in xcess f permissible exposure limits wh n unprotected by required personal protectivs equipment and clothing."

Present section 1910.93q(b)(13) should be revised to read "Protective clothing means protective clothing and equipment protective against actual work place hazards including, where present, vinyl chloride concentrations in excess of permissible exposure limits."

D. Reference. Section 1910.93q(c) should be renumbered 1910.93q(d).

E. Regulated Areas. Section 1910.93q(d) should be renumbered 1910.93q(e) and subsection (1)(ii) should be amended to read "polyvinyl chloride containing greater than 0.1% residual vinyl chloride."

Section 1910.93q(d)(2) renumbered as (e)(2) should be modified to read "Access to regulated areas shall be limited to authorized employees and other authorized persons."

F. Monitoring. Section 1910.93q(e)(1) and (2) should be rewritten and renumbered (f)(1) and (2) respectively and a new subsection f(3) should be added as follows:

"(1) Regulated Area Monitoring. Concentrations of vinyl chloride monomer in the regulated areas shall be monitored at representative sampling points. Frequency and pattern of sampling shall be adequate to represent employee exposure in

the work-place envir nment as confirmed by personnel monitoring under subsection (2) below.

"(2) Personnel Monitoring. Personnel monitoring shall be accomplished by collecting samples using suitable devices to be worn by the employee. Sampling shall be of such frequency and duration as to represent levels of exposure of employee to vinyl chloride and to establish the confidence level of regulated area monitoring to measure maximum concentration values as well as 8-hour time weighted average concentrations. Personnel monitoring shall be done at intervals of six months or less, if necessary, to re-establish confidence level of the work-place area monitoring. Personnel monitoring shall be of a sufficient number of employees so that a representative sample of exposures to vinyl chloride may be determined.

"3) Sampling and Analytical Procedures shall be in conformity with Appendix A to this regulation." (See Appendix B to these comments for Stauffer's proposed sampling and analytical procedures.)

Section 1910.93q(e)(3) should be renumbered (f)(4) and the first sentence should be revised to read: "Designated employee representatives shall be afforded an opportunity to observe monitoring and measuring required by this paragraph."

G. Engineering Controls and Work-Practice Methods. Section 1910.93q(f) should be renumbered (g). Throughout this section the words "detectable level" should be replaced with "permissible exposure limits".

Present section 1910.93q(f)(1)(iii), renumbered as 1910.93q(g)(1)(iii), should read "Wherever no feasible engineering or work practice method can be instituted immediately or where permanent measures cannot reduce exposure levels below the permissible exposure limits, respiratory protection shall be immediately provided in accordance with paragraph (h) of this section."

H. Respiratory Protection. Section 1910.93q(g) should be renumbered (h). Stauffer is in agreement with the requirement of positive pressure air supply respiratory protection; however, we object to the requirement for all applications of a full-face air mask. A full-face air mask restricts visibility, has a tendency to become fogged and may interfere with other safety equipment. Since the primary risk of exposure to vinyl chloride is respiratory in nature and there is little risk of dermal exposure to vinyl chloride vapor or liquid in most applications, half-face respiratory protection is adequate in most circumstances. Standard safety practice requires appropriate eye protection.

I. Protective Clothing. Section 1910.93q(h) should be renumbered (i) and should then be revised to read "employees entering regulated areas shall be provided protective clothing and equipment without charge, as appropriate to the risk of exposure to vinyl chloride monomer and other work-place risks. Entry into reactors and vessels containing vinyl chloride monomer in excess of the permissible exposure level shall require protective clothing to prevent skin contact with vinyl chloride monomer or other materials containing vinyl chloride monomer including full-body protective clothing, footwear or shoe covers and gloves in addition to the respiratory protection required in subsection (h) above."

In renumbered subparagraph § 1910.93(i)(2) the first sentence should be revised to read: "Where employees are exposed to substantial quantities of polyvinyl chloride powder capable of releasing vinyl chloride in quantities in excess of permissible exposure limits, employees shall also be . . ."

