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API TOXICOLOGICAL REVIEW

BENZENE

SECOND EDITION, 1960

This review was prepared at the Harvard School of Public Health, Boston, Mass., under the direction of Professor Philip Drinker. Anyone desiring to submit additional information or proposed changes for consideration prior to reissuance of this review is requested to send them to the American Petroleum Institute.

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API TOXICOLOGICAL REVIEW OF BENZENE

I. Substance

Benzene
Formula: C_6H_6

Structural formula: 

Molecular weight: 78.11
Synonyms: benzol
phene

II. Properties and Characteristics [1a, 2, 3]

Boiling point	= 80.1 C (176.2 F) at 760 mm.
Melting point	= 5.4 C to 5.5 C (41.7 F to 41.9 F).
Vapor pressure	= 74.6 mm of mercury at 20 C (68 F).
Liquid density	= 0.899 g per milliliter at 0 C (32 F).
Explosive limits	= 1.4 to 8 per cent.
Flash point	= 12 F (closed cup).
Refractive index	= 1.5016 at 20 C (68 F).
Specific gravity	= 0.8787 at 15 C (59 F).
1 mg per liter	= 313 ppm; 1 ppm = 0.00319 mg per liter.

Benzene is a clear, colorless liquid with a characteristic pleasant odor at low concentrations and a disagreeable odor at higher concentrations. It forms a highly flammable and explosive mixture with air at concentrations ranging from 1.4 to 8.0 per cent benzene by volume. Pure benzene burns with a yellow, luminous, smoky flame and is a fire hazard unless proper care is taken in handling and storage.

Benzene is relatively insoluble in water (0.08 g in 100 ml of water at 22 C) but is readily miscible in all proportions with alcohol, ether, acetic acid, chloroform, carbon disulfide, carbon tetrachloride, and similar organic solvents. Commercial benzene is practically never pure and usually contains varying amounts of xylene, phenol, and toluene; commercial benzene also contains traces of carbon disulfide (0.2 to 1.0 per cent), thiophene (0.1 to 0.2 per cent), olefins, naphthalene, and similar substances.

Chemically, benzene is the simplest of the aromatic hydrocarbons. It is relatively stable but is capable of a variety of substitution reactions such as chlorination, nitration, sulfonation, and alkylation. Benzene is an excellent solvent for most organic substances.

[a] Figures refer to BIBLIOGRAPHY on p. 6.

III. Manufacture, Uses, and Possible Sources of Exposure

Benzene is usually manufactured from catalytically reformed light naphthas from which it is isolated by distillation or solvent extraction.

Benzene is used as a solvent in many applications. It is also used as a component of some motor fuels and as the raw material for the manufacture of a host of synthetic chemicals. Examples are: styrene, phenol, aniline, DDT, chlorobenzene, cumene, nitrobenzene, diphenyl, cyclohexane, adipic acid, and detergents.

Because of its volatility, benzene presents a vapor hazard. The vapor may arise from numerous handling operations, as well as from leaks and accidental spills. Skin contact is a possibility when handling or packaging.

IV. Toxicology

a. Acute Effects

Acute benzene poisoning generally results from the inhalation of relatively high concentrations of vapor. Exposure to air containing benzene in concentrations of 19,000 ppm to 20,000 ppm (61 to 65 mg per liter of air) may cause death within 5 to 10 min, whereas concentrations of 7,500 ppm (25 mg per liter) are dangerous to life in one-half to one hour.[4] Severe toxic effects may be caused by 1-hour exposure to concentrations of 1,500 ppm (4.8 mg per liter). Concentrations of 500 ppm (1.6 mg per liter) may lead to symptoms of illness when exposure continues for more than a short time.[5]

Inhalation of 50 ppm to 150 ppm (0.10 to 0.48 mg per liter) of benzene for 5 hours caused slight headache, weariness, and lassitude. The red-blood count decreased, the white-blood count was unchanged except for mild lymphocytosis, eosinopenia, and monocytopenia. The albumin-globulin ratio increased slightly at lower concentrations but decreased with higher concentrations. The urinary coproporphyrins were increased, whereas the urinary sulfate ratio was decreased.[6]

Skin contact will cause dehydration and defatting which may lead to dermatitis. Systemic intoxication by cutaneous absorption is unlikely.

Drinking benzene causes acute symptoms with local evidence of acute irritation of the mouth, throat, and stomach. A tablespoonful or less of benzene when swallowed has been known to cause serious collapse. Subse-

quently, it may result in bronchitis or pneumonia which is probably caused by benzene entering the air passages.[7]

Acute exposure to benzene exerts a toxic action on the central nervous system. Benzene first behaves as a stimulant—in the early stages of acute poisoning, persons show excitement, euphoria, hilarity; then quite suddenly this changes to weariness, fatigue, and sleepiness, followed by coma and death.[8]

Acute exposure to benzene produces rapidly increasing symptoms of dizziness, excitation, and pallor, followed by flushing, weakness, headache, breathlessness, constriction in the chest, and fear of impending death. Visual disturbances, tremors, and muscular weakness are also encountered. The victim may lose consciousness and pass into coma or may develop acute mania and delirium. Convulsions occur frequently. Death may supervene almost at once or several hours to several days following exposure.[8]

Recovery from acute benzene poisoning requires from one to four weeks. Immediately after exposure there are temporary symptoms of chest and head pains, shortness of breath, giddiness, nausea, and loss of appetite. Evidence of unsteady gait, nervous irritability, and breathlessness may persist for two or three weeks, whereas cardiac distress and a peculiar yellow pallor to the skin may last for as long as a month. Recovery from acute poisoning is generally complete after this period, although evidences of chronic benzene poisoning may be encountered later.[8]

Benzene also sensitizes the heart muscle to the action of epinephrine, so that instant death may occur as a result of ventricular fibrillation.[1] Muscular activity increases the rate and severity of acute benzene poisoning. Persons dying of acute benzene poisoning generally show absence of clotting of the blood and widespread petechial hemorrhages in the brain, pleura, pericardium, urinary tract, intestinal tract, mucous membranes, and skin. There are no specific lesions of diagnostic importance.[8]

Local effects from acute exposure are seldom severe. Continued skin contact with benzene results in defatting of the skin and leads to erythema, dry scaling, and, in some cases, the formation of vesicular papules. Prolonged exposure may produce lesions resembling first- or second-degree burns. It may cause considerable irritation of the eyes or mucous membranes of the nose and throat on contact.

Benzene poisoning by skin absorption has received scant attention in the literature. The possibility of percutaneous absorption of benzene has been studied in three cases. Immersion of the hands and forearms from 25 to 35 min showed no evidence of skin absorption.[10] Unquestionably, small amounts of benzene can be absorbed through the skin, but it is very doubtful that enough would be absorbed by this route to cause systemic poisoning.[7]

b. Chronic Effects

Chronic benzene poisoning results from repeated or continuous exposure to relatively low concentrations of benzene vapor. The level and degree of exposure necessary to produce poisoning vary widely. There are at least two well-authenticated cases of poisoning by repeated exposures to 75 ppm.[11]

The toxic action is exerted mainly on the hematopoietic system. It may take months or even years to show harmful effects. Symptoms may be present over long periods, i.e. headaches, dizziness, fatigue, anorexia, and dyspnea. They may be varied and vague and not obviously connected with benzene poisoning.

During the early stages of poisoning, Heinz bodies may be present in the red-blood cells and a neutropenia is often seen. At this stage the blood picture may return to normal after removal from contact with benzene.

As chronic poisoning progresses, nausea and vomiting, burning sensations of the eyes and throat, and hemorrhages from mucous membranes, tongue, and gums become manifest. Purpuric spots and ecchymoses may follow the slightest injury, and epistaxis may occur. Menorrhagia, metrorrhagia, and spontaneous abortion may develop in otherwise healthy women. Blood examination at this point may show leukopenia (below 4,000 white cells), neutropenia, and a severe anemia. Later the platelet count falls so that thrombopenia is marked. The blood condition, at this stage, may have become irreversible. The clinical picture of a worker with chronic benzene poisoning at this stage is characteristic—he complains of headaches, giddiness, drowsiness, lassitude, loss of appetite, and nausea with occasional vomiting. He looks pale; is short of breath; has a rapid pulse, a low blood pressure, and a mildly elevated temperature. He may also have epistaxis, bleeding from the gums, a purpuric rash, or subconjunctival hemorrhages. The condition progresses slowly to acute leukopenia ending in fatal aplastic anemia.[8] Repeated small doses of benzene by mouth can produce the same type of chronic poisoning.[7]

Repeated contact of benzene with the skin will cause dehydration and delipidization predisposing to dermatitis.

