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November 16, 1994



Bruce Whitney, Esq.
Air Products and Chemicals, Inc.
7201 Hamilton Boulevard
Allentown, PA 18195-1501

Dear Bruce:

Here are the three speeches to which I was referring during my telephone conversation today with Thorne Harris, Andy Hanen and Denise Legendre. They include:

1. The Air Products testimony at OSHA hearings in Washington on 28 June, 1974 relative to vinyl chloride, including testimony by John Barr and Dr. Paul Kotin, our medical consultant.

2. A talk to the Society of Plastics Engineers in New York presented in 1975 which discusses how the OSHA hearings came about, the results, and the state of knowledge on vinyl chloride caused cancers at that time. (Oct. - Nov. 1974)

3. A talk entitled, "Who Should Tell The Worker?" which clearly assigns this responsibility to the employer. It also characterizes the nature of the Jimmy Carter administration's OSHA.

I'll look forward to learning how I might be of further help to you. Because I was heavily involved in CMA AIHC and CIIT efforts to bring science and reason to the regulatory scene beginning with vinyl chloride, I feel I can be of help to both Air Products and the industry in general in formulating and documenting the basic elements of an effective defense against the complaints described to me.

Incidentally, I will be in California at Catalytica, Inc. from November 27 to December 2. My number there is 415-940-6318 (office) or 408-748-8460 (apartment). Office fax there is 415-968-8754.

Regards.

Dick

Richard Fleming

RF:ta

Enclosures [3]

Vinyl Chloride -- Health Issues

23 January 1991

I. History

| | |
|---|---|
| 1949 | Russians observe hepatitis in plastics fabricating plant. PCB? |
| 1961 | Dow. Liver dysfunction down to 100 ppm (rodents). Recommend exposure limit of 50 ppm. |
| 1962 | American Conference of Governmental Industrial Hygienists - TLV 500 ppm. |
| 1964(?)-66 | Acroosteolysis in polycleaners. |
| 1956 | Start-up Pace |
| 1958 | Start-up Calvert City (closed 3/82-9/83) |
| 1970 - | Viola (Italy) reports cancer in rodents at >10,000 ppm. No angiosarcoma. |
| 1971 | Major European manufacturers launch inhalation studies (Maltoni). OSHA adopts 500 ppm. |
| 1973 | No increased CA in European workers. Maltoni finds tumors >250 ppm. Angiosarcoma. |
| 1974 | BF Goodrich, Louisville, 3 angiosarcomas. OSHA temporary standard 50 ppm. Rodents have angiosarcoma >50 ppm. OSHA announces permanent standard 1 ppm averaged over 8 hrs. No peaks >5 ppm for 15 min. (4/1/75). |
| 1983 | US case #38, Air Products, Calvert City. First exposure 1963. |

II. Toxicology

A. CNS depression (anesthetic [cardiotoxic, 1933])

B. Hepatic dysfunction

C. Polycleaner's disease. Acroosteolysis

D. Cancer

1. Rodent carcinogen.

2. Mutagenic in in vitro systems.

3. Angiosarcoma (ASL) in humans.

   a. No effective screening test.

   b. No effective therapy (survival 6 mos.)

4. Lung CA risk increased?

5. No other increased CA risk.

III. Epidemiology

A. ICI Registry; Doll, Richard. "Effects of Exposure to Vinyl Chloride: An Assessment of the Evidence", 13 April 1987.

B. No cases of ASL attributable to VC outside the occupational environment.

C. Persons with ASL exposed to several 100-thousands ppm. No ASL among persons exposed exclusively at <5 ppm. (Will there ever be? Latency.)

D. 157 cases world-wide (1/1/90)
39 cases in U.S.
15 BFG Louisville

E. Mean latency: US 25.7y.; World 23.9y.

F. Deaths in 1989: 5 (total); US 1 (first exposure 1955)

G. Prevailing Escambia neighborhood concentrations of 0.01 ppb are 1/5000,000 of occupational exposures not associated with ASL.

$$\frac{0.01 \text{ ppb}}{5 \text{ ppm}} = \frac{0.01 \text{ ppb}}{5000 \text{ ppb}} = \frac{1}{500,000}$$

Correcting for 40-hour workweek:

$$\frac{1}{500,000} \times \frac{168 \text{ hr/wk}}{40 \text{ hr/wk}} = \frac{1}{120,000}$$

H. Neighborhood levels are 1/24,000 of workplace standard, adjusted for duration of exposure.

$$\frac{.01 \text{ ppb}}{1 \text{ ppm}} \times \frac{168 \text{ hrs/wk}}{40 \text{ hrs/wk}} = \frac{1}{24,000}$$

IV. OSHA Standard (29CFR 1910.1017)

A. Medical surveillance (annual) -- "opportunity"

1. History: Alcohol, hepatitis, hepatotoxic agents, transfusion, hospitalizations.

2. Examination

3. "Blood work": Bilirubin, alkaline phosphatase, SGOT (AST), SGPT (ALT), gamma glutamyl transpeptidase (GGTP). "The laboratory tests commonly used by doctors to evaluate liver damage and liver function [the cited tests] are usually not helpful for determining if liver damage from vinyl chloride has occurred." - Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Public Health Service, August 1989.

B. Medical surveillance (6 mos.)

1. For "employee who has been employed in vinyl chloride or polyvinyl chloride manufacturing for 10 years or longer . . . " (4/1/75).

C. Emergency medical surveillance.

D. VC and respirator clearance statement.

E. Withdrawal from contact if exposure would result in material impairment.

F. Physician's equivalent and written rationale.

G. Records - Duration of employment + 20 years or for 30 years.

H. Reports of excess exposure and remedial steps.

1-7-91

THE UNITED STATES

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

DOCKET OSH-36

TESTIMONY OF

AIR PRODUCTS AND CHEMICALS, INC.

AIR PRODUCTS AND CHEMICALS, INC.
Five Executive Mall Building
656 E. Swedesford Road
Wayne, Pennsylvania 19087

# Testimony of Richard Fleming

Greetings --

## I. INTRODUCTION

I am Richard Fleming, Group Vice President of Air Products and Chemicals, Inc. I am responsible for the Chemical Group of our company headquartered at Valley Forge, Pennsylvania. Testifying with me today are Mr. John T. Barr, Technical Manager - Manufacturing and Dr. Paul Kotin, M.D., our consultant on VCM medical matters. Also with me are Dr. A. Ross Adams, General Manager, Plastics Division; Mr. T. L. Carey, Vice President of Manufacturing; and Mr. Joseph T. Sebastianelli, Attorney.

