

MATERIALS LICENSE

Amendment No. 16

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, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s); and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

"OFFICIAL RECORD COPY"

Licensee

1. Becton-Dickinson
Division of Becton, Dickinson and Company
2. Route 7 and Grace Way
North Canaan, Connecticut 06018

In accordance with application dated
March 12, 1985

3. License number 06-13514-01 is amended in its
entirety to read as follows:

4. Expiration date September 30, 1990

5. Docket or
Reference No. 030-06891

6. Byproduct, source, and/or
special nuclear material

7. Chemical and/or physical
form

8. Maximum amount that licensee
may possess at any one time
under this license

- A. Cobalt 60

- A. Sealed source
(AECL Model C-188,
Type 1, 2, 3 or 4)

- A. 1,500.00 curies

9. Authorized use

- A. To be used in an AECL Model J6500 Irradiator, Serial Number IR-21, for the
sterilization of medical, surgical, or laboratory products.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Route 7 and Grace Way, North Canaan, Connecticut.
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
12. A. Licensed material shall be used by, or under the supervision of William Case, Kenneth Barker, Donald Coons, Adrian Costa, Ronald Love, or individuals who have completed the training and test described in item 8 of application dated March 12, 1985 and item 2 of letter received July 8, 1985 and have completed three months of on-the-job experience in operating the irradiator.
B. Licensed material may also be used by individuals who have completed the training and test described in item 8 of application dated March 12, 1985 and item 2 of letter received July 8, 1985.
C. At least one individual named in Condition 12.A. shall be physically present at the authorized place of use whenever the irradiator is being used.
13. Sealed sources containing licensed material shall not be opened.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License num

06-13514-01

Docket or Reference number

030-06891

Amendment No. 16

(continued)

CONDITIONS

14. A. The ion exchange resin filter beds shall be monitored as specified in letter dated June 3, 1985 with enclosures. Whenever an apparent increase in radiation levels twice that caused by normal background at the beds is detected the licensee shall immediately cease operations and determine the cause of the increase.
- B. If the increase is caused by a leaking source, the source shall be removed from the pool and repaired or disposed in accordance with Commission regulations prior to resuming operations. If the increase is caused by another source of radiation or radioactivity then that cause shall be removed and the pool water decontaminated, if necessary, prior to resuming operations. If the apparent increase was caused by an instrument fault, the fault shall be corrected and the instrument appropriately recalibrated prior to resuming operations.
- C. A written record of the calibration of the AECL D/L 2 monitors and each alarm and subsequent radiation reading will be maintained for review by the Commission.
- D. For each actual increase in radioactivity, a report shall be filed within 5 days of the increase with the U.S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania, describing the results of the determination required by A above, the schedule for removal and disposal of the source of the radioactivity and the procedures followed or to be followed for the decontamination of the pool water and the results achieved.
15. The licensee shall have written operating and emergency procedures for the AECL Model J6500 Irradiator and such procedures shall be followed. A copy of these procedures shall be made available to each individual using or supervising the use of licensed material.
16. After installation of additional Cobalt 60 source(s) greater than the quantity for which a previous radiation survey has been conducted, and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report in duplicate of the results of the surveys shall be sent to the U. S. Nuclear Regulatory Commission, Region I, King of Prussia, Pennsylvania 19406, not later than thirty (30) days following installation of the source(s).
17. Sealed sources containing licensed material shall not be opened.
18. Licensed material shall not be used in or on human beings or introduced into products distributed to the public.

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(continued)

CONDITIONS

19. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated March 12, 1985 and letter dated June 3, 1985 and letter received July 8, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.



For the U.S. Nuclear Regulatory Commission

Original Signed By:

Jack Davin

Date SEP 11 1985

By

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406