Benzene is relatively insoluble in body fluids and tissues. Therefore, only small amounts are absorbed by the body. Equilibrium between blood and air is approached within a few minutes after exposure is begun, and practically complete elimination of benzene from the

blood occurs within a few minutes after exposure is terminated. Higher concentrations of benzene are obtained in tissues with a greater fat content, and saturation and elimination are more gradual.[13]

Human subjects inhaled benzene in concentrations of 340 micrograms per liter of air for 5 hours. Between 33 and 65 per cent of the inhaled benzene was retained (385 mg). During the desaturation period 3.8 to 27.8 per cent of retained benzene was excreted through the lungs and 0.1 to 0.2 per cent in the urine and other body excreta. Of the absorbed benzene, 9.7 to 42 per cent was excreted in the urine as phenol, 0 to 5.4 per cent as pyrocatechol, and 0.1 to 3.3 per cent as hydroquinone. Excretion of phenol and pyrocatechol was highest during the first 24 hours and complete in 48 hours, whereas hydroquinone took more than 48 hours. Excretion of organic sulfates in urine of exposed subjects was increased. The opinion was expressed that benzene affects the metabolism of proteins, the metabolites of which are excreted in urine as ethereal sulfates.[13]

Benzene is unique in its myelotoxicity. It has been shown that the introduction of an alkyl group into the aromatic ring results in a loss of its myelotoxic property. This difference may be a result of the difference in the metabolic pathway. Benzene is metabolized to phenols and quinones which inhibit cell production. The *in vivo* metabolites of alkyl benzenes are alcohols and carboxylic acids resulting from side chain oxidations. These compounds have a low-order toxicity and are devoid of specific cell destructive effects.[14]

A variety of reactions may be encountered as the result of the chronic effect of benzene poisoning. There is little correlation between the degree and duration of exposure and the severity or nature of the findings in the blood on microscopic examination.[15] They may consist of a reduction in red-cell, white-cell, or platelet levels—in any two of these or in all three. These changes may develop gradually or suddenly. The blood usually shows a moderate reduction in red cells (below 3.5 million), white cells (below 4,500), and platelets. Blood examinations for evidence of benzene poisoning should consist of a complete study of red, white, and platelet fractions. Progressive changes are more significant than the absolute levels.

In anemia caused by benzene, it has been shown that there is a constant increase in serum iron (average increase, 213 micrograms) which is associated with a reduction of transferrin (average reduction, 225 micrograms). The iron saturation of transferrin is above normal and is matched by iron saturation of the tissue. The cause of the disturbance of iron metabolism in benzene poisoning is the failure of the marrow to utilize iron as well as increased intake of iron supplied parenterally by transfusion.[16]

There is some evidence that chronic benzene poisoning produces a blood-clotting defect which is caused by functional and morphological as well as a quantitative alteration of the platelets.[17] The marrow cells exhibit a decrease in peroxidase in benzene poisoning. Because benzene inhibits granulocyte maturation, it may act on peroxidase metabolites, or the peroxidase may be used up in detoxifying benzene.[18]

The bone marrow may be hypoplastic, fairly normal, or hyperplastic in appearance. Abnormal forms r young cells may abound, and leukemia as a result of chronic benzene exposure has been reported. Various individuals differ in their bone marrow response to benzene—cases with symptoms fairly soon after exposure usually have fewer cells in the marrow, whereas cases developing later are more apt to have an increased number of cells in the marrow. It is believed that this represents an early weeding out of those who develop hypoplastic changes, rather than a gradual shift from one type of response to the other.[19, 20]

In a long-term follow-up of chronic benzene poisoning 4,538 cases were studied from 2 to 12 years after cessation of work involving exposure. There has been only one fatal case, six cases involving bone marrow changes, and one case of lowered resistance to infection.[21] The others were practically well but show varying degrees of neutropenia.

Benzene is eliminated from the body via the lungs and the kidneys. In one study C−14 labeled benzene was given orally to rabbits. In 2 days 45 per cent of the dose was eliminated in the expired air (43 per cent as unchanged benzene and 1.5 per cent as carbon dioxide), and 35 per cent was eliminated as metabolites in urine (23 per cent as phenol, 4.8 per cent as quinol, 2.2 per cent as catechol, 0.3 per cent as hydroxyquinol, 0.5 per cent as L-phenylmercapturic acid, and 1.3 per cent as *trans*-, *trans*-muconic acid). Five per cent of the administered radioactivity was found in the tissues occurring mainly as metabolites.[22]

Certain factors have been noted which influence individual variation in susceptibility to benzene. Overweight individuals are more commonly affected,[23] and a low-protein, high-fat, low-Vitamin C diet is said to promote the disease. The presence of heart or lung disease and liver or kidney damage are believed to predispose to the condition.[24] Pregnant women may be more susceptible to benzene poisoning.[4] Pathological changes in ovaries, testes, thyroid, and pituitary are attributed to benzene; and changes in women workers leading to sterility are emphasized.[25]

c. Recommended Limit of Atmospheric Exposure

The generally recognized maximum acceptable concentration for benzene vapor is 25 ppm by volume in air (0.08 mg per liter of air) for an 8-hour daily exposure.[1] In Germany the maximum permissible concentration to which workers may be exposed is 31.3 ppm by volume in air (0.1 mg per liter of air).[28] The Massachusetts laws have established 25 ppm as a maximum benzene concentration.[27]

V. Treatment

Acute benzene poisoning should be considered an acute emergency. Remove the victim from further exposure at once and call a physician immediately. The patient should be kept warm and quiet in the recumbent position. If breathing has stopped, artificial respiration should be started at once. Oxygen should be administered by a qualified person as long as necessary to maintain the normal color of skin and mucous membranes. This may prevent the development of severe pulmonary edema. Stimulants will rarely be necessary when adequate oxygenation is maintained.[1]

Care should be taken that rescuers are not also overcome by vapors.

Chronic benzene poisoning is extremely refractory to treatment. It is most important that the condition be diagnosed early and the individual withdrawn from further contact with the hydrocarbon. Blood transfusions are temporarily useful in combating severe anemia.

VI. Examination

The pre-employment examination should include a detailed history, physical examination, chest X-ray, and complete blood count. Workers with organic disease of the heart, lungs, liver, or kidneys should be eliminated, as should those with a history of previous benzene intoxication or evidence of an abnormality of the blood or blood-clotting mechanisms.[25, 24]

Periodic re-examinations should be carried out regularly, the frequency being determined on the basis of the probable degree of exposure. The examination should include a brief interval history and physical examination, together with a complete blood study. The presence of any of the blood changes described require re-examination at least twice at intervals of one week and a thorough study of the working conditions. Unless there is noticeable improvement on re-examination, the worker should be withdrawn from further exposure. The following changes call for re-examination: white-blood count less than 4,000, red-blood count less than 4,000,000, hemoglobin less than 12 g per 100 ml (80 per cent), blood platelets less than 100,000 per cu mm, differential count less than 50 per cent polymorphonuclear leukocytes, and more than a very few immature blood cells. The urine sulfate test may be used, not as a diagnostic test, but as a measure of the degree of the current benzene exposure. It does not measure the degree of benzene poisoning nor the blood changes present.[1]

VII. Precautionary Measures

The safety measures necessary for the prevention of benzene poisoning are primarily those designed to prevent the inhalation of benzene vapor. Proper ventilation, local exhaust, and closed systems should be used to maintain a concentration below the maximum acceptable concentration of 25 ppm by volume in air. All apparatus and piping should be inspected regularly and systematically for leakage. When excessive concentrations are unavoidably encountered in operations such as the cleaning of tank cars, vats, or storage tanks, air masks and protective clothing should be employed.[25] Employees should be fully instructed regarding health hazards which may be present in the handling of benzene and should immediately report any unusual symptoms r illness. Clothing wet with benzene should be removed promptly.

