of 10 CFR 35.961 (substituting similar experience in HDR brachytherapy specific tasks for those listed in 10 CFR 961(c), or who are named on a current NRC or Agreement State license, or a permit issued by a licensee of broad scope as an HDR medical physicist . In addition, the physicist must possess recentness of training requirement in 10 CFR 35,972; and, the physicist must possess recent, device specific training and experience for each make and model of HDR device used by the license as specified in Policy and Guidance Directive FC 86-4, Rev. 1. A record of such authorization must be maintained for subsequent inspection..*

**Note: the above condition from Generic TAR response issued 12/18/96 to RIII.**

21.  
19: (RESERVED)

#### SUPERVISION - PACEMAKER

22.  
20: The physicians responsible for implantation, follow-up, explanation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are\_\_\_\_\_

#### SUPERVISION - NUCLEAR PHARMACY

23.  
21: ~~At least one individual named in Condition\_\_\_ shall be physically present at \_\_\_\_\_ the authorized place of use whenever licensed material is being used.~~

~~Reviewer Note: Use Condition 21 with Condition 8 or 22}~~

**[Radiopharmacy rule made above condition obsolete]**

*Licensed material shall be used by, or under the supervision of:*

- (1) *a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32. 72(b)(2) and 32. 72(b)(4) of 10 CFR Part 32, or*
- (2) *authorized nuclear pharmacists, (name) (name). or (name).*

**[New condition above from example license Draft Reg Guide DG-0006, March 1997]**

SUPERVISION - BROAD

24.

~~22.~~ Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, \_\_\_\_\_, Chairperson. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

***[Reviewer's Note: Authorized user for Type A Broad License]***

25.

~~23.~~ (RESERVED)

Licensed material shall be used by or under the supervision of individuals designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

***[Reviewer's Note: Authorized user for Type B Broad License.]***

26.

~~24.~~ (RESERVED)

Licensed material shall be used by or under the supervision of individuals meeting the requirements stated in 10 CFR 33. 15(b)(1) and (2). The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

***[Reviewer's Note: Authorized user for Type C Broad License.]***

27. (RESERVED)

SUPERVISION - PORTABLE GAUGES

28.

25. Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have received the training described in application dated \_\_\_\_\_ and have been approved in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 5 years following the last use of licensed material by the individual

***[NOTE: This condition appears in NUREG 1556, Rev 1.]***

29.

26. Licensed material shall only be used by, or under the supervision and in the physical presence of, \_\_\_\_\_ or individuals who have successfully completed the manufacturer's training program for gauge users, have been instructed in the licensee's routine and emergency operating procedures and who have been designated by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users and their training for 5 years following the last use of licensed material by the individual.

30.

~~27.~~ (RESERVED)

SUPERVISION - RADIOGRAPHY

31.

~~28.~~ The individuals listed below are the only persons authorized by this license to act as radiographers or radiographers' assistants as defined in 10 CFR 34.2:

\_\_\_\_\_ Radiographers \_\_\_\_\_ Radiographer's Assistants

Licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have been designated in writing by the Radiation Safety Officer and have been trained:

A. As specified in application/letter dated \_\_\_\_ (and the letter dated \_\_\_\_ ): and

B. In accordance with the provisions of 10 CFR 34.43.

**[NOTE: New license condition as stated in NUREG 1556, Vol 2.]**

32.

29. (RESERVED)

#### SUPERVISION -WELL-LOGGING

33.

30: The individuals listed below are the only persons authorized by this license to act as logging supervisors or logging assistants as defined in 10 CFR 39.2:

Logging Supervisors

Logging Assistants

34.

31. (RESERVED)

#### SUPERVISION - IRRADIATOR

35

32. (RESERVED)

36

33: (RESERVED)

#### RADIATION SAFETY OFFICER

37.

34: The Radiation Safety Officer for this license is \_\_\_\_\_

38.

35—(RESERVED)

A. The Radiation Safety Officer (RSO) for this license is insert name of RSO.

B. *Before assuming the duties and responsibilities as RSO for this license, insert name of RSO shall have successfully completed one of the training courses described in Criteria in Section 8.8 of NUREG - 1556, Volume 1, dated May 1997. [Reviewer Note: Use this condition on portable gauge licenses per NUREG 1556, Vol.1.]*

OR

B. *Before assuming the duties and responsibilities as RSO for this license, insert name of RSO shall have successfully completed one of the training courses described in Criteria in Section 8.8 of NUREG - 1556, Volume 4, dated insert correct date.. [Reviewer Note: Use this condition on fixed gauge licenses per NUREG 1556, Vol. 4.]*



20. 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.

- G. The licensee is authorized to collect leak test samples for analysis by\_\_\_\_. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. **(This part of the condition is used for licensees NOT authorized to perform leak test analysis.)**

OR

- G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services. **(This part of the condition is used for licensees authorized to collect and analyze leak test samples)**

41.