J. Hygiene Facilities and Practices. Section 1910.93q(i) should be renumbered 1910.93q(j).

K. Emergency Situations. Section 1910.93q(j) should be renumbered (k) and subsection (k)(2)(ii) should be revised to read "Special medical surveillance by a physician shall be instituted within twenty-four hours for

employees present in the affected area at the time of the emergency who were exposed to levels of vinyl chloride monomer sufficient to cause a risk to health."

Subsection 1910.93q(k)(2)(iv) should be revised to read "An accident report on the emergency shall be reported as required in paragraph (r)(2) of this section where exposure of employees to vinyl chloride monomer was sufficient to create a risk to health."

L. Signs and Labels. The proposed signs and labels are inadequate to properly call employee and visitor attention to the varying types of risk present in vinyl chloride plants. We believe the following revisions necessary to insure appropriate warnings. Section 1910.93(k) should be renumbered (l) and subsection (l)(1) should be revised to read: Entrances to regulated areas shall be posted with signs bearing the legend:

DANGER!
HAZARDOUS CHEMICAL AREA
AUTHORIZED PERSONNEL ONLY

The signs required under this subsection (l)(2) should read:

DANGER!
HAZARDOUS CHEMICAL AREA
AIR-SUPPLIED EQUIPMENT REQUIRED
AUTHORIZED PERSONNEL ONLY

The labeling required under subsection (l)(3) should read:

VINYL CHLORIDE CONTAMINATED MATERIAL
HAZARDOUS CHEMICAL AGENT
DISPOSE OF OR DECONTAMINATE USING
AUTHORIZED PROCEDURES

Subsection (l)(4) should be revised to read "Containers of polyvinyl chloride containing vinyl chloride in excess of 0.1% by weight should be labeled:

POLYVINYL CHLORIDE
CONTAINS VINYL CHLORIDE
VINYL CHLORIDE IS A
HAZARDOUS CHEMICAL
ABSORBED BY BREATHING AND
THROUGH SKIN

The labeling required under this subsection (l)(5) should read:

VINYL CHLORIDE
DANGER
EXTREMELY FLAMMABLE GAS
UNDER PRESSURE
MAY POLYMERIZE WITH
EXPLOSIVE FORCE
POISON
EXTREMELY HAZARDOUS CHEMICAL
ABSORBED BY BREATHING
AND THROUGH SKIN

M. Maintenance and Decontamination. Section 1910.93q(l) should be renumbered (m) and subsection (m)(2) should be revised to read "Waste resins and other materials contaminated with vinyl chloride should be placed in appropriate containers pending disposal or decontamination."

Subsection (m)(4) should be revised to read "In maintenance or repair operations on contaminated systems

or equipment, including vessel entry, where there exists a risk of dermal exposure, employees engaged in such operations shall be . . . ."

N. Transportation Loading and Unloading. Section 1910.93q(m) should be renumbered (n) and the second sentence of subsection (n)(1) should be rewritten to read "Vent and purge effluent shall be returned to a process stream, or otherwise appropriately disposed of or contained."

O. Polymer Handling Operations. Section 1910.93q(n) should be renumbered (o) and the words "detectable levels" should be replaced with "permissible exposure limits".

P. Medical Surveillance. Section 1910.93(o) should be renumbered (p) and subsection (p)(6) should be revised to read "If the results of screening required by paragraph (p)(3) of this section are normal, screening shall be repeated annually for all employees entering regulated areas."

Q. Records. Section 1910.93q(p) should be renumbered (q) and subsection (q)(3) should be revised to read "The designated representative of employees shall be provided access to examine and copy records of monitoring and measuring."

R. Reports. Section 1910.93q(q) should be renumbered (r) and subsection (r)(2) should be revised to

read "Incidents which result in the release of vinyl chloride in excess of permissible exposure limits into any area which creates a risk to employee health shall be reported in accordance with this paragraph."

Subsection (r)(3) should read "Upon completion of any monitoring . . . which discloses that any employee has actually been exposed to levels of vinyl chloride in excess of permissible exposure limits, where such exposure has created a risk to such employees health, each such employee shall be individually notified in writing."

VII.

CONCLUSION

Stauffer Chemical Company proposes adoption of a permanent standard for vinyl chloride which will provide a three-phase reduction of permissible exposure levels based upon feasible engineering controls and work practices. We believe the proposed levels are reasonable and will prevent exposure of employees to any significant health risks.

