BELAM STUDY

Proposed Changes to the Scientific Protocol for the Study of Thyroid Cancer and Other Thyroid Disease in Belarus Following the Chernobyl Accident

On May 26, 1994, the document entitled, "Letter Arrangement for Continuing Cooperation Between the Ministry of Health of the Republic of Belarus and the United States Department of Energy on the Implementation of the Scientific Protocol for the Study of Thyroid Cancer and Other Thyroid Disease in Belarus following the Chernobyl Accident" was signed by representatives of both parties. Since the implementation of the Protocol in June 1996, the Project Program Directors from both Belarus and the US have determined the need for modifications to the original document. The following are the Belarusian and US proposed changes:

Section Number	Belarusian	US
Cover Page		The lists of the names of U.S. and Belarus Committees is out of date. Should it be left for what it was when the protocol was written or brought up to date? What about dating? Should the original date be left or the eventual date of approval by the Bi-National Advisory Group be inserted at that time?
1. BACKGROUND SIGNIFICANCE (paragraph 7)	Current text: The Chernobyl power plant is located in Ukraine, about 30 km south of the border with Belarus. Proposition: Replace "30 km" with " 5 km"	
3. METHODS 3.1. THYROID DOSIMETRY		Insert a list of publications which appeared since the protocol was written. This list is appended.
3.1.1. Measurements of ^{131}I activity in the thyroid. 3.1.1.1. Background Information		Proposition: Add the following text at the end of paragraph 2: "In addition, about 30,000 direct thyroid measurements were conducted in the Brest region. As a relatively large number of thyroid cancers have been observed in that region, it could be envisaged to add the results of these measurements to the dosimetry data bank. Unfortunately, it is not clear whether the identification of the children who were measured can be found." Reason: It may be difficult to assemble a cohort of sufficient size using only the people who were measured in the Gomel and Mogilev Oblasts. We found out recently that many direct thyroid measurements had also been carried out in the Brest Oblast. There is still an unresolved problem whether it will be possible to obtain sufficient information regarding these measurements in order to estimate reliable thyroid doses.

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3.1.2 Dose reconstruction based on thyroid measurements. 3.1.2.4. Work to be done.		Proposition: Add the following text at the end of paragraph 2: "Efforts should be made to collect in an electronic database all the reliable information released to the deposition on the ground and on the environmental concentrations of I-131 for the territory of Belarus." Reason: Many environmental measurements were carried out in Belarus by Belarusian and Russian teams; these measurements have never been collected in a single electronic database. This should be done. Current text: (paragraph 5) The information available on the environmental concentrations of ^{131}I and on the commercial distribution of foodstuffs will be provided by Belarus. Proposition: Delete the text: "on the environmental concentrations of ^{131}I." Reason: This will be a joint tri-national effort. Belarus alone should not be singled out.
3.1.4. Contribution of External Irradiation and of Internal Irradiation from Radiocesium to the Thyroid Dose. 3.1.4.2. Work to be done.		Proposition: Delete the last sentence: "Thus a pilot study...Radiation measurements." Reason: Such measurements are unnecessary if information can already be derived from the important number of exposure rate measurements that were made after the accident.
3.2. SAMPLING PLAN: COHORT STUDY OF MORPHOLOGIC AND FUNCTIONAL CHANGES. 3.2.2. Selection of Sample. 3.2.2.2. Availability of Dose Estimates.	Current text: The sampling strategy will be to select all eligible subjects with estimated doses above a certain value and to choose at random an appropriate number from among those at a lower dose level. Proposition: Insert after the word value: "(more than 1 Gy)"	