~~37.~~ (RESERVED)

- A. *Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.*
- B. *In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source received from another person shall not be put into use until tested.*
- C. *Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 3 years without being tested for leakage and/or contamination. **[Modified to be equivalent to program code for storage only inspection frequency]***
- D. *The leak 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, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2) and (c)(2) and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20 Region \_\_\_\_ ATTN: Chief, \_\_\_\_\_, . The report shall specify the source involved, the test results, and corrective action taken.*
- E. *Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to*

*perform such services. In addition, the licensee is authorized to collect leak test samples But not perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services (This part of the condition is used for licensees NOT authorized to perform leak test analysis.)*

OR

- E. *Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services. (This part of the condition is used for licensees authorized to collect AND analyze leak test samples)*

- F. *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.*

**[Reviewer Note: New condition from NUREG 1556, Vols. 1, 4, and 5 use the above condition for portable and fixed gauges, and self-shielded irradiator licenses]**

“TIE DOWN”

42.

- 38: 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.

**[Reviewer Note: Use for all licenses except medical]**

43.

- 39: 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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)

**[Reviewer Note: this condition should only be used for medical licensees.]**

44.

- 40: (RESERVED)

- 45.
- ~~41.~~ (RESERVED)

GAS CHROMATOGRAPHS

- 46. (RESERVED)
- ~~42.~~ In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 C~ 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with ~~no~~ ~~od~~ or stamped radiation caution symbols:

———— [Reviewer Note: 10 CFR 20.1901(b) obviates the need for this condition. Do not use this on any licenses after 1/1/94.]

- 47.
- 43. Maintenance, repair, cleaning, replacement and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

- 48.
- 44. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by NRC in the certificate of registration referred to in 10 CFR 32.210 or equivalent registration from an Agreement State.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

[Reviewer Note: Condition ~~48~~ 44.B should not be used with portable field devices.]

- 49
- ~~45.~~ (RESERVED)
- 50.
- ~~46~~ .(RESERVED)
- 51.
- ~~47.~~(RESERVED)

FEMA

- 52.
- 48. A. 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 10 CFR 20.1901 (a) and a minimum of the following instructions: DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND.
- B. 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.

- 53.
- ~~49.~~ (RESERVED)
- 54.
- 50. (RESERVED)

PORTABLE GAUGES

55.

54. Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container must be locked when in transport, storage or when not under the direct surveillance of an authorized user.

56

52. The licensee may remove *detach* the source or source rod from (manufacturer) Model numbers \_\_\_\_\_ gauges for the purpose of cleaning, maintenance, or repair of the gauge(s) in accordance with procedures outlined in (application/letter)( dated/received) (fill in date). **[This condition is used if the licensee is authorized to perform non-routine maintenance]**

57.

53. Any cleaning, maintenance, or repair of the gauge(s) that requires removal of the source rod shall be performed only by the manufacturer or by other persons specifically licensed by the Commission or an Agreement State to perform such services. **[This condition is used if he licensee is not authorized to perform non-routine maintenance]**

58.

54. (RESERVED)

Sealed sources or source rods containing licensed material shall not be opened or sources removed or detached from source rods or gauges by the licensee, except as specifically authorized.

59.

55. (RESERVED)

- A. If the licensee uses unshielded sealed sources extended more than 3 feet below the surface, the licensee shall use surface casing that extends from the lowest depth to 12 inches above the surface and other appropriate procedures to reduce the probability of the source or probe becoming lodged below the surface. If it is not feasible to extend the casing 12 inches above the surface, the licensee shall implement procedures to ensure that the cased hole is free of obstruction before making measurements
- B. If a sealed source or a probe containing a sealed source becomes lodged below the surface and it becomes apparent that efforts to recover the sealed source or probe may not be successful, the licensee shall notify the U.S. Nuclear Regulatory Commission and submit the report required by 10 CFR 30.50(b) (2) and (c)

**[Note to the Reviewer: Conditions 58 and 59 are used in NUREG 1556, Vol. I ]**

60. (RESERVED)

RADIOGRAPHY

61.

56. A. ~~Notwithstanding the periodic leak test required by 10 CFR 34.25(b), the requirement does not apply to radiography sources that are stored and not being used. The sources exempted from this periodic test shall be tested for leakage at intervals not to exceed 3 years. In addition, sources shall be tested for leakage within 6 months before use or transfer to another person.~~
- A. Notwithstanding the periodic leak test required by 10 CFR 34.27(c)(1) and (e) the requirement does not apply to radiography sources that are stored and not being used. The sources exempted from this test shall be tested for leakage before use

~~or transfer to another person.~~ No sealed source or device containing licensed material shall be stored for a period of more than ~~40~~ 3 years without being tested for leakage and /or contamination.