If the hands are likely to have contact with benzene, impervious gloves or protective creams should be used. Proper ventilation, routine plant inspection, control of benzene air concentration, and periodic medical examinations are all of the utmost importance.[25]

The concentration of benzene vapor in the air should be checked regularly in locations where the possibility of excessive exposure may be encountered. This may be done by a variety of procedures among which are the butanone method,[2] the *m*dinitrobenzene reduction method,[3] an absorptiometric method, and a photocolorimetric determination. The latter method involves the nitration of benzene with Stepanov mixture which forms *m*dinitrobenzene. This gives a color reaction with acetone in alkaline solutions. Under similar conditions toluene gives a faint violet color. Based on these photocolorimetric methods small quantities of benzene and toluene can be determined in air.[29] More recently a silica gel adsorption method has been reported.[30] Accurate quantitative study of atmospheric benzene as low as 0.003 mg per ml (0.9 ppm) may be determined by adsorption on activated silica gel and elution with absolute alcohol. The benzene content is then determined spectrophotometrically according to *ASTM Designation D 1017: Method*

of Test for Benzene and Toluene by Ultraviolet Spectrophotometry. The range of measurement is 0.003 mg to 1.28 mg per liter. The mean yield was approximately 98 per cent.

There are a number of instruments on the market which measure hydrocarbon air contamination. The presence of more than one hydrocarbon vapor, however, produces erratic results.

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2M—Aug. 1960

API TOXICOLOGICAL REVIEWS

SECOND EDITION

Benzene (1960)	$ .25
Butadiene (1959)	.25
Copper Naphthenate (1959)	.25
Naphthalene (1959)	.25
Naphthenic Acids (1959)	.25
Toluene (1960)	.25
Xylene (1960)	.25

AT THE MARCH 3, 1981, PUBLIC HEARING

TEXAS CHEMICAL COUNCIL TESTIMONY
ON EPA'S PROPOSED NEW SOURCE PERFORMANCE
STANDARDS FOR VOLATILE ORGANIC
COMPOUND FUGITIVE EMISSION SOURCES

My name is A. H. Nickolaus and I represent the Texas Chemical Council (TCC). The TCC is an association of 87 chemical compani s having more than 67,000 employees and representing approximately 90% of the chemical industry in Texas. Since over half of the nation's petrochemicals are produced by member companies operating in Texas, the proposed regulation is of vital concern to us.

The Texas Chemical Council has joined with the Chemical Manufacturers Association (CMA) in the preparation of detailed comm nts on the proposed regulation, and our combined written comments will be submitted prior to April 6, 1981. Today, I would like to highlight some of our concerns about this standard.

A. Definition Of Modification

First, to start off on a positive note, at our request the EPA has added an annual allowance of up to 5 1/2% for "process improvements" so that small, routine changes made to an existing process unit will not in themselves subject it to the new source standards. We thank the EPA for this consideration.

B. Performance Versus Equipment Standards, Etc.

When dealing with facilities broader than a specific process or installation, the TCC believes the EPA should set both a performance standard and an equivalent equipment or work-practice standard. If a performance standard is not possible, then at least an equipment and an equivalent work-practice should be set. This would allow the Synthetic Organic Chemicals Manufacturing Industry (SOCMI) the flexibility necessary to design and implement the most efficient and cost effective compliance program. The EPA has failed to do this for pumps, compressors, and valves in the proposed standard; although the TCC believes it is feasible to do so.

1. Pumps & Compressors

For both pumps and compressors, the EPA states in the pr ambl to this regulation (FR p. 1143 & 1144, Jan. 5, 1981) that a performance standard is not feasible because the application of measurement technology is technologically impractical. Yet in the January 1981 Preliminary Draft Control Technique Guideline for "Control of Volatil Organic Fugitive Emissions from Synthetic Organic Chemical, Polymer, and Resin Manufacturing Equipment", they specify measurement of emissions from these pieces as the means of determining compliance.

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The TCC recommends and requests that a similar monitoring option for pumps and compressors be added to this standard.

2. Valves In Gas & Light-Liquid Service

Contrary to the EPA's opinion, the TCC believes that a performance standard for valves in gas and light-liquid service is feasible. Snee and Kittleman of Du Pont have shown (Letter from T. A. Kittleman, Du Pont, to Glynda E. Willins, Radian Corporation, November 13, 1980) that a leak level of 2% is equivalent to the basis used by the EPA in the BID to estimate the leak reduction effectiv ness of the proposed regulation.

The TCC recommends that the EPA specify 2% of valves leaking as a "good performance" level that is equivalent to the prescribed monitoring program.

C. Emissions Abatement

The proposed standard requires that emissions be transported through a "closed vent system" to an "enclosed combustion device" or vapor recovery system and then defines an "enclosed combustion device" so as to exclude flares. We take particular exception to this. The TCC in our June 30, 1980, comments to the EPA on the Draft BID provided data showing 99+% efficiencies for a properly designed flare system. The EPA has taken a position, without any data, that flares may be only 60% efficient and that the burden of proof of better is on the SOCMI. We disagree. We have provided necessary data which should not be rejected arbitrarily. Further, since flares are standard abatement devices of long standing in both the chemical and petroleum-refining industries, we believe the burden of proof, with data, is on the EPA. The SOCMI has a heavy investment in flares and will strongly resist EPA's position that they are not acceptable emission control devices.

We recommend that the definition of "closed vent system" be modified as follows:

> "Closed Vent System means a system which is not open to the atmosphere and which is composed of piping, connections, and, if necessary, flow inducing devices that transport gas or vapor from fugitive emission sources to a device which provides 95% abatement or to an enclosed combustion device, vapor recovery system, properly designed flare system, or an equivalent control device as determined by paragraph 60.484."

D. Monitoring Frequency

The rational approach to how frequently monitoring for leaking valves should be performed (60.482f) would be based on a cost-effective analysis of leak occurrence and recurrence data. The EPA

has not done this. Instead, in the preamble (FR p. 1146, Jan. 5, 1981) they state clearly their basic commitment to a monthly monitoring schedule - apparently as an article of faith. In the BID the EPA has assumed an occurrence frequency biased to favor a monthly program (see attached Figure 1). In the absence of definitive data, the TCC finds it difficult to justify anything but the assumption of a linear leak occurrence with time. Using a linear relationship, a quarterly monitoring frequency gives the same results as the EPA claims for their monthly program (again see Figure 1).

The TCC has and continues to recommend that the required data be obtained and that a rational analysis of monitoring requirements be made. Until that time, the TCC believes the data in the BID cannot justify anything more frequent than quarterly monitoring.

The TCC recommends that monitoring requirements in the proposed standard be changed to a true quarterly frequency.

E. Leak Definition

As the EPA has correctly pointed out, most leakage comes from only a few valves, and the problem is to find and repair these. The EPA has proposed 10,000 ppmv as the definition of a leak. Recent EPA data show variations of nearly an order of magnitude in repeat measurements of leak rates on the same valve. For this and other reasons more fully developed in our written comments, the TCC again recommends that a leak be defined as 20,000 ppmv or greater. The leakage reduction attained will be essentially the same as at the 10,000 ppmv cut-off; but maintenance will be reduced by up to 30% as less maintenance effort will be spent on valves with inconsequential leak rates.

F. Alternative Standards

We commend the EPA for providing in paragraph 60.483 provisions for alternative standards. But in terms of monitoring programs, what the EPA giveth with one hand it taketh away with two. The problem is that an allowable percentage of valves leaking must be determined after the plant is built. Quality control experience shows that quality must be built into a product; it cannot be inspected in. Thus, the time to assure a low-leakage plant is in the original design before the plant is built. But a plant providing the best leak prevention options would have to meet a much lower allowable percentage valves than one not so well designed, and consequently, it would have much less opportunity for a reduced monitoring program than a poorly designed plant. This doesn't make sense; low-leak plants should require less inspection - high-leak plants more.

