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REPORT

Medical-Biological, Epidemiological, Dosimetrical, Computer-Informational, Administrative Activities for Implementation of Joint BelAm Scientific Protocol for the Studies of Thyroid Cancer and Other Thyroid Diseases in Belarus Following the Chernobyl Accident in the Framework of Invoice for the period of 01.10.1998 - 31.12.1998

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MINSK, 1998

Task No. 1: The management and administration of the BelAm Thyroid Study.

Milestone 1: Weekly meetings with the group leaders to discuss and record the progress of the Project and their reflection in the minutes.

(Administrative group)

In the fourth quarter Administrative Group conducted 12 meetings with Project Group Leaders. During these meetings Leaders reported for performed activity of their groups in the 4-th quarter. All the scheduled measures have been fulfilled..

Special meeting was dedicated to problem of quarter reports compiling. It was recommended to the Group Leaders to be more exact and detailed while formulating performed activity.

The question was also discussed regarding reconstruction of spaces for screening group. The reconstruction is going on according to the schedule. In the 1-st quarter 1999 it is expected to finish up the reconstruction.

The following questions have been also discussed at the meetings:

1. Set up an archive of hard copies. It was decided to store all hard copies in board-boxes before file cabinets will be purchased.
2. Share information with Gamely Dispensary cooperating with Sasakava Foundation. Data on 4.5K individuals examined in Sasakava Project will be given to BelAm Project as soon as computer data base will be set up. At present programs for data entry are at the process of installation.
3. Schedule cohort selection. Dr. Buglova was charged to get information of subjects addresses from local institutions of Ministry of Home Affairs. The information have been received. Screening schedule for January and February 1999 is in progress now
4. Update Operational Manual. Group Leaders have worked out their suggestions for changing of Operational Manual. Chief of Quality Control Group is in charge for changes to Operational Manual.
5. Train staff in accordance with the rules of activity performance in the Project. Training have been performed. Records of training are kept by Quality Control Leader and in Groups.
6. Provide Central Laboratory with reagents. It was noted that there is no regular deliveries of reagents for estimation of hormones and antibodies. Dr. Petrenko was charged to prepare detailed request for 1999 deliveries and send it to NCI. The request form has been sent.
7. Trip of mobile team to Khojniki. It was decided to send invitations to subjects to come to Khojniki Regional Hospital in December. Mobile team of 12 specialists worked in Khojniki from 14 to 22 December. 174 subjects have been examined.
8. Participate in data linkage workshop in Kiev. Head of DCC, representatives of Cancer Registry and Chernobyl Registry participated in the workshop. Mrs. Lesnikova reported about the results of the workshop. It was also discussed the Project experience of Kiev Research Institute of Endocrinology.

9. Formalization of diagnosis of thyroid diseases. Drs. Danilova and Polianskaja have prepared suggestions on algorithm of diagnosis formulating for physicians and on reference for data entry operators..

Among discussed questions there were also questions regarding equipment repair, acquisition of expenditures, and other current issues.

Milestone 2: Administrative support of cohort establishment to supply access to various informational sources, especially sources of address information.

(Administrative group)

For the reported period Administrative Group provided administrative assistance in getting address information for individuals moved to another places of residence following the accident. Administrative group found money to purchase expenditures. At the cost of Research Institute of Radiation Medicine and Endocrinology it was bought paper, toner, cartridges. It was arrange a transportation of mobile team and field trip of epidemiologists, dosimetrists, and screening team. Administrative group arrange contacts with Passport Offices, Ministry of Home Affairs.

Administrative support was provided to patients referral from the rajons. As well as some preparatory activity was performed for subjects examination in Khojniki.

Milestone 3: Coordination between Belarus and U.S. participants with respect to all activities of the Project.

(Administrative group)

All the activities of the Project were coordinated according to the following aspects:

1. Compiling of quarter reports. It was agreed to compile short reports describing all the tasks and milestones scheduled for the quarter.
2. Equipment repair. ABBOT instrument have been fixed. Question of payment for fixing of ultrasound probe is to be decided.
3. Acquisition of equipment, reagents and expenditures. Paper, toners, cartridges, computers have been purchased by American colleagues during their staying in Minsk, October 1998. A specified schedule of deliveries for 1999 have been prepared.
4. Appointment of Head of Quality Control Group. Dr. O.N. Polianskaja has been appointed to this position.
5. Personnel. Mrs. N.R. Lesnikova has been appointed to the position of DCC Head. Mr. A.V. Kuvshinnikov has been retired from the position of DCC Head and he works in Project as an advisor for computer aspects and is responsible for equipment utilization.
6. Brest file. Information of thyroid direct measurements in population of Brest Oblast occurred to be lost.
7. Meeting of bi-national Advisory Group. The meeting is scheduled for 1999.
8. Multiple visas. All necessary information have been sent to NCI.
9. Joint work of Belarus specialists and US experts. It was decided that in 1999 such work will be performed with small groups..

Task No. 2: The establishment of the cohort of subjects for study.**Milestone 4: Work to locate provisional cohort of 15,000 and select at least 1,000 accessible to the Minsk Dispensary***(Data Coordinating Center)**(Epidemiology Group)*

In the IV-th quarter (01.10.98.–31.12.98r) Epidemiology group completed searching of subjects included to the cohort through Address Offices of six oblasts of Belarus.. DCC set lists of provisional cohort subjects who according to previous information lived in Minsk and Minsk oblast and had status “no response within a month”, “wrong address”. Besides this file contains information on subjects who according to different sources moved to Minsk or Minsk oblast without exact address information, and all the subjects who according to dosimetric DB lived in Minsk or Minsk oblast at the moment of Chernobyl accident and had not been located in the initial search.

Epi Group sent a list of 1622 subjects to Address Offices of Minsk and Minsk Oblast. As a result of this activity 586 new addresses (36,1%) have been entered to mailing system of epidemiological base for sending invitations to examination scheduled for November of current year.

To verify addresses of children born 1982-1986 who is under 16 and could not be registered themselves in Address Offices Epi Group put the following task to DCC: to perform a selection of pairs considering their place of residence at the time of the accident according to the following parameters: family name of child and similar family names of provisional mothers. As a result of performed activity DCC create a file comprising 988 children and 4.784 mothers who lived in Gomel Oblast at the time of the accident. An attempt was made to define address of this group of children through address of provisional mother. Epi Group has sent a list to Address Office of Gomel Oblast.

For the reported period DCC made a preliminary review of possibility of additional subjects selection in total base of 39 K. For this purpose computer linkage was performed between DB of direct measurements and following DBs

- Chernobyl Registry,
- Polyclinics ## 32 and 25, Minsk city,
- Sasakava Foundation,
- WHO,
- National Dispensary of Radiation Medicine,

As a result of performed linkage 4.703 addresses have been obtained. This information was sent to Dr. Beebe for discussion.

Milestone 5: Determine current addresses of about 5,000 members of cohort for whom letters were sent and who did not respond.*(Epidemiology Group)*

Location of subjects not responded to invitation was continued in the 4-th quarter. Searching activity was performed through Address Offices of Minsk and Minsk Oblast and 3 Departments of Public Education (DPE) of Gomel oblast. The results of this activity are presented in Table 1.

Table 1. Results of address verification of provisional cohort subjects not responded the invitational letters

Result of searching activity	Number of subjects, abs. %		
	Address Office	DPE, Gomel oblast	Total
New address	586 (36,1%)	42 (3,5 %)	628 (22,2 %)
Confirmed former address	75 (4,6 %)	103 (8,5 %)	178 (6,3 %)
Moved within Belarus	12 (0,74%)	80 (6,6 %)	92 (3,3 %)
Moved out of Belarus	6 (0,4 %)	15 (1,2 %)	21 (0,7 %)
Death	1 (0,06 %)	-	1 (0,03 %)
Imprisoned	3 (0,2 %)	2 (0,2 %)	5 (0,2 %)
Lack of information	917 (56,5 %)	948 (78,5 %)	1865 (65,9 %)
Not reside verified address	18 (1,1 %)	17 (1,4 %)	35 (1,2 %)
Disagreement with DBDM	4 (0,3 %)	-	4 (0,1 %)
Total:	1622 (100 %)	1207 (100%)	2829 (100 %)

As a result of performed activity to 628 provisional cohort subjects informational letters with invitation to examination have been sent. 31 individuals have been excluded from further search (moved out of country, died, not fitted by age, imprisoned), 103 individuals (children of school age living in Gomel Oblast) are included to reserve group for examination by mobile team of Minsk Dispensary, to 75 subjects living in Minsk and Minsk Oblast who's address was confirmed by Address Office repeated invitations have been sent. *why not to 103 is final?*

Milestone 6: Determine the location of geographical areas with high numbers of people with identified current addresses for possible examination by mobile teams

(Epidemiology Group)

(Data coordinating Center)

To get the information of geographic distribution of cohort subjects of children age that could be examined by mobile team the lists have been sent to 10 DPE of Gomel oblast in 3-rd quarter. In the 4-th quarter we have received information from ^{VETKA} Bragin, Narovlia, and Bragin DPEs. Information of verified addresses is presented in Table 2 ?

Table 2. Results of searching activity of cohort subjects from high dose and randomized groups through DPE, Gomel oblast

Results of search	Number of subjects, abs.			
	Vetka	Narovlia	Bragin	Total
New address	24	5	13	42
Confirmed former address	18	53	32	103
Moved within Belarus	24	40	16	(80)
Not reside verified address	-	15	2	(17)
Moved out of Belarus	6	9	-	(15)
Imprisoned	-	-	2	(2)
Lack of information	109	205	634	948
Total:	181	327	699	1207

42
103
948

1093
= 86%

Performed by Epi Group activity allowed to define new addresses of 42 children and verify addresses of 120 provisional cohort subjects (confirmed address, moved out of Belarus, imprisoned). Thus 145 individuals living in Bragin, Vetka, and Narovlia rajons could be examined by mobile team of Minsk Dispensary.

In the 4-th quarter at the stage of invitation of subjects to be examined by mobile team in Khojniki DCC set up a file of 724 individuals who had statuses of "no response within a month" or "reserve". Address information was preliminary verified through Address Office and DPE. To 542 individuals living mostly in Khojniki (371 inds.) invitations to examination have been sent. Additional list of 182 provisional cohort subjects who had status "no response within a month" (rural inhabitants) was used by epidemiologists for addresses verification through local obstetrical stations of Khojniki rajon. During field trip of mobile team to Khojniki Epi Group worked with provisional cohort subjects of these two lists. To make a contact with cohort subjects epidemiologists visited 189 apartments, Technical School #131, Comprehensive Schools ##1,2,3,4, assisted in delivery of subjects from villages Malishev and Sudkovo to examination. As a result of performed epidemiological activity it was revealed the following: from the whole number of individual to whom invitations have been sent 5 inds. Moved out of Belarus, 47 - wrong addresses, 10 inds. could not come to examination because of military service, pregnancy, treatment in sanatorium, study. While verifying addresses of provisional cohort subjects from Alecsichi, Vit', Ezapov, Gubarevichi, Malishev, Partizanskaja, Poselichi, Rabets, Rudakov, Slobozhanka, Strelichev and Sudkovo villages who did not respond to previous invitations it was find out that 13 of them moved to new place within Belarus, 15 - wrong addresses, to 3 of them "reserve" status was given, and one individual is imprisoned. 25 subjects agreed to be examined by mobile team. Totally, 174 provisional cohort subjects have been examined by mobile team, 133 of them (76%) had previous status "no response within a month" and 41 had "reserve" status. High percentage of no-respondents among examined by mobile team confirms the possibility of involving mentioned subjects to cohort with the help of mobile team.

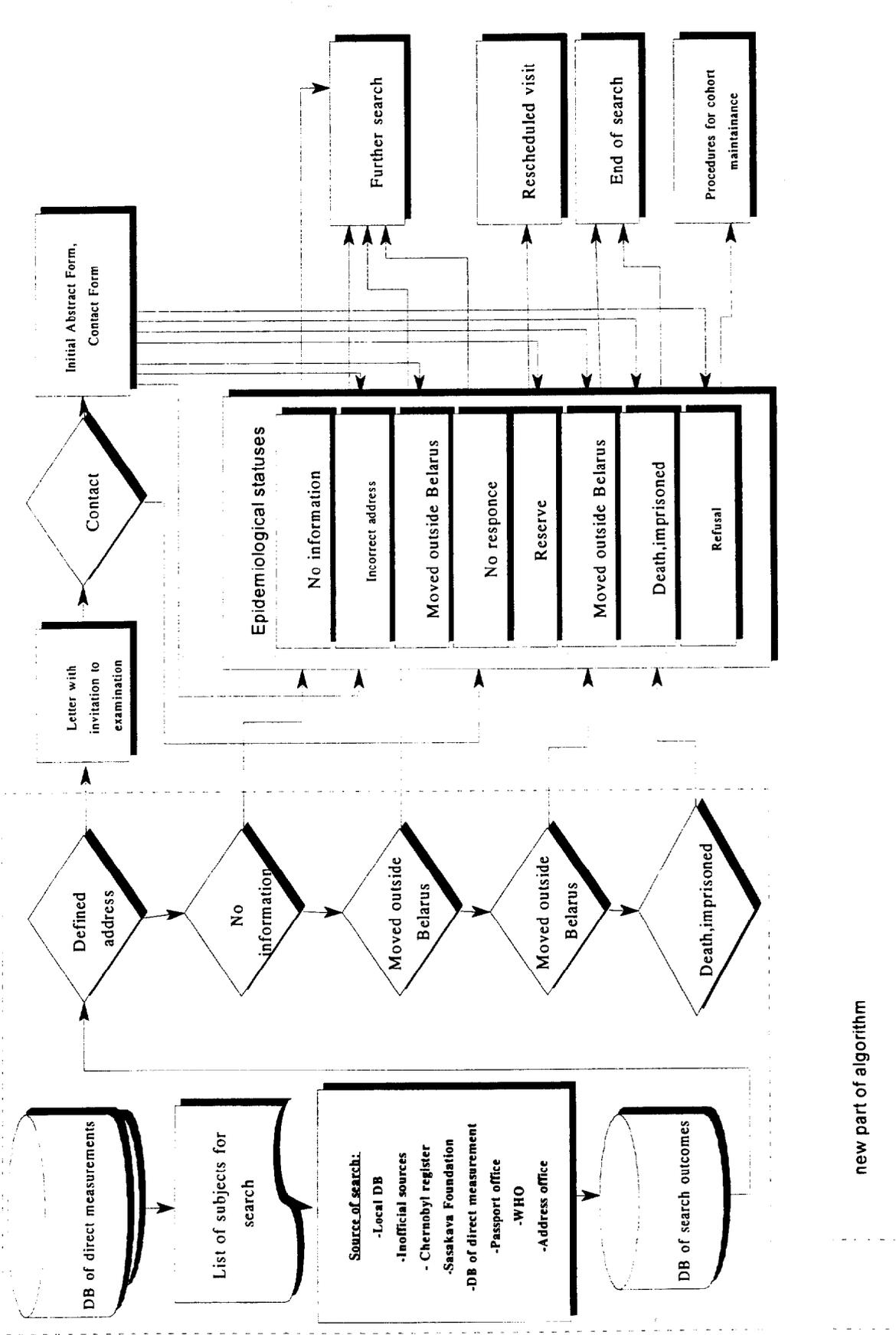
Milestone 7: Create initial data base of exposed "in utero"
(Epidemiology Group)

In the 4-th quarter epi group continued the activity aimed at setting up initial DB of cohort study of children born 26.04.86 - 31.01.87 and exposed "in utero". In the fourth quarter information on 12.900 inds. was entered to the DB. By now this file comprise information on 28 K of children exposed "in utero".

Task 3. The invitation and scheduling of subjects for endocrinologic examination

Milestone 9: Preparation of the letters of invitation, software and procedures for inviting and scheduling subjects for examination
(Epidemiology Group)

In the 4-th quarter epi group sent 2065 informational letters with invitation to examination. 248 subjects have been invited for October who's addresses were verified through Address Offices and DPE. In November invitations have been sent to 807 provisional cohort subjects who according to the data of Address Office live in Minsk or Minsk Oblast (597 inds.) and in other Oblasts of Belarus (210 inds.). For December the following groups of subjects have been invited: 445 cohort subjects for annual follow up



new part of algorithm

Fig.1. Algorithm of search and making contact with provisional cohort subject

examination in the National Dispensary (follow up visit), 23 inds. for initial visit (their addresses have been verified in the 3-rd quarter through DPE of Gomel Oblast), and 542 inds. for examination by mobile team (they have status "no response within a month" and live in Khojniki and Khojniki rajon).

For reported period 2.362 forms have been entered to epidemiological DB of cohort study, 1.357 of them have been entered in automatic mode.

((Data Coordinating Center))

In the fourth quarter DCC started working on reconstruction of the history of subjects searching through different sources. Up till now some part of searching results have not been entered to the DB because information was stored in separate files, and computer data processing system has not been developed.

For the reported period an algorithm and a part of software have been designed that allowed to keep the history of subjects searching, results of searching activity, and to combine it with existing epidemiological dB tracing current state of cohort as well as procedures of visits scheduling and invitation of subjects to examination. Such efforts will also allow to decrease a group of "no response within a month and to increase number of subjects invited to examination.

Algorithm for automatization of searching system is presented in Fig 1. Because of importance of questions related to cohort maintenance DCC have worked out software used for greeting of subjects with different holidays and all subjects passed examination received New Year greetings.

Task No. 4 The endocrinologic examination of subjects, including subsequent diagnostic procedures leading to the establishment of the final pathologic diagnosis.

Milestone 9: Screening up to 600 subjects in Minsk Dispensary, including the laboratory work.

(Screening Center)

Examination. Totally, for the reported period 591 inds. passed examination in the Screening Center: 465 (78.7%) - for the first time, and 126 (21.2%) - repeated. Mobile team examined 174 inds. (29.44%) in Khojniki (December 10-23, 1998).

From all examined subjects (591) in **69 (11.7%)** thyroid pathology have been revealed, in 16 of them (2.7%) - for the first time. Distribution of subjects according to revealed diagnosis is given below.

Thyroid cancer have been found in **8 (1.4%)** subjects. 2 of them (0.3%) the disease have been diagnosed for the first time, and in both of them - while repeated examination

1. L.I. ., born 1973., previous diagnosis - nodular goiter repeated examination - 22.10.98. Fine needle biopsy (FNB) of thyroid was performed, cytogram revealed the cells of papillary cancer. Hospitalization to the Clinic, Research Clinical Institute of Radiation Medicine and Endocrinology (RCIRME) - 29.10.98-05.11.98. Surgery in National Center of Thyroid Oncopathology (NCTOP) - 23.11.98 (pT1aN0Mo - according to the data of NCTOP). From the moment of screening examination to the moment of surgery 1 month have passed.
2. T.S. : born 1984 , previous diagnosis - nodular goiter, repeated examination - 08.12.98. Fine needle biopsy (FNB) of thyroid was performed, cytogram revealed the cells of papillary cancer. Hospitalization to the Clinic, Research Clinical Institute of Radiation Medicine and Endocrinology (RCIRME) - 16.12.98-24.12.98. Surgery in National Center of Thyroid Oncopathology (NCTOP) - 05.01.99 (pT2aN1aMo - according to the data of NCTOP). From the moment of screening examination to the moment of surgery 1 month have passed.

In both cases while repeated examination according to ultrasound data change of structure and fast enlargement in sizes of previously revealed thyroid malformations have been revealed. Such dynamics allowed to suspect thyroid cancer that was confirmed by thyroid FNB findings, and furthermore - by pathomorphological examination. The rest 6 cases of thyroid cancer have been revealed previously, 3 of them have been examined by the project initially and 3 - have passed repeated examination.

Diagnosis of nodular goiter at the stage of screening have been revealed in **33 inds. (5.5%)**. In 10 (1.7%) of the disease was revealed for the first time (9 - during initial examination and 1 - during repeated). In 23 subjects diagnosis was known previously (17 - examined initially). Besides, in **4 (0.7%)** inds nodular goiter have been suspected. By the time of this report submittal endocrinological department have examined 12 from 33 patients with nodular goiter. The diagnosis was confirmed in 2 from 4 patients with suspicion to it.

6 inds.(1%) have been examined with diagnosis of autoimmune thyroiditis. 3 of them have been diagnosed for the first time.

Besides 5 (0.9%) inds. have been examined with suspicion to autoimmune thyroiditis. In 4 of them the diagnosis have been confirmed in the Clinic RCIRME. 1 patient is scheduled to hospitalization for 1-st quarter 1999.

11 inds.(1.9%) have been examined with diffusive goiter IB. For the first time this disease have been revealed in 2 subjects (both during initial examination), previously known disease was in 9 inds. (6 of them have been examined initially). 2 inds. (0,3%) have been examined with diagnosis diffusive goiter, II degree (both of them have repeated examination).

Thus, the structure of thyroid pathology revealed in the 4-th quarter was the following:

Thyroid cancer	8	(11.6%)
Nodular goiter	37	(53.6%)
Autoimmune thyroiditis	11	(15.9%)
Diffusive goiter, 1B и 2 degrees	13	(18.9%)

As it is seen from given data the priority is for nodular goiter (53.6%).

Referral to thyroid FNB. At the screening stage 6 FNB have been performed for the patients with nodular pathologies. All the punctures were informative. Distribution of patient according to FNB results is the following: thyroid cancer -2, nodular goiter - 3, without changes - 1.

Referral to hospitalization. In the fourth quarter 44 subjects have been examined in the Clinic, RCIRME человека:20 children, 22 adults. 4 subjects have been consulted in NCTOP, 3 of them have been operated (2 - thyroid cancer, 1 - colloid-cystal goiter) One subject with previously revealed thyroid cancer had no signs of recedive and metastases..

Final Medical Conclusion and Recommendations. In the 4-th quarter Screening Center received from the Central Laboratory the following tests results: blood test - 1.041 indices, TSH - 155, Ab to TPO - 740, Ab to TG - 897, Calcium - 170, Parathyroid Hormone - 39. Thus, final diagnosis was made to 155 subjects. Screening Center has not received the results of iodine content in urine of subjects.

(Central Laboratory)

In the 4-th quarter Central Laboratory examined 597 subjects. The results of the Central Laboratory activity in the 4-th quarter:

- taken blood samples - 596
- filled forms of blood collection - 596
- refused from blood collection - 1
- taken urine samples - 592
- filled forms of urine collection - 597
- refused from urine collection - 5

Performed tests:

1. Content of TSH hormone- 594
2. Content of ionized Calcium- 594
3. Content of Iodine in urine - 580
4. Content of antibodies to TG - 510 (for 1-st and 2-nd quarters 1998)

5. Content of antibodies to TPO - 510 (for 1-st and 2-nd quarters 1998)

6. Content of parathyroid hormone - has not been estimated

Tests of thyroglobuline were not performed because of lack of reagents.

Estimation of functional state of parathyroid glands through the level of ionize calcium in blood serum

Estimation of ionized calcium was performed in blood serum of 594 cohort subjects. During the preliminary studies a value of regional norm was obtained (random sample of 150 healthy inds.) - $1,26 \pm 0,005$ ($M \pm \sigma 2$) mMol/l, range of distribution: 1,1 - 1,35 mMol/l. These finding of regional norm were taken as a control index of ionized calcium content in blood while reviewing the results of examination of cohort subjects. While making an individual review of calcium in examined cohort (594 inds.) 8 subjects (1,35%) had increased content of given index. Obtained data need to be further studied and need further examination of the cohort subjects. In particular, they should be subjected to examination of parathyroid hormone by radioimmunal method. Obtained data are entered to the "Paradox" DB for further reviewing.

Estimation of thyroid functional state through the level of TSH in blood and iodine excretion with urine.

TSH content have been estimated in blood serum of 594 cohort subjects. In 5 subjects (0,84%) decreased level of TSH in Blood serum have been revealed, in 4 subjects (0,67%) increased level of TSH have been found. Because of two months delay in TSH reagents delivery (reagents have been received on 21 December, 1998) blood serums of subjects come to examination in the forth quarter have been analyzed and are entered to DB and to the Forms of blood collection and processing. Obtained results of TSH in blood will passed to the Scening Center by January 20, 1999.

Estimation of autoimmunal status of the body to thyroid proteins through the level of antibodies to TG and TPO in blood serum.

Central laboratory performed an estimation of antibodies to TG and TPO in blood serum of 510 cohort subjects examined in the 1-st and 2-nd quarters of 1998 as antibodies reagents were delivered in August 1998 and could not be used because of limited expiration date in November - December 1998. Obtained results are entered to "Paradox" DB for further reviewing, to Forms of blood collection and processing.

In the 4-th quarter Central Laboratory entered Forms of urine collection and processing for 1.057 subjects, and Forms of blood collection and processing for 175 patients.

Shortcomings

Significant shortcoming is irregular delivery of reagents for estimation of thyroid hormones and antibodies to them in 1997 - 1998. Deliveries come with two or more months delay. Unfortunately, the problem of regular delivery is still unsolved.

Irregular deliveries lead to incomplete laboratory examination of the subjects and made impossible to put final diagnosis of thyroid disease and perform scientific review.

Milestone 10: Clinical Examination and Verification of Diagnosis in Patients with revealed pathology

(Quality Control Group)

Examination in Endocrinological Department of Clinic, RCIRME.

According to the results of screening by 01.01.99 46 inds. (7.8% from total number of examined) were hospitalized to Endocrinological Department of Clinic, RCIRME. Distribution of patient according to the final diagnosis is presented in Table 3.