APPENDIX A

Tabershaw-Cooper Associates Report - May 2, 1974

Mortality Study Comparing Vinyl Chloride and Polyvinyl Chloride

Worker Population vs. All U.S. Male Population for 1967

Cause of death with I.C.D. number	obs/exp	SMR[1]
All causes	352/467.28	75**
Tuberculosis (001-019)	1/5.71	19
Tuberculosis of respiratory system (001-008)	1/5.34	20
Malignant neoplasms (140-205)	79/77.16	110
Malignant neoplasms, buccal cavity and pharynx (140-148)	5/2.84	189
Malignant neoplasms, digestive organs and peritoneum (150-159)	19/21.67	94
Malignant neoplasms, respiratory system (160-164)	25/23.93	112
Malignant neoplasms, genital organs (170-179)	3/3.55	91
Malignant neoplasms, urinary organs (180-181)	1/3.60	30
Malignant neoplasms, other and unspecified sites (190-199)	17/11.75	155
Leukemia and aleukemia (204)	3/3.77	85
Lymphosarcoma, lymphatic and hematopoietic tissues (200-203, 205)	6/6.06	106
Diabetes mellitus (260)	7/6.31	120
Major cardiovascular and renal diseases (330-334, 400-468, 592-594)	155/207.46	80**
Vascular lesions affecting CNS (330-334)	13/24.48	57**
Rheumatic fever & chronic rheumatic heart dis. (400-402, 410-416)	5/6.87	78
Arteriosclerotic heart disease (420)	121/137.33	95
Nonrheumatic endocarditis (421, 422)	1/6.58	16
Hypertensive heart disease (440-443)	3/9.33	35
Other hypertensive disease (444-447)	3/2.60	124
Chronic & unspecified nephritis & renal sclerosis (592-594)	0/4.27	0
Influenza and pneumonia (480-493)	5/9.96	54*
Ulcer of stomach and duodenum (540,541)	2/3.83	56
Appendicitis (550-553)	0/0.66	0
Hernia and intestinal obstruction (560, 561, 570)	1/1.51	71
Gastritis, duodenitis, enteritis and colitis (543, 571, 572)	1/1.31	82
Cirrhosis of liver (581)	3/15.60	21
Hyperplasia of prostate (610)	0/0.39	0
Symptoms, senility and ill-defined conditions (780-795)	1/7.34	15
All other diseases (residual)	21/45.78	49**
Motor vehicle accidents (810-835)	17/32.70	56**
Other accidents (800-802, 840-962)	18/30.64	63**
Suicide (963, 970-979)	16/16.83	102
Homicide (964, 980-985)	1/11.98	9
Number of workers	7129	
Person-years	77341	

[1]SMR's adjusted for deaths with cause unknown. See Table 11.
*Significant at 5% level.
**Significant at 1% level.

May 2, 1974

APPENDIX B

Comments Regarding Sampling and Analytical Procedures

Stauffer Chemical Company proposes that the following sampling and analytical procedure be incorporated as a part of the permanent standard. The proposed sampling and analytical procedure is a modification of the original procedure developed by NIOSH and has been employed by Stauffer Chemical Company for sampling at its PVC resin plant at Delaware City, Delaware and at Stauffer's fabricating plants. Stauffer believes the proposed modifications will provide improved reliability and utility. In addition this suggested procedure has the advantage of being amenable to automation with available instrumentation technology.

The essential elements and advantages of the proposed sampling and analytical procedure are as follows:

1. Direct analysis by gas chromatography

   This procedure has proved reliable, accurate and precise. It is capable of meeting even the very stringent proposed requirements of detecting vinyl chloride at a concentration of 1 ppm with an accuracy of ± 50%. It is used quite regularly in laboratories and manufacturing operations and can be carried out routinely by properly trained personnel.

2. Analysis by infra-red absorption

This is a potential alternative procedure for the direct analysis of air samples. There remains the question of detection limit or sensitivity. We have not yet had the opportunity to test the manufacturer's claims of being capable of meeting the very stringent requirements of the proposed standard. However, it is believed that the available instruments are capable of detecting vinyl chloride at a concentration of at least 10 ppm.