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	Insert the following two sentences after the sentence noted above: "After randomization of people receiving less than 1 Gy dose for the thyroid there will be a search of their present addresses. If the search won't be effective, there will be another randomization of the cohort members."	
3.2.2.3. Other Criteria of Eligibility.	Current Text: Any other criteria of eligibility will have to be developed. For example, it might also depend on residence in certain regions accessible to the examining centers and visiting teams. Proposition: Delete the above noted paragraph in its entirety and insert the following paragraph: "Any other criteria of eligibility will be developed based on results of the search efficiency at the initial stage of the sample selection. The most interesting is to find people whose thyroid dose was more than 1 Gy, as the number of such people is restricted. It is possible that it will be necessary to include in the cohort people with high radiation doses, who were not included in the direct thyroid dose measurements in 1986. It may be possible to make a decision on this problem only after the search for all people with high doses is finished."	
3.3. CLINICAL AND DIAGNOSTIC METHODS 3.3.1. Palpation and Ultrasound Examination.	Current text: Palpation and ultrasound examination of the thyroid gland will be performed at intervals of (preferably) one or (at most) two years. Proposition: Replace sentence with: "Palpation and ultrasound examination will be performed to patients with found pathologies of the thyroid gland once in 3-6 months." Delete sentences 2 and 3 of paragraph 2. "A uniform size...(Table 3.3.1)." Replace with the following sentence: "To estimate the thyroid gland size with palpation one can use the WHO classification (Table 3.3.1.)." Delete sentences 4 and 5 of paragraph 3. "Standardized protocols....image display." Replace with: "Standard forms are completed for every participant of ultrasound thyroid screening and all results are written down into MOD (???). A bank of ultrasound pictures will be kept in the Screening Center."	Proposition: Replace table with the following: Table 3.3.1. Eliminate the old classification of goiter size, substitute the new WHO classification: Grade 0 = no goiter (that is, no thyroid enlargement) Grade 1 = thyroid enlarged but not visible with neck in normal position. Grade 3 = thyroid enlarged and visible with neck in normal position

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Section Number	Belarusian	US
3.3.2. Ascertainment of Thyroid Cancer.	Delete section in its entirety. Replace with the following: "Fine needle biopsy of the thyroid gland is recommended for: -All patients with palpated nodules and/or local changes in the thyroid gland detected by ultrasound screening with the size exceeding 1 cm. -Patients with nodules and/or local changes in the thyroid gland detected by ultrasound machine with the size from 5 mm to 1 cm if there are indirect signs of malignancy (change of echo structure or contours, change of the nodule size, swelling of the lymphatic neck nodules). -Patients who have thyroid ultrasound pictures with diffusion changes combined with swelling of deep lymphatic nodules. It is necessary to make surgery and histological analysis of tissue if there was suspicion or diagnosis of a malignant neoplasm. Increased level of serum tyroglabulin in earlier operated patients means that there are metastasis. Subjects with such analysis are thoroughly examined to exclude metastasis of lungs and bones. A radiologist has to examine with ultrasound machine the thyroid gland and neck. If there is a slightest suspicion of metastasis the patient has to be operated on and operated tissues will be histologically analyzed, or the patient will be prescribed a suppressive dose of levotyroxin (?) and he/she will be invited for another examination in 3-6 months. Cytological preparations are kept where the thyroid gland is examined and if necessary can be given to doctor. The surgeon oncologist complete a standard hospital form. He has to explain what kind of operation was performed. The extracted tissues are sent to an expert to perform a patho-morphological examination and filling of a standard form. The remaining tissues are sent to the Tissue Bank for the long keep."	