Air Products operates two plants for the production of polyvinyl chloride using the suspension process and located at Pace, Florida and Calvert City, Kentucky. Combined capacity of the two plants is approximately 200 million lbs./year, or approximately 3.5% of the total PVC industry. Air Products also operates a PVC compounding facility at Calvert City, and small PVC plastics fabrication plants at Morristown, New Jersey, Costa Mesa, California, Durant, Mississippi, and Homestead, Pennsylvania. In addition, we now operate a plant at Calvert City for the production of a different class of polymers, sold as water emulsions, which also uses vinyl chloride as one of several monomers for a portion of its output and we have a second plant of this type under construction at South Brunswick, New Jersey. The total

number of employees engaged in all these operations, including all service support and management is about 500.

Air Products is a non-integrated producer of PVC. We purchase all of our raw materials and are only very slightly integrated forward into fabrication using less than 2% of our PVC production. We are about 10th in capacity among PVC producers, but a relatively large proportion of our output is in special types of polymers. Our PVC plants have been operating since 1957 and 1959, each coming to Air Products as part of acquisitions of larger businesses, the Florida plant in 1969 and the Kentucky plant in 1971.

Air Products has participated in industry studies of health hazards of VCM and will continue to do so. Our own medical examination program, which will be discussed later by Dr. Kotin, has covered approximately 480 present employees. We have also studied the mortality experience of all employees who have worked in these plants. We have found no cases of angiosarcoma.

Air Products and Chemicals, Inc. is deeply concerned about the question of appropriate protection of the health of its employees and of all those involved in the VCM-PVC industry. We are participating fully in whatever activities we can recognize as worthwhile in developing facts that permit determination as to what that health protection means in practical terms. We believe in establishing and observing soundly conceived regulations designed to assure safe working conditions.

We are also very concerned that unwisely conceived and unnecessarily restrictive regulations not be promulgated. Such regulations work to the disadvantage of all concerned, worker, company, consumer, and the economy as a whole.

## II. OBJECTIVES OF TESTIMONY

Thus our purposes here today are as follows:

(a) To present for the public record a resume of our study of the health of our own employee population - and to offer the conclusions our medical consultants have reached from these studies at the present time. This is meant as a contribution to the national study of employee health in the VCM-PVC industry that is so urgently needed to guide the formulation of safe practices.

(b) To offer some perspectives on what we consider some key issues relative to arriving at appropriate regulations.

(c) To provide testimony on what we believe is feasible and workable and why, in the way of regulated occupational exposure.

(d) To offer some detailed comments on the proposed regulation for the consideration of those who will write the final one. These will not be presented orally at this meeting in the interests of time, but will be a part of our written submission.

III. EARLY TOXICOLOGY

In much of the information presented prior to and during these hearings it has been or will be stated by many observers that general concern about human exposures to vinyl chloride have passed through three distinct phases as follows:

Phase 1 - fire and explosion concerns and narcotic effects;

Phase 2 - concerns regarding AOL; and

Phase 3 - concerns regarding carcinogencity.

Phase 1 concerns were the only ones of significance from the inception of manufacture and polymerization of vinyl chloride in Germany in the early 1930's until the early 1960's, a period of 25 - 30 years. During this period, VCM was used as an anesthetic, such was the understanding of its toxicology during this time. A number of toxicological studies made in this period show only minor effects from exposures to what were usually high dosages for relatively short periods of time compared to the more recently published information concerning longer term exposures.[1] It is perhaps pertinent to note that many more persons have been injured or killed as a result of flammability and narcotic hazards than from any recognized toxicological effects of vinyl chloride.

AOL was first observed in PVC workers in 1960-1962 both here and abroad and in about 1966 a causal relation between VCM exposure and AOL was established. Since AOL occurrence

1. Documentation of the Threshold Limit Values for Substances in Workroom Air. American Conference of Governmental Industrial Hygienists (3rd Ed. 1971).

was almost exclusively among reactor cleaners who came into frequent physical contact with VCM, precautions were taken to limit or eliminate this and the incidence of AOL declined markedly. These and other plant and operational changes resulted in lower exposure of operating personnel generally to VCM concentrations.

IV. EXPOSURE EXPERIENCE

Industry conducted toxicology studies, exemplified by those extensively reported by Dow, showed that lower exposure levels were necessary to avoid the possibility of toxicological effects of chronic exposure. Specific standards of 500 ppm TWA and then a 500 ppm ceiling were set by ACGIH and later by OSHA and met by industry.

The actual levels of VCM in plant atmospheres to which workers were actually exposed is not a matter of record. The need for such information was not understood and the instrumentation to readily measure it was not available for most of the period of historical operation. Attempts now to reconstruct historical exposure levels are admittedly crude but they are nonetheless instructive. The lower explosive limit for VCM in air at ambient conditions is 3.6%, i.e. 36,000 ppm. In the phase 1 period this was the absolute upper limit of concern to plant operators. Even with a safety factor of 10, levels of 3,600 ppm would have been tolerated if no

other problems were found or expected. It is reasonable to expect that such levels were encountered at times in early operations by some individuals.

It is very difficult to reconstruct the pattern or frequency of early peak levels of exposure in any reliable way. It has seemed more realistic, and perhaps more pertinent, to attempt estimates of the average, long term continuing exposure to which an individual was subjected. Thus TWA data have been used to characterize the cumulative long term dosage thought to have been experienced by workers in PVC plants.

The Chemical Industry Association of the UK has recently stated their estimates of the <u>average</u> TWA exposure of workers in UK plants. These estimates show the following variation over time:

| | Average TWA |
|---|---|
| 1945 - 1955 | 1000 ppm |
| 1955 - 1960 | 400-500 ppm |
| 1960 - 1970 | 300-400 ppm |
| mid 1973 | 150 ppm |
| now | 50 ppm |

Since the technology and equipment used in UK operations, and the economic and safety considerations concerning VCM loss control were not appreciably different from those prevailing in the U.S. or other parts of the world, one could reasonably expect similar estimates to characterize operations in this country. In fact, it is our judgement that these figures <u>are</u> reasonable estimates of what prevailed, on average, in

this country. Our estimates for our own plants are about the same as this table. Note that these are average figures so that some plants must have been higher at least part of the time. Furthermore, it seems clear that within those plants some individuals probably had even higher exposures.

