

**UNITED STATES OF AMERICA**  
**NUCLEAR REGULATORY COMMISSION**

**Title:**           **PROTOCOL FOR STUDY OF THYROID DISEASE**  
**IN BELARUS AS A RESULT OF THE CHERNOBYL**  
**ACCIDENT - PUBLIC MEETING**

**Location:**       **Rockville, Maryland**

**Date:**           **Friday, September 9, 1994**

**Pages:**          **1 - 46**

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1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

3 \*\*\*

4 PROTOCOL FOR STUDY OF THYROID DISEASE IN  
5 BELARUS AS A RESULT OF THE CHERNOBYL ACCIDENT

6 \*\*\*

7 PUBLIC MEETING

8 \*\*\*

9  
10 United States Nuclear Regulatory  
11 Commission  
12 One White Flint North  
13 Rockville, Maryland

14  
15 Friday, September 9, 1994  
16

17 The above-entitled meeting convened, pursuant to  
18 notice, at 1:30 p.m., Ivan Selin, Chairman, presiding.

19  
20 COMMISSIONERS PRESENT:

21 IVAN SELIN, Chairman of the Commission  
22 KENNETH C. ROGERS, Commissioner  
23 E. GAIL de PLANQUE, Commissioner  
24  
25

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1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:  
2 DR. ANDREW BATES, Office of the Secretary  
3 MARTIN MALSCH, Office of the General Counsel  
4 JAMES TAYLOR, Executive Director for Operations  
5 DR. PAUL SELIGMAN, Acting Deputy Assistant  
6 Secretary for Health, DOE  
7 DR. BRUCE WACHHOLZ, Chief Radiation Effects  
8 Branch, Cancer Etiology Division, NCI  
9 DR. HARRY PETTENGILL, Director, Office of  
10 International Health Studies, Office of the  
11 Environment, Safety and Health, DOE  
12 DR. DAVID BECKER, Professor of Radiology and  
13 Medicine, Director, Division of Nuclear  
14 Medicine, Cornell University Medical Center, New  
15 York  
16 DR. GILBERT W. BEEBE, Health Statistician, NCI  
17 DR. SHLOMO YANIV, Radiation Protection and Health  
18 Effects Branch, RES  
19 JAKE WECHSELBERGER, Office of the EDO  
20  
21  
22  
23  
24  
25

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## P R O C E E D I N G S

[1:30 p.m.]

CHAIRMAN SELIN: It's a particular pleasure for the Commission to welcome such a broad range of -- such a broadly representative panel for this very interesting topic that we have today, the briefing on the studies of the effects of iodine-131 as released by Chernobyl on the incidence of thyroid disease, particularly for cancer.

We are participating in a joint DOE and NCI study which will fill a major gap in the world's knowledge of radiation effect and could affect our own regulations. We're quite anxious to hear about this important study.

Copies of the viewgraphs are available.

Commissioners?

We're very pleased to welcome our distinguished panel today.

Mr. Taylor?

MR. TAYLOR: Good afternoon.

I'd like now to introduce those at the table. First, to my left, is Paul Seligman, who is the Deputy Assistant Secretary for Health.

Does that stop with that or the environment too?

DR. SELIGMAN: That's fine. That's fine.

MR. TAYLOR: From the Department of Energy, just recently assumed that position and we're looking forward to

1 working with him at the Department.

2 Next to him is Harry Pettengill, who is also from  
3 that office and we're very happy to have him here. He's the  
4 Director of the office under Dr. Seligman.

5 To his left is our own staff, Shlomo Yaniv and  
6 Jake Wechselberger, who are my principal assistants in this  
7 area.

8 To my right is Bruce Wachholz. I believe you may  
9 have met him before, from the National Cancer Institute, and  
10 he is responsible for these projects.

11 Next to him is Dr. Dave Becker, who is assisting  
12 us in this area and is a specialist in the thyroid area.

13 Next to him is Dr. Gil Beebe, who is assisting and  
14 is very active, I believe, potentially under the leukemia  
15 protocol. Is that right?

16 DR. BEEBE: Both.

17 MR. TAYLOR: With those opening remarks, I would  
18 like to note that we're very pleased to have this  
19 opportunity to have the group here. I've long regarded what  
20 you'll hear about today as very important, important  
21 scientifically in the area of health, important from the  
22 standpoint that what we've been able to achieve to this  
23 point and what we hope we can achieve in the years ahead  
24 will be the first really major health effects studies  
25 following the Chernobyl accident.

1           The fact that we have progressed to this point, as  
2   you will learn, has been principally due to cooperation from  
3   the Republic of Belarus and we do have a protocol signed, as  
4   the Commission knows, with Belarus and are proceeding with  
5   the finishing protocol, both in the thyroid area, finish a  
6   second protocol with the Republic of the Ukraine.

7           With those opening thoughts, I'll ask Dr. Harry  
8   Pettengill to continue.

9           DR. PETTENGILL: Thank you, Mr. Taylor.

10          Chairman Selin, Commissioners de Planque and  
11   Rogers, it's a pleasure for me to personally introduce the  
12   subject of today's briefing, health research in Belarus.

13          We at the Department of Energy feel that the  
14   information being discussed today marks significant progress  
15   on the part of the United States government to effectively  
16   partner with former Soviet scientists and medical personnel  
17   to better understand the health impacts the Chernobyl  
18   accident had on then resident populations.

19          If I could have the first slide.

20          [Slide.]

21          DR. PETTENGILL: Today's briefing will highlight  
22   the development and status of the study of thyroid disease  
23   in juvenile populations in Belarus. In addition, Dr.  
24   Wachholz will also discuss a similar study to be carried out  
25   in Ukraine and will provide preliminary information



1 regarding the intention to evaluate the incidence of  
2 leukemia in selective populations in these countries as  
3 well.

4 First, however, it might be beneficial to briefly  
5 summarize the history of the U.S. involvement and detail  
6 those actions which have led to the formulation of these  
7 health-related studies. Of course, the singular historic  
8 event which directly created the necessity of what we are  
9 discussing today is, of course, the catastrophic accident in  
10 Chernobyl on April 26th, 1986.

11 Although worldwide response with offers of  
12 assistance were immediate, political circumstances being  
13 what they were, the U.S. did not successfully negotiate a  
14 memorandum of cooperation under the auspices of the Peaceful  
15 Uses of Atomic Energy until 1988. This action, which we  
16 commonly refer to as the MOC, created what is universally  
17 known today as the JCCC, as I refer it to, the Joint  
18 Coordinating Committee for Civilian Nuclear Reactor Safety.  
19 The United States Nuclear Regulatory Commission is the  
20 designated U.S. executive agent to this memorandum of  
21 cooperation.

22 Initially, the Joint Coordinating Committee  
23 included ten specific working groups and this was later  
24 expanded to include 12 working groups. Our presence here  
25 today and my discussions will focus on Working Group 7.

1 From its inception, Working Group 7 was unique and  
2 significantly different than the other working groups.  
3 Working Group 7 was given the sole responsibility to  
4 evaluate both the health and environmental consequences of  
5 Chernobyl.

6 The DOE has a long history of involvement and  
7 support to the evaluation of impacts on workers and other  
8 populations from exposures to ionizing radiations. DOE has  
9 had extensive experience in responding to and supporting  
10 studies on an international scale as well. Examples include  
11 our involvement in studies of Japanese bomb survivors and  
12 our environmental and medical support to the Marshall  
13 Islands for nearly 50 years. The DOE therefore volunteered  
14 and was designated to oversee and manage Working Group 7  
15 activities.

16 The Department of Energy initially set up two  
17 subgroups in Working Group 7, designated 7-1 and 7-2; 7-1  
18 was to develop environmental assessment end of the business  
19 and 7-2 was designated to look at the biologic and health  
20 impact capabilities. The approach selected by the  
21 Department of Energy in those early days was to develop a  
22 wide range of pilot projects to test the feasibility to  
23 build on longer term health and environmental impact  
24 studies.

25 If I could have the next slide.

1 [Slide.]

2 DR. PETTENGILL: In 1991, in late 1991 and early  
3 1992, the world, of course, witnessed the total dissolution  
4 of the Soviet Union. This event left the United States  
5 without formal arrangements for continuing work under the  
6 Joint Coordinating Committee with either Ukraine or  
7 Belarus. As an interim measure at that point in time, the  
8 then Assistant Secretary for Environment, Safety and Health  
9 at the Department of Energy led a delegation to the former  
10 Soviet Union countries in order to give reassurance of our  
11 interest to continue activities under Working Group 7.

12 By 1993, the United States had negotiated an  
13 agreement with Ukraine which in effect reconstituted the  
14 activities of the Joint Coordinating Committee there and set  
15 it up basically as a tripartite of the United States, the  
16 Russian Federation and Ukraine. Of course, annual meetings  
17 have been held since that time with those parties. In 1993,  
18 they were held in Kiev in Ukraine and '94, this year, in  
19 Moscow, Russia.

20 The Department of Energy, to effectuate its work  
21 in Belarus, signed a letter of arrangement with Belarus to  
22 continue ongoing Working Group 7 activities as a joint  
23 effort between us and them that were initiated under the  
24 auspices of the JCCC. This arrangement remains in force  
25 today and has not hampered our progress in impending health

1 studies.

2 If we could have the next slide.

3 [Slide.]

4 DR. PETTENGILL: In the fall of 1992, shortly  
5 after these activities, the Department of Energy undertook a  
6 review of all of its Working Group 7 research progress. Our  
7 desire was to identify and essentially eliminate non-  
8 productive and non-essential areas of research, to expand in  
9 areas of more essential research and to facilitate the  
10 progress of ongoing research beyond the then pilot phase  
11 work. As a result of this review, we decided to shift the  
12 emphasis of our activities towards direct health impact  
13 studies. We intend to develop and perform traditional  
14 epidemiologic studies on designated populations in all  
15 countries of the former Soviet Union. Environmental  
16 assessment aspects of Working Group 7 activities are now  
17 today more focused on dosimetry validation and on dose  
18 reconstruction methodologies to be utilized with the study  
19 populations.

20 Two near-term health outcomes reasonably expected  
21 in any sizeable population which has been exposed to  
22 moderate or higher levels of fission product releases are  
23 often thyroid disease and leukemia. Consequently, we have  
24 designed as an essential element of our program the  
25 inclusion of studies of thyroid disease in children and

1 leukemia in the clean-up workers that received higher doses.  
2 Early in the initiation of our Working Group 7 activities,  
3 the Department of Energy chose the National Cancer Institute  
4 to lead in the development of appropriate research protocols  
5 to study these specific health outcomes in both Belarus and  
6 Ukraine.

