

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

19-07538-01

Docket or Reference number

030-04544

Amendment No. 21

"OFFICIAL RECORD COPY"

Department of Health & Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-60)
5600 Fishers Lane
Rockville, Maryland 20857

In accordance with letters dated July 9, 1985, and July 29, 1985 License Number 19-07538-01 is amended as follows:

Item 1. (Name) is changed from Department of Health and Human Services, National Center for Devices and Radiological Health, ATTN: HFX-3 to Department of Health & Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-60).

Items 6., 7., 8. and 9. are amended to read:

- | | | |
|--|----------------------------------|--|
| 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. Any by product material with Atomic Nos. 1 through 83 | A. Any | A. Not to exceed 25 millicuries per radionuclide and 500 millicuries total |
| B. Americium 241 | B. Sealed Source | B. Not to exceed 50 millicuries total |
| C. Technetium 99m | C. Any | C. Not to exceed 1,000 millicuries |
| D. Cesium 137 | D. Sealed Source | D. Not to exceed 74 millicuries total |
| E. Iodine 125 | E. Sealed Source | E. Not to exceed 500 millicuries per source, 1000 millicuries total |

9. Authorized use

- A., B., C. and E. For use in research and development as defined in Section 30.4(q), 10 CFR Part 30.
- D. For use in calibration of radiation survey instruments.

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19-07538-01 PDR

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CONDITION

Condition 16. is amended to read:

16. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in applications dated April 21, 1977 and October 18, 1977; application received November 9, 1982; letters dated July 21, 1978, January 23, 1980 and October 21, 1981; letter received May 23, 1983 (dated May 19, 1984); and letters dated September 29, 1983, July 9, 1985 and July 29, 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:

By John E. Glenn

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

Date SEP 18 1985