## V. CURRENT SITUATION

The recent liver cancer findings are the legacy of this type of exposure. Each case found to date has involved an individual who has worked through periods of high level exposure by any current day measure, and all have worked for some time in jobs where the highest individual exposures have been encountered.

Thus far the extensive search of the human experience for angiosarcoma among workers in VCM-PVC has turned up 19 cases since 1961. Of these, 13 are in the U.S., found among the employees of 15 VCM plants and 36 PVC plants. Of the 13 cases, 7 have occurred at one PVC plant, 3 at another. A U.S. total of 4 PVC-VCM plants have had known cases. There are thus 47 plant populations who have no record of angiosarcoma although they have lived through periods of exposure well above levels no one would tolerate in the light of current information.

There is a considerable body of animal exposure data to show decreasing hazards with decreasing exposure levels of VCM. Moreover, the human experience in its plants reported by Dow at the February hearing has shown no incidence of angiosarcoma among its

workers from long term average exposures of between 100 ppm and 200 ppm/TWA. Air Products own health studies show one case of ADL and no other health problems related to exposure in our operations to date.

Although exposure levels in fabricating plants have generally been very low, exposures in a few jobs in these plants have historically probably been of the order of 15-25 TWA. Until the recent announcement of the GE wire coating case, and the case of the accountant at a vinyl sheet producing plant there were no reported angiosarcoma cases among fabrication plant employees. As we heard in yesterday's testimony, any relationship between these cases and exposure to VCM remains conjectural at this time. Careful study of the very large body of human experience already available in the history of PVC fabrication operations is clearly warranted and can shed important light on the hazards of relatively low level exposure.

Exposure levels in VCM plants are generally considerably lower than in PVC plants because of the continuous process technology of the monomer operations and the generally outdoor construction of these plants. Only one angiosarcoma case has been found among VCM workers and this man is reported to have worked on very high exposure tasks related to sampling and catalyst tube cleaning. He also worked in PVC for the final year of his working life.

All of these considerations lead to the idea of a relatively safe but readily measurable level of VCM in a work environment.

We therefore support the proposal for a 25 TWA exposure level effective October 5, 1974. As we will show later, we believe that this level is also feasibly attainable, though a difficult and expensive one to continuously meet 100% of the time, as we would hope to do under such a regulation. Lower levels, proposed for later achievement, are much more difficult and much more speculative as to achievement at this time in our view. This too will be elaborated on by Mr. Barr.

## VI. EFFECT OF STANDARD ON OPERATIONS

Any level of exposure that is required by a new standard that is below current achievement confronts a producer with essentially three alternatives:

1) Since he does not meet the standard, he can shut down and abandon the business. The economic consequences of this on the producer and his employees are apparent. The effect on his customers depends upon what alternative sources of material they can find. SPI testimony covers this in some detail.

2) He may make changes, involving capital expenditure or otherwise, to bring his operations into compliance. Depending on the severity of the standard this will take more and more fundamental and expensive changes and thus longer and longer times, and may reduce output although not stop it entirely.

3) He may decide to replace his current plant with a new one designed to meet the new standard. This route, of course, requires the most in time and capital money.

Thus far, all producers have been proceeding according to alternative #2. Everyone has obviously done the quickest, easiest, most effective things first. This has permitted most of us to quickly approach conformance to the emergency standard now in effect. I say approach because I do not believe any PVC producer is able to stay below 50 ppm 100% of the time at every location in his plant. I know that we are not, in spite of our most strenuous efforts, and I believe we may be ahead of a number of other producers in measures we have taken.

Because of the volatility of VCM and the internal pressures in PVC equipment, every flange, valve, pump, compressor, heat exchanger, and other piece of process equipment is a potential source of leaks. Much of the equipment must be opened routinely for cleaning and inspection to insure safe operation, and large quantities of air pass through other items of equipment such as centrifuges and driers. There is no one thing to be done to limit VCM loss to the plant atmosphere, there are literally hundreds of leaks or potential leaks to deal with. This should make it clear how hazardous are estimates

of future achievable VCM levels in plant air and how likely it is that excursions in these levels will unpredictably occur from time to time. Replacement of older equipment with newer types, designed with minimum leakage in mind, depends upon availability and deliverability of such replacements. Delivery of even an exhaust fan takes months in the current high capital spending environment. Major equipment takes many more months.

Although we at Air Products are not at all satisfied with our ability to guarantee conformance with the current emergency standard, we support the 25 TWA proposal for October 5, 1974. We need the delivery of new equipment to meet this level but have some confidence that we can meet it. The concept of a ceiling level, and how it is to be measured and administered requires clarification in the proposed standard, and Mr. Barr will cover this in our more detailed comments to follow.

Alternative 3 requires some comment. For any producer of PVC other than one who also produces VCM this is not currently a realistic alternative. Air Products for some time has been attempting to develop an assured source of supply for enough VCM to build a new, modern PVC plant. We are naturally reluctant to do this without such a source. Two years of contact and/or negotiation with every conceivable supplier has yielded nothing of substance. We can forsee no change in this situation for some time, at least until substantial new VCM capacity is announced for merchant sales and is nearing production. No such plant, which takes three years to build, is now in prospect. Under these circumstances, should any significant part of the industry be forced to shut down by unrealistic regulation, greatly increased concentration of the industry will surely result.

## VII. VENTILATION CONSIDERATION

Any estimate of achieveable levels in the plant atmosphere is of course dependent on the degree of plant ventilation permissible as well as on the degree to which VCM is released. Virtually all of the testimony presented in this hearing will be based on the basic presumption that very extensive use of strong ventilation is acceptable. This is so because no practical technology exists for the removal of VCM from large volumes of plant air. It seems clear from current information

that this presents no real problems but it must be recognized that unrealistic actions in the way of external environmental regulation can negate practicality just as easily as unsound in-plant regulations.

