QUALITY ASSURANCE/CONTROL PROGRAM

FOR

GOLD-198 SEED ASSAY MEASUREMENT SYSTEM

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ENCLOSURE III
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General Discussion:

All radiation sources used in medicine must be assayed for activity to an accuracy of ± 5%. To assure the accuracy of the activity measured for each Gold-198 seed, certain tests must be performed routinely on each component used in the assay.

Radiation, Safety & Nuclear Products, Inc., (RSNP) used two basic types of radiation detection systems in the assay of seeds:

1. A fixed-geometry ion chamber used for rapid counting and assay of seeds required to fill an order or to batch a shipment of irradiated seeds. The ion chamber is interfaced to a Keithley picoammeter and a 300 VDC battery. A test tube is placed in direct contact with the ion chamber, and individual seeds are placed into the test tube. The current generated across the ion chamber is a function of the radioactive strength of the seed and is measured by the picoammeter.

   Figure 1. illustrates the configuration of the ion chamber assay system.

2. A Capintec Dose Calibrator is used to confirm the readings of, and document the performance of the Ion Chamber Assay system.

ION CHAMBER

As described in the preceding discussion, the Ion Chamber system is a relatively simple system that measures the current generated across the ion chamber when a radioactive source is placed in contact with the top of the chamber. The system has no variable parameters which can be adjusted by the operator. The measured ion current (usually in the range of 0-50 nanoAmps (nA) is correlated to the actual radioactive strength of the seed being measured by use of empirically-determined algorithms.

To document the performance of the ion chamber system, the following tests are performed:

1. Daily constancy check for reproducibility in measuring a Cs-137 tube source, which has been mounted in a plastic rod to assure constant geometry. A log of the results is maintained.

2. At least once each quarter, a single Gold-198 seed is assayed and isolated for use in a "intercomparison study" to compare the measurement capabilities of the ion chamber system and the dose calibrator. Logs of these tests are also maintained.

ION CHAMBER (Cont.)

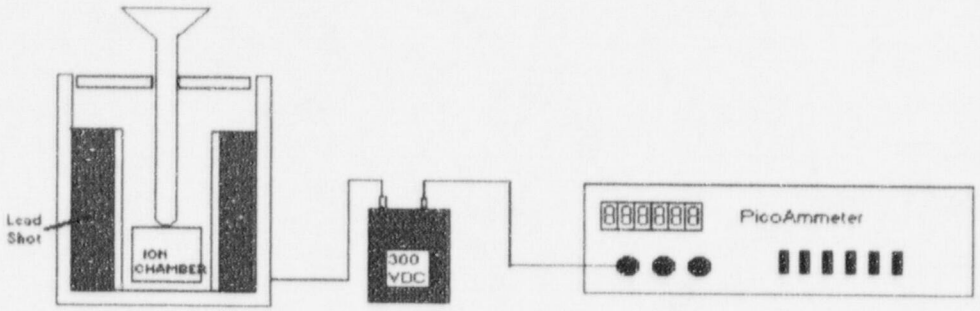

Figure 1. Ion Chamber Measurement System

DOSE CALIBRATOR SYSTEM

RSNP has adopted procedures very similar to the "model procedure" for calibrating dose calibrators that was published in Appendix C to USNRC Regulatory Guide 10.8, Revision 2, viz:

1. Test for the following at the indicated frequency and for the suggested tolerance:
   a. Constancy at least once each day prior to assay of seed strengths (± 5%).

   b. Linearity at installation and at least quarterly thereafter (± 5%).

   c. Geometry dependence is not applicable in that these procedures apply to "single seed" measurements.

   d. Accuracy at installation and at least annually thereafter (± 5%).

2. After repair or adjustment, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. To measure constancy, a Cesium-137 tube source, which has been mounted in a delrin rod to maintain geometry, is measured each day at each setting used on the calibrator. A log is maintained of these results.

4. At least quarterly, the calibrator is inspected to ascertain that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. To measure linearity, on at least quarterly intervals, two (2) Gold-198 seeds of differing strengths are isolated and assayed to obtain the current activity of each. A computer program then generates the theoretical activity of each seed on an hourly basis for the next 14 days. (The half-life of Gold-198 is ≈2.7 days, therefore at least 5 half-lives are covered during this 14 day period.)

   At least once each three days, each seed is counted and compared with the calculated theoretical activity. Differences greater than ± 5% indicate the need for repair or recalibration. Results of these tests are maintained.

6. Accuracy means that, for a given calibrated reference source, the indicated milliCurie value is equal to the milliCurie value determined by the NBS or by the supplier who has compared that source to a source that was calibrated by the NBS.

   RSNP has certified sources of Cs-137 and Ba-133 (≈250 μCi each) which are used for tracking of calibrator accuracy.

   At least annually, these sources are measured at the proper calibrator setting. The indicated milliCurie value is compared to the calculated "decayed" milliCurie value for that source. If the average of three (3) separate measurements does not agree within ± 5% with the certified value of the reference source, the calibrator is repaired or adjusted.

   Records of these measurements are maintained.