Table 3.

Distribution of subjects according to final diagnosis made in endocrinological department of Clinic, RCIPME.

IDC	Nosologic form	## of subjects, abs. %	
		abs.	%
193.0	thyroid cancer, state following surgical and (or) combined treatment	6	13
241.0	nodular nontoxic goiter	22	47.8
241.1	multinodular nontoxic goiter	9	19.6
245.2	autoimmune thyroiditis	5	10.8
242.0	diffusive toxic goiter	1	2.2
	post-surgical hypothyroiditis	1	2.2
	operated thyroid	1	2.2
	paratracheal cyst	1	2.2
	total	46	100

As it is shown from presented data nodular non-toxic goiter prevails in the structure of pathology of hospitalized patients. From 22 subjects with such diagnosis 4 inds have been referred to NCTOP for surgical treatment, three of them with suspicion to thyroid cancer (T.S. Tselujlo, L.I. Stelmack, V.V. Shevchenko) and one with thyroid adenoma N.A. Krotov)

At the clinical stage 15 thyroid FNB have been performed.

Deviations in final clinical diagnosis (D2) and screening diagnosis (D1) took place in 3 subjects

	(D-1)	(D-2)
D.A. Nikolaenko.A.	Diffusive goiter	Nodular goiter
T.V. Kirikova.	Diffusive goiter	Nodular goiter
A.G. Petrovsky.	Nodular goiter	Paratracheal cyst

By the time of report submitting two patients from four hospitalized in the 4-th quarter are still in the hospital

Hospitalization to NCTOP

For the 4-th quarter 3 subjects have been hospitalized to NCTOP. All of them had surgical treatment: 2 - thyroid cancer (initially revealed), 1 - nodular goiter. 2 subjects (suspicion to thyroid cancer and thyroid adenoma) have not come to hospitalization.

Milestone 11: Conduct the cytological and pathomorphological aspects of the Project.
(Screening Center)

For the reported period Project Cytologist examined 19 bioplates of subjects with thyroid nodular pathology. 105 slides have been reviewed. The results of this activity is the following: thyroid cancer - 4, suspicion to thyroid cancer - 1, atypical proliferation - 1, without pathology - 10, uninformative material - 3.

Updating of Cytological Form and Operational Manual was also performed. Now the question is to be decide regarding review of cytological materials stored in Clinic, RCIRME and NCTOP. Results of quality control of Cytological forms is presented in Milestone 12.

Milestone 13: Expert support of screening activities

(Quality Control Group)

Head of QC Group and expert-endocrinologist worked out a temporary manual for the Head of Screening Group with respect to questions not described in Operational Manual, i.e. criteria of conclusion "normal thyroid", rules for coding of nodular pathology and diagnosis under the question, procedure of patients treatment in terms not envisaged by Operational Manual, tracing of subjects who have not come to hospitalization.

For the reported period Head of QC Group reviewed 11 Pathomorphological Forms, 102 Hospitalization Forms, 31 Cytological Forms.

Review of Pathomorphological Forms showed that up till now patomorphologists use the form data from could not be entered to DB. It was also revealed that conclusions of pathomorphologists is in disagreement in some cases with conclusions of NCTOP in the main diagnosis and pTNM categories. There is also disagreement in number of revealed nodules according to the data of ultrasound examination (USE) and patomorphological examination (PME) (Table 4)

Table 4.
**Disagreement in diagnoses of Surgical Form. Pathomorphological, and Thyroid
 Ultrasound Examination Forms**

ID	Subject Name	Main Diagnosis		P TNM		Number of thyroid nodules	
		NCTOP	BelAm	NCTOP	BelAm	USE	PME
76 389		Nodular goiter	Thyroid adenoma	-	-	-	-
115353		-	-	T2a	T4a	1	2
189112		-	-	No	Nx	-	-
178925		-	-	T2a	T4	3	1
98 225		-	-	T2a	T4a		
110380				N1b	N1a		

At the joint meeting with participation of surgeon and pathomorphologist these cases have been discussed. It was found out that disagreement in main diagnosis (thyroid adenoma and nodular goiter) was caused by atypical cases and could be solved by involvement of the third specialist-expert. Disagreement in pT4 and pT2 is caused by different interpretation of pT by pathomorphologists. Disagreements in pT1a and pT1b are also possible.

Review of disagreements in the number of nodules revealed during USE and PME is given below:

1. Subject : while PME a nodule has been found of 1mm not visualized in USE, that could be explained by resolution capacity of USE method.

Subject : according to USE data - three nodules in left lobe - nodule of cyst type of 2mm; and in right lobe - 2 nodules of complicated structure, 17 mm, one under another in mid and low part of a lobe. In PME nodule in left lobe has not been confirmed, and in right lobe - it was described as one nodule of similar size and location.

Expert analysis of thyroid FNB data and cytological examination showed that they could not be entered to computer because of lack of revised and adopted Form. New version of Form is reviewed by US expert.

Results of thyroid FNB performed at screening stage are presented in Table 5

Table 5.
Distribution of subjects according to the results of thyroid FNB

Result of FNB	Number of subjects	
	abs. number	%
Not informative	4	12.9
Without changes	10	32.3
Cancer, suspicion to cancer	8	25.8
Adenoma	1	3.2
Colloid goiter	7	22.6
Cyst	1	3.2
Total	31	100

As it is shown from the table a part of not informative FNB was 12.9%. This fact allows to estimate the work of physicians performed this activity as good. From 8 subjects with suspicion to thyroid cancer 5 had surgical treatment and cytological diagnosis was confirmed by PME.

It was revealed shortcomings in forms completion of two subjects to whom 2 nodule have been punctured and only one conclusion was made. Following revision of slides made by cytologist correction in corresponding forms was made. To simplify identification of number and location of puncturing nodules the Form is added by thyroid diagrams (D1, D2). It should be mentioned that the work of cytologist is complicated by absence of preliminary clinical diagnosis in the Form of thyroid FNB.

While making revision of Hospitalization Form it was revealed that information of this form is insufficient for cohort maintenance and tracing of subjects, as it was mentioned above. Besides, in Surgical Hospitalization Form there is a lack of information whether this surgery initial or repeated.

Experts perform their advisory activity at the base of Clinic, RCIRME. Totally, 10 subjects have been examined.

Expert of USE regularly perform quality control of examination. Some problems with recording of thyroid images to MOD have been revealed. They were caused by breakage of device for recording to MOD.

There were claims to the work of USE specialist in conditions of field trip. "SIGMA" instrument used for field trips could not be compared in quality of images with "TOSHIBA" instrument. Besides, because of lack of recording device not delivered by American side, recording of thyroid images to MOD have not been performed.

There was also performed expert estimation of configuration of thyroid images DB and its connection to screening DB.

Thus, QC Group participated in theoretical and practical aspects of the Project and performed advisory activity.

Task No. 5 Operational Manual and Project forms

Milestone 13: Updating of the Operational Manual and study forms.

(Quality Control Group and Heads of Project Units)

Modernization of Operational Manual (OM) has been performed in following directions: edit of Russian version of the text, bring OM in accordance with actual procedure of examination, put necessary additions.

1.2. Background

Table Number of thyroid cancers annually revealed in children of Belarus from 1986 to 1997.

Year	Number of Cases
1986	1
1987	2
1988	4
1989	6
1990	28
1991	58
1992	65
1993	80
1994	80
1995	91
1996	84
1997	66

3.4. ABSTRACTING RECORDS BEFORE INITIAL CONTACT

(completely changed)

To provide information that could be useful while making contact with cohort subjects, on each subject selected to the cohort preliminary demographic and identification information is collected. To obtain this information DCC use computer file of direct measurements DB. The following information should be collected on each subject:

- ◆ Family name, name, patronymic of a subject (if necessary, parents also);
- ◆ Year of birth;
- ◆ Address at 26.04.1986.

3.5. OBTAINING CURRENT ADDRESSES

(Completely changed)

Obtaining of such information will require constant and intensive work of Epi Group and DCC during first three years of study.

As soon as DCC set up a file a subjects for search the main task will be to find and confirm current address of a subject. Search of information I performed in two stages. The first one is the searching stage performing by DCC through the following sources of address information:

- ◆ DB of Chernobyl Registry;
- ◆ Local DBs (Polyclinics ## 25, 32 of Minsk; National Dispensary of Radiation Medicine; Clinical Hospital of Minsk Oblast, Gomel and Mogilev Dispensaries)
- ◆ File of Sasakava Foundation;
- ◆ Files of IPHECA WHO;
- ◆ DBs of registries of Gomel and Mogilev Oblasts.

Following stage of search is performed by Epi Group through the following sources of address information:

- ◆ Central Regional Hospitals (CRH);
- ◆ Regional Departments of Public Education (RDPE);
- ◆ Regional Passport Offices;
- ◆ Address offices (Ministry of Home Affairs of Oblast);
- ◆ "Summons for individuals evacuated from the areas of dangerous active contamination".

Search via mentioned sources is performed through formed lists or through collation of information on hard copies.

As soon as address or any other information that can describe the result of search or subjects' status in Project (no information, change of address, military service, death etc.) will be received the data are entered to epi DB.

To defined addresses letters are sent with the aim to make an initial contact with a subject, address verification and invitation to examination.

4.2. INITIAL CONTACT WITH STUDY SUBJECTS

(Completely changed)

Initial contact with STUDY subject is performed by Epi Group with the help from DCC. A family (or adult subject) will receive a letter from Epi Group on behalf of the Ministry of Health describing the study, its benefits to individual and suggesting a specific date and time of appointment. With the letter will be a pre-printed, stamped card to be mailed back to Epi group. It will provide for confirmation of the offered appointment, a request for an alternative or deferred appointment.. Besides, through the post card Epi Group verifies the date of birth, place of residence at the time of the accident and phone number where the

subject can be reached. Copies of letters and appointment confirmation card are in Appendix C-4-1.

As soon as post card come back to Epi Group Initial Abstract Form (demography) is completed to the subject. Given form is entered to the epidemiological DB of cohort study by Epi Group personnel. Initial Abstract Form and Instruction for its filling in are in Appendix A-3-1.

Based on the information of subjects preliminary consent to screening examination DCC prepares a Registration Log for specific period of time. Registration Log is passed to Screening Group. If a subject has not come to screening examination, a repeated letter of invitation is sent to him or a contact with him is made by telephone in order to clarify the reasons of patient's absence at examination and appoint him a new date of a visit. This activity is performed by Epi Group.

Following the repeated contact with the subject a Contact Form is entered to Epi DB. This form and instructions for filling in of electronic variant are in Appendix A-3-2.

4.6. DOCUMENTING PARTICIPANT STATUS

(Completely changed)

While setting up a file of epidemiological base of cohort study to each subject one of ten statuses (refusal, death, no response within a month, preliminary consent, moved out of the Republic, reserve, not fitted by age, preliminary consent for mobile team examination, imprisoned) The status is given on the base of

- ◆ data received from the source of address information while making verification of current subject's address while verifying subject's current address.;
- ◆ information from Post Card returned to Epi Group
- ◆ results of phone calls with the subject

Status is a dynamical characteristic of subject's state in the Project. Current status is entered to Epi DB. Using query system developed by DCC Epi Group makes an analysis of subjects' state in the Project in accordance with each status.

4.2.1. HANDLING NON-RESPONSE

(completely changed)

Data Coordinating Center together with Epi Group handles non-response. Non-response (lack of information) could appear at the following steps:

- ◆ locating of subject through different sources of address information;
- ◆ getting back a letter with post office note "individual does not reside given address";
- ◆ no response to a letter mailed to defined address.

In accordance with above mentioned steps the following subjects files are created:

1. Subjects who can not be located at the step of current address identification (through sources of information described in Section 3.5);
2. Subjects who have status "incorrect address";
3. Subjects who have status "no response within a month".

The work with subjects from the first and the second files is performed the following way. If searching of address was done not through all possible sources of information, the

search is continued through unused by now sources. Subjects whose address was verified through all known sources of information are combined in a separate file the work with which probably will require new sources of information or combination of sources used by now (i.e. search of children by mother's address through Address Office).

To subjects from the third file not responded to invitation within one month a second informational letter is sent. If there is no response to the repeated invitation a review is made through what sources of information address verification was performed. If subject was located through all possible sources of address information Epi Group continues address verification. If address was verified through all sources or the fact that the address is correct is confirmed by new source non response could be explained by reluctance or impossibility to participate in Project. Such subjects comprises a separate file for further examination by mobile team.

5. EXAMINATION PROCEDURES, para 1

5.1 It is expected that subject will ordinarily arrive with his appointment card and self-interview form received by mail.

5.2 REGISTRATION AND INFORMED CONSENT, para 4

Person responsible for this procedure is registrar.

After obtaining consent registrar will print out bar-code labels with subject's ID to label them to data collecting forms, then date and label Control Form and put them to subject's envelope. Data collecting forms as well as specimen labels are attached at corresponding examining station. At each examining station, the study personnel will remove a label from the subject's envelope, label and complete the study form, and return the form to the subject's envelope. Specimens labels and ID labels are used for Blood and Urine collection forms, as well as for specimen containers. Examiner at each station will record information indicating whether the particular exam component was completed in the Control Form. The Control Form and instructions for its use appear in Appendix B-5-4. After receiving the envelope, the subject will be directed or taken to the first examining station where interviewing takes place.

5.2.2. URINE COLLECTION AND POST-COLLECTION PTOCEDURES AT THE EXAMINING CENTER

Para 2, starting from the second line.

Personnel assisting with the urine collection procedure will use the next available row of specimen labels and affix the first label on the specimen collection form along side the subject's ID label (which will be obtained from the subject's envelope). The remaining specimen ID labels of the same row will be attached first to the larger urine collection tube, then to the aliquotted specimen tubes. This procedure will establish the link between the subject's ID and the specimen ID (see Section 3.3).

5.2.2.2 EQUIPMENT AND SUPPLIES

(changes are typed italic)

Supplies needed for the urine collection *in the Screening Center* include

Item 3

- *Urine collection, processing and result form*

Item 4

Supplies needed for urine processing *in mobile team* include:

5.2.2.6 INSTRUCTIONS FOR STORAGE AND SHIPMENT OF URINE SAMPLES

(changes are typed italic)

The urine aliquots will be placed into *racks* and stored *in freezer* until shipment to the Central Laboratory. *After freezing aliquots will be placed into a plastic pack.* Shipments to the Central Laboratory will be made on a weekly or monthly basis. For shipment the samples will be placed into a *bag-refrigerator.* *After arriving to Central Laboratory a person responsible for samples storage will complete Part 2 in each form (urine shipment to Central Laboratory) which contains the following information: date of delivery, state of samples, name of person delivered a sample.*

5.2.2.7 DATA COLLECTION AND TRANSFER TO DCC

(completely changed)

Information regarding urine collection and processing will be documented on the Urine Collection and Processing Form. The form will be pre-labeled with the subject ID number. After determining that the subject is eligible for the urine collection, the nurse assistant will affix a specimen ID label onto the form and fill in Part 1 concerning sample collection recording the polyvitamin and medical information, the date and time of collection any problems with the sample. Data of urine processing procedure will be recorded onto Part 2 of the same form. The nurse assistant will document the number of filled tubes and quantity of urine in each of them. The form and instructions for its completion is presented in Appendix A-5-3.

If a urine sample is not collected on a subject, this fact will be recorded on the Urine Collection and Processing Form.

The urine samples themselves will be shipped to the Central Laboratory accompanied by the Urine Collection, Processing and Result

The Central Laboratory itself will perform the control under the urine collection and shipment as well as trace the obtaining of the results. All the information from forms will be entered to the local computer DB in the Central Laboratory and sent to DCC on disks.

5.2.5.4.1 COMPARISON WITH THYROID PALPATION, instead of ULTRASOUND**5.2.5.7 PROVIDING RESULTS TO THE STUDY PARTICIPANTS/EXIT PROCESS**

1-st para, 3-rd line

written copy of Summary of thyroid examination

1-st para, 10-th line

Original of Summary of thyroid examination will remain in the subjects envelope. The subject will also receive completed form of complex examination (adopted by the Ministry of Health) to be passed to home polyclinic. The physician will answer any questions and clarify any information that the subject or his parents find unclear. The subject will also be told that in case of abnormalities in blood he will be informed additionally by phone or mail.

5.3 REPORTING RESULTS TO HOME POLYCLINIC

After laboratory tests results are available, endocrinologist will fill in the Final Endocrinologic Summary and Recommendations. If some deviations will be found in blood test the information of this as well as new recommendations will be given to subject by phone or letter.

5.5.1 THYROID REFERRALS TO THE DESIGNATED ENDOCRINOLOGICAL FACILITY

CLINICAL PRESENTATION/HISTORY

3-rd line:

- diffusive goiter of 2-nd degree (only in combination with other criteria) and more.

8.1.1 DIAGNOSTIC CATEGORIES

8.1.1.1 THYROID CATEGORIES (According to ICD 9 Code)

Nodular goiter non-toxic 241

Excluded: thyroid adenoma (226), cyst adenoma (226)

Thyroid cyst 246.2

Excluded: cyst adenoma (226)

(Quality Control Group)

While working with forms we paid attention to formalization of entered data, and availability of information allowing to trace effectively subjects and perform quality control.

Particular attention was paid to formalization of diagnosis text. Clinical Group of the Project suggests that while analyzing cases of diseases depending on thyroid dose one should consider specificity of clinical course of thyroid pathology in patients with different dose loads. To perform such analysis diagnoses recorded to Preliminary and Final Medical Summary, as well as to Hospitalization, Endocrinological, and Surgical Forms should be formalized and compatible in details. Below is given our point of view to this question.

While formulating clinical diagnosis aside with nosological form having individual ICD code usually a series of clarifying parameters are used. Some of them are unique and describes only specific nosological forms, for example, TNM - is thyroid cancer, hypertrophied type, false nodular variant - chronic lymphocital thyroiditis. Others are universal, for example: level of thyroid increase, thyroid functional state. Thus, clinical diagnosis is formed from unique and univarsal parameters located in strict sequence. This sequence is regulated for endocrinologist by Pattern for formulating clinical diagnosis (Scheme 1), and for program engineer and data entry operator - by algorithm and reference envisaged for each diagnosis.

Pattern is suggested for use in all the forms containing text formulation of diagnosis: Preliminary and Final Medical Summary, Hospitalization Form, Endocrinological and Surgical.

We think that such approach on the one hand will allow to formalize diagnosis without creation additional codes, and on the other hand - will allow to keep unique text diagnosis and analyze evolution of not only nosological form but also each separate symptom at different steps of examination and time.

difficult to find the results of thyroid FNB performed at hospitalization stage by physician who does not work in the Project. This information is not envisaged by the forms, and so it comes to Screening Center and DCC not in time. That is why we suggest the following changes:

1). Hospitalization Form (Endocrinological):

FNB - No , if Yes , Date

Recommendations:

Referred to NCTOP - No , if Yes Date of hospitalization

2).Hospitalization Form (Surgical):

Surgery Yes , if No , note the reason:

patient refusal

no need in surgery

FNB No , if Yes , Date

Recommendations:

Form Individual Medical Interview. Item 3, the question concerns diseases not connected with thyroid

Pathomorphological Form has been reviewed.

Variants of forms for joint discussion are presented at Appendixes 1, 2, 3,4

(Data Coordinating Center)

For the reported period Section 9 "Data management" is in the process of review and updating in accordance with current procedures.

Milestone 14: Development of instructions for filling in and data entry of epidemiological, screening, laboratory, and hospitalization forms.

In the 4-th quarter 1998r. DCC completed instructions for filling in and data entry of epidemiological, screening, laboratory and hospitalization forms. The list of forms, instructions and corresponding annexes to Operational Manual is presented in Table 6.

Table 6

List of instructions for forms completion and data entry.

№	Form	Instruction how to complete	Instruction for data entry	Annex in OM
APPENDIX A DATA COLLECTION FORMS AND SPECIFICATIONS				
1	Initial Abstract Form	+	+	A-3-1
2	Contact Form	+	+	A-3-2
3	Initial Interview Form	+	+	A-5-1
4	Annual Interview Form	-	-	
5	Mother's interview (at the period of breast feeding)	-	-	A-5-2
6	Urine Collection, Processing and Results Form	+	+	A-5-3
7	Blood Collection and Processing Form	+	+	A-5-4

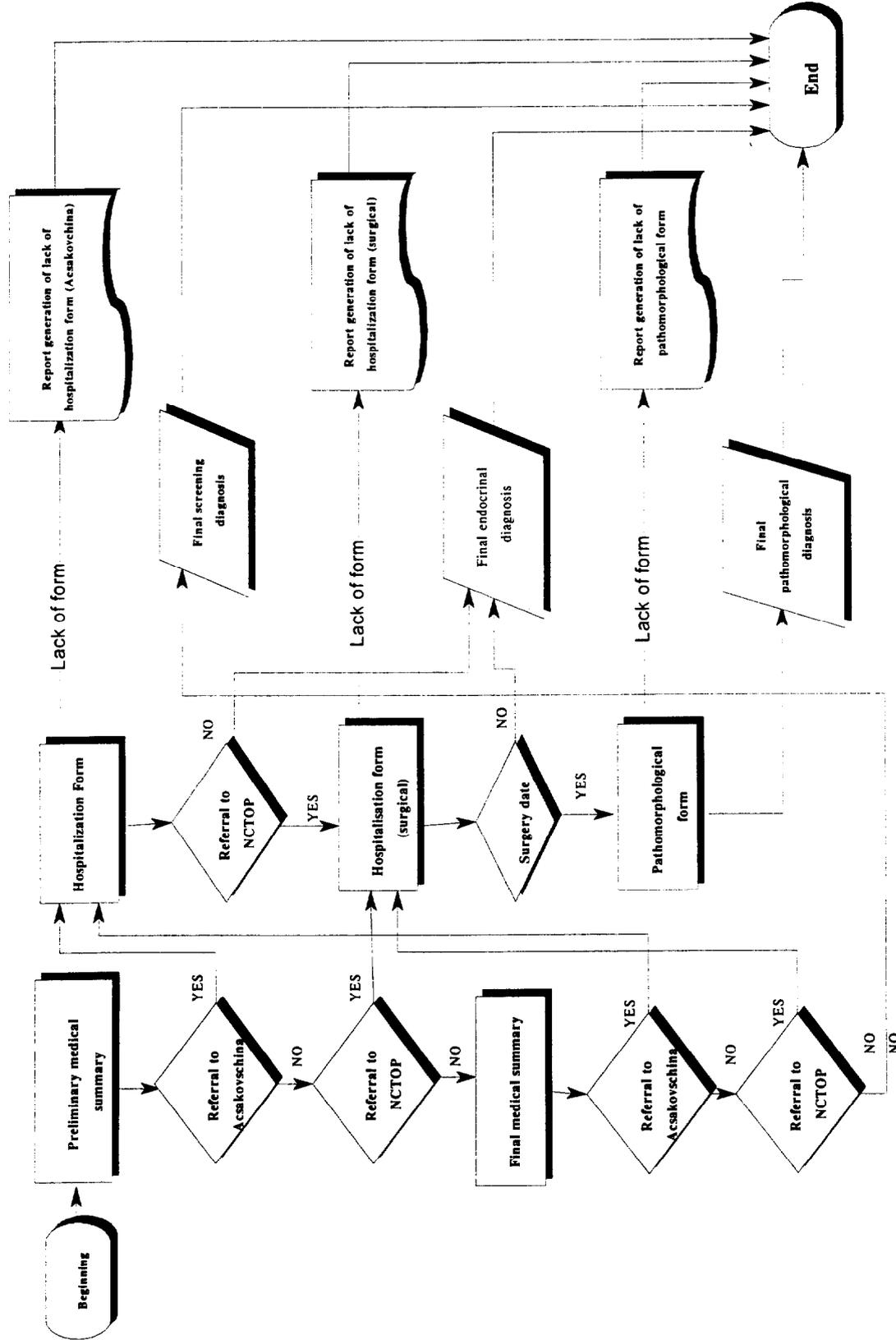


Fig 2. Algorithm for revealing missing clinical forms (Hospitalization (Acsakovschina), Hospitalization surgical, Pathomorphological)

8	Ultrasound Examination Form	+	+	A-5-5
9	Thyroid Palpation Form	+	+	A-5-6
10	Medical Interview Form	+	+	A-5-7
11	Needle Biopsy Form	-	-	A-5-8
12	Adverse Event Report	+	-	A-5-9
13	Blood Tests Results Form	-	+	A-6-1
14	Summary Of Medical Screening and Recommendations	+	+	A-7-1
15	Pathomorphological examination Form	-	-	A-8-1
16	Hospitalization Abstract Form	+	+	A-8-2
17	Death Data Form	+	-	A-8-3
APPENDIX B MANAGEMENT FORMS AND REPORTS				
18	Locator Form	-	+	B-5-2
20	Control Form	-	+	B-5-4
21	Transmittal Forms	-	-	B-5-5
22	Nonresponse Form	-	-	B-9-1

Milestone 15: Development of Quality Assurance Manual

(Quality Control Group, DCC)

In the 4-th quarter activity aimed at review of materials and improvement of Quality Assurance Manual was continued. General part of the Manual is presented in Appendix 5.

In the framework of quality control a process was initiated for development of algorithm for revealing of missing forms, diagnosis deviations on different stages regarding thyroid nodules according to ultrasound examination and pathomorphological examination.