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Section Number	Belarusian	US
3.3.3. Ascertainment of Hypothyroidism.	Current text: Serum (not plasma) will be obtained at 1 or 2 year intervals for measurement of TSH, free T_4 and total T_4 by immunoassay. Proposition: Replace "TSH, free T_4 and total T_4 by immunoassay" with "TSH and free T_4 by immunoassay." Remove last sentence "If free T_4 measurements are found to be satisfactory, total T_4 measurement may be discontinued after the first year".	Proposition: Delete first sentence. Replace with the following text: "Hypothyroidism to be ascertained by serum TSH on every visit, with Free T_4 or T_4 done whenever the TSH is abnormally high or low."
3.3.4. Ascertainment of Iodine Nutrition.	Proposition: Delete current paragraph in its entirety. Replace with the following: "The iodine content in urine will be evaluated for all patients for the first two years. After that it will be evaluated whether it is necessary to measure that parameter in the future. Creatinine will not be measured. The quality control of iodine measurements in the Central Minsk Laboratory will be performed with the help of the blind urine samples provided by other European Centers certified by the iodine content in urine."	Proposition: Delete current paragraph in its entirety. Replace with the following: "Iodine nutrition to be ascertained by measuring urine iodine content of a random urine sample on every subject at the first visit. This will perhaps be repeated at a time to be decided at a later date. In particular, sampling of a subset of subjects based on geographical distribution will not be done, 24-hour urine collections will not be done, urine creatinine will not be measured, and samples will not be sent to the University of Massachusetts for verification."
3.3.5. Ascertainment of Lymphocytic Thyroiditis.		Current text: Serum obtained under 3.3.3 will be used to measure antithyroid peroxidase (Anti-TPO) at 1 or 2 year intervals. Proposition: Delete "(Anti-TPO) at 1 or 2 year intervals" and substitute: "anti-TPO to be done on every visit, followed by anti-Tg, if positive."
3.3.6. Ascertainment of Hyperparathyroidism.	Proposition: Delete text in its entirety. Replace with: "Only ionized calcium content is measured in the blood serum of all patients. If an abnormal value of calcium is measured in serum then the parathyroid hormone content is checked."	Proposition: Delete the entire text. Replace with: "Hyperthyroidism to be ascertained by serum ionized calcium on every visit. When elevated, PTH immunoassay will be done in a reference laboratory."
3.3.7. Central Laboratory.	Proposition: Delete text in its entirety. Replace with: "Blood tests will be performed in the Central Laboratory in Minsk, especially organized and equipped for the study. The quality control of iodine measurements will be performed with the help of the blind urine samples provided by other laboratories.	Proposition: Delete the second sentence starting with "Selected duplicate..." to the end of paragraph. Add the text: "With increasing future workload, it may be necessary to open a second laboratory."

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Section Number	Belarusian	US
3.4 INTERVIEW, QUESTIONNAIRE PROCEDURES, AND EXAMINATION RECORDS. 3.4.1. Information on Personal History 3.4.1.2. Information on Medical History	Proposition: Delete in its entirety: Replace with the following: "Patient's history: -serious diseases not connected to thyroid, after 1986 -thyroid diseases -PB (??) of thyroid -operations related to thyroid diseases (comments) -Medications for thyroid – data is not collected. -Iodine consumption, goiter in community – are not ascertained by medical history, it will be ascertained by the iodine content in urine.	
3.4.2. Information from Medical Examination.	Proposition: Under "Physical examination", make the following changes: -General health – is not evaluated. -Physical and sexual development - are not evaluated Under "Tests performed", delete T_4 and T_3. Specify whether Tg content will be measured.	Proposition: Under "Tests performed", eliminate T-4, T-3 and Albumin.
3.4.3. Information for Record Linkage.	Proposition: Delete in its entirety. Replace with: "All standard forms have a bar-code sticker where a unique subject's ID, his first, middle, and family names are shown."	
4. STANDARDIZATION AND QUALITY CONTROL.	Proposition: Delete in its entirety. Replace with: "The obtained data objectivity is provided by the specially trained persons participation who know requirements of the scientific protocol."	

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Section Number	Belarusian	US
4.1. DOSIMETRY	Proposition: Add: "To calculate thyroid doses for cohort members it is necessary to create a data bank of dosimetric data. It will include the following: 1. Database for results of initial measurement of MED (??) near cohort members thyroid in May-June 1986, including all concomitant information (place of measurement, type of device, level of background radiation, etc). 2. Initial database for the irradiation doses calculation, prepared by the Moscow Biophysics Institute, together with results of the population interviews in 1988. 3. Database of radiation-hygienic data collected in places of cohort members living at the time of accident and soon after it. 4. Database of radioactive fallout (time and radionuclides content) on the republic territory. 5. Database of MED (??) data on dwellings territories at the time of accident. 6. Database of TLD measurements. 7. Database of administrative division of the republic territory. 8. Database of the personal reviewing results of cohort members (initial and successive reviews). 9. Database of identified cohort members and revised values of MED (??) near thyroid. 10. Database of external and internal thyroid irradiation doses. 11. Handbooks on dosimetric values, constants, and other information."	

