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DOCKET #: 030-01888

Dear Dr. Shanbaky:

Thank you for your letter of December 9, 1992 in response to which I am complying with the request which your outlined.

I. This letter will serve as a request for license amendment stating our intent to use a rectilinear scanner to perform the required patient dosage assays. As mentioned, we have been using the same equipment since 1962 and have always found good correlation with the radio-iodine that we have received from different suppliers in the past, namely originally Abbott Laboratories, Cambridge Nuclear (for a short period of time), and for the past 15 or more years, from Mallinckrodt Laboratories. Over all these years, we have never found any significant variations from our measurements and the stated potency of the isotopes which we have received.

II. Graph A demonstrates the calibration and the assay of individual capsules from Lot 3002049B Mallinckrodt I-131 capsules which Mallinckrodt labeled as 100 microcurie per capsule as of 12 noon Central time on 21 December 1992.

We selected six individual capsules at random the following day on 12-22-92 at 3 p.m. Eastern Standard time and counted each capsule two times for a full minute each time and averaged the results. Our scintillation counter has a sensitivity of 3500 counts per minute per microcurie at a distance of 11 cm. As shown in the tabulation beside the graph, the capsules never varied more than 3% and the average potency of each capsule was 91.85.

To demonstrate the close similarity and content of each

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capsule, on 12-30-92, all ten capsules were counted individually on 12-30-92 at a standard distance of 20 cm. As can be seen in this graph, the linearity was quite good and the slope of the curve is zero. It should be pointed out, that the first 6 capsules in graph one do not correspond to the 6 capsules used in graph A and again were taken randomly out of the supply of Mallinckrodt lot 30020490B.

Graph II demonstrates the adherence of the calibration and assay of the capsules to Beer's law. This testing was also done on 12-30-92 and again all ten capsules (again these do not correspond to the same numbers as in graph I or graph A) were selected at random. The receptacle for the capsules was placed at a distance of 20 cm. from the scintillation counter and each capsule was placed in the container successively without any change in geometry and each testing was done for a full minute times two an averaged and as can be seen from the graph and the data in graph II, there was very good adherence to Beer's law. The last determination was made with all ten capsules in the receptacle without any change in geometry and also indicates that there is no affective dead time.

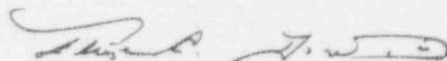
I have done other testing in the past, which indicates that our three inch sodium iodide crystal and counting apparatus can count up to 800,000 counts per minute without incurring any dead time.

As I mentioned, I am currently only using Iodine 131 and as you know all of the up-take and clinical testing that is accurate only to within 5% and I believe that the data I am presenting does show that the variation for any of these assays and calibrations is within 3%.

It was indeed a pleasure to meet with you and I do hope that this information complies with your request.

With many thanks for your considerations, I remain.

Yours sincerely,



E. C. Dow, M. D.

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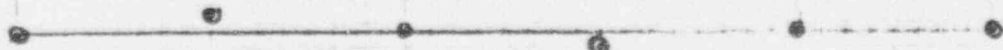
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GRAPH A

Calibration and assay of six random capsules from Lot 3002049 B Mallinckrodt I-131 capsules assayed by Mallinckrodt at 100 uci/cap as of 12 Noon CT on 12.21.92. This assay done on 12.22.92 at

3:00 PM EST on 12.22.92 @ which time and date capsules should assay at 91.7 uci/caps

**Sensitivity of counter: 3500 ncpm per microcuries at distance of 11.0 cm.



Capacule #	ncpm per capsule	uci/capsule @ 3500 ncpm per uci
#1	320,442	91.6
#2	329,898	94.3
#3	322,405	92.1
#4	312,610	89.3
#5	322,489	92.1
#6	320,961	91.7
AVERAGE	321,468	91.85

