December 23, 1974

SECY-R-75-183

For: The Commissioners

Subject: THORIUM AND OTHER NATURALLY OCCURRING ALPHA EMITTERS IN OPHTHALMIC GLASS

Discussion: Enclosed is a letter transmitting the results of our study on this subject to the Bureau of Medical Devices, FDA.

This matter was discussed at a Commission briefing on November 26, 1974.

Subject to your comments we propose to dispatch the letter, and to make copies available to the Army, Navy, Air Force, EPA, the JCAE, and AEC Public Document Room on December 31, 1974.

(signed) L. Manning Muntzing

L. Manning Muntzing
Director of Regulation

Distribution:
L. Muntzing
L. Gossick
L. Rogers
R. Minogue
R. Mattson
R. Barker
S. Yaniv
RS r/f
PSB r/f
OGC

See Rpts Jacket for Enclosures

Contact:
Dr. Roger Mattson
Extension 153-36955

OGC Romine 12/ /74

ID-thorian

OFFICE▶	RS:PSB	RS:AD/SHS	RS:DD	RS:DR	ADR	DR
SURNAME▶	SSYaniv:ab RFBarker	RJMattson	RBMinogue	LRogers	LVGossick	LMMuntzing
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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

Mr. David N. Link, Director
Bureau of Medical Devices and Diagnostic Products
Department of Health, Education, and Welfare
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Link:

Over the past 18 months, the Atomic Energy Commission, in cooperation with the Army, Navy, and Air Force, has been studying the possible presence of radioactive material in ophthalmic glass. The emphasis of our work was to determine if AEC regulations were violated and to what extent if any "source materials" appeared in ophthalmic glasses.

Currently, the AEC exempts from regulation or license requirements the possession or use of any "source material" (uranium or thorium or any combination of these materials) up to 0.05 percent by weight in any chemical mixture, compound, solution or alloy. There is a further maximum allowable limit of 0.25 percent by weight of thorium, uranium, or any combination of these materials in the rare earth oxides which are used in the manufacture of optical or ophthalmic glass. Therefore, it is conceivable that such glass could contain some thorium and uranium as unintentional natural contaminants.

The only significant radiation emitted by natural thorium and uranium is alpha radiation which has very little ability to penetrate material. Consequently, if these materials were present in spectacles, the radiation emitted could not reach the most sensitive structures of the eye. The cornea is the only eye structure that would be affected.

The study included the following elements:

1) appointment of a group of consultants--ophthalmologists, radiation biophysicists, radiation biologists and other experts--to help determine whether or not the presence of this trace material might have any deleterious effect on the eye;

2) a theoretical study on penetration of the human eye by alpha particles from glasses containing radioactive materials;

3) systematic radiation measurements on samples of all available types of ophthalmic glass manufactured in the U.S.A.

We have met with the Optical Manufacturers Association and presented our findings. The U.S. ophthalmic glass manufacturers through the OMA have proposed to develop an industry voluntary performance standard for radiation emission from ophthalmic glass which will be issued for public comment by January 1975 (see Enclosure 1).

Another aspect of this problem is that about 10 percent of the ophthalmic glass used in the U.S. is imported and hence would not be covered by a U.S. industry voluntary standard.

Representatives of the Bureau of Medical Devices and the Bureau of Radiological Health, FDA, have been informed of the progress of our study. The Bureau of Medical Devices has the primary cognizance of the ophthalmic glass industry in the United States. We are transmitting the findings of our study to you on the basis that the appearance of radioactive materials in ophthalmic glass does not result from violations of AEC regulations; indeed, the contamination cannot be prevented solely by the control of source material content. This is a matter deserving of continued surveillance by the Federal acency responsible for the safety of medical devices.

Sincerely,

Lester Rogers
Director of Regulatory Standards

Enclosures: See Reports Jacket

1. Press Release for Distribution by Optical Manufacturers Association (November 19, 1974)
2. Thorium and Other Naturally Occurring Alpha Emitters in Ophthalmic Glass--Summary of Radiation Survey
3. Radiobiological Evaluation of Thorium in Optical and Ophthalmic Glass
4. Penetration of the Human Eye by Alpha Particles from Glasses Containing Radioactive Isotopes

cc: Darwin N. Taras, USMC
Robert C. McMillan, USAMERDC
Major George S. Kush, AFSGPA
Capt. James H. Dowling, USN
Lt. Col. Edward W. Blackburn, DASG
Col. Lawrence T. Odland, USAFRHL
John C. Villforth, HEW
Dr. Wm. Mills, EPA

THORIUM AND OTHER NATURALLY OCCURRING ALPHA EMITTERS IN OPHTHALMIC GLASS

SUMMARY OF RADIATION SURVEY

Product Standards Branch
Directorate of Regulatory Standards
U.S. Atomic Energy Commission

December 1974

Introduction

Preliminary radiation measurements performed by military and AEC personnel in the last two years indicated that some ophthalmic glasses contain small amounts of naturally occurring emitters of alpha radiation.

Because of the concern about possible effects of alpha radiation on the cornea and in order to determine if the radiation detected was a result of violations of AEC regulations, we have performed systematic radiation measurements on samples of all available types of ophthalmic glasses manufactured in the U.S.A. The purposes of the measurements were as follows:

1. To determine the amounts and identity of naturally occurring alpha emitters in ophthalmic glass.
2. To identify the type (or types) of glass in which those alpha emitters are present.
3. To identify the source of the alpha contaminants in ophthalmic glass.

Sample Selection

We obtained from the four U.S. manufacturers of ophthalmic glass (American Optical Corporation, Bausch and Lomb Company, Corning Glass Works, and Schott Optical Glass, Incorporated) descriptions of the gross chemical compositions of the various glasses manufactured by them. There are many types (catalog numbers) of ophthalmic glass.

The same types of glass are sometimes produced by several manufacturers. In order to keep the number of samples at a reasonable size, we grouped glasses with similar chemical compositions and those produced by the same company. The number of different types of glass in a group varied from 1 to 10. In such a way, we obtained 28 different groups of glasses, containing 10 to 20 samples each. 140 different types of glass were examined and the total number of glass samples was 441.

To be able to retrace each piece of glass to its time and place of manufacture, and to the raw materials used, we had to obtain the ophthalmic glass samples in the form of pressing or strips, since in the grinding and polishing process the glass loses its identity. Pressings of glass made by American Optical and Bausch and Lomb were obtained from the manufacturers--these companies process all the glass they manufacture. Corning and Schott glass samples were obtained from the manufacturers and from a few other sources (distributors).

The sampling plan was designed under the following physical constraints:

1. The total sample included the products of the four companies.
2. The types of pressings made by each company were divided into groups of similar types with the requirement that a statement regarding radiation emission must be made about each group, independent of all other groups.

3. Each type of pressing in each group was included in the sample.
4. Each group was considered as an equally likely candidate to produce a significant proportion of pressing emitting more than a specified amount of radiation.

The four constraints indicated above, for all practical purposes, limited the immediate scope of the sampling study since initially the total sample size was hoped to be bounded by 250 pressings. Even though the sampling design almost doubled the 250 bound, only limited statements can be made about the proportion of pressings emitting significant radiation, and very little, if any, information was obtained on an upper confidence bound for the larger quantiles of distribution of alpha emissions from the offending groups. Thus, for all practical purposes, this experiemnt is considered as a screening experiment.

The procedure was as follows. Select a sample of 15 or 16 pressings from each group of pressings per company. If the true proportion of pressings which exceeds the specified radiation level is less than 0.03, the specified sample size will enable one to say with 80 percent confidence that the true proportion is covered approximately by the interval 0 to $\hat{p} + 0.10$, where $\hat{p}$ is the estimate of the proportion.

The samples were randomly chosen from the types of pressings within each group, subject to the restriction that every type was sampled at least once.

The required samples of pressings were also selected from company stocks in a random manner.

Measurements

From Table IV of the enclosed report by C. A. Tobias and A. Chatterjee it can be seen that the energetic alpha particles, which can penetrate into the cornea, are emitted by the short-lived radionuclides in the thorium series: ^{220}Rn, ^{216}Po, ^{212}Bi and mainly ^{212}Po. Because of their short half-life, they are in secular equilibrium with ^{228}Th. Thus, determination of the quantity present in a glass sample of any daughter of ^{228}Th will determine quantitatively the content of ^{228}Th and the alpha emissions from the glass due to thorium daughters. Alpha spectometry in this case requires tedious radiochemical procedures and is very time consuming. Several of the daughters of ^{228}Th can be identified and quantified by gamma spectrometry in a much simpler and faster procedure. We have chosen to measure the gamma emissions from ^{212}Pb because of a convenient peak of 238 keV.

In the chemical processing of the additives containing thorium, it is possible that the non-thorium daughter products of thorium decay may be separated and that a non-equlibrium condition exists.