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Section Number	Belarusian	US
4.1.6 Participation in International Model-Validation Studies.		Proposition: Delete in its entirety. Reason: Such participation in international model validation studies could be decided on an ad hoc basis.
4.2. CHARACTERISTICS OF SUBJECTS, INTERVIEWS, QUESTIONNAIRES	No changes.	
4.3 CLINICAL PROCEDURES	No changes.	
4.3.2. Ultrasound examination	Current text: (last sentence) Ultrasound phantoms will be imaged on a weekly basis, and the data stored on thermal records and on videotapes for computer ananlysis of changes in performance. Proposition: Change the word "weekly" to "monthly".	
4.4. LABORATORY PROCEDURES 4.4.2. Kits for Testing Thyroid Function and Anti-Thyroid Antibodies.		Proposition: Delete the last sentence in the paragraph: "If kits...kits" substituting the text: ""Procedural changes, new equipment will require overlap time during which duplicate tests will be run to assure reproducibility."
4.4.3. Individual Runs.		Proposition: Delete the text in its entirety. Replace with: "Serum assays will be performed in single determinations."
4.4.4. Control Sera.	Proposition: Add: "Results of the quality control procedure for all laboratory procedures will be represented as Levy-Jennings (??) graphs to make decisions on every group of analysis quality."	
4.4.5. Inter-Laboratory Comparisons		Proposition: Delete the second sentence in its entirety.
4.5 PATHOLOGY 4.5.2. Aspiration Cytology.		Current Text: "An expert cytopathologist will review the cytology slides for adequacy and accuracy of diagnosis at least 4 times a year." Proposition: Delete the text "at least 4 times a year". Add: "The U.S. consultant, based on most recent experience, will determine the frequency of reviews; 4 reviews per year may not be required."

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5. DATA COLLECTION, STORAGE, AND RETRIEVAL	Proposition: Delete the text in its entirety. Replace with: "The number and size of systems needed for the study are sensitive to a number of factors such as sample size, control intensity, volume and character of the processed and kept information, length of research etc."	
5.1 ASSUMPTIONS 5.1.1. Data acquisition locations:	Proposition: Delete text in its entirety. Replace with: "Clinical data: Radiation Medicine Dispensary (RMD) in Minsk Radiation Medicine Dispensary (RMD) in Gomel 3 teams RMD (Minsk) 1 stationary group: 2 endocrinologists; 2 ultrasound machines, etc 1 mobile group: 1 endocrinologist; 1 ultrasound machine, etc Dosimetric data: Stationary Center in Minsk, mobile teams."	
5.1.2. Central data analysis resource	Proposition: Add: "Center of Data Coordination (Institute of Radiation Medicine in Minsk)"	
5.1.3. Data to be accessioned: 5.1.3.1. Basic data.	Proposition: Replace with: "Biographic, and dosimetric information: obtained initially and updated at scheduled and unscheduled intervals."	
5.1.3.2 Data on research participant search (new)	Proposition: Add: "Data on the potential research participant search based on different sources of a subject in cohort status tracking."	
5.1.3.3. Previous examination data: (previously 5.1.3.2)	Proposition: Replace with: " -Clinical diagnosis -Cytological survey -Patho-morphological examination"	
5.1.3.4. Prospective survey data: (previously 5.1.3.3)	Proposition: Replace with: "-Physical examination -Thyroid and parathyroid test data -Pathology -Clinical diagnosis -Thyroid ultrasound	
5.1.3.5. Morbidity and mortality data (new)		