7 Dr. Wachholz, as Mr. Taylor indicated, is with us  
8 today. Dr. Wachholz is the Senior Program manager at the  
9 NCI for these important studies and will brief us all on the  
10 significant progress to date.

11 Thank you very much.

12 CHAIRMAN SELIN: Thank you, Dr. Pettengill.

13 DR. WACHHOLZ: Thank you, Mr. Chairman,  
14 Commissioners. It's a pleasure to have the opportunity to  
15 discuss these matters with you in collaboration with our  
16 colleagues and our sister agencies.

17 If I may have the first slide, please.

18 [Slide.]

19 DR. WACHHOLZ: I think that it's fair to say that  
20 this discussion will focus on health-related activities in  
21 both Belarus and Ukraine, as was indicated by Dr.  
22 Pettengill.

23 Next slide, please.

24 [Slide.]

25 DR. WACHHOLZ: In addition to the introductions

1 that were made previously with Dr. Becker and Dr. Beebe, to  
2 my right, I'd like to mention also that Dr. Andre Bouville  
3 is with us who is an expert in dosimetry and is with the  
4 National Cancer Institute.

5 Next slide, please.

6 [Slide.]

7 DR. WACHHOLZ: As indicated a few moments ago, the  
8 primary health effects end points were thyroid disease,  
9 especially thyroid cancer and specifically among children,  
10 and leukemia in clean-up workers. Although these were  
11 identified early on as one of several activities by the  
12 Department of Energy, as was indicated more recently, they  
13 have become the focus of the interagency activities.

14 Next slide, please.

15 [Slide.]

16 DR. WACHHOLZ: NCI's involvement commenced with  
17 some study groups in 1989 with the Department of Energy but  
18 a formal interagency agreement was initiated and signed in  
19 1990. As a part of that agreement, the NCI was requested to  
20 work with our Soviet counterparts, our then Soviet  
21 counterparts to, one, develop protocols for and implement  
22 long-term follow-up studies of thyroid disease, especially  
23 cancer, and secondly to develop protocol for the study of  
24 leukemia, and that's among the cleanup workers.

25 In the other half of the agreement, the Department

1 of Energy agreed to provide financial support in the form of  
2 equipment and supplies associated with the need for these  
3 studies. NCI and DOE reached agreement on matching support  
4 for infrastructure and administrative expenses, and I'd just  
5 mention in addition to that being a financial support that  
6 at present there is on the order of about six and a half  
7 FTEs at NIH that are working on these activities. Of course  
8 you're familiar with the support from the Nuclear Regulatory  
9 Commission that was referred to earlier.

10 The first thing we did was form two working  
11 groups, recognizing that not all expertise resides in the  
12 government. We have a working group of ten physicians and  
13 scientists on the thyroid studies and the chairman of that  
14 group is with us today, Dr. Becker. I would just point out  
15 that there are five people on here who are not government  
16 employees and I would just like to mention for the record  
17 that they all have volunteered their time over the last  
18 three or four years, which amounts to months of time that  
19 they have taken out of their schedules to assist us in this  
20 effort.

21 The areas of expertise cover the range of  
22 disciplines, dosimetry, dose reconstruction, endocrinology,  
23 radiation, thyroid disease, nuclear medicine, laboratory  
24 techniques, epidemiology and statistics. We recently have  
25 been in the process of adding additional names to this as we

1 begin to implement the operational side of things overseas,  
2 bringing in people who are fluent in the Russian language  
3 and that can supplement and stay for periods of time in  
4 Minsk or in Kiev to work with us on-site.

5 Next slide, please.

6 [Slide.]

7 DR. WACHHOLZ: We have a similar group working  
8 with us on the leukemia studies. That group is chaired by  
9 Dr. Beebe, who is two chairs to my right. Again, what I  
10 said with regard to volunteers for the thyroid group  
11 pertains also to the leukemia group.

12 Next slide, please.

13 [Slide.]

14 DR. WACHHOLZ: The first question is why do we  
15 have an interest in the thyroid, especially in the area of  
16 Chernobyl? First of all, the risk of thyroid cancer from  
17 exposure to I-131 is not known. Secondly, should there ever  
18 be a major release of fission products, I-131 is likely to  
19 be a major source of exposure to the public. To date, there  
20 have been several accidental reactor releases of I-131 which  
21 are listed on the slide. They give you a comparison of the  
22 magnitude of I-131 released, 20,000 curies wind scale, 15 at  
23 TMI, compared to 30 million at Chernobyl.

24 At the same time, there were approximately a  
25 million or over a million children exposed from the releases



1 at Chernobyl. Of those children at the time of and shortly  
2 following the accident, there were something over 100,000  
3 children whose thyroids were measured. One can question the  
4 uncertainty associated with those measurements. Different  
5 types of instruments, different types of shielding,  
6 calibration and so on, but nevertheless they are real  
7 measurements on real children.

8 I'd like to ask for the 35 millimeter slide, if I  
9 may, just to bring you to the geography here.

10 [Slide.]

11 DR. WACHHOLZ: This is a map of Chernobyl down in  
12 here. This is a map of cesium distribution and you have two  
13 major areas, obviously the area immediately around Chernobyl  
14 and area up in the area of Belarus, the Gomel area of  
15 Belarus. Some 70 percent of the fallout, as you know,  
16 occurred in Belarus, with other parts being mainly in  
17 Ukraine.

18 Next slide, please.

19 [Slide.]

20 DR. WACHHOLZ: What is the situation that exists  
21 there now? And this is the first of several viewgraphs or  
22 overheads that will give you reasonably up to date  
23 information. First of the number of thyroid cancers that  
24 have been identified in children. I should say persons who  
25 were children at the time of the accident. You can see that

1 in 1986 and 1987 you had very few. It began to build in  
2 1990 and really had major impact in 1991, '92 and so on.  
3 For 1994, the number is through the end of June.

4 Now, the question has been raised both  
5 scientifically, medically in the international community and  
6 so on, is all this due to radiation? At this point I don't  
7 think anyone could say based on hard scientific data, yes,  
8 it's due to radiation or to I-131. However, the temporal  
9 and spatial distribution of the cases certainly is  
10 suggestive and the circumstantial evidence is very strong.  
11 Initially there were questions are these really cancers, are  
12 they diagnosing them correctly? Pathologists in the United  
13 States as well as in the UK, as well as in Switzerland, have  
14 gone over these slides and I would say with over 95 percent  
15 confirmation of the original diagnosis. So, yes, they in  
16 fact are thyroid cancers.

17 The next question is are they due to radiation?  
18 While the circumstantial evidence is very strong, one cannot  
19 exclude some contributing factors such as ascertainment, the  
20 fact that these children are being looked at more  
21 intensively and with more sophisticated equipment than was  
22 previously the case, as well as possibility of other  
23 contributing factors. That's one of the reasons for some of  
24 these studies, to sort this all out and come up with some  
25 hard numbers.

1           COMMISSIONER de PLANQUE: Bruce, of course there's  
2 always the question are you finding more because you're  
3 looking? But also the degree to which this was  
4 investigated, is there a trend with that, a trend in time  
5 with just the degree of looking?

6           DR. WACHHOLZ: Yes, you'd have to say that there's  
7 --

8           COMMISSIONER de PLANQUE: In other words, did they  
9 look for more in 1990 than they looked in 1987?

10          DR. WACHHOLZ: Well, the degree of sophistication  
11 with which they looked and the breadth with which they  
12 looked increased in the years following. For example, WHO  
13 provided considerable equipment and ultrasound diagnostic  
14 units and so on, which really did not begin until about  
15 three years after the accident. So, after that, then you  
16 began to get these large increases. So, the answer to your  
17 question in the yes or no is yes. The extent to which  
18 that's a major contributing factor we have to sort out.

19          COMMISSIONER de PLANQUE: Can you give us any idea  
20 on the latency period?

21          DR. WACHHOLZ: Well, this was one of the reasons  
22 there were so many questions at the very beginning as to are  
23 these real. Dr. Becker may wish to amplify on this, but the  
24 expected time frame for the appearance of these was  
25 considered to be an absolutely minimum of about five years,

1 maybe longer. When they began to be reported in 1989, three  
2 years after the accident, and then 1990, four years,  
3 people's eyebrows went up and, "Are these real? Are they  
4 real cancers?" There were many speculations at that time as  
5 to whether they were real or not and that's why I say we as  
6 well as others have gone through all the pathology. But  
7 yes, there are questions on the latency. But I think at  
8 this point it's reasonably accepted that these cancers are  
9 real and, yes, they did occur earlier than expected.

10 Next slide, please.

11 [Slide.]

12 DR. WACHHOLZ: The next slide is in part a repeat  
13 of what you just saw. However, it does put it in the  
14 context of comparison with adult thyroid cancers and you  
15 have to look at the vertical axis on either side for the  
16 comparison. To the left is the numbers for adults, to the  
17 right the numbers of children. This is presented only to  
18 show that there is an increase also in adults, although our  
19 interest is primarily if not exclusively in children. If  
20 you look at the increase, it's perhaps a three times  
21 increase for adults, whereas with regard to children it's  
22 40, 50, 60, 70 times higher. There are reasons for this.  
23 I'll be glad to go into them, if you wish. Otherwise, we  
24 can move along.

25 Next slide, please.

1 [Slide.]

2 DR. WACHHOLZ: The situation in Ukraine shows a  
3 similar pattern, although the numbers and magnitude is a  
4 little different. They had a slightly higher baseline to  
5 start, but then it's a much larger country, 50 some million  
6 versus roughly 10 million. The increase showed itself about  
7 the same time frame, in 1989, '90. The magnitude is not  
8 quite as great as in Belarus.

9 [Slide.]

10 DR. WACHHOLZ: To put this in context of what this  
11 means per 100,000 children, the next slide shows the  
12 incidence in Belarus, which you can see goes from very low,  
13 about a tenth per hundred thousand to roughly 3.4 over the  
14 same time period and more or less mimics the absolute  
15 numbers.

16 [Slide.]

17 DR. WACHHOLZ: And the next slide shows the same  
18 information in Ukraine, going from a baseline of .06 or .07  
19 to .4 plus.

20 Now, what kind of studies would one project to  
21 take advantage of this unfortunate situation? We have  
22 proposed, and are in the process of initiating, case control  
23 studies and cohort studies. Case control studies, very  
24 briefly, we have to identify representative controls,  
25 individuals for each of the specific cases and in the case

1 of Belarus the time frame which the study began was March of  
2 1992, at which time there were 119 thyroid cases of children  
3 with thyroid cancer. We have identified two controls for  
4 each case. So, we have something on the order of 500  
5 children in the case control study. Later on I will give  
6 you a status report on the condition of each of these  
7 studies.