VIII. FABRICATION SITUATION

Consideration of fabricating operations as potentially regulated ones must also be given. There are sufficient data now becoming available to warrant a judgment that if resins containing not more than 0.05% by weight of uncombined VCM are shipped from the polymer plants that there is no need to regulate warehouses, shipping facilities or fabrication operations. Data to support this will be offerred by Mr. Barr. There are two possible places in fabrication operations that should have some elementary precautions in effect, however. Such precautions seem to be already adequately covered by existing OSHA requirements.

At the point where the PVC container is first opened, the contained air, although quite small in volume, and in absolute VCM content, may be high in VCM concentration. In an impervious container such as a tank car or a silo the concentration will usually be above the corresponding ppm of free VCM in the resin. In a porous container, like a paper bag, the concentration in the contained air will be very noticeably lower. In either case, this air should be exhausted outside of the work area by

appropriate ventillation means. In a similar way, gases evolving from the first heating and exposure of the molten resin should be similarly vented. With these simple precautions the atmosphere in the fabricating work space may be expected to be at levels not exceeding 2 ppm and probably very much lower. TWA's for such plants might be expected to average 1 or less for the employees involved.

We therefore recommend that fabrication facilities processing resins of less than 0.05% uncombined VCM be considered non-regulated areas within the meaning of the proposed standard.

I would now like to introduce John T. Barr, Technical Manager for Chemical Group manufacturing.

Testimony of John T. Barr, Regarding Technical Feasibility of the Proposed Permanent Standard.

These comments are presented for your consideration and are based on the best information available to us at this time. I shall discuss (1) the sources of exposure to our workers, and the methods of exposure reduction which we have used, (2) the methods of monitoring, (3) the programs for exposure reduction which we have in progress, (4) the situation in fabrication plants which we have studied, and (5) a summary of our specific comments on the proposed standard. In addition, we will submit a detailed written commentary on the standard, with suggested changes.

1. Sources of Exposure and Exposure Reduction Methods

About 80% of the PVC which is manufactured in the U.S. today is made by the process which APCI employs, that is, the batch suspension process, and most plants, as do ours, contain a multiplicity of relatively small reactors. These reactors must be opened frequently for charging and cleaning. It is the vapors from these operations, and from the VCM degassing from slurry and dried powder that form the greatest sources of VCM exposure to workers.

The second greatest source is the fugitive emissions from leaks at gaskets, valve stems, pump seals, and other mechanical joints in the piping of the plants. These two sources will continue to be a problem no matter how well maintained or how carefully operated is the plant.

Monitoring of the VCM concentrations taken in our plants during the last week in January disclosed that we had many areas around reactors, pumps, and weigh tanks that contained concentrations in the 200-400 ppm range, with a few isolated points even higher, although the general work space was usually in the 50-200 ppm range. This survey substantiated the results of earlier tests.

At this time, APCI accelerated its monomer exposure reduction program which had been started almost a year earlier. We mounted a major engineering and renovation program, including extensive revision to operating procedures, to reduce the chance of release of VCM inside the building; special retraining of operators; and augmentation of the total ventilation system for buildings and equipment. We instituted the use of airline respirators for reactor cleaning or entering vessels containing VCM, and while doing maintance work that could release VCM. We were fortunate that we had placed an order in the summer of 1973 for much of the equipment needed for the polymer building ventilation improvements, and that this was being in fact delivered in early 1974. Other equipment was obtained from wherever available and some was diverted from its intended application in other areas for this service. Immediate attention was given to the trouble spots, by the assignment of all available technical and maintenance personnel. This allowed us to reduce the exposures to the point that by the time the temporary standard of 50 ppm

took effect on 5 April, 1974 we were already in substantial compliance. Continued work has enabled us to achieve an average 8 hour TWA in the 20-25 ppm range for our workers in the polymerization building, and even lower for those in other job locations. Once again it must be pointed out that these are average TWA figures and many of our results are above this average.

Moreover, we still are having difficulty in maintaining our work spaces below the present standard of 50 ppm ceiling all of the time since it is impossible to guarantee that a leak will not develop, and that an employee will not be exposed temporarily to a concentration above a specified level, no matter what that level may be.

We want to emphasize the difficulty of a ceiling concept. Technology does not now exist that will give instantaneous readings of VCM concentrations at the worker breathing zone. Therefore, there must be an allowable time period in the standard for the monitoring system to sense a rise in concentration and to warn the employee to put on breathing protection. In addition, the use of that breathing protection must be permitted on a continuing basis when the designated ceiling is exceeded. We cannot understand the practicality or validity of a ceiling standard without such provisions, since it is not reasonable or enforceable, and in the last analysis, we believe that the best basis for the protection of a worker is the control of his total exposure.

Another point which also needs emphasis is that while stopping VCM emissions at their source is clearly the first exposure control priority, the ability to continue to utilize ventilation is essentia to overcome the effects of inevitable leaks and losses from any practical system.

2. Monitoring Methods

We have found that two basic monitoring programs are necessary for us to understand completely the problems which we must solve; (1) area monitoring, and (2) the determination of individual employee exposures by personal monitoring.

Area monitoring was first performed in our plants with a portable total hydrocarbon analyzer. This is still being used regularly as a leak detector and to cover those areas which are not covered by fixed point monitors.

We were able to have a 10-point fixed monitor in service in each plant by early April. This is a chromatgraphic device which separates and measures the actual VCM concentration. A second 10-point instrument is now in service, giving us 20 points for our area monitoring in each plant.

Personal monitoring has been in effect since late February using the carbon tube method, and we now have four months experience. We have found that 8 hr. measurements are more reliable and give more realistic data than do the shorter sampling periods which have been recommended.

All three of these instruments have been cross-checked and calibrated against our laboratory chromatagraphs, first by using identical samples on all instruments simultaneously, and second by taking field samples and rerunning them in the laboratory. We have found the correlation to be excellent and therefore recommend that both methods be employed.

j. Programs in Progress

We have completed nearly all of those things which can be done with materials and technology at hand. Further improvements require substantial outlays of engineering efforts, capital, and above all, time to obtain and install the necessary equipment.

We have had on order for almost 5 months now rotating vane compressors to replace the reciprocating machines currently in service in our monomer recovery section. These existing compressors are a source of monomer because of leaks at the shaft seals. The presently promised delivery indicates that we will have the new compressors in service by July of 1975.