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5.1.3.6. Clinical data (new)	Proposition: Add: "-Hospital data -Biopsy and cytology -Patho-morphological data	
5.1.7. Data Storage requirements:	Proposition: Replace with: " -Dosimetric data: 10 KB -Prospective survey data: 2 KB -Morbidity and mortality data: 2 KB -Clinical data: 2 KB -Thyroid image: 3 MB Data will be kept in the collection location. They will be transferred periodically to CDC into the central data base, where the data will be processed. Data will be copied both at DCC and in local data bases, to safeguard it. Summary of clinical data storage requirement: -Dosimetric data: 15,000 subjects x 10 KB = 150 MB -Search system for a subject in cohort state: 15,000 subjects x 10 KB x 30 years = 445 MB (??) [5.5 GB] -Prospective survey data: 15,000 subjects x 5 KB x 30 years = 225 MB (??) [2.25 GB] -Morbidity and mortality data: 15,000 subjects x 5 KB x 30 years = 225 MB (??) [2.25 GB] -Clinical data: 5,000 subjects x 2 KB = 10 MB -Thyroid images: 15,000 subjects x 3 MB x 30 years = 1,350 GB -General information: 5 MB Total storage requirements: 2,510 GB (??) [1,361.16 GB]"	

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Section Number	Belarusian	US
5.2. DATA ENCODING AND VERIFICATION SYSTEM	Proposition: Replace with: "At each patient examination center, patient data from history and physical examination will be entered into computer at the time of examination. All data will be identified by a unique code. There will be programmed checking of new entries to ensure that neither participant nor examination are falsely identified. Main data elements will be verified on data types and their range. Number values and text data will be tested for inconsistencies and range. It will be implemented by the programs developed by the data center stuff. Information from the examination centers will be transmitted to DCC daily by discs or via modems. Both DCC and examination centers will copy information not to lose it."	
5.3. DATA RECORDING STORAGE, AND ANALYSIS RESOURCES. 5.3.1. Computer requirements.	Proposition: Replace with: "The central system will consist of a local network, consisting of one server and 7 working stations with Pentium processors. It will be located in DCC in Institute of Radiation Medicine. Two stations will be used for data entry in DCC, 3 stations will be used to develop programs and analyze data in DCC, 2 computers are needed for data entry in DCC, 2 computers for epidemiological data entry, 3 computers for data entry in examination centers (locally), 2 computers for dosimetric data entry (locally), 1 computer in the central laboratory (locally). Computers in DCC, examination center, and central laboratory are provided by fax-modems to transmit data to DCC. The central server in DCC is provided by an uninterrupted power equipment UPS. Three personal computers with fax-modems will be installed in Gomel to analyze and transmit clinical and epidemiological data. One personal computer can be connected to an ultrasound machine in the examination center to memorize thyroid images. Mobile units also need portable computers: -2 for dosimetry -2 for mobile teams for data entry (one for each team). Additional System Definition: -The network server will have 10 GB hard drive and 64 MB memory -The personal computers will have 3 GB hard drives and 32 MB RAM.	Delete

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	For dosimetric data bank it is necessary to create a computer network which includes one file server and six computers (network is needed for information storage, software development, data processing, formation of exchange protocols and reports)."	
5.3.2. Ultrasound data	Proposition: Replace with: "The patient's thyroid image entry will be done through the ultrasound machine. The whole array of gathered for one day images will be written down to a magneto-optical disc (MOD) with help of a magneto-optical transformer. It will be sent to DCC for processing. In DCC it will be archived on a DAT cassette. Besides, all files on MOD are transformed into a special structure for use in an image database. This database will be linked to the screening results database. It is planned to keep this database on compact discs to have an effective access to it."	Proposition: Delete the text in its entirety. Replace with: ""Each ultrasound system will have an image digitizer (Camtronics Magneto Optical Disk (MOD) recorder). A standardized set of images will be recorded for each patient in whom normal findings are noted, and extra images will be recorded when abnormalities are found."
5.3.3. Computer backup	Proposition: "Every day data will be copied to streamer tapes which will be kept in a safe remote place."	Proposition: Delete the text in its entirety. Replace with: "Ultrasound images recorded on MOD disks will be backed up on DAT tapes at the DCC. Peripherals on the DCC system will include a DAT tape, MOD read/write device, and a R/W CDROM along with the other standard devices specified elsewhere. The DCC will transfer image data from the MOD disks to DAT tapes for long term archiving at a safe remote place, and will rewrite images onto CDROM disks in a format suitable for review on standard PCS located at or near the Ultrasound clinical units."
5.3.4. Software	Proposition: Replace with: "-Windows 98 -Novell Netware -MSACCESS -Visual Basic -C++ -SAS -STATISTICA' -MS EXEL"	Delete

