



Be/Am

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Germantown, MD 20874-1290

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**From:** Elaine Gallin, EH-63  
 Cherie Gianino, EH-63

**Date:** February 9, 1996

**Subject:** BELARUS//AMERICAN THYROID STUDY TRIP REPORT -  
 JANUARY 20-24, 1996

**Purpose:** (1) To determine the status of the BELARUS//AMERICAN (BE/AM) Thyroid Study through site visits and meetings with personnel.  
 (2) To present a draft Funding Agreement whose purpose is to provide supplemental support for Belarussian personnel working on the BE/AM Thyroid Study.

I. Sunday Evening (1/21) - American Delegation Meets to Discuss Strategy

| <u>Name</u>     | <u>Title</u>                   | <u>Organization</u>                |
|-----------------|--------------------------------|------------------------------------|
| Elaine Gallin   | Deputy Director                | International Health Programs, DOE |
| Cherie Gianino  | Health Scientist               | International Health Programs, DOE |
| Bruce Wachholz  | BE/AM Project Manager          | National Cancer Institute          |
| Andre Bouville  | Health Physicist               | National Cancer Institute          |
| Everit Mincey   | NCI Field Representative       | National Cancer Institute          |
| -----           | NCI Translator                 | National Cancer Institute          |
| Lynn Anspaugh   | Director of Risk Sciences      | Lawrence Livermore National Lab    |
| Larisa Anspaugh | Translator/meeting coordinator | N/A                                |

Everit Mincey/Bruce Wachholz provided an update on project and noted some issues to be addressed during visit. After this discussion, the Funding Agreement was changed to include a statement that the Agreement would be contingent on the project receiving national status. Next, Annex I, milestones, of the Funding Agreement was discussed. Dr.



Gallin noted Annex I needed editing. The milestones needed to be written for 3 months and include clear deliverables/tasks and dates. Administrative milestones need to be added, such as the formation of the Advisory Committee, approval of the BE/AM study as a state project, and completion of an organizational structure. Bruce Wachholz, Andre Bouville, and Lynn Anspaugh spent the rest of the evening reworking the milestones.

II. Monday (1/22) - Discussion of the Funding Agreement, Status of the Project, and Project Milestones

A. Monday Morning - Meeting at Ministry of Health

| <u>Name</u>           | <u>Title</u>                  | <u>Organization</u>         |
|-----------------------|-------------------------------|-----------------------------|
| American Delegation   |                               |                             |
| Inessa Drobyshevskaya | Minister of Health            | Ministry of Health          |
| Vladimir Orekhovski   | First Deputy Minister         | Ministry of Health          |
| Nicola Krisenko       | Deputy Minister               | Ministry of Health          |
| Edourd Glazkov        | Minister of Foreign Relations | Ministry of Foreign Affairs |
| Interpreter           |                               | Ministry of Health          |

Dr. Orekhovski greeted us and commented that the main discussion would be on the long-term Chernobyl Accident Thyroid Study of which the Minister of Health, Dr. Inessa Drobyshevskaya, is the President and the Deputy Minister, Dr. Nicola Krisenko, is the Project Manager. Dr. Gallin replied that as U.S. Representatives of DOE, we were pleased to be in Belarus. Dr. Gallin presented and reviewed the Draft Funding Agreement, noting that Belarus' input was necessary since the document was only a draft. Dr. Krisenko noted the economic difficulties in Belarus and that the fiscal year 1996 budget was not finalized. Dr. Krisenko explained that the Minister of Finance must figure out the framework for funding allocation for the state Chernobyl projects and the Minister is waiting to see how much support the United States will be able to give. Other discussions included the long-term nature of the project, the need to sign/amend the Funding Agreement each year, the status of the project, and the issue of customs and duties.

*The Minister of Health joined the meeting briefly to welcome us to Belarus and said that she would meet with us on Wednesday morning before our flight to discuss the status of the project and the decision on the Funding Agreement.*

B. Monday Afternoon - Meeting at Institute of Radiation Medicine

| <u>Name</u>         | <u>Title</u> | <u>Organization</u>                   |
|---------------------|--------------|---------------------------------------|
| American Delegation |              |                                       |
| Dr. Stazharov       | Director     | Institute of Radiation Medicine (IRM) |

Dr. Stazharov reviewed his role in the project, noting project accomplishments and readiness to start the pilot phase. The epidemiology, dosimetry, quality control, laboratory, and data control for the project which are located in the IRM are directed by Dr. Stazharov. IRM project participants have translated the Protocol to Russian,

developed various registration forms, identified project personnel at the Institute, identified 600 initial patients of the cohort, contacted more than 50 percent of those identified, and planned to start the Pilot Phase in November 1995 (delayed till February 1996).