We have been working for more than two years, and have spent more than a million dollars, on the development of a solvent cleaning system for the polymerization vessels. This would effectively eliminate the need to open or enter these vessels, and thus greatly reduce the exposure potential. We are not yet completely satisfied with the system, and a recent request for quotations on the required equipment to expand the system from its present level of operation resulted in

estimated delivery times of from two to two and a half years after the order is accepted.

Even standard equipment such as pumps and valves run several months to a year for delivery, and as all of the industry knows, it is impossible to get early delivery on monitoring equipment, apparently because of the large orders placed by governmental agencies. Other quoted delivered times for the type of equipment which we will need are:

| | |
|---|---|
| pressure vessels: | 2 years or more |
| instruments: | 12 to 14 months |
| field erected tanks: | 16 to 20 months |
| structural steel: | 10 to 16 months |
| centrifuges: | 20 months to 2 years. |

This situation will deteriorate rather than improve as more companies move to reduce their exposures and we can expect that at least two years will be necessary for any major capital improvements.

Even assuming, however, that major improvements are committed to, we cannot expect to accomplish any further order of magnitude improvements such as we have achieved in the past six months. The very fact that our worker exposure is now averaging 20-25 TWA in itself indicates that many of the readings are above 25, with a few above 50, and we expect that we shall have a very difficult time in maintaining all 8 hour TWA exposure at a level below 25 ppm, if, in fact, we can do it

at all. We can support the SPI proposal of 25 TWA as a goal that we have a reasonable hope of achieving by October, 1974, beyond that we cannot state with certainty the results of technology which is yet to be applied.

4. Fabricators Plant

We believe that PVC fabrication operations do not require regulation under standards being considered for VCM and PVC plants, since exposures to VCM at the fabricators' plants which we have studied are now very low.

The monomer content of resins has followed a pattern very similar to that of VCM in the workplace. Levels of 0.1-0.2% by weight in the resin were quite normal for many producers as recently as 1973. The steps which were taken to reduce worker exposure in PVC manufacturing plants have produced as a side effect a reduction of the residual monomer. In addition, other work programs have been aimed specifically at this problem, so that at present most producers can manufacture resin containing less than 0.1% free VCM. Some producers, as can Air Products with its line of specialty resin that represent a small portion of its output, manufacture resin with quite low residual levels. The great majority of the general purpose resins, however representing 65-75% of all production, now fall into the range of 0.025%-0.075% by weight. We believe that with present programs we can achieve a goal of 0.05% for all resin at the time of shipment from the plant, and the actual content by the time it is processed will be lower than this.

Our position was substantiated by the results of measurements of the VCM levels in a number of our customers' plants as well as in our own compounding and fabrication operations. We have found these levels to run no higher than 1-2 ppm, and they are generally well below 0.5 ppm. These results are being obtained while processing polymer of normal monomer content, and with the standard ventilation of the type which is required for ordinary industrial hygienic purposes.

A further important point is that there is no potential for a large release of VCM at a fabrication plant as there could be at a VCM or PVC operation.

Neither do we see any problem in the transportation of PVC. For example, should a 40,000 lb. truck load of PVC containing 0.05% VCM lose even half of its VCM over a several day trip, this would only amount to a loss of 10 lbs. of monomer, which would be so diluted along the route that it would be unmeasureable.

Thus, we can recommend without reservation the exemption from the standards of facilities involved in the handling of materials containing less than 0.05% by wt. uncombined VCM from this standard.

5. Comments on the Proposed Standard

We have prepared a detailed list of objections to the proposed standard as published, and have supplied alternate wording where its is needed. In the interest of brevity, we are submitting these in writing, as Appendix A, and ask that they be made a part of the record of this hearing. A brief summary will be given here.

1. We propose to substitute a limit of 25 TWA, 40 ceiling in place of the no detectable level.

2. Monitoring should include both the work zone and the employee.

3. Respirators may be of the half-face or full face, air supplied type, and shall be worn as soon as possible after it has been detected that the ceiling has been exceeded.

4. Impervious suits should not be required, but clean work clothing be furnished as appropriate.

5. We propose that the permanent standard not apply to PVC, waste streams or finished or semi-finished product, including compound, which contains less than 0.05% by weight uncombined vinyl chloride, or to the transportation or processing of PVC with this level of free VCM.

6. Conclusion

In conclusion, we respectfully submit that the proposed permanent standard fails to meet the basic requirements in the Occupational Safety and Health Act of 1970 either as to necessity, or as to technical and economic feasibility, and that it represents a substantial departure in principle from other standards. Many of its specific requirements are either impossible to meet or are unnecessarily restrictive, and some offer greater hazards than that which they propose to remedy. We therefore request your serious consideration of our comments and suggested changes.

I would now like to introduce Dr. Paul Kotin who has designed and administered our health examination program for our employees with any significant vinyl chloride exposure. He has done this with the close cooperation and on-site management of these programs at Calvert City, Kentucky by Dr. William N. Blalock, at Pensacola, Florida by Dr. Barkley Beidleman, Dr. Sanford Klein in Somerville, New Jersey and Dr. Herbert Hyman in Allentown, Pa.

PRELIM. TESTIMONY OF DR. PAUL KOTIN
REGARDING MEDICAL RESULTS

This is a report of the results of screening of present employees of Air Products and Chemicals, Inc., who are engaged in the handling of vinyl chloride monomer, and on the results of my examination of death certificates of those PVC employees who left the company or died while employed.

I was employed as a consultant by Mr. Richard Fleming, Group Vice President Chemicals Group of Air Products and Chemicals, Inc., in early February, 1974, for the specific purpose of establishing and conducting a medical evaluation and surveillance program for employees exposed to vinyl chloride. As a final step physicians were identified in the two areas where APCI has VC operators. Dr. William N. Blalock of Paducah, Kentucky, and Dr. Barkley Beidleman of Pensacola, Florida, agreed to serve and in consultation with them, a medical examination protocol was developed and carried out for employees in plants at Calvert City, Kentucky, under the supervision of Dr. Blalock, and at Pace, Florida, under the supervision of Dr. Beidleman.