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5.3.5. Other equipment	Proposition: Replace with: "Four copiers located at DCC, screening center, dosimetry group, and Gomel. Three laser printers for DCC, dosimetry group, and screening center. Three sources of uninterrupted power supply with serge protection (power 2 kW) are needed for a stable computer work for dosimetry group. File cabinet is needed for dosimetry group to keep archives. Computers and additional equipment have to be subscribed for a quartile service."	Delete
7. IMPLEMENTATION	Proposition: Replace with: "6,000 subjects were screened for the first 3 years; for the last year – 2,500. -Screening center was opened in Minsk. -Diseased patients are recommended to the NIKI RM (???) clinic in Axakovshina for thorough examination and therapeutical treatment; for surgery patients are recommended to Republican Center of Thyroid General Pathology (RC OP thyroid). -Central Laboratory is based in the Screening Center in Minsk Dispensary. -Project's pathomorpholog works in Minsk State Medical Institute and Republican Center of (OP thyroid). Perspective plan for the next 3 years: -To screen 9,000 cohort members for the first 3 years; for the fourth year – 2,600; for the fifth – 3,000; for the sixth – 3,400. -Repeated screening will be organized for cohort members: 1 time every 3-6 months for diseased, not less than 1 time every 1-2 years for every member. It will give 30-40% of the first time screened. -There will be organized 2 mobile teams during the fourth year; one in Minsk, another in Gomel."	Proposition: Delete the text starting with line 5: "Resource requirements...up to the end of this section ending with...the Oncology Center."
7.1 PERSONNEL		Proposition: Delete sections 7.1; 7.1.1; 7.1.2; 7.1.3; 7.1.4

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7.2 EQUIPMENT		Proposition: Delete in its entirety
7.2.5. Dosimetry equipment	Proposition: Field gamma spectrometer with an HPG detector	
7.2.6. Other equipment	Proposition: "-Transport for mobile teams transportation (itemize). -Transport for the cohort subjects transportation. -A bus for 60 people to transport cohort subjects or mobile teams. -Motor pool (itemize)."	
7.3. SUPPLIES		Proposition: Delete in its entirety
7.3.1. Supplies for clinical work	Proposition: Remove – "T_4 kits" Add: "Ordered according to the given form."	
7.4. PATTERN OF BI-NATIONAL COLLABORATION.	Proposition: Add: "The fiscal contribution of the Belarussian side (itemize ??)"	Proposition: Add at the end of paragraph 2: "(c) Local assistance needed to supplement the salary of the Belarusian personnel working on the study."
7.5. FUNDING		Proposition: Delete the heading 7.5.1; In the BALARUSIAN BUDGET paragraph: second line substitute "salaries of "for "paying"; delete in lines 3-5 the text: "purchase of such equipment and materials which are not stipulated in the protocol as a U.S. responsibility." In the U.S. BUDGET paragraph: delete entire text after the end of the first sentence. Add the following text: The budget will be reviewed annually and proposed to NCI leadership in the established process. U.S. will provide approved equipment and supplies and negotiated local support funds for the Balarusian project, for possible expansion of additional screening centers and mobile teams, training support for approved staff as well as funds to remunerate the study participants for their travel to the screening center. In U.S. the budget will include expenses for the travel for consultants, funds for the support contract, support to members of the Bi-National Advisory Group and funds for approved meeting travel for the purpose of reporting study data.
7.5.2 Sources of Funds.		Proposition: Delete in its entirety.

