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WORLD HEALTH ORGANIZATION

THE INTERNATIONAL PROGRAMME ON THE HEALTH EFFECTS OF THE CHERNOBYL ACCIDENT

(IPHECA)

PROTOCOL FOR THE PILOT PROJECT

"HAEMATOLOGY"

GENEVA 1994

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

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CONTENTS

Page

1. INTRODUCTION

In spring 1990, specialists from three republics of the USSR most affected by the Chernobyl accident (Belarus, Russia and Ukraine) worked out the basic principles for an international programme on health effects of the Chernobyl accident (IPHECA). The programme was expanded and refined in the course of discussion by many experts from various countries and its final form described in WHO document PEP/91.12.

The programme covers all the main aspects of the Chernobyl accident that relate to the health of the population of the contaminated territories and also those who took part in clearing up the aftermath of the accident. At the present time, only five pilot projects are being carried out under IPHECA: "Haematology", "Thyroid", "Brain damage in-utero", "Epidemiological Registry" and "Oral Health". The conduct of these projects will provide a basis for further long-term detailed projects under IPHECA.

The "Haematology" project is described in WHO document PEP/91.22.

The main purposes of the project are:

(a) to detect all cases of leukaemia, lymphoma and other haemoblastoses (see Annex 1) among inhabitants of population centres assigned at the time to "strictly controlled zones",

(b) to determine, if possible, the link between incidence of haemoblastoses and exposure to radiation, a negative result being seen as no less important than a positive.

The project envisages the following activities: clinical and laboratory diagnosis, epidemiological surveys, dosimetry, provision of equipment and diagnostic tools, courses for specialists, conferences, etc. The advantage for the population will be improved medical service.

A standard protocol on diagnostic and epidemiological studies for use in all three affected States is a prerequisite for high quality diagnostic work, coordination between various research groups, comparison of results, and presentation of concordant conclusions.

The development of this protocol, and compliance with it, are important aspects of the project.

2. AIMS OF THE PROTOCOL

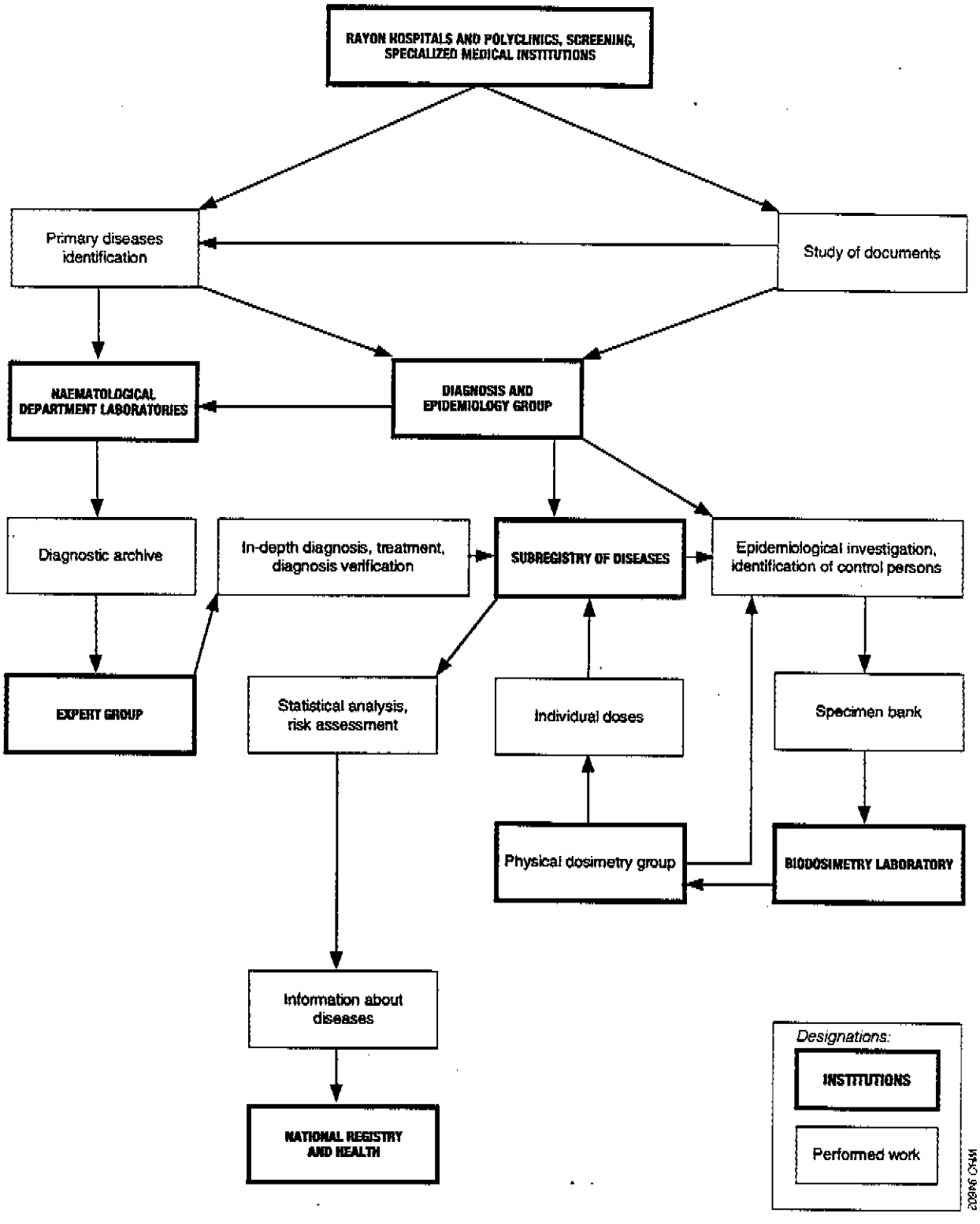
The protocol is intended for physicians, other medical staff, administrators and research workers in various fields who are working on the "Haematology" project in any of the three affected States (Belarus, Russia and Ukraine).

The protocol should:

- ensure that methodological approaches are the same in all three States;
- enhance the quality of medical examinations and scientific research;
- make it easier to exchange data and compare the results obtained;
- provide a methodological and information basis for organizing longer-term and more far-ranging projects under IPHECA.

