



CE R. B. ...
P. Lohman
L. W. C.
D. A. C.

Texas Department of Health

David R. Smith, M.D.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Carol S. Daniels
Deputy Commissioner for Programs

Randy P. Washington
Deputy Commissioner for Health Care Financing

Radiation Control
(512) 834-6688

Roy L. Hogan
Deputy Commissioner for Administration

October 4, 1996

Warren E. Jacobi, Section Chief
Radiation Control Division
Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80222-1530

RE: Registry of Radioactive
Sealed Sources and Devices
(Registry) Sheet
No. CO0573D102S

Dear Mr. Jacobi:

In September, 1993, major changes to the Texas Regulations for Control of Radiation (TRCR) were adopted. Among those changes was the addition of TRCR 41.29 (copy enclosed). This rule does not allow us to list any sealed source or device containing radioactive material on a Texas Radioactive Material License until appropriate safety information has been evaluated. The above referenced Registry Sheet is not adequate to meet the requirements of our rule in two ways. First, two sealed source model numbers cannot be found in the Registry, which indicates that they have not been evaluated. Although it was explained to one of our reviewers by Mr. Sia Afshari of Radiation Monitoring Devices, Inc. that the model numbers for these two sources are the same as those listed in the Prototype Testing section, we are required to make several assumptions that cannot and should not be made in the licensing process. Second, after each sealed source model number is the phrase "or equivalent." This defeats the purpose of the registry sheet. If a source other than the four listed on the first page of the evaluation is proposed, a new evaluation has to be performed.

For these reasons, we cannot recognize Registry Sheet No. CO0573D102S until you have issued an amendment to this sheet with appropriate corrections. We hope to hear from you soon.

Sincerely,

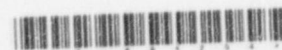
Ruth E. McBurney
Ruth E. McBurney, C.H.P., Director
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

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Enclosure

SRM cc: Mr. Steven L. Baggett, USNRC, NMSS
Mr. Sia Afshari, Radiation Monitoring Devices, Inc.

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- (6) the applicant submits the name and qualifications of the full-time RSO as specified in 41.27.

41.29 Sealed Source or Device Evaluation

No sealed source or device containing radioactive material shall be authorized on a specific license or general license until radiation safety information for that sealed source or device has been evaluated by the Agency, the Commission, another Agreement State, or a Licensing State.

- (a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source licensed by the Agency shall submit a request to the Agency for evaluation of radiation safety information about the sealed source or device containing a sealed source.
- (b) The request for review shall be submitted in duplicate.
- (c) The request for review shall contain sufficient information about the sealed source or device to include:
 - (1) the radioactive material contained, its chemical and physical form, and amount;
 - (2) details of design and construction;
 - (3) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
 - (4) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
 - (5) labeling;
 - (6) proposed uses; and
 - (7) procedures for leak testing.
- (d) For a device containing radioactive material, the request shall also contain sufficient information about the device to include:
 - (1) the radiation profile of a prototype device;
 - (2) method of installation;
 - (3) service and maintenance requirements; and
 - (4) operating and safety instructions.
- (e) After review of the request, the Agency may issue an evaluation documenting the information in 41.29(c) for sealed sources and 41.29(d) for devices containing radioactive material.

41.29(f)

- (f) The manufacturer/distributor submitting the request for evaluation of the safety information about the product shall manufacture and distribute the product in accordance with:
 - (1) the statements and representations contained in the request;
 - (2) documentation required to support the request; and
 - (3) the provisions of the evaluation.

41.30 Issuance of Specific Licenses

- (a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- (b) The Agency may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:
 - (1) minimize danger to public health and safety or the environment;
 - (2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
 - (3) prevent loss or theft of material subject to this part.

41.31 Specific Terms and Conditions of Licenses

- (a) Each license issued pursuant to this part shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to applicable rules and orders of the Agency.
- (b) No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to applicable rules and orders of the Agency, and shall give its consent in writing.
- (c) Each person licensed by the Agency pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

TEXAS DEPARTMENT OF HEALTH
1100 WEST 49th STREET
AUSTIN, TEXAS 78756-3199

OFFICIAL STATE BUSINESS
PENALTY FOR PRIVATE USE
TEXAS DEPT. OF HEALTH
1100 WEST 49TH STREET
AUSTIN, TEX 78756

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SOURCE CONTAINMENT AND DEVICES BRANCH
OFFICE OF NUCLEAR MATERIAL SAFETY
AND SAFEGUARDS
US NUCLEAR REGULATORY COMMISSION

~~REGULATORY CONTROL DESK~~

ATTN MR STEVEN L BAGGETT SECTION LEADER

WASHINGTON DC 20555

AUTO