Figure 5 of the enclosed report by C. A. Tobias and A. Chatterjee shows the variation in alpha activity as a function of time for natural thorium from which the non-thorium daughters were separated. The ratio of minimum to maximum alpha activity of the thorium series is about two. Thus measuring only ^{212}Pb, one can possibly underestimate the quantity of ^{232}Th present by a factor of 2.

Alpha spectrometry of the thorium fraction of certain ophthalmic glass samples showed ratios of ^{232}Th to ^{228}Th of 1 to 20. This implies that the thorium was in this case removed from the glass additives but ^{228}Ra (daughter of ^{232}Th) remained. Thus it appears necessary to determine the quantity of ^{228}Ra present as well. This can be accomplished by measuring the gamma emission from ^{228}Ac (a short-lived daughter of ^{228}Ra).

At a later date the data were examined for the 909 keV peak of ^{228}Ac. In a few samples it appeared that the ^{228}Ac activity was higher than the ^{212} Pb activity. Those samples were recounted for 1000 minutes each, and it was shown that the ^{228}Ac activity was indeed higher. The number of samples was too small to draw any quantitative conclusions. These results, however, together with the results of alpha spectrometry mentioned above, strongly suggest that also the measurement of ^{228}Ac is necessary in order to determine the potential alpha activity due to thorium daughters.

In the uranium series, it is sufficient to determine the quantity of ^{226}Ra in order to determine the relevant alpha emission due to uranium daughters. This was done by measuring the 325 keV peak from ^{214}Pb.

All the radiation measurements were performed by the AEC Health Services Laboratory, Analytical Chemistry Branch, Idaho Falls, Idaho. Prior to measurement each glass sample was ground into sand and a predetermined volume of this sand was placed into a standard counting vial and weighed.

The samples were counted on a Ge-Li detector for 30 minutes and the resulting gamma spectra evaluated for ^{212}Pb and ^{214}Pb. ^{212}Pb was assumed to be in secular equilibrium with ^{228}Th (and all the other daughters of ^{228}Th) and ^{214}Pb in equilibrium with ^{226}Ra (and all the other daughters). Because of the possibility that some of the ^{220}Rn (thorium series) and ^{222}Rn (uranium series) might have escaped during the grinding of glass into sand, several samples were recounted a few days later to see whether there was an increase in activity; none was found.

The verification of procedure accuracy was performed as follows:

1. Thorium series. In three glass samples the quantity present of ^{228}Th was very carefully determined by radiochemical separation and alpha spectrometry. The same glass samples were later measured in the same way as all other samples and their ^{212}Pb content determined. The results are given in Table 1.

Table 1

Verification of Procedure Accuracy

Thorium Series

	^{228}Th	^{212}Pb	^{212}Pb
	As calculated* from alpha spectrometry in dpm/gram	As calculated* from gamma spectrometry (directly on crystal) in dpm/gram	As calculated* from gamma spectrometry (sample changer) in dpm/gram
	1000 - 5000 min count time	1000 min count time	60 min count time
Sample A	27.8 ± 0.5	26.4 ± 0.3	25.2 ± 1.4
Sample B	13.1 ± 0.4	14.5 ± 0.2	13.0 ± 1.1
Sample C	16.6 ± 0.6	15.3 ± 0.2	18.0 ± 1.2

*Deviation shows only counting uncertainty.

In addition, thtee samples of known thorium concentration and known to be in equilibrium (New Brunswick Laboratory analyzed samples) and analyzed by flourometry and alpha spectrometry by the Health Services Laboratory, were used to verify the procedures of thorium determination using the ^{212}Pb and ^{228}Ac gamma emissions. These results are given in Table 2.

Table 2

Verification of Procedure Accuracy

Thorium Series

	New Brunswick Laboratory	Health Services Laboratory	%Thorium Calculated* As ^{212}Pb Using Gamma Spectrometry	%Thorium Calculat. As ^{228}Ac Using Ga: Spectrometry
	Analyzed Samples	Fluorometric and Alpha Spectrometry		
	%thorium	%thorium	%thorium	%thorium
Sample I	1.01 ± 0.01	1.01 ± 0.01	1.02 ± 0.02	1.08 ± 0.01
Sample II	0.101 ± 0.002	0.101 ± 0.003	0.103 ± 0.001	0.105 ± 0.002
Sample III	0.0102 ± 0.0001	0.0102 ± 0.0002	0.0104 ± 0.0001	0.0106 ± 0.003

*Deviation shows only counting uncertainty.

2. Uranium Series. We had available a sample of pitchblende with known specific activity of ^{238}U and known to be in equilibrium with all the daughters. In order to obtain similar specific activity and the same geometry as used during the measurement of glass samples, the pitchblende was diluted with SiO_2 and the ^{214}Pb content was measured in the same way as in all glass samples.

The results are summarized in Table 3.

Table 3

Verification of Procedure Accuracy

Uranium Series

	Specific Activity: ^{238}U Series	^{214}Pb as Calculated* from Gamma Spectrometry (sample changer)
		30 minute count time
Undiluted Pitchblende	6050 ± 40 dpm/g	6100 ± 40 dpm/g
Pitchblende Diluted with SiO_2	642 ± 5 dpm/g	630 ± 10 dpm/g

*Deviation shows only counting uncertainty.

Results

We have measured the activity of ^{212}Pb and ^{214}Pb in 441 samples of ophthalmic glass.

Table 4 gives the frequency distribution of the observed counting rates.

Table 4

Frequency Distribution of the Observed Counting Rates

Ophthalmic Glass Samples

Interval (dpm/g)	Pb_{212} Frequency	Pb_{212} Cumulative Proportion	Pb_{214} Frequency	Pb_{214} Cumulative Proportion
0.0-0.5	45	0.102	49	0.111
0.5-1.0	33	0.177	18	0.152
1.0-1.5	35	0.256	18	0.193
1.5-2.0	52	0.374	18	0.234
2.0-2.5	31	0.444	19	0.277
2.5-3.0	40	0.535	24	0.331
3.0-3.5	26	0.594	23	0.383
3.5-4.0	20	0.639	18	0.424
4.0-4.5	23	0.692	20	0.469
4.5-5.0	8	0.710	20	0.515
5.0-5.5	10	0.732	16	0.551
5.5-6.0	8	0.751	8	0.569
6.0-6.5	8	0.769	12	0.596
6.5-7.0	8	0.787	10	0.619
7.0-7.5	4	0.796	8	0.637
7.5-8.0	13	0.825	14	0.669
8.0-8.5	4	0.834	14	0.701
8.5-9.0	5	0.846	8	0.719
9.0-9.5	2	0.850	11	0.744
9.5-10.0	4	0.859	4	0.753
10.0-11.0	9	0.880	9	0.773
11.0-12.0	4	0.889	11	0.798
12.0-13.0	4	0.898	5	0.810
13.0-14.0	5	0.909	4	0.819
14.0-15.0	3	0.916	3	0.825
15.0-16.0	3	0.923	3	0.832
16.0-17.0	0	0.923	5	0.844
17.0-18.0	1	0.925	5	0.855
18.0-19.0	2	0.930	3	0.862
19.0-20.0	4	0.939	1	0.864
20.0-21.0	2	0.943	5	0.875
21.0-22.0	2	0.948	4	0.884
22.0-23.0	1	0.950	3	0.891
23.0-24.0	2	0.955	7	0.907
24.0-25.0	2	0.959	4	0.916
25.0-26.0	0	0.959	5	0.927
26.0-27.0	1	0.961	6	0.941
27.0-28.0	1	0.964	9	0.961
28.0-29.0	1	0.966	3	0.968

Table 4 (Continued)

Interval (dpm/g)	Pb_{212} Frequency	Pb_{212} Cumulative Proportion	Pb_{214} Frequency	Pb_{214} Cumulative Proportion
29.0-30.0	2	0.971	3	0.975
30.0-35.0	3	0.977	6	0.989
35.0-40.0	1	0.980	2	0.993
40.0-45.0	1	0.982	0	0.993
45.0-50.0	1	0.984	0	0.993
50.0 →	7	1.000	3	1.000

The actual values for the seven samples that exhibited ^{212}Pb activity in excess of 50 dpm/gram are as follows: 50.1, 55.9, 71.6, 125, 164, 197, and 359 dpm/gram. The corresponding ^{214}Pb activity of those samples is as follows: 0.1, 16.5, 26.0, 58.9, 31.7, 50.9, and 86.9 dpm/gram.* The ^{228}Ac activity of those samples was equal to the ^{212}Pb activity. All those samples were made by the same manufacturer and all contained significant amounts of rare earth oxides.

As described above, the radiation survey of the glass samples was designed to detect certain groups of ophthalmic glass which exhibited radiation levels higher than a certain level. Thus the samples were divided into 28 groups according to their chemical composition and manufacturer. The mean count rate and standard deviation for the 28 groups are given in Table 5.

