CHEMICAL MANUFACTURERS ASSOCIATION

June 19, 1995

Craig Edelman
Division of Health Statistics and Research
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Mr. Edelman:

A completed Application for Access to Protected Data is enclosed. We look forward to receiving your approval to transfer the previous death certificates from ENSR to Applied Epidemiology Inc. Three supplemental Assurance Forms, executed by Applied Epidemiology Inc., Softwhere Inc., and a consulting nosologist are enclosed.

If you have any questions, please call me at (202) 887-1192. Thank you for your cooperation.

Sincerely,

Has Shah

Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

Enclosures

2501 M Street, NW, Washington, DC 20037 Telephone 202-887-1100 Fax 202-887-1237

Responsible Care®
A Public Commitment

Commonwealth of Pennsylvania

Department of Health

HARRISBURG

(717) 783-2548

March 24, 1995

Hasmukh C. Shah, Ph.D., D.A.B.T.
Manager, Vinyl Chloride Panel
Chemical Manufacturers Association
2501 M Street, NW
Washington, DC 20037

Dear Dr. Shah:

We have reviewed your letter of March 1, 1995, requesting that Pennsylvania death certificates previously obtained by ENSR for the Vinyl Chloride Workers epidemiologic study be transferred to a new contractor, AEI.

In order to process this request, AEI must complete the enclosed Application for Access to Protected Data. In addition, any other organizations or contractors (including CMA) who will be receiving identifiable Pennsylvania mortality data must complete pages 12-15 of the application.

Please forward the materials to AEI for completion. Upon our receipt and review of the application, we will notify you in writing of approval to transfer records.

If you have any questions, please call me at 717-783-2548.

Sincerely,

Craig Edelman
Division of Health
Statistics and Research

P.O. BOX 90, HARRISBURG, PA 17108

Commonwealth of Pennsylvania

Department of Health

HARRISBURG

(717) 783-2548

I am writing in response to your recent request concerning access to protected data maintained on file by the Division of Health Statistics and Research.

Enclosed is an Application for Access to Protected Data and a User's Guide for Access to Protected Data. Please read the User's Guide before completing the Application.

If you have any questions, please call Craig Edelman at 717/783-2548. Thank you for contacting the Division of Health Statistics and Research.

Sincerely,

Patricia W. Potrzebowski

Patricia W. Potrzebowski, Ph.D.
Director, Division of Health
Statistics and Research

Enclosures

P.O. BOX 90, HARRISBURG, PA 17108

IC-1748

APPLICATION FOR ACCESS TO PROTECTED DATA

Pennsylvania Department of Health
Division of Health Statistics and Research
P.O. Box 90
Harrisburg, PA 17108
(717) 783-2548

July, 1993
(revised)

Please read *USER'S GUIDE FOR ACCESS TO PROTECTED DATA* before completing this application.

I. ORGANIZATION OR INDIVIDUAL REQUESTING ACCESS

A. Project Director: Hasmukh C. Shah, Ph.D., D.A.B.T.

B. Title: Director, Vinyl Chloride Panel

C. Organization: Chemical Manufacturers Association (CMA)

D. Street Address or P.O. Box: 2501 M Street N.W.

E. City, State, Zip Code: Washington, D.C. 20037

F. Telephone: (202) 887-1192
(area code)

G. Other persons who should be contacted if more information is needed:

1. Name: Carol Stack, Ph.D.

Telephone: (202) 887-1196

Address (if different than above):

2. Name: Kenneth Mundt, Ph.D.

Telephone: (413) 256-3556

Address (if different than above):

Applied Epidemiology Inc.

P.O. Box 2424
Amherst, MA 01004

H. Name and address of sponsor(s) or funding organization(s) for this project:

Chemical Manufacturers Association (CMA)

2501 M Street N.W.

Washington, D.C. 20037

II. TITLE OF STUDY OR PROJECT

An Update Of The Epidemiologic Mortality Study of Vinyl Chloride Workers

III. OTHER ORGANIZATIONS PARTICIPATING IN THIS STUDY OR PROJECT

List the names of organizations and/or individuals who will obtain identifiable information or individual case record data from Pennsylvania files and describe their roles in this study. Include consultants, outside nosologists, contractors, data processing vendors, subcontractors, and sponsoring or participating agencies or organizations. A "Supplemental Assurances Form" (see pages 12-15) must be completed by EACH organization (or individual) listed below and must be signed by responsible officials of that organization. The completed forms must be submitted as an attachment(s) to this application form.