8 With regard to Ukraine, we began the case control  
9 study in 1993 and that is still in the process of being  
10 determined. With regard to the cohort studies, which really  
11 is the major effort and the long-term effort which we  
12 anticipate will continue for a minimum of 15 to 20 years,  
13 assuming all the signs are favorable. Cohort studies are  
14 fixed population which is the cohort and dosimetry is  
15 carried out, dose reconstruction is carried out on every  
16 individual in the cohort and you follow the cohort for the  
17 occurrence of any health consequences.

18 In Belarus, there's a cohort identified in  
19 approximately 15,000 children. In Ukraine there's a cohort  
20 identified of approximately 70,000 children. The reason for  
21 doing these and the end point is the risk estimates for  
22 cancer, for nodules, for hypothyroidism as a function of  
23 dose to the thyroid, as a function of age at the time of  
24 exposure and with regard to the gender of the child.

25 Next slide, please.

1 [Slide.]

2 DR. WACHHOLZ: The objective of the thyroid cohort  
3 study more specifically is dose and time related morphologic  
4 and functional changes in thyroid glands of children exposed  
5 to radiation, risk estimates for nodules in cancer, as I  
6 indicated. In addition, comparison of the relative  
7 effectiveness of I-131 with that of x-ray and gamma  
8 radiation in inducing thyroid nodules in cancer and the risk  
9 estimates of the induction of hypothyroidism as a function  
10 of dose with regard to sex and age.

11 Next slide, please.

12 [Slide.]

13 DR. WACHHOLZ: Now, what do these studies consist  
14 of? Very broadly and generally, three components. First of  
15 all, sampling. How are you going to identify the cohort,  
16 first of all with regard to children that had measurements  
17 of their thyroid at that time. I indicated earlier this had  
18 a variety of techniques associated with it and we have to  
19 sort that out. Secondly, the sampling consists of those  
20 persons who are children or in utero at the time of the  
21 accident in 1986. Thirdly, although some might not include  
22 this as a criterion, we find that we have to make the point  
23 that this is a fixed cohort. You don't add children to it  
24 as time goes by just because someone outside the cohort has  
25 a cancer.

1           With regard to the medical and clinical side, this  
2       would be a proactive study. We would do annual or biennial  
3       follow-up examinations of each child with regard to the  
4       anatomy and function of the thyroid, with respect to  
5       palpation, with respect to ultrasound analyses, with respect  
6       to laboratory tests, blood hormones and such that are  
7       associated with thyroid function, fine needle biopsy as  
8       indicated by both the ultrasound scans as well as laboratory  
9       tests, and obviously if necessary proceed to surgical  
10      procedures and other treatment.

11           On the other side is the dose reconstruction  
12      effort which relies upon the measurements, but it also  
13      includes other factors such as I-131 fallout maps that are  
14      being developed in both countries, and individual  
15      information on exposure history of the individual such as  
16      their residents, where they lived, how long, where they  
17      moved to, when they moved, their food supply, where it  
18      originated, how much did they consume, et cetera.

19           COMMISSIONER de PLANQUE: Bruce, would most of the  
20      dose from iodine-131 be from fallout iodine as opposed to  
21      any kind of direct immediate --

22           DR. WACHHOLZ: The short answer to your question  
23      is yes.

24           COMMISSIONER de PLANQUE: I realize it's complex.

25           DR. WACHHOLZ: I'm sure you realize as well as I



1 do that I'll turn to Dr. Bouville if you want a more  
2 complete answer.

3 COMMISSIONER de PLANQUE: That's fine. I just  
4 wanted to make sure that was correct.

5 DR. WACHHOLZ: Am I correct on that, Dr. Bouville?

6 DR. BOUVILLE: Yes.

7 DR. WACHHOLZ: Thank you.

8 [Slide.]

9 DR. WACHHOLZ: On the next slide you have the  
10 initial estimates of the dose distribution of the 100,000  
11 plus children that were measured at the time or shortly  
12 after the time of the accident. Like I say, there are a lot  
13 of uncertainties associated with this, so please take the  
14 estimated seriously. In Belarus there were nearly 30,000  
15 children measured and in Ukraine over 75,000. You can see  
16 the distribution of doses with several hundreds if not  
17 thousands of children up in the areas of one grade or more.

18 COMMISSIONER de PLANQUE: And the bin sizes are  
19 real enough given the uncertainties?

20 DR. WACHHOLZ: I'm sorry?

21 COMMISSIONER de PLANQUE: The bin sizes are real  
22 enough given the uncertainties?

23 DR. WACHHOLZ: May I defer to Dr. Bouville?

24 COMMISSIONER de PLANQUE: Sure.

25 MR. TAYLOR: Would you like to go up to the

1 microphone?

2 DR. BOUVILLE: That's, of course, a point that  
3 we're going to need to investigate in depth and estimate  
4 some of those according to various iterations. It will be  
5 more in more detail as time goes on. My feeling for the  
6 time being is that the average uncertainty is about a factor  
7 of two.

8 COMMISSIONER de PLANQUE: Thanks.

9 [Slide.]

10 DR. WACHHOLZ: With regard to dose reconstruction,  
11 the next visual identifies the basic components that would  
12 go into this. In addition to the thyroid measurements with  
13 regard to the cohort studies, there are the case control  
14 studies where by and large you do not have thyroid  
15 measurements and the doses there would have to be estimated  
16 based on the cesium contamination deposition on the surface.  
17 In both the case control and the cohort studies, there would  
18 be an effort made to include the other factors that are  
19 identified here, namely through the food chain, especially  
20 the primary one, iodine-contaminated milk, but also the  
21 other sources of contamination, iodine-contaminated other  
22 food stuffs as well as inhalation of the iodines and  
23 external exposure from the cesium. These would all be done  
24 on an individual basis, so I'm sure you can appreciate with  
25 tens of thousands of children this is not a small

1 undertaking.

2 [Slide.]

3 DR. WACHHOLZ: What is the status of these several  
4 studies currently? First of all, with regard to the case  
5 control study in Belarus that as I say began in 1992, all of  
6 the cases and the control subjects have been selected; the  
7 pathology has been reviewed for almost all of the cases.  
8 The information regarding individual characteristics has  
9 been received from most of the subjects at this point. The  
10 individual dose reconstruction has yet to be completed. The  
11 analyses with the data that is in existence is in process,  
12 what shall I say, binationally. It's being done in parallel  
13 both in Belarus and in the United States. And a publication  
14 is in the initial stages of preparation and is well  
15 underway.

16 [Slide.]

17 DR. WACHHOLZ: With regard to the case control  
18 study in Ukraine -- I should say first that we expect that  
19 publication and the analyses to be complete by the end of  
20 this calendar year.

21 With regard to the case control study in the  
22 Ukraine, that was begun last year. At this point we have  
23 partial identification of cases. There are some 50 plus  
24 cases at this point that have been identified. We are  
25 currently in the process of identifying additional cases

1 and, of course, the control subjects to go with them. Dose  
2 reconstruction has yet to be carried out. Confirmation of  
3 pathology is underway as we speak. One of their  
4 pathologists is in the United States right now and that  
5 activity is ongoing.

6 [Slide.]

7 DR. WACHHOLZ: With regard to the larger effort,  
8 the cohort studies with regard to Belarus, we expect that to  
9 begin in 1994. The research protocol has been completed and  
10 the scientific peer review at NCI and NIH was completed last  
11 year.

12 Institutional review board approvals were received  
13 earlier this year. You may not be familiar with what is  
14 meant by institutional review boards. Anybody who has the  
15 opportunity to go through this unfortunate experience will  
16 know what I'm referring to. But these are more commonly  
17 known as human use committees, and that anything funded by  
18 the federal government must be approved by one of these  
19 institutional review boards. In the case of activities in a  
20 foreign country, an institutional review board counterpart  
21 must be established in the other country and function as  
22 does one of these boards in the United States.

23 In the case of NCI, we have institutional review  
24 boards. We established one and assisted them in going  
25 through the process in Minsk. Both the Belarussian one and

1 the NCI one were then forwarded to NIH and they are the  
2 arbiters of last resort. We received their approval earlier  
3 this year, in April.

4           You are aware that Belarus and the U.S.  
5 subsequently signed an agreement to implement the research  
6 protocol and some people in this room were present at that  
7 ceremony. In the meantime, we have been in the process of  
8 developing a very extensive and voluminous operations manual  
9 that covers specific guidance, directions and techniques,  
10 everything from laboratory tests to diagnostic activities to  
11 dosimetry. The purpose of this is to, one, have a  
12 straightforward guideline with regard to what should be  
13 done, how it should be done, procedures and so on because we  
14 realize over the period of time that we're talking about  
15 there are many people that are going to be involved, not all  
16 of whom are involved presently and there needs to be some  
17 continuity in terms of procedures with regard to that.

18           We have worked with our Belarussian colleagues to  
19 identify equipment that would be needed and we've worked on  
20 a three year time scale. We've met with them several times.  
21 We've met amongst ourselves several times and I think we're  
22 coming to closure on that, at least for the initial list of  
23 needed equipment.

24           Arrangements are in progress to obtain the  
25 services of and establish a person in Minsk to work with us.

1 A bilingual individual who's a physician and has been  
2 working with us over the last few months in the year to  
3 establish that contact on-site in Minsk. In addition, there  
4 are the usual activities of exchanges of experts in both  
5 directions. People have been here for training in various  
6 disciplines. They have identified a management team to  
7 carry out the study and we will work with them, but I would  
8 call your attention to the bottom item, the advisory  
9 committee. The protocol calls for a binational advisory  
10 committee in Belarus or with regard to the Belarussian  
11 study, half comprised of people they nominate, half  
12 comprised of people we nominate, not necessarily limited to  
13 citizens of the two countries. We would look to that to  
14 provide real time assistance on whatever difficulties may  
15 arise.

16 Next slide, please.

17 [Slide.]

18 DR. WACHHOLZ: With regard to the counterpart, the  
19 cohort study in Ukraine, the research protocol was completed  
20 early this year. It was reviewed scientifically by NCI and  
21 NIH and the comments have essentially been resolved. I hope  
22 to resolve the last one next week, next Monday, and I don't  
23 think that should lead to any difficulties. As soon as we  
24 do that, we will submit the document to our institutional  
25 review board at NCI. In Ukraine they have yet to establish

1 an institutional review board for this activity, and I will  
2 be assisting them to do so next week when I'm over there.

3 In addition, while that's been in the process,  
4 there has been active exchange of experts. As I indicated,  
5 their chief pathologist is in the States right now and they  
6 have been here for training in everything from endocrinology  
7 and ultrasound to epidemiology. They also have identified a  
8 management team to carry out the study in the Ukraine and,  
9 similarly to Belarus, there is an advisory committee that's  
10 called for by the protocol.