*0.05% by weight of thorium in equilibrium with all the daughters would result in ^{212}Pb activity of approximately 120 dpm/g and 0.05% by weight of uranium in equilibrium with its daugthers would result in ^{214}Pb activity of about 370 dpm/g.

Table 5

Results of Gamma Measurements - Ophthalmic Glass Samples

Group No.	Lead-212 Disintegration per minute per gram		Lead-214 Disintegration per minute per gram		Glass Description
	Mean*	Standard** Deviation	Mean*	Standard** Deviation	
1	1.84	1.28	3.71	2.00	Clear crown
2	3.27	1.28	13.15	2.28	High index segments for fused bifocals, contains 3-6% ZrO_2
2	2.55	0.97	5.46	1.62	High index segments for fused bifocals, contains ∿1% ZrO_2
4	3.12	1.57	2.87	1.92	Crown glasses - different tints
5	7.37	1.66	24.15	2.78	Barium segment - 5-7% ZrO_2
6	2.16	1.19	5.13	1.84	Flint segments; high lead content - 0-2% ZrO_2
7	2.19	1.24	4.40	1.85	Clear crown
8	15.39	3.11	6.34	2.27	Pink crowns - 2-3% rare earth oxides
9	18.82	2.35	9.90	2.42	Crookes crown - ∿6% rare earth oxides
10	2.11	1.31	1.78	1.89	Green crown - no rare earth oxides
11	1.93	1.26	2.45	1.83	Neutral crown
12	2.18	1.28	3.01	1.89	Tan crown
13	1.73	1.34	3.40	2.08	Blue crown
14	2.24	1.25	3.75	1.96	Yellow crown
15	2.08	1.28	2.81	2.00	Special glass for strengthening
16	10.00	1.80	27.48	2.80	Barium segments ∿7% ZrO_2
17	1.62	1.32	2.52	1.95	Clear crown

Table 5 (Continued)

Results of Gamma Measurements - Ophthalmic Glass Samples

Group No.	Lead-212 Disintegration per minute per gram Mean*	Lead-212 Disintegration per minute per gram Standard** Deviation	Lead-214 Disintegration per minute per gram Mean*	Lead-214 Disintegration per minute per gram Standard** Deviation	Glass Description
18	23.17	10.81	6.70	2.88	Tinted glasses - 1 to 10% rare earth oxid
19	64.56	23.38	16.37	7.14	Crooks glasses <10% rare earth oxides
20	1.65	0.88	3.02	1.30	Tinted glasses - no rare earth oxides
21	1.93	0.99	2.73	1.46	Tinted glasses - no rare earth oxides
22	2.60	1.15	4.14	1.91	Tinted glasses - no rare earth oxides
23	4.55	1.51	8.69	2.37	Photocromic glass - 1-10% ZrO_2
24	2.35	1.48	3.26	1.97	Welding and industrial glasses
25	2.72	0.89	8.28	1.67	Flint segments - 1-10% ZrO_2
26	1.29	0.73	2.09	1.15	Flint segments no ZrO_2
27	5.79	1.27	18.60	3.01	Clear barium segments - 1-10% ZrO_2
28	7.04	1.16	22.44	2.61	Tinted barium segments - 1-10% ZrO_2

*Background included.
The background pooled from 6 individual determinations is: for ^{212}Pb -- 1.32 ± 1.30 dpm/g
for ^{214}Pb -- 1.45 ± 1.85 dpm/g

**Standard Deviation includes both measurement error and the within group variability.

Since thorium and uranium are widely spread in the earth's crust and are present in very low levels in practically all sands and other raw materials used in ophthalmic glass manufacture, one can expect some low level "background" activity to be present in all samples.

We do not know, however, what the "background" activity of an uncontaminated ophthalmic glass is. We attempted, therefore, to define the glass background from the available data. In the majority of samples the count rates for both ^{212}Pb and ^{214}Pb were below 10 dpm/g. In another large group of samples at least one count rate was above 20 dpm/g. There was a scattering of count rates which lie between those regions.

We decided, therefore, to consider all glass samples in which the square root of the sum of the squares of ^{212}Pb and ^{214}Pb disintegration rates was below 20 dpm/g as uncontaminated and the mean of their count rates as the "ophthalmic glass background." 351 glass samples out of 441 met this criteria. This decision was of course arbitrary to a large degree.

The "background" values obtained from the 351 "uncontaminated" samples are as follows:

for ^{212}Pb	1.56* $\pm$ 3.89**
for ^{214}Pb	3.30* $\pm$ 4.84**

*The mean is adjusted for measurement background.

*The standard deviation includes both measurement error and the variability between the 351 samples.

Using the "ophthalmic glass background" we proceeded to estimate the percentage of "contaminated" samples in the 28 groups. The results together with the upper 80% confidence limit are given in Table 6.

Table 6

Percent (P) of "Contaminated" Lens Pressings in a Group and the Upper 80% Confidence Limit (C.L.) for the Percent

Group No.	Total Lens in Group	P	C.L.
1	15	0.00	1.18
2	22	13.64	20.35
3	16	0.00	1.10
4	10	0.00	1.76
5	20	90.00	94.91
6	16	0.00	1.10
7	15	0.00	1.18
8	16	37.50	47.89
9	16	68.75	78.02
10	16	0.00	1.10
11	18	0.00	0.98
12	16	0.00	1.10
13	18	0.00	0.98
14	15	0.00	1.18
15	12	0.00	1.47
16	15	100.00	100.00
17	16	0.00	1.10
18	16	25.00	34.60
19	16	75.00	83.50
20	15	0.00	1.18
21	15	0.00	1.18
22	11	0.00	1.60
23	15	0.00	1.18
24	16	0.00	1.18
25	16	0.00	1.10
26	15	0.00	1.18
27	16	50.00	60.45
28	18	72.22	80.61

Summary and Discussion

We have performed radiation measurements on 441 ophthalmic glass samples containing 140 different types of glass, which were divided into 28 groups according to their chemical composition and manufacturer.

90 samples (20%) exhibited activity in excess of 20 dpm/g, out of which 7 samples (1.6%) exhibited activity in excess of 50 dpm/g. Nine out of 28 groups contained samples with activity in excess of 20 dpm/g. Several of these groups consisted of several types of glass, and in some cases all the "contaminated" pressings came from a limited number of glass types. The most notable example of this is Group 18. There are ten types of glasses in this group, four of which contain "contaminated" samples. The "contaminated" samples have an average count rate for ^{212}Pb of 56.28 dpm/g, while others have an average of 3.60 dpm/g for ^{212}Pb.

This example illustrates that some of the groups are very broad in their coverage of glass types. It should also be noted that the variability within some types of glass is very large. For example, one glass type in Group 19 showed count rates of 125, 7.78, 359, and 197 dpm/g or a range of over 350 dpm/g for just four pressings.

Since sample size restrictions forced many types of pressings to be restricted to having just one or two representatives, the possibility exists that some of the lower count rates seen may be low outliers. Thus, one must also have a degree of suspicion for the "uncontaminated" groups which consist of several glass types which have only a few representatives.

The radiation survey of ophthalmic glass performed by us was of a limited scope and we were unable therefore to obtain definitive answers to all questions that we posed; however, the following preliminary conclusions can be drawn.

1) Due to widely varying ratios of ^{232}Th to ^{228}Th and non-equilibrium conditions observed in ophthalmic glass samples, it is clear that specifications of allowable presence of source material in weight percent do not adequately specify the radiation emitted from ophthalmic glass by radionuclides in the thorium series. The same is also true for the uranium series. There is an obvious need to set standards which will directly relate to radiation emissions from ophthalmic glass. One possible way is to specify the maximum allowable contamination by ^{228}Ra and ^{228}Th (for the thorium series) and by ^{226}Ra (for the uranium series). The ^{228}Ra could probably be identified by measuring the gamma from ^{228}Ac, the ^{228}Th by the gamma from ^{212}Pb, and the ^{226}Ra by the gamma from ^{214}Pb.

2) From the measurements performed it appears, although it is not proven, that radioactive contaminations are mainly present in some batches (but not all) of rare earth and zirconium oxides used in the manufacture of certain ophthalmic glasses.

3) Widely different radiation levels were observed in glasses having the same catalog number and made by the same manufacturer, depending upon the date of the manufacture. This suggests that with proper quality control it should be possible to manufacture all ophthalmic glasses with a very low radioactive contamination.

The radiobiological significances of ophthalmic glass contamination by alpha emitters is discussed in the report by G. W. Casarett et al, entitled "Radiobiological Evaluation of Thorium in Optical and Ophthalmic Glass." The relationship between the ^{212}Pb and ^{214}Pb activity and the possible dose to the germinal cells of the cornea are given in a report by C. A. Tobias and A. Chatterjee, entitled "Penetration of the Human Eye by Alpha Particles from Glasses Containing Radioactive Isotopes." (See, in particular, Tables XII and XIV, and Figures 6, 7, and 9.)

