



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

March 29, 1996

Mr. Frank Hawkins  
Director, Office of  
International Health Studies  
Department of Energy  
Germantown, MD 20585

Dear Mr. Hawkins:

Thank you for the draft minutes of the meeting at the Nuclear Regulatory Commission (NRC) on March 5, 1996, received here on March 14, on the eve of our departure for Minsk. Unfortunately, all of the NCI participants in the March 5 meeting, including Dr. Faye Austin, were out of the office last week. In keeping with your request that the draft minutes be made available only to those participating in the meeting, I have shared them with Dr. David Becker and Dr. Ihor Masnyk, both of whom were present at the meeting but who inadvertently were not included in the distribution of the draft minutes.

The meeting was a useful beginning effort to bridge the difficulties between us and I look forward to further progress toward a mutual understanding and resolution of issues, and a closer working relationship. In an effort to reflect the spirit of the meeting, it no doubt is necessary that the minutes convey the tension and difficulties that marked our relationship prior to March 5, but I wish that they could reflect a brighter tone and more positive outlook for the future.

I appreciate your explicit reference to the National Cancer Institute (NCI) as the project manager and appreciate your request, as the major funding source, for additional information regarding the project. If the Department of Energy (DOE) wishes to revise the terms of the existing interagency agreement, we welcome the suggestion to specify in writing a more detailed description of our respective responsibilities, and Dr. Gilbert Beebe, Dr. Andre Bouville, Dr. Ihor Masnyk and/or I will be pleased to work with you on its preparation. No doubt DOE, NRC and NCI each will want to carefully consider the new conditions governing continued participation before signing a revised interagency agreement.

While numerous comments could be offered in response to the specific text of the draft minutes with respect to facts, completeness and/or selectivity, we will confine ourselves to your action items and agreements, highlighted in bold type; these deserve individual comment. It should not be assumed, therefore, that we are in full agreement with *the remainder of the text of the minutes*. Specific comments follow:

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Page 2, item 2B - Responsibilities. We accept this action item with two provisions: (1) that we have adequate time to review the draft prepared by DOE staff and (2) that the final document should be considered as a set of internal guidelines on which our future interactions will be based. A letter of arrangement (or agreement) was just signed by Dr. Gallin and Dr. Krisenko in Minsk on the 20th of March. We all agreed to the text. It might send a wrong signal to our collaborators were we to start introducing changes at this time. This already was referred to by Dr. Gallin at the meeting on March 20 in that she stated that DOE wished to revise the implementation agreement to reflect a change in DOE's management responsibilities in Belarus.

Page 2, item 2C - Scientific Working Group. We welcome DOE participation in meetings of the NCI Working Group. We agree with the principle stated by Dr. Gallin that DOE should "participate as observers at our meetings with the Scientific Working Group." This wording should also be reflected in the text of this action item.

Page 3, item 2D - Reporting. Concerning the agreement paragraph, it should reflect three additional provisions: (1) that this agreement pertains only to foreign travel, (2) that the agreement apply to DOE and NRC as well as to NCI, and (3) that it be understood that NCI does not require a trip report from each participant in a visit abroad; accordingly, a single report, even if only a paragraph or two, may suffice for travel of several participants.

Concerning the action item, the reply is in preparation, and a response to the attachment was sent to DOE on March 8, 1996. It has been busy month for all of us.

Page 4, item 2F - Equipment/Supplies. Action item: we will be pleased to share what we know with DOE and NRC. We hesitate to involve the NCI scientific working groups in a search for ways to share the costs of the studies; that is neither their responsibility nor their area of expertise. We are willing to make inquiries of individual members, however.

Agreement: We are pleased that Lawrence Livermore National Laboratory (LLNL) will continue to be responsible for the procurement and shipment of equipment and supplies to Belarus, and, presumably, to Ukraine. This has been the understanding from the beginning, and the wording in the protocol was carefully crafted to exclude NCI from this responsibility (see attached).