11 [Slide.]

12 DR. WACHHOLZ: The next slide indicates what this  
13 comes down to, at least in terms of financial support and I  
14 would urge you not to focus on specific numbers so much  
15 because I have no doubt these will change as circumstances  
16 evolve and needs are known or changes in procedures are  
17 agreed upon. But it gives you some idea of the order of  
18 magnitude of carrying out the study in terms of equipment  
19 and supplies. The bottom category, training, workshops and  
20 so on, that is the part that's matched funding between DOE  
21 and NCI.

22 Next slide, please.

23 [Slide.]

24 DR. WACHHOLZ: One can ask the same question with  
25 regard to leukemia. Why are we interested in working with

1 this group of people over there? First of all, the risk of  
2 leukemia from low doses or low dose rates is essentially  
3 unknown.

4 Secondly, other populations have been exposed to  
5 different circumstances in terms of radiation exposure. The  
6 Japanese one was very acute, as you know. Occupational are  
7 very low exposures, and the clean-up workers associated with  
8 Chernobyl cover a fairly wide range of exposures. And while  
9 there are some 600-plus thousand clean-up workers  
10 collectively, our focus is on Ukraine, which has some  
11 100,000 to 150,000 clean-up workers within that country.

12 COMMISSIONER de PLANQUE: Bruce, there's been some  
13 talk over the years that the doses measured for the clean-  
14 up workers by their dosimeters are somewhat in question.  
15 Could you give us any sense of your latest reading of that?

16 DR. WACHHOLZ: Yes, some of the uncertainty that  
17 had been attributed to differences between the reported  
18 doses versus estimated doses by other means, such as  
19 biological dosimetry. Fairly recently we were informed that  
20 there had been some laboratory errors in the conduct of some  
21 of the biological dosimetry, and perhaps the reported doses  
22 are not as erroneous as had previously been anticipated.  
23 That's not to say that they're correct, just the multiplier  
24 between the two is perhaps smaller than was previously  
25 anticipated.



1 COMMISSIONER de PLANQUE: Was there any problem  
2 with the recorded doses being what they were in order to  
3 avoid exceeding any limits, occupational limits?

4 DR. WACHHOLZ: All I have to go on is probably the  
5 same things that you've heard.

6 COMMISSIONER de PLANQUE: Okay. No new  
7 information on that?

8 DR. WACHHOLZ: I don't. Dr. Bouville, do you have  
9 any hard information on that?

10 DR. BOUVILLE: No, no hard information.

11 COMMISSIONER de PLANQUE: Okay. Thanks.

12 DR. WACHHOLZ: Next slide, please.

13 [Slide.]

14 DR. WACHHOLZ: The objectives of the leukemia  
15 study are indicated here: to provide risk coefficients  
16 following exposure to low to moderate doses of radiation and  
17 to compare this information with the information that has  
18 been obtained from the studies in Japan; to assess the time  
19 response function and the influence of dose rate on the  
20 occurrence of leukemia among these workers; and to  
21 investigate the pathogenesis of radiogenic leukemia and  
22 provide for future studies of molecular biology; and to use  
23 the data, if possible, as an estimator for future leukemia  
24 and perhaps solid tumor excess among the clean-up workers in  
25 order to give them some perspective of what could be

1 anticipated in terms of public health issues among that  
2 group.

3 [Slide.]

4 DR. WACHHOLZ: What are these studies? They are,  
5 first of all, provided into two phases and you'll see a fair  
6 amount under phase I and very little under phase II. And  
7 that's intentional, because, until we have an opportunity to  
8 become involved in this and familiar with the information,  
9 the data, it seems premature to even identify, much less  
10 commit to a long-term epidemiological study.

11 So, the first phase is an 18 month activity which  
12 will be comprised of several parts. First of all, what are  
13 the sources of information with regard to the clean-up  
14 workers? First of all, it's they themselves and the  
15 information they provide in terms of where they were, how  
16 long they were there, what circumstances and so on, as well  
17 as the access to the several registries that exist in  
18 Ukraine, Chernobyl registry, cancer registry, leukemia  
19 registry and so on.

20 There are the dosimetric aspects to which you've  
21 already made mention. Not only the physical dimension of  
22 badges, radiation fields and information from the  
23 individuals, but several potential providers of information  
24 of biological dosimetry, such as the fluorescent in situ  
25 hybridization technique, glycophorin-A, electron

1 paramagnetic resonance, and make provision for storage of  
2 blood and bone marrow in case there are other indicators  
3 that need to be developed in the future that may be  
4 reasonably specific for these particular end points as a  
5 function of radiation exposure.

6 The third component, of course, is more along the  
7 lines of the medical and clinical diagnostic activity  
8 ascertainment, the identification of the cases, and one that  
9 sometimes is overlooked. But, namely review of the cases in  
10 terms of terminology because words don't always mean the  
11 same thing when you cross languages or cultures and we have  
12 to ensure that when they say something we understand what it  
13 is they mean, and vice versa as well.

14 Other activities are sort of indeterminate at this  
15 time, but they could provide such things as other tumors and  
16 general health.

17 And as I indicate, phase II would not be addressed  
18 and decisions made until well into phase I as to how that's  
19 going.

20 [Slide.]

21 DR. WACHHOLZ: What's the status of this  
22 particular activity in Ukraine? The scientific research  
23 protocol is in process. There was a workshop in the United  
24 States last February and March and a draft protocol was  
25 prepared and agreed to at that time. Several of us, Dr.

1 Beebe and myself and several others, are leaving tomorrow to  
2 go to Kiev to discuss the revisions of that leukemia  
3 protocol and we anticipate that there would probably be  
4 another meeting between the principals of the two countries  
5 before the end of the year, at which time we would certainly  
6 hope to have a final protocol.

7 The guesstimated budget for an activity of this  
8 nature is something on the order of \$3 million over a period  
9 of about ten years.

10 [Slide.]

11 DR. WACHHOLZ: Finally, I'd like to on the next  
12 slide just identify the principals that we are working with  
13 overseas.

14 First of all, in Belarus, the Minister of Health,  
15 some of you met Dr. Kazakov either in Minsk or earlier this  
16 year in Washington. As you know, there have been changes in  
17 government in both countries in the last month or so and as  
18 a consequence of that there are new ministers of health in  
19 both countries. We have not yet had the opportunity to meet  
20 either. They've only been there like two or three weeks and  
21 we have not been there in the last two or three weeks.

22 In addition, the Director of the Institute of  
23 Radiation Medicine, the primary institute in Belarus with  
24 which we work, is Dr. Stozharov, and the Deputy Director for  
25 Clinical Activities has been Dr. Larisa Astakhova to this

1 point.

2 [Slide.]

3 DR. WACHHOLZ: Similarly, in Ukraine we've been  
4 dealing with the minister of health as well as directors of  
5 the various research entities. You may have met or heard of  
6 the former Minister of Health, Dr. Yuriy Spizhenko. He is  
7 no longer minister of health, but he is a member of  
8 parliament and at present he is Chairman of the Public  
9 Health Issues of the Parliamentary Committee, so he is still  
10 very prominent and active in the health issues in Ukraine,  
11 but the newly appointed Minister of Health is Vladimir  
12 Bobrov.

13 In addition, you see the principals that we work  
14 with, the Director of the Ukraine Scientific Center for  
15 Radiation Medicine, Dr. Romanenko; the Director of the  
16 Institute of Endocrinology and Metabolism, Dr. Tronko; and  
17 in the area of dose reconstruction and dosimetry, Dr.  
18 Likhtarev, who is the Chief of the Department of Dosimetry  
19 and Radiation Hygiene, and that is in the Ukraine Center for  
20 Radiation Medicine.

21 I would mention only that with regard to  
22 particular of the leukemia studies that there are a number  
23 of other institutes that also are involved, the Institute of  
24 Oncology, Institute of Hematology, registries, et cetera.

25 I think this concludes my summary statement of

1     what has occurred, what the situation is, what our  
2     anticipated plans are and where we stand with respect to  
3     those plans. I and my colleagues will be pleased to answer  
4     any questions you might have. I realize this has been a  
5     superficial summary, but I hope it gives you some idea of  
6     the extent of our efforts and our hopes for the future.

7             Thank you very much.

8             CHAIRMAN SELIN: Thank you very much, Dr.  
9     Wachholz.

10            This is the latest in a number of cooperations and  
11     it's very interesting. The presentation is really almost  
12     entirely on how we're going about doing the study. Could  
13     you talk a little bit about what kind of results you might  
14     expect to get out of the study, a little bit about the  
15     medical side, perhaps even a little bit about just the basic  
16     radiology side?

17            DR. WACHHOLZ: I'll make a comment or two and then  
18     I'll defer to Dr. Becker for the medical perspective and  
19     techniques and so on.

20            In terms of what we hope to get out of it  
21     ultimately is a risk per -- I guess I have to say risk per  
22     grey area, risk per sievert now. It's so easy to say risk  
23     per rem -- for thyroid cancer and the other thyroid diseases  
24     from I-131, assuming we can separate out the contribution of  
25     I-131 from the other confounding contributors. We don't

1 have that information. We have it for x-rays and gamma  
2 rays. We don't have it for isotopes like I-131, which would  
3 certainly be the problem should there be a major accident.

4 I sometimes use the statement at NCI that if there  
5 is ever to be large scale exposure of the public it's not  
6 going to be from x-ray machines that have gone berserk but  
7 from something that's going to affect large numbers of  
8 people, and I-131 is a prime candidate for that. We have  
9 not had the opportunity, however tragic it is, the  
10 opportunity to study large numbers of people, especially  
11 children, that have been exposed to a wide variety of doses.

12 CHAIRMAN SELIN: Let me ask the question a little  
13 differently. Is there a model that's going to be tested or  
14 is this basically exploratory? Do you have a hypothesis?  
15 Do you have a pretty good idea of what you would expect to  
16 find and see? If that's what's going to turn up or will  
17 this be basic data on long-time exposure to the isotopes so  
18 that it's hard to say what kind of results to expect at this  
19 point?

20 DR. WACHHOLZ: Well, if you say is there a  
21 specific hypothesis to be tested, I guess the hypothesis is  
22 does I-131 lead to thyroid cancer.

23 CHAIRMAN SELIN: That basic?

24 DR. WACHHOLZ: That basic, yes.

25 Dr. Becker, would you like to -- or, Dr. Beebe --

1 DR. BEEBE: I just wanted to add to that we have a  
2 specific model suggested by NCRP, namely to the effect that,  
3 and I think it's guess work, the effectiveness factor, as  
4 they call it, for I-131 might be about one-third of what it  
5 is for gamma and x-ray. So we're sort of shooting at that,  
6 but what we're considering is anything in the range of one  
7 to one-tenth of the effectiveness. That's really the  
8 critical thing. After all, we know that radiation, gamma  
9 and x-ray, produce thyroid cancer, but we don't know about  
10 I-131.