Both reports are enclosed.

RADIOBIOLOGICAL EVALUATION OF THORIUM IN OPTICAL AND OPHTHALMIC GLASS

A Report to the
Directorate of Regulatory Standards,
U.S. Atomic Energy Commission

prepared by:

George W. Casarett, Ph. D.
Cornelius A. Tobias, Ph. D.
Marvin Goldman, Ph. D.
Budd Appleton, M.D.
Victor E. Archer, M.D.
David G. Cogan, M.D.

November 1974

TABLE OF CONTENTS

THE RADIOBIOLOGICAL PROBLEM OF THORIUM IN OPTICAL AND OPHTHALMIC GLASS

I. INTRODUCTION

For this report the term optical glass (or lenses) refers to ocular (eyepiece) glass lenses used in special instruments, for example, telescopes or microscopes. The term ophthalmic glass (or lenses) refers to ordinary standard glass lenses such as those used in spectacles. The term thorium-contaminated glass (or lenses) refers only to glass that is nonintentionally contaminated with thorium or other radioactive materials as a consequence of the natural presence of these "source materials" in the natural raw materials (silicates) used in the manufacture of the glass. The terms thorium glass (or lenses) and thoriated glass (or lenses) are used to refer to glass to which thorium has been intentionally added in manufacture, in addition to natural contamination, to achieve certain properties.

Currently the AEC exempts from regulation or license the possession or use of any "source material" (uranium or thorium or any combination thereof) up to 0.05% by weight in any chemical mixture, compound, solution or alloy.

Rare earth materials in silicates include about 0.1% thorium by weight. The maximum allowable limit of thorium, uranium or any combination of these in rare earth oxides used in the manufacture of optical or ophthalmic glass is 0.25% by weight. Therefore, it is conceivable that

such glass lenses could contain more than 0.05% thorium as an unintentional natural contaminant.

Thorium usually is not added intentionally in the manufacture of ophthalmic glasses. Thorium glass is unsuitable for ophthalmic lenses. Ophthalmic glasses may contain, however, traces of radioactive impurities from various sources, including thorium, to a small fraction of one percent.

Up to 30% thorium has been intentionally included in the manufacture of certain types of optical glass used in optical instruments such as telescopes and microscopes, to achieve certain properties. These glasses are used for highly specialized purposes. AEC regulations prohibit the use of such thorium glasses close to the eye, as in the case of eyepiece (ocular) lenses. In a few instances, however, thorium glass has been found in parts of instruments that are normally used close to the eye.

A hazard of the use of thorium-containing lenses in optical instrumental eyepieces is the exposure of the eyes and contiguous tissues to ionizing radiation.

This report addresses the following specific questions.

1. Can eye damage be expected from the radiation emanating from thorium, uranium, actinium and their daughter products in optical eyepiece lenses and ophthalmic lenses, and, if so, under what conditions?
2. Can the significance of the presence of these radioactive substances in these lenses, with regard to public health, be assessed on the basis of currently available information, and, if not, what additional information is required?

II. PHYSICAL DEFINITION OF THE PROBLEM

^{232}Thorium is an isotope of long half-life and the parent of the "thorium series" of natural radioactive isotopes. In this series, ^{228}Th, another thorium isotope, is also present. Furthermore, radioactive thorium occurs as ^{231}Th and ^{227}Th in the actinium series, and as ^{230}Th and ^{234}Th in the uranium series. Of these, ^{232}Th is of the greatest consequence, unless uranium or some of its daughters are also present. In addition, ^{229}Th occurs in the neptunium series, and there are five other thorium isotopes, ^{223}Th, ^{224}Th, ^{225}Th, ^{226}Th; these latter are probably not important for the safety problem being considered.

The isotopes pertinent to the problem at hand are those that emit alpha rays. These are shown in Tables I, II and III for the thorium, actinium and uranium series, respectively.

Table I

THORIUM SERIES

ABBREVIATED TABLE OF CONSTANTS[1]

	RADIATION	HALF-LIFE	DECAY ENERGY[2] MeV
^{232}Th	α γ	1.41×10^{10} yr	4.08
^{228}Ra	β γ	5.77 yr	0.055
^{228}Ac	β γ	6.13 hr	2.14
^{228}Th	α γ	1.913 yr	5.52
^{224}Ra	α γ	3.64 d	5.79
^{220}Rn	α γ	55 s	6.41
^{216}Po	α	0.16 s	6.91
^{212}Pb	β γ	10.6 h	0.58
^{212}Bi	α β γ	60.6 m	β2.25 α6.21
^{212}Po	α	3.04×10^{-7} s	8.78
^{208}Tl	β γ	3.1 m	4.99
^{208}Pb	Stable	Stable	

[1]Based mainly on: C. M. Lederer, J. M. Hollaender and I. Perlman, Table of Isotopes, 6th ed., Academic Press, 1967.

[2]Alpha-particle energies are somewhat below the decay energy.

Table II

ACTINIUM SERIES
ABBREVIATED TABLE OF CONSTANTS

	RADIATION	HALF-LIFE	DECAY ENERGY MeV
^{235}U	α γ	7.1×10^{8} yr	4.681
^{231}Th	β- γ	25.5 h	0.381
^{231}Pa	α γ	3.25×10^{4} yr	5.15
^{227}Ra	β- γ	21.6 yr	0.043
^{227}Th	α γ	18.5 d	6.15
^{223}Ra	α γ	11.4 d	5.98
^{219}Rn	α	4.0 s	6.95
^{215}Po	α	1.8×10^{-3} s	7.5
^{211}Pb	β- γ	36 m	1.37
^{211}Bi	α99.72% βγ 0.28%	2.15 m	6.75
^{211}Po	α γ	0.52 s	7.6
^{207}Ti	β- γ	4.8 m	1.44
^{207}Pb	Stable	Stable	

Table III

URANIUM SERIES
ABBREVIATED TABLE OF CONSTANTS

	RADIATION	HALF-LIFE	DECAY ENERGY MeV
^{238}U	α	4.51×10^9 yr	4.268
^{234}Th	β-	24.1 d	0.263
^{234}Pa	β- 1T.	1.17 m 6.75 h	2.23
^{234}U	α	2.5×10^5 y	4.856
^{230}Th	α	8×10^4 y	4.77
^{226}Ra	α	1600 y	4.97
^{222}Rn	α	3.82 d	5.59
^{218}Po	α β	3.05 m	α6.111 β0.28
^{214}Pb	β-	27 m	1.04
^{214}Bi	α β	19.7 m	α5.62 β3.28
^{214}Po	α	1.64×10^{-4} s	7.84
^{210}Ti	β-	1.3 m	5.5
^{216}Pb	α β-	21 y	α3.72 β0.061
^{210}Bi	β- α	5 d 3×10^6 y	β1.16 α5.04
^{210}Po	α	138.4 d	5.41
^{206}Pb	Stable	Stable	

The decay schemes of the thorium series shown in Table I and in Figure 1 indicate that, if all daughters are present in equilibrium, the rate of alpha emission is six times that from pure ^{232}Th. Even if the initial product has pure thorium, due to the rapid equilibration with some of its daughters, the rate of alpha-particle emission is usually not less than three times the rate of alphas from ^{232}Th alone.

About 30% uranium contamination by mass of thorium in equilibrium with its initial daughters yields radioactivity of ^{230}Th about equal in disintegration rate to ^{232}Th; potentially seven additional alpha-active decay products of uranium can be present also (see Table III and Figure 3). Daughters of ^{235}U with six alpha emitters among them may also produce additional radiation (see Table II and Figure 2). Thus, it is important to consider the possible presence of uranium and actinium and their decay products in thorium-containing glass samples.

B. Isotopes that May Contribute to Thorium Hazard

We shall first consider ^{232}Th in equilibrium with its decay products. One gram of this isotope emits about 4102 alpha particles per second. It follows that, if it is incorporated in glass of 4.5 cm^{-3} density, typical for optical glasses, then a concentration of 1% by mass yields 183 alpha particles sec^{-1} cm^{-3}. The alpha particle flux density on the surface of a glass containing 1% thorium in secular equilibrium with its daughters will be 0.39 particles sec^{-1} cm^{-2} (assuming that the range of the alphas in glass is 3.137×10^{-3} g cm^{-2}).

It is possible that natural uranium is present as a contaminant in the raw material used for the thorium glasses. Even if this uranium and its decay products are chemically separated from thorium prior to its incorporation into glass, the rate of alpha decay could be significant, since ^{230}Th, an isotope of 8×10^4 year half-life, emits alpha particles (see Table III and Fig. 3). If glass contained 1% uranium, the alpha disintegration rate of either ^{238}U or of its daughter, ^{230}Th (ionium) would be 558 particles per second in one cm^3 of glass. If the uranium were chemically separated out, this might still leave a ^{230}Th contamination of 2×10^{-3}% by mass in ^{232}Th, only detectable by mass spectroscopic or counting techniques; yet, this small amount of thorium would still contribute 558 alpha particles per second per cm^3.