Figure 1 is an organization chart for work on the Haematology protocol.

FIG.1 **Flow chart of conducting work within IPHECA "Hematology" pilot project**



3. TERRITORIES AND POPULATIONS

The studies are conducted on territories which were formerly part of the "strictly controlled zones" (see PEP/89.20), where radioactive caesium contamination was in excess of 15 Ci/km^2 (555 kBq/m^2). Approximately 270 000 people lived in these population centres. Those settlements are listed in the publication "A list of the centres of population in territories radioactively contaminated as a result of the Chernobyl disaster", Izdat, Moscow, 1993; they are to be found in the following administrative *raions*.

Belarus

Gomel oblast - Braginskij, Hojnikskij, Cecerskij, Buda-koselevskij, Vetkovskij, Dobruskij, El'skij, Loevskij, Kormjanskij, Narovljanskij, Lel'cickij *raions*;
Mogilev oblast - Kostjukovicskij, Slavgorodskij, Cerikovskij, Byhovskij, Klimovicskij and Krasnopol'skij *raions*.

Russia

Bryansk oblast - Novozybkovskij, Klincovskij, Zlynkovskij, Gordeevskij, Krasnogorskij and Klimovskij *raions*.

Ukraine

Kiev oblast - Ivankovskij and Polesskij *raions*;
Zhitomir oblast - Narodicevskij, Lucinskij and Ovrucskij *raions*.

In those population centres, all cases of leukemia, lymphoma and other haemoblastoses that occurred in 1992-1993 are recorded (Annex 1).

Every year, using the data valid on 31 December of the year concerned, an accurate record is made of the number of people living in study territories, their sex and age, and migration; people who came to reside in those areas for the first time in 1992-1993 are excluded from the study.

This pilot study does not include detection and recording of diseases among those who have left the territory.

Further development of the work will include special measures to seek out and include such people in epidemiological research.

The control subcohort shall exclude those who have died or changed their place of residence.

4. PRIMARY DETECTION OF HAEMATOLOGICAL DISEASES

Under this protocol, all cases of leukaemia and other haemoblastoses listed in Annex 1 must be identified. Some diseases may be identified in the course of annual clinical and laboratory examinations of the population. Most cases, however, will be detected in the *raion, oblast* or central medical institutions when patients consult a doctor because of illness.

In screening for haemoblastoses, on primary examination, the physician shall be guided by the following clinical signs:

- protracted fever and increased perspiration;
- skin haemorrhages and/or increased bleeding from the nose, mouth, gastrointestinal or urogenital tracts;
- sudden development of aphthous stomatitis and/or necrotic angina;
- distension of the lymph nodes, liver and/or spleen;
- loss of more than 10% weight over six months and other constitutional deterioration;
- ostalgia, arthralgia and/or spontaneous bone fractures.

A general record chart (OKSO) is completed for each person examined (see Annexes 2 and 3); the personal details must be entered on the spot without fail. The other sections can be completed later and other specialists can be brought in. If the results of the medical examination and laboratory tests are normal, the subject is not examined again that year.

People who show deviations from the normal indicators on general blood tests and who have any of the above-mentioned clinical symptoms, are sent to a haematologist for consultation.

A primary haematological examination form is completed for each suspected case of haemoblastosis (Annex 4).

The physician must contact the appropriate consultation service at once by telephone, telex or fax, to agree on what should be done next to diagnose the disease.

5. DETAILED DIAGNOSIS OF HAEMATOLOGICAL DISORDERS

The conclusive diagnosis and checking for haemoblastoses is carried out at oblast haematology departments and/or haematology clinics of research institutes of haematology or oncology.

The list of clinical and laboratory tests to be used for comprehensive diagnosis of haematological disorders is shown in Annex 5.

All forms of haemoblastosis are classified in accordance with the FAB classification. Confirmed haematological disorders are described in accordance with ICD-9.

Once the diagnosis of haemoblastosis has been confirmed, a standard form for haematological epidemiological examinations is completed (Annex 6). That form is kept with the completed general information chart (OKSO) and the primary haematological examination card.

6. QUALITY CONTROL OF EXAMINATIONS

The diagnosis is verified by a panel of experts appointed by the Ministries of Health of the States. The panel studies all documents on the disease in the relevant medical institutions: medical protocols, blood and bone marrow smears, morbid anatomical reports, death certificates and other relevant documentation.

If needed, the experts shall analyse data from archives and special laboratory information (Section 8).

Samples of diagnostic materials, a list of documentation and the registration technique are described in the procedural instructions endorsed by the Ministry of Health of each State.

The quality of haematological tests conducted in laboratories shall be checked by national centres for quality control of laboratory tests, using standard and control samples within and between laboratories, and at oblast, national and inter-State levels. The quality control programmes have separate protocols.

7. EPIDEMIOLOGICAL STUDIES

A group of epidemiologists will manage the subregister on diseases of the blood, receiving medical information on patients directly from the haematologists through medical and other documentation (OKSO, the primary haematological examination form, special dosimetric information, and data from the *raion* haematology clinics, oblast, hospitals and oncological, occupational and children's medical institutions where haemoblastosis patients are hospitalized, as well as from central specialized clinics and dissecting rooms), and from documents showing degree of disability and causes of death.

Personal details, medical and epidemiological information on patients shall be entered in the form for epidemiological research on haematology (Annex 6), whose identifier is the same as the first page of the general information card (Annex 2).

At every stage of study of the documents, the procedures on which the diagnosis was made or refined, the number of the medical document and the code of the medical institution, are entered on the epidemiological research form.

Epidemiological information on the patient includes case history, information on the health of the parents, brothers and sisters and children, changes in domicile, period of residence in the study territory, dates and duration of travel elsewhere, education, specialist training, professional career and occupations held, duration and type of contacts with occupational or domestic hazards, type of dwelling, life-style, diet and use of potentially contaminated foodstuffs. Special information is gathered on occupational and domestic contacts with ionizing radiation and of exposure to radiation for medical purposes (if there is confirmation, the medical record shall include the number of the document and the code of the medical institution).

