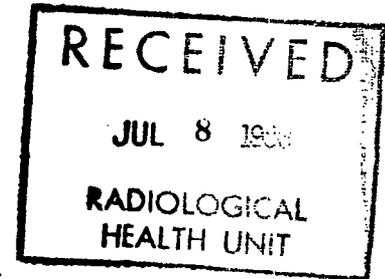


NUCLEAR MEDICINE, INC.



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July 3, 1986



Ms. Cynthia A. Sanders
Georgia Department of Human Resources
Radiological Health Section
878 Peachtree Street, N.E., Suite 600
Atlanta, GA 30309

Reference: Application for Registration of Sealed Brachytherapy
Sources, submitted by Nuclear Medicine, Inc.,
March 3, 1986

Dear Ms. Sanders:

In response to your letter dated June 4, 1986, Theragenics is pleased to provide additional information regarding the registration application of the Model 100 Palladium Seed.

(1) Description of Procedures

The role of Laser Industries, Inc. in the manufacture of the palladium seeds is limited to handling non-radioactive seeds. All manufacturing steps, including laser welding of the end cups, are performed prior to irradiating the seeds. Following mechanical assembly of the components by Theragenics the seeds are sent off-site to Laser Industries, Inc. for the laser welding of the end cups. The seeds are then returned to Theragenics for quality control checks of the welds. At this point the seeds are packaged and shipped to one of several possible reactor facilities. At the reactor facility, the seeds are irradiated in an irradiation capsule for a period of two to three weeks depending upon the activity level desired. The reactor facility then packages and ships the irradiated seeds back to Theragenics where leak testing and assay measurements are performed.

(2) Seed Activity Values

The seed activity values listed on page 19 of our registration submittal are mCi(compensated). These values account for a self-absorption of approximately 40% to 50% by the materials of construction. The information on page 3, item 6, of our submittal contains an error. The maximum activity (which is uncompensated) should be 10 mCi per seed rather than the stated 7 mCi. Therefore, to allow for possible variations or future needs, Theragenics requests a maximum seed activity value of 10 mCi on the certification.

(3) Principal Use of Model 100 Palladium Seed

We confirm that the principal use of the Model 100 Palladium Seed should be Exhibit 3, Code V, General Medical Use.

(4) Cadmium-109 Source

The cadmium-109 source we are currently using is identified on our Radioactive Materials License as Item 6E; it is a Model 101S disk source with a nominal strength of 10 uCi manufactured by New England Nuclear of N. Billerica, MA. In the future, we expect to request a license amendment to allow possession of other cadmium-109 sources.

(5) Dose Calibrator Linearity Procedures

Because radioactivity standard sources of the palladium-103 are not available (nor for the yttrium-90) a linearity check of a dose calibrator is more difficult. We believe that two different methods are valid for measuring the linearity response. In method I, a palladium-103 seed or a sample vial of yttrium-90 with an initial activity near the maximum is assayed over a period of a few half-lives. The assay data is plotted along with the calculated value based upon the equation of radioactive decay.

In method II (the one described in the application) two or more standard radioactivity sources of the same nuclide but with activities that differ by a large factor (perhaps 10) are assayed one at a time. The assay data can then be compared to the known source activity (corrected for decay) to evaluate the linearity of the calibrator. As a practical matter, we are not able to use Method II at this time because we do not now have the requisite sources. Method I has already been used with the yttrium-90 isotope; it demonstrated linearity satisfactorily over a large range of activities.

We therefore propose to continue to use Method I as described above to evaluate dose calibrator linearity.

(6) Disposal of Palladium Seeds

Any used palladium-103 seeds returned to Theragenics for disposal will be placed in properly identified and labeled lead containers and considered to be radioactive waste. As such, we will follow the guidelines in section V-G in our Radiation Safety Manual (attachment H to our application for license) which calls for storage and, ultimately, transfer of the material to Georgia Tech's Office of Radiological Safety for disposal.

(7) Patient Radiation Safety Procedure Guidelines

Theragenics believes that the patient education regarding necessary radiation precautions must be the responsibility of the physician and the hospital administering the treatment. Theragenics does not plan to provide specific detailed guidelines since these are readily available from the references provided in our application. A listing of these references will be provided in the package insert material that accompanies the shipments of palladium seeds.

(8) Seed Accountability

We will remove the words "significant number" from the referenced section on accountability and "recommend that if any seeds cannot be accounted for, the appropriate Federal or State licensing agency and/or the local Radiation Safety Officer should be contacted."

- (9) The draft label for the steel can, shown on page A-2 of the application, has an error. "Surface Activity ____ mCi comp." should be replaced by: "Surface Dose Rate ____ mrem/hr". Total Apparent Activity remains on the label and is the sum of all the assayed seeds contained within the container.

(10) Disposal of Contaminated Soak Wash Solution

The used soak-wash solution remaining after processing a batch of seeds is considered to be radioactive waste. It will be disposed of in a manner described in section V-G of our Radiation Safety Manual (attachment H to our application for license) which calls for storage and, ultimately, transfer to Georgia Tech's Office of Radiological Safety for disposal. The liquid will be stored in properly labeled, sealed containers.

Thank you for your review of our application. If more information is needed, please do not hesitate to call Mr. Robert Kirkland, our Manager of Engineering, who has provided this response.

Sincerely yours,



Richard A. Moore
Vice President

RAM:jtk