11 COMMISSIONER de PLANQUE: I would assume the dose  
12 effect or the dose response will also be of interest,  
13 assuming, in addition --

14 DR. BEEBE: Yes. Not just yes or no, but --

15 COMMISSIONER de PLANQUE: Right. It's not just  
16 yes or no, but do you wind up with a linear dose  
17 relationship or what is it?

18 DR. BEEBE: We hope to have an estimate of that  
19 particular parameter and all the detail that goes with the  
20 dose response function for I-131 in children and then the  
21 age variation and other factors.

22 CHAIRMAN SELIN: Following up on that, is this a  
23 large enough sample to try to look at the linear hypothesis  
24 when you get down to the smaller doses?

25 DR. BEEBE: I think so, particularly Ukraine. I



1 think that Belarus is more questionable from that  
2 standpoint, but Belarus is certainly big enough to test this  
3 factor suggested by NCRP, I think. But we've got a sample  
4 three times as large in Ukraine.

5 CHAIRMAN SELIN: What do the host governments hope  
6 to get out of this arrangement? I'm sure they're very  
7 interested in the basic scientific work, but is there some  
8 direct relevance to their treatment or to their health  
9 planning that they would hope to get out of this?

10 DR. WACHHOLZ: I think there are probably several  
11 answers to that question. Certainly they look upon this, I  
12 think, as assisting them in their public health care of the  
13 population, especially their children. And of course, when  
14 we're looking at children yearly with regard to function and  
15 anatomy of the thyroid, that's of great interest to them  
16 that that effort be carried out. And I think they are very  
17 anxious to work with Western scientists and Western  
18 physicians to ensure the conduct and quality of these  
19 studies both medically and scientifically. I wouldn't  
20 underestimate their interest in the scientific dimensions,  
21 but certainly there is a public health dimension that is  
22 equally important in their perspective.

23 CHAIRMAN SELIN: Where are the Russians on this?

24 DR. WACHHOLZ: I think I'll defer that question to  
25 Dr. Pettengill.

1           With regard to the activities in Belarus and  
2           Ukraine, let me say that with regard to Ukraine there is no  
3           association with the Russians.

4           With regard to Belarus, there is active  
5           cooperation between the Institute of Radiation Medicine in  
6           Minsk and the Institute of Biophysics in Moscow. There are  
7           three scientists in Moscow at the Institute that are  
8           actively working on this project with us and with their  
9           counterparts in Belarus, so, in that sense, yes, the  
10          Russians are involved.

11          If your question is specific with regard to  
12          studies in Russia, we do not at this time have active  
13          studies in Russia, and I'll defer to Dr. Pettengill who I'm  
14          sure can speak to that a little more.

15          DR. PETTENGILL: Yes, Mr. Chairman, under Working  
16          Group 7 activities we have been collaborating with the  
17          Russian Federation as well. The level of work and the  
18          status of those studies are much behind when compared to  
19          Belarus and Ukraine and I would offer that that appears to  
20          be more the circumstance of the Russian consideration rather  
21          than ours. The impacted populations in Russia and the  
22          Bryansk area certainly did suffer some exposure, but  
23          significantly less than Belarus and those areas of Ukraine.

24          Currently what we have is another institute that  
25          developed a proposal which we have funded, the Fred

1 Hutchinson Cancer Research Institute, which is working  
2 directly with the authorities in the Russian Federation and  
3 they're developing feasibility analyses on the ability to do  
4 a comprehensive epidemiologic review for both thyroid and  
5 leukemia in the Bryansk area.

6 COMMISSIONER ROGERS: I was just curious as to a  
7 couple of your comments. One, that one of the purposes of  
8 this study is to find out if cancers are induced by iodine-  
9 131. But then you also say you were surprised to see the  
10 incidence of these cancers appearing so early, three to four  
11 years after the event, which seemed to imply that you had a  
12 model in mind. So, how do you bring those together?

13 DR. WACHHOLZ: Yes. How do you make them  
14 compatible with each other? The expectation of latency was  
15 based on external exposure of x-ray and gamma ray studies  
16 that have been done of children that received exposure of  
17 the thyroid in the course of treatment for varying diseases.  
18 And in that context you had a minimum latency of at least  
19 five years if not longer, and so that was the "expected  
20 latency" with regard to iodine if there were cancers  
21 resulting from the iodine exposure.

22 COMMISSIONER ROGERS: And is that just with x-  
23 rays or --

24 DR. WACHHOLZ: Yes.

25 COMMISSIONER ROGERS: But iodine-131 puts out half

1       gammas and half betas.

2               DR. WACHHOLZ: We have no basis for identifying a  
3       period of time as latency for I-131. That was based  
4       strictly on the external --

5               COMMISSIONER de PLANQUE: This is uptake rather  
6       than external exposure.

7               COMMISSIONER ROGERS: Yes, but also it's a  
8       combination of beta particles --

9               COMMISSIONER de PLANQUE: Well, yes, but having it  
10      in the thyroid is different from having it --

11              COMMISSIONER ROGERS: Yes, sure.

12              COMMISSIONER de PLANQUE: -- incident from  
13      externally.

14              DR. WACHHOLZ: The majority of the exposure comes  
15      from ingestion, for children particularly, of contaminated  
16      milk.

17              COMMISSIONER ROGERS: Yes.

18              DR. WACHHOLZ: Dr. Becker may --

19              DR. BECKER: If I might comment, we have a large  
20      experience using I-131 both diagnostically and  
21      therapeutically around the world and our experience to date  
22      has not indicated any significant deleterious consequences  
23      from the diagnostic use of I-131, although it has mostly  
24      been used in adults and not in children, and this experience  
25      appears to be in children.

1           There is considerable skepticism as to what the  
2           potential is for this causing any problems since we continue  
3           to use I-131 in small amounts. In the past it was used in  
4           much larger amounts, as a matter of fact in considerably  
5           larger amounts in most of the population in these areas we  
6           are involved with. But we have ongoing areas, as you know,  
7           in the Marshall Islands and out West where there are fallout  
8           concerns that are persisting and these are very acute  
9           questions that we have to deal with.

10           In treating patients with radioiodine, we are  
11           faced with the great concern about the deleterious  
12           consequences. In this country, most patients with  
13           hyperthyroidism are treated preferentially with I-131. This  
14           is not true in Europe, for instance, where most patients are  
15           treated with antithyroid drugs, and radioiodine is used much  
16           less frequently. The reasons for this variation are not  
17           clear, but they differ geographically. For instance, in  
18           England and in Brussels radioiodine is used frequently.  
19           It's rarely used in Germany and Scandinavia and Italy, and  
20           the reasons for these are not clear but probably relate to  
21           medical practice and other more difficult issues to define.

22           COMMISSIONER ROGERS: Thank you.

23           COMMISSIONER de PLANQUE: I'm not quite sure how  
24           you ask this question, so maybe you'll help me in  
25           formulating the question. Devising the protocol for a study

1     like this is not easy. I'm wondering how much you were able  
2     to draw from the protocols used in other studies like,  
3     particularly, the RERF studies or any of the other major  
4     studies that have been used or did you pretty much have to  
5     start from scratch and treat this as a unique situation?

6             DR. BEEBE: Well, you draw as far as principles,  
7     but my experience with the A-bomb survivors I suppose gave  
8     me a kind of structure for this, particularly since we had  
9     the so-called MB-200 or adult health study and a similar  
10    study of children where we had longitudinal studies with  
11    bringing the children in for examination every two years.  
12    So, you know, there is experience and there are models that  
13    we could adapt to a degree, but it's a unique experience.

14            DR. WACHHOLZ: I would say also we drew heavily on  
15    experience with regard to exposure in other situations such  
16    as the fallout studies in Utah and downwind from the Nevada  
17    test site in terms of dose reconstruction. The Department  
18    of Energy and the Defense Department collaborated in  
19    supporting a rather large epidemiological study in Utah on  
20    thyroid disease and leukemia and it was not dissimilar to  
21    this except obviously in terms of numbers and complexity and  
22    so on, but, nevertheless, it was the same basic type of  
23    activity to relate exposures of individuals to health  
24    observations among populations, so there were bits and  
25    pieces that could be brought to bear.

1                   And then the clinicians in our group certainly  
2     have been involved in studies, both diagnostic and  
3     therapeutic as Dr. Becker makes mention, and there has been  
4     for some years thyroid toxicosis study at the National  
5     Cancer Institute, so these several things sort of all were  
6     drawn upon to develop a protocol of this nature along with  
7     the colleagues from overseas as to what the realities were  
8     --

9                   COMMISSIONER de PLANQUE: What's feasible.

10                  DR. WACHHOLZ: -- in those countries, yes.

11                  COMMISSIONER de PLANQUE: Okay.

12                  DR. BECKER: But, as you imply, this situation is  
13     a little different in that we are dealing with countries  
14     that have not had access to Western medicine, and many of  
15     the approaches taken in preparing a protocol have required  
16     first convincing the people that there was another way of  
17     doing things. It has taken three years and more to get the  
18     protocol to this point and a lot of these things that have  
19     held it up have been nonmedical issues, but very complicated  
20     and difficult ones.

21                  COMMISSIONER de PLANQUE: Okay.

22                  DR. WACHHOLZ: You have the scientific  
23     interaction. You have the cultural interaction. You have  
24     the language. So it's taken longer than would normally be  
25     the case if you sat down in Washington to design a protocol.

1 COMMISSIONER de PLANQUE: And that's tough enough.

2 You mentioned numbers of people involved, but it  
3 was a little scattered. Can you give me any rough feel what  
4 the overall manpower is for the project?

5 DR. WACHHOLZ: In the U.S. or --

6 COMMISSIONER de PLANQUE: Well, both, if you can,  
7 or split it out. Just ballpark. And if you can't do it  
8 now, that's okay.

9 DR. WACHHOLZ: Well, on the U.S. side at this  
10 point, I'd say it's in the dozens.

11 COMMISSIONER de PLANQUE: Okay.

12 DR. WACHHOLZ: In terms of professional staff over  
13 there, that's a little more difficult because the Institutes  
14 of Endocrinology and Radiation, they go out into the various  
15 clinics and poly-clinics throughout the country and we  
16 really don't know in terms of numbers how many people this  
17 involves. In terms of principals in the major cities,  
18 again, I'd say you're talking about one to two dozen of the  
19 senior people that we're working with in each country.