3. Direct analysis for vinyl chloride

Procedures such as gas chromatography and infra-red absorption are specific for vinyl chloride in air. Any procedure or instrument which does not provide for this specific analysis is considered completely unacceptable for the purpose of monitoring, since it provides unreliable or even misleading information. Included in this unacceptable category are those which determine only total hydrocarbons or organic compounds.

4. Direct analysis of the collected air samples without prior concentration or adsorption on inert materials

All concentration or adsorption steps should be avoided. They can lead to erroneous determinations due to losses of the volatile vinyl chloride during handling and introduction of contaminants from these operations, which may interfere with the accurate determination of vinyl chloride. Concentration and adsorption steps cannot be automated by presently available technology and therefore should be considered unsuitable for routine monitoring of regulated areas.

5. Collection of air samples in regulated areas in glass collecting tubes, stainless steel collecting tubes or plastic bags

Glass collecting tubes are recommended by NIOSH and have been found completely satisfactory in use under plant operating conditions. Stainless steel tubes are equally acceptable. The use of Tedlar or aluminized vinyl plastic bags has also been found completely satisfactory and reliable. Stainless steel tubing is recommended for the collection and conduction of air samples from a number of regulated areas to a central monitoring station. The use of hypodermic syringes to

collect air samples for analysis is considered unacceptable since it does not provide for a positive seal of the sample from collection to the time of analysis.

6. Collection of personnel air samples in plastic bags

These have been found satisfactory, safe and reliable in plant use. Glass or steel collecting tubes are deemed potentially hazardous to employees and therefore, their use is not recommended. It is proposed that personnel air samples be taken over a relatively prolonged time period. For ceiling value determinations this time period should be in the 5 to 30 minute range, with 15 minutes serving as the preferable period. For TWA determinations a 6 to 7-1/2 hour period should be used.

Proposed Proc dure for Obtaining Samples and Determining Vinyl Chloride Levels in Ambient Air

SCOPE:

This method is designed to sample and analyze for vinyl chloride in ambient air at concentrations between 1 ppm and 2% by volume.

PRINCIPLE:

Timed personnel monitoring samples are taken with small battery-powered pumps into aluminized vinyl bags. Vinyl chloride is determined directly in the air samples by gas chromatography using a flame-ionization detector (FID). A 10 ft. x 1/8 in. O.D. stainless steel column packed with the porous polymer Porapak S is used. The concentration of vinyl chloride is measured by comparing the peak height for vinyl chloride in the sample to the peak height in a synthetic mixture of vinyl chloride in nitrogen.

Environmental air samples are taken with pre-evacuated one-liter glass gas balloons. Opening of the Teflon valve will provide an almost instantaneous sample. Optionally the sampling time can be extended to 5 to 30 minutes by the insertion of approximate calibrated orifices into the sample inlet. The sample is then directly analyzed by the above procedure.

APPARATUS:

1. Hewlett-Packard 5750 Gas Chromatograph with flace ionization detector or equivalent.

2. Recorder with one millivolt span, one second full-scale response.

3. 10' x 1/8" stainless steel chromatographic column packed with 80/100 mesh Porapak S (Waters Assoc.).

4. Glenco gas-tight syringes 1 ml and 5 ml.

6. Calibrated Instruments portable battery-perated controlled flow pump(s). These pumps are available from the manufacturer preset for various pumping rates between 15 ml/min. and 223 ml/min. The rate can be changed by changing a single resistor on the control board of the pump. Further information is available from the manufacturer.

7. Calibrated Instruments aluminized vinyl sample bags, approximately 7 liter capacity.

8. Gum rubber tubing 1/8" I.D.

9. Vacuum pump.

REAGENTS:

1. Vinyl chloride, with a minimum purity of 95%.

2. Compressed nitrogen.

PROCEDURE:

A. Sampling System for Personnel Monitoring

1. Connect a portable pump with 15-ml/min. sampling rate to a 7-liter bag with a suitable length of gum rubber tubing.

2. Open the valve on the bag by turning counter-clockwise.

3. Clip the pump to the clothing of the person whose exposure is to be measured. The pump itself should be as close as possible to the person's nose and mouth as the sampling inlet is around the pump housing.