For sick children, the record shall also state the date of birth, occupations and occupational hazards of the parents, whether the mother had miscarriages, acute illnesses in the mother in the three months preceding pregnancy or during pregnancy, the course of childbirth and the postnatal period, the child's development, diseases suffered, and the state of health of the child's brothers and sisters.

An epidemiological research form is completed for each parent of a child suffering from leukaemia or other haemoblastosis.

Epidemiological information is gathered directly from patients and/or their relatives. The epidemiologists conduct interviews in hospitals where patients are being treated, and through field missions in the places where the patients live.

If the patient has an identical twin, the twin shall also be interviewed (if possible) and all the documents shall be completed for him or her also.

The section for data on reconstruction of individual dose shall be completed by specialists in dosimetry.

The epidemiologist and the specialist in dosimetry shall gather the basic information necessary for reconstruction of the dose of radiation from each patient and control subject, drawing on the individual questionnaires. That information shall be transferred in machine-readable form to the unit responsible for dosimetry.

In reconstructing doses, specialists in dosimetry shall be guided by the dosimetry protocol. These specialists shall evaluate the whole body and red bone-marrow doses, and shall enter the results in the blood diseases sub-register in machine-readable form.

The dose shall be determined as soon as possible after the disease has been diagnosed.

The physical methods for reconstruction of individual doses are supplemented by ESR spectrometry of tooth enamel and analysis of chromosomal aberrations in lymphocytes and somatic mutations in blood cells (the glycophorin test).

Tooth samples are obtained on medical indications or on autopsy. After labelling and registration, the sample is sent to the sample bank for storage and then for study to the ESR spectroscopy laboratory.

10 ml of blood for biodosimetry is taken from a vein through a sterile needle into a vacuum flask with heparin. The sample is then labelled, registered and sent to the cytogenetic laboratory in a cold box within 48-hours of the sample being taken.

Blood samples for biodosimetry must be taken from patients before they are given radiation treatment or chemotherapy.

The epidemiological work includes identification and monitoring of control cohorts, used for the assessment of possible links between haematoses and exposure.

The pilot project uses the "case-subcohort" method, which has a number of advantages over the "case-control" method.

It may be assumed that the 1000 individuals in the subcohort, stratified by age and sex, is sufficient to give the maximum statistical sensitivity when compared with the number of leukaemia and lymphoma patients expected in the study territories of the three States over a two-year period.

The subcohort shall comprise members of the population of the study territories taken from lists of people who have undergone medical examination in the course of annual screening (outpatient, clinical observation). The subcohort shall be stratified by age and sex in accordance with the age and sex distribution of leukaemia and lymphoma using 10-year age intervals for adults, and the following age groups for children and adolescents: mathematical <1; 1-4; 5-9; 10-14 and 15-19. The necessary numerical sex and age structure of the subcohort is determined and the subcohort includes individuals corresponding to the specific strata of the structure and

drawn at random from the list. The subcohort shall include 330-350 people from the study territories of each State.

The epidemiologist, with the consent of the selected member of the control subcohort, shall use the same questionnaire as is put to patients, and shall complete the epidemiological examination form (Annex 6). That information shall be transferred to the blood diseases sub-register and entered in the data base for storage, exchange with other data bases, and statistical analysis.

The specific procedures for epidemiological analysis using this method and other methods shall be set out in a special protocol on processing of epidemiological data.

8. SPECIMEN AND DATA BANKS

All information on patients and controls is kept in the corresponding archives and banks.

Out-patient cards, case-histories and records of morbid anatomical examinations and autopsies are kept at the institutions of examination and treatment.

Diagnosis morphological preparations, smears of peripheral blood and bone-marrow and fixed samples of tissue, are kept in laboratory archives.

Oblast hospitals and the leading haematology institutions shall arrange for the storage of fixed tissues and tooth enamel samples for ESR spectrometry.

Original samples of blood and bone-marrow shall be kept at oblast and national cryogenic banks.

Data entered on the epidemiological research form (see Annex 6) are kept on computer files in the sub-register of blood diseases in each of the three countries. The data shall be periodically checked, specified and extended, and duplicates erased.

Summary information on each case of disease shall be passed on to the corresponding state register after verification.

ANNEX 1

List of diseases included in the protocol

Disease	ICD-9 Code
1. Malignant neoplasms of lymphatic and haematopoietic tissue	200-208
1.1 Lymphosarcoma and reticulosarcoma	200 (200.0-200.08)
1.2 Hodgkin's disease (lymphogranulomatosis)	201 (201.0-201.9)
1.3 Other malignant neoplasms of lymphoid and histiocytic tissue	202 (202.0-202.9)
1.4 Multiple myeloma and immunoproliferative neoplasms	203 (203.0-203.8)
1.5 Lymphoid leukaemia (acute and chronic)	204 (204.0-204.9)
1.6 Myeloid leukaemia (acute and chronic)	205 (205.0-205.9)
1.7 Monocytic leukaemia (acute and chronic)	206 (206.0-206.9)
1.8 Other specified leukaemia acute erythraemic myelosis (Di Guglielmo's disease) chronic erythraemia megakaryocytic leukaemia	207 (207.0-207.8) 207.0 207.1 207.2
1.9 Leukaemia of unspecified cell type	208 (208.0-208.9)
1.10 Polycythaemia vera	238.4
2. Diseases of the blood and haematopoietic organs	284-285
2.1 Aplastic anaemia	284 (284.8-284.9)
2.2 Sideroblastic anaemia	285.0

ANNEX 2

GENERAL RECORD CHART (OKSO)[1]
GENERAL INFORMATION

0.1 Code of the medical establishment completing the chart (according to the OKPO - All-Union Classifier of Enterprises and Organizations)	
0.2 Date of completion of chart	
0.3 Date of examination	
0.4 Number of charts completed for the person examined	

1.1 Surname	
1.2 First Name	
1.3 Patronymic*	
1.4 Registration No. of the person examined (WHO)	
1.5 Registration No. (State Registry)	
1.6 Sex (1 - male; 2 - female)	
1.7 Date of birth	
1.8 Classification group	
1.9 Social or occupational group (1 - unorganized children; 2 - organized children; 3 - unemployed adults; 4 - employees; 5 - agricultural workers; 6 - livestock breeders; 7 - agricultural machine operators; 8 - builders; 9 - roadworkers; 10 - workers in industrial enterprises; 11 - foresters; 12 - pensioners; 13 - others)	
1.10 Code of the population centre where the examined person lives (according to "TERSON")	
1.11 Type of population centre (1 - city/town; 2 -settlement of urban type; 3 - rural)	
1.12 Date of arrival at the given population centre	

[1] Completion and coding will be carried out in accordance with the instructions in the OKSO (see Annex 5).