Page 5, item 2H - Interaction with Belarusians. We support this agreement wholeheartedly and hope that all individuals assigned to the task of directly interfacing with Belarusian colleagues and counterparts will respect this agreement.

Page 6, item 3D - Matching Funds. We certainly welcome DOE's assistance in resolving this mystery concerning the "lost" funds, since NCI still has not received any DOE funds other than the \$85,000 carryover from FY 1995.

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Page 6, item 3E - Funding Agreement. We agree with the wording of this agreement with but a slight correction. The \$50,000 returned by NCI to DOE (from a presumed total of \$250,000) is conditional upon receipt of the remaining balance of \$115,000 from DOE during FY 1996. It should be stated that this \$50,000 will go towards providing local assistance to Belarus, rather than for "personnel" support, which may sound like salaries. Furthermore, it should be stated that this was a one-time offer.

Page 7, item 4A - Leukemia Protocol. We believe that we have already provided DOE with a copy of the leukemia draft protocol, and if we have not, we should have. Another copy was mailed to Dr. Gallin March 26, 1996. At the proper time, when all the approvals will be obtained, we will also provide you with the copy of the final protocol.

Page 8, item 4B - Amendments. We believe that this action item is only partially representative of our discussion. We support the statement that DOE will draft a revised "Letter of Agreement" (or "Letter of Arrangement") for funding aspects. It is not clear, however, what is intended by the words, "scheduling provisions of the protocol." We feel strongly that the protocol should not be altered in any fashion at this moment, because it may lead to undesired postponements and re-reviews. Amendments of the funding agreement should be kept as an independent part of the documentation; agreement on any issues relating to the protocol must await precise clarification. The discussion during the meeting focused on DOE writing an addendum to the implementation agreement to reflect DOE's support for local assistance; in Minsk, however, DOE stated an intention also to revise management responsibilities (see comment page 2). The intent of this is not clear to us.

Page 8, item 4C - Summary. We agree with and support the first sentence.

We do not recall discussing specific topics for the agenda for such a meeting, but we look forward to working together on an agenda that will enhance our cooperation, and that will reflect the discussions that took place at the last meeting.

Finally, we recall that the idea of an ad-hoc review panel was tabled as inappropriate at this time. Mr. Taylor, Dr. Austin, and Ms. Kessler all advised against this.

Nota bene: although not pertaining to any action items or agreements, I feel I must add to the text of the minutes on page 6, item 3C - Priorities. Even though the subject matter was very important, it was not reflected in any high-lighted agreement. As I recall, after Dr. Gallin opened the discussion on convening an ad hoc committee to review the Chernobyl program to assist DOE in making programmatic decisions, Dr. Austin responded that this would go beyond our responsibilities and even beyond our authority, and should be a U.S. government policy decision involving at least State, NRC, DOE and NCI at an appropriate senior level. Therefore, this is a much broader question impacting on government-wide decisions that go beyond the purview of an ad hoc review committee. Mr. Taylor and Ms. Kessler both agreed with Dr. Austin's comments on this point.

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Concerning the second paragraph of the same item, it is stated that Mr. Hawkins invited Dr. Austin to a meeting with Dr. O'Toole to ask for additional funding for the project. Dr. Austin stated, as indicated above, that NRC and State representatives also should attend this session. All present agreed to this.

Sincerely,



Bruce W. Wachholz, Ph.D.  
Chief, Radiation Effects Branch

cc: NRC - Mr. J. Taylor  
Mr. J. Wechselberger  
Dr. S. Yaniv  
Mr. C. Stoiber  
DOE - Dr. E. Gallin  
Dr. M. Bhat  
DOS - Ms. C. Kessler  
NCI - Dr. F. Austin  
Dr. I. Masnyk  
Dr. G. Beebe  
Cornell University - Dr. D. Becker  
LLNL - Dr. L. Anspaugh