20 COMMISSIONER de PLANQUE: Okay. Thanks. Been  
21 very useful.

22 CHAIRMAN SELIN: Thank you very much. I've been  
23 hearing about this work so frequently from the EDO, who's  
24 really very pleased with the progress that's been made, and  
25 it's very nice to hear the professional side as well as the



1 managerial side.

2 DR. WACHHOLZ: Well, up until now there's been a  
3 lot of paperwork and a lot of planning. The interesting  
4 part is just beginning, as is the challenging part.

5 CHAIRMAN SELIN: Thank you very much.

6 DR. WACHHOLZ: Thank you for the opportunity.

7 [Whereupon, at 2:39 p.m., the above-entitled  
8 meeting was concluded.]

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CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING:    PROTOCOL FOR STUDY OF THYROID DISEASE  
                          IN BELARUS AS A RESULT OF THE  
                          CHERNOBYL ACCIDENT - PUBLIC MEETING

PLACE OF MEETING:    Rockville, Maryland

DATE OF MEETING:     Friday, September 9, 1994

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Carol Lynch

Reporter: Peter Lynch



# **U.S. RESPONSE TO CHERNOBYL: PROGRESS AND STATUS ON HEALTH RESEARCH**

**BELARUS**

**September 9, 1994**

**Harry J. Pettengill**

# **BACKGROUND**

## **JCC\CNRS - WORKING GROUP 7**

- **Chernobyl Accident on April 26, 1986**
- **Memorandum of Cooperation (MOC) under the Peaceful Uses of Atomic Energy Agreement signed in 1988**
- **Joint Coordinating Committee for Civilian Nuclear Reactor Safety (JCC\CNRS)**
- **Working Group 7: Health and Environmental Consequences**
- **Working Group 7 Pilot Projects**

# **BREAK-UP FORMER SOVIET UNION**

- **JCC\CNRS Structure Reorganized after the Former Soviet Union Break-up**
- **Continuation of Existing Working Group 7 Activities with Ukraine and Russian Federation; Tripartite JCC\CNRS Meetings in Kiev, Ukraine-1993; and Moscow, Russia-1994**
- **Letter Arrangement Signed with Belarus in April 1992**
  - **DOE and Belarus Ministry of Health to Continue Working Group 7 Activities Begun Under the Auspices of JCC\CNRS**

# **THE CHERNOBYL HEALTH RESEARCH FOCUS**

- **Working Group 7 Research Directions Re-evaluated**
- **Decided to Shift Emphasis in Working Group 7 Towards Health Impacts**
- **Perform Traditional Epidemiologic Studies**
- **Environmental Focus on Dosimetry and Dose Reconstruction**
- **Expected Near-Term Health Outcomes**
  - **Thyroid Disease**
  - **Leukemia**
- **National Cancer Institute-Project Managers for Studies of Thyroid Disease and Leukemia in Belarus and Ukraine**

**CHERNOBYL**  
**HEALTH-RELATED COOPERATIVE**  
**SCIENTIFIC RESEARCH PROGRAMS**  
**BETWEEN**  
**THE UNITED STATES**  
**AND**  
**BELARUS - UKRAINE**

**September 9, 1994**

**Bruce W. Wachholz, Ph.D.**



## **NCI WORKING GROUP MEMBERS PRESENT**

**David V. Becker, M.D.**

**Gilbert W. Beebe, Ph.D.**

**Andre C. Bouville, Ph.D.**

**Bruce W. Wachholz, Ph.D.**

## **RECOMMENDATIONS**

- **Thyroid Disease - Especially Cancer in Children**
- **Leukemia - Clean-up Workers**

## **DOE - NCI**

- **DOE-NCI Interagency Agreement Signed 1990**
- **NCI Requested to Work with Soviet Counterparts to:**
  - **Develop Protocols for and Implement Long-Term Follow-up Studies of Thyroid Disease, Especially Cancer**
  - **Develop Protocol for Study of Leukemia**
- **DOE to Provide Financial Support**
  - **Equipment/Supplies**
  - **NCI-DOE Matching Support for NCI Expenses**
  - **Some Funding Provided from NRC**
- **Two Working Groups Formed**

