

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ADMINISTRATIVE JUDGE

In the Matter of

RADIOLOGY ULTRASOUND NUCLEAR
CONSULTANTS, P.A.

(Strontium 90 Applicator)

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Docket No. 30-12688-MLA

ASLPB No. 87-556-02 MLA-R

AFFIDAVIT OF JOHN E. GLENN

I, John E. Glenn, being duly sworn, state the following:

1. I am Chief of the Nuclear Materials Safety Section B, Region I, U.S. Nuclear Regulatory Commission, located at 631 Park Avenue, King of Prussia, Pennsylvania, 19406. I hold a Ph.D. in Nuclear Physics and am a health physicist. A statement of my professional qualifications has previously been filed in this proceeding.
2. As part of my responsibilities, I review applications for licenses or license amendments to use byproduct material. Based on these reviews, I have been delegated the authority to issue and sign licenses or amendments, request additional information from applicants, or recommend denial of an application.

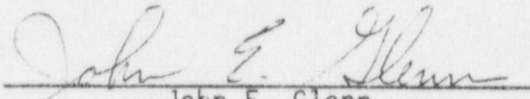
3. As part of my responsibilities set forth in paragraph 2, I have been assigned the overall review of this license amendment application, and have previously filed affidavits in this proceeding. In response to a Memorandum and Order (Information Relative to Motion to Reopen Record) dated September 29, 1987, I have reviewed my affidavits previously filed in this proceeding; the DECISION, dated February 9, 1987 and the submittal from Radiology Ultrasound Nuclear Consultants, P.A. (RUNC) dated February 24, 1987.
4. After this review, for the reasons more fully set forth below and in my previous affidavits dated December 15, 1986 and January 13, 1987, I conclude that RUNC has presented no new significant safety issue in its February 24, 1987 submittal that would have led to a materially different result had it been initially considered. In addition, I did take note of a possible misunderstanding in footnote 48 of the DECISION, dated February 9, 1987 and have considered a newly proposed method for selecting appropriate lesions for treatment in RUNC's submittal dated February 24, 1987.
5. In footnote 48, it is noted that P^{32} has a maximum beta energy of 1.72 MeV which is greater than the maximum beta energy of SR^{90} (0.54MeV). Although this statement is correct, SR^{90} is always found in equilibrium with its decay product, Y^{90} . The maximum beta energy for Y^{90} is 2.27 MeV (See Radiological Health Handbook, Public Health Service, U.S. Department of Health, Education and Welfare (1970),

Table I, at page 268.) I was aware of this fact when preparing my affidavits (see affidavit of Dr. John E. Glenn, dated December 15, 1986, at paragraph 16). Although Sr^{90} applicators will include the higher energy betas from Y^{90} , this information was part of the Staff's original reasoning and the problem of selecting lesions of appropriate thickness for treatment has not changed.

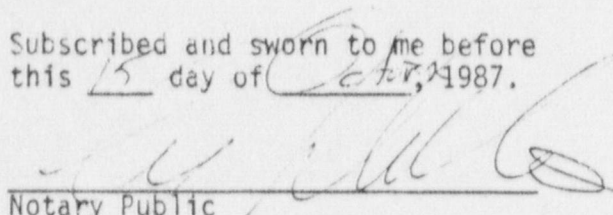
6. RUNC states, and I agree, that lesion thickness may be accurately determined by biopsy and review by a pathologist. However, there is no justification offered for assuming the thickness of multiple lesions based upon the measurement of a single lesion. Moreover, there is no explanation provided as to the appropriateness of treatment of lesions not measured based on this assumption. The alternate proposal of measuring thickness of each lesion by plicating is admitted by RUNC to be a gross estimate and incapable of distinguishing potentially significant variations of 0.5 millimeters (approximately 0.02 inches) or less between lesions. The staff cannot conceive of how variations in lesion thickness in this order of magnitude, gross or otherwise, can be detected by plicating. Absent further explanation, the staff has insufficient basis to accept this method of measuring.

7. RUNC has raised the issue that it would be advisable to have a pathologist review the appropriate selection of patients. I believe that review by additional specialists is also advisable. Such specialists might include dermatologists and plastic surgeons. It was for this reason that peer review at a medical research institution was previously cited by the staff as an appropriate method for conducting clinical trials of an experimental nature (see affidavit of Dr. John E. Glenn, dated January 13, 1987, at paragraphs 7, 8, 30).
8. The method described by RUNC cannot be adequately monitored by the Staff so that the Staff might determine whether it is being applied consistently, since (1) staff inspectors do not have the medical expertise to independently monitor patient selection on the basis of lesion thickness; and (2) inspection frequency for this class of license is one inspection every three years. For this reason, in cases where medical research is being conducted, it is the licensee who must provide the medical experts who will review the selection and treatment process for adequate safeguards to protect the interest and welfare of the patient. Refer also to paragraph 7 above.
9. Based upon the above considerations, I still conclude that RUNC does not have sufficient technical resources and has not established sufficient safeguards to demonstrate that the proposed therapy is safe and effective.

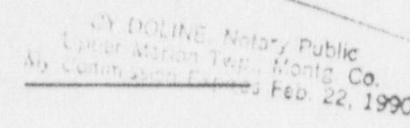
10. I attest that the foregoing is true and correct to the best of my knowledge and belief.


John E. Glenn

Subscribed and sworn to me before
this 15 day of Oct, 1987.


Notary Public

My Commission expires:


JOY DOLINE, Notary Public
Lynch Marion Twp., Montg. Co.
My Commission Expires Feb. 22, 1990

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USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ADMINISTRATIVE JUDGE

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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) Docket No. 30-12688-MLA

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CERTIFICATE OF SERVICE

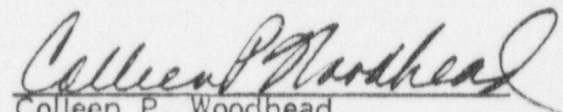
I hereby certify that copies of "NRC STAFF RESPONSE TO MEMORANDUM AND ORDER" in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system, this 20th day of October, 1987:

Charles Bechhoefer
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555*

G. A. Doener, M.D.
Radiology Ultrasound Nuclear
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W. T. Russell
Regional Administrator
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U.S. Nuclear Regulatory Commission
631 Park Avenue
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Docketing and Service Section
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555*



Colleen P. Woodhead
Counsel for NRC Staff