4. Fasten the bag to the person in a convenient manner, and switch the pump into the ON position. There will be a delay of approximately 30 seconds before the first sampling burst.

5. At the end of the sampling period, close the valve on the bag and turn off the pump. Samples should not be collected for more than 7 1/2 hours as the bags will burst from overfilling.

6. Disconnect the bag from the pump.

7. Evacuate a glass gas balloon to less than 0.5 mm Hg by connecting it to the vacuum pump.

8. Connect the bag to the evacuated balloon with the shortest possible connection.

9. Open the valve on the bag.

10. Open the valve on the gas balloon allowing the contents of the bag to flow into the evacuated gas balloon.

11. Close the valves on the gas balloon and the bag and disconnect the bag from the balloon. The gas sample is now ready to be analyzed by the gas chromatographic procedure below.

12. The bag can be emptied by pressing on the bag with the valve opened or by connecting the bag to the vacuum pump and thus evacuating the bag. The bag can then be reused.

B. Sampling System for Environmental Monitoring

1. Evacuate a glass gas balloon by connecting it to the vacuum pump.

2. Open the valve on the galss gas balloon allowing the air adjacent to the balloon inlet to be drawn into the collecting device.

3. The gas sample is now ready to be analyzed by the gas chromatographic procedure below.

C. Determination of Vinyl Chloride

1. Chromatographic conditions:

Injection port temperature: 150 °C
Detector temperature: 280 °C
Oven temperature: 115 °C
He carrier gas: 60 ml/min. at 75-80 psi
Air: 425 ml/min.
H_2: 40 ml/min.

Under these conditions vinyl chloride showed a retention time of 4 minutes.

2. Remove 1 ml of gas from the gas sample balloon with a gas-tight syringe and inject the gas into the chromatograph through the normal septum.

3. Replicate injections of a sample should produce peak heights for the vinyl chloride within 10% relative. Replicate injections may be desired until such reproducability of sample injection has been demonstrated. Ten 1-ml samples may be taken from one of the gas balloons without having a detectable effect on the contents of the balloon.

D. Calibration

1. For each calibration mixture, accurately determine the volume of a clean, glass balloon by filling with a suitable liquid and measuring the volume of the liquid. The balloons should be thoroughly dry before use for samples or calibration mixtures.

2. Flush a glass gas balloon thoroughly with vinyl chloride-free compressed air and close the valves.

3. In a thoroughly ventilated area, connect a suitable flow-controlling valve to a source of vinyl chloride and attach a length of latex rubber hose to the valve. Restrict the outlet of the hose to diminish back diffusion of air into the hose.

4. Open the valve and thoroughly flush the length of hose with vinyl chloride until free of air contamination.

5. With vinyl chloride flowing through the hose, insert the syringe needle through the wall of the hose.

6. Flush the syringe several times by withdrawing and depressing the plunger.

7. Withdraw the desired volume of vinyl chloride into the syringe. A good practice is to withdraw a slight excess of gas and then adjust to the correct volume immediately before injection.

8. Inject the vinyl chloride into the gas balloon through the side arm septum.

9. As both the balloon and the syringe were filled at atmospheric pressure, the concentration of any

calibrati n mixture can be calculated:

$$\text{vol \%} = 100 \times \frac{\text{Volume of vinyl chloride injected (ml)}}{\text{Volume of gas balloon (ml)}}$$

$$\text{ppm, volume} = 10^4 \times \text{vol \%}$$

10. To prepare calibration mixtures of less than 50 ppm, make dilutions by syringe from more concentrated mixtures. For example, to prepare a 10-ppm mixture, prepare a 1% mixture by adding 10 ml of vinyl chloride to a glass gas balloon filled with air. Remove 1 ml of the 1% mixture and inject into a glass gas balloon filled with nitrogen. The concentration is calculated:

$$\text{ppm by vol} = 10^6 \times \frac{\text{Volume vinyl chloride}}{\text{Volume Balloon I}} \times \frac{\text{Volume taken from Balloon I}}{\text{Volume Balloon II}}$$