Algorithm for revealing missing Hospitalization and Pathomorphological Forms is shown on Fig.2. Implementation of given algorithm is impossible now because of lack of data regarding subject transfer from Endocrinological Department to Oncological Department in Hospitalization Form, and lack of agreed Pathomorphological Form.

Algorithm for revealing disagreement in the main diagnosis is shown on Fig.3. Algorithm is based on comparison of ICD coded diagnoses from clinical and Patomorphological forms. Implementation of given algorithm is impossible at present because of above mentioned reasons.

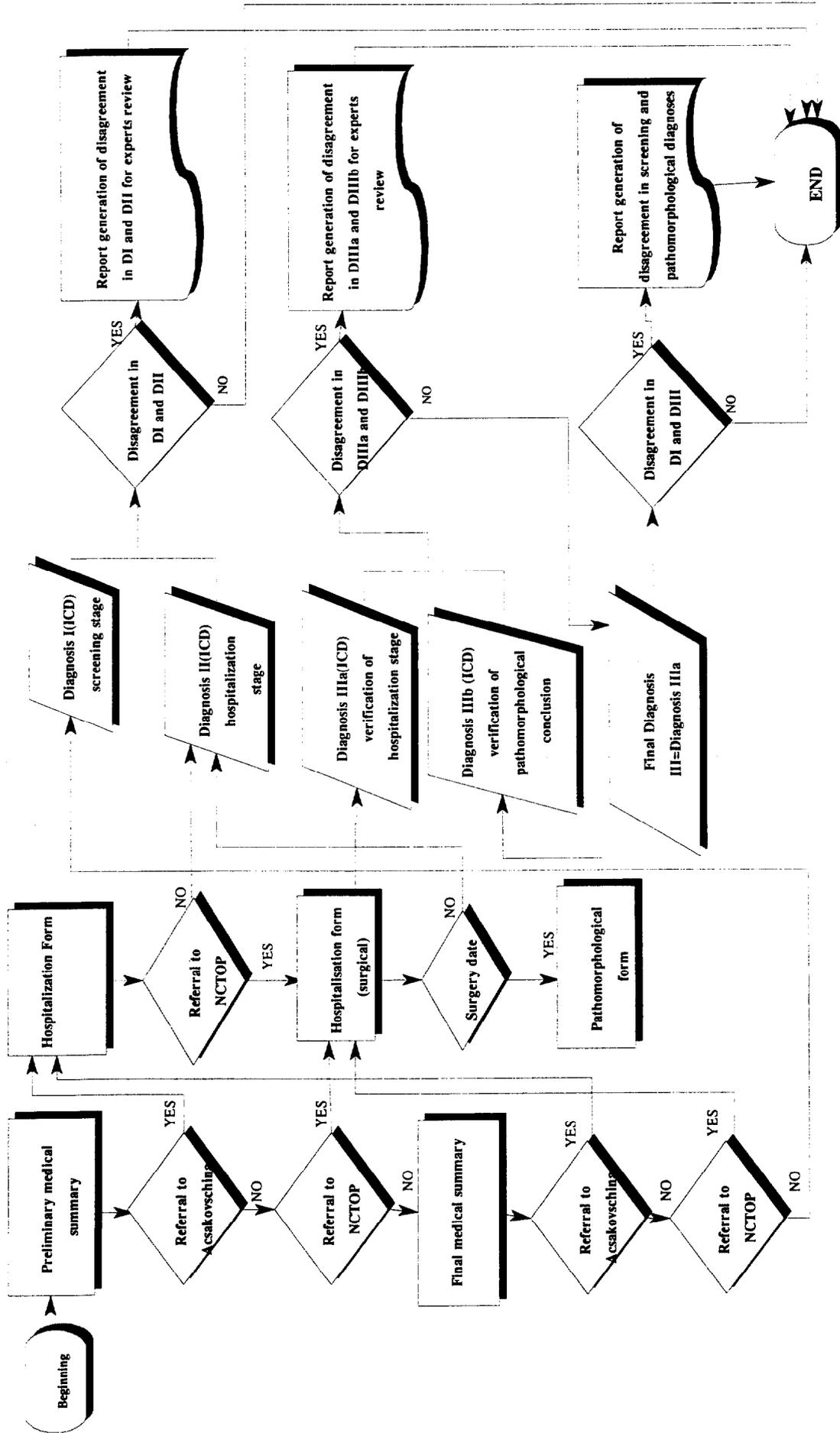


Fig 3. Algorithm for revealing of disagreements in the principal diagnosis

Algorithm for revealing of partial disagreement in diagnoses according to pTNM is presented in Fig.4. For its implementation it is necessary to make some changes to diagnosis formulation. pTNM categories should be distributed in DB to fields.

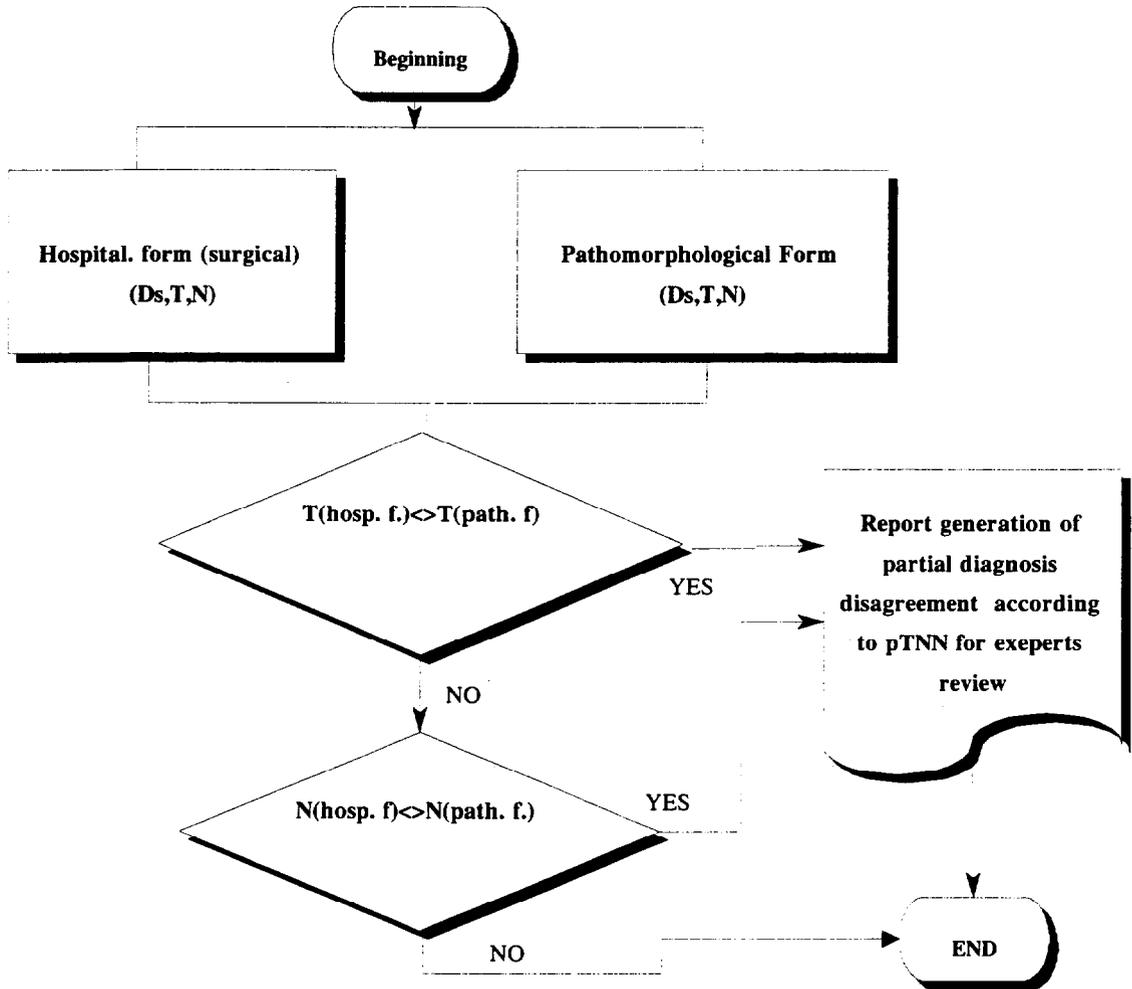


Fig. 4. Revealing of partial disagreement in diagnosis according to pTNM

Algorithm for revealing of partial disagreement in diagnose according to the number of revealed nodules is presented in Fig.5.

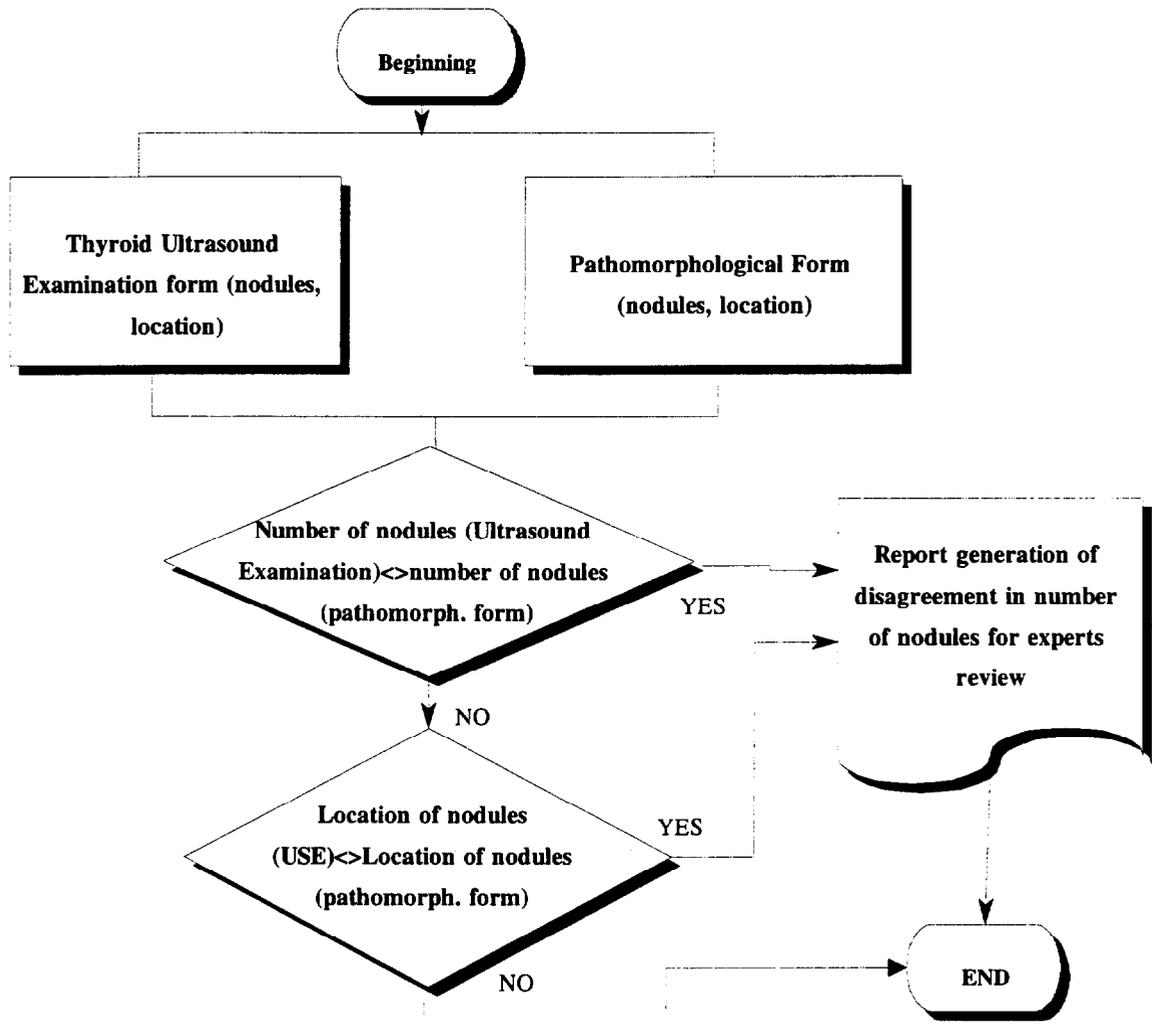


Fig. 5. Revealing of partial disagreement in diagnose according to the number of revealed nodules

Algorithm for control under the procedure of thyroid FNB in accordance with the requirements of the Protocol, and revealing of missing forms of cytological examination is presented in Fig.6. Implementation of given algorithm will be possible following acceptance of Cytological Form and making changes to DB.

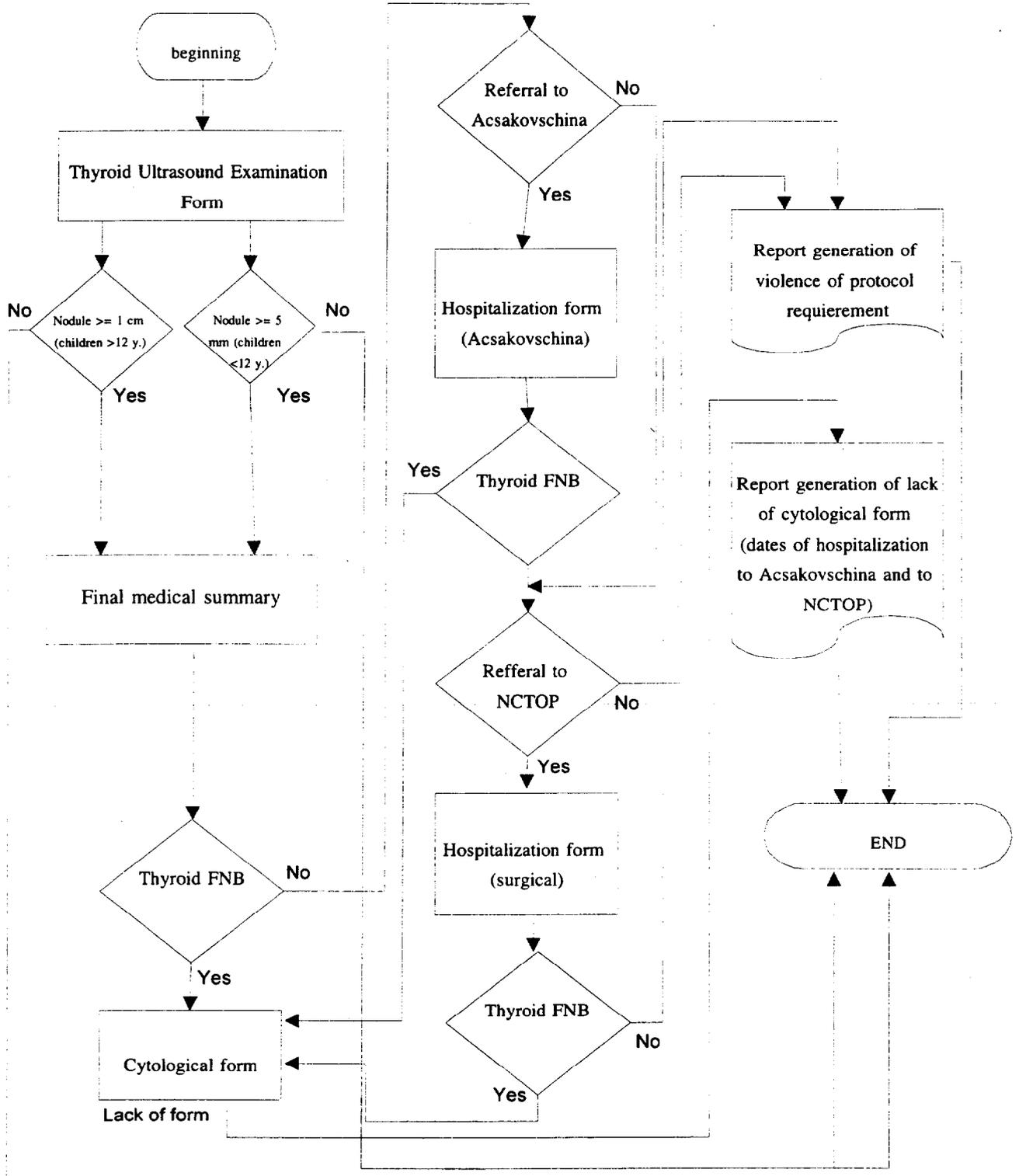


Fig. 6. Algorithm for control under the procedure of referral to thyroid FNB in accordance with the requirements of the Protocol, and revealing of missing forms of cytological examination

Thus, to automatize procedures of quality control it is necessary to make urgent changes to forms and DB structure as well as to data entry programs. Otherwise we will continue to accumulate information that is impossible to claim for analysis.

Task № 6. Data management.

Milestone16: Design of part of data entry software for epidemiological, screening and hospitalization information.

(Data Coordination Center)

For the reported period DCC has performed the following activities :

- development of software for data entry of Death Form, its experimental running
- experimental running of software for data entry of Pathomorphological Form
- experimental running of software for data entry of FNB and Cytology Form
- modernization of software for data entry of Summary of Medical Screening and Recommendations and Hospitalization Form;
- modernization of software for data transfer from Screening Center and Central Laboratory to DCC.

Experimental running of software for data entry of FNB and Cytology Form as well as Form of Pathomorphological examination showed the necessity of making changes to the structure of above mentioned forms.

Milestone 17: Data entry of epidemiological, screening, laboratory, and hospitalization forms.

Data entry by Project Units in the 4-th quarter is presented in Table 7

Table 7

Data entry by Project Units

N	Forms	Project Units
1	Initial Abstract Form	Epi Group(DCC local network)
2	Contact Form	Epi Group(DCC local network)
3	Death Form	Epi Group(DCC local network)
4	Initial Interview Form	Dosimetry Group(DCC local net.)
5	Urine Collection, Processing and Results Form	Central Laboratory
6	Blood Collection and Processing Form	Central Laboratory
7	Blood Tests Results Form	Central Laboratory
8	Locator Form	Screening Center
9	Control Form	Screening Center
10	Ultrasound Examination Form	Screening Center
11	Thyroid Palpation Form	Screening Center
12	Medical Interview Form	Screening Center
13	Summary Of Medical Screening and Recommendations	Screening Center
14	Hospitalization Abstract Form	DCC (local network)

15	Pathomorphological examination Form	DCC (local network)
16	Fine Needle Biopsy Form	DCC (local network)
17	MOD registration log	DCC (local network)

Presented in Fig.7 information is evidenced that data entry at the stage of screening is performed satisfactory.

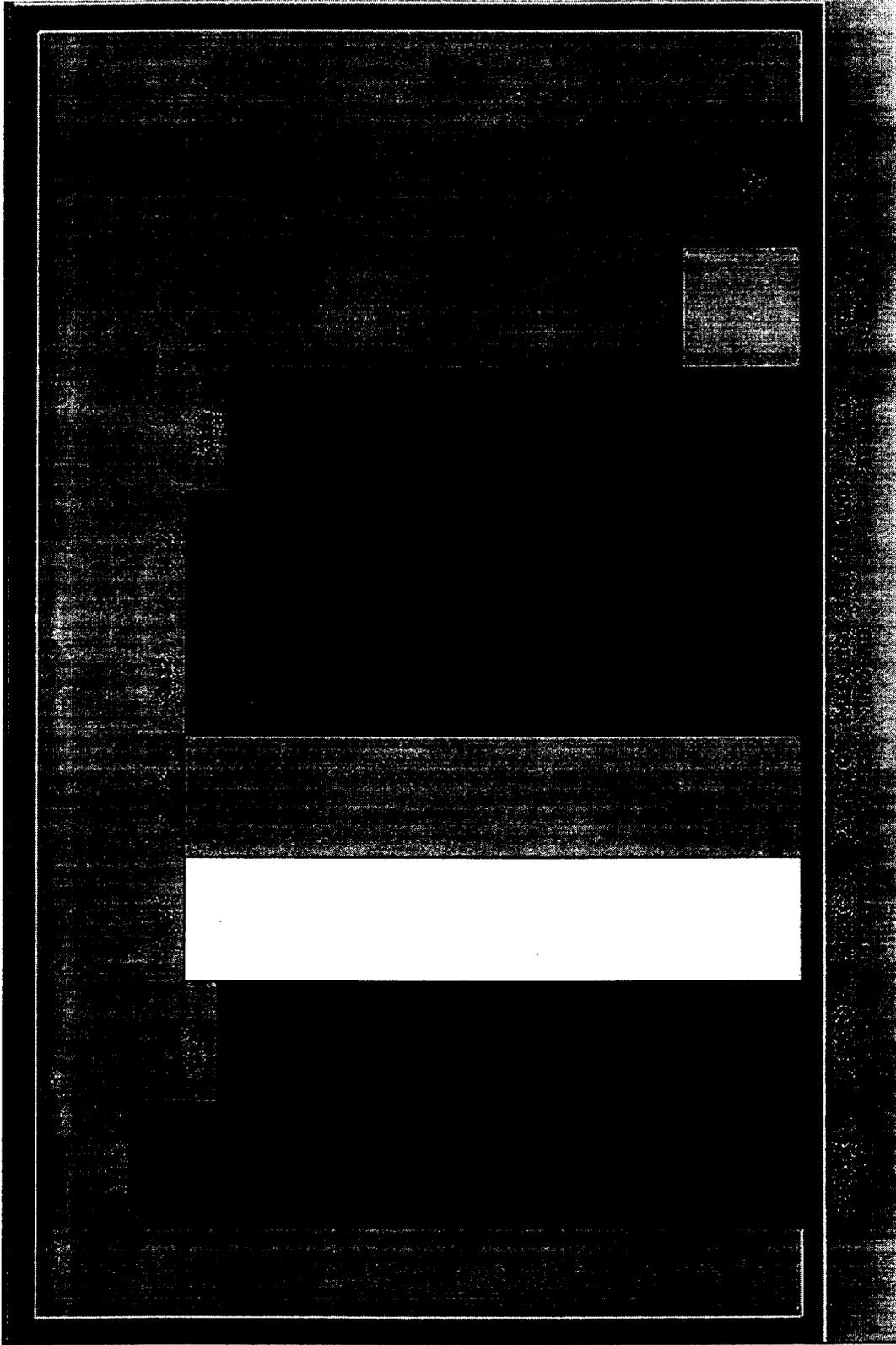


Fig. 7. Distribution of entered to DB screening and hospitalization forms

Milestone 18: Transfer to the DCC file server of the data, entered in local computers of the screening center and central laboratory, and quality control of these data.

(Data Coordinating Center)

For the reported period DCC personnel transferred data from Project Units to DCC server. Data came to DCC on disks periodically once a week. For given activity specially developed software was used. At the same time a check have been performed for data type and range. Numericals and numerical-leterral codes have been also checked for possibility and range.

Software is designed so that it selects newly entered records and does not touch records entered by the moment of ordinary data transfer. While adding data to server check is performed for presence of this record. If record is absent it is directly added, and if it is presented on server updating of record is made

Milestone 19: Design of part of the query software for the epidemiological, screening and hospitalization information.

(Data Coordinating Center)

For the reported period DCC has completed query subsystem for Epi Group. Example of the report generated by query subsystem on the base of the results of its activity according to chosen criteria is presented in Fig. 8.

DCC started designing report of screening examination, hospitalization, pathologies, number of made diagnoses, examined subjects for period of time and in accordance with sex.

Unfortunately, data received as a result of some queries reflects actual situation not adequately enough. This situation could be explained by insufficient formalization of forms in sections of making diagnosis, initially revealed disease or repeatedly, disease was revealed in the Project or out of Project, etc.

In the 4-th quarter DCC started designing DB of personnel. This DB will contain family names and names of all the staff involved in the Project. Besides, it will contain phone numbers, position, place of work, date of coming to Project and date of quitting, Project Unit. Each member of the Project will have personal ID number which will be noted in informational documents. DB will contain information of personnel certification, and also some additional information of personal data of Project employee.