# **U.S. NATIONAL CANCER INSTITUTE WORKING GROUP FOR THYROID STUDIES**

**David V. Becker, M.D., Chairman**

**Lynn R. Anspaugh, Ph.D.**

**Gilbert W. Beebe, Ph.D.**

**Andre Bouville, Ph.D.**

**A. Bertrand Brill, M.D., Ph.D.**

**Jacob Robbins, M.D.**

**Roy E. Shore, M.D., Dr.P.H.**

**Lester Van Middlesworth, M.D., Ph.D.**

**Bruce W. Wachholz, Ph.D.**

**Jan Wolff, M.D., Ph.D.**

# **U.S. NATIONAL CANCER INSTITUTE WORKING GROUP FOR LEUKEMIA STUDIES**

**Gilbert W. Beebe, Ph.D., Chairman**

**Lynn R. Anspaugh, Ph.D.**

**John D. Boice, Jr., Sc.D.**

**Andre Bouville, Ph.D.**

**Scott Davis, Ph.D.**

**Stuart C. Finch, M.D.**

**Geoffrey R. Howe, Ph.D.**

**Ronald Jensen, Ph.D.**

**L. Gayle Littlefield, Ph.D.**

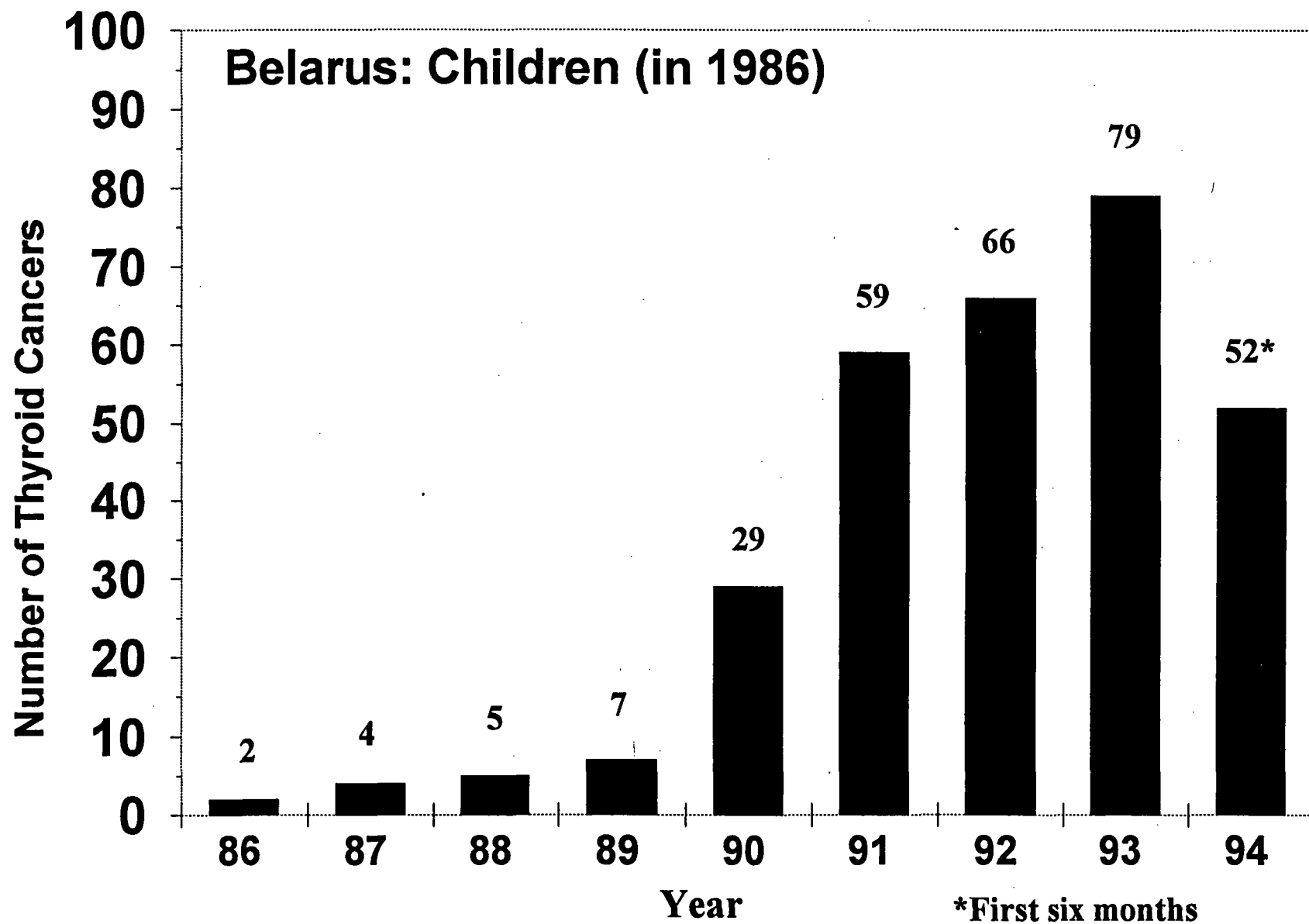
**Ian Magrath, M.B.**

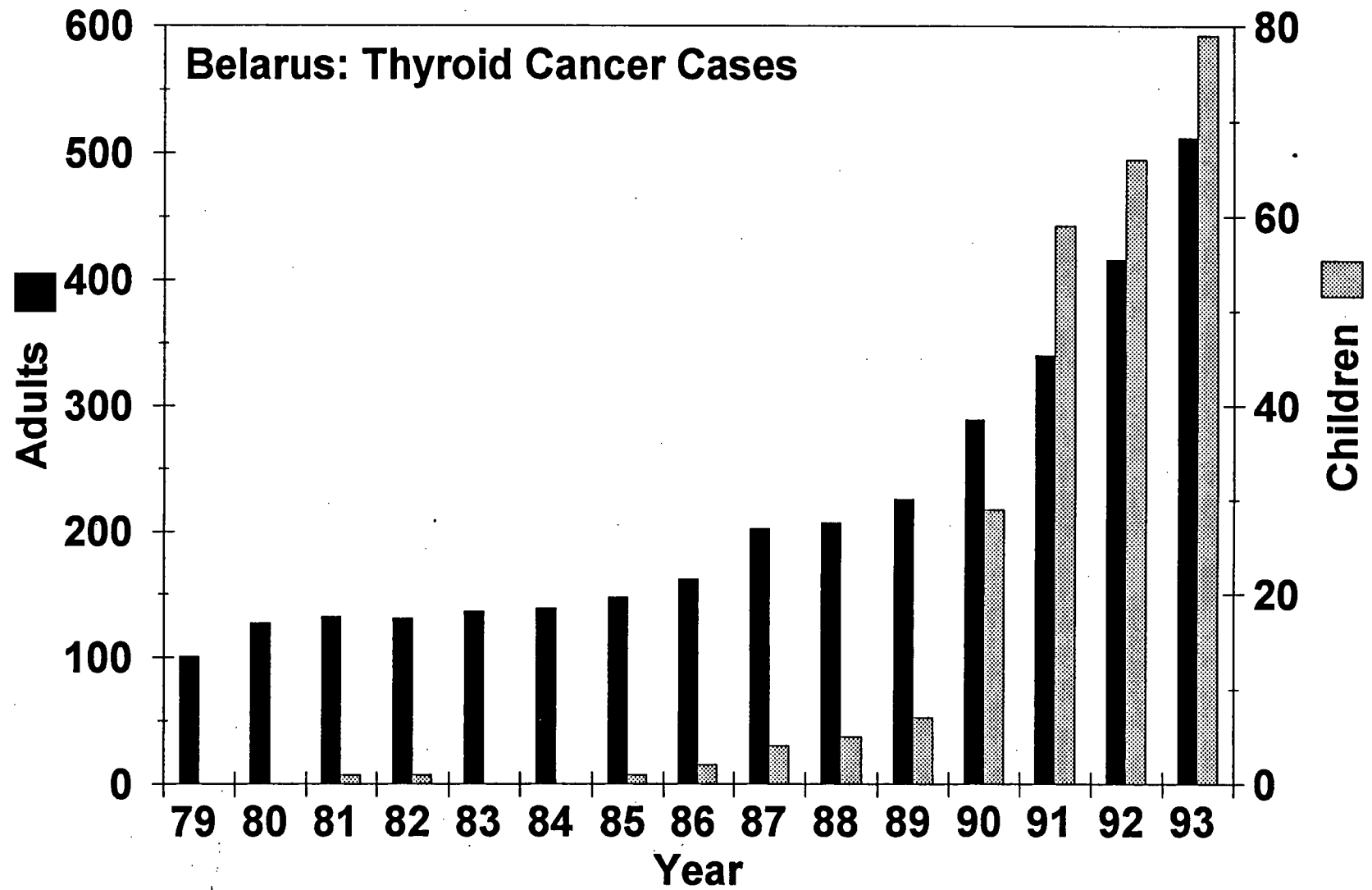
**Leslie Robison, Ph.D.**

**Bruce W. Wachholz, Ph.D.**

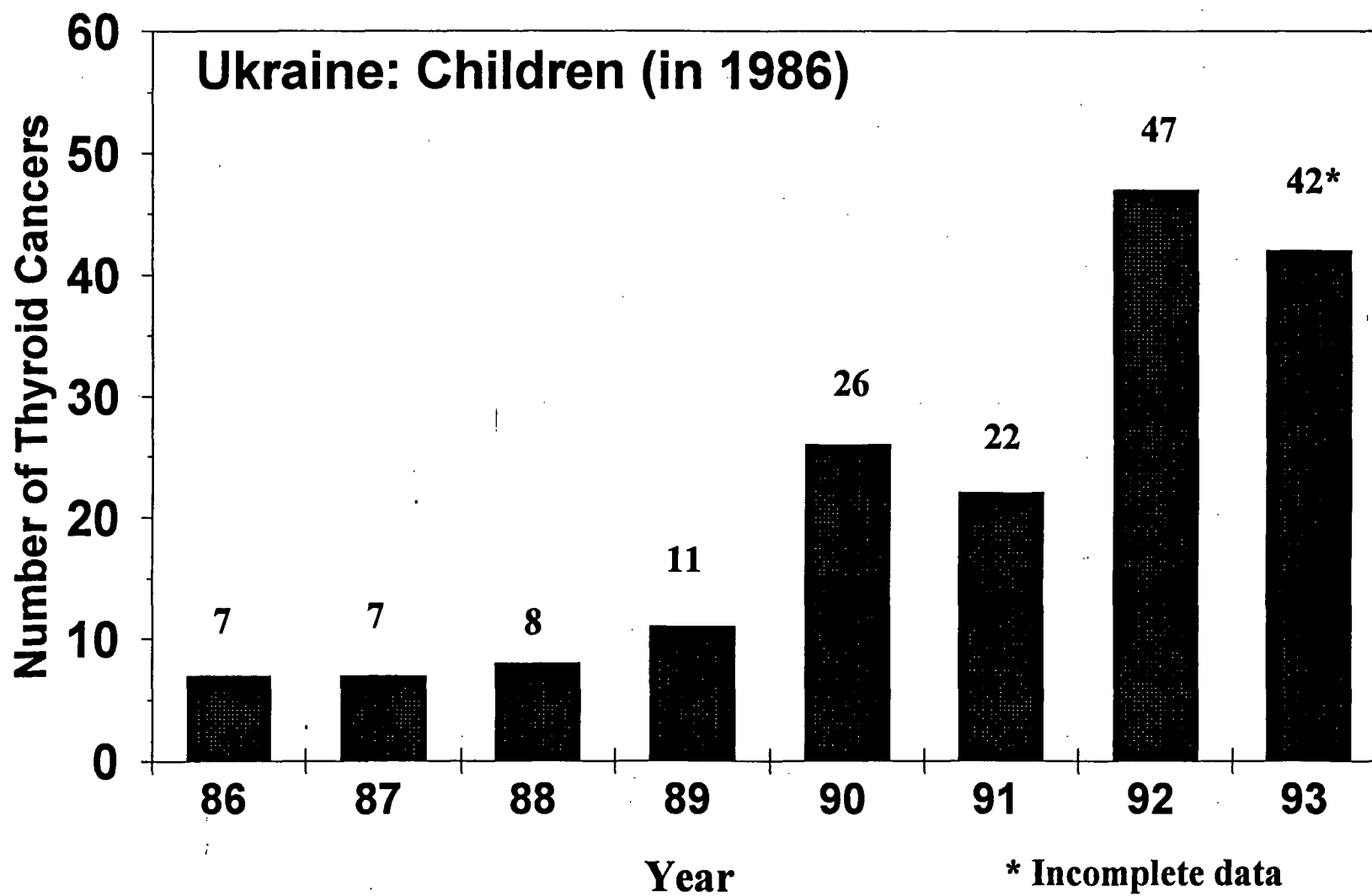
## **U.S. INTEREST - THYROID**

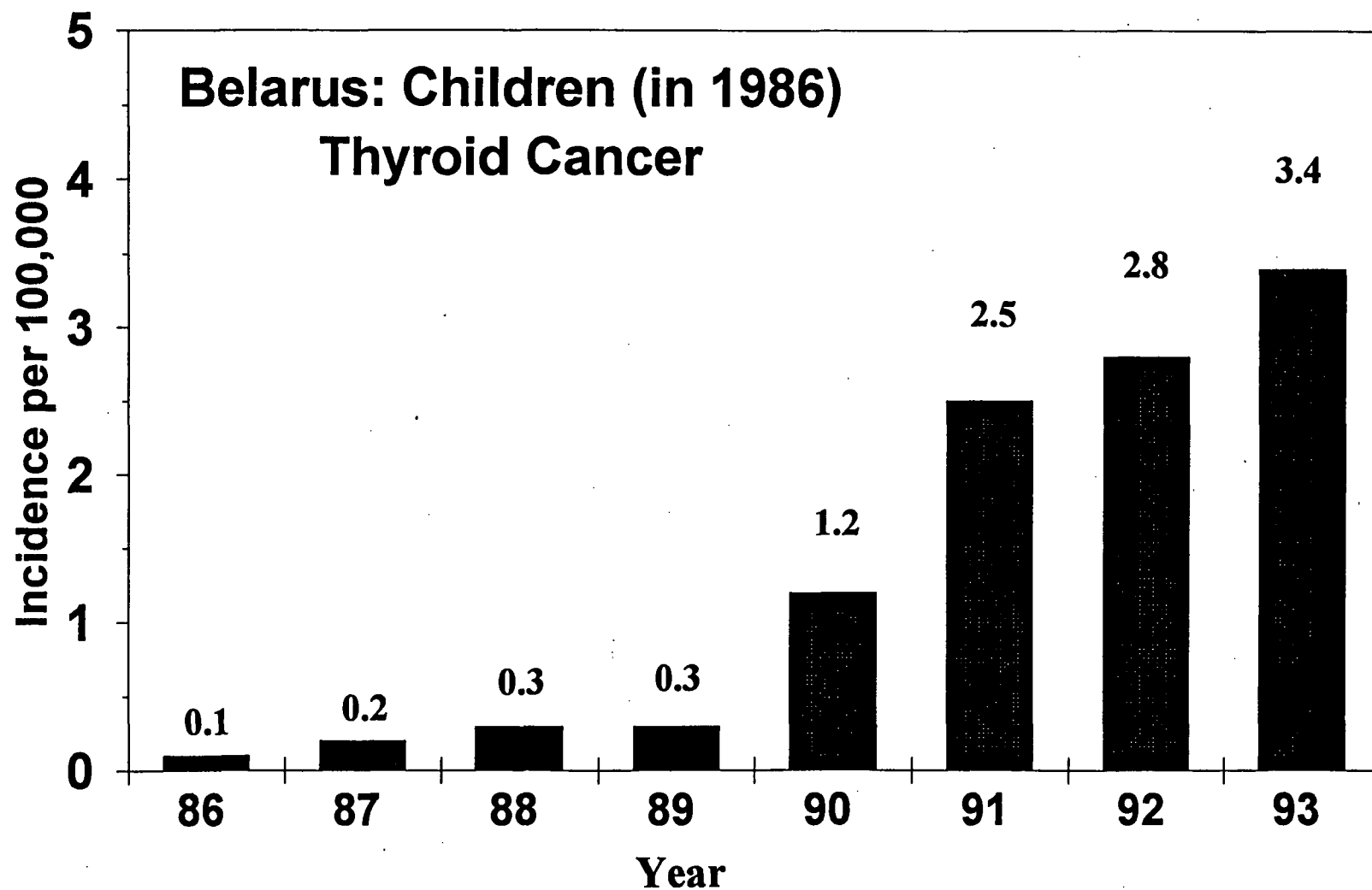
- Risk of Thyroid Cancer from I-131 Unknown
- I-131 Most Likely Source of Accidental Public Exposure
- Accidental Reactor Releases of I-131
  - Windscale, ENGLAND (1957) - ~ 20,000 Ci
  - Three Mile Island, U.S. (1979) - ~ 15 Ci
  - Chernobyl, UKRAINE (1986) - ~  $30 \times 10^6$  Ci
- Chernobyl -  $> 1 \times 10^6$  Children Exposed  
 $> 1 \times 10^5$  Children's Thyroids Measured