What is needed is an incentive for owners to build low-leak plants. Some assurance of an opportunity for reduced monitoring requirements in such plants would provide this. In our written comments (60.483c - Good Performance Incentive), we detail a statistical monitoring plan which results in reduced monitoring requirements for those who meet a "good performance" level equivalent to the BID basis.

The TCC strongly advocates the adoption of this proposal. Th advantages of a quality control approach is (1) greater emission reductions will be realized industry-wide because there is an incentive to do so, (2) the monitoring burden will be lessened on low-leak plants and increased on high-leak ones, and (3) well d fined rules on what can and cannot be done will be available to the owner at the design stage.

G. Determination Of Equivalence (60.484)

Although the TCC believes guidelines for approval of equivalent or alternate means of emission limitation should be specific so that, having met them, approval by the EPA Regional Offices is more or l ss authomatic; the proposed paragraph 60.484 seems to be overly detailed without accomplishing this purpose. The procedure in Subpart Ka, paragraph 60.114a for Standards of Performance for Storage Vessels for Petroleum Liquids Constructed After May 18, 1978, is simpler, more straight forward, and we prefer it to the present proposal.

H. Reporting, Recordkeeping, Etc.

The TCC believes that the proposed tagging, recordkeeping, and reporting is excessive and goes beyond that necessary to implem nt the required program and also beyond that required for compliance. In our written comments, we make detailed recommendations to corr ct this.

I. Need & Costs

In closing, whether it is legally appropriate or not, we cannot resist again stating our belief that this regulation is unnecessary and that the costs have been under-estimated. We re-affirm the comments we made to the EPA on June 30, 1980, and we recommend them to your attention.

Finally, on costs the EPA is still basing monitoring costs on two man-minutes per source despite their own data in Table C4 of th BID showing it took highly motivated contract workers an average of 3.4 minutes to perform this task.

AHN/rtg

2-20-81

DO 067894
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BEFORE THE

ENVIRONMENTAL PROTECTION AGENCY

COMMENTS OF THE

CHEMICAL MANUFACTURERS ASSOCIATION
AND TEXAS CHEMICAL COUNCIL
ON

EPA'S PROPOSED RULEMAKING OF

NEW SOURCE PERFORMANCE STANDARDS

FOR VOLATILE ORGANIC COMPOUND

FUGITIVE EMISSION SOURCES UNDER

THE CLEAN AIR ACT

Proposed Standards of Performance for New Stationary Sources; VOC Fugitive Emission Sources; Synthetic Organic Chemicals Manufacturing Industry, 46 Federal Register 1136 (January 5, 1981)	DOCKET NO. A-79-32

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§60.480(c)

In earlier drafts to subject proposed regulations, a problem was surfaced with the definition of modification as set forth in 40 CFR §60.14 as it might apply to fugitive emissions. A concern was expressed that continuing small changes routinely made to a process unit made for a variety of reasons might subject the entire existing unit to the NSPS fugitive emissions requirements. ~~The Agency's proposed §60.480(c) satisfactorily resolves this earlier concern.~~

W understand the Agencies' proposal in 60.480(c) to mean that process improvements, as defined in 60.481, costing up to 5 1/2% annually of the original investment in the affected SOCMI facility shall not by itself be considered a modification. This would satisfactorily resolve our earlier concern.

§60.481 -- "Closed Vent System".

In discussions with EPA's OAQPS staff we were led to believe that the regulations would not prelude safety valve emergency releases to flaring systems or the atmosphere. In this regard, the preamble at page 1140 attempted to clarify that closed vent systems can be used to transport relief valve discharges and fugitive emissions to a control device, such as a flare. The proposed regulations, however,

These comments are also submitted on behalf of the Texas Chemical Council (TCC) whose offices are located at 1000 Brazos Street, Austin, Texas 78701. The TCC is an association of 87 chemical companies having more than 67,000 employees and representing approximately 90% of the chemical industry in Texas. Like the CMA, the TCC has also worked with the EPA over the past several years in the furtherance of responsible environmental regulation. The TCC also requests that the comments made by them which are referenced in Appendix A of the EPA's "VOC Fugitive Emissions in Synthetic Organic Chemicals Manufacturing Industry - Background Information for Proposed Standards" be incorporated as part of the administrative record in this matter.

The comments we are submitting today make certain recommendations that attempt to clarify, and/or modify the Agency's proposed regulatory program to make technically more sound several substantive provisions, and to simplify procedures, recordkeeping, and reporting where the proposed requirements are either redundant, unnecessary, to demonstrate compliance with applicable control requirements, and/or would reduce the paper workload.

Nevertheless, we believe that the Agency has made significant progress in addressing many of the concerns raised by CMA in our earlier submittals to the Agency on earlier drafts of the subject proposal, and on various other Clean Air Act fugitive emissions programs. We believe, however, that additional modifications are still necessary in order to achieve a viable and reasonable technical fugitive emissions program..

§60.481 -- "Fugitiv Emission Source."

The definition of "fugitive emission source" includes compressors and pumps. Unfortunately the Agency has not included a definition as to the types of pumps and compressors not subject to the fugitive emissions NSPS requirements. As a result of this apparent oversight reciprocating pumps and compressors are included in the regulatory program. The potential problem we have with the inclusion of reciprocating pumps and compressors are their inability to accommodate double seals or any type of seal that EPA may utlimately require. Accordingly, we recommend that in order for EPA to avoid sealing problems associated with reciprocating pumps and compressors that such pumps and compressors be expressly excluded from the definition of "fugitive emission source."

§60.482(a)(1) - "dual mechanical seals"

As we have commented on several times in the past, it is inappropriate to require use of dual mechanical seals for pumps. We r commend that EPA cease using the term "mechanical" and merely define the seals to be used in pumps as dual seals. Such a modification would provide industry with some flexibility for a source to us any properly designed dual seal. This modification would allow for the use of either pressure or level control devices.

We compliment the Agency on adopting an equivalency regulation in §60.484(b) that will allow companies to demonstrate the equivalence of single seals where adequate and permanent monitoring will result in equivalent degree of controls.

limit closed vent systems to transporting emergency releases to an enclosed combustion device or vapor recovery system.

We are concerned that the clear language of the proposed regulations contradicts statements made by EPA's OAQPS, the preamble, and various support documents that emergency releases can be transported by a closed vent system to not only an enclosed combustion device and vapor recovery system, as well as, a properly designed flare system, and other equivalent control devices. Failure to correct this inconsistency and revise the regulatory language could result in unanticipated enforcement initiatives based on the language of th proposed regulations. In addition, failure to revise the definition of closed vent system would arbitrarily exclude other control devices and properly designed flare systems which in many instances can achieve or approach the same degree of hydrocarbon reduction as enclosed combustion devices or vapor recovery system at significantly lower costs.

In order to clarify this matter we would recommend that the definition of "closed vent system" be modified, as follows:

> "Closed Vent System" means a system which is not open to the atmosphere and which is composed of piping, connections, and, if necessary, flow inducing devices that transport gas or vapor from a fugitive emission source to an inclosed combustion device, vapor recovery system, a properly designed flare system, or an equivalent control device as determined by §60.484.

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In this regard we wish to reaffirm the position taken and made in the Texas Chemical Council's letter of 30 June 1980 to the EPA (comments on the Draft BID and Recommended SOCMI Standard) regarding flares and their use.

in rder to remedy this in onsistency.

As we discuss d above, we believe that a closed vent system should b defined generally enough so that VOC fugitive emissions can be transported to appropriately designed enclosed combustion devices, vapor recovery systems, as well as, properly designed flare systems, or an equivalent control device. As presently drafted, fugitive missions from pumps would be initially precluded from being controlled by catalytic combustion units unless a time consuming and costly equivalency demonstration can be made. Several of our member companies indicate that such control devices achieve equal or better control than the two systems presently recognized in §60.482(a)(3)(ii). To preclude catalytic combustion units without an adequate justification by EPA for requiring equivalency demonstration would have to be characterized as an arbritrary action.

The comments set forth above are equally applicable to pumps fugitive emissions regulated under §60.482(a)(7). We would hope that appropriate modifications consistent with a revised definition of closed vent system would be incorporated by EPA in the final version of §§60.482(a)(3)(ii) and (a)(7).

§60.482(a)(6) - delayed compliance

The proposed regulation requires that a leak be repaired as s on as practicable, but not later than 15 days after its detected, except as provided in §60.482(h). The exception allows extensions only where the repair is technically infeasible without a complete or partial process unit shutdown. The extension, however, cannot exceed the process unit shutdown.

The instant delay of compliance provision significantly improves n earlier drafts which imposed arbitrary deadlines and meaningless reporting requirements. We, nev rth l ss, have s veral recommendations

60.482(a)(4) - Liquid Leaks

This paragraph defines liquid dripping from a pump seal as a leak. However, the barrier fluid could be water so there would be no reason to repair a seal operated per 60.482(a)(3)(i) where the barrier fluid pressure is higher than the pump pressure so long as this higher pressure is maintained. We recommend that this paragraph be reworded to say:

> "Each pump shall be checked by visual inspection each calendar week for indications of liquids dripping from the pump seal. If indications of liquids dripping from the pump are seen, the vapor emissions shall be monitored by the methods specified in 60.485. A vapor concentration greater than 200 ppm above background shall constitute a leak."

§60.482(a)(3)(ii) and (a)(7) - "residence time."

In our review of this section we noticed an inconsistency between the proposed residence time and the technical data on residence time set forth at page 4-18 of the technical support document. See VOC Fugitive Emissions in Synthetic Organic Chemicals Manufacturing Industry - Background Information for Proposed Standards, EPA-450/3-80-033a, at 4-18 (November 1980). An appropriate modification of this requirement in the final regulations is necessary

special order and take up to one year f r delivery), and/or unforseen manufacturers and/or delivery delays (e.g., strikes, fires, raw material delays in delivery). Any one or a combination of the above scenarios would result in the necessary replacement part(s) not b available until after the next scheduled shutdown.

Since the proposed regulations would make continued operation after such a shutdown a violation of the Clean Air Act, we strongly recommend that a limited extension provision be incorporated by EPA into the regulations. We envision placing the burden of requesting such a request upon industry by requiring a formal submittal to EPA in which the source would have to justify the need for the furth r delay in repair and the projected time frame for achieving complianc . We recommend that §60.482(h) be amended to include the following regulatory language:

> "Delay of repair will be allowed beyond a process unit shutdown only where and for the period of time a source demonstrates to the satisfaction of the Regional Administrator or delegatee that repair of a leak by replacing physical equipment by replacing physical equipment exceeded the normal stock of spare parts and cannot be delivered until after the next shutdown, a special order of a part is required and cannot be delivered until after the next shutdown, and/or because of unforseen manufacturers and/or delivery delays, the replacement parts cannot be delivered until after the next shutdown."

The consequences of not including such a provision in the final r gulations could r sult in unanticipated and costly c ntinuances f a shutdown until the repair parts are obtained, or in the exp sure

which would further clarify the regulati ns and more accurately reflect real world operations.

First, we would recommend a definition of what situations qualify as technically infeasible in order to be accorded an extension after the initial 15 day compliance period. Such a clarification would minimize uncertainties and would reduce any unwarranted enforcement proceedings resulting where such an ambiquity in the regulations. Accordingly, we recommend that §60.482(h) be revised to include a definition of technical infeasibility, as follows:

> "For purposes of §60.482(h), technically infeasible shall mean where a repair within 15 days of leak detection would constitute an unsafe practice, could result in premature total process failure, or could cause an unscheduled complete or partial process until shutdown."

The second part of our recommendation on delayed compliance concerns th agency requirement that all repairs may not be delayed under any circumstances beyond a process unit shutdown. We concur that many of the remaining delayed repair actions will be remedied during a shutdown where repair actions can not be technically of safety be conducted while the process unit is in operation. As the Agency is aware, most schedule shutdowns are on an annual basis or based upon operating performance of the process unit. As a result, there may be some limited instances where replacement of leaking equipment may not be available until after tha shutdown is completed. Such instances include (but are not all inclusive) abnormal near term demands for replacement parts that exceed the quantity of replacement parts that ar normally maintained in stock and can not be replaced on short notice, the replacement parts/equipment are not off th shelf items and r quir long l ad time for deliv ry (i. ., some pumps require

the process unit would be greater than th missi ns from the fugitiv emission source(s)."

We believe such a revision would remedy an unnecessarily narrow and environmentally counterproductive requirement.

§60.482(b) - Compressor Standards.

As a general comment, the comments, issues, and recommendations we raised on pump standards are generally equally applicable to compressors. We do want to point out one inconsistency in the compressor standards which we believe should be clarified. In §60.482(b)(1) and (3) we are happy to note that the Agency only requires a seal system with certain characteristics be used for all compressors. This requirement would be consistent with our comment on §§60.482(a)(1) and (3) dealing with pumps, in which we objected to the Agency's requiring dual mechanical seals and not providing the necessary flexibility with a dual seal system requirement. The inconsistency exists because the Agency at §60.482(b)(4) then reverts to referring to dual mechanical s al systems.

Our substantive comments on §§60.482(b)(3)(ii) and (b) are reflected in our comments on §§60.482(a)(3)(ii) and (a)(2) above.

Our substantive comments on §60.482(b)(5) and its interrelationship with §60.482(h) are reflected in our comments on §60.482(a)(6) above.

Finally, our substantive comments on §60.482(b)(8) are refl cted in our comments on §60.482(a)(9) above.

§60.482(c)(5) - safety/relief valves in gas/vapor service.

As proposed, the section requires each safety/relief valve t r turn to emitting less than 200ppm above background after an emerg ncy pressure release no later than five calendar days after each epis de of pressure release. As proposed the regulation leaves a tremendous loophole which had to be an oversight. If a process unit is down five days after the release, it by definition will be in compliance.

to significant criminal and civil penalties for resuming peration without r pairing all leaks. We w uld consider it an arbitrary and capricious action of the Administrator to not provide such a remedy where the source has acted in good faith to repair all remaining leaks at the next scheduled shutdown, but solely because of uncontrollable events the necessary repair parts are not available.

§60.482(a)(9) - "Operation of Control Systems."

This provision essentially requires that all existing proposed fugitive emission control systems be operated at all times VOC emissions may occur. We are concerned that a conservative and narrow reading of this provision will essentially preclude a process units operation where expected or unexpected maintenance of the control system is required, or an emergency requires the control system to go down for repairs. It makes little sense to require the entire proc ss unit to shutdown where the control system has to go out of service for a short period of time to conduct maintenance and/or correct an emergency condition. In fact the start-up and shutdown of the process unit in most instances will probably result in greater emissions of VOC than if the process unit continued operation for the short period of time until the emission control system is back on line.

We recommend that this provision be modified to essentially allow a by-pass of VOC emissions where tha control systems must be taken out of service for maintenance or an emergency only where the net VOC emissions that will be bypassed would not exceed the excess emissions that would result from a shutdown and start-up of the process unit. We recommend that §60.482(a)(9) be revised to added a second sentence, as follows:

> "A source, howev r, may bypass the applicable c ntrol device set f rth in §§60.482(a)(3)(ii) and (iii) wher missions from an associated shutdown and startup of

§60.482(d)(2) be r v: :d, as follows:

> "(2) Each clos d purge system as required by §60.482(d)(1) shall return the purged proc ss fluid directly to the pr cess line, r shall collect the purged process fluid for recycle or disposal by means of a closed vent system."

The technical support document does not support the proposed regulations. Unless a modification is made, the Administrators actions must be characterized as arbitrary and capricious.

§60.482(f)(2) - "definition of valve leak"

The EPA has proposed 10,000 ppmv as the definition of a leak. In addition to being the same action level as set forth in the refinery CTG, we understand from a July 17, 1980, EPA meeting with the TCC that this particular level was also chosen because it is the top of the scale on the Century Volatile Organic Analyzer. Apparently EPA felt 10,000 ppmv would make compliance easier for the chemical industry. We have some significant disagreements with these underlying assumptions. We believe a higher trigger level would achieve essentially the same control with much improved maintenance efficiency.

The scale on the Century GC is a minor consideration. Readings higher than 10,000 can be obtained readily with a dilution apparatus. In addition, we are confident that equipment manufacturers will be able to supply instruments with direct reading scales to whatever level we require.

As the EPA has correctly pointed out, most of the leakage comes from only a few valves and the problem is to locate and repair thes . Based on the refinery data, about 98% of the emissions from valves in gas/vapor service will be from those having leak concentrations gr ater than 10,000 ppmv. Similarly, about 97% of the emissions will come from valves with screening values above 20,000 ppmv (Fig. 4-7A, EPA 600/2-79-044, "Emission Factors and Frequency of Leak Occurrence For Fittings in Refinery Process Units"). In a pr vious letter t

We assume EPA means five calendar days from resumption of normal operations after each episode of pressure release.

We want to commend the Agency for establishing a performance standard for safety/relief valves in gas/vapor service rather than specifying inflexible design standards. We would encourage the Agency to rethink the proposed pump and compressor standards to establish a performance standard for pumps and compressors (i.e., 10,000ppm). It is our view that a performance standard is more a simplistic regulatory program to implement and provides necessary flexibility for sources to install the most cost-efficient and effective emission controls and process systems.

§60.482(d)(2) - sampling systems.

As proposed the regulation limits the means of disposing of process emissions. The proposal provides the option of returning the fluid directly to the process line, or in the alternative, collecting the purged process fluid for recycle or disposal without VOC emissions to the atmosphere. This requirement amounts to a zero emissions requirement. As a fundamental concept the closed loop sampling system may be inappropriate or technically infeasible (i.e., low pressure process or tankage, safety requirements). Accordingly, this would require a collection system be used with no emission allowed. We note that no support for this premise is provided in the Agency's technical support document (see 4-22 to 23). In fact, the support document mentions that such fluids could be directed to a control device such as a properly designed flare.

In light of the lack of technical support for the proposed regulation, we recommend that the Agency include the use of closed vent systems to minimize emissions from sampling systems. We recommend that

§60.482(f)(3) - "monitoring frequency"

The pr posal ssentially requires that a monitoring program for valves be on a monthly basis for leakers and quarterly basis for non-leakers. We strongly endorse this proposal and caution against retreating to mandating monthly monitoring.

NO

One rationale the Agency might consider for requiring monthly monitoring is a reliance on refinery fugitive emissions data where the Agency ultimately required monthly monitoring.

The leak frequency data developed by EPA for the chemical industry are NOT similar to the refining data as EPA indicates on page 1141 of the proposal. The differences are summarized, as follows:

Source Type	Difference in leak frequency between SOCMI and refining data.
Valves	
•Gas service	Similar
•Light liquid service	SOCMI 50% of refining
•Heavy liquid service	Similar
Pumps	
•Light liquid	SOCMI 33% of refining
•Heavy liquid	Similar
Compressors	SOCMI>21% of refining
Relief Valves	SOCMI>45% of refining
Process Drains	Similar
Flanges	Higher

(See Attachment B & C for greater detail and discussion on this issue.)

The above differences do not account for the fact that the chemical industry studies were conducted using a Century OVA-108 instrument calibrated on methane while the refining studies were conducted using a Bacharach TLV instrument calibrated on hexane. Studies by Exxon Chemical (see Attachment D) on both instruments using both calibration gases show that 29 percent more leaks are found using the

the Agency, (s Attachment A) the TCC has shown that using a 20,000 ppmv action level versus 10,000 results in only 1% more emissions but r duces maintenance costs by 30%. This factor is of major significance since Section 111 requires the Administrator to take into consideration the c st of achieving continuous emission reductions.

In §60.48(5)(a)(4)(ii) methane at 10,000 ppmv is specified as the calibration gas. This requirement differs from the refinery data on which most of the technical support is based where hexane was us d for this purpose. A study of the relative response of various gases with respect to methane and hexane indicates that a methane calibrati n will, in effect, lower the trigger point to about 8,000 ppm with the Century GC and even lower with the Bacharach TLV meter. This means more maintenance effort will be spent on valves with inconsequential leak rates.

Recent data (Problem-Oriented Report, "Frequency of Leak Occurrence for fittings in Synthetic Organic Chemical Plant Process Units", EPA, Sept. 1980, DCN 80-231-372-05-35, Data Listing For EPA Project #68-03-2776, Radian Corporation, December 19, 1980) from EPA's studies on leak occurence and recurrence in the SOCMI show a wide variability in repeat screening values for the same source. For example in Figure 4-3 of the Problem-Oriented Report, on the second day, values of approximately 2000, 6000 and 15000 were obtained from repeat measurements on the same valve. It is important that maintenance efforts be spent on the large leakers and not on the small ones since some data indicate that attempts to repair these only made matters worse. Thus the trigger point should be set high enough to insure isolating only the bad leak rs. For these reasons - maintenance efficiency, the effect of methane calibration, and measurement variability, we again r commend that a leak b defin d at §60.482(f)(2) as 20,000 ppmv or greater.

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TCC recommends using a lin ar le k recurrence rate with time in the absence of data. Second the assumption that all the source types will have a uniform recurrence rate (20% per year) is not a logical assumption nor is it supported by the record. In the absence of data, a more logical assumption is that recurrence will vary in proportion to occurence.

EPA, given the lack of data on valve leak recurrence and occurence with time, has structured a monitoring program for valves as gas/vapor and light liquid service which calls for monthly monitoring for leakers and quarterly monitoring for non-leakers. EPA states that straight monthly monitoring for all valves may be required if recurrence is found to be important. We submit that the existing chemical industry data shows initial occurence to be less (by 50% in the case of light liquid valves) than the the refinery data. Because of this differ nce, we recommend that EPA require the monthly monitoring scheme only f r those owner operators desiring to show equivalance demonstration.

Since EPA has acknowledged that limited data are available on occurence/recurrence, we submit that EPA can only reserve the right to require more frequent monitoring when the data are available from those owner operators desiring equivalance.

§60.482(f)(4) - delayed compliance.

Our substantive comments on this section and its interrelationship with §60.482(h) are reflected in our comments on §60.482(a)(6) above.

§60.482(f)(7) - Accessibility Exclusion.

~~As we reviewed the proposed regulations, we identified an area dealing primarily with modified sources that will be subject to the new source performance standards, that EPA apparently has overlooked in the proposed regulations. As the Agency is well award, at older facilities many valves are not routinely accessible because of safety~~

Century calibrated on methane as compared to the Bacharach calibrated on hexan . Thus the SOCMI Data is probably ev n less than the refining data as shown above.

Since the above data show initial leak occurence frequency within the chemical industry to be less than the refining sector, we feel that EPA should require only true quarterly monitoring. We are of the pinion that the lower leak occurence frequency within SOCMI will more than offset the, admittedly, unknown effects of leak recurrence. EPA has offerred as a reason for possibly requiring monthly monitoring to be the potential importance of leak recurrence between valve monitoring intervals.

This analysis was performed without the benefit of review of EPA's chemical industry valve maintenance study which may provide further information on the importance of valve leak recurrence.

The above conclusions are discussed in further detail below and in the attachments.

The EPA continues to base occurence and recurrence leak rate assumptions on Table 4-2 from the final technical support document (copy attached as Attachment E) which is the same as taken from the draft technical support document. The Texas Chemical Council (TCC) commented on the issue of occurence/recurrence in comments submitted to EPA in June of 1980. These comments have not bean addressed by EPA and cannot be ignored. We wish to emphasize the points rais d in TCC's comments on this issue are still valid. In addition to TCC's earlier comments, we offer the following additional comments.

First, EPA's assumption of non linear leak recurrence with time is not based on any data but rather an "engineering judgment". The assumption that twice as many leaks will be found annually as c mpared to quarterly and twice as many leaks will be found quarterly as compared to monthly is simply not l gical and is n t supported by the record.

As the Agency is well aware, in existing facilities many valves are not routinely accessible because of elevation or because access to the valve bonnet is restricted, etc. Most, if not all of these, can be eliminated in an entirely new plant. But they become a problem in an older plant that becomes subject to this regulation because of modification.

To correct these problems, we propose valves that are inaccessible for safety reasons and that valves that are inaccessible for other r asons in modified sources be excluded from the requirement of 60.482(f)(1)-(6)

but subject to the new 60.482(f)(7)-(8). Accordingly, we recommend that the new 60.482(f)(7) and 60.482(f)(8) be added as follows:

"(7)(i) An owner or operator of a new or modified source subject to the requirements of 60.482(f)(1)-(6) may for valves that are routinely inaccessible for safety reasons monitor each inaccessible valve for leaks after a process unit overhaul prior to startup by pressuring with nitrogen to the system process pressure or 100 psig, whichever is less, and checking with a soap solution for bubbles, or other equivalent test method pursuant to 60.484."

"(ii) When a leak is detected, it shall be repaired as soon as practicable, but no later than the next scheduled shutdown, or consistent with 60.482(h)."

"(iii) For purposes of 483 or 484, inaccessible valves shall not be included."

considerations.

We propose that valves, at modified facilities subject to these requirements, that are inaccessible for safety reasons be excluded from the requirements of §§60.482(f)(1)-(6) but subject to a new §60.482(f)(7). This new provision would only apply to modified sources and not apply to new facilities. Accordingly, we recommend that a new §60.482(f)(7) be added, as follows:

> "(i) An owner or operator of a modified source subject to the requirements of §§60.482(f)(1)-(6), may for valves, that are routinely inacessible for safety reasons, monitor each inaccessible vale for leaks after a process unit overhaul prior to start-up by pressuring with nitrogen the system process pressure, or 100 psi, whichever is less, and checking with a soap solution for bubbles, or other equivalent test methods pursuant to §60.484."
>
> "(ii) When a leak is detected, it shall be repaired as soon as practicable, but no later than the next scheduled shutdown, or consistent with §60.482(h).
>
> "(iii) For purposes of §§483 or 484, inaccessible valves shall not be included."

As we reviewed the proposed regulations, we identified an area which the EPA has apparently overlooked in the proposed regulations. This area is inaccessible valves. These fall into two general categories, valves inaccessible for safety reasons and valves inaccessible because of elevation and/or configuration.

Certain chemical processes are carried out at such extreme conditions of temperature or pressure, or the chemicals themselves are so unstable or hazardous that the operation is done behind barricades and the like, and, for safety reasons, personnel are not allowed in these areas while the unit is in operation.

emissions. If properly implement d we believe this concept will provide a source the necessary flexibility t adopt a control program that is the most cost-effective for a specific site. In many instances a company will now be able to either implement the valve standards contained in §60.482(f) or adopt a alternative percentage valve approach that more appropriately can be implemented at a site. We recommend that the Agency retain this concept and needed flexibility in the final regulations.

Although we wholeheartedly support this concept, we have a few comments and questions, that need clarification by EPA, in order to improve upon the proposed alternative standard.

One matter we believe needs clarification is the criteria the Administrator will use in either approving or disapproving the request for an alternative standard as set forth in §60.483(a)(5). We are unclear if the criteria are set forth in only §§60.483(a)(1) and (2), or in §§60.483(a)(1-(4). Or in the alternative, are there other conditions and criteria not set forth in the proposal that the Administrator might consider/use in approving or disapproving the use of the alternative standard. We believe the Agency has a duty to clearly set out all the criteria it proposes to consider, the basis for each criteria, and limit approval/disapproval activiti s to this list of criteria.

In our discussion above concerning accessibility of valv s, w indicated that for certain NEW AND modified facilities subject to thes requirements, it was infeasible for safety reasons to subject ll the valves to the provisions of §60.482(f). Should a facility s ek an alternative standard pursuant to §60.483(a), the accessibility of certain valves would create a problem in calculatin a meaningful allowable perc ntage f leaking valves. We recommend that these valves not be included as part f th alternative program and be

"(8)(i) An owner or operator of a modified source subject to th requirements of 60.482(f)(1)-(6) may for valves that are routinely inaccessible because of elevation or configuration monitor each inaccessible valve annually using test methods pursuant to 60.485 or a soap solution for bubbles."

"(ii) When a leak is detected, it shall be repaired as soon as practicable, but no later than the next scheduled shutdown, or consistent with 60.482(h)."

"(iii) For purposes of 483 or 484, inaccessible valves shall not be included."

§60.482(g)(2) - delayed compliance.

Our substantive comments on this section and its interrelationship with §60.482(h) are reflected in our comments on §60.482(a)(6) above.

§60.482(h) - delay of repair

Our substantive comments on this section are set forth in detail in our comments on §60.482(a)(6) above.

§60.483 - alternative standards - percentage of valves leaking

9) The proposed alternative standard for valves in gas/vapor and valves in light liquid service establishes an allowable percentage of valves leaking approach for ascertaining compliance. As we have recommended in earlier submissions to the Agency, the chemical industry wholeheartedly supports the concept of using allowable percentages of valves leaking as a vehicle for regulating fugitive

New §§60.483(a)(7) and (b)(5) should be added, as follows:

> "An owner or op rator may terminate complying with an alternate standard, by writing the Administrat r informing of this decision and immediately complying with the requirements of §60.482(f)."

~~§60.483(b) - Alternate Work Practices~~

Although we believe §60.483(b) is intended to provide industry with the flexibility they need to carry out this program most efficiently the present wording of some provisions will greatly inhibit its use. In §60.483(b)(3) the request to implement on opti nal work practice program must show a percentage of valves leaking that is equal to or less than that under the §60.482(f) program. Taken literally this would rule out any statistical or any probability based inspection programs. These alternatives are mathematically exact and the uncertainty or tolerance in their performance levels is explicityly stated. Thus it is not possible to achieve equivalence at all times with 100% certainty. We recommend that a sentenc b added at the end of §60.483(b)(3) stating - "Statistical and/or probability based monitoring programs shall be soundly based mathematically and shall show equivalence to the required program within a plus or minus 10% variation".

This modification does not either lossen or tighten the requirement. It assures, however, that "on-the-average" the alternate w rk practice will equal the §60.482(f) standards although individual process units may be over or under the standard by a little bit at any particular time. It is worth noting that the percentage leaking under the §60.483(a) program is not truly an exact number either. It is obtained by averaging a specific six months data base so that for any given month, a process unit might or might not meet the standard. In fact, since it is an arithmatic average, the percentage leakers under the required program will exceed the standard half the time.

regulated pursuant to our proposed §60.482(f)(7). This solution would require a modified source applying for an alternative standard to clearly identify in the §60.483(a)(2)(iii) data those valves that will remain subject to §60.482(f)(7).

In determining compliance with the proposed §60.482 requirements, EPA clearly sets out a §60.482(i) the standard to be used in determining compliance. No similar provision exists for either §§60.483 (a) or (b). We are uncertain what, if anything, triggers a violation of the Clean Air Act. Or does the Agency mean, if you fail the test set forth in §60.483(a)(4), the provisions of proposed §60.482 are reinstituted? In order to make §60.483 enforceable, we recommend that a provision similar to §60.482(i) be added that sets forth the vehicle for the regulatory agencies measuring compliance with §60.483,as follows:

> "(c) Compliance with §60.483(a) in this subpart shall be determined by the performance test set forth in §60.483(a)(4). Compliance with §60.483(b) in this subpart shall be determined by review of records and inspection."

Another area of uncertainty concerns a sources ability to formally switch from an approved alternative standard back to the requirements set forth in §60.482(f). For a variety of reasons, at a point in time it may no longer be cost-effective for a source to comply with a §60.483 alternative standard. We recommend that EPA accord these sources the flexibility and ability to switch back to the §60.482(f) valve standards, after notifying the Administrator in writing that they no longer wish to be subject to an approved alternative standard, and will comply with the §60.482(f) standards.

percentage of valves leaking under §60.483(a)(3)".