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Both physicians are certified in the American Board of Internal Medicine. Dr. Blalock is a specialist in gastroenterology and hepatology, and Dr. Beidleman is a member of a large medical group with specialists in gastroenterology and hepatology. Following several meetings between myself and the two physicians, a screening and review procedure was adopted for the APCI employees at the two plants. Special emphasis was directed towards identifying and specifically testing for the two diseases for which there were demonstrated associations between VC exposure and disease -- acroosteolysis and angiosarcoma of the liver. These areas of emphasis were part of a complete review of each patient which included the following:

A complete and detailed medical history was taken on each employee. Afterward, a physical examination and a series of laboratory procedures were performed as follows:

| Pensacola, Florida (Dr. Beidleman) | Paducah, Kentucky (Dr. Blalock) |
|---|---|
| Chest x-rays | Chest x-rays |
| Hand x-rays | Hand x-rays |
| Blood urea nitrogen (BUN) | Blood urea nitrogen (BUN) |
| Uric acid | Uric acid |
| Phosphorus | Phosphorus |

| Pensacola, Florida (Dr. Beidleman) | Paducah, Kentucky (Dr. Blalock) |
|---|---|
| Calcium | Calcium |
| Alkaline phosphatase | Alkaline phosphatase |
| Total protein | Total protein |
| Albumin | Albumin |
| Bilirubin | Bilirubin |
| Cholesterol | Cholesterol |
| Globulin | Chloride |
| Glucose | Serum glutamic oxalacetic transaminase (SGOT) |
| Triglycerides | Lactic dehydrogenase (LDH) |
| Serum glutamic oxalacetic transaminase (SGOT) | Complete blood count (with platelets) (CBC) |
| Lactic dehydrogenase (LDH) | Serum glutamic pyruvic transaminase (SGPT) |
| Alpha fetoprotein (AFP) | |
| Carcinoembryonic antigen (CEA) | |
| Complete blood count (CBC) | |

Differences in the laboratory tests performed in Florida and Kentucky reflected the availability of laboratory resources. Testing showing abnormal laboratory findings in any employee were repeated to assure their authenticity. In addition to repetition of the preceding tests when indicated, the following additional tests were

performed on employees not previously having these tests:

| Pensacola, Florida | Paducah, Kentucky |
|---|---|
| Complete blood count with platelets (CBC) | Carcinoembryonic antigen (CEA) |
| Prothrombin time | Alpha fetoprotein (AFP) |
| Gamma glustamyl transpeptidase (GGTP) | Gamma glustamyl transpeptidase (GGTP) |
| Serum glutamic pyruvic transaminase (SGPT) | |

The persistence of abnormal laboratory findings or the presence of signs and symptoms suggesting liver toxicity was followed by a further reexamination of the employee for the specific purpose of determining the desirability of a liver scan and possible liver biopsy.

At Pace, Florida, 201 employees were tested, and 13 employees were found to have test results which varied from established norms. All these 13 employees were retested. Four employees had normal results on retest. Three employees had persistent minor variances which in our opinion did not require further testing at this time. These employees are schedules for retesting in 90 days to determine their persistence. Liver scans were performed on six employees, all of which were normal.

One case of acroosteolysis was found during the examination, and this employee has been removed from the polyvinyl chloride operation.

At Calvert City, Kentucky, 291 employees were tested. On the initial tests we found 97 employees who had findings which varied from recognized norms. Equipment malfunction was suspected, and upon retest 12 employees showed persistent abnormalities. These 12 were scheduled for immediate retest. Fourteen employees showed persistent equivocal variations as in the case of Pace and they are scheduled for retesting in 90 days.

Of the 12 employees with persistent abnormalities who were retested, six showed findings which directed to more complex and increasingly sensitive and diagnostic test procedures for liver physiology and anatomic state. The six employees were examined by liver biopsy and the results were as follows:

Two cases of Gilbert's disease, one case of intra-hepatic gall bladder, a congenital abnormality, one case of focal granuloma, tentatively diagnosed as sacro ID, and two cases showing no abnormality.

I also examined the death certificates of former employees who had been engaged in the manufacture of poly-vinyl chloride and who died either while working for or

subsequent to leaving the company. I was unable to identify any relationship between the causes of the deaths and exposure to polyvinyl chloride in their work environment.

Throughout the entire testing and examination programs at both APCI plants, there were constant discussions between the physicians on site and me, some on a daily basis at times. In addition, I have been to both the plants in Florida and Kentucky and have personally reviewed records with the local physician.

I would conclude at this time that except for the case of A.O.L. discovered in an employee in the Florida plant, the results of the screening comprising medical and environmental history, x-ray, physical examination, laboratory tests and where indicated liver scan and biopsy, no findings or diagnoses were made which point to exposure to VC as the causitive agent or mechanism. More specifically, we can state at this time that no cases of angiosarcoma have been identified.

Paul Kotin, M.D.

APPENDIX A

SPECIFIC OBJECTIONS

We submit the following specific objections to the proposed permanent standard as published at 39 FR 16896, et. seq., using the indexing contained therein:

1. Background: Vinyl Chloride is not the direct product of oxychlorination, which rather gives 1, 2--- dichloroethane that is cracked to VCM.

2. (a)(1) and (2): As stated before, evidence has not been presented that there is no safe level of exposure to VCM, and there is evidence that long term exposure to humans in the 100-200 ppm range causes no clinical harm. It has also been shown that the handling and processing of PVC is safe. The scope of the standard should be changed by striking the word "released", and changing the last phrase to "operations involving the manufacture of polyvinyl chloride." For the same reason change (a)(2) to read: "(a)(2) This section does not apply to the handling, transportation, or processing of PVC or its fabricated products containing less than 0.05% by weight of VCM, or to waste products or streams containing less than 0.05% by weight of VCM"

3. (b)(2): See objection No. 14. This section should be stricken.

4. (b)(3): A closed container which will actually prevent the escape of vinyl chloride gas is not practical, or needed. It is too heavy and cumbersome for practical use, and reopening for additions or removal of materials allows movement of vapors, and it is not feasible for permanent disposal. What is actually needed is a method of preventing contact of the workers with the polyvinyl chloride containing unusually high levels of VCM, and a method of maintaining the vinyl chloride level in the air below the specified limit. The objected to phrase should be changed to: "contact with or spread of the solids contained therein."

5. (b)(4): As was noted earlier, material containing less than 0.05% by weight vinyl chloride is not a hazard. The phrase should be changed to "contaminated means containing more than 0.05% by weight vinyl chloride."

6. (b)(5): See previous objection. Phrase should be changed to: "Decontamination means the reduction of vinyl chloride content to less than 0.05% by weight."