#1 #2 #3 #4 #5 #6

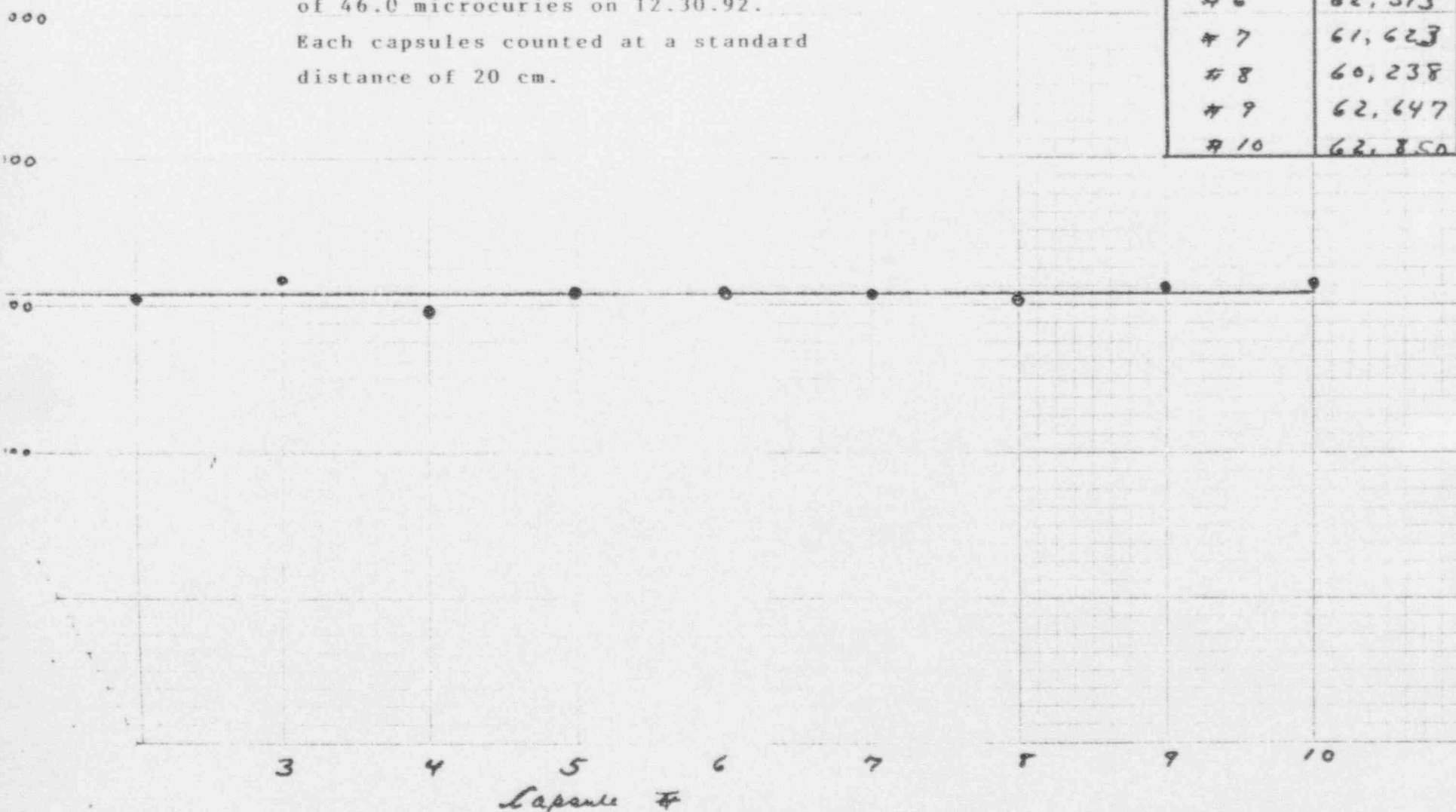
Capacule #

GRAPH I

Demonstration of the linearity of the activity of individual capsules of I-131 Mallinckrodt Lot 3002049B each of 46.0 microcuries on 12.30.92.