Dr. Stazharov noted that the IRM participants are ready to start the project's final phase and have planned the project for the next 5 years although problems may arise, such as movement of the data control center from the IRM to a new building and identical funding as last years even though fiscal year 1996 wages have risen from 60,000 Rubles to 100,000 Rubles. The limited budget is the most burning issue. Finally, he noted he is against using individuals from Brest Region for the BE/AM project and that his plans for the Brest cohort are a secret. Both Dr. Gallin and Dr. Wachholz voiced concern about not having access to the Brest cohort. Dr. Stazharov mentioned Sasakawa Foundation had supported work on a cohort of 50,000 in Gomel and Mongolev Regions from 1991 to 1995 and planned to continue their scientific work. Sasakawa Foundation plans to carve out 5,000 high dose children to study. This may be part of the BE/AM project cohort. Again, Dr. Gallin and Dr. Wachholz expressed concerns about losing an important group of high dose children and stated these issues must be resolved.

#### C. Late Afternoon - Meeting with Scientific Staff Working on BE/AM Project

| <u>Name</u>             | <u>Title</u>              | <u>Organization</u>             |
|-------------------------|---------------------------|---------------------------------|
| American Delegation     |                           |                                 |
| Dr. Krisenko            | Minister of Health        | Ministry of Health              |
| Dr. Stazharov           | Director                  | Institute of Radiation Medicine |
| Arthur Kuvshinnikov     | Chief DC                  | Institute of Radiation Medicine |
| Nadia Listnikova        | Assistant DC              | Institute of Radiation Medicine |
| Victor Sviatelik        | Deputy Director Tech Mgmt | Institute of Radiation Medicine |
| Valery Rzhetski         | Clinical Screen Patients  | Dispensary                      |
| Dr. Patrenko            | Head of Clinical Lab      | Institute of Radiation Medicine |
| Dr. Vorenetski          | Head of Epidemiology      | Institute of Radiation Medicine |
| Mr. Minenko             | Head of Dosimetry Lab     | Institute of Radiation Medicine |
| Two Dosimetrists Moscow |                           |                                 |

*Each person was introduced and discussed their role in project and their concerns.*

Dr. Gallin asked Dr. Krisenko if Annex I, the draft milestones for the first 3 months, could be discussed. She suggests that Bruce Wachholz, as the scientific manager, lead the discussion. The Belarussian scientists offer several changes to the milestones which were incorporated into Annex I.

### III. Tuesday (1/23) - Meeting and Tour of Dispensary, Discussion with Dr. Krisenko, and Negotiations at IRM

#### A. Tuesday Morning - Meeting and Tour of Dispensary

| <u>Name</u>            | <u>Title</u>          | <u>Organization</u>       |
|------------------------|-----------------------|---------------------------|
| American Delegation    |                       |                           |
| Dr. Krisenko           | Project Manager       | Deputy Minister of Health |
| Valery Rzheutski       | Head, Dispensary      | Dispensary                |
| Galina Nesterenko      | Deputy Head Doctor    | Dispensary                |
| Larissa Danilova       | Chief Endo Consultant | Dispensary                |
| Dr. Patrenko           | Head, Clinical Lab    | Dispensary                |
| Other Dispensary Staff |                       |                           |

After introductions of staff members, the discussion was opened to questions. Questions included the number of patients that could be handled, other international health studies currently being carried out in the dispensary (none), and other equipment or supplies that are still needed to carry out study (vehicles). Dr. Gallin asked if they would be ready to start examining the cohort as soon as the pilot study was completed. Their response indicated that hiatus was likely to occur and that examinations might not start until September 1996. She expressed concern about this possibility and emphasized the need to demonstrate continued progress. The Dispensary staff noted that in the past the dispensary was not involved in the writing of the Protocol or well integrated into the project. However, with Dr. Krisenko as Project Director, they now felt that they are involved in the project.