Первичные визиты

За период времени: 01.10.98 - 31.12.98

Из них, при условии :

Пол:	Без ограничения	Год рождения:	Без ограничения
Доза:	Без ограничения	Область:	Без ограничения
		Район:	Без ограничения

Произошло следующее распределение статусов :

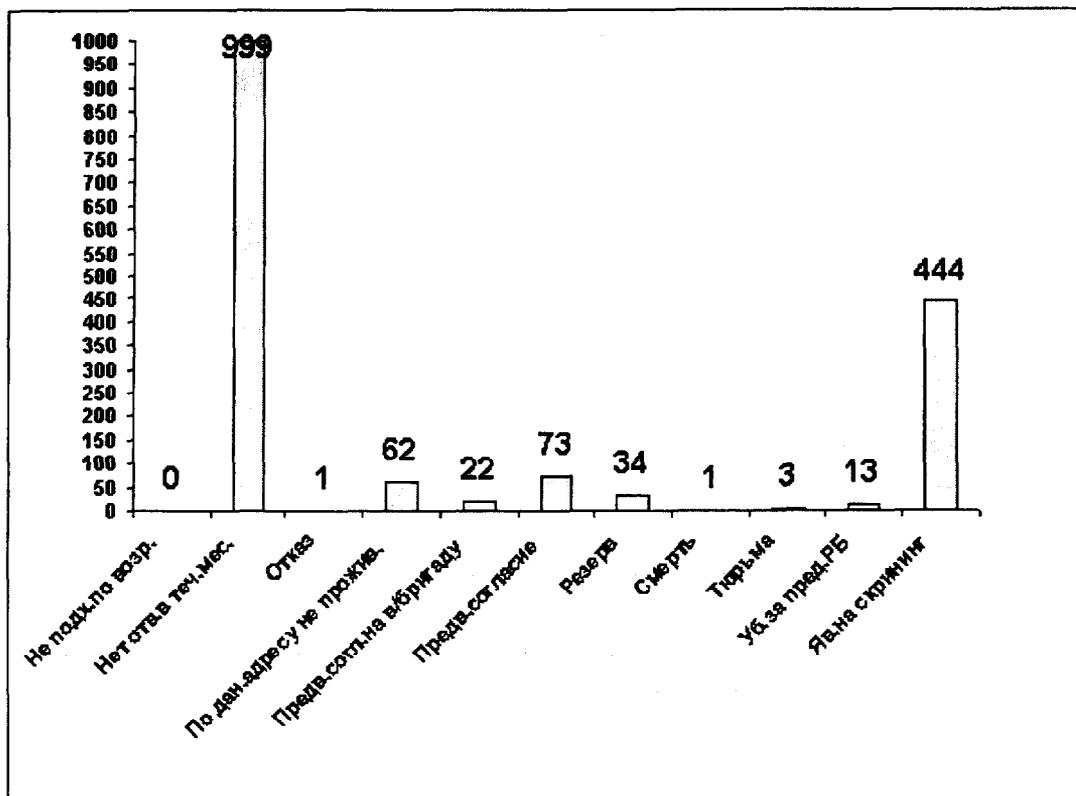


Fig.8 Example of report generated by query subsystem

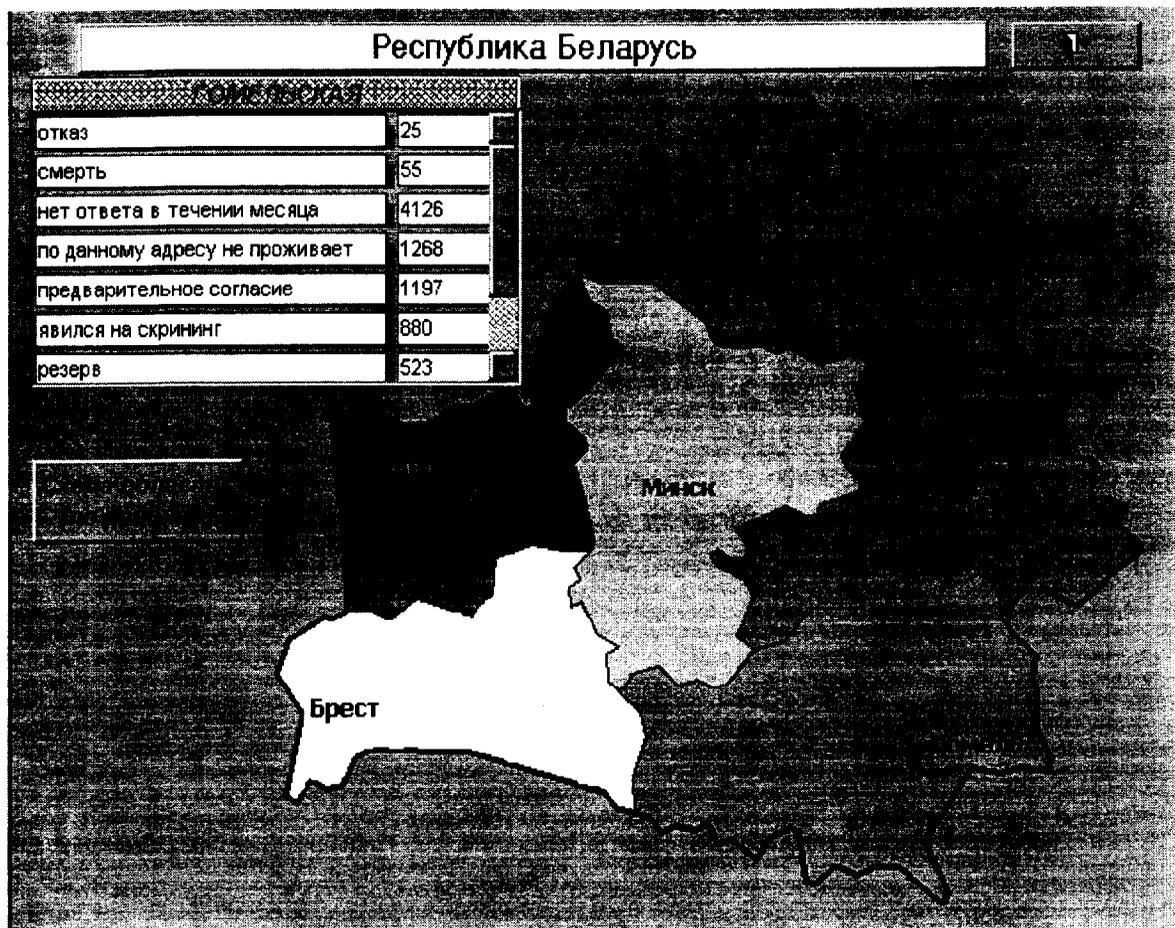


Fig. 9 Screen for estimation cohort state depending on the place of residence.

For the repeated period a software has been developed that allows to estimate this or that indices of cohort state depending on the place of residence. Thus, one could see on the map of the Republic dynamical changes in cohort state, for example, epidemiological statuses (Fig.9). Furthermore this software will be used for estimation of disease distribution and other clinical indices, revealed in the process of subjects examination.

Milestone 20: Analysis of the results and preparation some progress report on the cohort selection, scheduling of screening exams, subject flow through exams and data entry.

*(Data Coordinating Center).
(Epi Group)*

In the 4-th quarter 1608 individuals have been invited to initial visit. On the results of analysis of cohort state by the end of the quarter the following distribution of statuses occurred (Table 8).

Table 8
Distribution of statuses among invited to initial visit in the 4-th quarter

Status	Number of Subjects			
	October	November	December	total
No response within a month	194	466	368	1028
does not reside given address	4	16	34	54
Preliminary consent	31	302	3	336
Refuse	0	1	0	1
Death	0	0	0	0
Moved out of Belarus	0	1	3	4
Reserve	12	20	7	39
Does not fit by age	0	0	0	0
Preliminary consent to be examined by mobile team	2	1	143	146
Imprisoned	0	0	0	0
Total	243	807	558	1608

Thus, from the total number of invited for 4-th quarter 418 inds, have passed screening examination. 49 subjects came to initial screening with previously received invitations (agreed or voluntary shift of visit data). Totally, 467 subjects have passed initial screening in the 4-th quarter. Percentage of received consents to examination in the 4-th quarter is at average 29,6%, percentage of those who passed examination to those who was invited is -25,9 (Fig. 10). The majority of consents as well as visits to examination in compare to invitations was observed in November. This fact could be explained by use of address files from Address Office of Mink and Mink Blast in November.

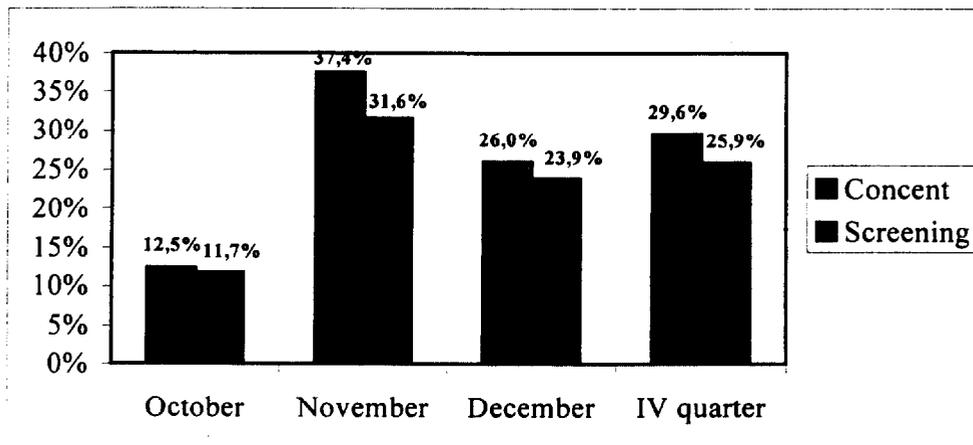


Fig. 10. Dynamics of indices of number of patients who gave consent to initial examination and undergone screening from the total number of invited

Fig. 11 shows distribution of preliminary consents given by cohort subjects to screening examination for the 4-th quarter day by day.

Fig 12 shows distribution of initial visits to screening for the whole period of Project activity by months.

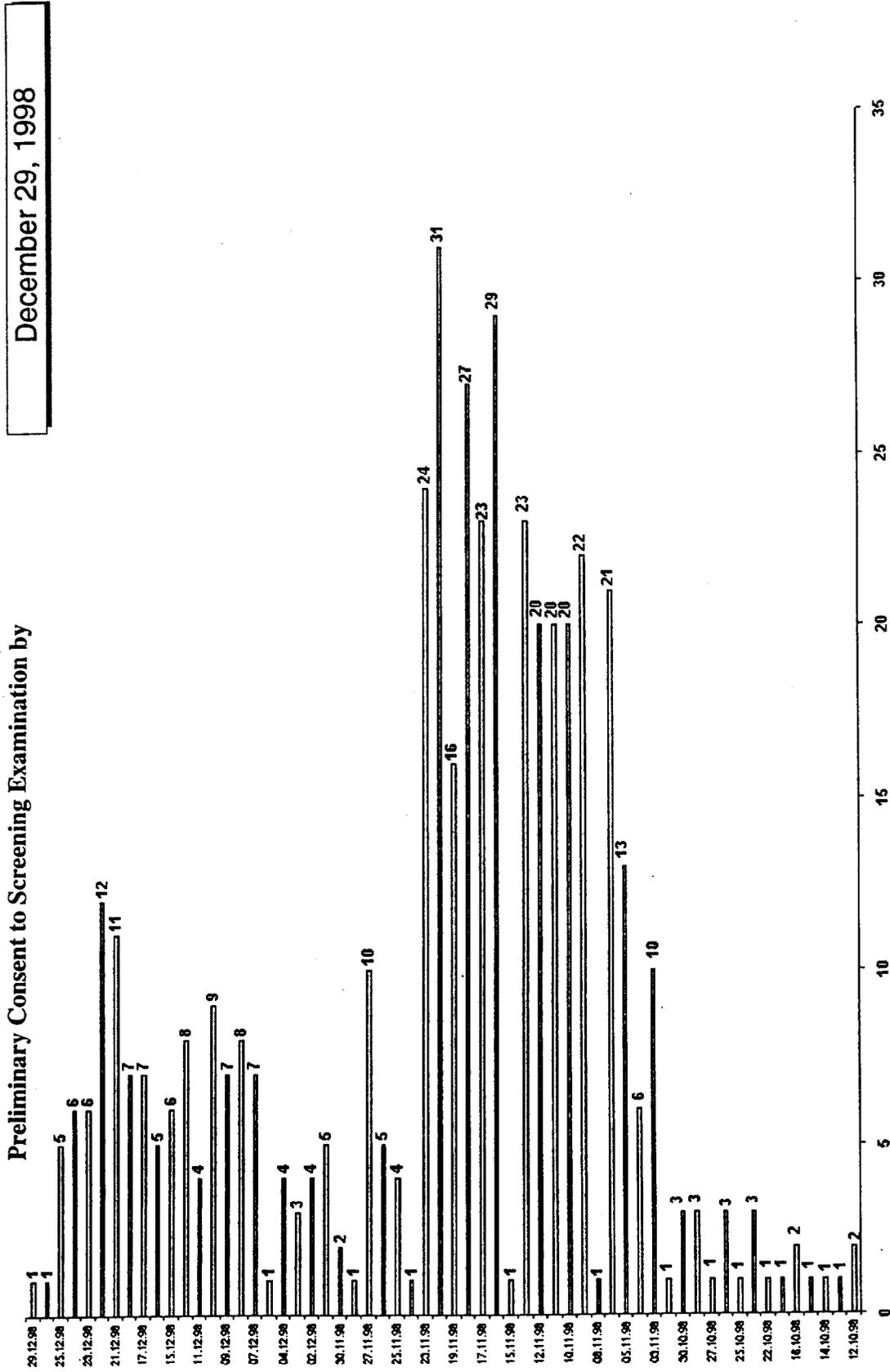


Fig.11 Distribution of preliminary consents to screening for reported period

Fig.11 Distribution of preliminary consents to screening for reported period

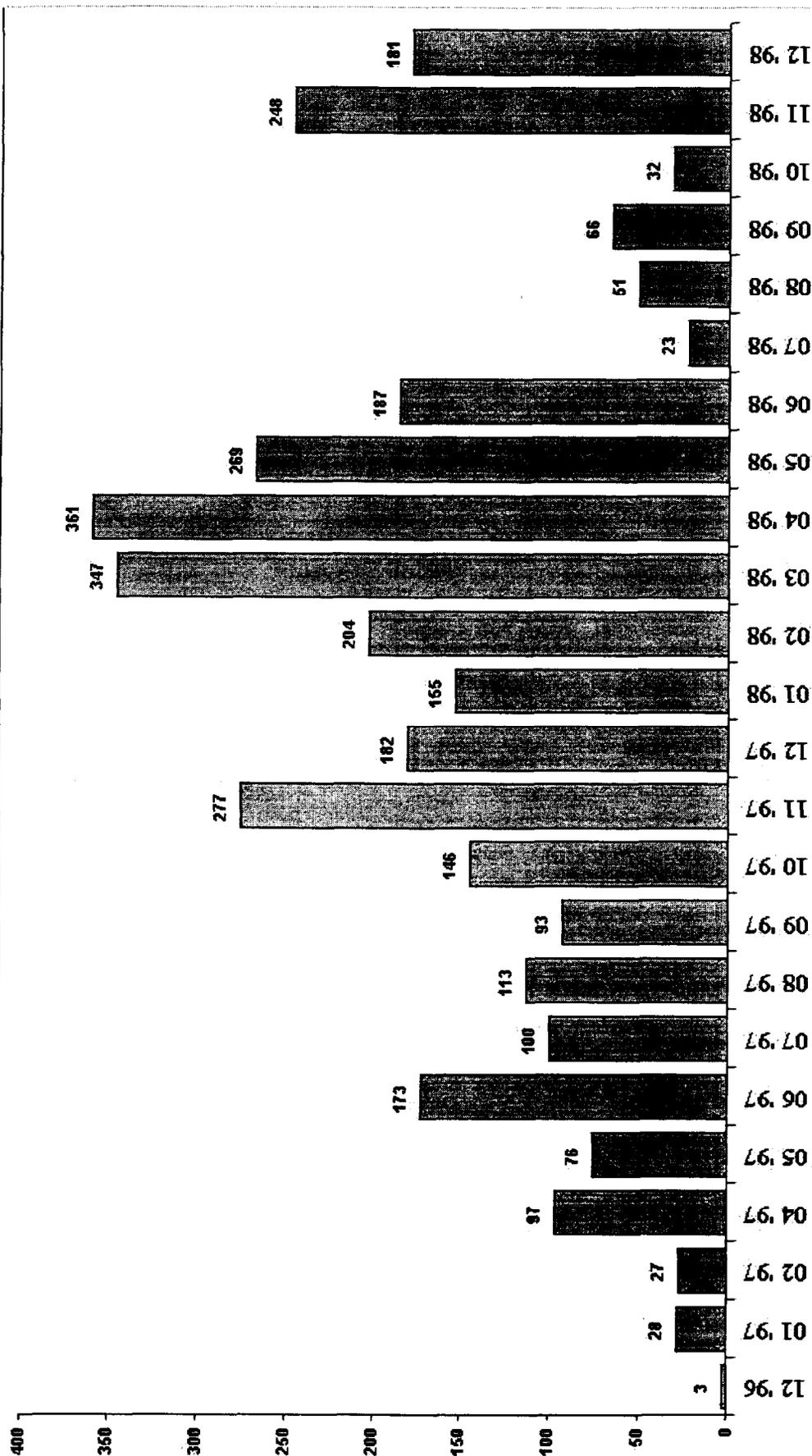


Fig. 12 Distribution of initial visits to screening for the whole period of Project activity

Percentage rate of number of subjects undergone examination to those given consent at average for the quarter is 87,3%, varying from 84,4% in November to 93,5% in October (Fig. 13).

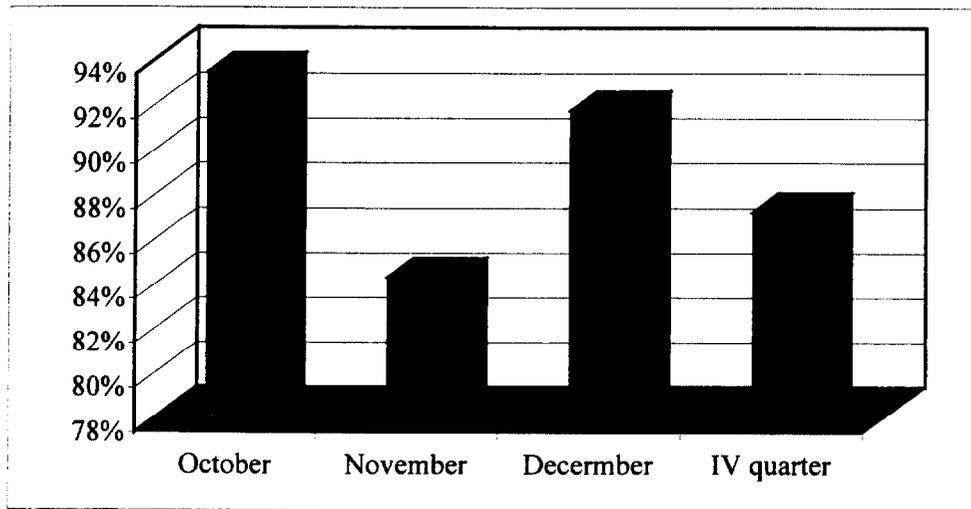


Fig. 13. Dynamic of indices of number of subjects undergone initial screening examination from the total number of those given consent

In the 4-th quarter subjects were invited to repeated visit.

443 invitations have been sent. Statuses of cohort subjects are distributed the following way (table. 8).

Table 8

Distribution of statuses among subjects invited to repeated visit in the 4-th quarter

Status	Number of Subjects
No response within a month	275
Does not reside given address	2
Preliminary consent	146
Refuse	1
Death	0
Moved out of Belarus	0
Reserve	18
Preliminary consent to be examined by mobile team	1
Imprisoned	0
total	443

Fig 14 presents distribution of repeated visits for the whole period of Project activity.

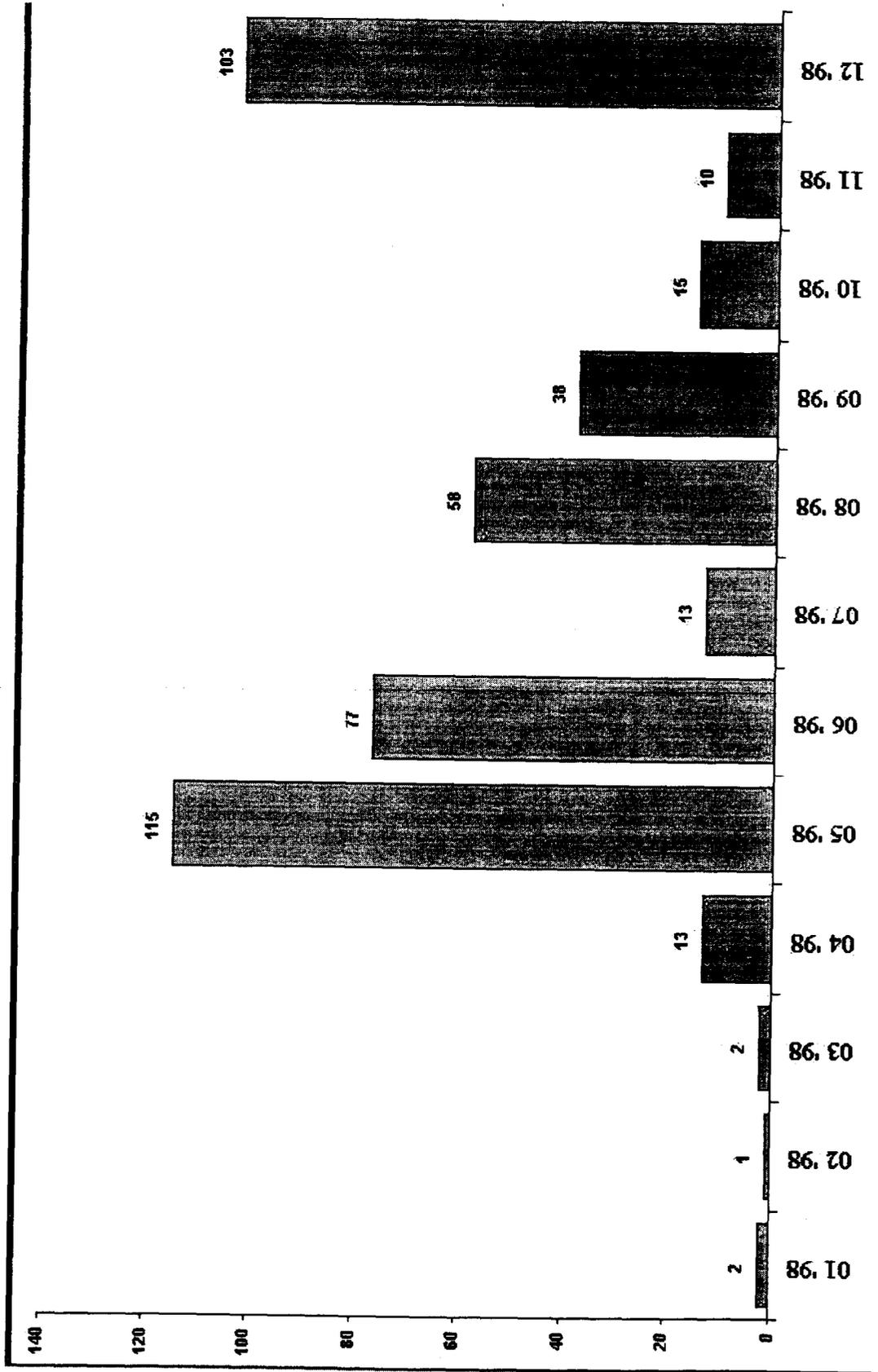


Fig. 14 Distribution of repeated visits to screening for the whole period of Project activity

Thus in the 4-th quarter 33% of invited subjects agreed to come to repeated examination, 62% from agreed subjects came to examination. Besides, 34 subjects came to repeated visit in accordance with invitations received before 1.10.98. Totally, 125 subjects have undergone repeated examination in the 4-th quarter.

Totally, for the period of screening activity 4.330 subjects have undergone initial examination (1.592 subjects from high dose group, and 1.838 - from low and middle dose groups).

Figs. 15 and 16 present current features of cohort state for the whole period

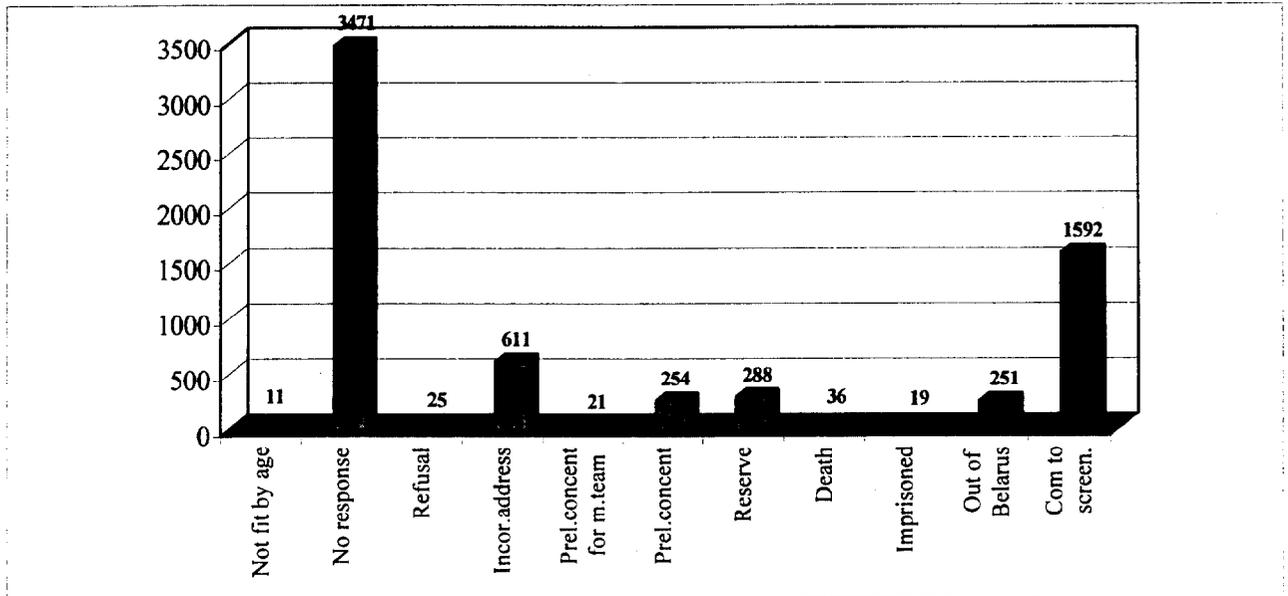


Fig. 15. Distribution of statuses of high dose group subjects undergone examination from 21.12.96 to 31.12.98.