Uranium can also cause the potential presence of alpha-particle emitters due to ^{235}U which is present with natural abundance of about 1/140. If uranium is a potential 1% contaminant, then there would be about 25 alpha particles sec^{-1} cm^{-3} contributed by it. Even if uranium is chemically separated, members of the actinium series might still be present. For example, the amount of protactinium isotope ^{231}Pa in equilibrium with the 1% uranium contaminant would represent only 5×10^{-8}% by weight of the contaminated glass. ^{231}Pa has a half-life of about 3.25×10^4 years. In some glass samples, A. Smith and J. McCaslin demonstrated the presence of ^{227}Ac, which is formed by decay of ^{231}Pa, as well as several of its daughters.

To summarize the above, one may state that ordinary chemical or physical measurements of the amount of thorium present cannot define precisely the amount of alpha, beta or gamma-emitting radionuclides. Decay products of thorium, isotopes from the decay of uranium and trace contaminants of other heavy elements can very significantly alter the number of particles and quanta emitted.

Preliminary analysis of glass samples submitted has demonstrated the presence of some alpha-active contaminants (see below). The recommendations will extend to the measurement of thorium and to possible hazards from its contaminants.

C. Summary of Measurements Obtained from Industrial Sources

Some optical glass samples from various industrial sources were surveyed for alpha and gamma radioactivity by means of three different techniques. Table IV, which contains some of these measurements, is presented only to demonstrate the need for further studies on the radioactivity of industrial glasses and for standardization of the manner in which such measurements are to be carried out in the future. An analysis of the numbers obtained would indicate that the Eberline portable scintillation counter is probably not sufficiently sensitive at low alpha-counting levels. The Frisch grid ionization chamber appears to be the most sensitive; at high concentrations of thorium, ionization chambers and fluorescent counters differed by a factor of about two.

An unexpected result appeared using ionization chambers to check low-thorium concentration samples; these samples had industrial labels specified

Table IV

SOME MEASUREMENTS OF THE ALPHA PARTCLES

EMITTED FROM INDUSTRIAL GLASS SAMPLES[1]

Sample	Thorium Content on Label %	Eberline Scintillation Counter[2] Counts min^{-1} cm^{-2}	Fluorescent Counter[3] Cts min^{-1} cm^{-2}	Alpha Ionization Chamber[4] Cts min^{-1} cm^{-2}
Lak-11	0.002	1.4	--	3.8
Lak-N-12	0.002	--	--	5.01
Lak-N-14	0.002	--	--	16.0
Lak-F	23	112	--	640
Lak-N-18	19	237	--	570
Lak-N-19	21	267	--	513
82291	18.1	--	253	--
86200	18.4	--	310	--

[1] Reports on these measurements are on file with S. Yaniv, Office of Regulations, USAEC, Washington, D.C. 20545.

[2] A portable health survey instrument.

[3] R. C. McMillian and S. Horne, U.S. Army, Fort Belvoir, Virginia.

[4] A. Smith and J. McCaslin, Lawrence Berkeley Laboratories, Frisch grid ionization chamber with 2 Pi solid angle.

by the manufacturers, indicating thorium content of about 0.002% or less. The alpha counting rates obtained from ionization chambers were more than ten times higher than expected.

In order to identify the sources of alpha-particle activity in the three "low-thorium" samples (Lak-11, Lak-N-12 and Lak-N-14), gamma-ray spectra were also obtained from some of the samples. The gamma-ray spectra identified the source of contamination in the "low-thorium" series as ^{235}U decay products, but ^{235}U itself was not present. The various isotopes in the sample very probably came from a small contamination of ^{227}Ra, a 21.6-yr half-life radionuclide; ^{231}Pa was not present. The decay products of this isotope, which are equilibrated with it, contain seven different alpha emitters, with energies between 5.0 MeV and 8.3 MeV (see Figure 3 and Table II).

Since the current status of measurements is clearly incomplete, and since some of these show alpha radioactivity in excess of that expected from samples containing 0.05% pure ^{232}Th by weight, we urge that a program be instituted to assay in detail the radioactivity of commercial glasses. This program should identify each of the radioisotopes present in significant quantities and, if possible, establish the source of these contaminants.

The measurement program should establish a standard assay method for the identification of various radioactive nuclides present in commercial glass samples. We suggest that the measurement method be based on gamma emission assay of bulk samples of glass, which will be more sensitive than alpha particle measurements with ionization chambers that depend on detection of alpha particle emission from the surface of the glass.

Pulse-height spectroscopy is also suitable for assessment of the degree of parent-daughter equilibration through measurement of the count ratio of certain gamma-ray photopeaks.

Since thorium concentrations measured by conventional methods can be misleading with regard to the amount and nature of radioactivity present, we propose that, in the future, regulations and recommendations regarding optical glasses should be based on the rate of emission and kinetic energy of alpha particles from a unit surface. This can be calculated from the results of bulk sample measurements and further checked by direct alpha counting methods.

D. Estimations of the Flux Density and Dose Due to Alpha Particles and to other Radiations Hitting the Corneal Epithelium

The flux density and dose due to alpha particles, beta rays and gamma rays from eyeglasses represents a complicated function of the thickness of air gap between optical glass and eye and of the depth of tissue below the corneal surface. Other variables are the time dependence of radioactive chain decay and magnitude of stopping power in tissue, air and glass.

In Appendix 1, Tobias and Chatterjee have calculated flux densities and doses for a variety of conditions. The dose levels quoted here are based on these calculations.

The dividing cells of the corneal epithelium may be regarded as the "critical cell layer" from the point of view of radiation injury. Usually these are located in a layer about 40 to 50 micrometers (μm) below the

corneal surface. There is normally also a lacrimal layer of variable thickness (up to about 10 μm) overlying the corneal surface. In this report the critical tissue depth, i.e., the distance from the surface of the lacrimal layer to the critical corneal cell layer is conservatively assumed to be 50 μm. For comparison, alpha radiation doses are given for tissue depths of 50 μm and 60 μm.

Professional user

It was assumed that persons using optical instruments, e.g., microscopes or telescopes, would be at exposure risk for 1000 hours annually, or about 20 hours per week. Since the users' eyes normally are quite close to the ocular of the instrument, we conservatively assumed an air gap distance of 0.1 cm between the surface of the glass and the outer surface of the lacrimal layer. Assuming also that the ^{232}Th is in equilibrium with its daughters and that the mass stopping power ratio between tissue and glass is 1.47, glass with 16% thorium by weight would deliver an alpha-particle dose of about 44 rads per year at the critical tissue depth of 50 μ, and about 18 rads at 60 μm tissue depth.

Under these circumstances, ordinary optical glass with thorium content of 0.05% by weight, would deliver an annual dose of about 0.14 rad at the critical tissue depth of 50 μm and about 0.055 rad at a depth of 60 μm. The actual dose values are very sensitive functions of the thickness of the tissue between the germinal cells and the outer surface of the cornea or lacrimal layer. The main contributions to the dose come from ^{212}Po and ^{216}Po.

With the additional assumption that the quality factor for alpha particles is twenty (see Appendix II), the annual alpha radiation dose at 50 μm tissue depth is about 880 rem for the thoriated (16%) glass and about 3 rem for glass containing only "traces" (0.05%) of thorium. At 60 μm tissue depth these doses are about 350 rem and 1 rem, respectively. These annual exposure values are greater than the general dose limit recommended for individuals of the general human population, i.e., 0.5 rem per year.

Individual wearing ophthalmic eyeglasses

It was assumed that the person wearing ordinary ophthalmic eyeglasses would have them on about sixteen hours every day, resulting in 6000 hours of use annually. An air gap distance of 1.5 cm was assumed between glass and lacrimal surface. In this situation, only ^{212}Po contributed to the critical dose. This isotope has 8.78-MeV alpha particles. Calculations were made for radioactive equilibrium. For ordinary ophthalmic eyeglasses containing only "traces" of thorium, the annual dose at the critical tissue depth of 50 μm is about 0.2 rad, and the annual dose at 60 μm tissue depth is about 0.1 rad. By way of example of an unlikely, unintentional case, for eyeglasses with 16% thorium by weight the annual dose would be about 70 rads at 50 μm tissue depth and about 32 rads at 60 μm tissue depth.

Use of the quality factor, QF = 20, gives an annual dose of about 4 rem at 50 μm tissue depth (2 rem at 60 μm tissue depth) for wearers of ordinary ophthalmic glasses, whereas in the unintentional case of one wearing

thoriated glasses (16% thorium by weight), the annual dose would be about 1400 rem at 50 μm tissue depth or about 640 rem at 60 μm tissue depth.