**Please note the above is on the example license in NUREG 1556, Vol. 2, however both 34.27(c)(3) and (e) state stored sources and DU in storage need not be leak tested. Therefore only part of this condition is struck.**

- B. The licensee is authorized to analyze leak test samples in accordance with (application/letter) dated fill in the date.
- C. Sealed sources authorized for a use other than radiography shall be tested for leakage in accordance with 10 CFR 34.25 27.

[Reviewer Note: B. C 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.]

62.

~~57. 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; and~~
- ~~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 the radiographic exposure devices and storage containers do not exceed those specified in 10 CFR 34.21.~~

**(RESERVED) [NOTE: Source loading is stated on certificate of registration and also see NUREG 1556, Vol. 2, Example License Condition 13].**

63.

~~58. (RESERVED)~~

64

~~59. (RESERVED)~~

#### WELL-LOGGING

~~65. (RESERVED)~~

~~60. Each source holder or logging tool containing radioactive material shall bear a legible and visible marking as specified in 10 CFR 39.31(a). The label must be on the smallest component that contains the licensed material which is transported as a separate piece of equipment. Regulation 39.31(a) is specific as to labeling. This condition is redundant - covered in regulation.~~

66.

- 61. A.. Notwithstanding the periodic leak test required by 10 CFR 39.35, the requirement does not apply to sources, except sources containing *more than 10 microcuries of* plutonium, that are stored and not being used. The sources exempted from this periodic test shall be tested for leakage before use or transfer to another person. No sealed source shall be stored for a period of more than ~~40~~ 3 years without being tested for leakage and/or contamination.

**[Note the above is not covered in P&GD 1-26, and must be coordinated with HQ prior to use.**

- B. The licensee is authorized to analyze leak test samples in accordance with (application/letter) dated fill in the date.
  - C.
  - B. Sealed sources authorized for a use other than well logging shall be tested for leakage and shall be inventoried in accordance with 10 CFR 39.35 and 39.37.
- 67.
- ~~62:~~ The licensee shall not vacate or release to unrestricted use a field office or storage location whose address is identified in Condition 10, without prior NRC approval.
- 68
- 63.(RESERVED)
- 69.
64. (RESERVED)

#### FIXED GAUGES

- 70.
- ~~65:~~ Each gauge shall be tested for the proper operation of the on-off mechanism (*shutter*) and indicator, if any, at *intervals not to exceed no longer than 6 months intervals* or at such longer intervals as specified *in the certificate of registration issued by the NRC under 10 CFR 32.2 10 or by an Agreement State. by the manufacturer and approved by NRC.*
- [Note: the above is modified per draft NUREG 1556, Vol. 4]***
- 71.
- ~~66~~ Installation, initial radiation surveys, relocation, removal from service, maintenance and repair of devices containing sealed sources shall be performed by (insert "the licensee or" if the licensee is authorized to perform non-routine operations [individuals within the licensee's organization] 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.

~~————— [Reviewer Note: Use Condition 66 when only the gauge manufacturer will perform all services, including mounting, or when licensee has designated a qualified individual to perform these activities.]~~

Installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source and non-routine maintenance or repair of components related to the radiological safety of the gauge (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding) shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services.

**[Reviewer Note: This condition is used when the licensee is NOT authorized to perform any non-routine operations. The above condition is modified per draft NUREG 1556, Vol. 4]**

- 72.
- ~~67. ——— 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.~~

~~[Reviewer Note: Use Condition 67 when the licensee will perform limited activities but not maintenance or repair.]~~

- A. *The licensee or persons specifically licensed by the Commission or an Agreement State to perform such services may perform (modify as necessary to identify operations that the licensee may perform) installation, initial radiation surveys, relocation, removal from service dismantling, alignment, replacement, disposal of the sealed source and non-routine maintenance or repair of components related to the radiological safety of the gauge.*

**[Reviewer Note: Part A of this condition is used to specify which non-routine operations may be performed by a licensee, if the licensee may perform all listed operations Part B of this condition is not used.]**

- B. (Modify as necessary to identify operations that the licensee may NOT perform) Installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed sources and non-routine maintenance or repair of components related to the radiological safety of the gauge shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services.

**[Reviewer Note: Part B of the condition is used to specify which non-routine operations a licensee is NOT authorized to perform. If the licensee may perform all listed operations, use only Part A of the condition. The above condition is modified per draft NUREG 1556, Vol. 4]**

73.