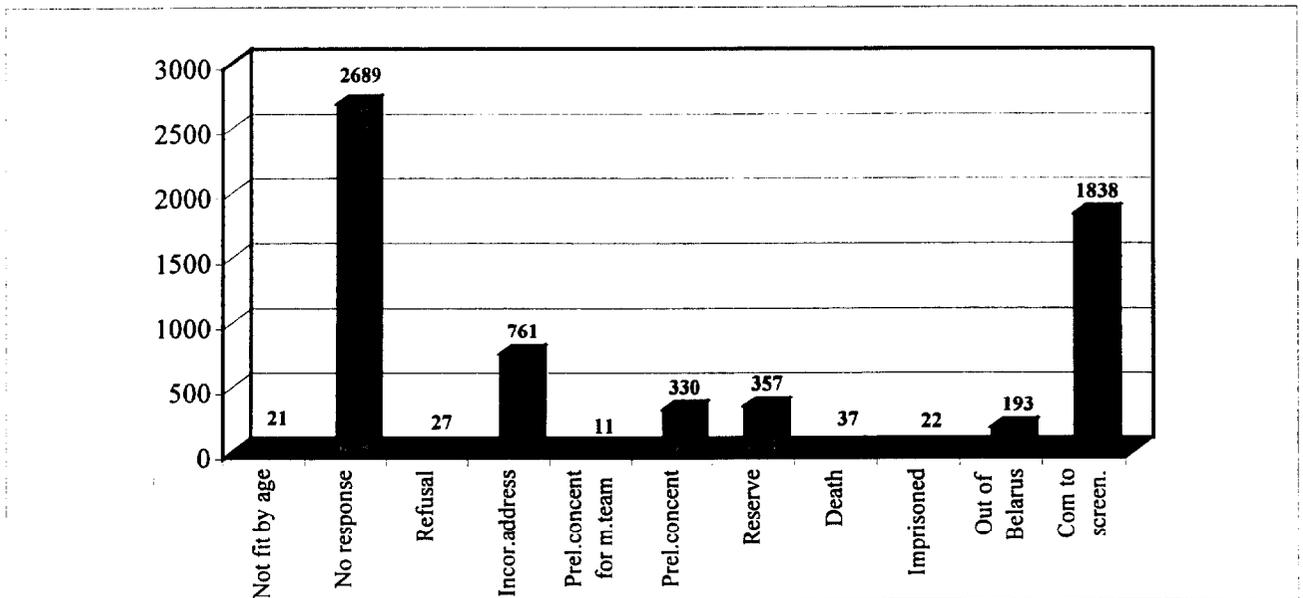


Fig. 16. Distribution of statuses of low and mid dose group subjects undergone examination from 21.12.96 to 31.12.98.

Results of searching activity for the whole period of Project operation are presented in Table 9.

Table 9

Results of searching activity for the period of 21.12.96 - 31.12.98 г., %

Searching outcomes	Group		Total
	High dose	Mid and low dose	
Subject address is defined	78,0	71,4	74,6
Subject address is not defined	22,0	28,6	25,4

Using different sources of address search it was managed to find addresses of 74,6% of cohort subjects. While contacting with cohort subject through found address the following results have been obtained (Table 10.)

Table 10

Results of contacts with cohort subjects through found address, %

Contacts outcomes	Group		total
	High dose	Mid and low dose	
response	37,9	45,1	41,4
no response	52,8	42,1	47,9
wrong address	9,3	12,1	10,7

41,4% of subjects whose addresses have been defined responded to invitation. At the same time response (contact outcome) was both positive (consent to screening in the Dispensary of Radiation Medicine or by mobile team), and negative (subject does not fit by age, imprisoned, moved out of Belarus) following which has been excluded from the cohort. High percentage of contacts is characterized by the result "no response" At the same time obtained experience of work with subjects through their places of residence (visit subjects places at Khojniki and Bragin), analysis of their coming to mobile team examination, twice confirmed through some sources subjects addresses allowed to make a conclusion that the majority of subjects not responded to invitation do reside defined address but do not have a possibility or wish to come to Minsk to examination.

Efficiency of subjects search for the past period agrees with those during pilot stage of project (search of 600 addresses) and is rather high.

Fig. 17 presents distribution of "no response" group by the rajons of Gomel Oblast. From this figure it is evident that the most perspective rajons for mobile team are Khojniki, Bragin, Retchitsa and Vetka rajons.



Fig.17 Distribution of “no respondents” by the rajons of Gomel Oblast

Fig.18 presents the number of deaths by the rajons of Gomel Oblast

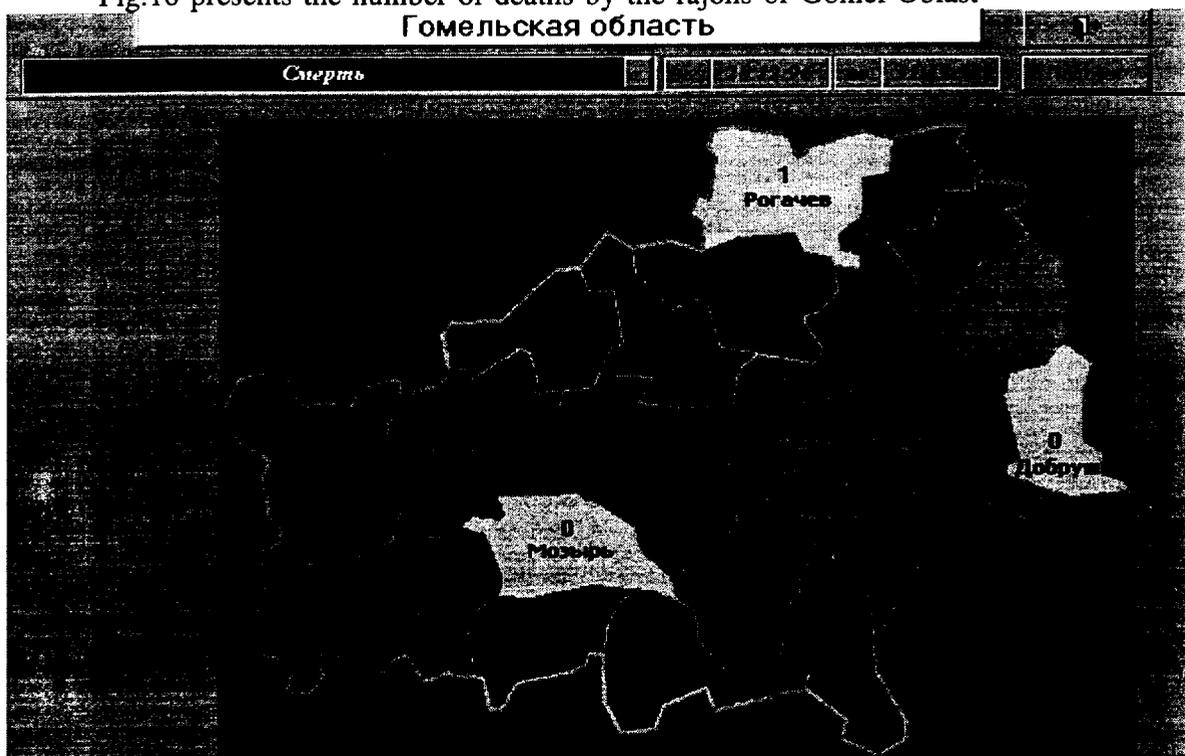


Fig. 18 Distribution of deaths cases by the rajons of Gomel Oblast

Review of presented data allows to select the following perspectives of cohort selection.

- Examination by mobile team at the places of residence of subjects with defined addresses, who do not response to invitation and comprise “reserve” group,
- Search through Address Offices subjects with undefined addresses;
- Increase subjects motivation to participate in Project

Review of cases of thyroid cancer revealed in the course of BelAm study.

(Quality Control Group)
(Screening Center)

As a result of screening examination of 3.435 cohort subjects for the whole period of Project activity 41 (1.2%) cases of thyroid cancer have been revealed.

Review of the structure of thyroid cancer patients showed that:

- in 13 (31.7%) subjects the diagnosis was made for the first time, at the same time in 2 of them (4.9%) - during repeated examination,
- rate female to male was 1.7:1,
- the majority of cases was revealed in 1998 г. - 12 subjects.

(Diagram 1.)(the 2-nd year of screening, 12 years following the accident), among the patients subjects under 6 y.o. at the time of the accident prevailed - 27 inds. (65.9%) (Diagram 2.),

- most of cases was diagnosed in children aged 11-14 y.o., i.e. in the period of puberty (15 subjects., 36.6%) (Diagram 3.),
- total number of subjects to whom diagnosis was made in childhood (under 17 y.o.) was 28 inds (68.3%). This figure more than twice exceeded number of adult patients (Diagram3)

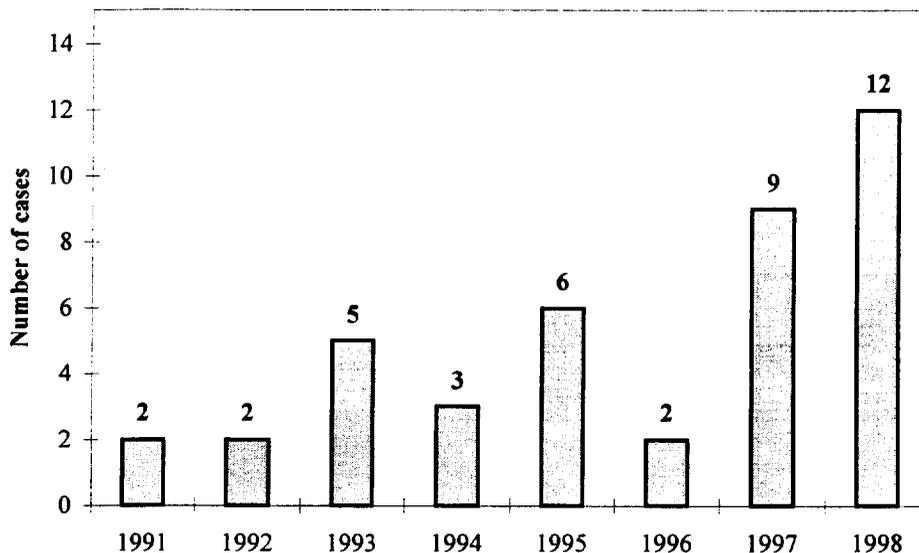


Diagram 1. Distribution of thyroid cancer cases depending on the year of surgery

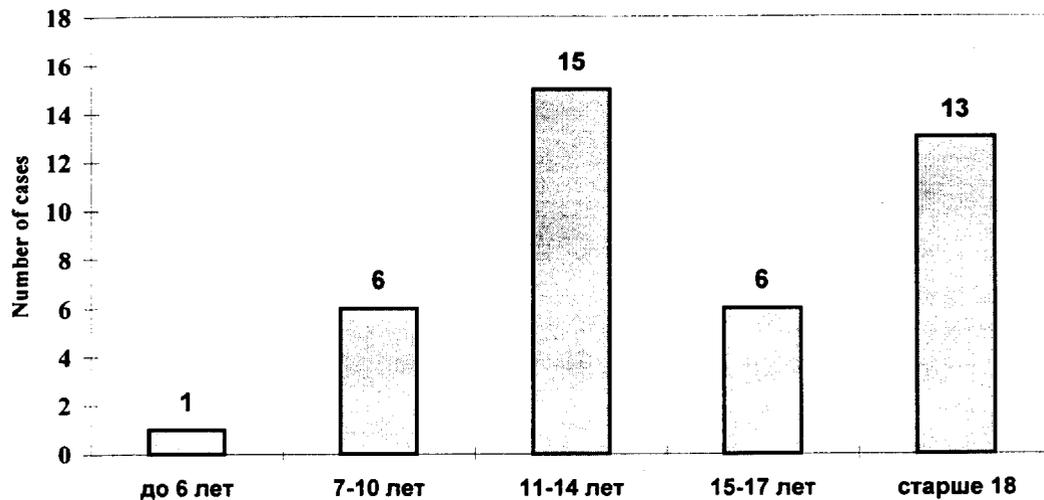


Diagram 3. Distribution of thyroid cancer cases depending on the age at the time of diagnostics

Preliminary review of thyroid cancer cases allows to mention the following:

- increase in number of thyroid cancers in 1997 and 1998 was happened at the cost of individuals aged 9 and more y.o. at the time of the accident
- one of the reasons of increase in number of thyroid cancers in the recent two years is a procedure of thyroid ultrasound screening that allows to reveal thyroid cancer at T 1-2.

It should be noted that all statements are of suppositional character and need to be verified and checked while enriching materials.

(Dosimetry Group)

For the period of 1997-1998 Dosimetry Group has performed the following activity:

1. For 100 cohort subjects thyroid doses have been calculated
2. Initial dosimetric interview has been performed for 3.453 cohort subjects.
3. Repeated dosimetric interview has been performed for 433 cohort subjects
4. 2.760 dosimetric forms have been entered to dosimetric DB.

Milestone 21: Design of image processing procedures, and data base of thyroid images.
(Data Coordinating Center)

For the reported period software for images processing modernized.

To optimize the work of the program initial algorithm have been changed. As a result of this the program creates not 300.000 catalogues corresponding to this or that subject ID as it was previously but only catalogues creating in processing of specific MOD. This significantly decreases time of program work.

In the course of program testing it was found out that in catalogue created for specific ID could also exist images not corresponding to given ID. It could be explained by the fact that program reads out N EXAM (# of examination) from image file, and through this index finds corresponding ID in the table of MOD registration log. Because at the time of image recording to MOD ultrasonographer keys N EXAM manually so the errors could occur while keying. It means: to each new ID at the time of recording to MOD a new N EXAM should correspond, but this does not always obeyed. To trace the correspondence of image files to specific ID of catalogue created for this ID at present it is suggested to perform visual control. Furthermore to avoid such mistakes it is expected to create a program that will read out necessary information directly from image file through recognition of ID and family name of subject.

To convert files of TIFF format to files of JPG format LVIEW PRO program is used. Active period of this program is limited by 20 days because we do not possess licensed copy of this program. That is why we need to obtain necessary version of the program or to develop program for conversion TIFF files to JPG files that could take long period of time

Task No.7 The Estimation of Individual Thyroid Doses for Members of the Cohort
Milestone 22: Conduct personal interviews for all subjects screened in the Project.
(Dosimetry Group)

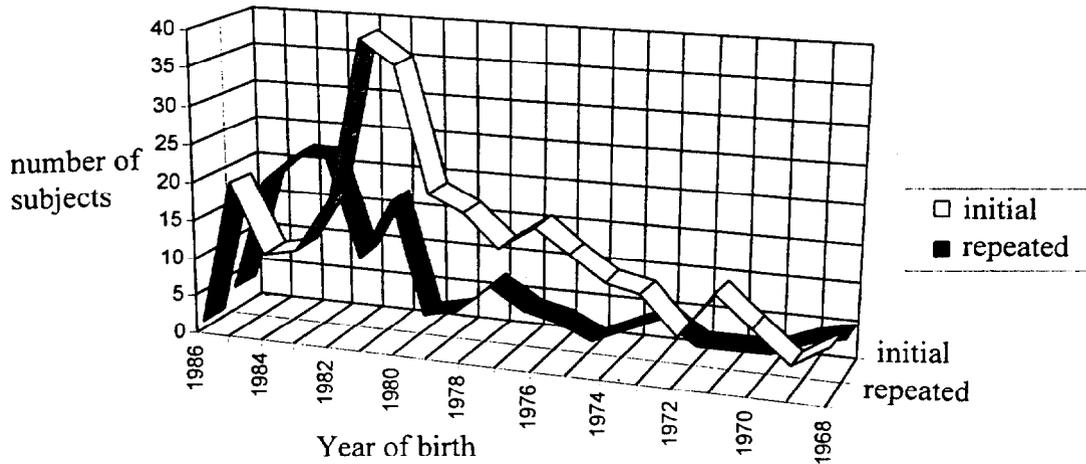
For the reported period (October 1 - December 30, 1998) 471 individuals were interviewed through individual dosimetric questioner (290 inds. - initial, 127 - repeated).

Review shows that the subjects come for examination

	initially	repeatedly
• on one's own	187	54
• together with mother	62	50
• together with father	17	14
• together with sister or brother	21	7
• with other accompanying	3	2

In the fourth quarter 7 questioners were completed for mothers in the period of breast feeding. 20 subjects came to interview without self-interview for Distribution of the cohort subjects is presented below

Age distribution of cohort subjects



Results of interviews with respect to the completeness of the subjects' answers is presented in Fig 22.1.

Table 22.1. Results of interviews with respect to the completeness of the subjects' answers.

Estimation of interview qual.	Initial interview	repeated interview
good	117	59
satisfactory	132	49
unsatisfactory	41	19

In the period of December 10 - 24, 1998 additional data collection through individual interviews was performed by the interviewer joined the mobile team in the town of Khoiniki.

Total number of cohort subjects come to examination was 174. 173 of them were interviewed (one subject refused from interview). 170 subjects were initially interviewed, and 3 - repeatedly)

Subjects come for examination

	initially	repeatedly
• on one's own	112	2
• together with mother	42	1
• together with father	4	-
• together with sister or brother	11	-
• with other accompanying	1	-

Distribution of 173 subjects' answers with respect to the quality of obtained data is shown in Table 22.2.

Table 22.2. Results of interviews with respect to the completeness of the subjects' answers.

Estimation of interview qual.	Initial interview	repeated interview
good	67	3
satisfactory	53	
unsatisfactory	50	-

Table 22.3. Total results interviews with respect to the completeness of the subjects' answers.

Estimation of interview qual.	Initial interview	repeated interview	total
good	184	62	246
satisfactory	185	49	234
unsatisfactory	91	19	110
TOTAL	460	130	590

Distribution of cohort subjects who had been interviewed in the reported period and in the period of 1996 to 1998 according to the dose intervals is presented in Table 22.4

Table.22.4.

Distribution of interviewed cohort subjects according to dose intervals.

Dose range, Gy	4-th quarter	1996-1998
< 0.3	206 (35%)	1036 (30%)
0.3-1.0	124 (21%)	809 (24%)
> 1.0	256 (44%)	1587 (46%)
Total	586 (100%)	3432 (100%)

Milestone 23: Enter to the data base information from interviews collected in the course of the quarter as well as data from 1000 interviews that have been performed earlier; prepare the section of the Dosimetric Operations Manual related to data entry.

Data entry of subjects' individual interview started in the third quarter was continued in the fourth only for initially interviewed.

For the current quarter all initial interview data of the current quarter (460 forms) have been entered and 1000 interview forms of 1997.

Totally, from the beginning of the Project to December 30 1998 2.599

It was reviewed and updated an instruction for conducting of initial interview (Appendix 6) considering changes to interview form (Appendix 7) that have been proposed at the meeting of dosimetrists in Minsk (October 1998). An instruction have been prepared

(Appendix 8) describing the procedure of data entry software usage and operator activity while entering data of the initial interview to the data base.

Milestone 24: Prepare software needed to calculate the individual thyroid doses on the basis of entered interview data; use this software to calculate doses for a sample of 100 subject.

Development of software for calculation of individual doses to thyroid based on entered data implements the method of individual dose reconstruction based on thyroid direct measurements of 1986.

To write a subprogram of individual thyroid dose calculation Visual Basic language (DBMS Access 8.0) was used. The basic information for subprogram of calculation is taken from two independent sources: 1 - Moscow DB of direct measurements; 2- DB of interview and radioactive contamination of the environment, called dosimetric DB. While calculating doses two parameters are taken from DB of direct measurements: date of measurements, and corrected thyroid dose rate

The rest of information is taken from dosimetric DB. The content and composition of tables described in [1,2] have been changed because of changes in initial and repeated interview forms.

As a result of subprogram operation for dose calculation received values of individual thyroid doses are filled in the following fields of the Patients Table: DirectDose and EcologicDose, that contain the values obtained on the base of direct measurements data and data of radioecological modelling, correspondingly. Using subject ID obtained doses could be requested and used by other project groups

At present while calculating individual thyroid doses the following suppositions and simplifications are used:

- Contamination of the territory of Belarus with radioiodine is described by one-day fallouts - April 26 in Brest oblast, April 27 in southern part of Gomel oblast, and April 28 in northern part of Gomel oblast and Mogilev oblast [3,4];
- Cows pasture period started prior to the moment of main radioiodine fall outs. Given supposition we have to introduce because in the former interview forms there is no question about the starting date of domestic cattle pasturing;
- Dose received at the cost of inhalation is calculated only for those subjects who deny milk consumption, dairy staffs, and green leaf vegetables in April-May 1986;
- For each cohort subject the starting date of I-131 intake is the date subjects arrival to contaminated territory
- Blocking effect of iodine preparations equal to 2 days following intake;
- Migrations to Vitebsk, Grodno, and Minsk oblasts is considered as ceasing of I-131 intake;
- Age-dependent values of thyroid parameters (mass, constant of effective half-extermination, calibrating factor) are divided into 18 periods and correspond to those presented in Table 24.1.

Table 24.1

Age-depended values of the parameters, used in program for calculation of individual thyroid dose

Age, year	SRP-68-01 calibration	Thyroid	Effective loss
	factor I-131, Bq per μRh^{-1}	mass, g	constant of ^{131}I in thyroid, d^{-1}
	CF	m	λ_{th}
0-1	99.5	1.3	0.127
1-2	101.8	1.8	0.120
2-3	103.4	2.3	0.117
3-4	104.8	2.7	0.114
4-5	106.6	3.2	0.111
5-6	109.5	3.9	0.108
6-7	111.3	4.8	0.106
7-8	117.8	5.7	0.103
8-9	122.3	6.6	0.101
9-10	126.5	7.5	0.098
10-11	129.9	8.4	0.096
11-12	132.4	9.3	0.096
12-13	134.5	10.2	0.096
13-14	136.4	11.1	0.096
14-15	138.7	12.0	0.095
15-16	141.7	13.2	0.095
16-17	145.5	14.7	0.095
17-18	150.0	16.2	0.094

Individual thyroid dose of a cohort subject from I-131 is estimated on the base of time-integrated content of I-131 in thyroid:

$$D(T) = \frac{E}{m(T)} * Q \quad (1)$$

when $D(T)$ - age dependent thyroid exposure dose, Gy;

E - effective energy of decay I-131, 3.68×10^{-14} J Decay $^{-1}$ [6];

$m(T)$ - age dependent thyroid mass, kg; presented in Table 24.1

T - subject age in April-May 1986, years

Q - time integrated content of I-131 in thyroid, Bq s

Calculating formulas describing time-integrated content of I-131 in the thyroid depending on different ways of radioiodine penetration to the body and that are used in the work are presented in [6,7]. In given papers formula (1) is presented in the following way

$$D_m(T) = K_{\text{day}} * E/m(T) * G(T) * F(T) \quad (2)$$

when

$K_{day} = 86400$, number of seconds in 24 hours, d^{-1} ;
 $G(T)$ – calculated activity of ^{131}I in thyroid, Bq;
 $F(T)$ – function describing ^{131}I kinetics in thyroid, d.

^{131}I activity in thyroid at the moment of measurement is calculated in accordance with the following formula IIIЖ

$$G(T) = CF(T) (P_{th} - P_b) \quad (3)$$

when $CF(T)$ – calculation factor from thyroid dose rate measured by SRP-68-01 to ^{131}I activity in thyroid, Bq per, age dependent values of CF are presented in Table 1

P_{th} - SRP-68-01 readings under thyroid, μRh^{-1}
 P_b - "background" readings of SRP-68-01, μRh^{-1}

Kind of $F(T)$ function used for calculation of individual dose of the cohort subject is estimated through individual interview and is realized in 12 variants of ^{131}I penetration to the body

In the program of individual dose calculation the following ways of ^{131}I penetration to thyroid are presented

- Inhalative penetration to thyroid

$$F(T) = \text{Exp}(L_{Th}(T) * T_m) / L_{Th}(T) \quad (4)$$

when Exp – exponential function;

$L_{Th}(T)$ – effective loss constant of ^{131}I in thyroid, d^{-1} , age dependent values of thyroid mass are presented in Table 24.1

T_m – time interval between the date of subject measurement and the starting date of ^{131}I fallouts, d.

- Per oral penetration of ^{131}I with milk during the whole iodine period

$$F(T) = \text{Exp}(L_{Th}(T) * T_m) / L_{Th}(T) * (1 / L_c - 1 / L_g) / \\ (1 / (L_c - L_{Th}(T)) * (1 - \text{Exp}(-(L_c - L_{Th}(T)) * T_m)) - \\ 1 / (L_g - L_{Th}(T)) * (1 - \text{Exp}(-(L_g - L_{Th}(T)) * T_m))) \quad (5)$$

when $L_c = 0.63$ – constant of biological half decontamination of milk from ^{131}I , d^{-1} ,
 $L_g = 0.15$ – constant of grass decontamination from ^{131}I , d^{-1} ,

- Per oral penetration of ^{131}I with milk without break while taking stable iodine (date of thyroid dose rate measurement is less or equal to the starting date of iodine prophylaxis):

$$\begin{aligned}
F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
& (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e)) - \\
& 1 / L_g * (1 - \text{Exp}(-L_g * T_e))) / \\
& (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_m)) - \\
& 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_m)))
\end{aligned} \tag{6a}$$

when T_b – time interval between starting date of iodine prophylaxis for cohort subject and starting date of fallouts ^{131}I , d.