Dose to the germinal layer from daughters of the uranium and actinium series

We have demonstrated in this report that ordinary optical or ophthalmic glasses sometimes have contamination from daughters of the uranium and of the actinium series. Quantification for these in terms of weight is meaningless. We are assuming that the amounts are expressed in curies of the parent isotope per gram glass. In these units 0.0547 nanocuries of a given isotope emit the same number of alpha particles per unit time as 0.05% ^{232}Th contamination. For equivalent radioactivity of the parent isotopes ^{226}Ra and ^{231}Pa, we have the following dose ratios, expressed in rads, at 50 μm tissue depth and 1.5 cm air gap for alpha particles.

$$\frac{\text{Dose (thorium series)}}{\text{Dose (Ra daughters)}} = \frac{3}{2}$$

$$\frac{\text{Dose (thorium series)}}{\text{Dose (Pa daughters)}} = \frac{3}{2}$$

Thus, minor radioactive contamination in optical eyepiece or ophthalmic glass from the U and Ac series can produce significant alpha exposure of the corneal epithelium.

Dose due to beta and gamma rays

At the 50 μm tissue depth in cornea, the doses from beta radiation of thorium daughters are of the same order of magnitude as those from alpha radiation. From glass containing 0.05% thorium, with exposure of 6000 hours, the dose is between 0.24 and 0.58 rads per year at the germinal

layer. Since, for beta radiation, the Quality Factor is one, the rem dose from beta radiation is much less than that from alpha rays. Doses from gamma radiation are smaller than those from beta rays.

III RADIOPATHOLOGIC EFFECTS

There is no adequate information bearing directly on the effects of low rates of protracted alpha irradiation from external sources on the tissues of the eye or contiguous structures in man or experimental animals. Therefore, there is no direct evidence bearing upon the tolerable levels of alpha irradiation of these structures under these conditions of exposure.

Since uranium mine workers are routinely exposed to a certain concentration of radon and its daughter products in air and to other radioactive dust, it is conceivable that some of these individuals might develop eye lesions as a result. Actually the range of alpha particles emitted from radon is not sufficient for a significant number to reach the dividing layers of germinal epithelium of the cornea. Radioactive dust particles can deposit on the surface of the eye, however. No excessive incidence of ocular lesions has been observed or reported in uranium mine workers, incidental to studies of lung cancer risk in relation to atmospheric alpha-irradiation exposure from radon and radon daughter products. It should be noted that the detection or assessment of ocular effects was not the object of study in this case, however. We know of no reports that indicate the appearance of radioactivity in the eye structures resulting from inhaled or ingested natural radioactivity.

No unusual incidence of pertinent ocular lesions has been observed or reported among individuals who use ordinary ophthalmic glasses or optical eyepiece lenses which might have had a high thorium content.

Three categories of possible ocular damage must be considered in relation to radiation from external sources of thorium, namely: (1) degenerative or inflamatory lesions in the superficial epithelia of the eye and contiguous structures; (2) oncogenic effects in these structures; and (3) effects on the crystalline lens. If the dose is high enough, alpha radiation might contribute to the first two categories of effects, and the more penetrating, low-LET radiations might contribute to all three types.

A. Degenerative or Inflammatory Lesions

The bulk of radiopathologic experience with radiations of low linear energy transfer (LET) (X-, beta- and gamma- radiations) indicates that the dose rates (in rads) from either 16% thoriated glasses or glasses with lower thorium content are too minor to cause significant inflammatory lesions and that the degenerative lesions from these radiations would probably remain unnoticed in skin or other structures with epidermoid or stratified squamous epithelium (such as conjunctiva, eyelid mucosa, or corneal epithelium).

However, in view of recently increasing radiobiologic evidence that the effectiveness per rad of high-LET radiations for a variety of non-neoplastic and neoplastic effects is little diminished at low doses and dose rates, as compared with X- and gamma-radiations, and the relative

biological effectiveness (RBE) of high-LET radiations rises as dose and dose rate decrease, it should be recognized that a QF value only as high as the commonly used value of 20 for alpha radiation may not be as high as the actual RBE at low doses and dose rates for some effects. The annual alpha radiation doses in the critical tissue layer at 50 μm depth (germinal layer of the corneal epithelium) which may be obtained by multiplying the rad dose by the quality factor of 20, turned out to be as follows:

1. When optical glasses of 16% thorium content are used 0.1 cm from the cornea for up to 1000 hours per year, the rem dose might be as high as 880 rem/year. For 0.05% thorium the dose is about 3 rem/year.
2. When ordinary ophthalmic spectacles are used with thorium content of 0.05% or less, for up to 6000 hours per year, the rem dose might be about 4 rem/year.

The exposure from the thoriated glass would in all probability cause some degenerative changes; these might remain masked due to the high regenerative power of the cornea. The exposure from ordinary ophthalmic spectacles is not likely to cause detectable degenerative changes.

It is difficult to be certain on the basis of experience with radiations other than alpha radiation that such annual doses of alpha radiation (in rems), or perhaps even higher doses in rems if the RBE is considerably higher than 20, would not eventually cause, or at least combine substantially with other conditions to cause a significant

incidence of degenerative or inflammatory lesions in epithelia so exposed which might be detectable if studied adequately.

A 30% thorium contamination in glass lenses could give doses nearly twice those cited for the 16% thoriated lenses.

B. Oncogenic Effects

Since there has been no definitive study of possible radiation-induced neoplasms in ocular and contiguous tissues, much less any study of this effect in relation to protracted alpha radiation from thorium-containing lenses or other external sources, the possible oncogenic effect of these lenses must be considered theoretically in terms of the present state of philosophy, knowledge and estimates of risk of radiation-induced cancers of various kinds.

With ever-increasing follow-up time in epidemiologic studies of leukemia and cancer incidence in relation to radiation exposure, there has been increasing evidence of radiation induction of neoplasms of relatively long latency and at lower doses in many tissues of the body. For the various types of neoplasms on which there are presently sufficient data to provide or allow approximation and assumption of dose-effect relationships, estimates of risk per rad have been made on the basis of linear dose-effect relationships or the assumption of such a relationship. On the basis of such observed or assumed linear relationships at higher doses, upper limits of possible risk at low doses and dose rates far below the levels of observation (where the actual risk per rad could be much lower or even approach zero for low-LET radiation, but not necessarily so for high-LET radiation) have been estimated by means of extrapolation (e.g., in the NAS-NRC BEIR Committee Report, 1972).

On this basis the BEIR Committee (1972) estimated the risk of radiation induction of the following neoplasms, in terms of excess deaths (or cases) per 10^6 persons exposed per year per rem to pertinent target tissue, to approximate: 1 for leukemia (all forms except chronic lymphocytic); 2.5-9.3 (cases, not deaths) for thyroid cancer for exposed children (risk several times greater for children than adults); 1 for lung cancer; 3 for breast cancer for exposed women; 0.2 for cancer of skeleton; 1 for cancer of the gastrointestinal tract; and possibly 1 for cancer at other sites not included above.

Although radiation induction of cancers of skin and other epidermoid tissues has been documented, the data on dose in relation to effect are not yet adequate to establish dose-effect relationships which can be used to yield risk estimates such as those described above. At the present time the risk per rad for radiation induction of skin cancer is regarded as either being low relative to that for leukemia or certain other cancers, or as possibly being higher than now appreciated owing to a combination of long latency, insufficient follow-up, and inadequate study to date.

The impression that tumors of cornea are generally very rare has been noted. At face value, this would suggest that radiation-induced tumors of cornea would be even more rare. On the other hand, it has been noted that tumors of the limbus of the cornea and conjunctiva (especially Bowen's carcinoma) are relatively more frequent, and that most common are basal cell carcinomas of the eyelids, especially the lower lid which is the most common site in the body for such tumors.

Although sizeable doses of radiation are required to contribute substantially to the promoting factors (tissue degeneration, inflammation, etc.) of carcinogenic mechanisms, even modest doses of radiation at low dose rates may contribute substantially to the cellular initiating (mutational) factors of the mechanisms. Low radiation doses can readily induce cancers that have high "spontaneous" incidence by virtue of the provision of promoting factors by means other than the radiation doses in question. Therefore, it is wise and prudent to suspect the possibility that alpha radiation in small doses (rads) at low dose rate (high RBE) from thoriated lenses might contribute considerably to the high "spontaneous" incidence of carcinoma of epithelial tissues contiguous with the cornea, if not the cornea itself.

Recent studies have pointed to the possible synergistic effects between radiation and other carcinogenic agents. For example, uranium miners who are exposed to atmosphere of the mines develop much more lung cancer if they are also heavy smokers. Alpha particle irradiation might aggravate the possible carcinogenic effects of environmental irritants that act on the limbus of the cornea and conjunctiva.

