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March 1, 1988

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Administrative Judge
Presiding Officer
Atomic Safety and Licensing Board
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Docket No.30-12688-MLA
ASLBP No.87-542-01 MLA
Strontium 90 Applicator

Your Honor:

This letter is to uphold my application for the supplementation of my license for the use of a Strontium applicator in the treatment of superficial skin cancers.

The requirements of the Nuclear Regulatory Commission are that the use of the isotope must be "safe and effective".

1. The use of Strontium applicator in certain superficial skin cancers is safer than the use of other beta emmitting isotopes in the treatment of various conditions.

If radioactive phosphorus, a Beta emitter, is used for the treatment of a pleural effusion in the chest cavity or ascites in the abdominal cavity, there is the risk of leak of radioactive material from the puncture wound or at the time of instillation. Exposure of the skin due to contamination may be the result.

This risk is not present with the Strontium applicator since the Strontium in the applicator is well encapsulated.

2. Use of the Strontium applicator which is routinely licensed by the Nuclear Regulatory Commission in the treatment of superficial lesions of the eyeball is a high risk treatment.

My application expressly excludes lesions which involve the eyeball since I do not have training as an ophthalmologist.

Diplomate of the
American Board of Radiology
American Board of Nuclear Medicine
Board of Radiology in Radiation

3. In the facial area where the skin overlies bone, beta radiation is far superior to other treatments. Considering a superficial x-ray unit which emits energies around 50 to 140 KEV, the bone absorption underlying the skin lesion is two to three times the amount given to the skin. This means if a skin tumor is treated with 5,000 Rads the underlying bone would absorb 15,000 Rads, a dose within the range of risk of bone necrosis.

4. The effectiveness of Beta therapy is public property by the publication by W.K. Sinclaire and H. Blondal. A copy of the publication was submitted to you previously.

5. One of the arguments of Mr. Quinn was that the radiation from Strontium applicator is less energetic and therefore, less effective than the radiation emanating from P32.

This statement by Mr. John Glenn is erroneous and/or false. Mr. Glenn apparently was not aware that the effective radiation from the Strontium applicator originates from the Yttrium 90 but the radiation of lower energy from Strontium is filtered out in the commercially available applicator.

This point of the lower energy of the beta particles from Strontium compared with P-32 was used by the experts as a reason to deny the application. It is for this reason that the decision reached by the Nuclear Regulatory Commission is based on a false assumption and has, therefore, no validity.

6. The statement of Mr. Glenn is true that the treatment would take several hours.

We are aware of this fact and we will not avoid any effort, regardless of the time, to help a patient in a precarious situation. This point does not represent any objection against the use of the Strontium applicator.

On the contrary, such patients can not be treated by Linear Accelerator because it is technically impossible to occupy the Linear Accelerator for almost one day to treat such a patient at regular time intervals.

7. Mr. Glenn stated that the amount of radiation given by the Strontium applicator is far beyond permissible limits allowed by the Nuclear Regulator Commission.

Mr. Glenn obviously is not aware of the concept and definition of the integral dose comprising the total radiation exposure and radiation burden given to a patient.

The attached sheet will explain that the treatment of 100 carcinomas of the skin treated with the Strontium Applicator is equivalent to one treatment of Cobalt therapy

under normal conditions using a 10 x 10cm. portal. I suggest that this calculation be handed to Mr. Glenn and that he supplement his knowledge in the application of radiation in humans.

8. As far as the question of biopsy is concerned: the implied proposal to biopsy every one of the 100 lesions would appear impractical. Imagine the looks of the face and neck of the patient after 100 biopsies. The spouse of the patient coming home after the procedure would think the patient was attacked by 100 porcupines. Multiple biopsies are not necessary since an experienced clinician has enough judgement to confirm the identity of the lesions after one or maybe two biopsies.

Very sincerely yours,

G. A. Doener, M. D.

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P.S. One of the reasons that I insist in the use of the Strontium applicator was my experience with a patient who was treated some years ago for multiple squamous cell carcinomas of the face, at St. Vincents Hospital in New York during my residency.

This lady served the ultraviolet lamps in the New York Athletic Club used for tanning the skin of the athletes. This patient developed about 100 squamous cell carcinomas of the skin of her face. The treatment was successful, however, repeated treatments through the years resulted in necrosis of the underlying nasal and adjoining bones with loss of the nose.

Such a result could certainly be avoided with the Strontium applicator.