* derived from father's first name

ANNEX 2
cont'd.

DOSIMETRIC DATA

2.1 Thyroid dose derived from direct radiometric measurement (cGy)	
Reconstructed thyroid dose (cGy) 2.2 Minimum	
2.3 Mean	
2.4 Maximum	
2.5 Effective equivalent dose from internal and external exposure in 1986 (cSv)	
2.6 Effective equivalent dose from internal and external exposure from the beginning of exposure until the time of examination (cSv)	

EXPOSURE TO HARMFUL FACTORS

3.1 Exposure to harmful substances and other adverse occupational factors coded according to Decree No. 555 of the Ministry of Health of the USSR	
3.2 Exposure to harmful factors and other adverse occupational factors coded in accordance with Decree No. 555 of the Ministry of Health of the USSR	
3.3 Smoking (1 - does not smoke; 2 - has stopped smoking ; 3 - smokes)	
3.4 Alcohol consumption (1 - none/several times a year; 2 - several times a month; 3 - several times a week)	

ANNEX 2
cont'd.

HEALTH STATUS

4.1 Health group 1 to 5 coded in accordance with Decree No. 770 of the Ministry of Health of the USSR	
4.2 Disability group according to the conclusions of VTEK [a medical panel for assessing fitness for work]	
4.3 Reason for disability classification (ICD-9)	
4.4 Date of classification as disabled	
4.5 Date of death	
4.6 Cause of death in accordance with ICD-9	

CHRONIC DISEASES OF THE PARENTS
(when children are being examined)

5.1 Chronic disease of the mother 1 (ICD-9)	
5.2 Chronic disease of the mother 2 (ICD-9)	
5.3 Chronic disease of the father 1 (ICD-9)	
5.4 Chronic disease of the father 2 (ICD-9)	

CHRONIC DISEASES OF THE PERSON EXAMINED: BEFORE EXPOSURE TO RADIATION

6.1 Diagnosis of the disease (code in accordance with ICD-9)	
6.2 Date of establishment of the diagnosis	
6.3 Diagnosis of the disease (code in accordance with ICD-9)	
6.4 Date of the establishment of the diagnosis	
6.5 Diagnosis of the disease (code in accordance with ICD-9)	
6.6 Date of establishment of the diagnosis	

ANNEX 2
cont'd.

ACUTE AND CHRONIC ILLNESSES OF THE PERSON EXAMINED:
AFTER RADIATION EXPOSURE

7.1 Diagnosis (in accordance with ICD-9)	
7.2 Date of establishment of the diagnosis	
7.3 Detected (1 - on (self) admission to a physician; 2 - in screening programme; 3 - on hospital examination)	
7.4 Illness (1 - recorded for the first time; 2 - known earlier)	
7.5 Course of the illness (1 - acute; 2 - chronic but not exacerbated; 3 - exacerbation of chronic illness)	
7.6 Illness (1 - acquired; 2 - congenital)	
7.7 Morphological verification of the disease (1 - carried out; 2 - not carried out)	
7.8 Outcome of the illness at the time of examination (1 - recovery; 2 - improvement; 3 - unchanged; 4 - worsening)	

8.1 Diagnosis (in accordance with ICD-9)	
8.2 Date of establishment of the diagnosis	
8.3 Detected (1 - on (self) admission to a physician; 2 - in screening programme; 3 - on hospital examination)	
8.4 Illness (1- recorded for the first time; 2 - known earlier)	
8.5 Course of the illness (1 - acute; 2 - chronic but not exacerbated; 3 - exacerbation of chronic illness)	
8.6 Illness (1 - acquired; 2 - congenital)	
8.7 Morphological verification of the disease (1 - carried out; 2 - not carried out)	
8.8 Outcome of the illness at the time of examination (1 - recovery; 2 - improvement; 3 - unchanged; 4 - worsening)	

ANNEX 2
cont'd.

9.1 Diagnosis (in accordance with ICD-9)	
9.2 Date of establishment of the diagnosis	
9.3 Detected (1 - on (self) admission to a physician; 2 - in screening programme; 3 - on hospital examination)	
9.4 Illness (1- recorded for the first time; 2 - known earlier)	
9.5 Course of the illness (1 - acute; 2 - chronic but not exacerbated; 3 - exacerbation of chronic illness)	
9.6 Illness (1 - acquired; 2 - congenital)	
9.7 Morphological verification of the disease (1 - carried out; 2 - not carried out)	
9.8 Outcome of the illness at the time of examination (1 - recovery; 2 - improvement; 3 - unchanged; 4 - worsening)	

10.1 Diagnosis (in accordance with ICD-9)	
10.2 Date of establishment of the diagnosis	
10.3 Detected (1 - on (self) admission to a physician; 2 - in a screening programme; 3 - on hospital examination)	
10.4 Illness (1- recorded for the first time; 2 - known earlier)	
10.5 Course of the illness (1 - acute; 2 - chronic but not exacerbated; 3 - exacerbation of chronic illness)	
10.6 Illness (1 - acquired; 2 - congenital)	
10.7 Morphological verification of the disease (1 - carried out; 2 - not carried out)	
10.8 Outcome of the illness at the time of examination (1 - recovery; 2 - improvement; 3 - unchanged; 4 - worsening)	

ANNEX 3

INSTRUCTIONS FOR THE GENERAL RECORD CHART ON THE PERSON EXAMINED (OKSO)

The general record chart (OKSO) is the document for the "Epidemiological Registry" pilot project of the WHO IPHECA and also one of the primary documents for the pilot projects "Thyroid", "Haematology", and "Brain Damage in-Utero".