If one accepts the linearly extrapolated risk estimates which have been made (NAS-BEIR Report, 1972) for other tissues, a possible risk of the order of 1 excess case of cancer of epithelial tissues associated with the eye per million exposed persons per year per rem to the germinal cells of these tissues may not seem grossly out of the question.

C. Effects on the Crystalline Lens of the Eye

Since alpha particles are stopped by a very thin layer of tissue, the radiation doses to the crystalline lens come from associated X- and gamma-radiation.

It is unlikely that these radiations, at the dose rates applied, would cause opacities in the human crystalline lens.

IV. DISCUSSION

In view of the discussions above, the primary radiobiological criterion in consideration of radiation protection of the public in the matter of thorium and other radioactive contaminants in optical eyepiece or ophthalmic glass lenses is the possibility of the contribution of the irradiation of the germinal cells of the epithelia of the cornea, conjunctiva, eyelids, and nearby skin to oncogenesis in these structures.

Certainly it would be worthwhile to obtain dose-effect and RBE information on the effects of protracted alpha irradiation on the eyes and contiguous tissues of experimental animals and to carry out controlled biomicroscopic and epidemiologic oncogenesis studies of persons whose eye regions have been exposed to various high levels of alpha radiation. Although such studies would take a long time to accomplish, at low dose rates, some data could be secured in small rodents with higher levels of radioactivity in 2-3 years.

Meanwhile, in view of the possible radiopathologic effects and oncogenic risks discussed above, the modern radiation protection philosophy,

requiring that radiation exposure be kept as low as practicable and that additional risk should be commensurate with added benefit, should be invoked and implemented.

The National Council on Radiation Protection (NCRP) has recommended a maximum permissible dose (MPD) for individuals in the general public that is applicable to skin, eyelids, conjunctiva, cornea and crystalline lens of eye, namely, 0.5 rem per year. Using a QF (Quality Factor) of 20 for alpha radiation would convert the 0.5 rem to 0.025 rad of alpha radiation per year.

If exposure of the germinal cells of the cornea were kept below 0.5 rem per year, it seems likely that the germinal cells of the epithelia of eyelids, conjunctiva and nearby skin would recieve no more and probably less on an integrated basis. With this limit it is virtually certain that significant degenerative and inflammatory changes would not be caused, and it appears unlikely that a significant or detectable excess in incidence of tumors of these epithelial structures would be caused.

This level of radiation dose to the germinal cells of the cornea (using a QF of 20 for the alpha radiation component) would correspond roughly to the dose received in 1,000 hours per year from a lens positioned about 0.1 cm from the surface of the cornea, as in ocular use, and containing about 0.009% thorium equilibrated with its decay products, or to the dose received in 6,000 hours per year from a lens positioned about

1.5 cm from the surface of the cornea, as in ophthalmic spectacle use, and containing about 0.006% of thorium equilibrated with its decay products.

These figures, 0.009% and 0.006% thorium in glass are exceedingly low and might present practical problems if a recommendation to enforce their limits were made.

Glass with thorium content of 0.001% produces a flux density in air of about 1.8 particles hr^{-1} cm^{-2} or less. This low intensity is comparable with alpha fluxes from radon in the atmosphere.

Gamma-ray detectors receive their signals not only from the surface but mainly from the bulk of glass. With appropriately calibrated scintillation counting and pulse-height analysis, there should be no difficulty in identifying the isotopes contained in glass, measuring the degree of approach to radioactive equilibrium and performing quantitative calibration.

We urge that a survey of available optical and ophthalmic glasses be undertaken at this time by a group qualified in radiological physics which would employ alpha-particle measuring chambers as well as pulse-height analysis. A task for such a group might be development of standardized instrumentation for the use of industry and the regulatory agencies.

The concentration of <u>thorium</u> as such is perhaps not relevant in glasses of low thorium content. It has been demonstrated (see above) that some of these glasses also contain significant amounts of other alpha activity, notably members of the actinium series.

In order to be practical, it seems prudent that the recommendations of the Committee should be to the effect that optical glasses that directly and routinely expose the eye from close distances should contain no "measurable" alpha-particle activity. The recommendations below reflect this view.

V. RECOMMENDATIONS

1. In view of the fact that exceedingly low rates of emission of alpha particles from any of the natural radioactive series can lead to significant dose accumulations in the germinal cell layers of the cornea and in epithelial layers of the conjunctive and, further, in view of the possibly high relative biological effectiveness (RBE) of alpha-particles for the production of neoplasms, we recommend that:

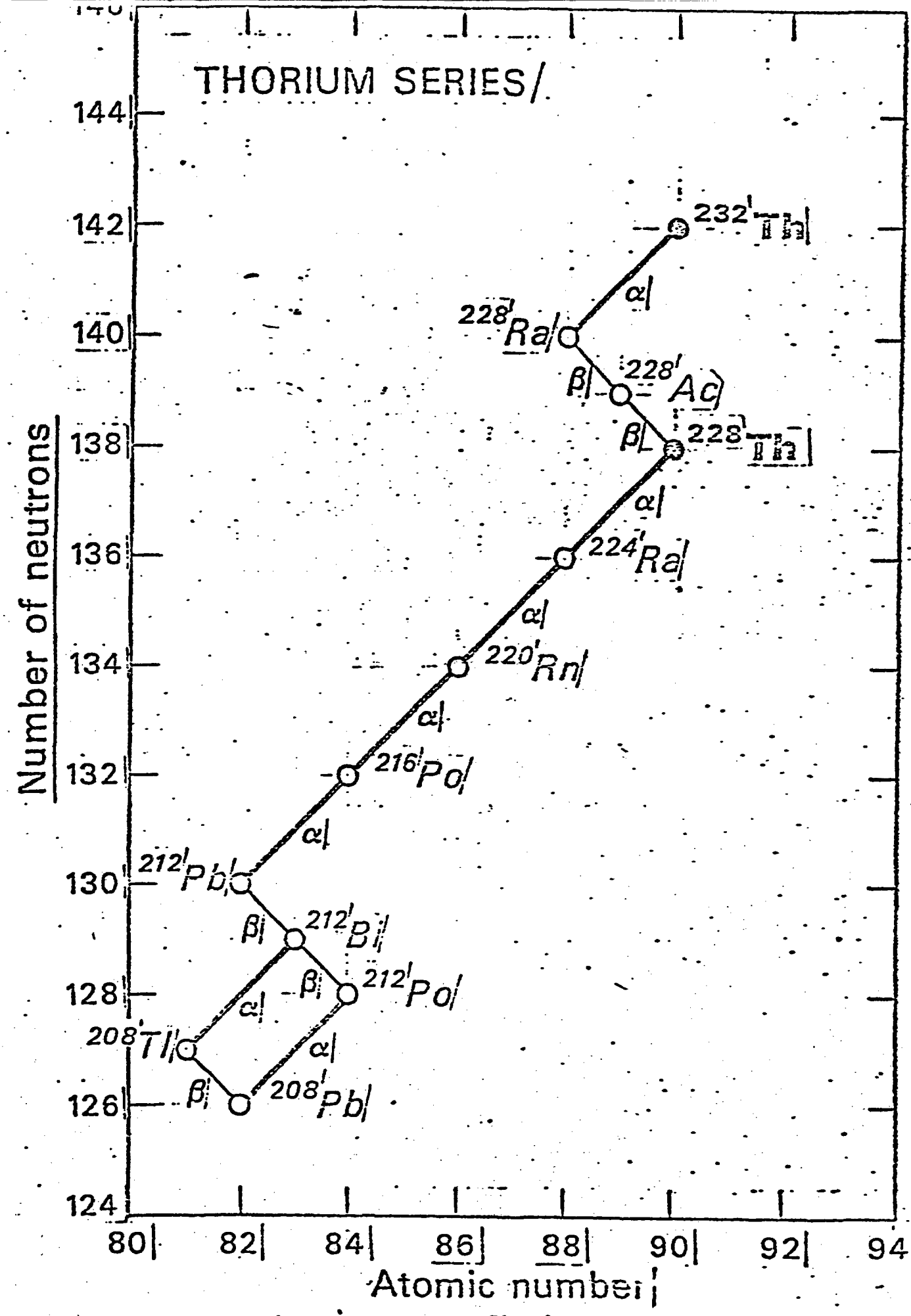
   Optical instrument eyepiece glasses and/or opthalmic eyeglasses should have at all times surface alpha-particle flux density of less than 0.15 alphas/cm^2/min. or 9 per hour.

2. In order to comply with Recommendation (1) we suggest that:

   Instrumentation and measuring methods should be standardized and made available to the appropriate industrial sources and regulatory agencies.

   In all probability a combination of surface alpha-particle monitors and gamma-ray, pulse-height spectroscopy will be involved.