~~68. Installation, initial radiation surveys, relocation, removal from service, or any similar activity with devices containing licensed material shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services. The licensee may initially mount the device only in accordance with written instructions provided by the manufacturer; however, the device may not be used until surveyed by a person specifically licensed by the Commission or an Agreement State to install gauges. The licensee may maintain, repair, or replace device components not directly associated with the device's sealed source, its related shielding, or the device's on-of mechanism; and that will not result in increased radiation levels in accessible areas about the device.~~

~~[Reviewer Note: Use Condition 68 when the licensee has requested authorization only to mount gauges.]~~

The licensee may initially mount a gauge if permitted by the certificate of registration issued by NRC or an Agreement State and under the following conditions:

- A. the gauge must be mounted in accordance with written instructions provided by the manufacturer;

- B. the gauge must be mounted in a location compatible with the “Conditions of Normal Use” and “Limitations and/or Other Considerations of Use” in the certificate of registration issued by NRC or an Agreement State;
- C. the on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
- D. the gauge must be received in good condition (package was not damaged); and
- E. the gauge must not require any modification to fit in the proposed location.

Mounting does not include electrical connection, activation or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the Commission or an Agreement State to perform such operations.

**[The above condition is modified per draft NUREG 1556, Vol. 4]**

- 74. ~~69.~~ Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the Commission or an Agreement State. A record of the results of this survey shall be maintained for the duration of the license.
- 75. ~~70.~~ The licensee shall operate each gauge within the manufacturer’s specified temperature and/or environmental limits such that the shielding and shutter mechanism of the source holder are not compromised.
- 76. ~~71.~~ The licensee shall assure that the shutter mechanism is locked in the closed position during periods when a portion of an individual’s body may be subject to the direct radiation beam. The licensee shall review and modify as appropriate its “lock-out” procedures whenever a new gauge is obtained to incorporate the device manufacturer’s recommendations.
- 77. ~~72.~~ (RESERVED)  
*The licensee may maintain, repair, or replace device components not related to the radiological safety of the gauge (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding); and that do not result in the potential for any portion of the body to come into contact with the primary beam or in increased radiation levels in accessible areas.*  
**[The above condition is added per draft NUREG 1556, Vol. 4]**
- 78. (RESERVED)
- 79. (RESERVED)
- 74. (RESERVED)

IRRADIATORS

- 80. ~~75.~~ 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.~~

~~[Reviewer Note: Use this condition for self-contained irradiators.]~~

*The licensee shall not repair, remove, replace, or alter any of the following: electrical, and mechanical systems that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may affect safe operation of the irradiator. These activities may be performed by a person specifically licensed by the Commission or an Agreement State to perform such services. **(This condition is used for licensees NOT authorized to perform non-routine maintenance.)***

OR

*Except for the repair or maintenance operations described in (letter/application) dated (fill in the date). the licensee shall not repair, remove, replace, or alter any of the following: electrical, and mechanical systems that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may affect safe operation of the irradiator. These activities may be performed by a person specifically licensed by the Commission or an Agreement State to perform such services. **(This condition is used for licensees authorized to perform non-routine maintenance.)***

**[Note: New condition per NUREG 1556, Vol. 5]**

81.

76.

For each J. L. Shepherd and Associates, Mark I or Model 81-22 cesium-I 37 Irradiator installed and used, the licensee shall:

- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
- B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
- C. Have room monitors installed that will:
  - (I) Operate at all times when the irradiator is in use; and
  - (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
  - iii) Detect any radiation leaking from the irradiator door; and
  - (iv) Be visible to the irradiator user when he is next to the irradiator; or
- D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
  - (I) Determine the radiation level at the irradiation door when the door is closed; and
  - (ii) Check for any increase in radiation levels each time the irradiator door is opened.

- E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, stop using the irradiator and notify the Radiation Safety Officer, and if required by 10 CFR Parts 20, 21, or 30, report by telephone, to NRC, Regional office referenced in Appendix D of 10 CFR Part 20; and
- F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

82.

~~77.~~ The procedures contained in *the manufacturer's* instruction manual for the-Model \_\_\_\_\_ device *the irradiator authorized by this license* shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

83 (RESERVED)

~~78.~~ The licensee is authorized to use the following sealed sources in the irradiator:

<u>Manufacturer</u>	<u>Model No</u>

84.

~~79.~~ (RESERVED)

*Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated \_\_\_\_\_*

**(NOTE: Condition applies only to converted teletherapy units Region may use without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

85.

80. (RESERVED)

*Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the letter/application dated \_\_\_\_\_*

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

86.

~~81.~~ (RESERVED)

*Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the letter/application dated \_\_\_\_\_*

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

87.

~~82.~~ (RESERVED)

*Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having a visible and audible alarm within the treatment area, based on the commitments described in the letter/application dated \_\_\_\_\_*

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

88. Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the letter/application dated \_\_\_\_\_.

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

89. Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from (as requested by licensee) based on the commitments described in the letter/application dated \_\_\_\_\_.

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

90. Notwithstanding the requirements of 10 CFR 36.31 (a), the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated \_\_\_\_\_. The radiation room door key shall be attached to the portable survey meter.

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

91. Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated \_\_\_\_\_.

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

92. Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room which must be activated prior to irradiation which would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the letter/application dated \_\_\_\_\_.