Applied Epidemiology, Inc. (AEI)	Contractor to CMA
Elizabeth Smith, Medical Records Systems Manager and Consulting Nosologist	Consultant to AEI
Rainer Noess, Softwhere Inc., Computer Programmer	Consultant to AEI

IV. INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

Has this research project been reviewed and approved by an Institutional Review Board (IRB) for the Protection of Human Subjects? (An IRB approval is required if this study or project involves any "followback" activities to families, next-of-kin, or the study subject based on information provided by Pennsylvania records.)

[ ] YES: Give the name of the review board and date of approval below and attach a copy of the approval to this application.

[X] NO: Indicate reason.

Neither CMA nor AEI has an institutional review board in place at this time. Moreover, this update study does not include provisions for follow-back from death certificates to next-of-kin, physicians, hospitals, or any other individuals.

V. SUMMARY OF STUDY PROTOCOL OR PROJECT ACTIVITIES

You may append a copy of your complete study protocol (or selected sections) to this application; however, the abstract that you provide in response to these questions should be self-contained so that it can serve as a complete and accurate description of the project though separate from any appended document. Include the following information (A-F) in the description of your research plan or project activities.

It is understood that some requestors might only be indirectly involved in research or statistical activities (e.g., preparing and maintaining data files to be used in the research efforts of other organizations) or for government agency projects. If any of these situations apply, you should first describe your own activities and then indicate how the identifiable data released to you will be provided to and used by other organizations.

IN RESPONDING TO THE FOLLOWING QUESTIONS, BE AS CLEAR AND AS SUCCINCT AS POSSIBLE USING THE SPACE AVAILABLE. If you require additional space for answers, insert a separate page(s) and number each answer.

A. **Describe the health or medical problem addressed by your study or activities.**

Mortality in the industry-wide cohort of vinyl chloride workers has previously been updated through 1982. Since that date, it is anticipated that a substantial number of additional deaths has occurred among the cohort. Updating the study through 1992 will allow a number of important scientific questions regarding human exposure to vinyl chloride to be addressed.

B. **List the primary study or project objectives, and include a description of the hypotheses to be tested.**

How does the overall mortality experience of this cohort compare with a.) that of the general U.S. male population and b.) regional mortality patterns in those parts of the U.S. in which the majority of study plants were located?

2) Does the previously observed excess of mortality due to angiosarcoma of the liver (ASL) continue to appear as the cohort ages? Does the magnitude of the excess increase, decrease, or remain the same as the

C. **Summarize the project's data collection methods, indicating specific followback procedures, if they apply.**

Deaths that have occurred in the cohort since 1982 will be identified using the National Death Index and any other relevant sources of information (e.g. company records). Death certificates will be requested from the appropriate state vital records offices. All death certificates will be reviewed by a professional nosologist who will identify and code and all underlying and contributing causes of death according to the ICD revision in effect at the time of death. These data will then be combined with data collected in previous updates for this

D. **Summarize the project's analysis, indicating how the data will be used.**

Overall and cause-specific Standardized Mortality Ratios (SMRs) will be calculated using the observed numbers of deaths in the cohort and expected numbers derived by applying age-, calendar year-, and sex specific national and regional mortality rates to the person-year distribution of the cohort. SMRs and 95% confidence intervals will be calculated and reported for total deaths and for cause-specific deaths. Additional statistical analysis will be conducted as deemed appropriate.

E. **Describe any data files that will be linked with the data provided and specify the source of these data files.**

Expected numbers of deaths in the cohort will be calculated using national and local mortality rate files created with publicly available data from the National Center for Health Statistics.

F. **In what form and to whom will the results of your study or activities be released?**

A technical report for the Chemical Manufacturers Association and a manuscript suitable for publication in the peer-reviewed literature will be prepared when the analyses are completed.

B. cohort ages?

3) Is there evidence of association between vinyl chloride exposure and cancer at any anatomical site other than the liver? If so, how does this association(s) compare with that with ASL in terms of the influence of age at first exposure, duration of employment, period(s) of exposure, estimated latency, etc.?