T_e – time interval between final date of iodine prophylaxis for cohort subject and starting date of fallouts ^{131}I , d

- Per oral penetration of ^{131}I with milk without break while taking stable iodine (date of thyroid dose rate measurement is more than starting date of iodine prophylaxis but less or equal to the final date of iodine prophylaxis):

$$\begin{aligned}
F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
& (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e)) - \\
& 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \text{Exp}(-L_g * T_e))) / \\
& (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_b)) - \\
& 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_b)))
\end{aligned} \tag{6b}$$

- Per oral penetration of ^{131}I with milk without break while taking stable iodine (date of thyroid dose rate measurement is more than the final date of iodine prophylaxis):

$$\begin{aligned}
F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
& (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e)) - \\
& 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \text{Exp}(-L_g * T_e))) / \\
& (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_b) + \\
& \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_e) - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_m)) - \\
& 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_b) + \\
& \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_e) - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_m)))
\end{aligned} \tag{6c}$$

- Per oral penetration of ^{131}I with milk was broken because of lack of iodine prophylaxis (date of thyroid dose rate measurement is less or equal to the ceasing date of milk consumption):

$$\begin{aligned}
F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
& (1 / L_c * (1 - \text{Exp}(-L_c * T_s)) - \\
& 1 / L_g * (1 - \text{Exp}(-L_g * T_s))) / \\
& (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_m)) - \\
& 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_m)))
\end{aligned} \tag{7}$$

when T_s – time interval between ceasing date of milk consumption for cohort subject and starting date of fallouts ^{131}I , d.

- Per oral penetration of ^{131}I with milk was broken while taking stable iodine (date of thyroid dose rate measurement is less or equal to the ceasing date of milk, date of thyroid dose rate measurement is less or equal to the starting date of iodine prophylaxis):

$$\begin{aligned}
 F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
 & (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e) - \\
 & \text{Exp}(-L_c * T_s)) - 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \\
 & \text{Exp}(-L_g * T_e) - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_m)) - \\
 & 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_m))) \quad (8a)
 \end{aligned}$$

- Per oral penetration of ^{131}I with milk was broken while taking stable iodine (date of thyroid dose rate measurement is less or equal to the ceasing date of milk; date of thyroid dose rate measurement is more than starting date of iodine prophylaxis but less or equal to the final date of iodine prophylaxis):

$$\begin{aligned}
 F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
 & (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e) - \\
 & \text{Exp}(-L_c * T_s)) - 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \\
 & \text{Exp}(-L_g * T_e) - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_b)) - \\
 & 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_b))) \quad (8b)
 \end{aligned}$$

- Per oral penetration of ^{131}I with milk was broken while taking stable iodine (date of thyroid dose rate measurement is less or equal to the ceasing date of milk; date of thyroid dose rate measurement is more than the final date of iodine prophylaxis)

$$\begin{aligned}
 F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
 & (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e) - \\
 & \text{Exp}(-L_c * T_s)) - 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \\
 & \text{Exp}(-L_g * T_e) - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_b) + \quad (8c) \\
 & \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_e) - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_m)) - \\
 & 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_b) + \\
 & \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_e) - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_m)))
 \end{aligned}$$

- Per oral penetration of ^{131}I with milk was broken without taking stable iodine (date of thyroid dose rate measurement is more than ceasing date of milk consumption):

$$\begin{aligned}
 F(T) = & \text{Exp}(L_{\text{Th}}(T) * T_m) / L_{\text{Th}}(T) * \\
 & (1 / L_c * (1 - \text{Exp}(-L_c * T_s)) - 1 / L_g * (1 - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_c - L_{\text{Th}}(T)) * T_s)) - \\
 & 1 / (L_g - L_{\text{Th}}(T)) * (1 - \text{Exp}(-(L_g - L_{\text{Th}}(T)) * T_s))) \quad (9)
 \end{aligned}$$

- Per oral penetration of ^{131}I with milk was broken while taking stable iodine (date of thyroid dose rate measurement is more than ceasing date of milk consumption; final date of iodine prophylaxis is less or equal to ceasing date of milk consumption)

$$\begin{aligned}
 F(T) = & \text{Exp}(L_Th(T) * T_m) / L_Th(T) * \\
 & (1 / L_c * (1 - \text{Exp}(-L_c * T_b) + \text{Exp}(-L_c * T_e) - \\
 & \text{Exp}(-L_c * T_s)) - 1 / L_g * (1 - \text{Exp}(-L_g * T_b) + \\
 & \text{Exp}(-L_g * T_e) - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_Th(T)) * (1 - \text{Exp}(-(L_c - L_Th(T)) * T_b) + \\
 & \text{Exp}(-(L_c - L_Th(T)) * T_e) - \text{Exp}(-(L_c - L_Th(T)) * T_s)) - \\
 & 1 / (L_g - L_Th(T)) * (1 - \text{Exp}(-(L_g - L_Th(T)) * T_b) + \\
 & \text{Exp}(-(L_g - L_Th(T)) * T_e) - \text{Exp}(-(L_g - L_Th(T)) * T_s))) \quad (10)
 \end{aligned}$$

- Per oral penetration of ^{131}I with milk was started when subject arrived to contaminated area after fallouts had begun, and then it was broken.

$$\begin{aligned}
 F(T) = & \text{Exp}(L_Th(T) * T_m) / L_Th(T) * \\
 & (1 / L_c * (\text{Exp}(-L_c * T_1) - \text{Exp}(-L_c * T_s)) - \\
 & 1 / L_g * (\text{Exp}(-L_g * T_1) - \text{Exp}(-L_g * T_s))) / \\
 & (1 / (L_c - L_Th(T)) * (\text{Exp}(-(L_c - L_Th(T)) * T_1) - \\
 & \text{Exp}(-(L_c - L_Th(iAge)) * T_s)) - \\
 & 1 / (L_g - L_Th(T)) * (\text{Exp}(-(L_g - L_Th(T)) * T_1) - \\
 & \text{Exp}(-(L_g - L_Th(T)) * T_s))) \quad (11)
 \end{aligned}$$

when T_1 – time interval between the date subject arrival to contaminated area and starting date of fallouts ^{131}I , d.

Subprogram of dose calculation via method of direct measurements as incoming parameters receives the following indices of fields from the table of data base of direct measurements and dosimetric data base:

- Date of thyroid dose rate - field "Meas_Date";
- Corrected thyroid dose rate (mR/h)
- Information of subject migration in April-May 1986 - terms of staying in the settlement is estimated as difference of two fields of the table Departure86 - "Date". At present, coding is not implemented
- Average daily milk consumption for the period April-May 1986 is calculated from the tables of milk and dairy staffs consumption
- Ceasing date of milk local milk consumption - field "Time_Stop"
- Starting date stable iodine intake - field "Time_Block"
- Number of intakes of stable iodine; based on this information ceasing date of stable iodine intake is calculated.

Final result of calculations is field in to the field DirectDose of the Patients Table.

Exposure dose calculation using designed subprogram is performed for 100 subjects presented in the report for the second quarter 1998. Appendix 9 presents the results of

current dose calculation of thyroid exposure dose in comparison with the results of calculation performed in the second quarter and Moscow DB, when

- Dose_2 – doses calculated in the 2-nd quarter;
- Dose_4 – doses calculated in the 4-th quarter;
- Dose_M – doses of Moscow DB.

Milestone 25. Develop and implement calculation procedures to simulate the DP-5 detector response to radiation sources located in the human body for standard and non-standard geometries

(Dosimetry Group)

Because of some objective physical reasons A simulation of GM tube response by Monte Carlo method is a challenging problem. Therefore, the work started with preparation of the counter and the probe models, their validation against available experimental information, and a development of the procedure for Monte Carlo simulation of this detector.

Preliminary results achieved in 1998, prior coming to ORNL, were presented in milestone reports of the BelAm study's dosimetry group and in most complete form in [8].

The Monte Carlo simulation of detector response have been performed with the Monte Carlo program MCNP [5] and using such valuable tools as SABRINA [10] and POV-Ray [11]. As in previous work, the model development and visualization efforts in this study were eased considerably by use of various graphical software like SABRINA [10] and POV-Ray [11]. The version of SABRINA ported to Windows 95/NT [7] was provided for current work by Dosimetry Research Group of ORNL. The POV-Ray program was upgraded to a new version, namely version 3.1.

The mathematical human body and thyroid phantoms used in the study are described in [8-10]. As in previous work, the newborn phantom was not considered.

Variance reduction techniques available in MCNP are not applicable to coupled electron-photon transport, thus reducing the number of allowed techniques to those compatible with analog simulation mode. In analog simulations used here to calculate age-dependent calibration factors of DP-5 the only variance reduction technique used was cell-dependent low energy cut-off of electron transport. Also, the source was considered to be ^{131}I which made possible to get the calibration factor through a single run. Evidently, such source definition would not be possible while simulating the detector response to other radionuclides distributed in the human body. All these problems forced a development of a combined, two-step approach to simulate the detector responses.

The principal idea of the combined approach is to divide the problem space into two regions. In one region the simulation of electron transport is unnecessary and simulation could be performed with higher efficiency and in the second region, which is a region of detector itself, the electron transport is essential to defining the detector response. These two regions are divided by a surface which serves as source surface for the detector. Therefore, the purpose of the first simulation is to collect and preserve information on

particles entering the second (detector) region. MCNP provides for such calculations through the use of 'surface source' option. Under this option MCNP creates a file of particles location, direction, energy, and weight as they cross the surface. This file serves in subsequent runs to provide source particles originating from the surface.

An advantage of such two-step procedure will be observed when running many cases differentiating only by the detector orientation within the source surface. For example, the surface source file is created after simulation of the human body phantom which has a complicated geometry. This is run once. To simulate the detector response then one can use the surface-source already created and make the simulation with simpler geometry of the detector as many times as necessary. Changes of the detector orientation are simulated by spatial transformation of particles tracks recorded in the surface-source file. This means that overall gain from using the two-step procedure would be proportional to the number of detector orientations to be studied within the same source surface.

The results obtained with use of the two-step procedure were compared with previously calculated in single analog runs for QA purposes. Both data sets are compared in Table 25.1. As seen from the table, there is a good agreement between the data sets thus validating the combined, two-step computational procedure.

Table 25.1. Calibration factors of DP-5 to ^{131}I calculated by two methods, $\mu\text{Ci h mR}^{-1}$.

Phantom	single run		two-step run
	1×10^7 histories	2×10^7 histories	1×10^7 histories
1 y	$6.51 \pm 0.38^*$	6.44 ± 0.25	6.41 ± 0.38
5 y	6.89 ± 0.42	6.94 ± 0.27	6.94 ± 0.42
10 y	8.83 ± 0.61	8.51 ± 0.42	8.59 ± 0.57
15 y / female	9.44 ± 0.67	9.45 ± 0.46	9.51 ± 0.67
Adult	11.26 ± 0.86	11.07 ± 0.66	11.16 ± 0.85

* Error values correspond to 2σ confidence interval.

The surface source files generated once for every phantom in the series are then used in simulation of the different detector orientations within the same surface. Among disadvantages of the two-step procedure is the creation of large surface source files. For example, for 10^7 histories the generated surface source files vary from 180 to 270 Mbytes in size, depending on phantom.

Study of various violations of measurement geometry

With the two-step procedure described above the calibration factor dependence on the orientation of the detector (rotation) was studied. Fig.25.1 presents geometry for the 1-year old child phantom. This figure represents the cross-section of the phantom and detector in plane $x=0$. The standard position for the detector is shown in the figure, i.e. the detector

axis is parallel to lateral dimension (x -axis) of the human body, and the detector axis is located at the same height as the center of thyroid. The detector's inside is not shown.

The detector has cylindrical external shape which serves as the surface source for the second step. With such surface source it is possible to simulate various detector orientations produced by rotation about the detector axis which is parallel to x -axis. Because the detector construction allows measurements with open and closed window, each probe location was simulated for both situations. In Fig.25.2, the detector cross-section is shown as well as various rotation angles at which simulation have been performed.

As it is seen from Fig.25.2 the counter is located asymmetrically inside the detector. This is due to the fact that DP-5 detector is based on two GM-counters. The second counter is a low-efficient small GM-counter (see Fig. 3) which is operational at high exposure rates when the first tube (SBM-20) count rate approaches a limit caused by the counter's dead time. It was indicated previously that in real measurements of ^{131}I activity in thyroid only SBM-20 counter was responsible for the DP-5 response, hence it was the only one considered in the present DP-5 detector model.

Because of the GM-counter placed asymmetrically inside the detector the maximum of the detector efficiency is not observed at standard detector position but rather when the detector is rotated at angle $\alpha \approx 37^\circ$, or saying in another words the surface source is rotated at angle $\alpha \approx -37^\circ$. This is shown at Fig.25.2 as a black triangle at the lower right corner. Other considered locations are also marked by solid triangles. It seen that due to asymmetry of the probe the total detector rotation angle range studied was from -37° to $+217^\circ$. The calculated angular dependencies of calibration factors for the adult phantom are represented at Figs.25.3 below. Calculated data, having statistical uncertainty within 3 - 5%, are compared with measured results reported by Institute of Biophysics, Moscow (IBP) [17]. These measured data were stated to have uncertainty of 30%. It seen from Fig. 25.3 that calculated and measured data are in a satisfactory agreement for closed detector window while measured points are systematically lower that calculated ones, and for open detector window the disagreement is more.

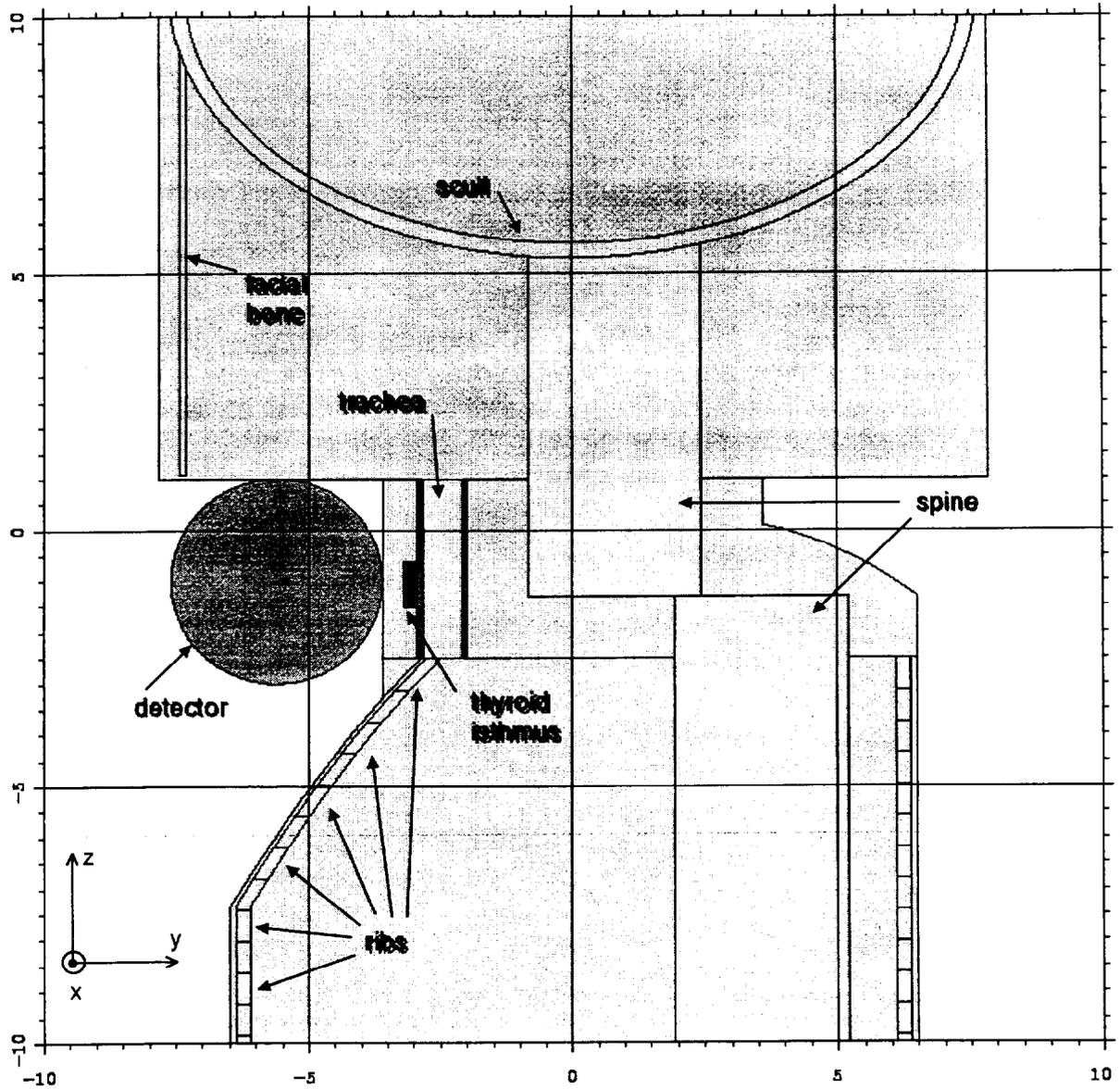


Fig.25.1 MCNP plotting of the 1 year old phantom and the DP-5 detector. Cross-sectional view in the $x=0$ plane. The detector interior is not shown.

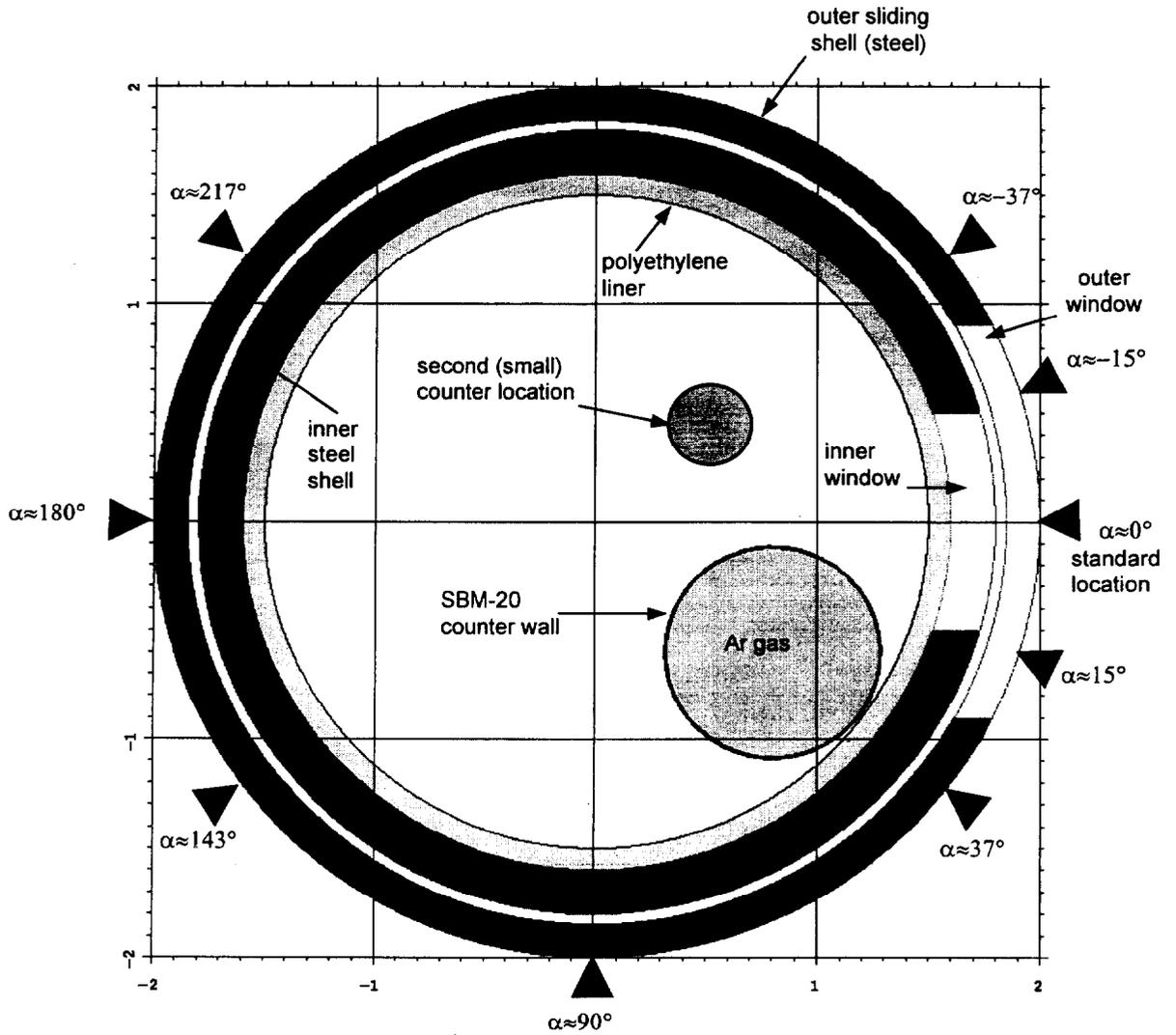


Fig. 25.2. Cross-sectional view of the DP-5 detector model. Window is open. Black triangles indicate directions to center of the source at various rotations of the probe. The detector rotation angles are shown.

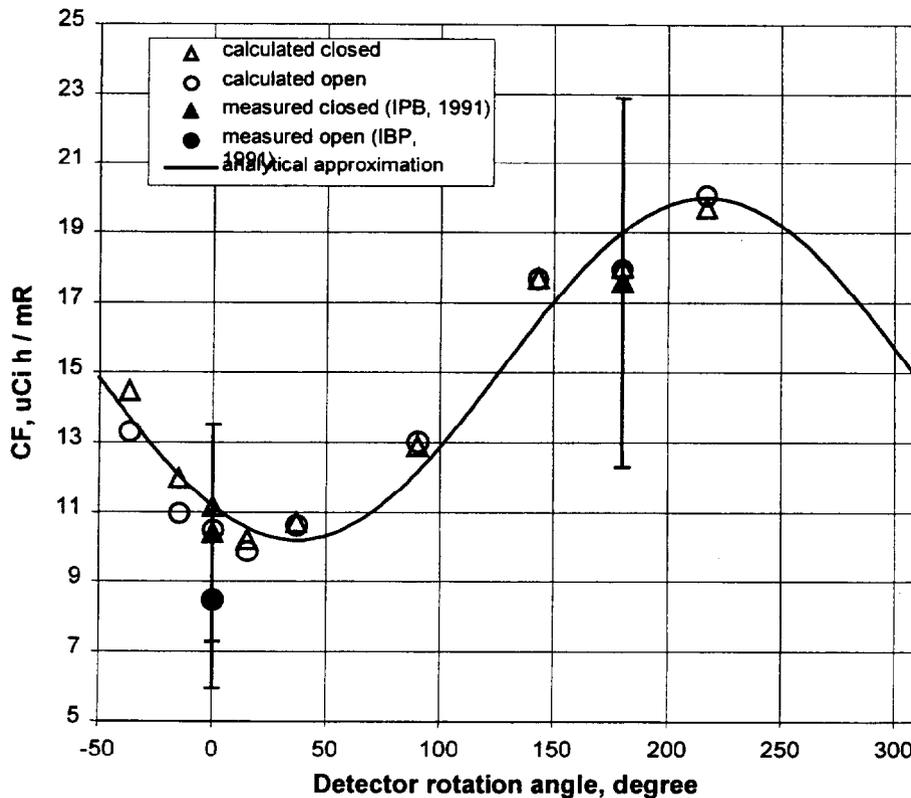


Fig.25.3. Angular dependence of the DP-5 calibration factor for the adult phantom. Error bars are shown only for measured points [11] (solid dots). Calculated points (open dots) have statistical error 3 - 5%.

The calculated data points were fitted by an analytical function of the form: $f(\alpha) = a \cdot \sin(\alpha - (\frac{\pi}{2} + b)) + c$, where fitted values of the parameters a , b , and c are listed in the Table 2 below. The last column in the Table 2 gives a value of a minimum of the analytical angle-dependent calibration factor. This minimum which correspond to a maximum detection efficiency is observed not in the standard detector position but after rotation of the detector at angle b .

Table 25.2. Parameters of the approximation function for angle-dependent calibration factors.

Phantom	$a, \mu\text{Ci h mR}^{-1}$	$b, ^\circ$	$c, \mu\text{Ci h mR}^{-1}$	$c - a, \mu\text{Ci h mR}^{-1}$
1 y	4.3	37	9.9	5.6
5 y	4.2	37	10.5	6.3
10 y	5.0	37	13.0	8.0
15 y / AF	5.1	37	13.9	8.8
Adult	4.9	37	15.1	10.2

Below at Fig.25.4 calibration factors (detector window closed) calculated for standard position and for position after rotation through an angle b are plotted. It is seen that rotation at angle b results in systematically lower calibration factors, which are in a very good agreement with the previous estimate of IBP.