**(NOTE: Region may use for converted teletherapy units without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

#### NUCLEAR PHARMACIES

93 (RESERVED)

- ~~83. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:~~
- ~~\_\_\_\_\_ (1) 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~~
  - ~~\_\_\_\_\_ (i) 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.~~

**[Radiopharmacy rule made condition obsolete - MEMO 5/30/97]**

94. (RESERVED)

- ~~84. 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.~~

**[Radiopharmacy rule made condition obsolete - MEMO 5/30/97]**

95. (RESERVED)

- ~~85. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.~~

**[Radiopharmacy rule made condition obsolete - MEMO 5/30/97]**

96.

- ~~86. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in \_\_\_\_\_~~

97

~~87. (RESERVED)~~

98.

~~88. (RESERVED)~~

99.

~~89. (RESERVED)~~

100.

~~90. (RESERVED)~~

TELETHERAPY

101.

- 94 Notwithstanding the requirements of 10 CFR 35.647, the licensee is authorized to extend until \_\_\_\_\_ the time interval for inspection and servicing of its teletherapy unit.

**[NOTE: Region may use without consultation with NMSS in accordance with instructions in P&GD 1-26, July 1997]**

102. (RESERVED)

- ~~92. Notwithstanding the requirements of 10 CFR 35.961 \_\_\_\_\_ perform the duties of the teletherapy physicist for those full calibration and spot checks measurements specified in 10 CFR 35.632 and 10 CFR 35.634.~~

**(NOTE: Region may NOT use without coordination with NMSS in accordance with instructions in P&GD 1-26, July 1997)**

103.

- ~~93. The teletherapy physicist for this license is \_\_\_\_\_.~~

104.

- ~~94. The license is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in~~

~~10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.~~

**[NOTE: Region may NOT currently use this condition without coordination with NMSS in accordance with instructions in P&GD 1-26, July 1997.]**

105.  
~~95:~~ (RESERVED)  
 106.  
~~96:~~ (RESERVED)

#### CARDIAC PACEMAKERS

107.  
~~97:~~ (RESERVED)  
 In accordance with ~~10 CFR 74.15~~, 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 Fuel Cycle Safety and Safeguards and Transportation, U. S. Nuclear Regulatory Commission, Washington, DC 20555. In addition, the licensee shall complete and distribute NRC Form 741 as required by ~~10 CFR 70.54~~.  
**(NOTE: deleted in Nov 1994 with issuance of P&GD 83-29 REV 2 )**
108.  
~~98:~~ 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.
109.  
~~99:~~ The licensee shall report by telephone to the U.S. Nuclear Regulatory Commission, Regional office referenced in Appendix D of 10 CFR Part 20\_\_\_\_ ATTN: Chief, 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 in accordance with 10 CFR 30.50 (b)(2). A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days *in accordance with 10 CFR 30.50(c)(2)*.
110.  
~~100:~~ The licensee shall report to the U.S. Nuclear Regulatory Commission, Region \_ ATTN Chief, \_\_\_\_\_, within 10 days of loss of contact with a nuclear pacemaker patient.
111.  
~~101:~~ 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.
112.  
~~102:~~ (RESERVED)  
 113  
~~103:~~ (RESERVED)

#### MEDICAL - GENERAL

- 114 (RESERVED)

- ~~104.~~ Notwithstanding the requirements of 10 CFR 35.20(a), the licensee is not required to develop and implement an ALARA program [Reviewer Note: Use Condition 104 for licenses only authorizing 35.500.] **Now covered by 20.1101**
115. (RESERVED)
- ~~105.~~ Notwithstanding the requirements of 10 CFR 35.22 the licensee is not required to establish a Radiation Safety Committee.  
 [Reviewer Note: Use Condition 105 for institutional licensees which only authorize 35.500 devices]  
**(MUST consult with NMSS; not approved by PGD 1-26)**
- ~~106.~~ 116. Needles or standard medical applicator cells containing licensed material as wire shall not be opened by the licensee.
- 117 (RESERVED)
- ~~107.~~ Notwithstanding the provisions of 10 CFR 35.49, "Suppliers," the licensee is authorized to receive \_\_\_\_\_ from \_\_\_\_\_ in accordance with procedures outlined in \_\_\_\_\_.  
**(Radiopharmacy rule made condition unnecessary.)**
- ~~108.~~ 118. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35.  
 [Reviewer Note: Use Condition ~~108~~ 118 for limited medical use programs that have non-broad human research programs.]
- ~~109.~~ 119. (RESERVED)  
*Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium- 192 as seeds encased in nylon ribbon and palladium- 103 as seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions only to the extent that the instructions are not applicable to the type of use proposed by the licensee.*  
**(Note: The above condition does NOT require coordination with NMSS per P&GD 1-26)**
- ~~110.~~ 120. (RESERVED)  
*Notwithstanding the requirements of 10 CFR 35.\_\_\_\_, the licensee may use the alternative method for \_\_\_\_ (recordkeeping or posting) \_\_\_\_ as described in the letter/application dated \_\_\_\_*  
**(Note: The above condition does NOT require coordination with NMSS per P&GD 1-26)**
121. *Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the letter/application dated \_\_\_\_\_*  
**(Note: The above condition does NOT require coordination with NMSS per P&GD 1-26)**

122. Notwithstanding the requirements of 10 CFR 35.415(a)(4), the licensee may use the alternative method for determining the dose rates in contiguous restricted and unrestricted areas described in the letter/application dated \_\_\_\_\_  
**(Note: The above condition does NOT require coordination with NMSS per P&GD 1-26)**
123. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care a patient with a temporary eye plaque implant in place, in accordance with procedures described in letter/application dated \_\_\_\_\_.  
**(Note: The above condition does NOT require coordination with NMSS per P&GD 1-26)**

MEDICAL-BROAD

- 124.
111. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every 6 months for all other sources and/or devices.  
 Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).
- 125.
- ~~112. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400 and 10 CFR 35.500 the licensee may use for any medical use any by-product material or reagent kit. The licensee shall possess and use by-product material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.~~
- Notwithstanding the requirements of 10 CFR 35.49(a) the licensee may use any byproduct material for 10 CFR 35.400 and 35.500 uses.*  
**[NOTE: Condition modified by Memo dated May 30, 1997, Guidance on the RADIOPHARMACY RULE, you may use for Broad Medical Licensees, however, in accordance with PGD 1-26 regions MUST consult with NMSS for approval to use.]**
126. (RESERVED)
- ~~113. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except sections 35.49(a) and (b), 35.100, 35.200, and 35.300.  
**[Radiopharmacy rule made condition obsolete - MEMO 5/30/9 7]**~~
- 127.
- ~~114.~~ (RESERVED)
- 128.
- ~~115.~~ (RESERVED)
- 129.
- ~~116.~~ (RESERVED)
- 130.
- ~~117.~~ (RESERVED)

MEDICAL-BRACHYTHERAPY REMOTE AFTERLOADERS

131

~~118.~~ In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

132

~~119.~~ In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (uSieverts/hr), time, date and name of the individual making the survey.
- D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

133.

~~120.~~ Prior to initiation of a treatment program, and subsequent to each source exchange, - using the \_\_\_\_\_ for each high dose rate remote afterloading brachytherapy unit devices and tests shall be performed in accordance with the following:

- A. A radiation survey shall be made of:
  - 1. The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 0.25 milliroentgen per hour.
  - 2. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:
    - (a) That radiation levels in restricted areas are not likely to cause personal exposure in excess of the limits specified in 10 CFR 20.1201.
    - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.
- A. *The source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 0.25 milliroentgen per hour.*
- B. *All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:*
  - (1) *That radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207, and 20.1208.*

(2) *That radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a).*

C. *Records of the survey results shall be maintained for inspection by the Commission for 3 years.*

134.

~~121.~~ The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

- A. Installation and replacement of the sealed sources contained *in each high dose rate remote afterloading brachytherapy device(s) unit.*
- B. Any maintenance or repair operations on *'the any high dose rate remote afterloading brachytherapy unit(s)-I and associated equipment* listed in Item 9, Subitem(s) involving work on the source safe, the source drive unit, 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.

135.

~~122.~~ (RESERVED)

*The Medical Physicist for this license is \_\_\_\_\_*

136.

~~123.~~ (RESERVED)

~~*Medical Physicists shall meet the training criteria established under 10 CFR 35.961 and shall be designated in writing by the licensee's Radiation Safety Committee.*~~

137

~~124.~~ (RESERVED)

*The Medical Physicist(s) for this license (is/are) \_\_\_\_\_ or individuals designated in writing by the licensee's Radiation Safety Committee and who meet at least one of the following criteria:*

- A. *the training and experience criteria established in 10 CFR 35.96 1(a) or (b); or*
- B. *identified as a Medical Physicist on a Commission or Agreement State license that authorizes the use of a high dose rate remote afterloading brachytherapy device; or*
- C. *designated as a Medical Physicist by a Commission or Agreement State license of broad scope that authorizes the use of a high dose rate remote afterloading brachytherapy device; or*
- D. *identified as Teletherapy Physicist on a Commission or Agreement State license and has completed the manufacturer's training on the use of a high dose rate remote afterloading brachytherapy device; or*
- E. *designated as a Teletherapy Physicist by a Commission or Agreement State license of broad scope and has completed the manufacturer's training on the use of a high dose rate remote afterloading brachytherapy device; and, having*

*received training, for the specific make(s) and/or model(s) of remote afterloading device(s) used by the licensee.*

***[Reviewer's Note: This condition is for use with limited Part 35 licensees who have requested to authorize their own HDR physicists (medical physicists) in accordance with the criteria set forth in 10 CFR 35.961 and commit to training the physicists for the specific make(s) and/or model(s) of remote afterloading devices(s) they possess.]***

MEDICAL-BRACHYTHERAPY REMOTE AFTERLOADERS (High, Medium, and Pulsed Dose Rate)

138.

