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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

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ATOMIC SAFETY AND LICENSING BOARD PANEL

Before Administrative Judge: Charles Bechhoefer BUCKETING & STVLOR

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In the Matter of

RADIOLOGY ULTRASOUND NUCLEAR
CONSULTANTS, P.A.

(Strontium 90 Applicator)

Docket No. 30-12688-MLA ASLBP No. 87-556-02 MLA-R

September 29, 1987

MEMORANDUM AND ORDER
(Information Relative to Motion to Reopen Record)

In a Decision dated February 9, 1987 (LBP-87-4, 25 NRC 79), I denied the application of Radiology Ultrasound Nuclear Consultants, P.A. (R.4C) for an amendment to its byproduct materials license to permit it to use a strontium-90 (Sr⁹⁰) plaque applicator for the treatment of malignant skin lesions. In doing so, I found that the treatment with the Sr⁹⁰ applicator would not be "safe and effective" for all the uses proposed by RUNC. I also noted that RUNC had failed to respond to questions posed by me on December 23, 1986 (and scheduled to be answered by January 16, 1987). Although I did not base my decision on procedural grounds (i.e., default), I observed that I would have needed the substance of the answers in order to determine whether criteria for a license authorizing use of the applicator only for shallow lesions, for which the treatment was demonstrated to be "safe and effective," could

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be formulated. LBP-87-4, <u>supra</u>, 25 NRC at 86, 91-93, 95 (slip op., pp. 12, 22-26, 30).

By letter dated February 24, 1987, RUNC belatedly filed answers to my December 23, 1986 questions. By then, I had lost jurisdiction over the proceeding; but by Memorandum dated March 3, 1987, I forwarded the information to the Commission, which retained jurisdiction to deal with the information.

By Order dated September 11, 1987, the Commission construed RUNC's February 24, 1987 filing as a motion to reopen the proceeding. The Commission directed me to consider whether it meets the standards for evaluating such motions set forth in 10 CFR § 2.734 and, if so, to reopen the proceeding.

Treating RUNC's filing as a motion to reopen the record, I invite the Staff's comments as to whether RUNC's filing meets those standards. I note that the criteria for reopening set forth in 10 CFR § 2.734 are as follows:

- (1) The motion must be timely, except that an exceptionally grave issue may be considered in the discretion of the presiding officer even if untimely presented.
- (2) The motion must address a significant safety or environmental issue.
- (3) The motion must demonstrate that a materially different result would be or would have been likely had the newly proffered evidence been considered initially.

Among other matters, I ask the Staff to address the third criterion and, in particular, whether RUNC has set forth a potentially meaningful

way of isolating the thin lesions for which treatment with a $\rm Sr^{90}$ applicator may be "effective". The Staff may also wish to comment on whether the method described by RUNC can be adequately monitored, so that the Staff might determine whether it is being applied consistently.

The Staff should respond within 15 days of the date of service of this Memorandum and Order. (However, because the response to the third criteria may involve matters of substance, I will be prepared to grant the Staff additional time, if needed, for such matters as consultation with Region I or with its expert consultants). After receiving the Staff's response, I will determine whether a reply from RUNC and/or an oral presentation would be necessary or useful. The Staff may wish to address this subject as well.

IT IS SO ORDERED.

PRESIDING OFFICER

Charles Bechhoefer Administrative Judge

Dated at Bethesda, Maryland this 29th day of September, 1987.