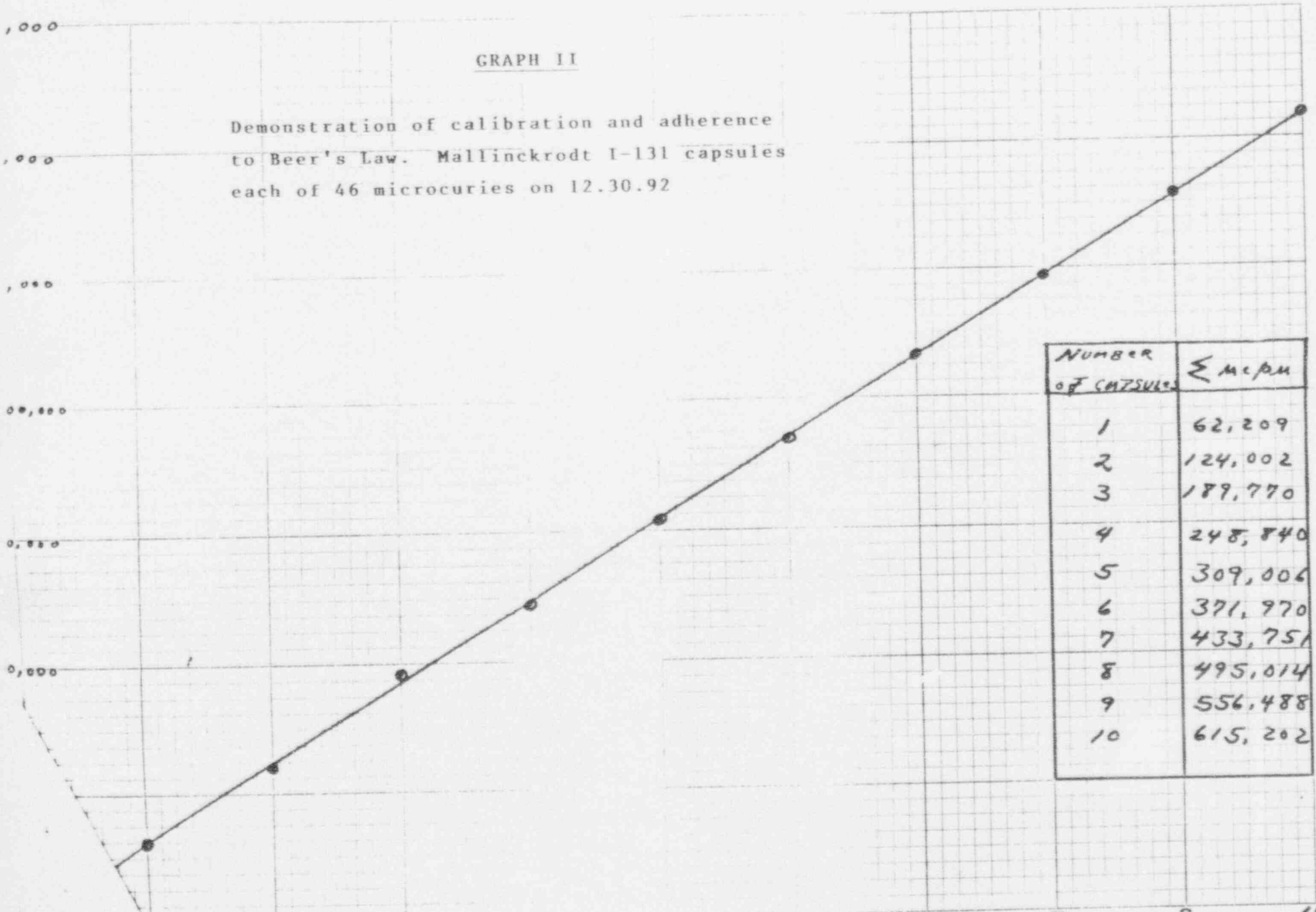
Each capsules counted at a standard distance of 20 cm.

Capsule #	mcpm per capsule.
#1	62,498
#2	60,802
#3	63,291
#4	62,039
#5	62,230
#6	62,313
#7	61,623
#8	60,238
#9	62,647
#10	62,850



GRAPH II

Demonstration of calibration and adherence to Beer's Law. Mallinckrodt I-131 capsules each of 46 microcuries on 12.30.92



NUMBER OF CAPSULES	Σ mcpm
1	62,209
2	124,002
3	189,770
4	248,840
5	309,006
6	371,970
7	433,751
8	495,014
9	556,488
10	615,202

No of capsules counted - From Lot 3002049 B - MALLINCKRODT