The OKSO consists of the following sections:

1. General information
2. Dosimetric data
3. Exposure to harmful factors
4. Health status
5. Chronic diseases of the parents (when children are being examined)
6. Chronic diseases of the person examined: before exposure to radiation
7. Acute and chronic diseases of the person examined: after radiation exposure

The OKSO is filled in for all persons examined under the pilot projects of IPHECA: Epidemiological Registry, Thyroid, Haematology, Brain damage in-Utero.

The main sources of medical information when completing the OKSO are the medical out-patient chart and the child's developmental history. These documents are official forms for recording the results of medical examinations for self admission patients, during screening programmes and on examination in hospital.

To complete the OKSO, use is also made of the following documents, directories, classifiers and codifiers:

1. Birth certificate (for children), passport for persons over 16 years of age, i.e. documents confirming identity
2. The International Classification of Diseases - ICD-9
3. The All Union Classifier of Enterprises and Organizations (OKPO)
4. The Directory of Codes for Population Centres (TERSON)
5. The Codifier for Harmful Substances and Adverse Occupational Factors contained in Decree No. 555 of the Ministry of Health of the USSR
6. Data bank of the national registry, established in the raion

The surname, forename, patronymic, and diagnoses of diseases are to be filled in clearly in Russian in the appropriate places in the document. Numbers are written only in Arabic form.

All dates are to be entered only in Arabic numbers in the following order: day (two digits), month (two digits), year (the last two digits for the year), for example, 2 March 1988 is entered as 020388.

Dates and codes under OKPO and TERSON are to be entered without dividers. If some data are not available, a dash is entered on the corresponding line.

ANNEX 3
cont'd

Only one copy of the OKSO is completed and it remains with the health establishment in the form of an insert in the out-patient chart. The information contained in the OKSO will be transferred to a personal computer directly at the raion level.

1. **General Information Section**

All the lines in this section are to be completed by medical records clerks.

0.1 OKPO code for the given establishment together with the control segment.
0.2 date of completion of the chart
0.3 date in the accounting years when the multidisciplinary examination is conducted
0.4 number of charts completed for the person examined
1.1 Surname - this is entered in block capitals in Russian in accordance with the document certifying identity
1.2 Forename - entered in the same way as 1.1
1.3 Patronymic - entered in the same way as 1.1
1.4 WHO Registration No. of the person examined. A registration No. attributed to the person examined. This is the serial number of the patient who is undergoing multidisciplinary examination. Each person examined must be assigned a single registration number. The registration numbers of different people should be the same in any given establishment.
1.5 State Registry Registration No. Registration number of the State Registry is entered if the person examined is already in it. If the patient is not in the State Registry a dash is entered.
1.6 Sex-1 is entered for males and 2 for females
1.7 Date of birth. The date of birth is entered in accordance with the document certifying identity
1.8 Classification group - the following codes for classification groups are entered:
1 - those who took part in clearing up after the Chernobyl accident;
2 - persons who were evacuated or who voluntarily left the "alienation" zone
3 - inhabitants of territories contaminated with radionuclides - adults and children
1.9 Social or occupational group - the code for social and occupational group is entered in accordance with the text in this box on the chart:
1.10 The TERSON Code of the population centre in which the person examined lives.
1.11 The type of population centre where the person examined lives - the code for this is entered in accordance with the text in this box of the chart
1.12 Date of arrival to the population centre - the date when the person examined began to live permanently in this centre.

"Dosimetric data" section

This section is to be completed by specialized dosimetric teams working under the pilot projects of the IPHECA programme.

"Exposure to harmful factors" section

1. Exposure to harmful substances and other adverse occupationsl factors - the code is entered in accordance with the codifier for such substances and factors contained in the decree No. 555 of the Ministry of Health of the USSR.
2. As for line 1.
3. Smoking - a code is entered in accordance with the text given in the box
4. Alcohol consumption - a code is entered in accordance with the text in the box.

ANNEX 3
cont'd.

"Health status" section

This section is to be completed using the results of the multidisciplinary examination.

1. Health group - one of the following codes is entered:
   - health group 1 - healthy; examination revealed no abnormalities;
   - health group 2 - practically healthy, only functional changes are found;
   - health group 3 - a chronic illness in the compensation stage [the body can compensate at present];
   - health group 4 - a chronic illness in the subcompensation stage [the body cannot fully compensate at present]
   - health group 5 - a chronic illness in the decompensation stage [the body cannot compensate and medical intervention is needed at times].

2. Disability group - entered in accordance with the conclusions of the VTEK (medical advisory panel for assessing fitness for work).

3. Cause of disability - the diagnosis of the main illness that led to the disability and its code under ICD-9 is entered.

4. Date of establishing disability - the date is entered on which the examinee was certified as disabled by VTEK.

5. Date of death

6. Cause of death - the diagnosis of the main disease that led to death and its code under ICD-9.

"Chronic diseases of the parents" section
(when children are being examined)

Enter on lines one and two, diagnoses of chronic diseases of the mother, and on lines three and four, chronic diseases of the father, together with their codes under ICD-9. The priority order in which information on diseases is entered is as follows: malignant neoplasms, pathology of the thyroid, haemoblastoses, endocrine disorders, metabolic disturbances (particularly diabetes mellitus), cardiovascular diseases (particularly hypertension), neuropsychic disorders, tuberculosis, congenital anomalies, diseases of digestive and respiratory organs.

"Chronic diseases in the person examined: before exposure to radiation" section

This section is completed in on the basis of the data available in the primary medical records for the person examined (outpatient chart, child's developmental history). Since the dates of commencement of radiation exposure in different people may not coincide with the date of the Chernobyl accident, it is necessary to indicate the diagnoses of chronic diseases that occurred also after 26 April 1986, if they appeared before the beginning of radiation exposure. This is applicable, for example, for participants in clearing up the consequences of the Chernobyl accident who began such work in 1987 or in subsequent years.

ANNEX 3
cont'd

Diagnoses of at most three chronic diseases are entered on lines 1,3 and 5. If the person examined has had only one chronic disease then it is indicated on line 1 with dashes entered on lines 3 and 5. If the person examined has had two chronic diseases then they are entered on lines one and three and a dash is entered on line five. If the person examined has had more than three chronic diseases, another OKSO form is completed. If the person examined has had no chronic diseases, a dash is entered on the first line.