*Tour of Dispensary - clinical lab, supplies, ultrasound equipment.*

#### B. Tuesday Afternoon - Meeting between Dr. Gallin and Dr. Krisenko

Dr. Gallin defined DOE's role in managing the financial aspects of the project. In addition, she discussed the need for open communication and the need to know what other projects were being planned that might impact on or overlap with the BE/AM Thyroid Study. She noted her concern over Dr. Stazharov's ability to undermine project, the need to define the impact of the Sasakawa Foundation/Belarus agreement on the BE/AM Thyroid Study, and the need to resolve the issue of the Brest cohort. Dr. Krisenko noted that a number of these issues would be resolved by February 15, 1996.

## C. Tuesday Afternoon - Meeting at the Institute of Radiation Medicine

| <u>Name</u>         | <u>Title</u>          | <u>Organization</u>             |
|---------------------|-----------------------|---------------------------------|
| American Delegation |                       |                                 |
| Dr. Krisenko        | Deputy Minister       | Ministry of Health              |
| Dr. Stazharov       | Director              | Institute of Radiation Medicine |
| Galina Nesterenko   | Deputy Head Doctor    | Dispensary                      |
| Larissa Danilova    | Chief Endo Consultant | Dispensary                      |
| Arthur Kuvshinnikov | Chief DC              | Institute of Radiation Medicine |
| Victor Sviatelik    | Deputy Dir Tech Mgmt  | Institute of Radiation Medicine |
| Dr. Rzhetski        | Head                  | Dispensary                      |
| Dr. Patrenko        | Head of Lab           | Institute of Radiation Medicine |
| Dr. Voreneski       | Head of Epidemiology  | Institute of Radiation Medicine |
| Mr. Minenko         | Head of Dosimetry Lab | Institute of Radiation Medicine |
| Two Dosimetrists    |                       | Moscow                          |

Dr. Stazharov began the discussion with a comment on the insufficient level of funding (\$10,000 for 3 months work will only give an average wage of \$50 per person for 40 people that are working on the project). He also wanted clarification of several items stated in the Funding Agreement; the basis for the amount of funding for the whole year, what no taxation of funds meant, and what indirect costs (10 percent) meant. Dr. Gallin responded that: 1) indirect costs are any costs incurred on the project that are not for support of personnel on the project; 2) with regard to the level of U.S. funding, the original Protocol stated that Belarus would provide funds to support the Belarussians on the project and that the U.S. intention is only to supplement wages. Dr. Gallin noted that, with our current budget situation, we can only commit \$40,000 at this time for personnel support for the next year. If we can show the project continues to progress, e.g., the pilot study is completed and the cohort examinations begin, it may be possible to identify other funds from other sources; and 3) no taxation means that funds would be exempt from all taxes and duties except for personal income tax. Dr. Krisenko noted that the Belarus Government would comply with the Belarus agreement in the Protocol to provide support their own personnel, but the budget for November 1995 was not finalized. He noted several possible problems in the proposed budget program; new taxation of 12 percent on all Chernobyl projects was expected and funding was missing for specialized dispensaries and screening in the dispensary. Dr. Krisenko noted that, as the project progresses, more funding will be needed for the dispensary. The level of expertise needs to be high on this project. He explained that this new budget program will run from 1996-2000. Dr. Stazharov noted that the amount of U.S. funding offered is not sufficient to complete the dosimetry tasks and milestones must be cut. Dr. Wachholz replied that the milestones are interconnected and cannot be cut. The only thing one can do is delay all the milestones if the money is not sufficient. Dr. Krisenko also raised concern about payment of the Moscow group. Dr. Gallin assured Dr. Krisenko that he is the Project Leader and that he would be involved in and asked for his concurrence with the condition of the contract with the Moscow dosimetrists. *Discussion continued around the table endocrinology,*

*computer data center, dosimetrists, etc. All Belarussian scientists agreed that more funding is needed.* Dr. Gallin noted that we sympathized with their situation, but emphasized how important it was to continue with this work. Again, she emphasized the U.S. funds were only supplemental and that Belarus must share in funding the project. If agreement can be reached on a Funding Agreement and progress can be made on the milestones, the U.S. will work on identifying more funds. She noted that the United States has already spent a considerable amount of funds on equipment, supplies, and the support of American scientists and hope the project will progress in a speedy fashion. Dr. Wachholz noted if the Belarussians' are judicious in identifying the needs of personnel, funds will stretch much further. Then Dr. Gallin asked what is the minimum amount of funding necessary for 3 months. Dr. Krisenko replied \$12,000/month or \$36,000/3 months. Dr. Gallin ended by saying that we could go back to our office and share their concerns, but believed that we would be unable to supply that amount.

