

1 they propose to remedy.

2 We therefore request your serious consideration of
3 our comments and suggested changes.

4 MR. FLEMING: Now, Doctor?

5 DOCTOR KOTIN: My name is Paul Kotin. I am a
6 physician, graduated from University of Illinois Medical
7 School, and my specialty is pathology; I have been a practic-
8 ing pathologist and experimental pathologist during all of my
9 career, a career which began with World War II, following
10 which I entered the private practice of medicine in pathology
11 for two years, went to the University of Southern California
12 where I was, for fifteen years, leaving as the Paul Professor
13 of Pathology.

14 I entered Government service in 1961 as the Scien-
15 tific Director for Etiology at the National Cancer Institute;
16 five years later served as the Founding Director of the
17 National Institute of Environmental Health Sciences.

18 I was with Government until 1971, when I left to
19 go to Temple University as Dean of the Medical School and
20 Vice President for Health Sciences, and since June 1st of
21 this year I have been Vice President for Health, Safety and
22 Environment of the Johns-Manville Corporation.

23 My entire research career has been devoted to
24 environmental diseases, especially environmental carcinogenesis,
25

1 and when not with the Government I worked both sides of the
2 street; I was a consultant for a variety of Federal agencies
3 as well as a consultant to private industry.

4 What I would like to do now is give you a report
5 of the results of the screening of the present employees of
6 Air Products and Chemicals Incorporated, who are engaged in
7 the handling of vinyl chloride, and on the results of an
8 examination of death certificates of those VCM employees who
9 left the company or died while employed.

10 I was employed as a consultant by Mr. Richard
11 Fleming, Group Vice President, Chemical Group of Air Products
12 and Chemicals, in early February 1974, for the specific pur-
13 pose of establishing and conducting a medical evaluation and
14 surveillance program for employees exposed to vinyl chloride.

15 MR. KLINE: Excuse me, Your Honor. If I could
16 interrupt, our copies don't have the good Doctor's presenta-
17 tion.

18 Would you have any extra copies, Doctor?

19 DOCTOR KOTIN: No. Actually, I don't because it
20 was rewritten as of last night, incorporating the most recent
21 data from our studies of employees and data from laboratory
22 tests. It will be submitted for the record.

23 JUDGE MYATT: All right, Doctor; proceed.

24 DOCTOR KOTIN: As a first step, two physicians
25 were identified in the areas where Air Products has vinyl

1 chloride operations -- Doctor William M. Blaylock, of Paducah,
2 Kentucky, and Doctor Bartley Beitelman, of Pensacola, Florida
3 agreed to serve, and in consultation with them, a medical
4 examination protocol was developed and carried out for
5 employees in plants at Calvert City, Kentucky, under the
6 supervision of Doctor Blaylock, and at Pace, Florida under
7 the supervision of Doctor Beitelman.

8 Both physicians are certified by the American Board
9 of Internal Medicine. Doctor Blaylock is a specialist in
10 gastroenterology and hepatology, and Doctor Beitelman is a
11 member of a large medical group who are specialists in gastro-
12 enterology and hepatology.

13 Following several meetings between myself and the
14 two physicians, a screening and review procedure was adopted
15 for Air Products' employees at the two plants. Special empha-
16 sis was directed toward identifying and specifically testing
17 for the two diseases for which there were demonstrated associ-
18 ations between vinyl chloride exposure and disease -- aco-osteo-
19 lysis and angiosarcoma of the liver.

20 These areas of emphasis were just part of the com-
21 plete review of each patient, which included the following:

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

25 Chest X-ray.

1 Hand X-ray.

2 A battery of laboratory tests which I will name,
3 for the purpose of making a point in a few moments.

4 Blood urea nitrogen.

5 Uric acid.

6 Phosphorous.

7 Calcium.

8 Alkaline phosphatase.

9 Total protein.

10 Albumin.

11 Bilirubin.

12 Cholesterol.

13 Globulin.

14 Glucose.

15 Serum glutamic acid transaminase SGOT.

16 Lactic acid.

17 Dehydrogenase.

18 LDOT.

19 Alpha-feta protein.

20 Carcinoembryonic antigen.

21 Complete blood count with platelets.

22 And serum glutamate pyruvic transaminase SGPT.

23 I list this battery of tests, over half of which are
24 specifically directed to the liver, to indicate that it is a
25 battery that is required to evaluate liver function. No one --

1 not even this group, is fully informative at all times.

2 Minor differences in the laboratory tests performed
3 in Florida and Kentucky reflected the availability of labora-
4 tory resources.

5 Testing showing abnormal laboratory findings in any
6 employee were repeated to assure their authenticity. In addi-
7 tion to the repetition of the preceding tests, when indicated,
8 the following additional tests were performed on employees
9 not previously having these tests: the two important ones
10 were liver-scans and liver biopsies.