E. Calculation of Vinyl Chloride Concentration

1. Chromatograph a calibration mixture under the conditions and technique given in Section B.

2. Choosing the calibration mixture resulting in a peak height for vinyl chloride closest to that observed in the sample, calculate the concentration in the sample:

$$\text{concentration} = \frac{\text{peak height sample x concn. of mix}}{\text{peak height calibration mix}}$$

3. The concentration of the calibration mixture should always be of the same order of magnitude as that of the sample.

APPENDIX C

Proposed Alternative Standard for the Manufacture of Vinyl Chloride and Polyvinyl Chloride Resin Products Submitted by Stauffer Chemical Company

Comments by J. Wister Meigs, M.D.
Associate Clinical Professor, Occupational Medicine
Yale University

Stauffer Chemical Co. has proposed that exposures of workers to vinyl chloride (VC) vapor in the air of work places be limited to a 25 part per million (ppm) time-weighted average (TWA), with a 40 ppm ceiling maximum by October 5, 1974; that such exposures be reduced to 15 ppm TWA and 30 ppm ceiling maximum by October 5, 1975; and to 10 ppm TWA and 20 ppm ceiling maximum by October 5, 1976. They have asked me to comment on the health implications of this proposal.

The Stauffer proposal is a response to the proposed OSHA permanent standard of zero exposure to VC in the air, determined as less than 1 ppm & 0.5 ppm. All these proposals recognize the occurrence of angiosarcoma of the liver in certain workers who had frequent exposures to high concentrations (several hundred ppm) of VC over periods of many years, generally at least 15 or more. Since January 1974, 20 cases of angiosarcoma of the liver have been identified throughout the world among present or former workers in VC plants, a population that may be in the 20,000 range. Probably less than 3,000 of these had exposures to VC for 15 years or more. It must be presumed that VC is itself a carcinogen. Animal exposures to chemically pure VC have been followed by cancer development. Mice appear to be more sensitive to this agent than other animals tested. Angiosarcomas

of the liver have been described in mice exposed to 50 ppm VC vapor 4 hr./day, 5 days/week for 2 1/2 years. Higher doses were reported to cause higher incidence of angiosarcoma.

The reasonable probability that VC can itself be a cause of angiosarcoma of the liver does not exclude the possibility that other chemicals or conditions in vinyl products manufacture may be important in angiosarcoma development, nor the probability that host factors and/or other environmental factors play contributory roles. Nevertheless, reduction of worker exposure to VC vapors should be followed, eventually, by reduction in incidence of angiosarcoma of the liver.

The presumption, in the proposed OSHA permanent standard, that, for health reasons, worker exposure to VC must be reduced at this time to zero poses both scientific and health policy problems, even if "zero" were to be redefined as 1 ppm. One difficulty lies in the implied assumption that the risk of angiosarcoma of the liver in vinyl products workers can be handled without reference to other environmental health risks. This implied assumption should be recognized as not only incorrect but possibly dangerous to health. For example, vinyl products manufacture entails risks of explosion. An engineering solution to employee exposure to VC that inadvertently increased explosive vapor risks might easily kill more employees from occupational accidents than it saved from angiosarcoma of the liver. Some years ago, an industrial hygiene engineering "improvement" in controlling a chemical that was explosive as well as toxic was the underlying cause of a later serious explosion.

Satisfactory control of health hazards to workers from VC demands the

broadest possible view. The word "satisfactory" is intended to imply that compromises must be made by all parties including the public. The example of possible explosion hazards of engineering "solutions" is only an indication of the complexities. There are many carcinogens in our environment. During the 20 years 1950-69 the male cancer death rate in the U.S. increased by almost 20%. Increases in lung cancer deaths accounted for more than half of this increase. Tobacco smoke, especially cigarette smoke, is clearly linked to lung cancer development. Perhaps it is a co-carcinogen with such materials as asbestos fiber or products of fossil fuel combustion, both generally and in specialized industrial exposures. Logical consistency would mandate an immediate and total ban on smoking materials of all kinds in all places of business coming under OSHA, if zero exposure to known carcinogens were to be adopted as the primary principle in dealing with them. Attractive as this might sound to those of us including myself who dislike tobacco smoke and avoid it whenever possible, such a ban might have consequences rivalling those of the Volstead Act in social undesirability.