The recommendations made here represent the absence of reliable data on the carcinogenic effects of alpha particles on cornea. Further clarification of this subject and, perhaps, modified recommendations, could result subsequently from a research program in which the effects of protracted alpha radiation on the structures of the eye are experimentally determined.


THORIUM SERIES
Number of neutrons
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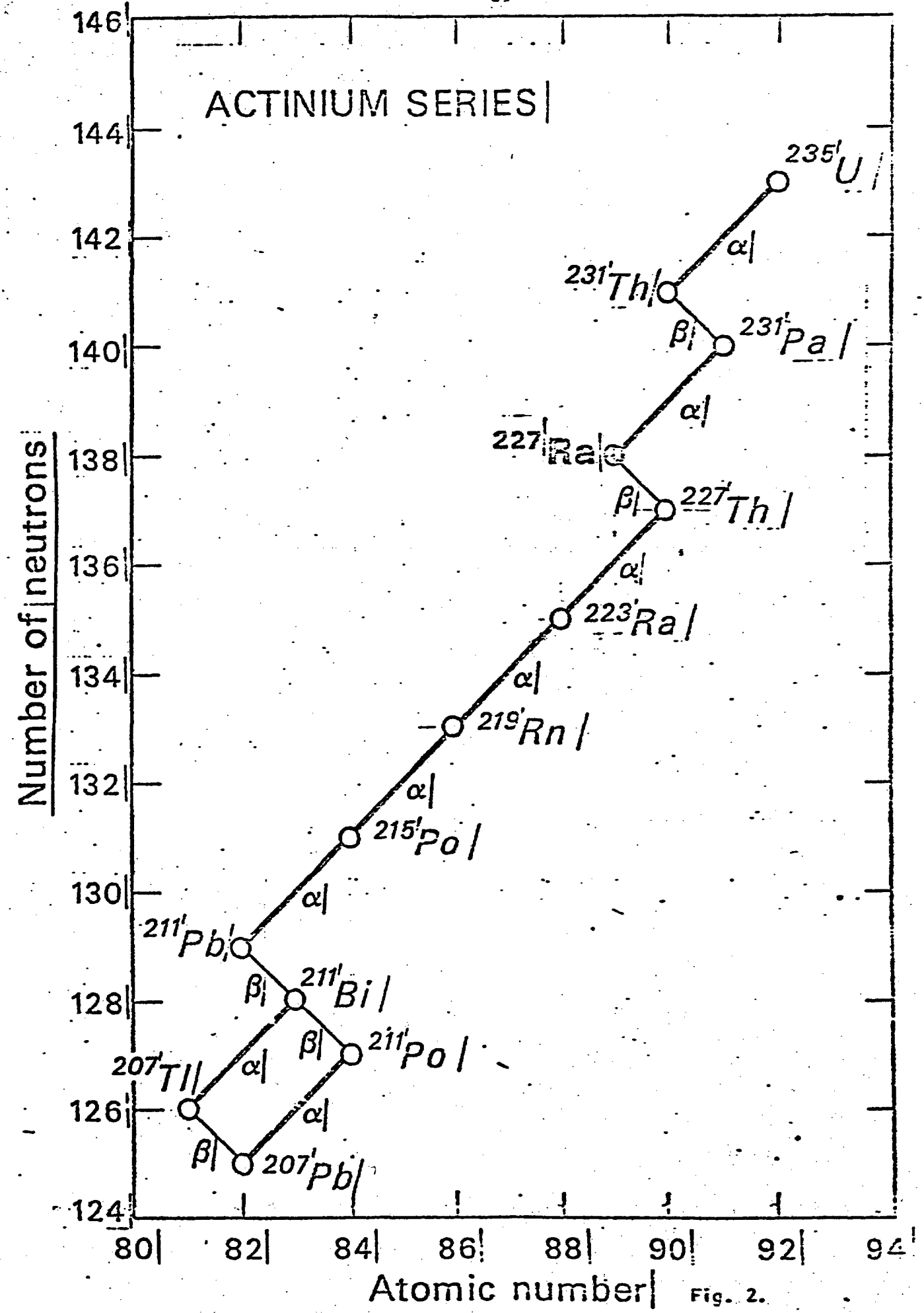
142
140
138
136
134
132
130
128
126
124
80
82
84
86
88
90
92
94
Atomic number
232 Th
α
228 Ra
β
228 Ac
β
228 Th
α
224 Ra
α
220 Rn
α
216 Po
α
212 Pb
β
212 Bi
β
212 Po
α
208 Tl
α
β
208 Pb

Fig. 1.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Atomic number
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136
134
132
130
128
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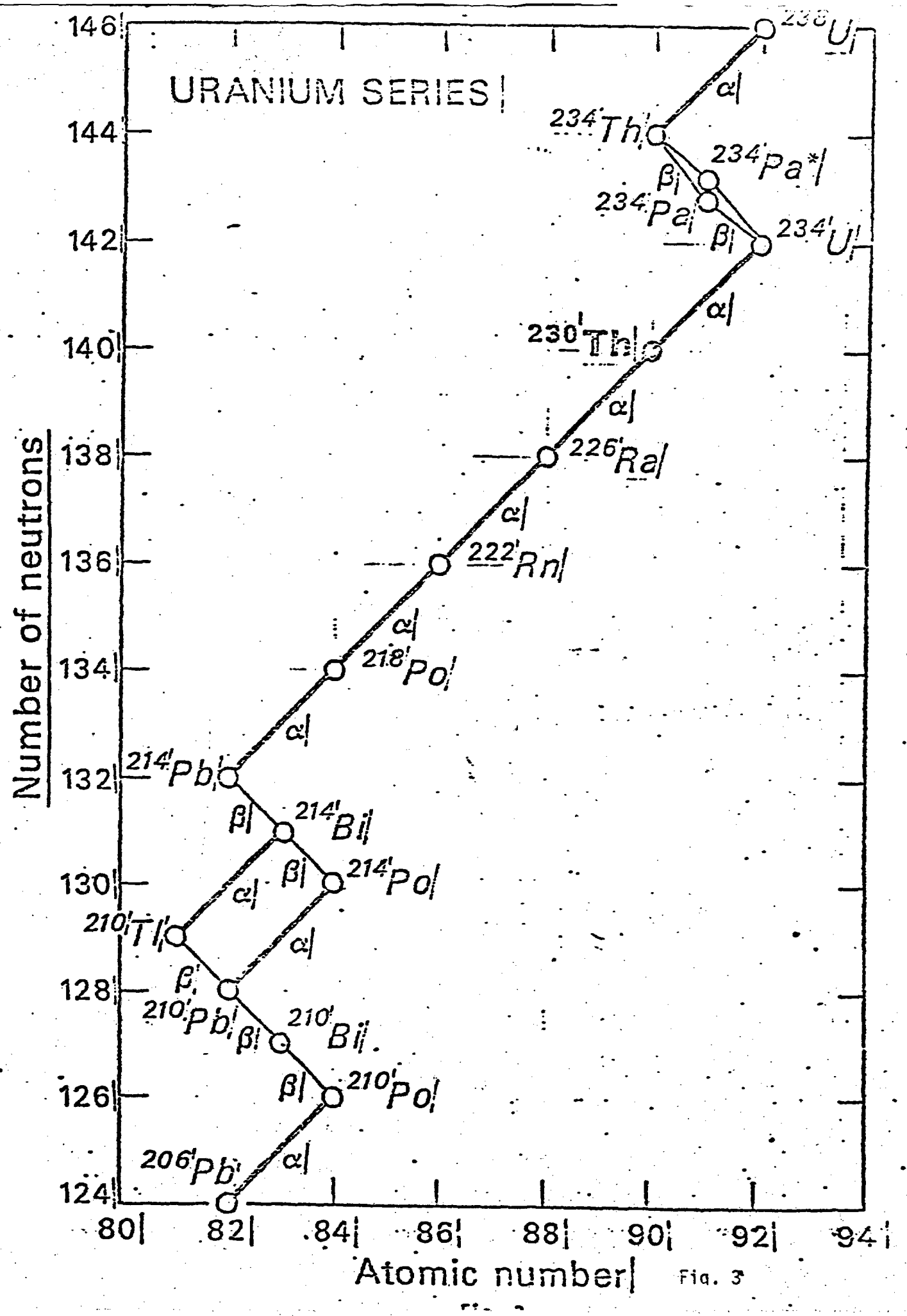
82
84
86
88
90
92
94
235U
231Th
231Pa
227Ra
227Th
223Ra
219Rn
215Po
211Pb
211Bi
211Po
207Tl
207Pb
α
β

Fig. 2.


URANIUM SERIES
Number of neutrons
Atomic number
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138
136
134
132
130
128
126
124
80
82
84
86
88
90
92
94
α
β
238U
234Th
234Pa*
234Pa
234U
230Th
226Ra
222Rn
218Po
214Pb
214Bi
214Po
210Tl
210Pb
210Bi
210Po
206Pb

Fig. 3