11 The persistence of abnormal laboratory findings, or
12 the presence of signs and symptoms suggesting liver toxicity
13 was followed by a further re-examination of the employee for
14 the specific purpose of determining the desirability of a
15 liver-scan and possible liver biopsy.

16 At Pace, Florida, 201 employees were tested, and 13
17 employees were found to have test results which varied from
18 established norms. All these 13 employees were retested;
19 four employees had normal results on retest, three employees
20 had persistent minor variations which, in our opinion, did not
21 require further testing at this time. These employees are
22 scheduled for retesting in 90 days to determine their persist-
23 ence.

24 Liver-scans were performed on six of the 13, all of
25 which were normal. One case of acroosteolysis was found

1 during the examination, and this employee has been removed
2 from vinyl chloride operations.

3 At Calvert City, Kentucky, 291 employees were
4 tested. On the initial tests, we found 97 employees who had
5 findings which varied from recognized norms. Equipment mal-
6 function was suspected, and verified, and upon retest, 29
7 employees showed persistent abnormalities.

8 These 29 were scheduled for immediate retest. 16
9 employees showed persistent equivocal variations; as in the
10 case of Pace, Florida, they are scheduled for retest within
11 90 days.

12 Of the 13 employees with persistent abnormalities
13 when retested, six showed findings which directed to more
14 complex and increasingly sensitive and diagnostic tests for
15 liver physiology and anatomic state.

16 The six employees were examined by liver biopsy,
17 intravenous pyelogram, upper and lower gastrointestinal series,
18 a gallbladder X-ray, a repeat of the chest X-ray, and a com-
19 plete physical re-examination.

20 Of the six biopsies, two were diagnosed as cases of
21 Gilbert's disease, a congenital abnormality of enzyme metabol-
22 ism, one case was identified as having chronic gallbladder
23 disease with an anatomically abnormal gallbladder -- an intra-
24 hepatic gallbladder, a gallbladder buried within the liver,
25 and this is what gave us the cold spot on the liver-scan.

1 One case was diagnosed as having chronic gallbladder
2 disease with coexisting persistent hepatitis.

3 One case showed chronic persistent hepatitis subse-
4 quent to an infectious hepatitis, and one case showed no
5 abnormality.

6 I also examined the death certificates of former
7 employees who had been engaged in the manufacture of vinyl
8 chloride and who died either while working for or subsequent
9 to leaving the company. I was unable to identify any relation-
10 ship between the causes of death and the exposure to polyvinyl
11 chloride in their work environment.

12 Throughout the entire testing and examination pro-
13 grams at both Air Products plants there were constant discuss-
14 ions between the physicians on site and myself; often on a
15 daily basis. In addition, I have been to both the plants in
16 Florida and Kentucky and personally reviewed records with the
17 local physician.

18 I would conclude at this time that except for the
19 case of acroosteolysis discovered in an employee in the
20 Florida plant, the results of the screening comprising medical
21 and environmental history, X-ray, physical examination, labora-
22 tory tests -- and where indicated, liver-scan and biopsies --
23 findings or diagnosis which point to VCM as a positive agent
24 or mechanism were not identified.

25 More specifically, we can state at this time that

1 no cases of angiosarcoma have been identified.

2 JUDGE MYATT: Before you start, Mr. Fleming, you
3 have submitted your statement and Mr. Barr's, and an appendix
4 with it which is attached to it?

5 MR. FLEMING: Yes, sir.

6 JUDGE MYATT: All right, Mister Reporter, for the
7 record, the statement of Air Products will be Exhibit 23-A
8 and the Appendix will be 23-B, and I will ask you to designate
9 in the record, although you do not have a copy, the report of
10 Doctor Kotin as 23-C, and he is to supply us with a copy of
11 that as quickly as possible.

12 (The documents referred to were
13 marked for identification as
14 Exhibits 23-A, 23-B and 23-C,
15 inclusive.)

16 JUDGE MYATT: Mr. Kline, proceed.

17 MR. KLINE: Before beginning with the actual question-
18 ing, I would ask that, if you would, you provide in the post-
19 hearing comment, the various job classifications in your
20 various plants, the approximate exposure of persons in those
21 job classifications -- that is, what sources do they come
22 near, and whether -- indicate if you could whether it is an
23 intermittent type exposure or a continuing exposure.

24 MR. FLEMING: We will of course provide whatever
25

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. Following 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 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-detectable 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 above 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, Flammable 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 mechanical 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 amended 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 concurrence 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 palpation. (ii) A serum specimen 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 glutamyl 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 constructive. 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.

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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 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-detectable 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 above 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, Flammable 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 repellent 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 mechanical 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 amended 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 concurrence 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 palpation. (ii) A serum specimen 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 glutamyl transpeptidase (GGTP), (e) platelet count and (f) Additional tests that may optionally be considered for use in screening include: