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From E. R. Smith 3-11-76

Mr. Don R. Goodwin
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Dear Mr. Goodwin:

Enclosed herewith, on behalf of the Vinyl Chloride and Polyvinyl Chloride Producers Group of The Society of the Plastics Industry, Inc. ~~are~~, are ~~the~~ ~~Proposed Standard for Vinyl Chloride~~ published in 40 Fed. Reg. 59532 on December 4, 1975. As we testified at the public hearing on the Proposed Standard on February 3, 1976, we commend the Agency for adopting an approach which allowed an open exchange of information between the technical people of the Agency, the industry, and other interested parties. We also support the Agency's utilization of a Quantitative Risk Assessment Analysis in determining the appropriate control technology, although as I also testified we believe the Agency did not weigh finely enough the costs against the benefits likely to be achieved in protecting public health.

Although there is much with which we agree, there are also a number of individual statements and assertions in the Proposed Standard and supporting documents which we consider erroneous. The two documents I am enclosing to spell out our differences are as follows:

1. Comments on the Standard and its supporting documents prepared by the Technical Subcommittee of the Vinyl Chloride and Polyvinyl Chloride Producers Group; and
2. Comments by the Health Subcommittee of the Vinyl Chloride and Polyvinyl Chloride Producers Group.

AIR POLLUTION

We urge the Agency to take these comments into account before the final Standard is promulgated; to correct the errors noted in the attached statements; and to weigh more carefully some of the control requirements whose costs we believe far exceed any potential benefit.

There were four specific matters raised when the EPA panel was questioning me during the public hearing on February 3. To complete the record, the following comments are respectfully submitted.

1. We were asked by Mr. Farmer (Transcript of Proceedings, hereinafter: "Tr." page 68) to comment on "...the uses of PVC and then the possible substitutes for PVC in all these end use applications." EPA's own reports on this question have already covered the widespread and diversified uses of PVC in the medical, construction, appliance, electrical, transportation, packaging and many other industries.

As to the concept itself, we respectfully submit that substitutability per se is not a valid issue. First, our legal research confirms Dr. Kuzmack's observation that there is no authority in the Clean Air Act for EPA to ban selected uses of PVC (Tr. 52). Secondly, under the proposed Standard, the level of VCM emissions would be reduced by 95 percent; at such low levels there is no clearly established health risk and, hence, no danger to the public health which must be further obviated. Finally, even given exhaustive investigation of questions interrelating safety, costs, availability of raw materials, production and technological capability, capital investment and other related issues, as a practical matter substitutability remains an imponderable. Thus, under the circumstances of this case, we do not believe it would be fruitful for EPA to explore these issues further.

2. In response to Dr. Knelson's question (Tr. 71) about dialysis machines, the principal usage of PVC is in the extensive tubing which circulates the patient's blood through the machine.

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3. To Dr. Marcus (Tr. 76) I promised to clarify the dates "... when Maltoni first informed industry and industry first informed EPA ..." about the preliminary results of Maltoni's inhalation studies with rats. Industry was first informed at a technical symposium in Bologna, Italy held from April 9 to April 12, 1973. This can be confirmed by Dr. Saffiotti of NIOSH who was in the audience. The USA VCM/PVC industry representatives did not report to EPA; this information was reported to NIOSH as required by regulations promulgated under §20 of the Occupational Safety and Health Act.

4. Dr. Marcus also asked (Tr. 82) for a response on SPI's position regarding toxic substances legislation. We generally support the moderate, responsible approach of the McCollister Bill (H.R. 7664).

Finally, we want to re-emphasize our belief that EPA leadership is needed to develop a vinyl chloride health research program under the joint sponsorship of expert representatives from government, industry, labor and other interested groups. A further reason for this approach was provided on the very day of the EPA hearing on the Vinyl Chloride Standard by way of the sensationalized disclosure of a new study relating to whether vinyl chloride is a potential mutagen. The report in question was not available to any of the industry representatives who testified at the hearings, nor was it made a part of the record. Instead, it was released directly to the press by the Health Research Group, under circumstances which did not permit rational discussion of the information or informed industry comment. We comment in more detail on this subject in the attached Comments.

Thus, while the vinyl chloride and polyvinyl chloride producers obviously believe that the concerns raised in the study should be explored further, they do not believe that a press release provides the best means to evaluate the risks involved nor the further precautions, if any, which should be observed.

The producers have expressed their willingness to provide their full share of the costs of jointly-sponsored research in the best interests of the general public and

of the workers directly involved. The questions involved are too important to be dealt with by acrimonious and sensationalized debate. Unfortunately, recent history indicates that until the government exercises leadership in bringing all interested parties together, we are all too likely to see more time and money wasted on disputed research and incomplete or even biased discussion of scientific evidence.

In closing our written submission to EPA, we again want to express appreciation for the careful manner in which EPA is handling the development of this Standard. We would be pleased to respond to any further questions you might have or which might arise as a result of the comments of others.

Respectfully submitted,

Ralph L. Harding, Jr.
President

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COMMENTS ON
ENVIRONMENTAL PROTECTION AGENCY'S
PROPOSED STANDARD FOR VINYL CHLORIDE
AND
ITS SUPPORTING DOCUMENTS

Prepared by
VCM and PVC Producers Group
The Society of the Plastics Industry, Inc.

February 23, 1976

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COMMENTS ON
ENVIRONMENTAL PROTECTION AGENCY'S
PROPOSED STANDARD FOR VINYL CHLORIDE
AND
ITS SUPPORTING DOCUMENTS

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Health Subcommittee Comments on Proposed Vinyl
Chloride Standard.

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COMMENTS ON
ENVIRONMENTAL PROTECTION AGENCY'S
PROPOSED STANDARD FOR VINYL CHLORIDE

Introduction:

Representatives of the Vinyl Chloride Monomer and Polyvinyl Chloride Producers Group of The Society of the Plastics Industry, Inc. have reviewed the Environmental Protection Agency's Proposed Standard on Vinyl Chloride and its supporting documents and have prepared these reports incorporating various comments and suggestions for revisions.

These Comments are divided into two sections. The first includes general comments on the Preamble to the Standard, the Standard, and its supporting documents; the second covers comments by the Health Subcommittee of the VCM and PVC Producers Group.

In the preamble EPA made five specific requests for additional information or Comments. We are responding to three requests and have suggested that the individual companies respond to the remainder.

1. The first request was for additional data on ". . . resins containing less than 50% vinyl chloride". Industry decided that

this request was relevant to only a few companies and that the companies involved could better present the information. Hence, we will offer no Comments.

2. The second request was to ". . . furnish information and data on laboratories and pilot operations. . ." to enable EPA to make a reasonable judgment on whether such facilities should be exempted or included in the Standard. We gathered information from 15 companies and, on the basis of that data, request hereinafter the exclusion of certain, smaller-sized vessels from the entire Standard.

3. The third request was for ". . . interested parties to submit additional information on stripping technology." We decided not to comment on this area because EPA has been kept completely up-to-date on stripping technology. If there is any new information, individual companies are in a better position to comment.

4. The fourth request was for Comments on the daily averaging concept. We believe

that the averaging-by-grade concept is essential, but that the 24 hour averaging is much too restrictive and should be expanded to make plant scheduling possible. A monthly or 30 day average is suggested.

5. The final request from EPA concerns the wisdom of permitting the manual venting of reactors to regain control prior to and in prevention of a massive release of vinyl chloride when the relief valve would otherwise discharge. As discussed in the following Comments, we contend that this concept must be accepted by EPA.

COMMENTS ON
PREAMBLE TO STANDARD

The conclusions presented in the support documents which are subsequently used to justify the need for a Vinyl Chloride Standard are of major concern to the industry. The information alleged as evidence of adverse health effects, the existing ambient air levels and the extent of human exposure to vinyl chloride are overstated because the data on which it is based is not as accurate as it should have been. Consequently, the Preamble to the proposed Standard contains some errors, and uses some obsolete data which lead to unjustified conclusions.

One reason the data is in some respects deficient was the large amount of information industry was required to produce in an extremely limited period of time. On May 30, 1974, the industry was requested by Mr. Don R. Goodwin of EPA to provide the following data on very short notice.

- A. Process flow sheet showing all sources of air emissions, composition, and pounds emitted per pound of product and per hour. Actual data is preferred but best estimate would be acceptable.
- B. Emission control devices described in detail with investment and operating cost data.

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- C. Fugitive emissions estimated by material balance.
- D. Emission control procedures.
- E. Ambient air sampling results with plant layout showing sampling points.
- F. Description of each emission source in terms of stack height, stack diameter, gas flow, gas temperatures, etc.

Even for a large company with abundant resources the task was difficult especially since the companies were involved at the time in proceedings before OSHA. Most data were provided to EPA by mid-summer, 1974. The quality of the data naturally suffered and much of the information supplied by the industry was a "best estimate" or "best guess."

Fugitive Emission Data

The industry believes that EPA's estimate of the amount of fugitive emissions in the ambient air is overstated because it used a materials balance accounting which incorrectly combined polyvinyl chloride solids and gases and because it failed to take into account fugitive emission reductions which had been and are being achieved as a result of the OSHA Standard.

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The requested estimate for fugitive emissions was determined by materials balance test. The test is inherently inaccurate. An engineering material balance is an assembly of measurements and analyses reduced to pounds of material. It is highly unusual if the weight of material going into the process equals the weight of material coming out.

Items that distort material balance data are: measurement errors, railroad car scales are seldom more accurate than 2%, tanks are seldom precisely calibrated and gauging is often 5% or more in error. Moreover, many PVC manufacturers overfill 50 lb. bags of resin by four to eight ounces to avoid short-weight complaints by customers. Particulate emissions from solids collection systems are highly variable and very difficult to determine (EPA in its Standard Support and Environmental Impact Statement Table 4-11 shows representative losses from solids handling equipment which range up to 1% of the material collected.) Even in one of the most highly regulated industries, ethyl alcohol manufacture, the Department of Treasury accepts a material balance accountability of 95% or more as being the most accurate reasonably measurable.

In addition, there was a major deficiency in the calculation of fugitive emissions by EPA. EPA hired the

Houdry Division of Air Products and Chemicals, Inc. to compile and correlate fugitive emissions data supplied by industry in 1974. Based on this data Houdry issued a report entitled Engineering and Cost Study of Air Pollution Control for the Petrochemical Industry Volume 9 Polyvinyl Chloride Manufacture (EPA-450/3-75-006-1). Within that report, Tables PV-1, PV-2, PV-3 and PV-4 show net material balances for each process. Houdry estimated representative unaccounted for material (fugitive emissions) for the various resin processes as follows:

<u>Resin Process</u>	<u>Unaccounted for PVC (Fugitive Emission) % of Material Processed</u>	<u>Unaccounted for VCM (Fugitive Emission) % of Material Processed</u>
Suspension	0.76	0.76
Dispersion	0	0.96
Bulk	0.45	0.45
Solvent	0	0.03

Industry believed that the unaccounted for losses were divided between vinyl chloride gas losses and polyvinyl chloride solid losses, and so informed the Agency. But, in the Agency's treatment of the data all such losses were assumed to be vinyl chloride gas, and EPA modified the data from their contractor as follows:

<u>Resin Process</u>	<u>Fugitive Emissions of VCM % of Material Processed)</u>
Suspension	1.52%
Dispersion	0.96%
Bulk	0.90%
Solvent	0.03%

EPA's modification inflated what was already a "best estimate" by nearly 100%. Having arrived at an estimate of "fugitive emissions" that cannot be verified, EPA now proposes to reduce it by 90% by equipment and procedure specifications.

EPA also did not sufficiently consider the impact of the OSHA Standard on fugitive emissions. The industry-wide survey on which EPA bases its Standard is over 1-1/2 years old, during which time a Standard promulgated by the Department of Labor Occupational Safety and Health Agency was being put in effect to control and to limit worker exposure to vinyl chloride monomer. The Preamble does not adequately address the changes made to attempt to comply with the OSHA requirements; in fact, these have reduced fugitive emissions.

Paraphrasing EPA's statements supporting their selection of fugitive emissions as a major emission source, the industry data shows the individual fugitive emission

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sources cited by EPA are small and the total of all these sources is small if they could be accurately measured.

Misuse of Fugitive Emission Data

In addition to our concerns about how EPA determined the amount of fugitive emissions, industry is also concerned with the misuse of the early fugitive emission data gathered by the Agency. There has been repeated reference in the Preamble and the Standard Support documents to "some occasional peak concentrations as high as 33 ppm" (emphasis supplied). The STAR Document correctly states at 4.2.2 that there was only "One instantaneous value of 33 ppm [which] was observed at a distance of 0.5 km from the (center) of the plant and 4 mean values exceeded 1 ppm. The data from the 24-hour integrated samples indicated the highest value to be 0.55 ppm for the November, 1974 study." (emphasis supplied)

Even more puzzling is EPA's unwillingness to use information in its possession. The Preamble states that the results of the extensive environmental test program at three plants "conducted...from November 1974 to June 1975 are not discussed in detail because they are still being analyzed." The STAR Document, Section 4.2.6 contains some of the raw data and a brief analysis of part of this test program which show that the concentrations found at the time

are less than those predicted to prevail after industry complies with the proposed Standard. The arithmetic average of 1903 24-hour measurements was 0.005 ppm, and no sample --taken 1000 m or more from the source--was above 0.1 ppm.

We believe that before an excessive Standard is imposed on an industry, EPA should have at least analyzed this data in greater detail and taken it into consideration.

Angiosarcoma Case Data

This is another area which causes industry concern. The Preamble and the supporting documents imply that persons who have been exposed to vinyl chloride at lower levels than usually encountered in polyvinyl chloride production have developed angiosarcoma. Preamble p. 59532, col. 3; Standard Support Document p. 2-3; STAR Document, p. 72 Section 6.3.1.

In support the Agency relies on one United States case and three European cases of workers exposed to vinyl chloride but not directly involved in polyvinyl chloride production. At the time the proposed Standard was issued, however, the U.S. case had been dropped by NIOSH from its listing of workers with angiosarcoma. The three European cases also suggest either substantial exposure to vinyl chloride or a primary site other than the liver. Case

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Italy 01 is shown to have had as the primary site the pericardium. Case Sweden 02 is shown to be a vinyl chloride production worker, in an old acetylene process where the exposure was high. Case W. Germany 03 was a filler of aerosol cans, where the leakage is thought to have been severe, and therefore, experienced a high exposure.

When the proposed Standard was issued or shortly thereafter, EPA had more recent information that there was "no evidence that living around vinyl chloride plants is a factor in the occurrence of liver angiosarcoma" (Risk Assessment Document E-5); and no evidence "that angiosarcoma has been produced by vinyl chloride monomer in the general population" (Hearing Transcript, p. 42).

Since the Preamble and supporting documents discuss only questionable worker cases and not more recent information available to the Agency, they create a misleading impression about potential danger to the public health.

Additional Errors

The Preamble and Support documents also contain additional errors, for example:

- (1) Incorrect conversion factors are used to convert from liters to gallons

throughout the proposed Standard and the Standard Support Document (e.g., see 161.65(c) and 8.2.4, pp. 8-23, respectively; discussion concerning emissions from process equipment.),

(2) An error was made in calculating the residual vinyl chloride vapor in a reactor leading to a standard only 50 percent of the proper value (see pp. 4-71,

(3) The statement is made that the decision by the Agency to promulgate a Standard for asbestos based upon best available control technology has not been tested in the courts. At best, this is confusing. The legality of the asbestos Standard has been tested in six cases and five of them result in the decision that it is illegal, at least to the extent the Standard is

based upon work practices. See, U.S. v. Adamo Wrecking Co., CR No. 5-80297 (E.D. Mich, June 6, 1975); U.S. v. Harvey Wrecking Co., No. 74 CR 758 (N.D. Ill. 1975); U.S. v. National Wrecking Co., No. 75 CR 755 (N.D. Ill. 1975); and

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U.S. v. Big Chief, 7 ERC 1840 (E.D. La., April 23, 1975).

(4) In 40 F.R. 59532, Column 3, para. 3 the statement is made that: "Occupational exposure studies have strongly implicated vinyl chloride as a human chemical carcinogen which causes tumors in many different sites..." Industry believes the source of this statement to be the Tabershaw-Cooper report presented by industry at the OSHA hearing, in which the authors specified that this finding is not statistically significant. There are several parallel studies which show no such suggestion.

Impact of 10 ppm Limitation is Unclear

After reviewing the Preamble and proposed Standard on vinyl chloride emission as well as the Standard Support and Environmental Impact Statement, Emission Standard for Vinyl Chloride, the industry believes that EPA has not stated its intent clearly with regard to emission limitations in the wording of the proposed Standard. EPA has generally selected the best available control technology and has set limits which it believes will force the plant owner/operator to the

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limit of that control technology. On page 5-3 of the Standard Support Document, EPA points out that it has not used "conceivable alternatives which represent more stringent levels of control than those included in this chapter." The Agency also states:

"...there are emission points for which double control measures could achieve a small increment in emission reduction at a disproportionately high cost. For example, two carbon adsorption units could be installed in series so that a second carbon adsorption unit could be used to collect any emissions from the first carbon adsorption unit during break through."

This philosophy, however, is not evident in the wording of the Standard. In every case in the Standard where a concentration limit or emission is specified the words are "...is not to exceed 10 ppm; is not to exceed 0.001 kg/100 kg of PVC; there are to be no vinyl chloride emissions; or contains no more than 2.0 percent." The language in the Standard leads to the conclusion that the limitations can never be exceeded.

In the operation of any control system there are, as EPA notes, in the Standard Support Document with regard to carbon adsorbers, aberrations and variations. Some of these factors are:

1. In the case of cyclic equipment such as carbon adsorbers, a short aberration in the vent concentration called break through when a new bed is switched on and the old one regenerated.
2. There is a problem regarding equipment reliability. If one could purchase or build each item of equipment to function at 99% of the time, a highly unusual situation, assembly of a series of five or ten items quickly reduces that availability to 95% or 90%. Even duplicating systems cannot guarantee 100% availability.
3. The problem of measurement accuracy contributes to variation. EPA has

specified a highly sophisticated vinyl chloride detector as the measuring device. These detectors are subject to random errors or precision errors which tend to equalize over a period of time and system errors which are the built-in bias of the measuring instrument.

4. In use of "best available control technology" there is a final factor which might be called uncertainty with respect to commercial use." When an agency requires the use of "best available technology," it is assumed the technology has been developed and is or may be available for commercial application. What is not established is how the proposed technology may work when applied in a number of different plants which have different processes. Even though "best available control technology" may be available, there is an enormous uncertainty as to

how reliable and dependable this technology will be when applied on a commercial basis at specific plants.

Since as a practical matter it is inevitable that the 10 ppm limitation will be exceeded at some time unless multiple back-up systems are employed at a "grossly disproportionate cost," the Standard should allow for measurement on a time-weighted average basis.

Problems Created by 24-Hour Averaging

EPA recognized the averaging problem in the setting of a single limit of 0.04 kg/100 kg when it set a second limit for dispersion resins of 0.20 kg/100 kg and permitted averaging across resin grades on a daily basis. While all the changes noted are improvements over the single limit concept of 0.04 kg/100 kg for all resins and processes, they are still inadequate and pose undue hardship on the industry.

If EPA plans to base the limits on best available technology, the limits should be more closely keyed to resin processes and resin grades. For example, a representative PVC plant might produce the following resin grades:

	<u>Contained VCM After Stripping</u>
Product Line A	200 ppm
Product Line B	900 ppm
Product Line C	400 ppm

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With all three lines running equally, the twenty-four average concentration is 500 ppm. However, if one line produces product B 70 percent of the time and product A the remaining time (in conjunction with lines A and C as shown), the average emission for a thirty-day period would be 337 ppm. Since the limitation is calculated on a twenty-four hour basis, on any given day, the plant manager would have to balance production based on meeting the Standard rather than what customers had ordered. It is likely that some easily stripped resins would become overstocked and artificial shortages of less easily stripped resins would occur. A longer averaging period of thirty days coupled with some maximum daily limits is essential for necessary operating flexibility and is thus compatible with EPA's goal of emission limitation.

The industry believes the current daily averaging proposal for stripping imposes a hardship on the entire industry, is especially restrictive on the small producer, and, thus, should be extended to 30 days.

Reactor Opening Loss Emission Averaging

In the case of reactor opening limitation, the requirement that each reactor opening must meet the limitation is burdensome, and, in addition, may cause hazardous

situations. EPA has discussed in the Standard Support Document on page 4-71 its logic in developing the Standard. It requires that each reactor run an average of 3.5 batches before opening and cleaning. The rate of fouling and/or the need for cleaning varies from one resin recipe to another. Traditionally, on the completion of each batch, the plant owner or operator has made a judgment based on inspection, heat transfer, equipment condition or history as to whether the reactor should make another batch or whether it should be cleaned. Failure to clean at the proper time leads to a high percentage of runaway reactions and emergency venting to the air. Cleaning too often is costly and results in higher emissions. The proposed Standard requires multiple batches between each opening and cleaning; thus, a plant operator with a reactor that fouls after one batch must choose between violating the Standard or operating a reactor in an unsafe manner. This was certainly not EPA's intent in proposing the Standard.

The reactor opening emission should be changed to permit averaging all reactor openings over a 30-day period.

Dispersion Resins

The Preamble and the proposed EPA Standard imposes different requirements for the production of polyvinyl

chloride dispersion resins from those which are applicable to the production of other types of resins. EPA recognized the greater difficulty in stripping dispersion resins and the existing state of the technology relating to stripping of dispersion resins. 40 F.R. 59537-38. As EPA recognized in the Preamble to the proposed Standard, achievement of the requirements for dispersion resins in the proposed Standard is dependent upon the development of more advanced control technology in the period subsequent to the promulgation of the Standard and prior to the effective date of some of its provisions. 40 F.R. 59538.

Extensive scientific research is presently being conducted to develop this control technology and these efforts have been successful for many dispersion resin products. However, after more than ten months of concentrated research, there still remain several dispersion resin products which cannot be stripped to 2000 ppm RVCM. Stripping capability for these dispersion resins range from 3000 to 10,000 ppm RVCM. It now appears uncertain that sufficient time remains to allow development, engineering, equipment procurement, installation, and demonstration of the necessary stripping equipment within the maximum compliance time. Due to these factors, the industry requests additional consideration by EPA regarding dispersion resins prior to promulgation of the final Standard.

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Specifically, the industry requests the allowable RVCM content of certain dispersion resins to be set at 6,000 ppm. The specific dispersion resins to which this 6,000 ppm limit should apply shall be based on a manufacturers demonstration that specific resins cannot be stripped to a commercial scale of 2,000 ppm.

The industry pledges its efforts to continue re-searching methods of stripping all dispersion resins to an RVCM level of 2,000 ppm or less and invites EPA to reevaluate the status of dispersion resin stripping technology in mid-1978 and to amend the regulation as appropriate.

Conclusion

Industry concludes that fugitive emissions have been inaccurately calculated, the impact of the OSHA Standard has been inadequately considered, the angiosarcoma cases insufficiently analyzed and errors of fact considered in the Preamble. Therefore, the industry respectfully suggests EPA analyze carefully our suggestions and revise the Preamble and Standard accordingly.

COMMENTS ON THE STANDARD

61.60 Applicability.

It is recommended that 61.60 be amended by addition of the following:

"(d) Research, development and quality control facilities using test equipment of 500 gallons and below are exempt from the provisions of this standard. Facilities with test equipment larger than 500 gallons shall be limited in emissions to 5 pounds vinyl chloride monomer for every 100 pounds of product. No other part of this standard shall be applicable to these facilities."

Rationale:

Research, testing, and pilot plants are important tools in developing new products, improving productivity, devising new procedures to achieve lower emissions, and enhancing safety. Such work involves reactions of vinyl chloride in small glass vessels, miniature reactors set up on a laboratory bench and/or small reactors. These facilities are operated on a "need to investigate" basis and therefore operate intermittently. To require that each reaction or other experiment be

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fully equipped with the various required control devices to meet a 10 ppm maximum concentration would be extremely burdensome as well as delay needed work to advance emission and safety control technology.

Many experimental equipment set-ups are not permanent installations. In fact, a particular set-up may involve only one experiment. To comply with the proposed Standard, the operator would have to conduct emission tests on each laboratory set-up, submit reports on the tests, an initial operating report, a semi-annual report and maintain records of emissions for two years.

In addition to testing and reporting, the requirements in the section on fugitive emissions become quite cumbersome in pilot operations. The sample flask system on a small reactor becomes almost as large as the reactor itself. Pilot size pumps are simply not available with double mechanical seals. Finally, a formal leak detection and elimination procedure would be burdensome, and stripping of waste water to 10 ppm VCM concentration seems excessive in this case.

The current data in Table I, collected from 14 SPI companies representing 75 percent of the nameplate PVC

Table 1

EMISSION DATA ON
LABORATORY AND PILOT FACILITIES
UTILIZING VINYL CHLORIDE

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<u>Company Code</u>	<u>Reactor Size (gal.)</u>	<u>Number of Units</u>	<u>Produced Rate (lb/yr)</u>	<u>Estimated Total Emissions per Year (lb)</u>	<u>Resin Use</u>
A	50	2	30,000	400	Testing and scrap
B	0.4	6	1,084	89	Experimental
	3.25	1	987	100	Experimental
	300	1	36,450	5,000	Tests, trials in lab and to customers
C	50	1	17,000	2,800	Sold as off grade
D	0.5	1	192	48	Scrap
	0.8	4	2,112	697	Scrap
	0.8	2	600	878	Scrap
	15	6	23,100	240	Scrap
	30	1	960	240	Scrap
	30	2	28,800	266	Scrap
	1100	2	666,000	10,656	Scrap
E					Divided between:
	300	2	113,812	10,000	1. Experimental evaluation & tests
	5	3	400	6,075	2. Customer samples
	10	1	100	3,038	3. Remainder is placed in landfill (about 80%)
F	.5	1	380	25	Experimental
	10	2	27,338	1,600	Experimental
	50	2	136,687	10,800	Experimental
G	.5 to 2	11	16,000	225	Scrap
	50 to 100	5	10,000	500	Scrap
	750	2	50,000	2,000	Customer Sampling and scrap
H	200	1	72,900	17,045	Testing
	15	1	5,468	928	Testing
	10	1	608	100	Testing

Table I

<u>Company Code</u>	<u>Reactor Size (gal.)</u>	<u>Number of Units</u>	<u>Produced Rate (lb/yr)</u>	<u>Estimated Total Emissions per Year (lb)</u>	<u>Resin Use</u>
I	0.5	7	2,245	110	Testing
	50	7	75,634	4,870	Testing
	200	1	2,430	192	Testing
	220	1	12,029	3,110	Testing
	500		7,594	60	Testing & sampling
	1,000	1	33,413	460	Testing & sampling
J	5	4	76	8	Testing & scrap
	30	1	5,285	321	Testing & scrap
	300	1	31,894	2,582	Testing & scrap
	2.5	1	1,823	100	
K	10	1	606	30	
L	12.5	4	15,480	1,548	
	200	1	24,000	2,400	
M	30	2	34,172	375	Product research
N	10	2	66,582	21,920	Blending and/or scrap
	30	1	24,698	2,740	Blending and/or scrap
O	0.5	1	1,200	1,700	Testing
	1	7	1,063	350	Testing
	10	2	304	50	Testing
	100	1	6,075	1,000	Testing
	500	1	1,519	100	Testing
	600	1	364,500	4,000	Testing & blending into normal production

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capacity in the U.S. illustrates that estimated emissions from 113 test sources account for less than 0.06 percent of the total monomer emissions from all sources before control and 1.0 percent after all model plant controls are in use.

The vessels used for these experiments range from under 1 gallon to 1100 gallons. The ninety vessels of 50 gallons and below represent more than 50 percent of these emissions sources. It is recommended that vessels "500 gallons and under" be exempt from all emission standards because of the aforementioned data and because OSHA guidelines adequately protect the workers. Vessels over 500 gallons should be regulated to limit emissions to 5 pounds vinyl chloride monomer per 100 pounds of PVC produced.

61.64 Emission standard for polyvinyl chloride plants.

61.64 (a) (2)

Rationale:

There is an error in the basic assumption used to arrive at the figures of 0.001 parts of vinyl chloride released from reactor openings per 100 parts of polyvinyl chloride produced. This arises from the calculation shown on page 4-71 of the Standard Support Document EPA 450/2-75-009 (see also the preamble to the Standard in 40 FR 59538). Where

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a reported result of 8000 ppm of vinyl chloride is used as 0.008 lb/lb, the reported analysis is in mole percent, or volume percent, not in weight percent. In order to convert to weight percent it is necessary to multiply by the ratio of the molecular weights of vinyl chloride and air, or 62.5/28.8 or 2.17. Performing the calculation correctly gives a figure of 0.002 parts per 100 parts, and 61.64 (a) (2) and the remainder of the Standard should be corrected to this figure.

In addition there is an inherent assumption in the Standard Support Document that a given number of reactions can always be run prior to opening a reactor. Reactor opening is totally dependent upon the rate of fouling by the particular process, the particular resin recipe and the particular reactor involved. Reactors of some processes must be cleaned and/or opened after every batch while others may run almost indefinitely. Any effort to force a minimum number of runs on each reactor will create a safety problem as discussed elsewhere in these comments.

In processes where multiple batches are run, upsets take place requiring a reactor to be opened for a safety check. At times fouling becomes worse for a period of a few days to a week requiring the reactor to be opened every batch.

Allowing a facility to average their allowance over 30 days will not increase their total amount of emission and will allow a producer to open a reactor when necessary. The allowance of this change will also require the following change in 61.67 (g) (5) (i):

"The reactor opening loss for which an emission limit is prescribed in 61.64(a) (2) is to be determined as follows:

(i) Except as provided in paragraph 61.67(g) (5) (ii) of this section, the reactor opening loss is to be determined using the following equation:

$$C = \frac{W(2.60)(10^{-6})(cb)}{YZ}$$

where:

C = kg vinyl chloride emissions/kg product

W = capacity of the reactor in m³

2.60 = density of vinyl chloride at one atmosphere and 20° C in kg/m³

10⁻⁶ = conversion factor for ppm

cb = ppm by volume vinyl chloride as determined by Test Method 106 or a portable hydrocarbon detector averaged for the reactor openings which occurred during the 30 day period.

Y = number of batches produced during the 30 day period

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Z = average kg of polyvinyl chloride produced per batch in the number of batches produced during the 30 day period

(A) If Method 105 is used to determine the concentration of vinyl chloride (cb), the sample is to be withdrawn at a constant rate with a probe of sufficient length to reach the vessel bottom from the manhold. Samples are to be taken for 5 minutes within 6 inches of the vessel bottom, 5 minutes near the vessel center, and 5 minutes near the vessel top.

(B) If a portable hydrocarbon detector is used to determine the concentration of vinyl chloride (cb), a probe of sufficient length to reach the vessel bottom from the manhole is to be used to make the measurements. One measurement will be made within 6 inches of the vessel top. Measurements are to be made at each location until the reading is stabilized. All hydrocarbons measured are to be assumed to be vinyl chloride.

(C) The production rate of polyvinyl chloride (Z) is to be determined by a method submitted to and approved by the Administrator.

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(D) Where more than one reactor size is used, the reactor opening loss is calculated for each reactor size. The reactor opening loss for all reactors is then calculated as an average of the losses for the individual sizes weighted for the production from each reactor size.

$$C = \frac{C_1 Y_1 Z_1 + C_2 Y_2 Z_2 + C_3 Y_3 Z_3 \dots}{\frac{Y_1 Z_1}{1 \ 1} + \frac{Y_2 Z_2}{2 \ 2} + \frac{Y_3 Z_3}{3 \ 3} \dots}$$

(ii) A calculation based on the number of evacuations, the vacuum involved, and the volume of gas in the reactor is hereby approved by the Administrator as an alternative method for determining reactor opening loss for postpolymerization reactors in the manufacture of bulk resins."

Therefore the industry recommends that 61.64(a)(2) be amended as follows:

"...0.002 kg vinyl chloride chloride/100 kg (0.002 lb vinyl chloride/100 lb) of polyvinyl chloride product, averaged over a thirty (30) day period, with the product determined on a dry solids basis. This requirement applies

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to any vessel which is used as a reactor and a stripper. In the bulk process, the product means the gross product of pre-polymerization and postpolymerization."

61.64(b), (c) & (d)

The inclusion of the words "is open and" in the last sentence of this paragraph is inconsistent with the wording "before opening" in paragraph 61.65(b) (6) (i) to which this sentence applies. To resolve this discrepancy, we suggest the last sentence of paragraphs 61.64(b), (c) & (d) be reworded as follows:

"This requirement does not apply to equipment that meets the requirement in 61.65(b) (6) (i), or losses which occur from operations which are in compliance with 61.64(e)."

Rationale:

The addition at the end of paragraph 61.65(b) (6) (i) is requested to avoid double accounting for the minute amount of vinyl chloride vapor remaining in the vapor space over stripped resin in the stripping vessel.

61.64(e) (1)

This section should be modified to read:

"...through the stripping operation on each

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calendar day, measured at the end of the stripping operation, may not exceed:...."

Of course, monthly averaging would be preferred.

61.64(e) (1) (i)

Apparently the word "chloride" has been inadvertently omitted from this paragraph. Also, consistent with our prior comments on dispersion resin stripping, paragraph 61.64(e) (1) (i) should be reworded as follows:

"2,000 ppm for polyvinyl chloride dispersion resins, excluding latex resins, and excluding specific dispersion resins for which commercial improved stripping technology is not available."

We also recommend insertion of a new paragraph (iii) as follows:

"(iii) For specific polyvinyl chloride dispersion resins for which commercial stripping technology is not available, the residual vinyl chloride concentration shall be reduced to 6,000 ppm. The specific dispersion resins to which this limit applies shall be based on a manufacturer's demonstrated inability to successfully strip individual resins on a commercial scale."

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61.65 Emission standard for ethylene dichloride, vinyl chloride and polyvinyl chloride plants.

In 61.65(b) (i) and throughout the preface and Standard, an incorrect conversion factor has been used for liters and gallons. The correct ratio is 3.8 l/gal., not 4.1 or 4.4 as used. We believe that the basic unit intended was the gallon, so all of the liter equivalents should be corrected.

For clarity, the words "...of rail cars or trucks" should be inserted after "unloading operation...."

61.65(b) (3) (iii)

No account has been taken of the use of reciprocating compressors which are widely used in the industry. We recommend that paragraph 61.65(b) (3) (iii) be retitled "Rotating Compressors", that a new paragraph (b) (3) (iv) be inserted entitled "Reciprocating Compressors" with wording essentially the same as paragraph (b) (3) (ii), and that present paragraph (b) (3) (iv) "Agitators" be renumbered (b) (3) (v).

61.65(b) (4)

Section 61.65(b) (4) is discussed in the preface (40 FR 59539) where several permitted alternatives are discussed. We believe that the Standard should be complete in itself, and not depend on the preface for interpretations. Therefore, we request that the wording of this paragraph be changed to read as follows:

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"Leaking from relief valves may be minimized by connecting the discharge to a process line or recovery system where practical. Alternatively, rupture disks may be used before relief valves not connected to a process line or recovery system. Such installations must be made in accordance with good safety practices."

61.65(b)(5)

Rationale:

Discharges from relief valves are controlled in the PVC plant by methods including, but not limited to, proper instrumentation, injection of chemicals, and the manual venting of gases to the monomer recovery system or other stand-by methods. Use of these techniques is the primary response to a reaction upset.

When these actions fail to establish temperature and pressure control a hazardous condition is created. As pressure and temperature rise toward relief ratings, the rate of reaction more than doubles for every 10° C rise and the "degree of being out of control" becomes a geometric progression. For this reason the quantity of VCM evaporated in order to

gain control of the reaction at burst pressure is significantly greater than that needed to regain control at lower pressures and temperature via the manual venting technique.

Use of manual venting to the atmosphere recognizes this problem and relies on VCM evaporation to cool the reactor contents. Manual venting can permit the reactor to be brought under control more quickly. Since the manual valve can be completely closed, a lower total quantity of VCM will be emitted to the atmosphere. Once a relief assembly, including rupture disk and relief valve, functions it is not certain that the relief valve will reseal; this would permit continuing emission of VCM. It is estimated that manual venting will reduce potential emissions by 50 to 80 percent.

The Standard expressly forbids manual venting of vinyl chloride to the atmosphere, even in cases of extreme emergency. It is conceivable that there will arise on very infrequent occasions the necessity for doing this. An example could be in the case of failure of abatement equipment or very severe weather, such as a tornado, which has so badly damaged the plant that the installed safety equipment is inoperable, and manual venting of a small part of the reactor charge could prevent the uncontrolled venting of the entire

charge. Such occurrences are not expected to happen more than once in a few years, but when they do, operators should not be forbidden to exercise good judgment. The required reactor chart record will show when this has happened, and the owner should report the occurrence, just as in the case of a relief valve release.

Accordingly, the use of manual venting to the atmosphere should be permitted after all normal controls have failed, but prior to the use of the last resort, the emergency relief device. It must be understood that this assembly is a primary device for preventing a major catastrophe, the rupture of a reactor.

It is not practical to construct a gasholder or abatement device large enough to handle all of the monomer from all of the reactors in a plant or even one large reactor. Therefore we request that paragraph 61.65(b) (5) be amended as follows:

"(5) Emergency manual venting to the atmosphere shall be permitted only when all other methods of control have been exhausted. These discharges shall be reported within 10 days to the Administrator, in accordance with paragraph (a) of this section."

61.65(b) (7)

The use of the word "no" in paragraph 61.65(b) (7) is inappropriate because the prohibition is impractical, if not impossible to enforce. However, since we agree with the spirit of this provision, we would suggest the following amendment:

"(7) Samples: Unused portions of vinyl chloride samples shall be returned to the process or to an abatement device, and sampling techniques shall be such that sample containers are purged into a closed process system."

61.65(b) (9) (i)

It is recommended that the first sentence of this section be changed to read as follows:

"The concentration of vinyl chloride in each inprocess wastewater stream containing greater than 100 ppm vinyl chloride measured immediately as it leaves a piece of equipment shall be reduced to less than 10 ppm by weight before being mixed with any other in-process wastewater stream which is

10 ppm or less; before being exposed to the atmosphere; before being discharged to a wastewater treatment process; or before being discharged untreated as a wastewater. This paragraph does apply..."

Rationale:

This change is proposed to clarify the Standard. Presently the Standard can be interpreted to require stripping all wastewater streams separately. The intent to prohibit compliance through dilution is retained in the revised wording. It is also requested that the 100 ppm limit specified in the preceding draft Standard be reinstated.

61.66 Equivalent equipment and procedures.

Industry has expressed its objections to the use of Test Method 106 as the reference method for determining vinyl chloride levels in stationary sources. There is no doubt that the use of Test Method 106 will provide data with an accuracy in parts per billion (ppb), but this grossly exceeds the practical requisites of the proposed Standard. Since each vent to the atmosphere must be controlled to less than 10 parts per million (ppm), practical alternatives to Test Method 106 must be permitted.

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As an alternate method of determining vinyl chloride levels, a portable hydrocarbon detector can be used. When used it requires the assumption that all hydrocarbon vapors being measured are the same substance (in this case vinyl chloride); this measurement technique is specifically mentioned in Section 61.67 Emission Tests at (g) (5) (i) (B).

There are two types of portable hydrocarbon detectors in use and each is accurate to 1 ppm or better at the 5-10 ppm level. One unit is a flame ionization detector and one is an infrared analyzer. The infrared system measures continuously while the flame ionization detector measures sequentially (the latter being an "add on" to a gas chromatograph). Each can be calibrated as frequently as desired to prove accuracy.

These portable detectors could be used to analyze every stack or discharge with as much accuracy as Method 106 considering the degree of accuracy needed. Testing could be performed on a time schedule and as long as all readings were below 10 ppm volumetric flow through the stack would not need to be determined.

Furthermore, another method of checking emissions would be to transpose a sensing head from the permanent vinyl

chloride monitoring system into the stack.

EPA's reference standard is at best a laboratory tool with exquisite sensitivity but no real engineering practicality in the plant. Since the portable hydrocarbon tester is permitted for reactor testing in 61.67(g)(5)(i)(B), can it not be assumed to be an acceptable tool for practical, alternative use. Would not a transposed sample head fall into the same category.

Because we believe the suggested alternatives are appropriate, we strongly urge EPA to permit other acceptable methods for testing.

To accomplish this, industry requests that 61.67(g)(1) and 61.67(g)(4)(i) be amended to read:

Test Method 106 or an alternative such as
a portable hydrocarbon detector is to be
used to determine...

61.67 Emission tests.

We feel 61.67(c) of the Emission Tests should be amended to read as follows:

"(c) Any emission test is to be conducted while the equipment being tested is operating at the time of the test or under other relevant conditions as

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may be approved by the Administrator based on representative performance of the source."

Rationale:

The reason for the requested change is that the maximum production rate of a plant under optimum conditions may not be feasible or safe at the time of the test. Flexibility under conditions existing at the time must be allowed to insure that operator safety and public welfare is protected. Unique operating constraints may also require that tests be performed at levels well below maximum rates, owing to individual processes, which would require the Administrator's approval.

61.67(e)

Paragraph 61.67(e) should be amended to read:

"(e) All samples are to be analyzed, and vinyl chloride emissions are to be determined within 30 days after the emission test. The owner or operator shall report the determinations to the Administrator by a registered letter dispatched within ten days following the determination."

Rationale:

The industry believes that the request for immediate dispatch of the determination would pose a substantial burden; furthermore, the need for such urgency has not been established.

61.67(g) (1)

In the Preamble of the proposed Standard 40 FR 59542 under the "Emission Tests", it is stated that "...portable hydrocarbon detectors or Method 106 can be used to determine the degree to which vinyl chloride has been removed from equipment prior to opening the equipment to the atmosphere." In the regulation itself, the only mention of the option of using the portable hydrocarbon detector in this application is 61.67(g) (5) (B). It is recommended that 61.67(g) (1) should state that the portable hydrocarbon detector can be used for the testing required in 61.64(a) (2).

61.67(g) (3) (ii)

Delete "...as the resin is transferred out of the stripper."

Rationale:

This change is requested in conjunction with the revision to paragraph 61.64(b) to resolve potential conflicts in interpretation of the Standard. The two revisions prevent double accounting for the same emissions. The changes are

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consistent with the Preamble and achieve the required level of control. This permits using the stripper vessel for operations subsequent to the stripping operation without incurring substantial investment penalty to control emissions which are already reduced to the limits specified in this paragraph.

61.68 Initial report.

It is recommended that paragraph (c) be changed to read as follows:

"(c) The statement is to contain the following information: (1) a general description of the method used or the procedure adopted to insure compliance with the Standard (2) A description of the methods which have been incorporated into the standard operating procedure for measuring or calculating the emission for which emission limits are prescribed in 61.65(b) (1) (i) and (b) (6) (i) (3) A statement that each piece of equipment is installed and that each piece of equipment and each procedure is being used."

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Rationale:

For many abatement systems employed in the industry, the detailed description of the equipment, the operating conditions, and the functional characteristics of the equipment are trade secrets and, in many cases, patentable technology. The use of this technology by other parties should be on a technology-fee basis which is established by the company developing the abatement equipment. If EPA would like additional information concerning the system, a Section 114 request under the Clean Air Act would be an appropriate approach.

61.69 Semi-Annual report.

Rationale:

Section 61.69 (b) (1) requires a report 180 days after the effective date, while Section 61.68 requires a very comprehensive initial report 90 days after the effective date. The magnitude of these two reports is such that the allowable time is insufficient, and it is unlikely that all the facilities and procedural approvals required for the semi-annual report will be available immediately after the effective date.

It is requested, that 61.69 (b) (1) be amended as follows:

"...the first report is to be submitted
within 270 days of the effective date, or
180 days after the initial report, whichever

comes first, unless..."

To clarify the intent of the Standard, paragraph 61.69

(c) (2) should be changed by substituting the words:

"(2) The owner or operator shall include a summary of the analytical results on the stripped resin. Test Method 107 or equivalent is to be used."

61.69(c) (2) (i)

Rationale:

Once again, the Preamble discusses alternative methods of compliance for reporting the results of batch stripping, but these alternatives are not mentioned in the appropriate section of the Standard. We request that paragraph 61.69(c) (2) (i) be amended to agree with the Preamble at 40 FR 595343 and that it read:

"If batch stripping is used, process samples shall be taken on statistically determined frequency so that when supported by the instrument printout of the stripper vessel, it represents the performance of the process. A written procedure for this will be submitted to the Administrator for his approval.

Records will include the date, and amount,
type and grade of resin processed."

61.69(c)(2)(ii)

Rationale:

The instrument charts for a continuous stripper reflect inadequately the degree of control attained over the process, and in a system operating properly, a single sample per day is adequate.

Therefore, we request that Section 61.69(c)(2)(ii) be amended as follows:

"...or at intervals of 24 hours for
each grade..."

61.69(c)(3)

The Preamble discusses alternative methods for determining the emissions for reactor openings, but these are not included in 61.69(c)(3). The use of calculations, together with actual data on openings, will demonstrate the reproducibility of the standard procedure. Industry, therefore, requests that this paragraph be amended:

"(3) The owner or operator shall include
in the report a record of the average
total emissions from reactor openings
as is prescribed in 61.69(a)(2), either

by actual emission measurements, or by calculations performed under an approved standard procedure, and properly supported by recorded data."

Rationale:

The requirement for testing after each opening would seriously impact productivity without increasing the effectiveness of the Standard. This will have a non-uniform impact across the industry because of the difference in the size of various equipment employed in resin plants.

61.70 Recordkeeping.

It is recommended that 61.70(a) be amended as follows:

"(1) A record of the vinyl chloride detector results, including the location of each measurement and an individual summary of the measurements which have exceeded the accepted definition of a leak."

Additionally, in this section it is recommended that paragraphs (a)(1)(ii) and (a)(2) be eliminated.

Rationale:

The leak detection program submitted by the owner or operator and approved by the Administrator requires a vinyl

chloride detector which obtains samples from one or more points on a continuing sequential basis. This detector determines the vinyl chloride concentration at various points within the plant and provides a continuous record of such analysis for individual points by location and time. Based on this record, the owner or operator determines the background vinyl chloride concentration, and based on an approved definition of a leak, determines when a leak occurs. When a leak occurs the operator or owner takes action to repair the leak and disappearance of the leak indication from the detector record shows the promptness and adequacy of such repair. This record provides EPA with data on the occurrence of leaks, their duration and their repair.

The need for a written statement explaining the cause of the leak and the specified action taken to eliminate it is not apparent. The objective of the Standard is to limit vinyl chloride emissions and the function of the recordkeeping is to provide evidence that the Standard is being met. The vinyl chloride detector data provides all necessary records to show that leaks are detected, when they are detected, their duration, and when the leak has been repaired.

A question arising from this type of record is what should the owner or operator do who achieves a part of his overall plant vinyl chloride detection with routine tests via a portable monitor. When this occurs a record of leak determination, time of occurrence, duration and time of repair should be provided. This coverage could be provided easily in the leak program Standard Operating Procedure.

The requirement that a continuing record be kept of minor leaks and searches by the portable monitor adds nothing to EPA's knowledge once they have certification by the owner or operator that he is using an approved leak detection and repair procedure.

Test Methods.

These comments are directed to the analytical methods in the proposed Standard.

Method 106.

Tedlar bags are very expensive (\$91 each). It is recommended that Saran bags (\$6 each) be allowed as alternatives.

Section 4.3.1 specifies a strip chart recorder for the gas chromatograph, while section 6.4 calls for measurement of peak area with an automatic integrator. The industry believes that the strip chart recorder is adequate for this use and

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that the automatic integrator is unnecessarily elaborate and expensive (\$5,200) when peak height, triangulation, and disc integrators are sufficiently accurate for this use.

Most gas chromatographs are designed to use hydrogen and air for their flame detectors. When so used, they are capable of detecting 0.5 ppm vinyl chloride in air. This is sensitive enough to monitor the 10 ppm limit that the Standard calls for. The replacement of air by oxyben as the combustion gas therefore seems unnecessary.

The use of a heated sample loop and automatic sample valve (Section 4.3.1) is not necessary since the bag sample is not heated. A gas tight syringe is adequate for transferring the sample from the bag to the gas chromatograph.

The method allows the use of only one specific column (Section 4.3.2). This should be revised to permit use of any column which provides adequate resolution of the vinyl chloride peak.

Method 107.