- ~~125. A. Access to the rooms housing the afterloading brachytherapy device shall be controlled by a door at each entrance.~~
- ~~B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on off" control is reset at the control panel.~~
- ~~C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once each day of use. Records of test results shall be maintained for inspection by the Commission for a period of three years.~~
- ~~D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.~~
- A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use. Records of test results shall be maintained for inspection by the Commission for a period of three years.
- D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

139.

~~126.~~ (RESERVED)

140

127. (RESERVED)

WASTE DISPOSAL

141.

~~128. (RESERVED)~~

*The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:*

- A. *Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.*
- B. *Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.*
- C. *A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.*

142

~~129. 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.~~
- ~~C. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.~~

**[Note this condition same as regulation in 10 CFR 35.92]**

143.

~~130. (RESERVED)~~

144

131. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letter dated \_\_\_\_\_

[Reviewer Note: Use this condition when a waste storage plan has been submitted.]

~~145~~

132. (RESERVED)

~~146~~

133. (RESERVED)

#### INCINERATION

147.

~~134~~: Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, 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 Part 20.

[Reviewer Note: The part of this former standard condition regarding ash residue disposed of as ordinary waste is deleted. A TAR must be sent to NMSS to obtain this authorization if the licensee requests ash disposal as ordinary waste and provides information required by the Commission. Otherwise, all ash residue from incineration is to be treated as radioactive waste.]

148.

~~135~~: (RESERVED)

#### TRANSPORTATION

149.

~~136~~: The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

150.

~~137~~: (RESERVED)

151.

~~138~~: (RESERVED)

#### DISTRIBUTION

152.

~~139~~: (RESERVED)

153

~~140~~: The licensee may distribute material from \_\_\_\_\_ [Reviewer note: For use on distribution only licenses]

154

~~141~~: Pursuant to 10 CFR 32. \_\_, the licensee is authorized to distribute the (smoke detectors or self-luminous products) specified in Condition \_\_\_ to persons exempt from the requirements for a license pursuant to 10 CFR 30. \_\_\_\_, or equivalent provisions of the regulations of any Agreement State.

155.

~~142~~: The following (smoke detectors or self-luminous products) may be distributed provided the amount of (isotope) contained in the device does not exceed the amounts specified in the following table:

Device Model

Maximum Quantity per Device

156.

~~143~~: The licensee shall submit periodic material transfer reports as specified in 10 CFR 32.

157.  
~~144.~~ Each device distributed under this license shall be manufactured, tested, and labeled in accordance with the statements, representations, and procedures contained in (application(s)/letter(s)) dated \_\_\_\_\_.

**[Reviewer's Note: Conditions 154 -157 are for exempt distribution licenses only.]**

158  
~~145.~~ This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR ~~30.18~~ 30.14 through 30.20, inclusive, or equivalent regulations of any Agreement State.

159.  
~~146.~~ (RESERVED)

*Each device distributed pursuant to the conditions of this license shall be in accordance with the following table:*

<u>Device Model Number</u>	<u>Isotope</u>	<u>Source Model Number</u>	<u>Maximum Activity Per Source</u>
----------------------------	----------------	----------------------------	------------------------------------

160.  
~~147.~~ (RESERVED)

MISCELLANEOUS

161  
~~148.~~ Licensed material shall not be used in or on human beings.

162  
~~149.~~ This license does not authorize commercial distribution of licensed material.

163  
~~150.~~ This license does not authorize possession or use of licensed material.

164  
~~151.~~ This license does not authorize distribution to persons licensed pursuant to 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, or 10 CFR 35.600 32.72 or 32.74; to persons exempt from licensing; or to general licensees.

*(NOTE: Condition modified by Memo dated May 30, 1997, on Guidance on the RADIOPHARMACY RULE. Use for Manufacturers and Distributors)*

165.  
~~152.~~ The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

166.  
~~153.~~ The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

167.  
~~154.~~ Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
168.  
~~155.~~ 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 maintained for 5 years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.
- 169  
~~156.~~ Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
- 170  
~~157~~ Pursuant to 10 CFR 20.1301(c)] and in reliance on statements, procedures and representations made by the licensee in the application/letter dated \_\_\_\_ the following maximum radiation levels are hereby authorized in the following unrestricted areas:
- |                                |                          |
|--------------------------------|--------------------------|
| <u>Maximum Radiation Level</u> | <u>Unrestricted Area</u> |
|--------------------------------|--------------------------|

***(Note: The above condition requires coordination (TAR) with NMSS P&GD 1-26)***

171.  
~~158.~~ The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

[Reviewer Note: This condition may be used when the reviewer doesn't specify manufacturers or model numbers (e.g., gas CHROMATOGRAPHS, bone mineral analyzers).]