C. cohort. ICD codes will be computerized and translated into a common code for uniform analysis and reporting. No death record followback investigation will be performed as part of this study.

VI. EMPLOYEE REGISTRY DESCRIPTION

This section (pages 5-6) should be completed only if you are planning to include Pennsylvania records in an Employee Registry.

The following information is required to provide the Department of Health with assurances that Pennsylvania records included in an Employee Registry will be used solely for statistical purposes in medical or health research.

A. What is the date that the Registry was founded?

B. What is the purpose of the Registry?

C. What is the eligiblity criteria for including persons in the Registry?

D. Will the records be flagged to identify them as Pennsylvania records?

☐ YES ☐ NO

E. Will the records be stored separately from administrative records?

☐ YES ☐ NO

F. Is your organization OSHA regulated?

☐ YES ☐ NO

If yes, can you guarantee that Pennsylvania death records will not be released to OSHA?

☐ YES ☐ NO

G. List below each study which uses records from the Employee Registry. All current studies should be included as well as anticipated studies.

A summary protocol for each study listed above must be attached to this application form. The summary should include the following information.

1. Title of Study.

2. Description of the health or medical problem addressed by your study.

3. List of the primary study objectives and a description of the hypotheses to be tested.

4. Summary of the project's data collection methods, indicating specific followback procedures, if they apply. Refer to the User's Guide for the guidelines which must be followed when using Pennsylvania records for followback activities.

5. Summary of the project's analysis and how the data will be used.

6. Description of any data files that will be linked with the data provided and the sources of these data files.

7. The form in which the results of the study will be released. Copies of any reports that are published externally should be forwarded to the Division of Health Statistics and Research.

If the complete protocol is sent in lieu of this summary, the sections from the protocol which contain the above requested information should be highlighted.

If Pennsylvania records are released for inclusion in your Employee Registry, summary protocols of any future studies (which are not included in this application) must be forwarded to the Division of Health Statistics and Research for written approval prior to using any Pennsylvania records in the study.

Any changes to study protocols, particularly with respect to followback and additional uses of the data, must be submitted to the Division of Health Statistics and Research.

VII. RECORDS AND/OR IDENTIFIABLE DATA REQUIRED

A. In the matrix below, indicate the type and form of records, identifiable data, and/or individual case record data requested. Provide an "X" in EACH box that is applicable:

	Review of Records	Copies of Records	Facsimiles/ Computer Listings	Computer Data Tapes
Death Records		X		
Cancer Records				
Other (specify)				

B. Complete this section only if you are requesting review of records or copies of records.

1. How many names do you expect to submit to the Department? 8,700

2. Is year of death and/or date of cancer diagnosis known for each name?

[X] YES [ ] NO

If yes, please specify range of years involved: 1983 - 1992

3. How many future searches do you expect to request? Unknown

4. Name the organization(s), including your own, which will be requesting review of records or copies of records (itemize your responses if more than one organization will be involved).

Applied Epidemiology Inc., Amherst, MA will be requesting copies of death records as epidemiology consultant to the Chemical Manufacturers Association

C. Complete this section only if you are requesting cancer facsimiles, computer listings, or computer data tapes.

1. Please list below the specific data items that you expect to obtain from each data file and/or those items that are specifically needed for your study.

2. How many future requests for this data do you expect to make? _____

VIII. MAINTAINING THE CONFIDENTIALITY AND SECURITY OF IDENTIFIABLE DATA

A. How will you maintain the confidentiality and security of identifiable data obtained from Department of Health records? (Identifiable data refers to any information which could permit the identification of any individual. This is not only name and address, but also individual case record data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.)

Only key Applied Epidemiology Inc. personnel who are directly involved with this project, the nosologist (E. Smith), and the computer programmer (R. Noess) will have access to confidential study data. The office in which the data will be handled and processed during the study is never left unlocked. All computer systems in which the compiled data will reside are protected with access codes and passwords.

B. Disposition of identifiable data:

1. How long will you store copies of records or other identifiable data?

All study death certificates, will be archived by the contractor, AEI, until the year 2007 (10 years following completion of the study).

2. How will you dispose of copies of records or other identifiable data?

After the ten years have elapsed, the certificates will be destroyed by shredding. Should CMA desire another mortality update of this cohort prior to that time, this destruction date would be extended.