The integrator record specified in 5.3.6 seems unnecessarily elaborate as the measuring device. Here, especially, the vinyl chloride peak is so sharp that any measurement other than peak height would be difficult. A strip chart recorder

with sensitivity of 1 millivolt full scale is adequate for this use.

Regarding 5.3.2, Supelco, Inc. Supelco Park, Bellefonte, Pennsylvania 16823, recently announced that they are discontinuing Carbopack A. However, they say that 0.2% Carbowax 1500 on Carbopack C gives the same separation of vinyl chloride as 0.4% Carbowax 1500 on Carbopack A.

Equilibrium data for the vinyl chloride - water system are available which conflict with the EPA K-value of 5.0×10^{-6} (p. 59552, Column 2). Air Products reports a value of 1.3×10^{-6} which is more consistent with a value of 0.9×10^{-6} determined by Ethyl Corporation. Brackets have been omitted from equation 107-5. In addition, the constant in equation 107-5 (2.066×10^{-3}) depends on the K-value for water and should be corrected accordingly.

The last paragraph under 9.2 is not applicable to equation 107-5. Equation 197-5 applies only to water samples, where $TS = 0$. Reference to 197-5 should be deleted and the paragraph relocated after equation 197-4.

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COMMENTS ON THE STANDARD SUPPORT AND
ENVIRONMENTAL IMPACT STATEMENT

CHAPTERS 1 and 2

These chapters are general summaries, and are very similar to the Preamble and Standard, and our comments on those documents are given above. We present below our comments on some remaining chapters. We attempt to avoid repetition; however, there are some issues discussed below which we have covered in earlier Comments.

CHAPTER 3

3.1 General

Preliminary production data for 1975 show a production of about 3.6 - 3.8 billion pounds (1.6 - 1.7 billion kg) of PVC. This represents 65 percent of the total 1974 production. The industry is now mature, and thus has become cyclic, following the general economy. The decrease in production created a depression in the sales price and profits, further reducing the capability of the industry to support massive expenditures of capital, or to raise prices to recover regulatory costs.

3.2.2 PVC Production

3.2.2.1 Suspension Polymerization

The polymerization cycle varies from about 4 to 14 hours. A reasonable average might be about 10-12 hours/batch rather than the stated six hours.

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The saturation point for vinyl chloride in water is about 1100 ppm at standard conditions, thus it is impossible to have concentrations of 2000 ppm. (pp. 3-15).

The industry data of June, 1974 was not obtained by a uniform reporting system, nor does it represent present conditions. The Agency has discounted the effect of solid wastes in the "unaccounted" or fugitive losses; these are substantially higher than that used by the Agency. The industry disagrees with EPA's statement on pp. 16-17: "most producers assume that the unaccounted for loss...consists primarily of VC vapor..." (pp. 3-16, 17, Table 3-10, fn. 2).

The Agency is quite correct on the inaccuracy of short-term material balances, and this was the basis for Table 3-10.

3.2.2.2 Dispersion Polymerization

Not all dispersion reactions are run at higher rates than suspension reactions. There is a great diversity of processes within the dispersion group of products. Dispersion resins involve longer cycle times and lower productivity, in terms of pounds per gallon reactor capacity, than suspension reactions.

The size of the dried particle is determined by the droplet size produced in the spray drier. The particle size in the emulsion particle itself is colloidal (sub-microscopic). Spray dryers are used predominately; therefore, because there

are no discrete particles that permit use of a centrifuge.

Latex resins may have more or less soap than other dispersion formulations. Some have none at all and depend on other stabilizing agents. Low-soap latexes offer a special problem in their capacity to withstand strenuous stripping conditions.

The origin of the data in Table 3.6-3.9 is not reported, nor is the specific process for Table 3.7 identified.

3.2.2.3 Bulk Polymerization

The second reactor, called a postpolymerization or popo reactor, may be cleaned after every batch and must be opened to transfer the product. The first reactor, called a prepolymerizer or prepo vessel, may require opening or cleaning after every batch.

More recent estimates by bulk producers (N.J. State and Region II Joint Meeting on Vinyl Chloride, Trenton, N.J., May, 1975) indicate that total losses in the bulk process are about one percent, not 2.4 percent as stated in Table 3.8.

3.2.2.4 Solvent Polymerization

The process description of this method omits the resin solution stripping and the precipitation processes. The outflow from the continuous reactor is quite easy to strip since no polymer is present as a separate phase, thus there is no problem with diffusion rates. Therefore, when

the resin is precipitated it is essentially free of monomer. Also, the reactor is operated for long periods of time without opening since a solvent is used as the reaction medium, and the reactor does not foul.

As a result, the estimates of emissions in Table 3-9 are incorrect, the two largest items, reactor opening loss and dryer loss, being non-existent. The sole manufacturer of this type of product states that current measurements indicate a VC loss of about 0.05 lb/100 lb product.

It should be noted that in this process stripping occurs before a slurry is formed, so that the general concept of the regulation does not fit this process (see comments on Chapter 8).

3.2.3 Summary

As noted above, the tables attached to this chapter are in error for the reasons given. Industry presently estimates that VC losses to the air are below 50 percent of those given in Tables 3-5 through 3-9. This is supported by the EPA monitoring program held in the spring of 1975.

CHAPTER 4

4.1 Adsorption

4.1.1 Carbon Adsorption

Page 4-6 states as follows:

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"The optimum source for application of carbon adsorption given the present state of the art is high concentration, low volume, low temperature streams, such as polyvinyl chloride plant monomer recovery systems, closed slurry blend tanks containing nitrogen or other inerts and vinyl chloride storage areas."

This statement clarifies the whole area of carbon adsorption application and in effect eliminates the potential use of activated carbon for such streams as dryer exhausts which have low VCM concentration, are high in water and particulate content and are composed mainly of air. Any other discussion of removing vinyl chloride from dryer exhaust streams in this section or others are related to untested technology. Untested technology cannot be considered for a control device. There are a number of technical reasons why activated carbon adsorption will not perform on resin dryer exhausts which have previously been discussed with EPA. The discussion of the cost of activated carbon for dryer exhaust cleanup on page 4-5, page 4-6 and Table 4-3 is irrelevant since the technology is not applicable to this source.

The discussion on page 4-7 of vinyl chloride adsorption by ion exchange resins, points out a possible area of research but as EPA noted, this is an unproven technology.

Page 4-11, Incineration

EPA points out on pages 4-11 and 4-12 that the application of flares, catalytic afterburners, and incinerators to control emissions via dryer exhaust is possible but due to the large volumes of air, is not applicable to dryer exhausts. Some minor errors noted on pages 4-16 and 4-17 are:

(1) Spray towers, spray chambers and venturi scrubbers are ineffecient devices for contacting gas and solvent thus achieving an exhaust concentration of 10 ppm VCM is highly unlikely.

(2) Scrubbing VCM from gases to 10 ppm concentration using water or aqueous solutions of sodium carbonate or sodium hydroxide is not possible using present technology.

(3) Use of a lower volatility solvent is not feasible. The solvent must be boiled or vaporized in the stripping column of the system to remove the vinyl chloride, and if the vinyl chloride is not completely removed, the target 10 ppm VC concentration in the vent will not be achieved.

4.5 Control of Fugitive Emissions

Page 4-25

EPA's insistence on sealess pumps or double mechanical seals for rotating equipment generates costs which are disproportionate to the benefits achieved in emission reduction. A properly fitted single mechanical seal on a liquid vinyl

chloride pump has an estimated leakage rate of 0.03 pounds of vinyl chloride per twenty-four hours. A mechanical seal on a reactor agitator leaks approximately 0.015 pounds of VC per twenty-four hours when first charged and 0.0015 pounds per twenty-four hours at the end of the reaction. Thus, a normal single seal reactor gland would leak about 0.0082 pounds of VCM in a normal twenty-four hour period, according to the best estimates of a major seal manufacturer. The inherent faults of so-called sealess or canned pumps has already been discussed with EPA.

The application of double seals or double packing systems to reciprocating pumps in VC-PVC service is under development. The use of double packing sets works very well in clean liquids, but the major use of reciprocating pumps is in dirty liquid and popolymer service where the application is questionable. The industry is willing to try and adapt double packing to reciprocating machinery but it does expect to seek relief from the proposed Standard if the technology cannot be developed. In view of the very low emissions there appears to be no reason for EPA not to provide such relief.

Page 4-26, Sample Flask

This control, if needed, should apply to monomer manufacture only and to pure vinyl chloride samples taken in a PVC plant. The technology on which this control is based

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was developed by Dow to handle samples of refined monomer and the projected losses from sampling are based on samples taken in a monomer plant. Flushing samples back into a process is a very simple matter for a liquid chemical. Sampling reactor slurry and other resin containing material is not amenable to this type of control. Consideration should be given to routine control samples versus non-routine sampling for process "trouble shooting." A routine sample is taken on a frequent basis as opposed to a process trouble shooting sample that might be taken once or twice a year. EPA should consider limiting the scope of this control to routine samples containing 20 percent or more vinyl chloride monomer by weight.

Page 4-27, Leakage from Relief Valves

EPA's concern for relief valve emissions is based primarily on reactor or polymerizer control problems. A properly selected, installed and maintained relief valve is less likely to leak than any given shut-off valve in an industrial plant. The industry sets its relief valves at least 10% higher than the vessels' normal working pressure. The valve seats are lapped and the valve tested for leaks at its operating pressure. If a relief valve is actuated it is removed, cleaned, the seats relapped and the assembly tested for leaks. All valves are cleaned and checked at least annually. A recent survey of 76 relief valves in a dispersion

resin plant showed no leakage by any relief valve.

A relief valve is a rugged device machined to close tolerances as compared to a rupture disc which is basically a thin metal diaphragm that must be very carefully installed to avoid premature failure. Even a carefully installed rupture disc will leak or fail after a period of use due to metal fatigue or minor corrosion.

In a cyclic process a rupture disc has a limited life and will start to leak on a statistically determinable basis. When a relief valve is actuated it vents off dangerously high vessel pressure and reseats. When a rupture disc and relief valve are in series and the vessel relieves, frequently pieces of the rupture disc lodge in the relief valve seat and prevent its closing when the pressure is relieved.

The chemical industry has the knowledge and know-how to select proper relief devices for its equipment. The industry believes safety valve leakage is not a problem and the specification of relief devices should be left to industry determination. Leak testing of relief devices on a regular basis should certainly be viewed as an equivalent to the proposal if not superior to it. Finally, industry wants to stress the fact that downstream manifolding of primary relief valve discharges is not an acceptable safety practice.

Manual Venting of Gases

The requirement that all gases manually vented be ducted through a control device shows that EPA does not fully appreciate the violence of an uncontrolled vinyl chloride polymerization. The request by industry was for emergency manual venting to be considered the same as a relief valve release, i.e. something to be avoided if humanly possible but permissible in order to prevent disaster.

PVC polymerizations are generally catalyzed by the decomposition of an organic peroxide into free radicals. These free radicals then initiate into polymer chains. For a controlled polymerization the peroxide catalyst is selected carefully based on the planned temperature of polymerization and the peroxides rate of decomposition at that temperature. A reactor producing 1,000 pounds of resin per hour generates 700,000 BTU/hr which must be removed. A loss of reactor cooling in the absence of relief devices would cause the vessel to rupture within an hour. Assuming the reactor operated at 100 psi gauge and 123° F, a relief valve would be set at 120 psi gauge. When the relief valve actuated the temperature would be 134° F and the rate of heat generation would be at least 1,400,000 BTU/hr. If the reactor had been manually vented when all control was lost at 123° F the rate of venting to control the reactor would have been 62 pounds

of VCM per minute. If the relief valve were the sole method of control, the rate of venting would be at least 150 lb/min. When a prudent plant operator loses cooling and/or power he adds reaction short stop and manually vents some VCM to obtain mixing and to maintain control until the short stop is fully effective. If he has a functioning vapor recovery system he uses it, but many times this is also not functioning for the same reason (loss of cooling). During upset conditions in resin manufacturing, depending on individual plants and processes, relief devices can become fouled or inoperative. Therefore, the prudent plant operator would try and control before the relief devices are actuated if possible, and even when they are actuated, it is prudent to supplement their venting with manual vents. The outright ban on manual venting of reactors to the atmosphere is a hazardous requirement.

Page 4-30

On page 4-30, last paragraph, it is stated: "A gas-holder can be installed...to hold all the vinyl chloride contained in an entire reactor batch...." While this might be correct technically, it certainly is not practically correct for all reactors. Industry believes some reference to the number of reactors and their size should be included in this statement. Based on the assumptions on page 4-36 a 35,000 gallon reactor would require a gasholder of 640,000

cubic feet. This is impractical for only one reactor, let alone an entire plant.

4.7 Gasholder and Purgewater System

Page 4-32

Gasholders will be useful in reducing emissions, but they will not be the panacea for all problems. It is impractical to construct one of such size that all monomer in all reactors can be vented to it in case of an emergency. Indeed, even building one large enough to hold all the contents of a 35,000 gallon reactor is impractical. Their applicability to bulk processes is questionable because of the presence of water.

Page 4-34

The figures used on pages 4-34 and 4-35 are incorrect. The reference should be to Table 3-6, not 3-5, and the reactor opening loss is 0.14 kg/100 kg, not 0.46.

The figure of 0.35 lb of VC loss from opening a purged 4,000 gallon reactor is low by a factor of 2.17 because of an error in calculation on page 4-71.

4.8 Improved Stripping

See Preamble for discussion on this issue.

4.9 Reactor Opening Loss Controls

The suggestion is made on page 4-46 that existing equipment can be fitted with high pressure spray heads and

washed down without opening. This is incorrect for the majority of existing reactors, which do not have nozzles of adequate size to permit passage of the spray head.

Page 4-47

The implication is that all resins and all processes can readily increase the number of batches per reactor cleaning to 40 to 200 batches. Reactor opening is wholly dependent upon the rate of fouling by the particular process, the particular resin recipe and the particular reactor involved. Some reactors of some processes must be cleaned or opened after every batch while others can run much longer. Any effort to force a minimum number of runs on each reactor will create a safety problem as discussed elsewhere in these Comments.

4.10 Emissions and Control Techniques for Inprocess Wastewater

Page 4-50

The discussion of polyvinyl chloride plant in-process waste water should be modified throughout to note that the suspension resin process is involved. Waste water from the other PVC process does not match the waste streams from the suspension resin process.

Page 4-71

The error in the calculation of the emission has been pointed out several times in the record. For the record, the

calculated emission should have been 0.00002 lbs. VCM/lb, not 0.00001 lbs.

Page 4-72

The calculation shown on this page is in error. In calculating the volume of gas remaining in the reactor, the true density (not bulk density) should be used. Using a true density of 87 lbs/cubic ft., the gas volume calculates to be 393 cubic ft., and the remaining VCM is 0.0013 #VCM/100 #PVC.

Page 4-76

EPA declares: "Each of these techniques can reduce the vinyl chloride content of the gas being treated to less than 10 ppm." This statement should be qualified by noting that not all of these methods have been demonstrated under operating conditions on a commercial scale for all of the sources listed.

Page 4-81, Table 4-3

This table shows that an achievable emission limit of zero is technically possible through the application of control systems to the monomer recovery system, slurry blend tanks, and centrifuge emission sources. These numbers are in error, impossible, and inconsistent with the emission limitations proposed. Therefore, this Table should be corrected to show that there will still be emissions from these sources.

Page 4-83

Table 4-4 indicates that the achievable emission levels for light ends vents and finishing column vents are zero through the use of incineration. These numbers are in error, impossible, and inconsistent with the emission limitations proposed. Therefore, this Table should be corrected accordingly.

CHAPTER 5

Industry is pleased that the Administrator has considered cost and benefit in the preparation of the Standard. This is a proper and necessary step. However, we do not feel this has been carried far enough. Several requirements remain which offer little benefit in terms of emission reduction for the costs required. They are: requiring replacement of single seals on rotating equipment with double seals; installation of car unloading purge units at plants where monomer delivery by rail car is infrequent; the requirement for stripping all dispersion resins to 2000 ppm; and excessive recordkeeping.

Also, the Agency has not taken sufficient cognizance of either the cost of, or the improvements from, efforts made to comply with the OSHA Standard. Some of the efforts are complimentary, others are totally separate, and the costs are not altogether overlapping.

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EPA must be cognizant of the very short time allowed for compliance under Section 112 to allow development, engineering, equipment procurement installation, and demonstration of the necessary equipment. This crash program in itself involves extra costs.