On lines, 2,4 and 6 are entered the dates of establishment of the diagnoses of chronic diseases. For example, if the outpatient chart indicates the date for the diagnosis of a chronic disease as 12 March 1987, the figure 120387 is entered on the line. If the day in the month when the diagnosis was established is not indicated for some reason but the month and the year are known, for example, March 1987, then the figure 000387 is entered on the line. If it is impossible to determine the day and the month of establishment of the diagnosis but the year is known, for example, 1987, then the figure 000087 is entered.

Section "Acute and chronic diseases of the person examined: after exposure to radiation"

This section is completed on the base of data available in the primary medical records (outpatient chart, child's developmental history). Information is entered for all diseases contracted by the person after radiation exposure.

On lines 7.1; 8.1; 9.1 and 10.1 are entered the diagnoses of the diseases contracted and their ICD-9 codes.
On lines 7.2; 8.2; 9.2 and 10.2 are entered the dates of establishment of the diagnoses.
On lines 7.3; 8.3; 9.3 and 10.3 a code in entered in accordance with the text in the box.
On lines 7.4; 8.4; 9.4 and 10.4 a code is entered in accordance with the text in the box.
On lines 7.5; 8.5; 9.5 and 10.5 a code is entered in accordance with the text in the box.
On lines 7.6; 8.6; 9.6 and 10.6 a code is entered in accordance with the text in the box.
On lines 7.7; 8.7; 9.7 and 10.7 a code is entered in accordance with the text in the box.
On lines 7.8; 8.8; 9.8 and 10.8 a code is entered in accordance with the text in the box.

If the person examined has contracted less than four illnesses, a dash is placed on the unused lines. If he or she has contracted 5-8 illnesses, then another copy of the OKSO is completed.

Where the volume of information cannot be accommodated on the available lines in the OKSO, a second, third or further card is completed for the person examined. In this case only the following lines in the general information section are completed in full: 0.1; 0.2; 0.3; 1.1; 1.2; 1.3; 1.4; 1.6; 1.7; 1.8; and the corresponding lines for entering the necessary information. On line 0.4 of the first OKSO chart, the total number of charts completed for the person examined is entered, i.e. the first and additional ones.

ANNEX 4

Primary Haematological Examination Form

The form is completed by a physician (therapeutist, paediatrician of haematologist) when the patient is referred to the haematology unit for precise diagnosis of leukaemia, lymphoma or any other blood disease; the patient is sent to the department with personal details completed in the general information card (OKSO) (Annex 2, first page).

The rest of OKSO can be completed at another stage by other specialists.

1. Case-history

1.1 Date of previous examination in current year.

1.2 Symptoms (underlying):
- high temperature, perspiration
- haemorrhaging
- enlarged lymph nodes
- weakness, loss of appetite, deterioration of eyesight, headaches, dizziness, weight loss (>10%), skin rashes, abdominal pains, aching bones
- none.

1.3 History of the disease (underlying)
- sick for 1, 2, 3 weeks
- sick for 1, 2, 3 or more months.

2. Data from the examination (underlying)

2.1 General
- height
- weight
- body temperature on examination
- pulse
- cystolic blood pressure
- diastolic blood pressure.

2.2 Symptoms of bone marrow damage

2.2.1 Signs of infection
- lungs
- mouth (throat)
- neurogenital system
- skin
- blood
- other locations.

2.2.2 Haemorrhaging
- skin
- sclera
- ocular fundus

ANNEX 4
cont'd

- respiratory system
- urogenital system
- CNS
- other location.

2.2.3 Symptoms of growing neoplasm (underline)

Peripheral lymph nodes:

- enlarged	yes, no
- if yes, size of lymph nodes	1-2 cm, 2-3 cm
- location (underline):	
neck and subclavian	right, left
inguinal and tibial	right, left
other locations	(identify)
- consistency:	hard, soft, resilient
- pain on palpation	yes, no
- sensitivity	yes, no
- alteration of skin over lymphatic glands	yes, no.

Liver:

- enlarged on palpation	yes, no
(if yes, a margin is beneath costal arch)	(cm)
- surface on palpation	smooth, uneven
- sensitivity on palpation	yes, no.

Spleen:

- enlarged on palpation	yes, no
- surface on palpation	smooth, uneven
- consistency on palpation	dense, soft, resilient.

Abdomen:

- enlarged lymph nodes	yes, no
- palpable tumour	yes, no
- if yes, location of tumour	epigastric, mesogastric, hypogastric.

Extranodular/extramedullary formations:	yes, no
if yes, location	skin
	gums
	CNS
	testicles
	other locations.

ANNEX 4
cont'd

3. Anomalies in the blood picture of adults requiring further clinical and laboratory testing to confirm or rule out some haematological disease:

1.	Date of analysis	— — —
2.	Erythrocytes	<3.0 and >6.0 x10^{12}/l.
3.	Haemoglobin	<120 and >160 g/l.
4.	Colour index	<0.8 and >1.1
5.	Reticulocytes	<5 and >20‰
6.	ESR	<3 and >30 mm/hour.
7.	Thrombocytes	<150 and >450 x 10^9/l.
8.	Leukocytes	<3.5 and > 12 x 10^9/l
9.	Blasts	>0%
10.	Promyelocytes	>0%.
11.	Myelocytes	>0%
12.	Immature granulocytes	>0%
13.	Stab neutrophils	>10%
14.	Segmented neutrophils	<40% and >75%
15.	Basophils	>3%
16.	Eosinophils	<1% and >10%
17.	Prolymphocytes	>0%
18.	Lymphocytes	<18% and >45%
19.	Plasma cells	>1%
20.	Normoblasts	>0%
21.	Anisocytosis of erythrocytes	Present, absent
22.	Poikilocytosis of erythrocytes	Present, absent.