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9. <u>REPORTS, PUBLICATIONS.</u> 9.2. <u>Press Releases and Public Announcements.</u>	<u>Proposition</u>: Transmittal of examination results to subjects. Examination results are reported to cohort members right after finishing screening process and a completed form with a Conclusion on the thyroid examination will be given to them. Results of laboratory analysis will be reported either in a letter or by telephone if there are some abnormalities.	
Appendices		<u>Proposition</u>: Delete appendices A, B, C, and update Appendix D

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10. PROJECT MANAGEMENT 10.1 OVERSIGHT GROUP.		Proposition: Change title from "OVERSIGHT GROUP" to "BI-NATIONAL ADVISORY GROUP". Replace with: "Belarusian and NCI authorities will be assisted by a Bi-National Advisory Group consisting of 10 members, five to be named by Belarusian Ministry of Health and five by the U.S. National Cancer Institute (after consultation with other U.S. sponsoring agencies). Nominations should reflect the well-established reputation of each candidate from the following areas of expertise: endocrinology, radiation biology, radiation dosimetry, radiation epidemiology and clinical sciences/pathology. Following its establishment the Advisory Group will be self-perpetuating body selecting future members from among those nominated by the sponsoring agencies and by its own membership. Members of the Bi-National Oversight Group will serve five-year terms except that, initially in order to provide reasonable continuity, the candidates will be appointed for three-, four-, five-, six-, and seven-year terms from each national authority. Members may not serve more than two terms. Project staff may not serve as members of the Advisory Group. Former staff members should observe a two-three years hiatus from any involvement in project operations. The Advisory Group will select its own co-chairmen, one Belarusian and one American (the latter would have been already selected by American membership as the Chairman of the American moiety). The Bi-National Advisory Group will meet at least once a year in Belarus. It may hold other meetings when necessary or upon request from either the Belarusian or U.S. Project Director. The co-chairman will jointly administer the activities of the Advisory Group including such matters as the agenda, number of meetings each year, alteration of chairmanship, etc. The Advisory Group will respond to requests for advice from the Belarusian and American Project Directors and will initiate its own agenda topics and investigations. It will be responsible for (1) recommendations of changes in the governing research protocol based on suggestions made to it by either the Belarusian or the U.S. Project Director, or on its own

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		observation, (2) review of budgets presented by the Belarusian and U.S. Project Directors (budget approvals are the responsibility of the Ministry of Health in Belarus and the NCI Director in U.S.), (3) review of the progress of the work on the basis of official reports; e.g., the quarterly reports of the Belarusian Project Director, information presented at its meetings, reports of site-visits, and its own investigations, and (4) advice on publication policy. With the approval of the co-chairman, data created by project activities will be made available to individual Advisory Group members for informational and review purposes. The Advisory Group will determine its own agenda and operating rules, including the rotation order of individual members; the Group has the right to close the meetings to convene in executive sessions. The Belarusian Project Director will provide secretarial and other logistical support for the Group's meetings and activities in Belarus and the U.S. Project Director for meetings in the U.S. The official communication language will be in English. The Project Directors shall be responsible for providing competent translations and interpreters. Travel expenses for the American component to Belarus or Belarusian to U.S. will be covered by the American side."
10.2 MANAGEMENT		Proposition: Replace with: "The Project Directors will be responsible for scientific activities (e.g., clinical, laboratory, dosimetric, and epidemiologic), for administration (e.g., personnel, data management, training, fiscal matters, allocation of resources), for preparation of required reports, and for communication with the press and with various entities of the governments. In their respective areas, they will be responsible for logistic support for the Bi-National Advisory Group. Reallocation of supplies and equipment provided by the U.S. Government will require consent of the U.S. side. One of the crucial tasks for the Belarusian Project Director is the appointment of a Quality Assurance Officer."

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