172. (RESERVED)  
~~159.~~  
 173.  
~~160.~~ (RESERVED)

174.  
~~161.~~ (RESERVED)  
*Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.2 10 or by an Agreement State.*  
***(NOTE: New condition from NUREG 1556, Volume 1, use with any license that authorizes sealed sources and devices)***

#### EMERGENCY PLANS/DECOMMISSIONING

(Also see teletherapy condition no.104)

175.  
~~162~~ In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

176

~~163.~~ In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR [30.35(d) or 40.36(b) or 70.25(d)] for establishing decommissioning financial assurance.

[Reviewer Note: This is a general possession limit for no decommissioning financial assurance for cases where the possession limit is not explicit in license Item 8.]

177.

~~164.~~ In addition to the possession limits in Item 8, the licensee shall further restrict the possession of \_\_\_\_\_ to quantities less than \_\_\_\_\_ in accordance with the provisions of 10 CFR \_\_\_\_\_

178.

~~165.~~ In addition to the possession limits in Item 8, the licensee shall further restrict the possession of [unsealed licensed material or readily dispersible source material] to quantities less than [10 or 10 times the applicable limits in Appendix C of 10 CFR Part 20 *B of IQ CFR Part 30*, or 100 mCi] as specified in 10 CFR [30.35(d) or 40.36(b) or 70.25(d)].

[Reviewer Note: This is a general possession limit for intermediate level decommissioning financial assurance.]

179.

~~166.~~(RESERVED)

180.

~~167.~~ If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer Note: To limit the possession limit for a Type C Broad License to eliminate the need for financial assurance for decommissioning also use standard condition no.176]

181.

~~168.~~ If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer note: To limit the possession limit for a Type B Broad License to eliminate the need for a decommissioning funding plan also use standard condition no. 178.]

182.

~~169.~~ (RESERVED)

- A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
- B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:

<i>Carbon 14</i>	<i>100 millicuries</i>
<i>Krypton 85</i>	<i>100 millicuries</i>
<i>Iodine 129</i>	<i>10 microcuries</i>

*Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A*      *100 microcuries*

***(Reviewer’s Note: This condition limits the possession limit for a Type C Broad License to eliminate the need for financial assurance for decommissioning).***

183.  
~~170.~~ (RESERVED)

- A. *If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.*
- B. *Notwithstanding 10 CFR 33. 100, Schedule A, Column I, the applicable quantities, for the purpose of performing the unity calculation as provided in Section A of this condition, for the following radionuclides are:*

<i>Carbon 14</i>	<i>10 curies</i>
<i>Krypton 85</i>	<i>10 curies</i>
<i>Iodine 129</i>	<i>1 millicurie</i>

*Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33. 100, Schedule A*      *10 millicuries*

***(Reviewer’s Note: This condition limits the possession limit for a Type B Broad License to reduce to \$750,000, the requirement for financial assurance for decommissioning.)***

184.

~~171.~~ (RESERVED)

185.

~~172.~~ (RESERVED)

186.

~~173.~~ (RESERVED)

187.

~~174.~~ (RESERVED)

188.

~~175.~~ (RESERVED)

189.

~~176.~~ (RESERVED)

190.

~~177.~~ *Irradiation and distribution of foods for human consumption shall be in accordance with the rules and regulations of the Food and Drug Administration.*

191.

~~178.~~ *Replacement-exchange of the source/source-holder combination for sources identified in 35.500 may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual.*

***(Reviewer's Note: To be used in licenses authorizing 10 CFR 35.500.)***

## STANDARD CONDITIONS FOR EXEMPTIONS REQUIRING NMSS COORDINATION:

192. *Notwithstanding the requirements of 10 CFR 34.20(a), and pursuant to 10 CFR 34.51, radiographic equipment authorized for use in radiographic operations under this license need not comply with the torque criteria of Section 8.9.2(c) of American National Standard N432 - 1980*  
**(Note: The above condition requires coordination (TAR) with NMSS P&GD 1-26)**
193. *Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. [[Exceptions may be made on a case-by-case basis in accordance with the procedures described in the letter(s) dated \_\_\_\_\_]] The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.*  
**(Note: The above part of the condition in [[ ]] requires coordination (TAR) with NMSS P&GD 1-26)**
194. *Notwithstanding the requirements of 10 CFR 35.961 \_\_\_\_\_ may perform the duties of the teletherapy physicist for those full-calibration and spot-check measurements specified in 10 CFR 35.632 and 10 CFR 35.634.*  
**(Note: The above condition requires coordination (TAR) with NMSS P&GD 1-26)**
195. *The license is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.*  
**[NOTE: Region may NOT currently use this condition without coordination with NMSS in accordance with instructions in P&GD 1-26, July 1997.]**