Industry respectfully suggests that EPA expend more effort on the fine tuning of the cost/benefit ratio. As noted, there are several requirements in the Standard where we believe the costs for compliance are grossly disproportionate to the benefits achieved.

CHAPTER 6

Once again, it is gratifying to see that an Environmental impact study has been undertaken. It is of increasing importance to assure that regulatory action is understood properly in the light of energy consumption, and that results commensurate with efforts are achieved.

The discussion of potential adverse environmental impacts on page 1-24, 1-27, and 1-28 regarding increased water consumption seems to be overstated. EPA expects increased water consumption from the use of such control systems as a reactor water purge system, improved stripping, waste water stripping, and carbon adsorption. We believe that there will be little, if any, increased water consumption and certainly nothing approaching the 6-38% range as noted on page 1-28 and as detailed in Table 6-13 on page 6-42.

The reactor water purge control technique, according to Table 6-13, clearly results in the greatest water consumption. It should be noted, however, that only a small percentage of the PVC industry intends to utilize the reactor water purge control method. Also, there is no technical reason that water used for reactor purging cannot be used over and over again in a completely closed cycle. Obviously, water used in this type of system would have to be stripped of vinyl chloride content prior to discharge. Recycling of such water would minimize stripping requirements thereby conserving energy and would also minimize the use of our natural resource (water). We believe the numbers presented for reactor water purging are in error.

The second noted source of increased water consumption as a result of applying the necessary controls is that noted for improved stripping. We question the quantities listed in Table 6-13. Steam requirements of 1,500-2,000 kg of steam per 10,000 kg of product are stated on page 6-5 for improved stripping. Using the highest amount stated (2,000) and calculating the steam requirements for a model 150 million pound per year plant as shown in Table 6-13, an increased water consumption of 3.6 million gallons/year is determined as compared to the quantity of 7 million gallons/year shown in Table 6-13. Similarly, other numbers presented in Table 6-13 for improved

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stripping are in error. As noted on page 6-5, primary stripping, which is already used by most plants, requires 3,000-4,000 kg of steam per 10,000 kg of product and improved stripping will require an additional 1,500-2,000 kg of steam per 10,000 kg of product. While these facts may be correct for some plants, they are not correct for the industry as a whole.

Improved continuous stripping technology is not applicable to dispersion resins due to the extreme differences in stability of dispersion resins versus suspension resins. Batch stripping, will continue to be employed for dispersion resins. Nevertheless, the steam quantities given on page 6-5 are greater than that required for stripping dispersion resins. Moreover, recipe water and steam stripping water do not discharge to a sewer, but rather are emitted to the atmosphere in the drying operation. Therefore, there is no increased waste water from improved dispersion resin stripping.

For improved stripping of both suspension and dispersion resins, the quantity of steam sparged into the slurry which would result in increased water consumption is less than the 3,000-4,000 kg of steam per 10,000 kg of product stated on page 6-5. We conclude there will be no increased water consumption due to improved stripping, and no adverse environmental impact.

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The quantity of increased water consumption, as shown in Table 6-13, for water stripping is also questionable. The basis for such number is not given. It is technically possible to strip vinyl from these waste water sources by recycling such waste water sources to slurry stripping systems. By doing so, the amount of additional steam required is negligible.

Increased water consumption data given for carbon adsorption is also questionable. First, this Table assumes carbon technology will be utilized across-the-board for the industry. Many producers certainly do not intend to use carbon adsorption. Additionally, even if carbon adsorption is used, regeneration with hot nitrogen is technically possible as noted on page 4-61. Obviously, if hot nitrogen is used, there would be no increased water consumption.

Considering all other factors as noted above, it is questionable whether there would be any increased water consumption as a result of compliance with the proposed Standard. Thus, it seems that EPA should make a more realistic analysis of the situation than it presently has done. Additionally, the percentage increase of water consumption as noted is meaningless in itself, particularly when based on the average of the range of numbers as shown in Footnote 1 of Table 6-13. The average of this range is extremely misleading and unrepresentative of industry operations for certain types of plants. When

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considering the range of base water consumption, the percentage increase is less than significant.

The concern for hydrogen chloride emissions is overstated. Incineration will be used only to a small extent in monomer manufacture and to a lesser degree in the PVC industry because of economics.

The effect of solid waste on a carbon bed is purely conjectural at this time. Not enough is known of bed life to permit an estimate, and the one to three years presented has no basis. It cannot be regenerated if contaminated by polymers, since PVC is less combustible than carbon.

Of particular interest to industry is the diffusion modeling work, and we are concerned that only annual maxima are presented. No where is there any guidance as to what is occurring outside the plants because industry has been informed by the Agency that these maxima occur within 80-220 meters of the emission point; that is, still well within the plant limits for all but the smallest plants. Worst conditions have been assumed here, and the diffusion model has not been confirmed by actual measurements at operating plants as reported in the STAR document.

CHAPTER 7

Economic Impact Analysis

The Environmental Protection Agency is to be commended for preparing an economic impact analysis related to the capital and operating costs required for compliance with the proposed emission Standard for Vinyl Chloride. Industry will limit its comments herein to the inflationary impact of the Standard, and some specific examples where the costs of compliance with the Standard are disproportionate to the benefits to be achieved in emission reduction.

Inflationary Impact

The inflationary impact of compliance with the proposed Standard will be significant. EPA, in the Standard Support and Environmental Impact Statement, p. 1-34, estimated a 7.3% increase will be required in the selling price of polyvinyl chloride resin in order to maintain precontrol profitability and encourage a continued flow of capital to this industry. In 1976, the sales value of polyvinyl chloride resin will be approximately One Billion Dollars. A 7.3% increase (conservative by our estimate) will have, at the very least, a \$70 million inflationary impact on the economy. The actual impact will be more than \$70 million because of the necessary mark-ups over cost at each intermediate manufacturing and distribution level between the polyvinyl chloride producer and the ultimate customer.

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We believe the 7.3% increase to be low because EPA has underestimated both capital expenditures and annual operating costs. The Agency postulates that \$200 million capital and annual operating costs of over \$70 million will be required by the Standard. The industry believes the Agency overlooked some critical factors in arriving at these figures.

(1) No adjustments for inflationary factors were included. The estimates for capital expenditures and operating costs were developed in late 1974--early 1975. An analysis of increases already realized or reasonably anticipated in engineering, material, and construction costs indicates that these numbers should be escalated by at least 10% to recognize 1976 costs and by another 12% for 1977 costs. On this basis alone the actual expenditure must be raised from \$200 million to between \$220 and \$250 million.

(2) Several capital estimates are low. For example:

(a) A carbon adsorption system for control of emissions in the model suspension polyvinyl chloride plant is listed at

\$333,000. A realistic installed cost in 1975 is \$450,000. Costs in 1976 will, obviously, be even higher. This one item translates to an underestimation of the capital cost to the industry of approximately \$3 million in 1975 dollars.

(b) Although incineration will probably not be widely used for control of vinyl chloride emissions, the capital and operating costs noted in the document are understated for this alternative. Given present inflation rates and the underestimated capital costs industry estimates, for the model polyvinyl chloride suspension plant, Table 7-8, the capital cost for incineration will be closer to \$6 million rather than \$3 million. For a vinyl chloride monomer plant, capital estimates for incineration would be increased by a factor of 2 or 3 over the stated \$1.369 million (Table 7-7). These changes will worsen the costs and returns on investment shown for Case B and control scenario #4 in the document. It is recognized that this will not be

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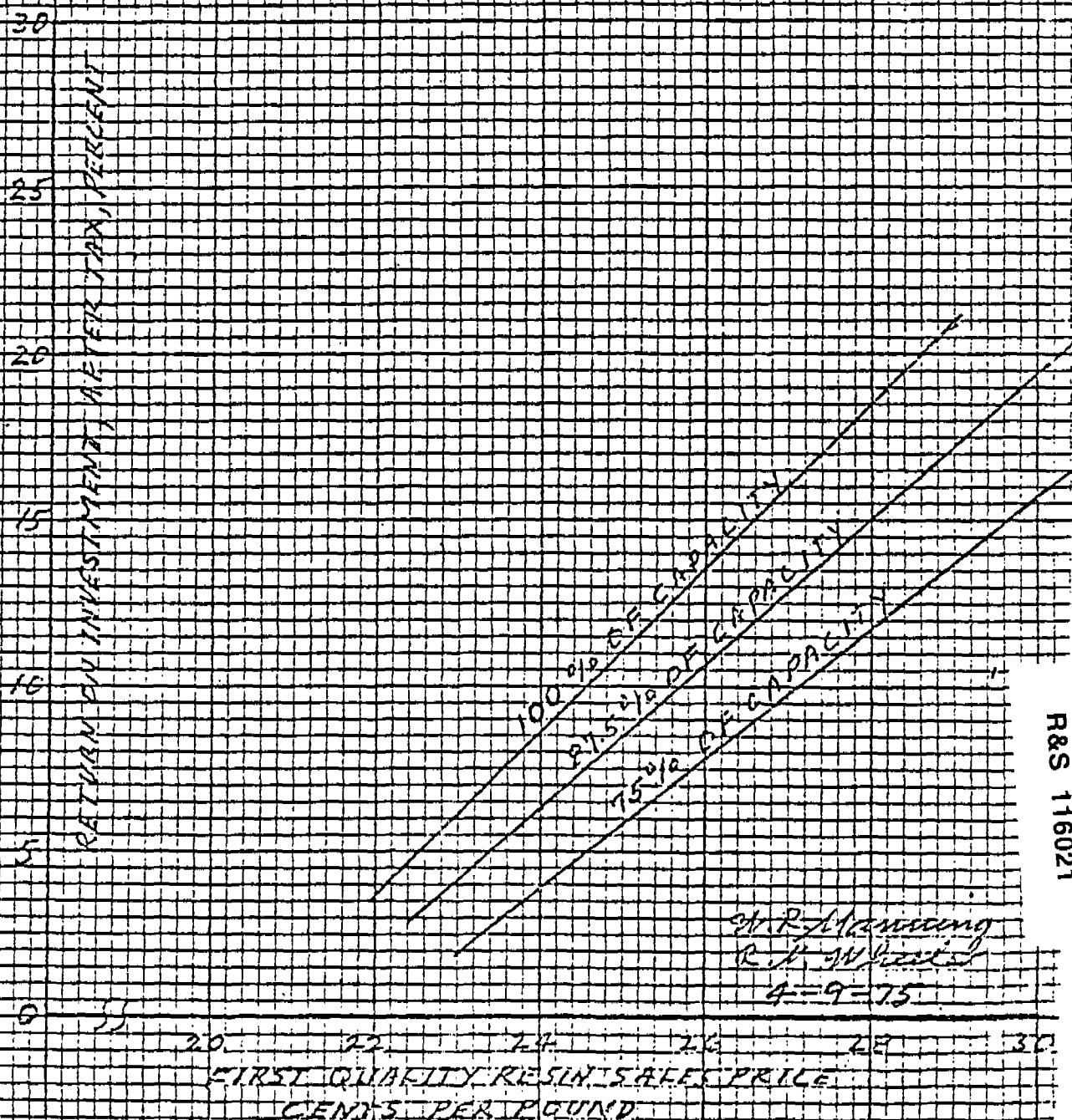
the typical situation. If it were, the capital cost of \$200 million would rise to over \$300 million before the adjustments noted above.

In addition, we believe the return on investment is overstated in the Standard Support Document because of the following:

(1) All calculations in the Document have been run on the basis of operation at 100% of capacity. Real operating levels, averaging good and bad years, are closer to 85 - 90% of capacity. For example, for 18 months in 1973-4 the polyvinyl chloride industry operated at 95% capacity. Then for a period of about six months in early 1975 operating rates dropped to 50% of capacity as new plants were being completed just as customer demand dropped off abruptly because of a recession. In late 1975 operating rates recovered to 70% of capacity as demand improved. An example of the manner in which operating rates affect return on investment is shown on the attached Table II.

(2) The cost of administration, selling, R&D, and interest is understated in the tables

TABLE IV
NEW SUSPENSION PVC RESINS PLANT
150,000,000 POUNDS PER YEAR
RETURN ON INVESTMENT
AS A FUNCTION OF
FIRST QUALITY RESIN SALES PRICE
AND
OPERATING RATE, % OF CAPACITY



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on Financial Impact for Polyvinyl Chloride plants (7-46, 7-47, and 7-49). For example, the use of 2.5% of the installed capital cost per year should be raised to 3.5 - 4.0% in Cases A and B. The increased cost of complying with the regulations (technology costs, record keeping and reporting costs, etc.) is substantial and interest on investment and taxes and insurance all rise with the extra capital needed for compliance. Even the basic case for an uncontrolled plant does not seem to reflect adequate research or licensing costs. These expenditures are necessary to remain competitive and typically amount to between 2 and 4% of sales dollars. If these additional factors are considered in developing the return on investment, industry believes EPA's figures will be more accurate.

Costs Versus Emissions Benefits Achieved

EPA, in proposing the Vinyl Chloride Standard has considered costs, risks and benefits. In choosing a control method or device, the Agency's criterion has been that said method or device will be used unless the costs are grossly disproportionate to the benefits achieved. Industry believes the Agency overlooked some areas where costs outweigh the

benefits anticipated. For example:

(1) The proposed Standard indicates that water stripping for the total plant (Case B) will, in fact, be required for a typical polyvinyl chloride plant to be in compliance. Using the model plant (Table 7-12) figures, a total investment of \$179,000, or approximately 4% of the total capital requirement, is necessary for water stripping. Furthermore, annual operating costs of approximately \$600,000 (or 45% of the total) will be incurred. But the monomer recovered will only be 1.4% of all precontrolled losses. These costs are disproportionate to the benefit received. For the entire industry, elimination of water stripping from suspension polyvinyl chloride plants would save over \$5.5 million in investment and some \$18 million in annual operating costs.

(2) The proposed Standard requires that compressors and pumps in vinyl chloride monomer service be evacuated to a recovery system before they are opened for maintenance or

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inspection. We estimate that the installation costs of a system to accomplish this for model suspension plant would be \$30 - \$50,000 and for the entire industry (including dispersion plants) over \$1 million. The benefit to be achieved would be of an order of magnitude of only 5 - 10 lbs. per year for the model suspension plant--an almost infinitesimal percentage. This is clearly a case of no significant benefit for a major expenditure.

(3) The proposed Standard requires a most vigorous program of leak detection, repairs and records of corrective action. If the Standard were to allow "leak patrols" on a once weekly basis, unless the continuous monitoring shows readings over the designated leak level, and if stripped slurry analyses were required only once a day, an estimated annual cost savings of \$100,000 could be realized in the model plant. The loss of monomer by the suggested rule, in our estimate, would be less than 10,000 pounds per year for the model plant. Therefore, eight percent of the annual operating cost for the model will be required to capture

as little as 0.2% monomer emission. This cost appears to us as being disproportionate to the benefits achieved.

The limited amount of time allowed for response has not allowed us to finish our analysis; however, we believe there are additional examples where enormous costs will be required for very little benefit achieved in terms of emission reduction. Therefore, industry requests it be allowed to submit additional data with respect to this issue as soon as the analysis is completed.

Finally, in reviewing the economic impact analysis data, some mathematical errors as well as errors of omission and consistency have been found. None of these are of major consequence. For example, Table 7-40: It appears that the Tenneco/Plemington, Tenneco/Pasadena, and Union Carbide plants were omitted from the Table. Table 7-15: The total annualized cost for a model EDC/VCM plant should be \$773,000 rather than \$793,000. It appears that a rechecking of the data presented is required to determine that the information is mathematically accurate and complete.

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CHAPTER 8

General

Much of the reasoning in this chapter has been restated in the preamble, and is reflected directly in the standard. Comments already have been made on many points in our comments on those documents, but will be summarized again here for emphasis.

8.1 Selection of Emission Sources

Undue emphasis is placed on fugitive emissions. The contractor for the Agency's Section 114 survey in 1974 estimated fugitives to be 20 percent of the total emissions; the Agency revised this upward to 40 percent by counting reported solid losses as gas. Yet, in Section 8.5.1 an example of 1.36 percent particulate losses is used (211 kg/hr from a 136 kg lb/yr plant), losses which the Agency has denied.

