

**APPLIED
EPIDEMIOLOGY
INC.**

Reference: VCHC-4.0-EPI-UPDATE

January 15, 1996

Dr. Hasmukh Shah
Manager, Vinyl Chloride Panel
Chemical Manufacturers Association
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. Shah:

Enclosed are the two revised addenda to the contract to conduct the study, "Update of Mortality Among Vinyl Chloride Workers" CMA Reference number VCHC-4.0-EPI-UPDATE. Since I first drafted these addenda, the extent of the delays in receiving data, the missing data, and the disarray of the archive shipped to us, have become clearer. I feel that with the exception of the release pending from New York City and the death information the previous contractor holds, we have received all the information we are going to receive. We now understand what we will need to do to complete the study. Furthermore, the decision of New York City should not alter the purpose of these addenda: should they not agree to the transfer the death information the previous contractor now holds, we will proceed with the death information that we can reconstitute from other sources.

On Friday, January 12, Dr. Jonathan Ramlow met with our staff at AEI, and after updating him on the current status of the study, we reviewed the draft copy of Addendum A (as I recall, Addendum B was approved by the Vinyl Chloride Panel at the October 31 meeting). Based on this discussion, I have modified Addendum A, which essentially requests six months' additional personnel costs and related expenses, and a six-month extension to complete the project by October, 1997 (versus eight months, as in the first draft).

Jonathan mentioned that the Vinyl Chloride Panel would have a conference call this coming Friday, so I am sending you the addenda by fax so that a decision on Addendum A might be reached. Please let me know if you or the Panel feels that any changes are necessary, and I will send signed copies by express courier for CMA's signature.

P.O. BOX 2424 • AMHERST, MA 01004



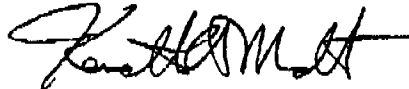
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CMA 112649

(Dr. Shah, January 15, 1996. page 2)

Please call me if you have any comments or questions. I hope that your move to Arlington was a smooth one. Thank you for your assistance once again.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Kenneth A. Mundt', written in a cursive style.

Kenneth A. Mundt, Ph.D.

enclosures

cc: Dr. Ramlow

CMA 112650

(Addendum A, Page 1 of 3)

VCHC-4.0-EPI-UPDATE

January 15, 1996

ADDENDUM A

Data Transfer Delays and Replacement of Missing Study Materials

Background:

As described in detail in a letter dated August 29, 1995 from Dr. Kenneth A. Mundt of Applied Epidemiology, Inc. (AEI) to Dr. Hasmukh C. Shah of the Chemical Manufacturers Association (CMA), substantial delays in the transfer of materials critical to conducting the Update of Mortality Among Vinyl Chloride Workers have resulted in unanticipated increases in personnel costs to AEI. Additionally, the previous contractor has been unable to deliver part of these materials, including an estimated 1,000 death certificates for deaths occurring among cohort members prior to 1983. Replacing these death certificates and other records at this time will require additional effort and resources.

This addendum to the original agreement describes: 1) the added expenses incurred by AEI resulting directly from the data transfer delays; and 2) the additional time and resources required to a) replace the missing materials, b) organize the collection of paper and electronic records received from the previous contractor into a useable archive, and c) identify information necessary to reconstruct some of the missing records and files. A new time line for the mortality update is also provided.

Data Transfer Delays and Reconstruction of the Study Archive:

According to the original agreement between CMA and AEI, all study materials and data were to be transferred to AEI from the previous contractor by May 1, 1995. As of January 1, 1996, the delay reached eight months, during which time AEI retained staff exclusively for the purposes of this study. Two months of this time were required for preparing the detailed protocol, leaving six months of unanticipated delays.

Replacing Missing Materials:

Materials critical to meeting the terms of the original agreement, but not received by AEI include an estimated 1,000 death certificates: 829 from the previous update, and up to 200 missing from the batch of older death certificates. The most straightforward of these to replace are the estimated 360 identified using the National Death Index (NDI), which began registering deaths in 1979. Certificates for deaths occurring prior to 1979 may be much more difficult to obtain, and consequently, all lost certificates may *not* be replaced.

CMA 112651

(Addendum A, Page 2 of 3)

Other missing information is the standard documentation and coding manuals to the previous contractor's data files. Although several tapes have been received, none were accompanied by such necessary information. Also, no files with death information have been received.

Total Delays and Budget for Added Costs:

Of the study milestones, AEI prepared a peer-reviewed protocol during the delay period. This effort represented a two-month personnel effort, leaving a six-month period of unanticipated staffing costs. Costs associated with the replacement of missing death certificates will be limited to searches and requests for copies of death certificates. Extending the NDI search back to 1979 will be unnecessary, as the tape containing the results of the previous NDI submission has been located and successfully read. Thus, expenses will be incurred for study staff, death certificate searches (if state of death known or suspected), death certificate copy charges and nosological coding. The personnel effort for this part of the project is estimated to be two months, for a total of eight months.