OSHA has a responsibility to deal with this known and controllable carcinogen or co-carcinogen (tobacco smoke) in a reasonable way just as it should deal with vinyl chloride reasonably. For VC this requires consideration of responsibilities of other regulatory bodies in addition to OSHA, namely the Environmental Protection Agency and the Consumer Products Safety Commission. VC vapors are discharged from plants manufacturing vinyl products. Concentrations in the atmosphere around such plants have been estimated in the 1 ppm range, but definitive information is not yet available. Vinyl products themselves can be expected to give off small quantities of VC. Actual concentrations are believed, from theoretical calculations, to

be considerably less than 1 ppm, and a few measurements in support of this have been made, but further measurements need to be made under a variety of conditions of temperature, humidity, radiation (including infra-red and ultraviolet) and interaction with other chemicals in common consumer use.

Pending the availability of information as to actual and reasonably accurately estimated exposures of the general public to VC, around industrial plants using it, and, in consumer products, standards for exposures of workers to VC should continue on a temporary basis at the lowest levels known to be feasible within overall obligations to workers and the public. The obligations include the need to maintain jobs for employees and provide products to the public while questions of relative risk are being answered and protective steps are taken in reasonable and orderly sequence.

With respect to the proposed zero standard to be measured as less than 1 ppm, all evidence available to me suggests that it would be inappropriate at this time. Not only are there credible reports that it would be technically unattainable, but its acceptance would imply a degree of risk to the general public that isn't supported by current evidence. There may be better evidence on this question after cancer epidemiologists have studied time-trends and area experience in the incidence of angiosarcoma. From the Connecticut Tumor Registry we know that 2 cases of angiosarcoma of the liver were diagnosed from 1950-71, 2 more in 1972 and another 2 in 1973. Environmental histories of these patients are incomplete but exposures to plastics may have occurred in at least 2 of the recent cases. If one were to accept 2 excess cases of malignant disease per year in Connecticut as the current contribution of VC to the total Connecticut cancer burden, they would

represent less than 0.5% of the conservatively estimated annual contribution of tobacco smoke to Connecticut cancer cases and deaths in the form of lung cancer alone. Connecticut experience should be compared with that in other parts of the country. If evidence develops that angiosarcomas of the liver are beginning to occur in patterns indicating risks at extremely low levels of exposure, the plastics industry will need to devote effort and expense toward developing substitutes with less carcinogenic potential. In that event, heavy investment in reduction of employee exposure below levels suggested by Stauffer would seem misdirected. These more complex controls would operate for so short a time that their beneficial influence on cancer incidence would be marginal at best.

Evidence about angiosarcoma cases in populations whose approximate degree and length of exposure were estimated indicates a dose-response relationship. Cases occurred in subjects who had been exposed to several hundred ppm of VC for many years. No cases have been reported as yet in groups of men exposed for 10-25 years to VC concentrations in the less than 100 ppm range. A trend in one study toward excess numbers of metastatic cancers with primary site undetermined in men with heavier and longer exposure to VC raises the possibility that careful search will identify more cases of angiosarcoma of the liver as the primary site in subjects who die of metastatic cancer. If this possibility were to be confirmed, it would add urgency to the need for comprehensive evaluation of each option available for handling the overall risk. The decision as to the degrees and types of risk to which workers may be subjected will need review and up-dating at least annually until epidemiological studies of human experience have provided reasonably reliable estimates of relative risks of

exposures to measured and calculated past concentrations of VC either in manufacture or use of vinyl products. Animal studies will be needed to quantify and compare cancer risks from VC and other aspects of vinyl products manufacture or use with risks from all pertinent exposures that might occur in manufacture, distribution and use of substitutes for vinyl products.

The final decision whether vinyl plastics or other materials will be manufactured and sold must be reached with recognition of the fact that the public will eventually pay for the cost of the decision, and consumers should, therefore, be involved, through suitable representatives in the search for reasonable solutions to the problem. For the present, however, based upon the available medical evidence and human experience data, it is my opinion that the worker exposure levels proposed by Stauffer are reasonable.

J. Wister Meigs

J. Wister Meigs

New Haven, Connecticut
June 24, 1974