Many of these losses are too small to be significant. For example, a number of plants receive monomer primarily by pipeline, yet maintain car unloading stations for use every two or three years when their monomer supplier undergoes a plant turnaround. In this manner a 150 MN lb/yr "typical plant" would unload an average of about ten cars per year, and would require a \$50 M or higher investment for a probable reduction of 40 lb/yr of vinyl chloride emissions.

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This would seem to be a "grossly disproportionate" cost-benefit ratio, and this restriction should be reconsidered. Other requirements seem to be similar; sampling, especially for slurry samples; manual venting in an emergency, and leakage from relief valves. Careful rewording of the standard can clarify those applications where such precautions are really productive.

8.2.3 Other Stack Emission Sources

The Agency recognizes the unproven nature of stack abatement devices such as carbon adsorption or solvent scrubbing. Considering the stringent time limits imposed by Section 112, and the large amount of capital which industry will spend, some thought should be given to alternate actions in case these devices prove unworkable. Carbon beds have never operated under commercial conditions on dilute streams or in streams containing substantial amounts of oxygen; bed life, polymer or peroxide formation, and efficiency under such conditions are unknown.

Industry has requested that the averaging time on the monomer content of stripped resin be extended from twenty-four hours to thirty days. This will reduce the impact on the small producer who can only produce one grade at a time, and who still has a grade which cannot be stripped below the required levels.

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Furthermore, no equipment functions with a 100 percent on-line time. A 90 percent stream factor is a very satisfactory performance. Allowance must be made for normal maintenance and repair. The concept of no instantaneous break through is not realistic, and the standard should be based on a longer term average of thirty days.

The units for conversion of liters and gallons is incorrect, as is the calculation leading to the 0.001 kg/100 kg product loss limit for reactor opening. In regard to the latter, this too, should be averaged over a thirty day period. Under the present regulation an operator who has a mechanical failure on the second batch after opening will commit a violation when he opens the reactor for repair even though it may run one or even a hundred batches before the next opening. This is not the intent or spirit of the regulation and should be corrected.

The Agency insists on zero discharge from relief valves, excepting natural disaster, but invites manmade disaster by insisting on rupture disks without proper safeguards, and by forbidding manual venting in an emergency.

It is difficult to determine how the Agency will police the proscription of operator error. Who gets a citation when an experienced and well-trained employee makes a mistake in judgment, the employee or the employer?

8.2.4 Fugitive Sources

The erroneous basis for the action in this area was discussed above. Another error is in the assumption that larger pressure vessels will withstand vacuum. Many will not, despite a substantial pressure rating; this leaves water purge as the only practical method of gas removal. This can be very difficult on a remote tank in cold weather.

The formalized leak patrol appears to be more punitive than regulatory. The area monitor charts serve the same purpose of recording the promptness of response.

The standard on wastewater is unclear and corrective language has been suggested.

8.4 Reporting

The Agency must realize the tremendous task it has set for both itself and industry in attempting to take all the readings for determining compliance on all source points, preparing the necessary reports, requests for variances, compliance programs, and approved procedures, forwarding these to the Administrator, receiving his reply, and acting on the reply all within 90 days of promulgation. Total confusion will result from even the slightest lack of coordination in all of these frantic activities at 50 or so plants, and in the Administrator's office. It may be wise to omit this original report, or delay it for 90 to 180 days.

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Industry has asked that the first semi-annual report be set for 180 days after the initial report. It has also asked for a reduction in the overall recordkeeping and reporting area in a way that will give the Agency the needed information without an avalanche of paper.

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Health Subcommittee Comments on Proposed Vinyl Chloride Standard

A.

INTRODUCTION

These comments have been prepared by the Health Committee of the Vinyl Chloride and Polyvinyl Chloride Producers Group of SPI. The Committee has analyzed the Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride ("STAR Document"), the Quantitative Risk Assessment Community Exposure to Vinyl Chloride ("Risk Assessment Document") and the Administrator's explanation preceding the proposed Vinyl Chloride Standard published in 40 Fed. Reg. 59523 et. seq. Our comments are divided into three parts: (A) an introduction and general critique of the documents as they pertain to public health matters; (B) a detailed discussion of certain specific objections; and (C) an appendix listing by page and line questions we have about parts of the documents.

At the outset, we believe that the Environmental Protection Agency has set for itself a high goal in the documents it has issued accompanying the proposed Standard. The STAR Document brings together in one place much of the information known about vinyl chloride and its health effects up to early 1975. The Risk Assessment Document is a necessary concept, and we applaud the approach of the Agency and hope that it will be used in the future. Our criticism is not with the process, which we endorse, but with some of the data, facts and interpretations drawn by the Agency.

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1. Risk Assessment Document

Our principal criticism of the Risk Assessment Document is that at times it appears to be written to justify a conclusion already reached by the Agency rather than to set forth the scientific framework, and options open to the Administrator to make a difficult decision.

We believe a Risk Assessment Document should have two main purposes. First, it should assist the Administrator in reaching a decision about the wisest course to pursue in regulating chemicals such as vinyl chloride by identifying and attempting to quantify the various risks posed by the chemical and by describing the risk reduction which can be anticipated by various control techniques. Second, it should assist public understanding of the difficulties facing the Agency when it regulates a substance about which hard facts are unavailable and where extrapolation from existing data can be made only with limited reliability.

As will be set forth in greater detail we believe that the discussion of the "no threshold" assumption and the use of a "Log-Probit" model could have been more complete and objective. In all likelihood, such difficulties could have been solved if the Risk Assessment Document had been circulated in draft form and discussed with all interested parties before it was published. The Agency did so with most of the documents which were issued to accompany the Standard and in general, we understand that comments it received from interested parties were constructive.

If this process had been followed, we believe that the Risk Assessment Document would have presented a fairer and more complete discussion of the scientific background against which the Administrator's decision was made and would therefore have been of greater assistance to him and to the public in understanding his decision.

2. STAR Document

We also believe that some attempt should have been made to update the STAR Document when it was reissued in December. The information in that report was gathered almost twelve months prior to its final publication and in the intervening time certain additional information about the health effects of vinyl chloride had been gathered. For example, we understand from a statement by Dr. William Marcus that further investigation of so-called "community cases" was undertaken and that the Agency has concluded that there is no "evidence that angiosarcoma has been produced by vinyl chloride monomer in the general population." (Transcript, p. 42) We think this information should have been included.

We recognize that it is almost impossible to ensure that any scientific publication is absolutely current when it is published in the form of a STAR Document. However, in such cases, an errata or addendum could be issued at the time of its final publication and we urge the Agency to adopt such a procedure.

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I. No Threshold Concept

The Risk Assessment's assumption of "no threshold" for a carcinogen is probably the most important assumption of the Document because it determines the mathematical model used in subsequent calculations. We believe that the Risk Assessment Document should have included the available evidence that VCM may have a threshold.

The Executive Summary flatly states "it is generally considered prudent to assume that there is no threshold for chemical carcinogens". That statement is not borne out by the text. On Page 3 the authors properly state that the no threshold assumption "is generally accepted as prudent in radiation carcinogenesis." They continue that for chemical carcinogenesis the model is usually considered to provide "an upper limit to the level of effects likely at extremely low doses...." See also B-2. We do not believe that the Risk Assessment Document should slide without further discussion from what is considered prudent in radiation carcinogenesis to what may be excessively cautious for chemical carcinogenesis.

The concept of "no-threshold" is in no way a universally accepted concept among scientists. There are numerous references in scientific literature to attest to the marked difference of

opinion among scientists: Dinman^{1/}, Stokinger^{2/}, Friedman, and many others have correctly pointed out that the body contains defensive detoxification mechanisms, which are capable of detoxifying and repairing low level responses to carcinogens.

There is even more specific evidence that the body contains certain defensive mechanisms capable of detoxifying VC and that there is a threshold for VC. Existing scientific data show that the routes of metabolism of vinyl chloride are markedly dependent upon the dosage inhaled or ingested. The data which were summarized at the February 3 hearing by Dr. P. J. Gehring are consistent with a threshold below which the body is able to handle small amounts of vinyl chloride without adverse effects. Dr. Gehring's testimony is now a part of the record, and we believe that if the Administrator is to accept the "no threshold" assumption, his decision should be discussed in a final document in the context of an empirical background which suggests that a metabolic threshold exists.

II. Log-Probit Model

The Risk Assessment Document accepts the linear dose-response model for purposes of determining the probability of developing angiosarcomas. Since individual susceptibility appears to be an

1/ "Non-Concept" of "No Threshold" - Chemicals in the Environment, Burtram D. Dinman, Science Vol. 175, pp. 495-497, Feb. 4, 1975.

2/ Sanity in Research and Evaluation of Environmental Health, H. E. Stokinger, Science Vol. 174, pp. 662-665, Nov. 12, 1971.

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important feature in the development of angiosarcomas in workers equally exposed to vinyl chloride, we think a log-probit model would have been more appropriate. Indeed, the authors of the Risk Assessment Document acknowledge that biological responses generally are better represented by a log-probit model. Apparently, ease of application and conservatism in approach caused rejection of what would otherwise have been a more appropriate model.

A more objective approach would have pointed out that the log-probit model fits more closely the Maltoni data, the only data which is cited for dose-response relationship.

Cases of liver angiosarcoma/experiment

<u>Dose</u>	<u>Maltoni</u>	<u>Linear</u>	<u>Probit</u>
50	1	.75	.99
250	4	3.74	4.13
500	7	7.47	6.85

In addition, the angiosarcoma-epidemiological data is also more consistent with a log-probit model. Based on the Third National Cancer Survey, the crude incidence rate for the entire nation is 0.0128 per 100,000 population per year. The Risk Assessment Document used this rate to estimate the expected incidence of angiosarcoma within five miles of PVC and VCM plants studied as 0.59 cases per year giving a total of 5.9 cases for the ten-year period of the Study. Using the Risk Assessment Document's projections there were an estimated 4.9 cases within the five mile radius for the ten-year period. If we then take the authors' estimate of one excess case per year for the past ten years (See p. 7) and add it to the 5.9 figure established from the Survey, we would expect 15.9 angiosarcomas for the ten year period. In actuality by

extrapolation only 4.9 cases were found. The probability of finding five or fewer cases when almost 16 were expected is less than two chances in 1000 (.002), using the Poisson approximation. The epidemiological survey results do not fit the linear dose-response model, and we believe are further evidence that the log-probit model would have been more appropriate.

We also do not believe the Study should state that "the two approaches give results that are indistinguishable" (P. ii). This is just not the case at the tails of the curve which are the sectors of concern in this Standard.

Use of a log-probit model would have given the Administrator an option which on the face of the document was not brought to his attention. The Administrator assumes that the controls which must be adopted on promulgation of a final standard similar to the proposed one will reduce emissions by 95%. Implicit in the acceptance of this emission reduction and the use of a linear model is the Agency's acceptance that the standard imposed by Section 112 is met by a reduction of risk of 95%. If the Log-Probit model is used, however, the same percent reduction in risk, albeit to a much lower absolute value, can be attained by an emission reduction of 70%.^{3/} Since the costs of

^{3/} Using the Maltoni data, the linear model gives a rate of 4×10^{-6} at an assumed concentration of 17 ppb in the ambient air. To effect a 95% reduction in risk using that model the concentration must be reduced by 95% to 0.85 ppb. The log-probit model gives a rate of 0.04×10^{-6} using the same data. To reduce the rate by an equivalent amount ($0.04 \times 10^{-6} \times 0.05 = .002 \times 10^{-6}$), concentrations in the ambient air need to be reduced from 17 ppb to 4.6 ppb.

The assumptions used in the calculation of the maxima are given, which overstate the possible exposure to vinyl chloride.

- 1) An average wind speed of 0.5 meters per second (1.1 mph) was used. The climatic data taken during 1975 at three plants averaged well over 5 mph.
- 2) No consideration was given to wind direction. This is very important since it can be presumed that any direction other than downwind will provide no detectable exposure.
- 3) No thermal buoyancy was used in the source stream. PVC plant drier outlets usually are above 140°F., and many other source points are mixed with live steam. These thermal gradients have a significant effect on effective stack height and mixing and, therefore, on the actual ground level concentration.
- 4) Average emission rates of 4.25% of the production of suspension plants were used and these emission rates are not representative of present day PVC & VCM operations.

The greatest deficiency in data prepared to support the proposed standard is the absence of an effort to correlate the actual monitoring results of 1975 with the model results, or to consider population distribution relative to prevailing winds. Analysis of the downwind data recorded by EPA at a Louisville, KY, plant provides an arithmetic mean value less than 5 ppb at 1 mile compared to the predicted average value of 37 ppb on page A-3 of the Risk Assessment Document or less than 5% of the projections derived from the diffusion model. (Also see Table 4.1.2

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STAR Document). Figure 1 is a plot of average measured concentrations from the 31 off-site downwind monitoring points at the Kentucky plant. Table I is a recalculation of the exposure for each area segment for which a population is given on page 1, multiplied by the rat lifetime risk calculated by Schneiderman (ANYAS 246 (1975) p. 239) to give an overall lifetime risk of <0.07 cases for 4.6MM persons, or <1.5 cases per 100MM lifetimes. Dividing by an average lifetime of 70 years and multiplying by 8 to adjust to 24-hour exposure this yields an annual risk of less than 2×10^{-9} , which is indistinguishable against the normal background of 0.128 per million for the general population, even assuming an equal sensitivity of rat and human.

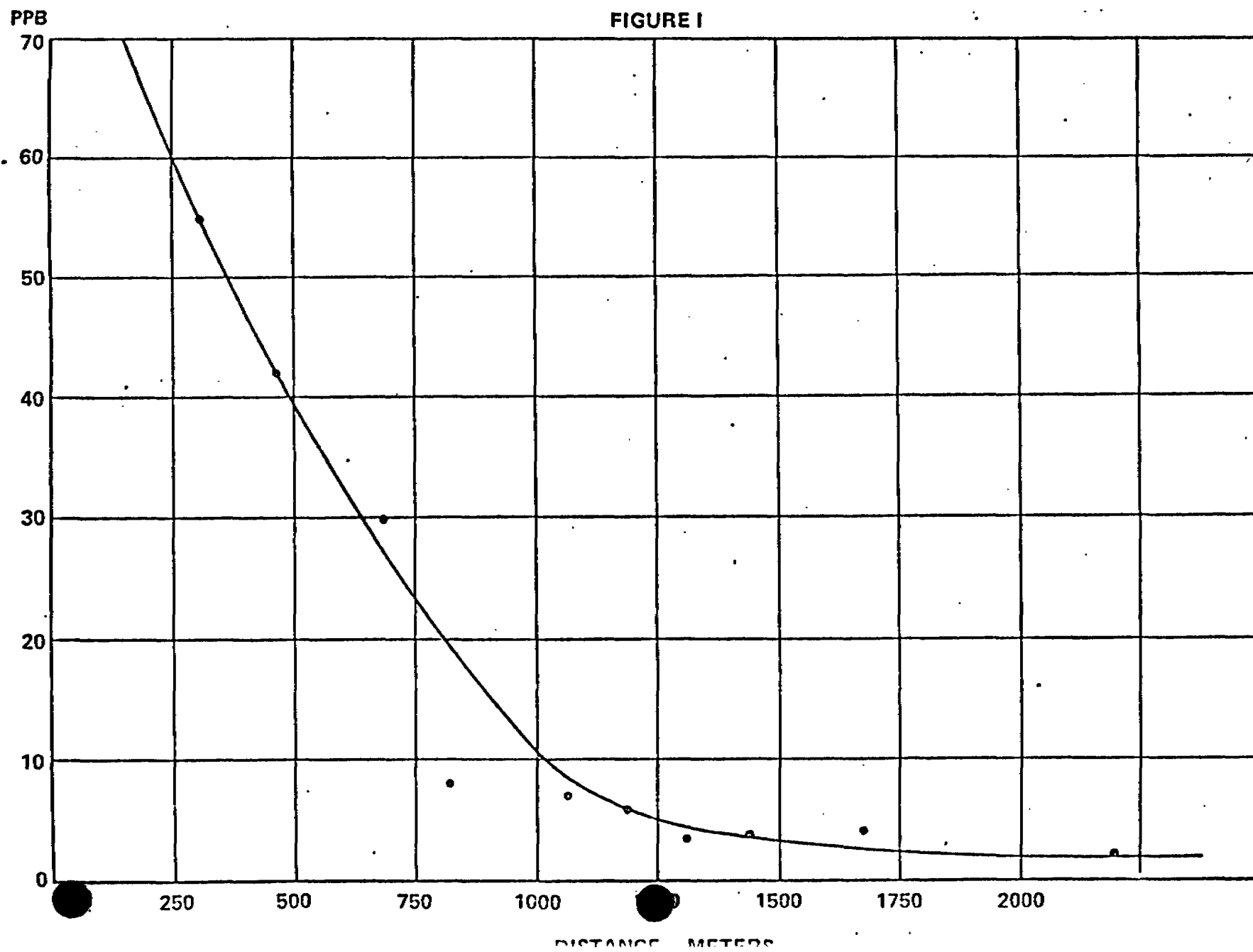
In view of these actual data, we find it difficult to understand how the authors of the Risk Assessment Document could use 17 ppb as the mean concentration of vinyl chloride for purposes of its predictions. Based on actual observations, concentrations are far less than this.