ANNEX 4
cont'd

Anomalies in the blood picture of children requiring further clinical and laboratory testing to confirm or rule out some haematological disease:

Age (years)	<1-5		5-14
1. Date of analysis		----------	
2. Erythrocytes	<3.5 and >5.5 x10^{12}/l		<3.5 and>6.0 x 10^{12}/l
3. Haemoglobin	<110 and >200 g/l		<120 and >160 g/l.
4. Colour index		<0.8 and >1.1*	
5. Reticulocytes	<10 and >25‰		<5 and >20‰
6. ESR		<2 and >20 mm/h	
7. Thrombocytes		<150 and >500 x 10^9/l	
8. Leukocytes	<4 and >20 x 10^9		<4 and > 10 x 10^9/l
9. Blast		>0%	
10. Promyelocyte		>0%.	
11. Myelocytes		>0%	
12. Immature granulocytes		>0%	
13. Stab neutrophils		>10%	
14. Segmented neutrophils	<10% and >75%		<30% and >75%.
15. Basophils		>3%	
16. Eosinophils		<1% and >10%	
17. Prolymphocytes		>0%	
18. Lymphocytes	<10% and >80%		<20% and >50%
19. Plasma cells	>2%		>1%
20. Monocytes		<2% and >15%	
21. Normoblasts		>0% after 7th day of life	
22. Anisocytosis of erythrocytes		Present, absent	
23. Poikilocytosis of erythrocytes		Present, absent.	

* Values between the columns are independent of age.

Name and occupation of referring physician. ----------

Date of completion. ------ ------ ------

ANNEX 5

DIAGNOSTIC TESTS

Test	Level		
	National	Oblast	Raion
1. Peripheral blood analysis	+	+	+
2. Cytochemistry of blasts in the peripheral blood	+	+	-
3. Cytological examination of bone marrow	+	+	-
4. Cytochemistry of blasts in the bone marrow	+	+	-
5. Immunophenotyping of blast cells	+	-	-
6. HLA - typing	+	-	-
7. Karyotyping	+	-	-
8. Histological examination of biopsy material (lymph nodes, liver, spleen, bone marrow trepanate)	+	+	-
9. Cerebrospinal fluid examination	+	+	-
10. Examination of somatic mutations	+	-	-

ANNEX 6

FORM FOR EPIDEMIOLOGICAL INVESTIGATION IN HAEMATOLOGY

To be completed for each patient and control

GENERAL INFORMATION

0.1 Code of medical institution completing general information card (in OKPO[1])	
0.2 Date of completion	
0.3 Date of examination	
0.4 Number of cards completed for the subject	
1.1 Surname	
1.2 First name	
1.3 Patronymic	
1.4 Registration number of subject (WHO)	
1.5 Registration number (state register)	
1.6 Sex (1-male; 2-female)	
1.7 Date of birth	
1.8 Registration group	
1.9 Socio-occupational group (1 - children not in institutions;2 - children in institutions; 3 - non-working adults; 4 - civil servants; 5 - arable agriculturalists; 6 - dairy agriculturalists; 7 - agricultural machine operators; 8 - construction workers; 9 - road builders; 10 - factory workers; 11 - forestry workers; 12 - pensioners; 13 - other)	
1.10 Postal code of domicile	
1.11 Type of domicile (1 -city; 2 - town; 3 - village)	
1.12 Date of taking up residence in that centre of population	

[1] All-union code number for institutions and organizations.

CONTACT DATA

2.1 Passport series and number .....
2.2 Series and number of birth certificate .....
2.3 Place of birth .....
2.4 Full postal address.....
.....
Home telephone number..... Work telephone number .....

INFORMATION ON DISEASE

3.1 Diagnosis .....
.....
ICD-9 code .....
3.2 Basis of diagnosis:
Blood analysis (yes, no), myelogram (yes, no),
cytochemistry (yes, no), bone marrow biopsy (yes, no),
lymph node biopsy (yes, no), spleen (yes, no),
liver (yes, no), other organ (specify), autopsy .....
3.3 Diagnostic institution .....
3.4 Date of diagnosis .....
3.5 Sources of information (institution, document code, date)
.....
.....
.....
.....
3.6 Date of death .....
3.7 Institution issuing death certificate .....
.....
Number ..... Date of issue .....
3.8 Main cause of death .....
.....ICD-9 code.....

INTRODUCTORY PART OF QUESTIONNAIRE

4.1 Questions answered by (enter code on right) .....
The patient - 1; the mother - 2; the father - 3; the spouse - 4; brother or sister - 5; son or daughter - 6; other - 7 (specify)
4.2 Surname .....
4.3 First name .....
4.4 Patronymic ..... of the respondent
4.5 Full postal address .....
..... home telephone number ..... work telephone number.....

EDUCATION AND EMPLOYMENT

5.1 Education (enter code) .....
Incomplete-1, secondary-2, secondary specialized-3, incomplete higher education-4, higher education-5
5.2 Marital status (insert code on left) .....
Unmarried-1, married-2, widowed-3, divorced-4.
5.3 Place of work, type of occupation (including study at higher educational institution, work on private land, or pension):

No.	Company or institution	Year: beginning, ending	Work done	Contacts with toxic substances

SMOKING

6.1 Did the subject ever smoke regularly, for at least six months: yes, no (underline).
6.2 At what age did the subject begin to smoke regularly: ..... age
6.3 Does the subject smoke regularly at present: yes, no
6.4 At what age did the subject cease to smoke regularly: ..... age
6.5 Number of cigarettes....., enter code ..... (per day-1, per week-2, per month-3)

CONSUMPTION OF ALCOHOL

7.1 Has the subject ever consumed alcohol (vodka, cognac, etc.) regularly, i.e. at least once a week for six months: yes, no.
7.2 At what age did the subject begin to drink spirits regularly: .....age
7.3 Does the subject drink spirits regularly at present: yes, no.
7.4 At what age did the subject stop consuming spirits regularly: .....age
7.5 During regular consumption, what quantity of spirits did the subject drink:..... millilitres (grams, code ..... (per day-1, per week-2, per month-3).

DISEASES IN THE CASE HISTORY

8.1 Was there ever a diagnosis of "tumour" or "leukaemia": yes, no.
8.2 What type of tumour was diagnosed, and at what age:.....
8.3 Other chronic diseases:.....
Disease
ICD-9 code ..... age (99 if unknown) .....
ICD-9 code ..... age (99 if unknown) .....
ICD-9 code ..... age (99 if unknown) .....
ICD-9 code ..... age (99 if unknown) .....
8.4 Congenital diseases or defects: .....
.....