7. (b)(6): As stated elsewhere, the concept of "no detectable level" is impracticable and unenforceable. Such a definition will lead only to endless contention as to whether or not detection had occurred. A reasonable and safe level must be established as the standard, and the detection method must be more sensitive than the established level so that there can be no doubt as to the findings. No specific comments can be made on the proposed monitoring method because it is not published. However, any method can, and will be, improved with use, and limits of detection will be reduced. This is another reason why specific numerical limits must be established, not limits of detection. This section should be stricken in its entirety.

8. (b)(8): This definition is completely impractical. Vinyl chloride will always be present, and there is no evidence of harm from short, low level exposure, or any method of testing for, or treating medically, any results of such exposure. NIOSH on 11 March originally proposed emergency to mean "an exposure which resulted in acute symptoms." Their definition should replace that used here.

9. (b)(9): As noted in the previous comment, there always will be contact with low levels of vinyl chloride in the air, and as noted later, the definition and application of protective clothing needs revision. It has not been established that short-time bodily contact with vinyl chloride vapor is harmful. Numerous animal and human exposures, such as, for example, those cited in "Documentation of the Threshold Limit Values for Substances in Workroom Air," American Conference of Governmental Industrial Hygienists, Third Edition, 1971, pages 277-8, show only mild, reversible clinical changes for very substantial exposures. All evidence to date indicates that if harmful effects occur to humans, they come as the result of long-time inhalation at high levels, and thus efforts to protect workers should be aimed toward reducing inhalation exposure. Follwing the reasoning used in objection number 8, this should be changed to read: "Exposure means (i) inhalation of sufficient VCM vapor to cause acute symptoms, or, (ii) inhalation of concentrations of vapor above the permitted ceiling for longer than 15 minutes or, (iii) contact of the unprotected skin with liquid vinyl chloride."

10. (b)(10): Because of the suggested change in section (a)(2), this section is no longer needed and should be stricken.

11. (b)(13): In order for clothing to be truly protective against vinyl chloride, a gas, it must be completely impervious and provide whole-body protection. As stated above, no evidence is at hand that skin contact with dilute vapors is harmful. It is implied

by subsequent paragraphs (k) and (l) that the protective clothing spoken of here is not of this type, thus we recommend a change in wording to read, "Protective clothing means clean whole-body work clothing, such as pants and shirt, or coveralls, or a smock." The later applications of this defined phrase assures adequate worker protection. The need for more than normal protection has not been demonstrated except for special tasks.

12. (c) ?: The significance of this portion is not clear and an explanation is requested.

13. (4)?: This appears to be a typographical error and should read (d). In keeping with the changes requested above in sections (a) and (b), this should be changed to read: "(d) Regulated area shall be established where (i) VCM is manufactured, reacted, repackaged, stored, or used, or (ii) PVC is manufactured, or (iii) PVC containing more than 0.05% by weight VCM is processed."

14. (d)(2): It is necessary for service men, contractors' employees, governmental agencies' employees, delivery men, and others to enter regulated areas. The section should be changed to read: "employees and others whose presence is necessary for normal operation of the facility."

15. (e)(2): A minimum of two types of monitoring must be utilized, zone monitoring to alert employees to an excursion above the designated ceiling, and personal monitoring to determine actual exposures. Technology does not now exist that permits instantaneous measurement of actual exposure measured on the person of each employee. The section should be changed to read: "(e)(2) The monitoring shall provide: (i) a record of the VCM content of the general work space, (ii) a method of alerting employees within a period of no more than 15 minutes when the area exceeds the allowable ceiling content of VCM, and (iii) a method of determining the actual 8-hr. TWA exposure of each employee on a regular basis."

16. (e)(3): Details of an observation procedure have no place in a standard, and intrude on the employee-employer relationship. Adequate opportunity for review of an individual's records by himself or his physician and by governmental agencies are provided for in sections (p) and (q). Unlimited observation of calibration and procedures will disrupt and impede the operation, and reduce its effectiveness. This section should be stricken.

17. (f): As stated above, it has not been shown that it is necessary or that it is feasible to operate on a non-detectable standard. Evidence is on record that shows safe conditions exist at levels above even the temporary standard. The use of an indefinite term such as "feasible" makes interpretation of of the standard subject to personal opinion, and thus unenforceable and impossible for compliance. A program such as is called for here is not required in the standard for other suspected carcinogens, see 39 FR 3756. Operation at a non-dectable limit

would require, because of the proximity of other operations in the normal chemical works, wearing of respirators by all employees, and transients, including those in vehicles or walking between areas. This is obviously impractical. This section should be changed to read: "(f)(1) The employer shall undertake a program to assure that employees are not exposed to levels of VCM above an 8-hr. TWA of 25 ppm, nor to instantaneous levels aabove 40 ppm for more than 15 minutes. (2) Each employer shall provide respiratory protection for his employees in accordance with paragraph (g) of this section."

18. (g): The specification of only full face masks with self-contained air supply is improper. Workers are required to wear safety glasses and many of these are prescription-fitted. Cleaning and adjusting of these is impossible without removing the masks. A better fit and less leaks are obtained with half-face masks. Self-contained units with more than a few minutes air supply are heavy and tiring, and will restrict free movement to and from vessels. Pressure-demand masks require greater exertion than do full-flow units. We recommend that where masks are required that half-face, air line-supplied, full-flow types also be permitted. Our workers have been using this type for several weeks with very satisfactory results. Paragraphs (g)(2) and (3) should be changed to read: "(g)(2) Respiratory protection shall be worn by employees whenever the monitor alarm indicates that the area is above the allowable ceiling, or whenever there is reasonable expectation that an operation will result in the release of VCM into the atmosphere at a concentration above the ceiling. (3) Respirators shall be either half-or full-face, type C, air supplied, and capable of operation in the full-flow mode."

19. (h): See objection 11. The clothing and its purpose is not properly defined here. Bodily contact with dust is not known to be a hazard. If protection is needed, it would be for the eyes or lungs. The requirement for a change each time the area is left would be unduly onerous for workers in drying, loading, and bagging areas, as well as for fork-lift drivers, instrument men, and others who move about continually in their work. Exemption from this standard has been requested for resin with less than 0.05% by weight VCM, and other OSHA regulations cover the dust problem adequately. This section should be changed to read: "(h) Protective clothing: (1) Employees working in regulated areas shall be provided with clean work clothing, such as coveralls,shirt and pants, or smocks on a daily basis. This clothing shall be removed upon the last exit of the day from the area. (2) Shower facilities shall be made available to all employees."