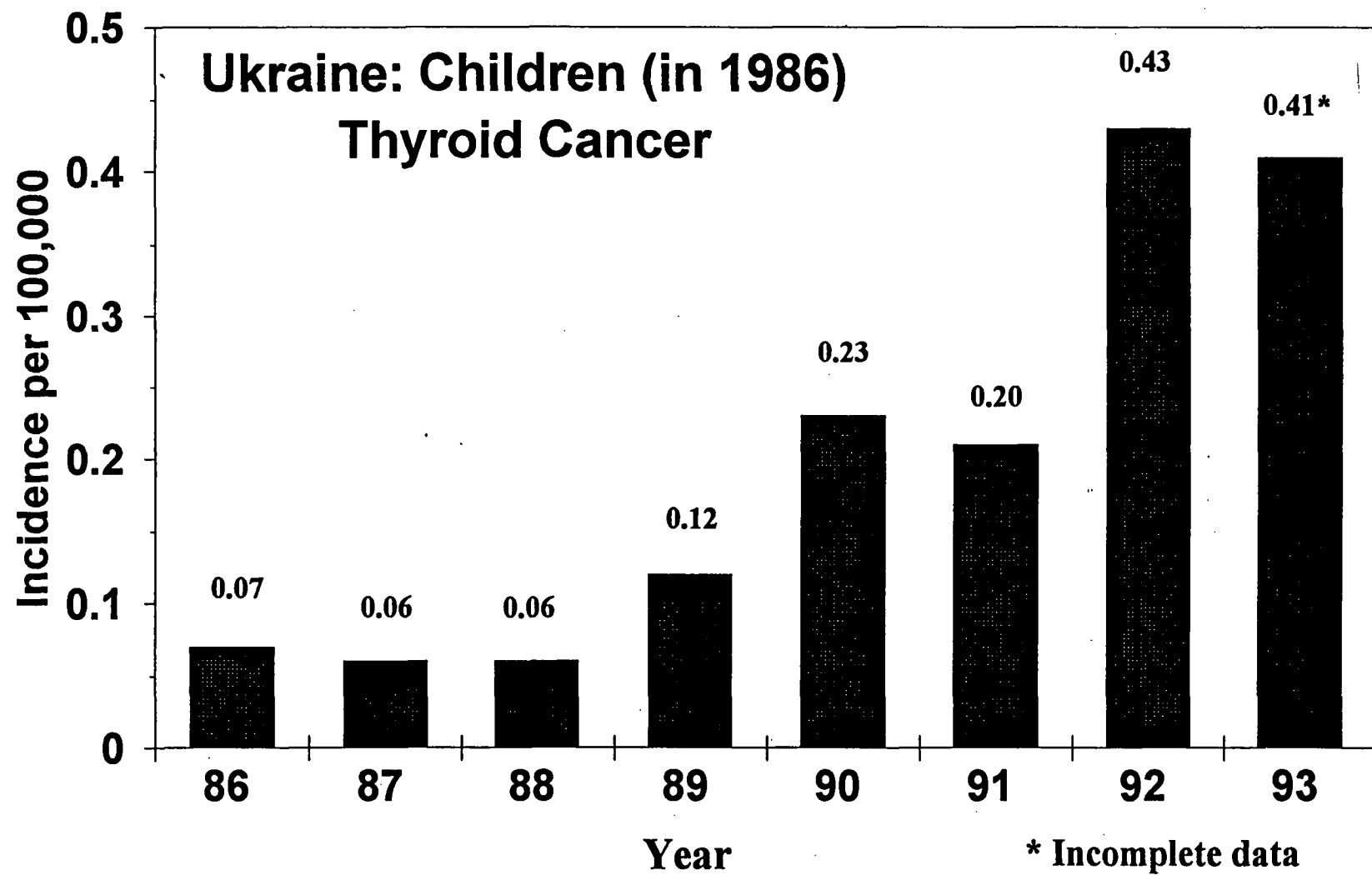












# THYROID STUDIES

- Case-Control Studies

- Belarus (1992) - 119 Cases of Children with Thyroid Cancer
- Ukraine (1993) - Number of Cases to Be Determined

- Cohort Studies

- Belarus - 15,000 Children
- Ukraine - ~70,000 Children
- Risk Estimates for Cancer, Nodules and Hypothyroidism
  - Dose
  - Age (at time of exposure)
  - Sex

# **THYROID COHORT STUDIES**

## **OBJECTIVES**

- Dose- and time-related morphologic and functional changes in the thyroid glands of children exposed to radiation from radioactive materials released from Chernobyl
- Risk estimates for nodules and cancer as a function of dose in relation both to sex and to age in 1986
- Comparison of the relative effectiveness of I-131 with that of X ray and gamma irradiation in inducing thyroid nodules and cancer
- Risk estimates for induction of hypothyroidism as a function of dose in relation both to sex and to age in 1986

# **THYROID COHORT STUDIES**

## **BELARUS AND UKRAINE**

- **Sampling**
  - 1986 Thyroid Measurements
  - Children or in utero, 1986
  - Fixed Cohort
- **Annual/Biennial Follow-up Examinations**
  - Palpation
  - Ultrasound
  - Laboratory Tests
  - Fine Needle Biopsy (as indicated)
- **Dose Reconstruction**
  - 1986 Measurements on Thyroid
  - I-131 Fallout Maps
  - Exposure History (Residence, Diet, etc.)

**THYROID DOSE DISTRIBUTION  
FROM THE CHERNOBYL ACCIDENT  
AMONG CHILDREN WITH THYROID MEASUREMENTS**

Estimated Dose (Gy)	Belarus	Ukraine
0-0.3	13,556	45,938
0.3-1	8,631	19,293
1-2	2,806	5,684
2-5	1,743	3,698
5-10	370	1,012
>10	111	530
TOTAL	27,217	76,155

# THYROID DOSE RECONSTRUCTION

- Cohort Studies: Based on Thyroid Measurements
- Case-Control Studies: Based on  $^{137}\text{Cs}$  Ground Deposition
- Factors Contributing to Exposure of the Thyroid:

Primary:  $^{131}\text{I}$ -contaminated Milk

Other:  $^{131}\text{I}$ -contaminated Foodstuffs

Inhalation:  $^{131}\text{I}$ ,  $^{132}\text{I}$ ,  $^{133}\text{I}$

External Irradiation:  $^{134}\text{Cs}$ ,  $^{137}\text{Cs}$



# **STATUS OF THYROID STUDIES**

## **Belarus**

### **Case-Control (1992)**

**All cases and control subjects selected**

**Pathology reviewed for most cases**

**Individual information received from most subjects**

**Individual dose reconstruction yet to be completed**

**Analyses in process**

**Publication in initial stages of preparation**

# **STATUS OF THYROID STUDIES**

## **Ukraine**

### **Case-Control (1993)**

#### **Partial Identification of Cases**

#### **Current Efforts**

- **Identify Additional Cases**
- **Identify Control Subjects**
- **Dose Reconstruction**
- **Confirmation of Pathology**

# **STATUS OF THYROID STUDIES**

## **Belarus**

**Cohort (1994)**

**Research Protocol Completed**

**NCI/NIH Scientific Peer Review Completed**

**Institutional Review Boards**

**Belarus - Established and Approved**

**NCI - Approved**

**NIH Approval Received**

**Belarus and U.S. Signed Agreement to Implement Protocol**

**Operations Manual in Preparation**

**Priority Equipment Needs Identified**

**Arrangements in Progress for Semi-resident Representative**

**Exchange of Experts**

**Training**

**Belarussian Management Team**

**Advisory Committee**

# **STATUS OF THYROID STUDIES**

## **Ukraine**

**Cohort (1994)**

**Research Protocol Completed**

**NCI/NIH Scientific Peer Review Completed  
Resolution of Comments Imminent**

**Institutional Review Boards**

**Ukraine: Yet to be established**

**NCI: To be submitted following resolution of peer review  
comments**

**Exchange of Experts**

**Training**

**Ukrainian Management Team**

**Advisory Committee**

# ESTIMATED COSTS

## FOR THE FIRST THREE YEARS (U.S. \$ \*)

	Year 1		Year 2		Year 3	
	Belarus	Ukraine	Belarus	Ukraine	Belarus	Ukraine
Equipment	890	1,000	380	130	240	220
Supplies	290	560	450	460	700	770
Training, Workshops, Travel, Non- government salaries/fees	500		500		500	
TOTAL	3,240		1,920		2,430	

\*(in thousands)

## **U.S. INTEREST - LEUKEMIA**

- Risk of Leukemia ("Low" Doses/"Low" Dose Rates) Unknown
- Previous Exposure Populations
  - Japanese - Acute
  - Occupational - Low
- Chernobyl - ~ 600,000 Clean-Up Workers

# **LEUKEMIA STUDIES**

## **OBJECTIVES**

- Provide risk coefficients following exposure to low-to-moderate doses of radiation, and compare with Japanese data
- Assess time-response function and the influence of dose rate
- Investigate pathogenesis of radiogenic leukemia and provide for future studies of molecular biology
- Estimate future leukemia and solid tumor excess among clean-up workers

# LEUKEMIA STUDIES

## PHASE I - 18 Months

- Sampling - Sources of Information:      Clean-Up Workers  
   Registries
- Dosimetry
  - Physical:      Badges  
                                 Radiation Fields  
                                 Questionnaires/Interviews
  - Biological:
    - Fluorescent in Situ Hybridization for Translocation Analysis (FISHTA)
    - Glycophorin-A (GPA) Somatic Cell Mutational Assay
    - Electron Paramagnetic Resonance (EPR)
    - Storage of Blood and Bone Marrow
- Leukemia:      Ascertainment (1986-1992)  
                                 Diagnostic Review/Terminology
- Other

## PHASE II - Long-Term Epidemiological Study



# **STATUS OF LEUKEMIA STUDIES IN UKRAINE**

**Scientific Research Protocol**

**Draft Protocol Prepared - March, 1994**

**Revised Protocol Subject of Meetings - September, 1994**

**Final Protocol Anticipated Before January, 1995**

**Projected Budget: \$3M over 10 years**

# **BELARUS**

- **Minister of Health**

Current - Inissa M. Drodyshevskaya

Former - Vasily S. Kazakov

- **Director, Institute of Radiation Medicine**

Alexander N. Stozharov

- **Deputy Director, Institute of Radiation Medicine**

Larisa N. Astakhova

# **UKRAINE**

- **Minister of Health**  
Current - Vladimir A. Bobrov  
Former - Yuriy Spizhenko,  
Member of Parliament
- **Director, Ukraine Scientific Center for Radiation Medicine**  
Anatoly Ye. Romanenko
- **Director, Institute of Endocrinology and Metabolism**  
Nikolai Tronko
- **Chief, Department of Dosimetry and Radiation Hygiene**  
Ilya Likhtarev