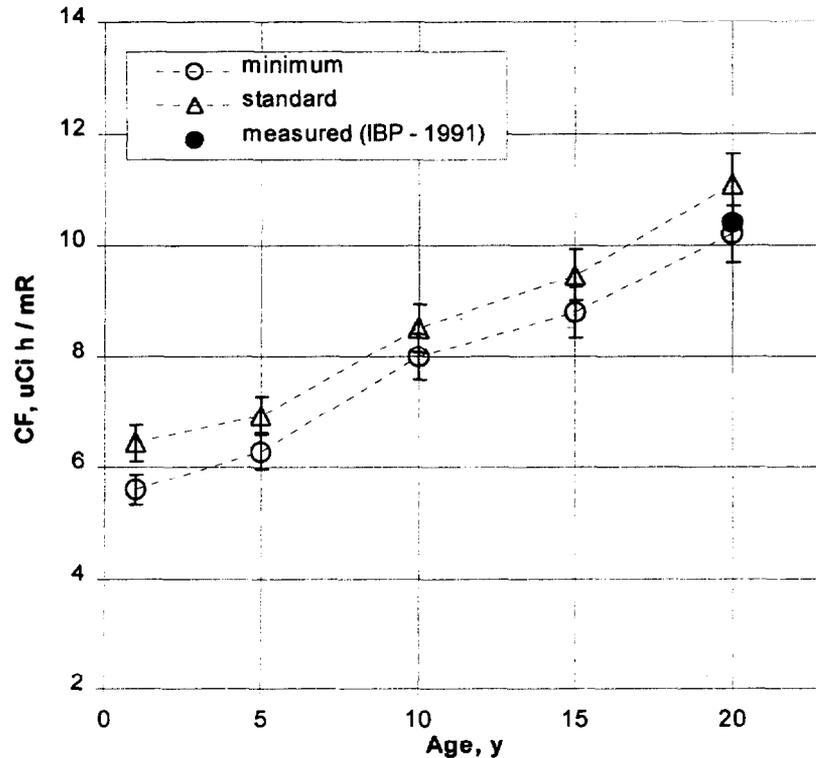


Fig.25.4. Comparison of the DP-5 calibration factors calculated in the detector standard position and minimum calibration factors after detector rotation. It is also shown as a black circle the result obtained by [17].

The model of DP-5 detector allows simulating of the open and closed detector window. The detector response at various angles was studied in both modes. At Fig.25.5 the angle-dependent ratios of calibration factors calculated with open and closed window are shown graphically.

It is seen from Fig.25.5 that the ratios are age-dependent and there is a maximum difference of about 10 % between the detector response with open and closed window. The solid circle in the Fig.25.5 indicates a result derived from data reported by IBP [17] which demonstrates open window effect on calibration factor to be as much as 18 %. That is, the calculated and the measured effects of open window to calibration factors differ approximately 2 times. One explanation of this disagreement could be that calculated responses were produced with surface source (two-step procedure) which includes only photons crossing the detector surface. Is the observed discrepancy due to an absence of electrons in the surface source? To answer this question the analog calculation has been performed for the detector in the standard position with opened window. Unlike previous analog calculations the electron cut-off energies in the thyroid, neck, and trachea were set to be equal 0.1 MeV. Such cut-off was considered to be low enough, because the open detector window does not assume the open counter wall. There is a 1 mm polyethylene liner between the counter wall and the outer space. Such a barrier would effectively prevent low energy electrons from entering the probe. The calculation result had demonstrated that the effect of electrons coming through the open window in the standard

detector position for the adult phantom is not more than 3 % for the ^{131}I . This means that the discrepancy observed between the calculated and the measured values is not due to the electron contribution, only. The other possible reasons could be:

- the position of the GM counter relative to the window in experiments differs from the position assumed in calculations;
- variations of constitution and age among the group of 73 measured persons, e.g. of thickness of a tissue overlaying the thyroid.

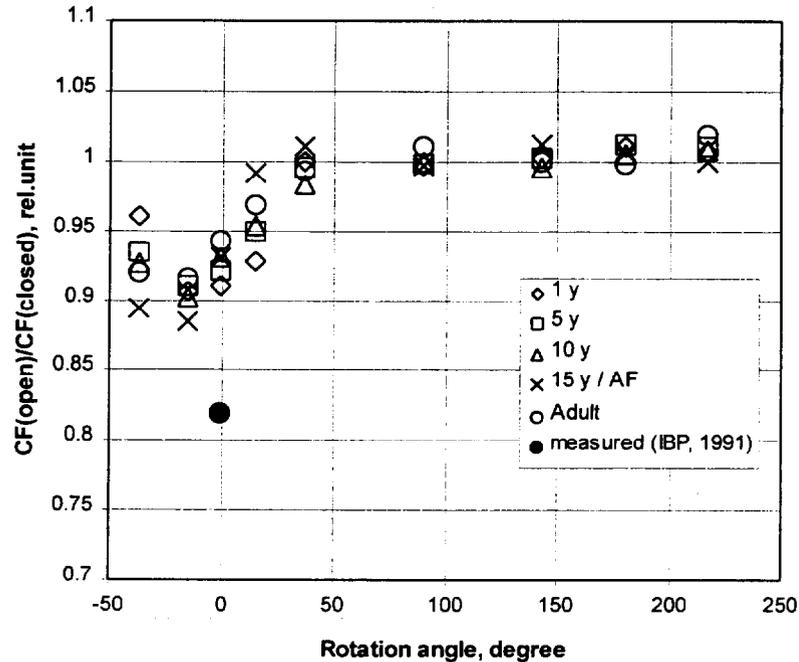


Fig. 25.5. Angle-dependent ratio of DP-5 calibration factors for open and close detector window calculated for various phantom ages.

The next step of the DP-5 detector simulation was to consider an alternative positioning of the probe during measurements. This is referred as an 'orthogonal' position, because the probe is orthogonal to normal position. Such position is very similar to the standard probe position in measurements with NaI detector of SRP-68. Although such position of the detector seemed to be a relatively rare in measurement campaign of 1986, the calibration factor corresponding to 'orthogonal' position should demonstrate most considerable deviation from the standard position. Therefore this case was simulated, too.

The simulation has been performed using the two-step procedure, also. The surface-source file was prepared for the orthogonal position for 5 phantoms in the study and it was used in four runs with the closed detector window looking up, down, left, and right. Results for these four orientations are averaged and presented at Fig.25.6. The calculated points (open circles) are presented with their statistical uncertainty; the solid circle shows the result of IBP [17], its reported uncertainty was 20%.

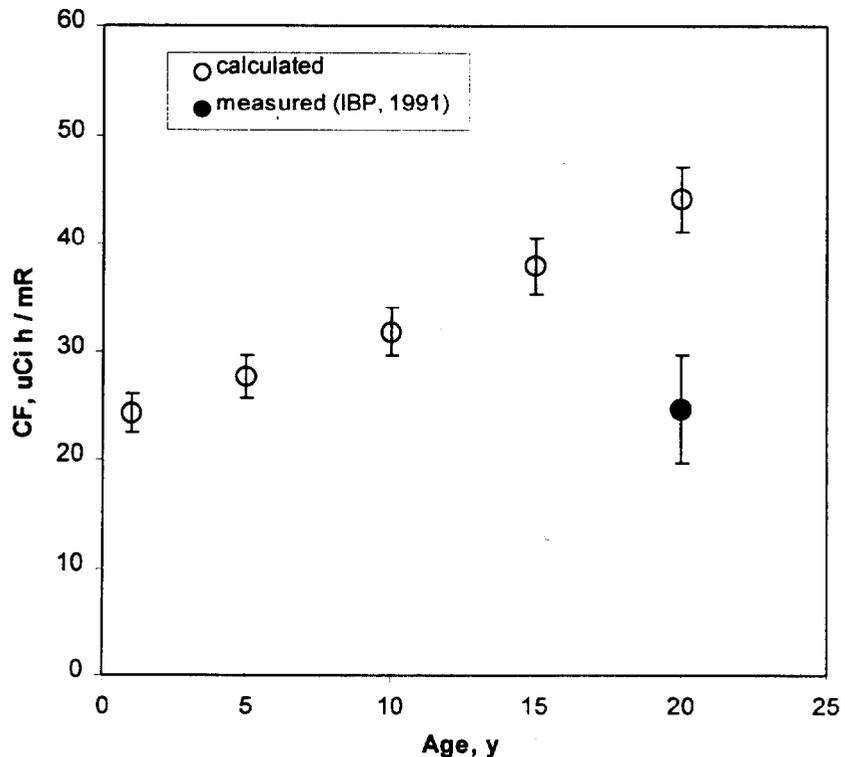


Fig.25.6. Age-dependent calibration factors of DP-5 for orthogonal position of the detector.

It is seen from Fig.25.6 that the calculated and the measured points disagree far beyond their uncertainty limits. The reason of such a discrepancy has to be verified because of the value of the discrepancy (factor of 2) would introduce a considerable error to dose estimates in cases when the measurements were known to be performed with the detector in the orthogonal position.

The possible origin of the disagreement noted in Fig.25.6 could be deficiencies in either the computational procedure or the measured data (e.g. caused by a contribution from activity in the whole body, or by a greater uncertainty due to a decrease of detection efficiency in orthogonal geometry). Therefore, the calculated data were checked and verified. This was done by running a series of analog simulations for sources of various geometry. The main idea of the check was to compute a ratio of the calibration factors in 'normal' and 'orthogonal' positions. As it can be seen from Fig.25.6 and data in Table 25.2, the 'orthogonal-to-normal' ratio for the adult phantom is 2.4 for measured data and 3.9 for calculated data. Therefore, this ratio was calculated for the given detector model for a number of cases which are described below.

The sources considered were: 1) a parallel beam in air; 2) single point source in air; 3) two point sources in air; 4) two point sources in water cylinder representing the neck; 5) two elliptical volume sources (thyroid lobes) in water cylinder. Such selection of source geometry should account for major effects influential to the detector response when the problem geometry goes from simplest case (parallel beam) to realistic (volume source in water) case. In Table 25.3 below the main results are presented. To understand these numbers and especially the considerable difference between ^{131}I and ^{60}Co in the geometry

of parallel beam, the energy dependence of the efficiency have been calculated for cases A and B with monoenergy photon sources. Results are shown at Fig. 25.7 and 25.8 below. The absolute efficiency per particle per MeV is presented at Fig. 8 for parallel beam and isotropic point source in both locations 1 and 2 (see Table 25.3).

Table 25.3. Ratios of calibration factors for a number of simple sources in two locations corresponding normal (1) and 'orthogonal' (2) placement of the DP-5 detector.

Case	Source geometry ^a	Description	Ratio 'orthogonal' / normal	
			$\frac{CF_2}{CF_1} \approx \frac{\eta_1}{\eta_2}$ ¹³¹ I	⁶⁰ Co
A		Parallel beam	3.87 ± 0.33 ^b	2.36 ± 0.09
B		Single point isotropic source	3.67 ± 0.31	3.47 ± 0.13
C		Two point isotropic sources in free air	3.54 ± 0.31	3.48 ± 0.13
D		Two point isotropic sources in water cylinder	3.09 ± 0.25	3.43 ± 0.14
E		Two elliptical volume sources in water cylinder	3.95 ± 0.35	4.21 ± 0.19

^a 1 - normal detector position, 2 - 'orthogonal' position

^b all listed errors correspond to 1 standard deviation

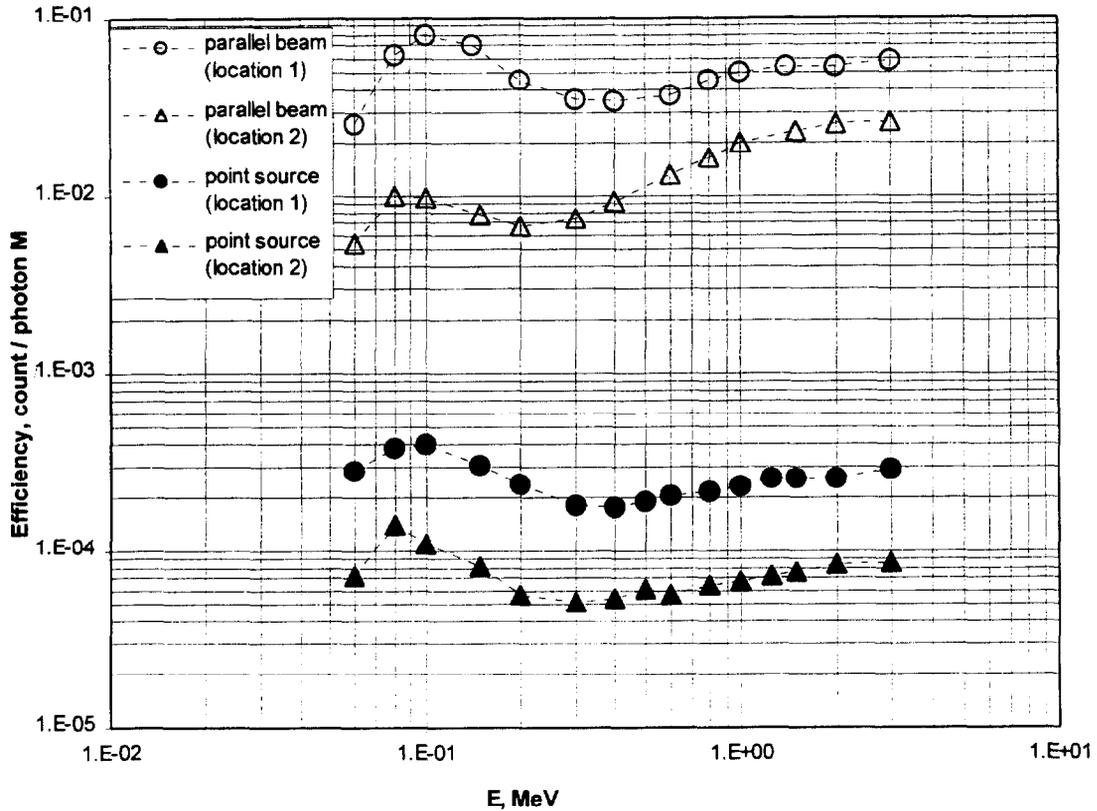


Fig.25.7. Comparison of the energy-dependent DP-5 efficiency in two geometries, namely, a parallel monoenergy beam (open points) and isotropic point source (solid points), for two locations of the source (see Table 25.3 for details).

It is seen from the data presented in Fig.25.8 that energy-dependent efficiencies demonstrate similar behavior. However, the parallel beam points demonstrate different energy dependence in location 1 and 2, while point source energy dependence for both locations is almost the same.

To make differences in energy dependence more clear, the ratios of the data presented at Fig.25.7 are plotted at Fig.25.8. It became clear that plotted ratios have very different energy dependence in the energy range below 0.4 MeV. That is, while the point source ratio is approximately constant, it varies within 3 and 4, the ratio for the parallel beam varies from 2 to 9. From data presented at Fig.25.9 it is evident why the ratios listed in the Table 25.3 for case A (parallel beam) for ^{131}I and ^{60}Co are different while other ratios are approximately the same.

The data calculated and presented in Table 25.3 and Figs. 25.7 and 25.8 increase our confidence in the calculated DP-5 calibration factors for 'orthogonal' location of the detector. Nevertheless, the additional simulations could not prove the validity of the calculated data, because the detector model is simplified comparatively to the real detector. There is a speculation that the results observed in the case of ideal parallel beam incident along the axis of cylindrical model of the detector are just computational artifacts caused

by idealization of the detector structure and the beam geometry. Furthermore, truly parallel beam sources do not exist in the real world.

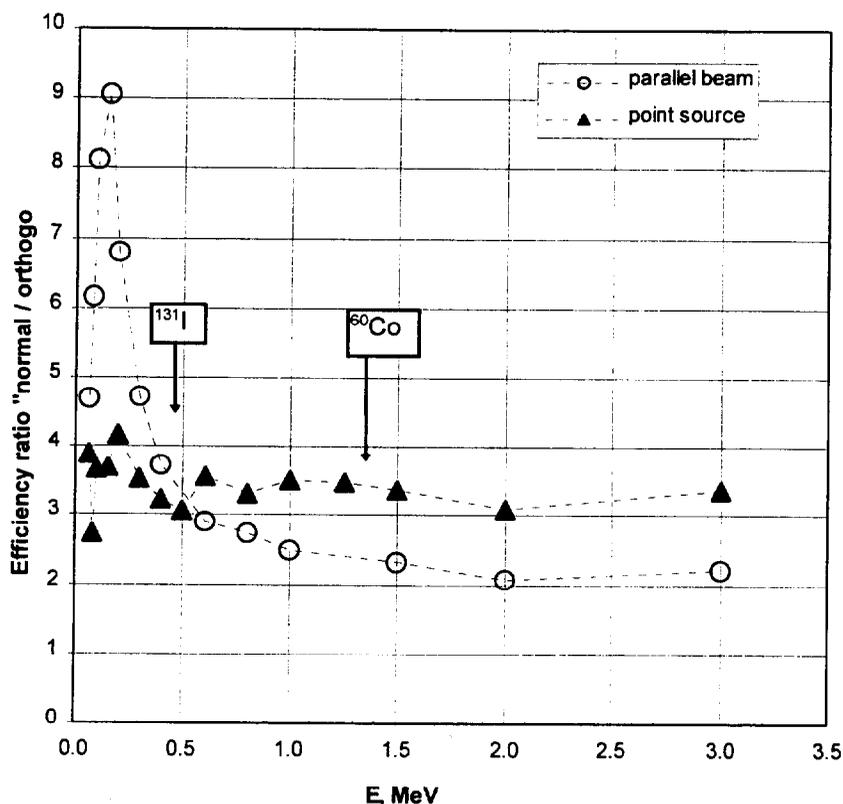


Fig. 25.8. The energy-dependent ratio of the DP-5 efficiencies to monoenergy isotropic point source and parallel beam in locations referred as 1 and 2 (see Table 25.3 for details).

To resolve this issue independent experimental data could be used. Such data could be obtained by measuring the detector response to several standard radioactive sources placed at different locations relatively the detector. Previous measurements undertaken in 1993 in Institute of Radiation Medicine in Minsk did not succeed because of low sensitivity of DP-5 to the available standard radioactive sources. Therefore, would experiments be performed again they should be made at a standard calibration facility in the geometry of pencil beam or with point sources of higher activity. Such measurements followed by Monte Carlo simulation of the current idealized detector model in real measurement conditions would be invaluable to validate the simulation approaches.

Another reason to undertake an experimental work with the DP-5 dose-rate meter is that the available experimental data are sparse and unique. Therefore, the new experimental data could be a reliable basis to resolve the above mentioned discrepancies between the simulated data and measured ones as well as they would make a solid basis for validation and improvements of the detector model provided the latter would be shown necessary.

The year 1998 visit to ORNL has resulted in a significant progress in calculation of the DP-5 characteristics which were unknown before. These include age-dependent calibration factors for a variety of geometrical conditions.

Two-step simulation approach was developed to allow more efficient simulation of the DP-5 gas-discharge detector response. The use of the two-step procedure had considerably reduced computational expenses, e.g. an estimated gain in overall computational performance is about of factor of 10.

The DP-5 responses were calculated under various geometrical conditions and impact of the detector rotation was estimated. The source considered was ^{131}I in thyroid. The number of considered cases was doubled by simulation of the detector with open and closed window. The results of calculations were analyzed and presented in the analytical form convenient for further use in the dose assessment.

The comparison with available experimental data had been made where possible. The calculated data have shown good agreement with available measurements for closed window, the only measured point for detector with open window was less approximately 10% than the computed data. The discrepancy is observed between calculated and measured data for the detector placed orthogonal to the standard position. The only available measured value is 44% less than calculated one.

The calculated calibration factors in the orthogonal detector position were indirectly verified in a series of analog simulations covering various source geometries from simplest parallel beam to thyroid-like volume sources. Results of these simulations have increased the confidence in the calculated DP-5 calibration factors for orthogonal detector position. However, need for alternative independent high quality experimental data to resolve the observed discrepancy is evident. Such experimental work should be undertaken prior coming to the next extensive calculations for radioactive sources other than ^{131}I distributed throughout the human body.

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APPENDIX

FORM OF PATHOMORPHOLOGICAL EXAMINATION

ID

Name of patient. | _____

Date of birth | _____

Date of surgery | _____

Place of surgery | _____

Date of examination | _____

Place of examination | _____

Hystological number(s) _____

Examined material: Vital Fixed

Paraffin blocks Hystological slides

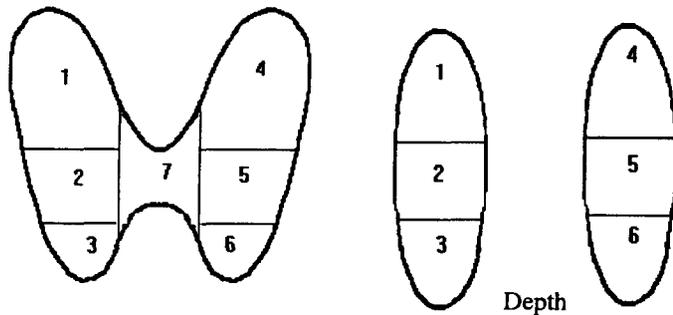
Primary documentation of macroscopic examination

1. MACROSCOPIC EXAMINATION

1.1. THYROID TISSUE

	WEIGHT (g)	Size (mm)			CONSISTENCY
Right lobe					
Left lobe					
Isthmus					
Right lobe + Left lobe					
Left lobe + Isthmus					
Thyroid Nodule					

1.2. Thyroid nodules (localization with mark on diagram)



node characteristics	right lobe (nodes)				left lobe (nodes)				isthmus (nodes)	
	1	2	3	4	1	2	3	4	1	2
Max. diameter(MM.)										
Capsule:										
• absent										
• partial										
• complete										

consistency:																			
• soft (elastic)																			
• flabby																			
• dense																			
• very dense																			
Condition:																			
• homogeneous																			
• heterogeneous																			
• thyroid tissues																			
• with white taint																			
Crystal changes																			
• absent																			
• completely																			
• partially																			

1.3. Lymph nodes

Number: single several (2-3) many (>3)
 Localization: neck rightside leftside central
 upper./mediastenal non identified

2. HISTOLOGICAL EXAMINATION

2.1 THYROID TISSUE

Follicles: macrofollicular colloid cysts
 normofollicular solid
 microfollicular

Epithelium: **FUNCTION** **CELL CONTENT**
 hypo A-cells
 norm B-cells

Strome:
 sclerosis yes no if yes
 focal weak
 diffusive moderate strong
 inflammatory infiltration yes no if yes
 Focal Diffusive Granulomatosis
 other deviations (specify)

2.2. Thyroid nodules

	right lobe				left lobe				isthmus	
	1	2	3	4	1	2	3	4	1	2
Hyperplastic (adenomatous)	<input type="checkbox"/>									
Adenoma	<input type="checkbox"/>									
Hystological type Variant	_____									
Carcinome	<input type="checkbox"/>									
Hystological type Variant	_____									

OPERATIONAL MANUAL FOR QUALITY ASSURANCE

General statements

One of practical tasks of BelAm Project is to get acquainted the specialists with quality assurance procedure of medical study.

The aim of Quality Assurance is to obtain objective information through standardization of the process and minimizing of errors of objective and subjective nature. To implement this it is necessary to solve the following tasks:

- design Operational Manual (OM) of Project,
- prepare standard forms,
- train and certify personnel,
- quality control (QC) of equipment,
- QC of performed procedures
- QC of made decision
- QC of information collection and processing

Design of Project OM and standard forms is performed before the Project start. But at the initial stage of the study (during first three years) they could be updated and modernized. Updated forms and OM are dated and stored in the form of interim documents. Any changes are registered by DCC. Administration and Group Leaders should be provided with text of OM and informed of all changes.

Personnel training is performed prior to their work in the Project, and in case when changes made to OM. This training suggests acquaintance with principals and tasks of the Project, with corresponding Sections of OM, including documents and instructions for their completion. Following training names of specialists, dates and certification status are registered. All information is stored in DB of personnel (DCC). DCC informs Group Leaders about the necessity of recertification. Terms of certification of different groups of specialists are given in OM.

QC of equipment is based on the following data: list of equipment used at specific stage of the study, regulations for control under the technical state of each piece of equipment pointing out the periodicity of the control and reference to current document reflecting technical state of equipment, QC reports (Annex) submitted to DCC in standard form and in fixed terms.

QC of procedure, as a rule, envisage direct survey under the implementation of this procedure and its comparison with the description in corresponding Section of OM. One should remember that at the stage of examination there could be few procedures (for example, collection of sample, its storage, transportation, test) and each of them should be under separate control.

While performing QC of made decision an estimation is made whether this decision corresponds to criteria of OM. Making decision means the following: identification of subject, giving status to cohort subject, making diagnosis, referral to hospitalization,

estimation of laboratory tests, cytological and pathomorphological conclusion, etc. All disagreements appeared in the course of the Project should be studied by experts to reveal the reasons and make agreed decision.

In QC of data collection and processing one should take into account the correspondence of subject's passport data with those marked at bar-code label; follow all the instructions for forms completion, perform manual coding and editing for completeness of all fields, use IDC codes described in OM. To estimate the quality of data cross logic comparison is used. There is also studied a compatibility of data from different specialists and their equipment.

Quality Assurance has multilevel nature. Responsibility for its performance is laid on examiners themselves (self-control), Group Leaders, Project Administration, expert including international, QC expert, DCC, and incharged persons. The results of QC are put to the Form of QC Report.

Appendix 6.

Data of Individual Interview Form*Instruction for filling in*

Individual Interview Form is completed by interviewer during initial interview of examinee ("E") and his accompanys. Given form is primarily designed for interviewing parents of examinee. But if only examinee is presented He/She should be asked all the questions regardless the age. But if for "E" it is difficult to answer this or that question interviewer should not press him/her.

Procedure of interview.