Because CMA has diligently attempted to obtain the missing materials and assisted AEI with the preparation of releases for all states, AEI will absorb two months of payroll. Other expenses are limited to cost, and the discounted overhead rate as in the original agreement:

Personnel (six months study staff)	\$61,422
Death certificate charges (1,000 x \$9)	9,000
Death certificate searches (additional fee of charged by states if certificate number unknown) (300 x \$5)	1,500
Coding of death certificates by nosologist (1,000 x \$2.50)	<u>2,500</u>
Total direct costs	\$74,422
Overhead (10%)	<u>7,442</u>
TOTAL ADDENDUM A	\$81,864

This estimated budget is made in good faith based on facts known at this time. Applied Epidemiology, Inc. reserves the right to revise this budget if additional delays occur, or if the minimal information necessary to replace the lost materials is not made available. No guarantee that all missing death certificates can be replaced can be made.

Time Line:

Given the data transfer delays resulting in six months' lost time, and the additional two months required to obtain missing death certificates and creating the study archive, the total

(Addendum A, Page 3 of 3)

additional time required to complete the update is approximately eight months. However, AEI will expedite the completion of the study by requesting an extension of only six months, which would move the targeted project completion date forward to October 1, 1997. All milestone, deliverable and invoicing dates are accordingly extended six months.

The next payment under the original contract will be due May 1, 1996. Payment for the additional services described in this addendum shall be made in two installments of \$40,932 each, the first to be invoiced upon execution of this addendum (by February 1, 1996), and the second on or about March 15, 1996.

To date, two interim reports have been submitted (Interim Report 1 on July 1, 1995, and Interim Report 2 with the study protocol on August 1, 1995). Note that the second interim report was submitted ahead of schedule. Given the delays in transferring materials to AEI, the following schedule of interim reports will replace that in the original agreement:

Interim Report 3	February 1, 1996
Interim Report 4	May 1, 1996
Interim Report 5	September 1, 1996
Interim Report 6	January 1, 1997
Interim Report 7	May 1, 1997

This new schedule includes two additional interim reports than in the original agreement.

Accepted:

The signatures below indicate acceptance of this addendum:

For CMA:

For Applied Epidemiology, Inc:

NAME: date
TITLE:

Kenneth A. Mundt, Ph.D. date
President

CMA 112653

(Addendum B, Page 1 of 2)

VCHC-4.0-EPI-UPDATE

January 15, 1996

ADDENDUM B**Extension of Mortality Update Through December 31, 1994**Background:

According to the original agreement between the Chemical Manufacturers Association (CMA) and Applied Epidemiology, Inc. (AEI), AEI will update the mortality of the vinyl chloride workers cohort from January 1, 1983 through December 31, 1992. Because of delays in the transfer of necessary data, the study has been delayed, and it now will be possible to extend the update an additional two years, through December 31, 1994.

Justification for the Extension of Follow-up:

Given the age of the study cohort, an estimated 150 to 175 deaths may occur among cohort member *per year* during the most recent two years for which National Death Index (NDI) search services are available. These additional 350 possible deaths will enhance the statistical power of the overall study, and will provide the most up-to-date results at the completion of the study in 1997. Furthermore, given the substantial investment in the present update, the additional resources needed are quite modest for the information gained.

Budget:

Personnel (subtotal)	\$1,735
K.A. Mundt (1 hr. @\$75)	75
L. Dell (8 hr @ \$50)	400
R. Luippold (16 hr @ \$35)	560
R. Noess (4 @ \$50)	200
E. Mundt (20 @ \$25)	500
NDI search (6,000 records for 2 additional years)	2,700
Death certificate charges (350 x \$9)	3,150
<u>Coding of death certificates by nosologist (350 x \$2.50)</u>	<u>875</u>
Total direct costs	\$8,460
<u>Overhead (10%)</u>	<u>846</u>
TOTAL ADDENDUM B	\$9,306

CMA 112654

(Addendum B, Page 2 of 2)

Time Line:

Provided that the modified time line in ADDENDUM A is accepted, additional modifications to the time line will not be necessary by reason of ADDENDUM B. Payment for the services described in this addendum shall be made upon issuance of periodic invoices as the work is accomplished.

Accepted:

The signatures below indicate acceptance of this addendum:

For CMA:

For Applied Epidemiology, Inc:

NAME: date
TITLE:

Kenneth A. Mundt, Ph.D. date
President

CMA 112655