#### IV. Wednesday (1/24) - Negotiations at IRM and Ministry

##### A. Wednesday Morning - Meeting at the Institute of Radiation Medicine

| <u>Name</u>         | <u>Title</u>              | <u>Organization</u>             |
|---------------------|---------------------------|---------------------------------|
| American Delegation |                           |                                 |
| Dr. Krisenko        | Project Manager           | Deputy Minister of Health       |
| Dr. Stazharov       | Director                  | Institute of Radiation Medicine |
| Galina Nesterenko   | Deputy Head Doctor        | Dispensary                      |
| Arthur Kuvshinnikov | Chief DC                  | Institute of Radiation Medicine |
| Nadir Listnikova    | Assistant DC              | Institute of Radiation Medicine |
| Victor Sviatelik    | Deputy Director Tech Mgmt | Institute of Radiation Medicine |
| Dr. Rzhetski        | Clinical Screen Patients  | Institute of Radiation Medicine |
| Dr. Patrenko        | Head of Lab               | Institute of Radiation Medicine |
| Dr. Vorenetski      | Head of Epidemiology      | Institute of Radiation Med      |
| Mr. Minenko         | Head of Dosimetry Lab     | Institute of Radiation Medicine |
| Two Dosimetrists    | Moscow                    |                                 |

Dr. Krisenko summarized the Belarus funding situation again and asked for the U.S. dollar amount to be funded for 1996. Dr. Gallin reiterated that the total amount of monies will be at least \$40,000 annual and \$10,000 would be the first payment. Dr. Krisenko replied that, until they receive a budget from the Belarus Government, they could not commit to the milestones in Annex I, and, therefore, could not sign the agreement.

**B. Wednesday Late Morning - Meeting at the Ministry of Health**

| <u>Name</u>         | <u>Title</u>       | <u>Organization</u>             |
|---------------------|--------------------|---------------------------------|
| American Delegation |                    |                                 |
| Nicola Krisenko     | Project Manager    | Deputy Minister of Health       |
| Dr. Stazharov       | Director           | Institute of Radiation Medicine |
| Dr. Drobyshevskaya  | Minister of Health | Ministry of Health              |

Dr. Drobyshevskaya discussed the Belarus budgetary situation and noted that it would probably be cut by more than 60 percent for fiscal year 1996. She noted that, until the Belarus budget was known, there could be no agreement with the Funding Agreement nor Annex I, the milestones, of the Agreement.

**ISSUES TO BE RESOLVED WITH BELARUS:**

1. The BE/AM Thyroid Study is not a national priority. The European Union has thyroid studies that are recognized at this level. The Belarussians would have to declare the BE/AM Thyroid Study as a State Project. The State Project status would decrease problems with customs duties and taxes, other taxes, and would increase the probability of Belarussian funding.
2. Dr. Stazharov's role in project. Although Dr. Krisenko, Deputy Minister of Health, was identified by the Ministry and Council as the new Project Manager in November 1995 (replacing Stazharov), he has not been approved by signature.
  - The Institute of Radiation Medicine (IRM) is run by Dr. Stazharov and it is Dr. Stazharov who oversees the dosimetrists, epidemiology, quality control, and data processing personnel for the project
  - IRM falls under the Minister of Health in the Organizational Structure, but is funded by the Minister of Chernobyl Affairs.
  - Dr. Stazharov is suing the Minister of Health.
  - Dr. Stazharov wants to change the organizational structure so that he falls under the Minister of Chernobyl Affairs, Minister Kinick.
  - One of the American Delegation has seen a document from Dr. Stazharov to his staff which suggested that he was ordering them to stop working on/slow down efforts on the project.
3. Location of the Data Coordination Center - the IRM is moving and it would be advantageous to move the DC to the Dispensary.
4. Agreement on level of U.S. support and milestones.
5. Level of Belarus support for project is still unknown.