

26 July 1996

EPIDEMIOLOGICAL STUDY OF LEUKEMIA AMONG UKRAINIAN CLEAN-UP WORKERS

Highlights of NCI/IPSN meeting. Rockville, 24 July 1996.

1. Purpose of meeting:

Presentation by the U.S. participants of the status of the Ukraine/U.S. joint study of leukemia among Ukrainian clean-up workers and informal discussion on the manner in which the American and French scientists will coordinate their efforts in the implementation of Phase I of that study.

This meeting was a follow-up of the meeting that took place in Vienna on 17 April 1996.

2. Participants:

Annie Sugier	Institut de Protection et de Sureté Nucléaire (IPSN)
Maurice Gomolinski	Institut de Protection et de Sureté Nucléaire (IPSN)
Patrick Gourmelon	Institut de Protection et de Sureté Nucléaire (IPSN)
André Oudiz	Institut de Protection et de Sureté Nucléaire (IPSN)
Margot Tirmarche	Institut de Protection et de Sureté Nucléaire (IPSN)
Ihor Masnyk	National Cancer Institute (NCI)
Gilbert Beebe	National Cancer Institute (NCI)
André Bouville	National Cancer Institute (NCI)
Stuart Finch	Cooper Hospital/University Medical Center (UMDNJ)
Shlomo Yaniv	Nuclear Regulatory Commission (NRC)
Patricia Holahan	Nuclear Regulatory Commission (NRC)
Frank Hawkins	Department of Energy (DOE)
Ruth Neta	Department of Energy (DOE)

3. Review of the scientific protocol:

Gil Beebe, Stu Finch, and André Bouville presented the scientific protocol of the Ukraine/U.S. joint study and stressed the work that needs to be done during Phase I of the project. A copy of the transparencies that were shown during these presentations was provided to the delegation from IPSN.

A number of questions and comments were addressed to the presentors, either for clarification purposes or to underline the difficulties associated with some aspects of the project. Regarding the access to data, it is fairly clear that the Ukrainians will want to keep control of their databases

but that sample sets of data could be communicated to the U.S./French team for review. Regarding dosimetry, it was mentioned that the International Agency for Research on Cancer plans to hold a meeting at the end of September on the assessment of methods for individual dosimetry that could be applied to the clean-up workers and on the harmonization of protocols for studies of cancer risks among clean-up workers. There was a strong feeling that the participation of U.S. and Ukrainian scientists at that meeting was desirable.

4. Approval status of the project:

The scientific protocol was peer-reviewed in the U.S. on 29 May. The written review of the protocol (a copy of which was transmitted to the French delegation) is very positive; the reviewers did not see the need to make revisions to the protocol, but provided a number of suggestions that may help to implement the protocol.

The protocol was then submitted for approval to the Institutional Review Board of NCI on 15 July; written comments are not yet available, but informal communications indicate that only a few changes will be requested. After modifications, the protocol will be submitted to the NIH for approval, and finally to DOE for funding.

Barring difficulties, the protocol could be signed by appropriate U.S. and Ukrainian personalities late September or early October. However, Frank Hawkins indicated that we should not underestimate the difficulties of a financial nature that need to be overcome before the signing ceremony.

5. Scientific administration:

5.1. Technical steering committee.

A technical steering committee, composed of three members from the IPSN and of three members from the U.S., will be responsible for the preparation of the program of collaboration and for the establishment of procedures to implement the program. The designated members of that technical steering committee were announced during the meeting. They are:

Patrick Gourmelon, Philippe Hubert, and Margot Tirmarche for the IPSN, and Gilbert Beebe, André Bouville, and Stuart Finch for the U.S.

Short curriculum vitae (one- to two-page long) of the members of the technical steering committee will be provided to Annie Sugier and to Shlomo Yaniv before the first meeting of the committee.

Observers will be allowed to attend the meetings of the technical steering committee. In particular, DOE and NRC will be informed of such meetings and invited to send observers.

It was tentatively decided that the first meeting of the technical steering committee will take place on 21-22 October 1996 in Washington, D.C.

5.2. Other working groups.

During Phase I of the project, the scientific overview of the study will be assigned to the U.S. and to the Ukrainian Working Groups. IPSN will be invited to participate in all meetings of the U.S. Working Group.

If it is demonstrated in Phase I that a long-term study is feasible, Phase II of the project will be undertaken. The scientific overview of Phase II will be under the responsibility of an Advisory Group composed of five members designated by Ukraine and five members designated by the U.S. At least one member of this Advisory Group will be designated by the IPSN.

6. Logistics and funding:

The IPSN contribution of \$250,000 was received by the NRC a few months ago; this contribution will be used for providing equipment, supplies, and logistics to the Ukrainian team.

The U.S. contribution is uncertain, as DOE, which is expected to be the main contributor, has not yet received its appropriation for fiscal year 1997. Frank Hawkins indicated that, in principle, DOE will support the leukemia study, but that there is a need to meet with representatives of NCI and NRC, maybe as early as next week, in order to discuss the level of funding.

Following the policy established for the thyroid studies, local assistance (salary supplements, essentially) will be provided to the Ukrainians upon demonstration that the work is progressing in a satisfactory manner according to agreed-upon milestones. Under the assumption that the leukemia study will be undertaken in October, a tentative list of milestones has been prepared by the U.S. and Ukraine. The IPSN is invited to comment on this list of milestones (which was distributed to all participants) before the end of September.

Maurice Gomolinski indicated that the IPSN has an office in Kiev, equipped with computers, FAX machines, and a scanner that allows for the rough translation of Russian texts into English and conversely. Such an office could be of a practical use during the implementation of the study.

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