

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated May 6, 1991,	
1. Celcor Therapies, Incorporated		3. License number 20-28108-02 is amended in its entirety to read as follows:	
2. 200 Wells Avenue Newton, Massachusetts 02159		4. Expiration date August 31, 1995	
		5. Docket or Reference No 030-31729	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Cesium 137	A. Sealed source (ORNL-50-RAMCO or ISO-1000)	A. 1000 curies	
9. Authorized use			
A. For use in AECL Gammacell 1000 self-contained irradiator for irradiation of biological specimens and blood.			

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities at 200 Wells Avenue, Newton, Massachusetts.
11. A. Licensed material shall be used by or under the supervision of individuals who have completed the training described in application dated April 30, 1990 and letter dated July 20, 1990 and have been approved in writing by the Radiation Safety Officer.
- B. At least one individual qualified under Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.
- C. The Radiation Safety Officer for this license is Amy L. Bolwerk.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

20-28108-02

Docket or Reference number

030-31729

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CORRECTED COPY

(Continued)

CONDITIONS

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen 3; or
  - (ii) they contain only a gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. 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 and the source shall be removed 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, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

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(13. continued)

## CONDITIONS

- G. The licensee is authorized to collect leak test samples for analysis by Victor Evdokimoff, CHP, Boston University medical Center, Boston, Massachusetts. 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.
14. 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.
15. 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. Application dated April 30, 1990  
B. Letter dated July 20, 1990  
C. Letter dated May 6, 1991

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Steven L. Baggett

Date AUG 13 1992

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406

AUG 13 1992

License No. 20-28108-02  
Docket No. 030-31729  
Control No. 114711

Cellcor Therapies, Incorporated  
ATTN: Ms. Amy L. Bolwerk  
Radiation Safety Officer  
200 Wells Avenue  
Newton, Massachusetts 02159

Dear Ms. Bolwerk:

Enclosed is the Corrected Copy of Amendment No. 01 for License No. 20-28108-02.

In the process of auditing our files an error was found in your license. On Page one of three of your license, the license number in Item 3 was incorrect. Item 3 was corrected to read 20-28108-02.

We apologize for any inconvenience this error may have caused.

Sincerely,

Original Signed By:  
Steven L. Baggett

Francis M. Costello, Chief  
Industrial Applications Section  
Division of Radiation Safety  
and Safeguards

Enclosures: Corrected Copy for Amendment No. 01

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Costello

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08/11/92

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