DISEASES AMONG BLOOD RELATIONS

8.1 Was leukaemia every diagnosed - in the mother: yes, no
8.2 In the father: yes, no
8.3 In the grandmother (specify which): yes, no
8.4 In the grandfather (specify which): yes, no
8.5 In the brother: yes, no
8.6 In the sister: yes, no
8.7 In a son: yes, no
8.8 In a daughter: yes, no.
Please write out any further information on type of tumour and age of onset in relative.
.....
.....

8.9 Does the subject have children born after April 1986: yes, no.
8.10 Are there any congenital diseases or growth defects: yes, no.
8.11 If yes, specify the pathology along with the name, sex and date of birth of the child:
.....
.....
(further epidemiological investigation must be made)

REPRODUCTIVE CASE HISTORY
(to be completed for women)

9.1 At what age did menstruation begin: ..... age
9.2 Has there been menstruation over the last year: yes, no
9.3 At what age did menstruation stop: ..... age
9.4 How did menstruation stop (enter code:..... with age-1, after surgery-2, as a result of illness-3)
9.5 Pregnancies (normal childbirth, miscarriage, abortion, extrauterine, stillbirth etc.): yes, no.
9.6 How many pregnancies (twins count as one pregnancy) .....
9.7 Age at first pregnancy: .....age
9.8 Number of term pregnancies: .....
9.9 Age at birth of first child: .....age

FOETAL AND CHILD DEVELOPMENT
(to be completed for children under 15)

10.1 Age of mother at birth of the child ..... age
10.2 Did the mother suffer from any acute diseases in the year preceding the child's birth: yes, no.
10.3 If yes, specify which, and the month and year of illness .....
10.4 Were there complications in pregnancy: yes, no
10.5 If yes, specify, and state which month .....
10.6 In which month of pregnancy did the birth take place .....
10.7 Were there complications in childbirth: yes, no
10.8 If yes, specify .....
.....
10.9 Measurements of child at birth: height ..... cm., weight ..... grams
10.10 Did the child develop normally: yes, no
10.11 If no, specify anomalies .....
.....

10.12 What childhood diseases did the child suffer, and at what age .....
.....
10.13 Does the child suffer from congenital or chronic diseases: yes, no
10.14 If yes, specify .....
.....
10.15 Are there other children in the family: yes, no
10.16 If yes, list them, stating sex and year of birth .....
.....
10.17 Are those children healthy: yes, no
10.18 If no, specify the chronic diseases of the child and the age at which they occurred
.....
.....
10.19 Did the child examined attend a pre-school institution: yes, no
10.20 Is the child a satisfactory student: yes, no (do not complete for pre-school children)

For children born after April 1986 who have contracted leukaemia or any other haemoblastosis, COMPLETE AN EPIDEMIOLOGICAL EXAMINATION FORM FOR EACH PARENT.

DATA FOR RECONSTRUCTION OF AN INDIVIDUAL DOSE OF RADIATION

1. LPA participant, number and series of certificate, by whom issued .....
   .....
2. Year of participation in the LPA .....
3. Dose sustained during participation in LPA, according to document .....
4. Title of document .....
5. Other information on dose sustained during participation in LPA
   Dose, rem .....
   Source of information .....
6. Date of evacuation from 30 km zone (day, month, year) .....
   From which population centre .....
7. Date of removal from contaminated territory .....
8. Information on measurements of radioactive caesium in the body

When	Where	How much (microcuries)
.....	.....	.....
.....	.....	.....
.....	.....	.....

9. Body weight (kg) .....
10. Information on ESR dosimetry of tooth sample
    Date when sample was taken .....
    Organization to which it was sent .....
    Which tooth .....
    Was there a jaw X-ray, and if so when .....
11. Information on the taking of blood samples for dosimetry
    Date of sampling .....
    Organization to which the sample was sent for biodosimetry .....
12. Information on dosimeters issued for external exposure determination .....
    TLD issuing date .....
    Organization to which TLD was sent for analysis:
13. Any medical exposure for therapeutic purposes (yes, no).....(if yes, conduct an epidemiological investigation)

14. Any diagnostic examination involving radiopharmaceutical preparations (yes, no)..... (if yes - conduct epidemiological investigation)
15. Any regular X-ray or fluoroscopic examinations, annual (yes, no) .....(if yes - specify)
16. Any professional contact with sources of radiation (yes, no) ..... (if yes - conduct epidemiological investigation to establish details and circumstances of contact)

Organization	Years
.....	From..... to .....

17. Occupation, main activities from year to year (including school and advanced education, attendance at pre-school institutions, work at home, private agriculture, pension)

Year	Educational/economic activity
1986	
1987	
1988	
1989	
1990	
1991	
1992	
1993	

18. Domicile and type of accommodation (year by year)

Year	Domicile Oblast, raion, population centre	Type of accommodation Wooden-1 Stone-2	Floor
1986			
1987			
1988			
1989			
1990			
1991			
1992			
1993			

19. Excursions from domicile in 1986

Destination (oblast, raion, town, village)	Date of departure	Date of return

20. Total period of residence (in months) at permanent domicile in the following years:

1987	
1988	
1989	
1990	
1991	
1992	
1993	

21. Excursions to other places and length of stay (in months):

Year	Destination (oblast, raion, town, village)	Duration of stay (months)
1987		
1988		
1989		
1990		
1991		
1992		
1993		

22. Average daily consumption of whole milk, April-June 1986 (in litres)
Milk produced at home .....
Milk purchased from suppliers .....

23. Foodstuffs consumed after June 1986 (mark products consumed with a cross in the appropriate year).

Year	Milk		Potatoes	Greens	Meat	Game	Mushroom	Berries
	Litres per day		Private	Private	Private			
	Private	Shop						
1986								
1987								
1988								
1989								
1990								
1991								
1992								
1993								
1994								
1995								
1996								

24. Regular consumption of home grown or locally produced potatoes (yes, no) _____
25. Regular consumption of home grown or locally produced greens and other vegetables (yes, no)
26. Regular consumption of local mushrooms (yes, no) _____
27. Regular consumption of local game (yes, no)_____
Wild boar _____
Venison_____
other _____ (specify)

28. REMARKS

29. Full name of the specialist who completed the form _____

30. Organization _____

31. Date of completion _____ _____ _____

32. Signature _____