COMPARISON OF COBALT 60 AND STRONTIUM-YTRRIUM APPLICATOR

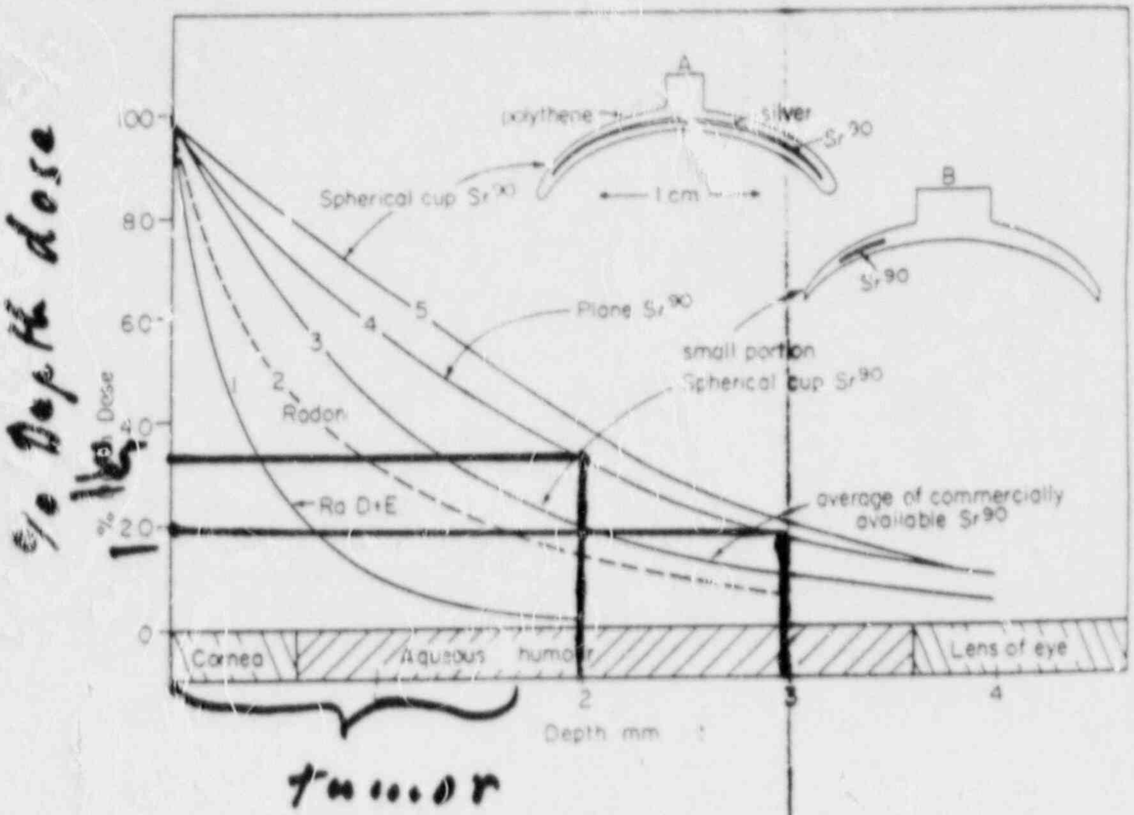
COBALT 60	STRONTIUM-YTRRIUM APPLICATOR
ROUTINE TREATMENT OF A TUMOR OF 5 CM DIAMETER AT 10 CM DEPTH IN A BODY OF 20 CM AP DIAMETER.	TREATMENT OF 100 SKIN CANCERS OF 1 CENTIMETERS SQUARE AND 0.2 CM THICKNESS.
PORTAL 10 X 10 CM = 100 SQUARE CM.	100 PORTALS EACH 1 CM SQUARE = 100 SQUARE CM.
RADIATION DOSE 100 RADS AT THE TUMOR MINIMUM.	RADIATION DOSE 100 RADS AT THE TUMOR MINUMUM.
VOLUME IRRADIATED 10 X 10 X 20 = 2000 CC.	VOLUME IRRADIATED 100 X 0.2 = 20 CUBIC CM.

2000/20=100

THE VOLUME OF IRRADIATED BODY TISSUE OF 100 SKIN CANCERS OF 0.2 CM THICKNESS ARE IRRADIATED WITH 100 RADS FROM STRONTIUM-YTTRIUM APPLICATOR IS ABOUT EQUAL TO NOT MORE THAN A SINGLE COBALT 60 TREATMENT OF 100 RADS TUMOR DOSE OF THE SAME AREA OF 100 SQUARE CM.

INVERSELY, WHEN 100 SKIN CARCINOMAS ARE TREATED WITH STRONTIUM YTTRIUM, THE RADIATION EXPOSURE OF THE PATIENT IS NOT MORE THAN A SINGLE COBALT 60 TREATMENT TO A PORTAL MEASURING 10X10 CM SQUARE.

ASSUMED TUMOR SIZE 5 CENTIEMETERS IN DIAMETER. LESS THAN 25% OF RADIATION IS IN CANCEROUS TISSUE.	ASSUMED TUMOR SIZE OF 1 CM SQUARE AND 0.2 CENTIMETERS THICKNESS CLOSE TO 100% OF THE RADIATION IS IN CANCEROUS TISSUE.
75%+ OF RADIATION IS NONCANCEROUS TISSUE.	ONLY A SMALL PART OF THE RADIATION IS NONCANCEROUS TISSUE
UNDESIRABLE RADIATION BURDEN 75% +.	THERE IS ONLY A MINIMAL RADIATION BURDEN TO NORMAL TISSUE.


% Depth dose
% Dose
100
80
60
40
20
0
A
polythene
silver
Sr 90
1 cm
Spherical cup Sr 90
B
Sr 90
Plane Sr 90
small portion
Spherical cup Sr 90
Radon
Ra D+E
average of commercially available Sr 90
1
2
3
4
5
Cornea
Aqueous humor
Lens of eye
2
3
4
Depth mm
tumor