20. (i)(3): There is no evidence that non-food chewing products" are dangerous to use in this context, thus this phrase should be stricken from the section. Add the words, "Drinking fountains are not prohibited."

21. (j)(2)(iii): The protective nature of a shower against contact with liquid vinyl chloride is not explained. If the liquid has been in contact with the skin, the indicated treatment is an emollient salve and anti-frost bite treatment, since the boiling point is -13°C., or 9°F. This section should be stricken.

22. (k)(2): Taking sections (k)(2) and (l)(4) together, all persons would be required to wear impervious suits at all times since every operating plant will have some maintenance or vessel entry in progress most of the time. The wearing of full impervious suits itself offers a health hazard, especially in southern climates, because of heat stress and fatigue. Gloves, shoe covers, and water-resistant clothing that allows air circulation, are adequate to protect the worker for vessel entry, and are safer and more comfortable. Section k(2) should be stricken.

23. (k)(3)(4): As written, this would require all product containers to bear this label. Exemption has been requested for PVC with less than 0.05% by weight. The words "more than 0.05% VCM should be substituted for the words "contaminated" and detectable levels."

24. (k)(5): Containers are not defined as to whether this includes all process vessels, reactors, pipe lines, etc., or are inside or outside the regulated area. The label is redundant for inside the regulated area. The statement as to explosive polymerization is incorrect, and the Department of Transportation does not so classify VCM. This should be changed to read: "(5) Shipping containers for vinyl chloride or mixtures containing more than 0.05% by weight VCM shall be labeled: "Vinyl Chloride, Flamable Gas Under Pressure, Cancer Suspect Agent and Anesthetic."

25. (l)(2): This section would prevent shipment of product as written if interpreted literally. It is acceptable only if the definitions of contaminated and closed containers are changed as given above.

26. (l)(4): As noted in the objection to paragraph (k)(2), impervious suits are not necessary and are harmful to the health of employees. This should be changed to read: "(l)(4) In maintenance, cleaning, or repair of equipment or vessels including reactors, employees who may reasonably be expected to be exposed to levels of vinyl chloride above the designated ceiling shall wear respirators, as defined in paragraph (g)(ii). Water repellant clothing, and foot covering shall be supplied to those engaged in washing or cleaning vessels for use while in the interior of the vessels."

27. (1)(7)(i): The protective clothing is not defined, and its protective factor is not known. The regulation is impossible to interpret or enforce. The need for skin protection against dilute VCM vapors is not demonstrated, and therefore the paragraph should be stricken.

28. (1)(7)(iii): Various reliable mechnaical warning stand-by devices are well-known, and are in approved use in several states. They have been found to be more dependable than human observers. This paragraph should be ammended by adding (i) "a suitable mechanical warning standby device may be substituted for the observer so long as another employee is on the same operating floor."

29. (n): Exemption has been requested for PVC containing less than 0.05% VCM for the reasons noted earlier in our comments. This section should be changed to read: "(n)(1) Polyvinyl chloride should be transferred or removed from containers only under conditions of local ventilation which will control dust levels as required by general industrial hygiene regulations. (n (2) Hot operations shall also be carried on under adequate local ventilation."

30. (o): Medical data are not now available to define adequately the proper diagnostic program for existing cases of angiosarcoma, short of biopsy, nor is there concurrance on an early warning test. Consequently, the precise nature of the tests must be obligatory to protect the employee. This section should be changed to read:

> "(o) Medical surveillance: Not later than December 31, 1974, a program of medical surveillance shall be instituted and each employee who will work regularly in a regulated area shall be required to take a medical examination in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO). All medical examinations and tests shall be provided without cost to the employee. (1) At the time of initial employment or upon institution of screening, and annually thereafter, a medical history checklist shall be completed by the employee. This list shall include questions concerning; (i) Alcohol intake. (ii) Past history of hepatitis. (iii) Past exposure to potential hepatotoxic agents, including drugs and chemicals. (iv). Past history of blood transfusions, and (v) Past history of hospitalizations. (2) A physical examination shall be performed, which will include: (i) Specific attention to detecting enlargement of liver or spleen by abdominal palpatation. (ii) A serum speciman shall be obtained for screening with respect to the following bio-chemical determinations of liver function. (a.) Total bilirubin, (b) Alkaline phosphates, (c) Serum glutamic pyruvic transaminase (SGPT, (d) Gamma glustamyl transpeptidase (GGTP), (e) platelet count and (f) Additional tests that may optionally be considered for use in screening include:

Lactic dehydrogenase, serum protein determinations, and serum protein electrophoresis. (iii) X-rays of the chest and hands, (iv) tests leading to a conclusion by the physician as to the advisability of working in respirators, and (v) such other tests as the physician may deem appropriate. (3) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories accredited by the College of American Pathologists or licensed under 43 CFR Part 74. (4) A complete and accurate record of the results of medical examinations shall be made and maintained for 20 years past the employees 65th birthday. Upon separation or retirement, the name of the employee shall be transmitted to the appropriate governmental registry, and the employee notified of this transmittal."

31. (p)(i): Medical records may not be disclosed without permission of the person and under present law records turned over to governmental agencies become public property. Thus in (p)(i) the words "medical records" should be stricken.

32. (q): The reporting requirements are excessive. Reporting all detectable amounts released in an area does not contribute to employee protection, and it will not be possible to determine the exact amount in most cases. Fugative leaks at pump seals, gaskets, release from polymer (either waste or product) and VCM from any other sources continually release insignificant but detectable amounts of VCM into the air. The requirement of letters to an employee each time a detectable amount is found is punitive and not constuctive. No good purpose would be served even if it were possible for the employer to comply with these provisions, and the employee and the agency have ample opportunity to see the monitoring results. This form of notification is not required in other carcinogen standards. This paragraph should be changed to read: "(q)(2) Emergencies shall be reported in accordance with this paragraph. --- (2)(ii)(A) An estimate of the amount of material released, if available, - - - "Paragraph (q)(3) should be stricken in its entirety.