TABLE I

<u>Area Segment</u>	<u>Population, Thousands</u>	<u>Average Concentration ppb</u>	<u>Risk</u>	<u>Total Lifetime Cases</u>
<1/2 mile	47	45	5.4×10^{-7}	~0.03
1/2 - 1 mile	203	6	$<10^{-8}$	~0.002
1 - 3 miles	1,491	2	$<10^{-8}$	~0.01
3 - 5 miles*	2,838	<0.5	$<10^{-8}$	<0.03
	4,579			<0.072

*EPA has recognized that vinyl chloride deteriorates under conditions found in the ambient environment, yet it does not recognize the effect in the model. In addition, no EPA sampling data shows detectable vinyl chloride concentrations at beyond 3 miles from a PVC or VCM plant. The reduction in population exposed is obvious.

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IV. Epidemiology

We also believe the Risk Assessment Document could have been more objective in presenting the epidemiological data. There are now 18 confirmed cases of angiosarcoma of the liver in the United States among persons occupationally exposed in high concentrations of vinyl chloride. None of the confirmed cases has occurred among persons involved exclusively in PVC fabrication or among persons whose exposure is only as a result of living in the vicinity of vinyl chloride production facilities. There are perhaps another 17 or 18 confirmed cases of liver angiosarcoma associated with exposure to vinyl chloride in the rest of the world.

Exposures to vinyl chloride among those who have developed hepatic angiosarcomas have been estimated because precise exposure data is unknown. All these estimates indicated that those who developed angiosarcoma had a very high exposure generally related to reactor cleaning. Reasonably precise exposure data are available for VC workers at the Dow Chemical Company plant at Midland, Michigan. None of these workers who had a lower exposure developed hepatic angiosarcoma.

The basic conclusion reached by the Risk Assessment Document on the epidemiological data is that "this survey has produced no evidence that living around vinyl chloride plants is a risk factor in the occurrence of liver angiosarcoma." (emphasis ours) However, the authors of the study then take great pains to minimize this conclusion. They suggest several reasons why the survey might have resulted in minimum findings, but do not discuss those reasons in sufficient detail.

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The arguments the Document advances for not accepting its own conclusion are:

1) The latent time of 17 years means that the first exposure must have occurred prior to 1957 when the quantities of vinyl chloride produced were much less than current production.

Comment: This argument is only partially accurate. The angiosarcomas so far recorded in the United States show a latency period ranging from 12 to 32 years from known first exposure. In Great Britain one case has been reported with a latency of 9 years. (NIOSH Report 1975) Thus, using the U.S. minimum latency of 12 years, we are looking back to production in the year 1962 at the latest and perhaps even later. Vinyl chloride has been in production for 40 years. The atmospheric concentration for some plant sites could have been much higher than it is now although there is no way to retrospectively determine quantitatively how much community exposure occurred in the past. If we assume higher atmospheric exposures in the past than at present, fewer production facilities than exist now, and a latent period that is somewhat dose dependent we do not see that any conclusion can be arrived at other than that these factors may well balance each other.

2) This survey did not include the place of occupation of the currently suspected collection of liver angiosarcoma cases. Therefore, it underestimates the risk of living near a vinyl chloride plant.

Comment: Although it is not as true now as 40 years ago, workers tend to live near their place of work. Thus, there at least is as much likelihood that the 4.5 mile perimeter includes persons occupationally exposed as it does persons without any occupational exposure. We do not see any basis for saying that the risk is thereby underestimated. If anything the lack of occupational data should result in an overestimate of risk.

3) All existing liver angiosarcoma cases may not have been detected.

Comment: This is always true in any epidemiological study but hardly a basis to discount a survey unless there is some evidence that non-detected angiosarcomas exist in the exposed group.

4) The high percentage of cases having only residence at time of death obscures possible previous residence near a vinyl chloride plant.

Comment: The opposite situation is equally possible, that a person whose place of residence at the time of initiation of the tumor was not near a vinyl chloride facility and then moved near a production facility prior to death. There is no reason to believe that one situation is more likely than the other. We certainly agree that the residence at death does not necessarily indicate where most of the lifetime was spent.

5) A significant rate of change of diagnosis occurred when the cases on file were examined by pathologists at the National Cancer Institute.

Comment: This is not unusual with any type of tumor when the pathological specimens are submitted to a panel of pathologists who are specialists in the specific organ or tumor. In view of the low autopsy rate in the United States there is no way of insuring the accuracy of the incidence data for liver angiosarcoma and the number of changes in previously diagnosed cases could be more than balanced by cases that were never properly read by the pathologist and are therefore not included in the national figures.

All in all, the self-criticism by the authors themselves is unconvincing. The lack of risk based on present epidemiological data speaks for itself and may well throw into question the basis of the stringent proposed Standard.

V. Non-Carcinogenic Effects

In discussing the non-cancer effects of VC, the Risk Assessment Document does not discuss the possibility that VC may be a mutagen and/or a teratogen although this question has been raised in the scientific literature, the popular press, and suggested in the STAR Document. We recognize that research into the mutagenic/teratogenic effects, if any, of vinyl chloride is of recent origin and a number of defects exist in existing studies.

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Nevertheless, since the matter has received considerable publicity, it would be advisable for the document to discuss such studies as exist, if only to point out their limitations and the inability to draw any conclusions at the present time.

The only studies available on the effects on the fetus of community exposure to VC at the time the Risk Assessment Document was published was the report by Infante of an apparent increase in the incidence of birth defects in 3 Northern Ohio communities with nearby VC polymerization facilities. This study was reviewed and extended by the Center for Disease Control of the Public Health Service in a second study which reported that it could establish no relationship between the observed birth defects and VC exposure.

Any other concerns about community effects come from the extrapolation of work place exposures to the community exposures. Until very recently there has been only indirect evidence of any risk of genetically mediated disease as a result of VC exposures. This indirect evidence consisted of:

1. Evidence that VC is mutagenic in certain microbial test systems;
2. Indication of mutations in mammalian cells due to VC metabolites;
3. Demonstration in some studies that VC produces chromosomal changes in somatic cells in workers.

Direct evidence that VC may be mutagenic in man has become available only very recently in a report by Infante, et al. They report increased fetal wastage in wives of men occupationally exposed to VC in a polymerization plant where angiosarcoma of the liver has also been observed. We have two general comments about this study. First, it is related only to occupational exposures and has no direct relevance to vinyl chloride in the ambient air which is the focus of EPA's attention. Second, the study has several significant weaknesses as follows:^{4/}

1. Limited size of population studies;
2. History obtained from husband rather than wife;
3. Data based on history only, no physician or hospital corroboration and no indication of age of wife;
4. VC exposure is not shown to be the only variable in the study;
5. No indication of incidence is given for the general population; it is not clear that rubber workers is the proper cohort for the comparison.

No human data are available with regard to any possible teratogenic effects of VC. Animal studies by Johns et al. show that VC is not teratogenic for rats, mice or rabbits either alone or administered in conjunction with ethanol.

^{4/} It also seems to be inconsistent with a December 1974 article, Chromosomen - Untersuchungen bei Vinyl Chlorid-Exposition, von I. Fleig and A. M. Thiess; Arbeitsmedizin, Sozialmedizin, Präventivmedizin 9, (12), pp. 280-283 (1974) which concludes that under the working conditions existing at BASF (Ludwigshaven, Germany) there was no evidence that the influence of VC had a mutagenic effect. We have been unable to trace the Norway Study to which Dr. Marcus referred at the hearing (Tr. p.73).

Conclusion & Recommendations

The most reasonable conclusion which can be drawn from the Risk Assessment Document and the other documents issued as part of the proposed Standard is that vinyl chloride poses no health risk for the general public because of the small concentrations which exist in the ambient air. Nevertheless, we believe a joint research effort should be developed because there are gaps in our knowledge of the health effects of the chemical at low doses.

An examination of the record demonstrates industry's participation in studying the health effects of vinyl chloride and in making these results public. Numerous scientific publications resulting from industry sponsored research can be found in the scientific literature beginning as early as 1961 and arrangements have been made to provide the government agencies with all reports of currently sponsored research. While there has unfortunately been at times a problem of maintaining a completely cooperative attitude, there must be increased efforts to arrange joint industry, labor, academic and government studies. There is serious need for cooperative studies to supplement and extend those already being sponsored and planned by the plastics industry through MCA coordinated and other research programs as well as those of government agencies. These studies should include:

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1. Early detection and treatment of vinyl chloride induced injury. The University of Louisville has a major study under way in this area and the MCA Technical Panel on Vinyl Chloride Research is currently considering sponsoring additional work by this group. Additional studies by other groups may be desirable.

2. Metabolism studies. These studies need to be extended if we are to understand the mode of toxic action of vinyl chloride and its metabolites. Industry has sponsored most of the research in this area and expects to continue its efforts.

3. Mutagenic studies. Enough data are available to indicate concern for the potential mutagenic effects of high exposures to vinyl chloride. Likewise, available data indicate that low level exposures may not result in mutagenicity. It is obvious that research of the highest quality is needed to investigate and quantify the mutagenicity of vinyl chloride and to establish the practical hazard if one exists.

4. Human epidemiology. Perhaps no area requires joint effort as much as epidemiology particularly as related to cancer and birth defects. New methods of investigation must be developed and the resources of the government agencies must be properly directed to evaluate properly the effects of low levels of exposure on employees

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and the public. Industry has been the leader in investigating worker populations, but the facilities and authority of the government must be used to study potential effects on the public health. These studies must be well designed, carefully conducted, objectively analyzed, and properly reported. "Quick and dirty" studies have no place in issues as important to society as management of vinyl chloride and its products.

We are not suggesting that government necessarily pay for the total cost of the studies which should be conducted. The burden should be shared by all interested parties. We do believe, however, that the government should take the lead in calling together interested parties with a view to establishing a consensus on what areas should be studied, who can best conduct the necessary studies, and the protocols which should be followed. The alternative, as we see it, is continued dispute over factual issues rather than concentrating on policy considerations which should flow from established scientific evidence.

Executive Summary

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
i	4	1-7	General Comment. Diffusion modeling methods, at best, offer only an approximation to the true state of affairs and can never substitute for actual monitoring data, which (although available) was unfortunately not taken into consideration. The weighting schemes proposed to account for the types, numbers and sizes of plants and the meteorological conditions are quite arbitrary, and different (but just as reasonable) choices for these weights would lead to a value much less than 17 ppb.
i	5	7	No cause and effect could be established by CDC <u>Morbidity & Mortality</u> , July 19, 1975, so the assumption should not have been made.
i	5	1-10	General Comment. Using animal data to predict human response is a very risky practice, because no real assessment of the validity of such an extrapolation has been made. The dose-response data for vinyl chloride is quite sparse (essentially only the Maltoni data is available), and no replications of such data are available for assessing the accuracy and precision of such data. The epidemiologic data available is of varying quality, and the Tabershaw-Gaffey data is the best data available and it was not used. There was considerable selectivity in the employment of information from these various studies, and the resulting conclusions drawn in this report are clearly unrepresentative of what the collection of studies taken together indicate.
i	6	1-5	General Comment. The assumption that a lifetime exposure to rats would produce the same number of effects as a lifetime exposure to humans has never been verified. The use of a linear model is certainly a very conservative procedure, but it does not provide as good a fit to the Maltoni data as a log-probit model (which is more often recommended when dealing with dose-response relationships of the type we are examining). The authors seem to have used the linear model more for convenience in computation than for its ability to accurately characterize the dose-response relationship. Indeed, there is no reason for preferring the linear model to the log-probit model, and, statistically speaking, the log-probit certainly provides a much better fit to the Maltoni data. The numbers in this paragraph certainly cannot be accepted at face value based on all the shaky assumptions used in arriving at them. Clearly, some consideration of the statistical variations surrounding these numbers should be made.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
ii	1	8	350 ppm is too low a dose. A much more appropriate dose would be that related to reactor cleaners over time period prior to 1974. Air Products' testimony at OSHA Hearing reports more realistic dosages in both U.S. and the United Kingdom. (STAR 6.1.4)
ii	2	6	"Two other important facts about vinyl chloride carcinogenesis resulted from this analysis: 1) at some time in their lives about 7.5% of all highly-exposed workers are expected to get liver angiosarcomas due to vinyl chloride exposure with double this rate of primary cancer at all sites combined. 2) Of all the cases of liver angiosarcoma which have thus far been produced by vinyl chloride, only 38% of them have been diagnosed as of 1974." These are not facts but at best extrapolations from the models used in the study. The reasoning in arriving at the projection that 7.5% of all highly-exposed workers will get angiosarcoma is flawed. A correction factor is derived from the Tabershaw-Cooper Study and applied to the incidence date obtained by Nicholson. This is not appropriate since the hire dates in the Tabershaw-Cooper Study are a function of the starting dates of the plants in the T-C Study and not applicable to the single plant—Nicholson Study. If a correction factor is to be applied then the factor should be multiplied by the T-C rate so instead of 7.5% the percentage would be 1.2%; highly significant to the surviving workers.
ii	2	8	What is dosage for "highly-exposed workers" which relates to 7.5% expectancy of angiosarcoma?
ii	2	1-13	General comments. The probability 0.0031 (of a worker getting angiosarcoma at sometime in his life per year of exposure) is based on an incidence rate of 0.02, a value which is certainly <u>not</u> representative of the epidemiologic data as given (see, for example, the Tabershaw-Gaffey data, which are based on the largest sample size and provide the lowest incidence). No statistical measure of the error associated with this estimate is provided.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
ii	3	1-3	General Comments. The fact that the probability estimate from the animal data (namely, .0052) is reasonably close to the estimate for the epidemiologic data (namely, .0031) says nothing about the <u>accuracy</u> of either of these estimates (i.e., two point estimates close to each other in value can be way off from the true value), and actually, in this case, only reflects the selective choice of what epidemiologic data to use to insure reasonable agreement with the animal data. There is no statistical basis for having much confidence in either of these numbers.
ii	5	1-12	General Comments. The fact that the better fitting log-probit model provides "low dose" (i.e., 17 ppb, which is too high) estimates of the number of cases per year of exposure which are 1/10 to 1/100 the size of those provided by the linear model casts serious doubt on the validity of extrapolation and on the use of the linear model itself. In addition, the use of a more reasonable and much smaller value than 17 ppb would considerably decrease these expected case values even more.
iii	1	5	"No conclusion can be drawn from the survey at its present stage of completion." This proposition is difficult to rationalize since the authors have already stated that their model predicts one excess liver angiosarcoma death with the 5-mile radius for each of the past 10 years. If we accept the actual number of cases projected to be found, i.e. (286/176 multiplied by 3) and add the upper bound of one excess angiosarcoma death per year for the past 10 years to the expected 5.9 from the <u>Third National Cancer Survey</u> we have an observed 4.9* vs. an expected 15.9. The probability of 5 or fewer cases with an expected of 15.9 based on the Poisson approximation is less than .002. If the expected were 13 the approximate probability would be .01. Is an observed of 5 (or less) reasonable in the light of an expected of 15.9? Any reasoned conclusion must be that the high values of risk resulting from the author's model are inconsistent with the upper end of model's risk. The survey begs a conclusion that the data does not support the upper spectrum of the modeled risk and is very consistent with no detectable risk.

...cont'd

*Case 3 has been confirmed as not being angiosarcoma. Therefore, only 2 unconfirmed cases remain in table 2 of Appendix E.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
cont'd			
iii	1	5	Another conclusion which should have been stated in the summary is that based on the CDC survey, "There is no evidence of clustering on a state-wide scale."
2	2	1-5	General Comments. The fact that the extrapolation from animal data to humans was based on assuming a (maximum) 168 hour exposure time per week (7x24) is certainly questionable in view of the remarks made in this paragraph regarding time spent away from home, etc.
2	3	4	General Comment. The statement that "the agreement between the two studies was good" does not say anything about the <u>accuracy</u> of either modeling approach. In fact, since both OAQPS and Teknekron used similar modeling procedures (except that the latter included data on meteorological conditions), they would be expected to provide reasonably comparable values. In this regard, the 25% discrepancy is somewhat <u>high</u> and reflects how much variation can be expected with such modeling procedures. It is regrettable that the authors made no use of this 25% figure in studying the sensitivity of their predictions. Of course, the accuracy of such diffusion modeling is completely unknown and can only be assessed with actual monitoring data (which was <u>not</u> done in this report). EPA had such data (which strongly refutes the 17 ppb figure), but chose to ignore it.
3	2	1,2&3	"Unfortunately, it has not been possible to make a systematic comparison of the diffusion modeling results with data obtained from actual monitoring..." How can one talk about a risk assessment for community exposure to vinyl chloride without actually confirming the community exposure? EPA had monitoring data (STAR Series December 1975 pp. 29-30) which clearly shows the 17 ppb assumption not possible.
3	2	3-6	General Comment. Again, the authors refer to the difference of up to 25% between the two diffusion modeling efforts as an estimate of the uncertainty of these efforts, but do nothing to assess the effects of such uncertainty on their final conclusions. This is typical of much of this report--the final numbers coming out are (as the authors admit) greatly affected by such uncertainties, and no efforts have been made to assess the effects of such uncertainties.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
3	3	13-18	General Comment. The statement is made that "by using animal data, we can avoid such problems" (e.g., with regard to assessing health effects due to PVC and VCM exposures). However, the animal dose-response data is quite sparse and no replicate studies are available to assess the variation in such data, so that any conclusions are tenuous.
4	2	1-5	General Comment. "For technical reasons", the linear model was used instead of the log-probit to assess health effects. These reasons appear to be based on ease of computation and conservatism, etc., which are not sufficient justification for disregarding consideration of the better-fitting log-probit model, especially since no strong case for using only the linear model has been made.
4	5	1	"of the four occupational..." The Administrator should be advised of the epidemiology study on British Petroleum PVC workers published in Lancet, December 13, 1975, pg. 1197 to 1199, "Mortality Study of Workers in a Polyvinyl Chloride Production Plant."
4	5	12	"The result of the analysis is an estimate of the probability per year of exposure that a person will get angiosarcoma sometime in his life." This estimate pertains only to highly exposed workers. An updated Tabershaw-Copper report will issue before the Administrator promulgates a standard. This report will be the most complete study in the world. It will have greater than 95% follow-up; have a cohort size of 11,000 humans and will have 2,000 new records of a much older group of workers. Assumptions related to incidence of angiosarcoma and all cancers should be reviewed and revised based on this report.
4	5	14-15	General Comment. The issue of "competing risks" cannot legitimately be ignored, as it was; there are available statistical techniques for performing competing risks analyses, given adequate data.
5	2	2&3	In view of the admitted limitations of the Marsteller study which failed to compare exposed workers with a suitable control group, failed to consider the effect of alcohol intake and lacked exposure data, the alleged ratio should have been seriously qualified. In addition, under German law doctors are required to report "suspicions" of occupationally-related disease to insurance carriers as well as the government agency responsible for industrial hygiene. In this case, 70 cases of liver disease were reported without "findings stated"; they were apparently filed as a precaution.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
5	2	6,7&8	Allowance should have been made for the rat Zymbal Gland, which is an organ unique to rodents and particularly responsive to other chemical carcinogens (STAR 6.1.4). There is no way to extrapolate the incidence of neoplastic change in the organ in the rat to what might be expected in man. High local concentrations of chlorinated organic substances in the gland and the cellular characteristics of the organ are unique. There is consequently no valid basis for assigning an additional "non-angiosarcoma" tumor to man for each Zymbal Gland tumor. One must utilize organs and disease in which the conditions of exposure and response are fundamentally similar. Any use of the Zymbal Gland data for this purpose is inappropriate and misleading, primarily because of intense local exposure by lipid insoluble agents.
5	4	1-10	See exposure comments on Executive Summary, ii, paragraph 1, line 8. In addition, the data referred to was developed by Dow Chemical Co. records and is unlikely to be representative of the entire industry. It appears that, at least in some plants, exposure was much higher than indicated by the study.
6	1	8,9&10	The only real data to validate the modeling projections do not support and are not consistent with the linear model used in the study.
6	3	3	"1) The number of cancers at all sites caused by vinyl chloride is twice the number of liver angiosarcomas". There has been no "cause and effect" ever established; only associations and the cited data do not support the assertion.
6	3	3	"2) The number of people with severe liver damage is 30 times the number of liver angiosarcomas". Again this is not a result or fact but an assumption which should be clearly so stated.
7	2	1-8	General Comment. The authors "judge that the number of liver angiosarcomas produced per year of exposure in people residing near vinyl chloride plants is somewhere between less than one and 10 cases." This clearly has to be a very subjective statement, based on the fact that no proper statistical analyses were performed to accurately provide something like a confidence interval for the true number of cases. Also, there is no quantitative assessment of the validity of <u>any</u> of the assumptions leading up to these numbers, and so the numbers themselves are essentially meaningless. It goes without saying, then, that any manipulations involving these numbers (e.g., multiplying by 30) lead to just as questionable values.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
7	4	6	"Unfortunately, the diagnosis of these cases has not yet been confirmed by the National Cancer Institute." It is difficult to understand why confirmation of 3 tissue specimens could not have been requested on a special basis for such an important document. The consequence of negative readings of these slides would suggest it is safer to live within 5 miles of a plant using VCM than outside that radius.
7	4	7	"In addition one infant whose parents lived within one mile of a plant died of a relatively common liver tumor." Since this is irrelevant, it is difficult to understand why the statement was included in the document?
7	5	4-7	The authors overlook the fact that PVC and VCM plants have been in operation in Niagara Falls for thirty years. There are no confirmed angiosarcoma cases in the vicinity of these plants. Upper New York State is similar to Connecticut in that a Tumor Registry is available. The Administrator should have been advised that the model would predict angiosarcoma cases in Niagara Falls or Louisville if it were valid. The facts show no cases in Niagara Falls after extensive epidemiology by CDC.
8	1	2-3	"If the lower rates in the range of the above analysis were to be true, increased incidence of angiosarcoma would not be observable." Can there be any other conclusion than that the facts do not support a model which predicts 10 cases per year?
Appendix A			
A-1	Last	0-1/2	Population of 47,000 is not correct because Texas City, Texas, population distribution should be in 1/2 to 1 mile annulus.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
A-2	3	1-2	"Second, the overall U.S. population has grown about 5% since the 1970 Census, but it is not known whether the areas covered in this study have grown similarly." True, but the document should also have noted factors which will reduce the exposed population. Certain plants have or will shutdown and this will change population density gradient significantly. These plants are: 1) Hicksville, N.Y.; 2) Uniroyal at Painesville; 3) Carbide Dispersion Plant at South Carlestown; 4) Goodyear at Niagara Falls reduced; and 5) Monsanto at Springfield, Mass.
A-3	4	Table of Data	This table completely overlooks EPA's own monitoring data and the reduction in VCM emissions brought about by OSHA compliance.
A-4	2	1-15	General Comment. The weights reflecting the meteorological conditions Low, Average, High and Very High are somewhat arbitrary and their values are subject to error. The way these weights were used in arriving at the 17 ppb figure means that it is very important to consider how much variability is associated with their specification.
A-4	3	16-27	General Comment. The weighting of a "large" PVC plant as being equivalent to 2.3 "average" PVC plants, because a "typical" large PVC plant has a production of 350 million lb/yr as opposed to a "typical" average PVC plant with 150 million lb/yr, is certainly an arbitrary procedure and has no statistical justification. A similar criticism for the weighting 1300/700 for "large" VCM plants can be made on the same grounds. The effects of different weighting schemes should have been examined.
A-5	1	10-11	"Since there are a total of 4.6 million people exposed within 5 miles of plants, the average exposure of these people is $76.4/4.6$ or 17 ppb." Clearly EPA's own monitoring study cannot support the 17 ppb assumption. No discussion is offered to the Administrator of the impact of the OSHA standard on VCM emissions. In addition, the diffusion model includes solid and gas losses and does not take into account EPA's most recent monitoring data, see also comments on the technical standard, <u>supra</u>. The report deals with 17 ppb average community exposure in an absolute sense but the available data hardly support even 1 ppb. The implications of this difference in mathematics are critical to a rational decision by the Administrator.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
Appendix B			
B-1	1	9	"Ideally, we should use human data throughout and avoid the problem of extrapolating from an animal model to human beings." The Tabershaw-Cooper Study will be completed before the Administrator reaches his decision. (See previous comments) This data should be analyzed before the standard is finally promulgated.
B-2	2	1-5	Constraining the linear model so that it passes through the origin should be based on <u>a priori</u> rather than on <u>a posteriori</u> considerations. In fact, a slightly negative intercept is obtained without this constraint, and this suggests the possibility of a "threshold effect" (which could possibly be verified with further experimentation).
B-3	3	6	"Estimates of the total number of cancers caused by vinyl chloride are based on the slope of this line, not on the intercept." It would seem appropriate to comment on the special nature of the zymbal gland which is unique in rats.
B-3	4	1-2	The slope standard deviation estimates are only valid if the linear model is the correct one to use, and this is certainly open to debate.
B-3	5		The Maltoni animal data fits the log probit model better than the linear model, and there appears to be no reason why this should not be stated.
B-3	5	1-18	General Comment. The goodness-of-fit table looks impressive, but actually means very little because of the way in which the fitted model is eventually used. In particular, the fact that the linear model fits the data reasonably well in the region of experimentation means absolutely nothing with regard to extrapolation (i.e., prediction) <u>outside</u> the region of interest; in fact, a model can really perform well within the region of experimentation, but not be at all valid outside the region. Also, a similar table based on fitting the log-probit model would have indicated a much closer fit to the data, and, statistically speaking, the log-probit model would clearly be preferred on goodness-of-fit grounds alone.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
B-4	4	1-7	General Comment. The assumption that the community exposure would be continued for 24 hrs/day, 7 days/week is certainly an over-statement.
B-6	1	3-6	"...would have been caused by emissions over the past 20 years, during which total vinyl chloride production increased from about 10% of its current level." Seven PVC plants operated more than 25 years: DOW, BFG, Goodyear, Uniroyal, Union Carbide, Monsanto, and Firestone. Consequently, if the risk model were accurate, one would expect a higher incidence of angiosarcomas around those plants. In addition, the latency period is between 12 and 32 years; it would be more accurate to use a range.
B-6	2	1-18	General Comment. With regard to the error analysis presented, it really doesn't mean very much to even attempt to do such an analysis when the errors inherent in the extrapolations from high to low doses and from animals to humans cannot be quantified. With regard to the other sources of error mentioned, the use of the standard deviations of the estimated slopes to quantify this source of error is not valid unless the model itself is valid. The errors associated with the diffusion modeling procedures are not really reflected by the 25% discrepancy between the OAQPS and Teknekron predictions, since this only gives a rough measure of precision but says absolutely nothing about accuracy. Thus, the error estimate of 33% given on page B-7 doesn't really mean anything. Also, the arguments given concerning the errors associated with the numbers of estimated cases have no sound statistical basis whatsoever.
B-6	4	1-2	"Ideally, an estimate of the errors in the diffusion modeling could be derived from a comparison with actual monitoring data." The statement suggests either that data was unavailable or if available could not be analyzed. Such data is in EPA's possession, and it is frankly impossible to understand why the diffusion model was not validated using that data. Why wasn't the Administrator advised of the consequences of this validation which logically follows from the data shown in Table 4.11 of the STAR Document?

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<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
Appendix D			
D-1	4	16	"One case is regarded as insufficient information to disprove the conclusion that the latent time in rats is independent of dose." One case may be insufficient evidence to disprove the conclusion, but there is other information, which the Risk Assessment Document studiously neglects to mention, pointing to the conclusion that time-to-tumor is dose dependent. (Paper by Albert, R. E. and Altshuler, B. in 1973 concerning considerations relating to formulation of limits for unavoidable population exposures to environmental carcinogens.) Also the Maltoni analysis supports a dose dependence.
D-2	4	1-5	Time-to-tumor is computed for man as 19.6/72. The 19.6 is based upon the assumption that all neoplasms that are to occur have already occurred.
D-4	1	1-5	General Comment. It is not justifiable to conclude that the incidence among just the most highly exposed workers is about 0.02 based on the results of the four epidemiologic studies of Table 1. First of all, it is invalid to ignore the Tabershaw-Gaffey report and to selectively choose those studies giving the highest rate. In fact, the Tabershaw-Gaffey study probably provides the most reliable (statistically speaking) estimate of the time incidence rate because of the large sample size involved. Also, the .02 is only an estimate and, as such, should have a statistical measure of error associated with it.
D-4	2	20	"... $0.02 \times 3.8 = 0.076$." Should be corrected by using Tabershaw-Cooper incidence rate.

<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
D-5	3	6	General Comment. The value of .0031 (the probability per year of exposure that a highly-exposed worker will develop angiosarcoma sometime in his life) is based on the .02 incidence rate, which itself is a highly questionable value. The quantification of the errors in the numerical estimates of parameters leaves a lot to be desired. The authors, by <u>intuition</u> , specify a possible range of values for the incidence rate, and they also provide only empirical guesses about the variation in chronic dosage and in the number of hours of daily exposure. Therefore, their value of 0.67 is highly suspect. Also, the conceptual errors in the formulation of the model are not quantifiable.
D-6	5	1-16	General Comment. The use of the factor 1/1.68, which is based on a comparison of the human annual incidence rate (.0031) and the animal rate (.0052), is highly suspect in view of the possible large errors in these estimated incidence rates. Also, saying that these two incidence rates are "close" to one another does not say anything about the accuracy of either one of the estimates. In fact, it is probably the case that both are way off from the true value, based on the unresolved numerical and conceptual problems associated with their determination.
D-7	5	2	Reference 16 is missing from report.
D-7	5	13	See comment on Page 5, Paragraph 2, Lines 6-8.
D-7	6	1-19	General Comment. The use <u>solely</u> of the Monson study to get at the ratio of all cancers to liver angiosarcomas is highly suspect in view of the fact that some studies (e.g., those of Ott et.al. and Wagoner) were not used because <u>no</u> angiosarcomas were observed and that others (e.g., Nicholson et.al. and Tabershaw et.al) were not used because no elevated rates were found. Such selectivity clearly gives a biased impression. Also, no estimate of error with regard to the Monson factor is given.
D-8	2&3	NA	No discussion was given to baseline population rates for the BSP test.

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<u>Page</u>	<u>Paragraph</u>	<u>Line</u>	<u>Remarks</u>
Appendix E			
E-1	Last Paragraph	Last Line	"...national survey of all liver angiosarcomas..." A more accurate statement would be "...national survey of all liver angiosarcomas (subject to confirmation)..."
E-3	2	1	"A total of 286 cases were identified." This statement should reflect the uncertainty which still exists as to the actual situation. "A total of 286 <u>possible</u> cases were identified."
E-4	2	1	"176 cases remained..." Should read "...176 <u>possible</u> cases remained..."
E-4	3	8	"...only six cases, as shown in Table II." The statement is misleading. For distances less than five miles only three* possible cases of angiosarcoma have been found.
E-4	4	1-8	Case 1 is inappropriately included in this cohort as the document apparently admits.
E-4	7	L	Case 6 is mistakenly used instead of Case 5. The speculation about transplacental carcinogenesis is inappropriate. The fact is we do not know whether VC played any causal role in the cancer. If there is no evidence of VC's involvement, why speculate in a Risk Assessment Document.
E-5	5	1-16	General Comment. The fact that the survey produced <u>no evidence</u> that living around vinyl chloride plants is a risk factor in the occurrence of liver angiosarcoma is an important finding, despite some remarks to the contrary and this fact should have found its way into the main body of the document.

*Now reduced to two cases, see footnote page 3.