1. Put the date of interview.
2. Mark with "x" symbol participants of interview.
3. Put family name of "E". If at the time of the accident "E" had another family name, put it below.
4. Put the name of "E".
5. Put the patronymic of "E".
6. Put the date of birth of "E".
7. Mark with "x" symbol sex of "E".
8. Put detailed current address of "E". Do not make any comments on right fields regarding from what time "E" reside given address.
9. Put address of "E" at the time of the accident.
- 9a. Mark with "x" symbol from what material walls of building where "E" lived at the time of the accident were made.
- 9b. Put the floor where "E" lived at the time of the accident.
10. Mark with "x", if "E" was evacuated (moved him/herself) from the place of residence (place of staying at the time of accident) in the period 26.04 - 31.05.86.
11. Put in the table information of "E" movements in 1986 following the accident from the place of residence (place of staying at the time of the accident). Special attention should be paid to the period of 26.04 -31.05. It is necessary to record in details the rout of "E" movements in that period including week ends and holidays trips.

In the field "movements in 1986" put Oblast, Rajon, Settlement (place, if it was summer camp, sanatorium, rest house etc.).

In the field "duration of staying" should be put the duration of staying in mentioned settlement, i.e. in field "from" put date of arrival (day, month) and in field "to" date of departure (day, month)

If "E" can not remind more or less exact date of arrival, interviewer should use suggested code, that should be put to field "code". So code shows approximate date of arrival to given settlement. The date of departure will be the date (code) of arrival to another mentioned settlement etc.

If "E" moved to a new place of residence, in the field "PPR" put "x". symbol

To the line "time of staying outdoor" the information should be put the following way:

If "E" suggests as an answer interval estimation of time of staying outdoor, put it correspondingly to field "from" and "to".

If "E" suggests as an answer exact number of hours of outdoor staying put it to field "from", field 'to' will be empty.

12. Put to the table information of 'E' movements from the place of residence for the period of 24 days and more in the following years.

In the field "Where" put Oblast, Rajon, Settlement (place, summer camp, sanatorium, rest house etc) of movement.

In the field "Year of movement" put the year of movement.

If 'E' moved to a new place of residence, in the field "PPR" put "x" symbol.

In the field "duration of staying" put the duration of staying (in months) in the mentioned settlements. If 'E' moved for the period from 24 days to 1 months, consider it as a movement for the term of 1 month.

Do not put information of movements for the period of less than 24 days below the table. Do not make any comment on the fields.

13. Mark with "x" symbol appropriate variant of answer.

Questions 14-14d refers to the place of residence (place of staying at the time of the accident).

14. Put how many hours 'E' usually spent outdoor in spring and summer period before the accident.

If "E" suggests as an answer interval estimation of time of staying outdoor, put it correspondingly to fields "from" and "to".

If "E" suggests as an answer exact number of hours of outdoor staying put it to field "from", field 'to' will be empty.

14a. Mark with "x" symbol appropriate variant of answer

Do not suggest to 'E' variant "do not remember" as a possible answer.

14b. If 'E' could remind more or less exact date when staying outdoors was limited put it.

If for 'E' it is difficult to remind exact date, mark appropriate variant with "x" symbol.

14c. During what period this limitation continued. Do not forget to record in what units 'E' mentioned the term (days, weeks).

14d. Put how many hours 'E' usually spent outdoor in the period of limitation.

If "E" suggests as an answer interval estimation of time of staying outdoor, put it correspondingly to fields "from" and "to".

If "E" suggests as an answer exact number of hours of outdoor staying put it to field "from", field 'to' will be empty.

15. Pay attention that this question deals with the period of 26.04 - 31.05.86.

15a. Mark with "x" symbol appropriate variant of answer

Do not suggest to 'E' variant "do not remember" as a possible answer

15b. It is necessary to receive from 'E' the following information

1. When did 'E' start taking stable iodine;
2. Did 'E' take them daily;
3. During what period did 'E' take them

If 'E' could remind more or less exact starting date of stable iodine intake mark it in the calendar for April-May 1986 it.

If for 'E' it is difficult to remind exact date, mark appropriate variant with "x" symbol.

Record whether 'E' took stable iodine daily, if no - how many times a week.

Record during what period 'E' took stable iodine Do not forget to record in what units 'E' mentioned the term (days, weeks).

15c. Mark with "x" symbol appropriate variant of answer

16. Pay attention that this question deals with 'E' regular milk consumption before the accident.

Using suggested codes put to the table information of milk consumption the following way.

In the field "what milk" record appropriate variant of K1 code.

In the field "source" record appropriate variant of K2 code.

In the field "how many liters for one intake" record the quantity of milk (in liters) that 'E' consumpt for one intake.

In the field "how many times per day" record how many times per day 'E' consumpt milk

In the field "how often" record appropriate variant of K3 code.

16a. Pay attention that this question deals with 'E' regular milk consumption in the period of 26.04 - 31.05.86.

Mark with "x" symbol appropriate variant of answer

Do not suggest to 'E' variant "do not remember" as a possible answer 15a.

Take into account that answer variant "no" means that 'E' continued to drink milk from the same source and in the same quantity during the whole mentioned period.

Using suggested codes put to the table information of milk consumption in the period of 26.04 - 31.05.86 the following way.

In the field "what milk" record appropriate variant of K1 code.

In the field "source" record appropriate variant of K2 code.

In the field "settlement" . If 'E' in the period of 26.04 - 31.05 moved from the place of residence, this field should correspond to the field "movements in 1986" of 11 item. If 'E' did not moved during the mentioned period, to the field "settlement" put the place of residence.

Field "period of consumption". This field should reflect changes in milk consumption in the period April-May 1986. The following variants are possible.

1. "E" in the period April-May 1986 did not move from the place of residence but quitted milk consumption in the mentioned period. If 'E' could remind more or less exact date of quitting of milk consumption put this date to the field "from" to the field "to" put the date 26.04.86. If for 'E' it is difficult to remind the date, so use suggested K4 code that should be put to the field "code". The code shows approximate date of quitting of milk consumption.

2. "E" moved from the place of residence, but quitted milk consumption prior to movement. Information is put the same way as in previous variant.

3. "E" moved from the place of residence and before movement continued milk consumption. In this case date of quitting of milk consumption is considered as a date of movement.

Information of milk consumption in the places to which 'E' moved is put the following way.

If "E" consumed milk, in fields "from" ("code") and "to", correspondingly, information is put corresponding to the date of arrival and departure from the given settlement.

If in places (or in some of them) where 'E' moved 'E' did not consumpt milk, fields "from", "to", and "code" will remain empty.

If 'E' quitted milk consumption, to the field "from" date of arrival to given settlement is put, and in the field "to" the date of quitting of milk consumption is put.

If for 'E' it is difficult to remind exact date, use suggested K4 code

In the field "how many liters for one intake" record the quantity of milk (in liters) that 'E' consumpt for one intake.

In the field "how many times per day" record how many times per day 'E' consumpt milk

In the field "how often" record appropriate variant of K3 code.

16b. Using previous table record the date (correspondingly - code) of quit of milk consumption. It is very important to put the date correctly.

What date consider the date of quitting of milk consumption?

Date of departure from the place of residence (place of staying at the time of the accident), if «E» consumpted milk before departure and moved outside contaminated area or was taken to summer camp, sanatorium, rest house, etc.

Date of quitting of milk consumption, if «E» did not move from the place of residence or quitted milk consumption before movement.

Starting date of milk substitutes consumption, i.e. date when "E" quitted fresh milk consumption and started dry, concentrated or condensed milk.

16c. If "E" could remind more or less exact starting date of pasture of home cow (goat) in spring 1986, record this date (day, month).

If for "E" it is difficult to remind a date chose the variant from suggested list and mark with "x" symbol appropriate variant of answer

Do not suggest to 'E' variant "do not remember" as a possible answer

If 'E' remember that during the period 26.04 - 31.05.86 cow (goat) was not pastured (fed by hay), in this case mark the variant "end of may and later".

17. Pay attention that this question deals with the period of 26.04 - 31.05.86.

Mark with "x" symbol appropriate variant of answer

17a. If 'E' could remind more or less exact date when breast feeding was quitted put this date (day, month).

If for 'E' it is difficult to remind exact date, mark appropriate variant with "x" symbol.

18. Pay attention that this question deals with the period of 26.04 - 31.05.86.

Mark with "x" symbol appropriate variant of answer

Do not suggest to 'E' variant "do not remember" as a possible answer

18a. Complete the table the following way.

In the field "type of food staff" chose those food staffs 'E' consumpted

In the fields "how many times a day" and "how many times a week" record how often 'E' consumpted given food staff

If "E" suggests as an answer interval estimation of time of staying outdoor, put it correspondingly to fields "from" and "to".

If "E" suggests as an answer exact number of hours of outdoor staying put it to field "from", field 'to' will be empty.

In the field "how much for one consumption" record how much 'E' consumed given food staff per one intake and in the field "units of measurement" record units of measurement (grams or liters)

19. Pay attention that this question deals with 'E' consumption of green leafy vegetables in the period of 26.04 - 31.05.86. in the place of residence (place of staying at the time of the accident). Do not consider green leafy vegetables if they were cooked

Mark with "x" symbol appropriate variant of answer

19a. Fill in the table the following way

In the field "type of green leafy vegetable" record appropriate variant of K1 code. If 'E' consumed several types of green leafy vegetables (glv) list them below and put the information to the table separately for each type of glv.

In the field "source of consumed glv" record appropriate variant of K2 code. Take into consideration that imported glv means glv bought in a store. It mostly belongs to 'E' who lived in cities. GLV from private farm, dacha, local markets refers to glv of local production.

In the field "starting date of consumption" put the information the following way.

If 'E' could remind more or less exact starting date of consumption of mentioned type of glv, put this date to field 'date'

If for 'E' it is difficult to remind date, use suggested K3 code that should be put to field 'Code'

In the field "amount of consumed glv" record what amount of glv (approximately) 'E' consumed a day (grams).

In field "how often" record appropriate K4 code.

20. Record regular daily ration (grams) of 'E' at present.

Do not make comments how many times a week 'E' consumed given type of staff as question refers to daily ration.

20a. It means mushrooms consumption at mushroom period and consumption of cooked mushrooms. Mark with "x" symbol appropriate variant of answer.

21. If in medical records there is an information of 'E' WBC examination (WBC -whole body counter - a device in the form of armchair that is used for estimation of radioactive contact in the human body), put it in to the suggested table the following way.

In the field "where" record name medical institution and settlement where examination was performed.

In the field "height" record height of 'E' at the time of examination.

In the field "weight" record weight of 'E' at the time of examination.

In the field "when" record month and year of examination..

In the field "activity" record measured activity

In the field "units of activity" record units of measured activity (мкCi, nCi, kBq, other).

If you record information of WBC examination from the words of 'E' complete only field "where" of the given table

22. Ask whether 'E' undergone annual x-ray or fluorographic examination regularly. Mark with "x" appropriate variant. If the answer is "yes", record from what year.

22a. Ask whether 'E' undergone specialized x-ray examination. Mark with "x" symbol appropriate variant. If the answer is "yes", complete the table.

22b. Complete the table the following way.

In the field "what part of body" record code corresponding to part of body.

In the field "when " record month and year when x-ray was made.

In the field "where" record medical institution where x-ray was performed.

23. Ask whether 'E' undergone diagnostic examination with radio pharmacological preparations (radio pharmacological preparation - is radioactive preparation that is given to the patient for diagnostic purposes, for example, examination of kidney function, thyroid etc.) Mark with "x" symbol appropriate variant. If "yes", complete the table.

23a. Complete the table the following way.

In the field "what body organ" record code corresponding to body organ.

In the field "when" record month and year when 'E' undergone diagnostic examination with radio pharmacological preparations.

In the field "when" record name of medical institution where radiopharmacological diagnostics was performed

24. Ask whether 'E' was subjected to medical exposure with therapeutic reasons.

Mark with "x" symbol appropriate variant. If "yes", complete the table.

24a. Complete the table the following way.

In the field "when" record month and year when 'E' was subjected to medical exposure with therapeutic reasons..

In the field "when" record name of medical institution where 'E' was subjected to medical exposure with therapeutic reasons

Strictly follow instruction for filling in interview form

Stay in the framework of suggested form of answers recording, do not make any marks and comments on the fields

After completion the Initial Interview Form should be passed to

_____ *and stored in the Dosimetry Laboratory*

Draft 20.12.98

APPENDIX 7

INITIAL INTERVIEW FORM

<i>Patient's bar-code</i>

1. Date of inquiry:

Day	Month	Year						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>		

2. Code of questioned person:

Self-examined	<input type="checkbox"/>	
Mother	<input type="checkbox"/>	
Father	<input type="checkbox"/>	Other relatives <input type="checkbox"/>
Sister, brother	<input type="checkbox"/>	Others <input type="checkbox"/>

3. Surname of subject:

--

Surname at the time of the accident:

--

4. First name of subject:

--

5. Patronymic of subject:

--

6. Date of birth:

Day	Month	Year						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>		

7. Sex : male female

8. CURRENT HOME ADDRESS:

OBLAST

--

RAYON

--

SELSOVET

--

SETTLEMENT

--

STREET/HOUSE/APPT

--

PHONE '

--

9. ADDRESS AT THE TIME OF THE ACCIDENT:

OBLAST

--

RAYON

--

SELSOVET

--

SETTLEMENT

--

STREET/HOUSE/APPT

--

9a. Type of residence:

wood	<input type="checkbox"/>	panel	<input type="checkbox"/>											
brick	<input type="checkbox"/>	other	<input type="checkbox"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> </tr> </table>										

9b. What floor did you live?

--	--

10. Were you, evacuated or moved yourself during the period of April-May 1986?

yes no

13. Did you attend a school or pre-school facility in 1986 ?

kindergarten school did not attend

14. How much time did you spend outdoors in spring and summer time before the accident (hours per day)?

Spring from to Summer from to

14a. Did you limit the amount of time you spent outdoors after the accident, in comparison to your usual habits at this time of the year?

yes no (move to i. 15) do not remember = 3 (move to i. 15)

14b. When did you limit staying outdoors?:

Day Month

If exact date is not known, please, chose some from the following:

end of April beginning of May
middle of May end of May and later

14c. For how long did this limitation continue (weeks, days (underline))?

14d. How much time (hours) did you spend outdoors during limitation?

From to

Item 14-14d: good satisfactory unsatisfactory

15. Iodine prophylaxis carried out in April-May 1986:

yes no (move to i. 16)
do not remember (move to i. 16)

15a. Kind of iodine preparation:

- antistrumine (white small pill sweet)
- thyroidine (small pill sweet)
- thyroxin (white small pill)
- iodinealcohol solution (iodine for wounds treatment)
- some drops of iodine with water or milk
- iodine to the skin
- lugol solution
- KI
- do not remember

15b. Point the day when you started taken iodine preparations?

April-May 1986

MO	Tu.	we	Th.	Fr	sa	su
					26	27
28	29	30	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

If you do not remember, choose appropriate answer from the following variants:

end of April beginning of May
middle of May end of May and later

How long did you use them:

daily several times a week how many times?

During what period of time did you take iodine preparations (how many weeks, days (underline))?

15c. Who conducted the iodine prophylaxis?

Independently local physicians
in the place of evacuation physicians in hospital

Item 15-15c: good satisfactory unsatisfactory

16. Using suggested codes, put the information about milk consumption before the accident in to the table:

Codes	
Milk: (K1)	cow = 1 goat = 2 mother = 3; milk blend = 4 powder milk = 5
Source: (K2)	from private farm = 1 from local dairy = 2 from store = 3 in preventive clinic = 4
How often: (K3):	every day = 1 few times a week = 2 few times a month = 3 did not consumt = 4 <input type="checkbox"/>

Milk (code K1)	Source (code K2)	Litres per one consumption	Times per day	How often (code K3)
		□, □ □ □		
		□, □ □ □		
		□, □ □ □		

16a. Did you change consumption of milk in April-May 1986?

yes no (move to i.16c) do not remember (move to i.16c)

Using suggested codes, put the information about milk consumption in the period of April-May 1986 in to the table:

Codes	
Milk: (K1)	cow = 1 goat = 2 mother = 3; milk blend = 4 powder milk = 5
Source: (K2)	from private farm = 1 from local dairy = 2 from store = 3 in preventive clinic = 4
How often: (K3):	every day = 1 few times a week = 2 few times a month = 3
Period following the accident): (K4)	end of April = 1 may holidays = 2 after May holidays = 3 end of May, June = 4

Milk (code K1)	Source (code K2)	Settlement	Date (from-to) (if exact date is unknown put K4 code)			Litres per one consumption	Times per day	How often (code K3)
			from	to	Code			
						□, □ □ □		
						□, □ □ □		
						□, □ □ □		

16b. Date of quitting of milk consumption ___/___/86.

If the exact date is unknown, choose appropriate answer from the variants given below:

end of April beginning of May
middle of May end of May and later do not remember

16c. Starting date of cattle pasturing in 1998: ___/___/86.

If the exact date is unknown, choose appropriate answer from the variants given below:

end of April beginning of May
middle of May end of May and later do not remember

17. Did you consume your mother's milk in April-May 1986?

yes no (move to i.18)

17a. When breast feeding was quited:

Day Month

□ □ □ □

If the exact date is unknown, choose appropriate answer from the variants given below:

end of April beginning of May
middle of May end of May and later do not remember

APPENDIX 8.

Individual Interview Form

Instruction for data entry.

Data entry from paper "Individual Interview Form" to computer data base is performed by operator. Data base is implemented in Microsoft Access DBMS. After opening of DB via Microsoft Access a window will appear on the screen with two fields for entry: **Name** and **Password**. To open DB operator should enter his/her name and personal password. After keying of password a window will appear on the screen **Screening Data Entry, chose the button "individual Interview"**. Furthermore on the window **Enter patient's code** enter indentificational code of the subject and date of interview (day, month, year). Data entry form will appear on the screen. Number, name, numeration of fields in the data entry form corresponds to Individual Interview Form.

Procedure of data entry.

1. **Date of interview.** Entered. Check correctness of entry.
2. **Participants of interview.** To mark the participants of interview put mouse pointer to appropriate variant of answer and click mouse button.
3. **Surname of subject and Surname at the time of accident.** Entered from initial form. Check correctness of entry.
4. **First name of subject.** Entered from initial form. Check correctness of entry.
5. **Patronymic.** Entered from initial form. Check correctness of entry.
6. **Date of birth.** Enter to the field the date (day, month, year).
7. **Sex.** To enter sex put mouse pointer to the button of variants and click the mouse. Choose necessary sex. Your choice will be entered to the window.
8. **Current home address.** In the field **Oblast** call for list of oblasts. To do this put mouse pointer to the button of variants and click the mouse. Choose necessary oblast. Your choice will be entered to the window of given field. In the field **Rajon** call for list of rajons. From suggested list chose appropriate rajon. . In the field **Settlement** call for list of settlements. From suggested list chose appropriate settlement. To the fields, **Street, House, Building, Apartment, Phone** text information is keyed.
If at present subjects lives outside Belarus put his/her address in field **Address outside Belarus** as text information.
9. **Address at the time of the accident.** In the field **Oblast** call for list of oblasts.. Chose necessary oblast. Your choice will be entered to the window of given field. In the field **Rajon** call for list of rajons. From suggested list chose appropriate rajon. . In the field **Settlement** call for list of settlements. From suggested list chose appropriate settlement. To the fields, **Street, House, Building, Apartment, Phone** text information is keyed.
If at present subjects lives outside Belarus put his/her address in field **Address outside Belarus** as text information..
- 9a. **Type of residence.** Point appropriate variant of answer. If the variant is "other, in the field **other specify** put text information.
- 9b. **What floor did you live.** Numerical information is entered to the field.
10. **Were you evacuated or moved yourself during the period of April- May 1986**
Choose appropriate variant.

To start the next group of questions press the button **Move to i. 11-12.**

11. Migrations from the place of residence in 1986. To enter the information into the fields **Oblast, Rajon, Settlement, Place of rest** use the button of pictogram with envelope. A window will appear on the screen **Address entry**. In the field **Oblast** call for list of oblasts.. Chose necessary oblast. Your choice will be entered to the window of given field. In the field **Rajon** call for list of rajons. From suggested list chose appropriate rajon. . In the field **Settlement** call for list of settlements. From suggested list choose appropriate settlement. To the field **Place of rest in Belarus** text information is keyed. To exit from the window press **OK** button.

Movements outside Belarus in 1986 are entered into the **Address (outside Belarus)** as text information.

Duration of staying. Date of arrival (day, month, year) is entered into the field **From**, Date of departure is entered into the field **To**. To the field **Code** numerical information is entered..

If subject moved to new place of residence point it in the field **Place of Residence Time spent outdoors**. Into the fields **From, TO** numerical information is entered
In the field **Estimation (Item 11)** call for list of estimates. Choose appropriate one from suggested list..

12. Movement outside place of residence for more than 24 days and change of place of residence in the following years. Pay attention! You should not enter information from the field of the table **Where to (Oblast, Rajon, Settlement)**

Into the field **Year** numerical information is entered

If subject moved to a new place of residence point it in the field **Place of residence**

Into the field **Duration of staying** numerical information is entered.

To start the next group of questions use pictogram i13-14d.

13. Did you attend a school or pre-school facility in 1986. **Point appropriate variant of answer.**

14. How much time did you spend outdoors before the accident. **To the fields From and To numeric information is entered.**

14a. Did you limit the amount of time you spent outdoors after the accident. **Choose appropriate variant of answer.**

14b. When did you limit staying outdoors. **To the fields From and To numeric information is entered. If exact date is unknown chose appropriate variant of answer**

14c. For how long did this limitation continue. **Put numeric information and units of measurement (days or weeks)**

14d. How much time did you spent outdoors during limitation. **To the fields From and To numeric information is entered.**

In the field **Estimation (Item 14-14d)** call for list of estimates. Choose appropriate one from suggested list..

15. Iodine prophylaxis carried out in April-May 1986 Choose appropriate variant of answer.

15a. **Kind of iodine preparation.** Choose appropriate variant of answer.

15b. **Point the date when you started taken iodine preparations.** To the field a date is entered. If exact date is unknown chose appropriate variant of answer.

How often. Choose appropriate variant. If answer several times a week, into the field **How many times** enter numeric information.

During what period of time did you take iodine preparations. **Put numeric information and corresponding unit of measurement (days or weeks)**

15c. Who conducted the iodine prophylaxis. Choose appropriate variant.

In the field Estimation (Item 15-15c) call for list of estimates. Choose appropriate one from suggested list..

To start the next group of questions use pictogram i.16_17a.

16. Using suggested codes fill into the table information of milk consumption before the accident Numerical information is entered to all fields of the table

16a. Did you change consumption of milk in April-May 1986 1986. Choose appropriate variant of answer.

Using suggested codes put to the table information of milk consumption in the period of April-May 1986. To the fields What milk (code K1) and Source (code K2) numerical information is entered. In the Field Settlement text information is entered. Into the fields From and To Terms of milk consumption date is entered (day, month, year), into the field code – numeric information. Into the field Litters per one consumption, Times per day, How often numeric information is entered.

16b. Date of quitting of milk consumption. To the field a date is entered (day, month, year) If exact date is unknown chose appropriate variant of answer.

16c. Starting date of cattle pasturing in 1986. To the field a date is entered (day, month, year) If exact date is unknown chose appropriate variant of answer

17. Did you consume breast milk in April-May 1986. Choose appropriate variant of answer

17a. When breast feeding was quitted To the fields Day and Month numeric information is entered. If exact date is unknown choose appropriate variant of answer

In the field Estimation (Item 16-17a) call for list of estimates. Choose appropriate one from suggested list..

18. Consumption of milk products in April-May 1986. Choose appropriate variant of answer

18a. Complete the table with the following information. In to the field food call for list of food staffs. From suggested list choose corresponding food staffs. In the field units of measurement call for list of units of measurement. Choose appropriate units of measurement. In the rest fields of table enter numeric information

In the field Estimation (Item 18-18a) call for list of estimates. Choose appropriate one from suggested list..

19. Consumption of green leafy vegetables (glv) in April-May 1986. Choose appropriate variant of answer

19a. Using suggested codes put the information of consumption of glv in April-May 1986 into the table. Into all fields of table, except field Date numerical information is entered. Into the field Date date is entered (day, month, year)

20. Your casual daily food allowance(current). Into all fields numerical information is entered

20a. Did you eat local mushrooms Chose appropriate variant of answer

To start the next group of questions use pictogram i.21_24.

21. How often were you examined with a WBC. Into the field Where text information is entered. Into the fields Height, Weight, Month, Year, Activity numerical information is entered. In the field Units of measurement call for list of units. From suggested list choose appropriate units.

22. Did you undergo regular x-ray or fluoroscopic examination Choose appropriate variant. If Yes, into the field Starting what year enter numeric information

22a. Did you undergo x-ray specialized examination. Choose appropriate variant

22b. How many times. Into the fields Organ, Month, Year numerical information is entered. Into the field Where text information is entered.

23. Did you undergo diagnostic examination with the use of radiopharmaceuticals.

Choose appropriate variant.

23a. How many times. Into the fields Organ, Month,

Year numerical information is entered. Into the field Where text information is entered

24. Did you undergo radiation treatment Choose appropriate variant

24a. When and where did you undergo radiation treatment.. Into the fields Month and Year numerical information in entered. Into the field Where text information is entered

Into the field Interview was conducted by surname of interviewer is

In the field quality estimation of conducted interview call for list of estimates. Choose appropriate one from suggested list.

Exit from the data entry form saving entered information is performed via Exit button located in upper right corner of screen.

Exit without saving of entered information is performed via Cancel button.

Entry of the next form is performed via Choose subject. Button.