3. If there are no plans to dispose of some or all of the identifiable data, please explain why.

Should CMA select another contractor to perform a subsequent update study, CMA will request individual state permission to transfer archived records from AEI to the approved contractor.

C. Approximate date of study completion: March 31, 1997

D. Will you require followback investigations based on information provided by Pennsylvania records to obtain additional information from decedent's next-of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned in the records?

[ ] YES [X] NO

If YES, briefly describe the following:

1. Types of followback respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

2. Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labelled appropriately).

3. Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to followback individual must also be attached and labelled appropriately.)

E. Will any of the identifiable data obtained from the records and/or followback investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?

[ ] YES [X] NO

If YES, please explain.

F. Will the identifiable data obtained from the records or followback investigations be used either directly or indirectly for any project or purpose other than the one described in Part V?

[ ] YES [X] NO

If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from Pennsylvania Department of Health records.

IX. APPLICANT ASSURANCES

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from the Pennsylvania Department of Health.

A. The identifiable data obtained following written approval from the Department of Health will be used only for the study proposed and the purposes described in the "Summary of Study Protocol or Project Activites" (Part V) and in the "Employee Registry Description" (Part VI). Use of the information for a project or purpose other than that described in Parts V and VI will not be undertaken unless a separate application form for the subsequent project has been submitted to, and approved by, the Pennsylvania Department of Health.

B. No individually identifiable data will be released without prior written approval by the Pennsylvania Department of Health.

C. If data extracted from Pennsylvania records are used in any publication, the following statement must be included in such publication or any other release of the data:

> These data were supplied by the Division of Health Statistics and Research, Pennsylvania Department of Health, Harrisburg, Pennsylvania. The Pennsylvania Department of Health specifically disclaims responsibility for any analyses, interpretations or conclusions.

D. I have thoroughly reviewed the contents of the *User's Guide for Access to Protected Data* dated July, 1993, and I will adhere to the guidelines set forth therein.

E. All statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

Hasmukh C. Shah, Ph.D., D.A.B.T.
Project Director's Name

Director, Vinyl Chloride Panel
Project Director's Title

Chemical Manufacturers Association (CMA)
Organization

Hasmukh Shah — June 7, 1995
Signature — Date

ATTACHMENT A

IC-1748

PENNSYLVANIA DEPARTMENT OF HEALTH
APPLICATION FOR ACCESS TO PROTECTED DATA
SUPPLEMENTAL ASSURANCES FORM

A separate Supplemental Assurances Form (pages 12-15) must be completed and signed by EACH organization listed on page 3 of the application form as participating in this study. The Supplemental Assurances Form(s) must then be submitted as an attachment to the application form. Additional copies of pages 12-15 may be made as required.

Name: Kenneth Mundt, Ph.D.

Title: President

Organization: Applied Epidemiology, Inc.

Street Address or P.O. Box: P.O. Box 2424

City, State, Zip Code: Amherst, MA 01004

Telephone: (413) 256-3556
(area code)

A. How will you maintain the confidentiality and security of identifiable data obtained from the Department of Health records? (Identifiable data refers to any information which could permit the identification of any individual. This is not only name and address, but also individual case record data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.)

Only key Applied Epidemiology Inc. personnel who are directly involved with this project, the nosologist (E. Smith), and the computer programmer (R. Noess) will have access to confidential study data. The AEI office in which the data will be handled and processed during the study is nevery left unlocked. All computer systems in which the compiled data will reside are protected with access codes and passwords.

B. Disposition of identifiable data:

1. How long will you store copies of records or other identifiable data?
All study death certificates, will be archived by the contractor, AEI, until the year 2007 (10 years following completion of the study).

2. How will you dispose of copies of records or other identifiable data?
After the ten years have elapsed, the certificates will be destroyed by shredding. Should CMA desire another mortality update of this cohort prior to that time, this destruction date would be extended.

3. If there are no plans to dispose of some or all of the identifiable data, please explain why.
Should CMA select another contractor to perform a subsequent update study, CMA will request individual state permission to transfer srchived records from AEI to the approved contractor.

C. Approximate date of study completion: March 31, 1997

D. Will you require followback investigations to obtain additional information from decedent's next-of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned on the records?

☐ YES ☒ NO

If YES, briefly describe the following:

1. Types of followback respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

2. Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labelled appropriately.)

3. Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to followback individual must also be attached and labelled appropriately.)

E. Will any of the identifiable data obtained from the records and/or followback investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?

☐ YES ☒ NO

If YES, please explain.

F. Will the identifiable data obtained from the records or followback investigations be used either directly or indirectly for any project or purpose other than the one described in Part V of the Application for Access to Protected Data?

☐ YES ☒ NO

If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from Pennsylvania Department of Health records.

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B. No individually identifiable data will be released without prior written approval by the Pennsylvania Department of Health.

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D. I have thoroughly reviewed the contents of the *User's Guide for Access to Protected Data* dated July, 1993, and I will adhere to the guidelines set forth therein.

E. All the statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

KENNETH A MUNDT
Name

PRESIDENT
Title

HAMMEL ENGINEERING INC
Organization

Signature

5/19/95
Date

ATTACHMENT A

IC-1748

PENNSYLVANIA DEPARTMENT OF HEALTH
APPLICATION FOR ACCESS TO PROTECTED DATA
SUPPLEMENTAL ASSURANCES FORM

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Name: Rainer Noess

Title: _____

Organization: Softwhere, Inc.

Street Address or P.O. Box: P.O.Box 350

City, State, Zip Code: Goshen MA 01032

Telephone: 413 268-3260
(area code)

A. How will you maintain the confidentiality and security of identifiable data obtained from the Department of Health records? (Identifiable data refers to any information which could permit the identification of any individual. This is not only name and address, but also individual case record data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.)

Only key Applied Epidemiology Inc. personnel who are directly involved with this project, the nosologist (E. Smith), and the computer programmer (R. Noess) will have access to confidential study data. The AEI office in which the data will be handled and processed during the study is never left unlocked. All computer systems in which the compiled data will reside are protected with access codes and passwords.

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D. Will you require followback investigations to obtain additional information from decedent's next-of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned on the records?

[ ] YES [X] NO

If YES, briefly describe the following:

1. Types of followback respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

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D. I have thoroughly reviewed the contents of the *User's Guide for Access to Protected Data* dated July, 1993, and I will adhere to the guidelines set forth therein.

E. All the statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

RAINER NOESS
Name

PRESIDENT
Title

SOFTWHERE, INC.
Organization

Signature 5/24/95
Date

ATTACHMENT A

IC-1748

PENNSYLVANIA DEPARTMENT OF HEALTH
APPLICATION FOR ACCESS TO PROTECTED DATA
SUPPLEMENTAL ASSURANCES FORM

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Name: Elizabeth Smith

Title: Consulting nosologist

Organization:

Street Address or P.O. Box: 1 Springfield St., Apt. 402

City, State, Zip Code: Chicopee, Ma., 01013

Telephone: (413) 784-2465
(area code)

A. How will you maintain the confidentiality and security of identifiable data obtained from the Department of Health records? (Identifiable data refers to any information which could permit the identification of any individual. This is not only name and address, but also individual case record data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.)

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1. Types of followback respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

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[ ] YES [X] NO

If YES, please explain.

F. Will the identifiable data obtained from the records or followback investigations be used either directly or indirectly for any project or purpose other than the one described in Part V of the Application for Access to Protected Data?

[ ] YES [X] NO

If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from Pennsylvania Department of Health records.

APPLICANT ASSURANCES

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from the Pennsylvania Department of Health.

A. The identifiable data obtained following written approval from the Department of Health will be used only for the study proposed and the purposes described in the "Summary of Study Protocol or Project Activities" and "Employee Registry Description" (Parts V and VI of the Application for Access to Protected Data). Use of the information for a project or purpose other than that described in Parts V and VI will not be undertaken unless a separate application form for the subsequent project has been submitted to, and approved by, the Pennsylvania Department of Health.

B. No individually identifiable data will be released without prior written approval by the Pennsylvania Department of Health.

C. If data extracted from Pennsylvania records are used in any publication, the following statement must be included in such publication or any other release of the data:

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D. I have thoroughly reviewed the contents of the *User's Guide for Access to Protected Data* dated July, 1993, and I will adhere to the guidelines set forth therein.

E. All the statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

Elizabeth A. Smith, RRA

Name

Consulting Nosologist

Title

Organization

Signature 5-25-95

Date