The advantages of the quality control approach advocated here is that: (1) greater emission reductions will be realized industry-wide because there is an incentive to do so, (2) the monitoring burden will be lessened on low leak plants and increased on high leak ones, and (3) well defined rules on what can and cannot be done will be available to the owner at the design stage.

60.483(c) - Good Performance Incentive

Although we believe 60.483(b) is intended to provide industry with the flexibility they need to carry out this program most efficiently, the present wording of some provisions will greatly inhibit its use. In 60.483(b)(3) optional work practice programs must show a percentage of valves leaking that is equal to or less than that under the 60.482(f) program. Taken literally this would rule out any statistical or probability based inspection system in new plants if they provide the best leak prevention options in their original design. The time to assure a low-leakage plant is when it is being designed and built. Quality control experience shows that quality must be designed into a product; it cannot be inspected in.

But the owner needs some incentive to put in more expensive high performance equipment. In establishing a fixed-period, 100% monitoring program the EPA has provided no incentive to reduce emissions by quipment design since the better a plant is controlled and engineered initially, the less chance there is to reduce monitoring through an alternate work practice. In fact, the required monitoring program does not directly address the real problem of preventing leakage which can be drastically affected by valve and packing selection. This is unfortunate. The regulation should encourage the owner to put in the best leak prevention options available.

Quality control experi nce shows that quality must be designed into a product; it cannot be inspected in. Thus the time to assure a low leakage plant is when it is being designed and built. But the owner needs some incentive to put in more expensive high performance quipment. In establishing a fixed-period, 100 percent monitoring program, the EPA has provided no incentive to reduce emissions by equipment design since the better a plant is controlled and engin red initially, the less chance there is to reduce monitoring through an alternate work practice. In fact, the required monitoring program does not directly address the real problem of preventing leakage which can be drastically affected by valve and packing selection. What is needed is some "good performance level" which, if designed to and met, would result in reduced monitoring requirements.

Snee and Kittleman of E. I. du Pont de Nemours & Company pr sented a paper describing statistical inspection plans for monitoring fugitiv emissions from leaking valves on April 16-17, 1980, to the National Air Pollution Control Techniques Advisory Committee and then followed this up with a second paper (Letter from T. A. Kittleman (Du Pont) to Glynda E. Willins (Radian Corporation), November 13, 1980) on choosing a good performance level. These papers provide a sound technical base for both statistical inspection plans and performance levels. They show that the required inspection program results in essentially a two percent of valves leaking based on the technical support document model plant examples. It seems reasonable then to allow operators to adopt inspection plans that will assure a two percent leakage rate within a plus or minus ten percent variation.

We recommend that §60.483(b)(3) have added to it a second paragraph stating - "(ii) Owners or operators may commit to an inspection program that will ssure a two percent of valv s leaking within a ten percent plus or minus variation without determining the

We recomm nd that the EPA include a third alternative as follows:

"60.483(c) Valves in gas/vapor and valves in light liquid service - good performance incentive.

(1) Owners or operators may commit to an insepction plan which allows annual inspection after not more than 2% leaks are detected in five successive quarters.

(2) Inpsection requirements under 60.482(f)(1) and (3) are reinstated whenever the 2% good performance level is exceeded.

(3) All leaks found will be repaired and inspected monthly until repair effectiveness is demonstrated in two successive months.

(4) Any other inspection plan will be allowed by the Administrator if it can be shown to be equivalent to 60.483 (c)(1),(2), and (3)."

The advantages of the quality control approach advocated here is that: (1) greater emission reductions will be realized industry-wide because there is an incentive to do so, (2) the monitoring burden will be lessened on low-leak plants and increased on high-leak ones, and (3) well defined rules on what can and cannot be done will be available to the owner at the design stage.

A major incentive would be less inspection for low-leak plants. This makes sense; low-leak plants should require less inspection, high-leak plants more. Quality control inspection plans provide this option while at the same time including a check for deterioration in performance which, when detected, results in the requirement to return to more frequent inspection. But before these plans can be used some means of rewarding, rather than penalizing, those who build low-leak plants must be provided. What is needed is some "good performance level" which, if designed to and met, would result in reduced monitoring requirements.

Snee and Kittleman of Du Pont presented a paper describing statistical inspection plans for monitoring fugitive emissions from leaking valves on April 16-17, 1980 to the National Air Pollution Control Technique Advisory Committee and then followed this up with a second paper (Letter from T. A. Kittleman, Du Pont, to Glynda E. Willins, Radian Corporation, November 13, 1980) on choosing a good performance level. These papers provide a sound technical base for both statictical inspection plans and performance levels. They show that a good performance level of 2% leaks is equivalent to EPA's BID basis used to estimate the leak reduction effectiveness of EPA's proposed regulation. It seems reasonable then to allow operators to adopt inspection plans that will assure a 2% leakage rate will not be exceeded.

In their papers Snee and Kittleman illustrated the use of a skip-period monitoring concept with a plan which would be widely used for monitoring fugitive emissions. Skip-period inspection plans have been used to inspect the quality of manufactured products for more than 25 years. These plans are widely used throughout industry and have a solid mathematical and statistical basis. Their proposed plan calls for five successive quarters of good performance to be followed by yearly inspection as long as good performance is continued to be demonstrated. If the specified level of good performance is exceeded, then the plant must return to quarterly inspection. Any leaks found must be repaired and monitored until the repair effectiveness has been demonstrated for two consecutive months. The proposed regulation should be amended to provide for the use of this, or any equivalent, alternative.

a m ans of btaining an equivalency determinati n of alternative test methods and procedur s. We recommend that a new §60.485(e) be added that authorizes seeking equivalency determinations of test methods and procedures and sets forth the criteria the Agency will use in evaluating an equivalency application. (The procedure would mirror that set forth in §60.484 for equivalence of alternative means of emission limitation.

§60.486(c) - Recordkeeping Requirements

This subsection requires that various technical data dealing with detailed schematics, structural designs, and design specifications shall be kept in a log, that is r-adily accessible, ostensibly at the site. We have no reservations about making this data/information available upon a reasonable request of EPA. We do, however, have reservations about being required to collect all this data and hous it in one location. As a matter of corporate operations much of this information/data are not always kept together, nor are they needed to be kept together for purposes of assuring and/or demonstrating compliance with the fugitive emission standards.

As the Agency is well aware, the Agency under Section 114 has the authority to require a source to "establish and maintain such records" in order to determine whether a person is complying with any standard under Section 111, or carrying out any provision of the Act. The Agency has not demonstrated how the required reports are necessary to ascertain and/or carry out Section 111 of the Clean Air Act. Further, th Agency has not demonstrated why all the proposed information must be kept in a readily accessible location when industry indicates it will make such data available upon request by EPA. We believe the provisions in §60.486(c) as proposed exceed the authority vested und r Section 114 to the Administrator, and imposes an arbitrary and capricious requirement unless modify to reflect industry's willingn ss

2/c

§60.484(b)(1) - Equivalence Determination

As proposed §60.484(b)(1), limits applying for an equivalence determination for an alternative means of emission limitations to th wner or operator of a facility. We are concerned that this artifical limitation may limit the incentive for or ability to use innovative technology. We believe that the manufacturers and/or vendors of new and/or innovative technology should also be authorized to apply for an equivalence determination. In a real world context few companies are going to purchase such a system unless the manufacturer and/or vendor will state that EPA has essentially approved the system. Accordingly, if EPA truly desires to encourage the use of innovativ technology, it should atthorize the manufacturers and/or vendors to also request equivalency determinations. We recommend that the first line of §60.484(b)(1) be modified, as follows:

> "(1) Each facility owner or operator, a manufacturer, or a vendor applying . . ."

§60.485 - Test Methods and Procedures

The test methods and procedures set forth in the proposed regulations are essentially based on the state of technology as of this date. We are concerned that the regulations do not 'rovide the necessary flexibility to approve in the future the use of new instruments that may use different calibration systems which provide equivalent or more accurate results. We believe the regulations must provide

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data for EPA should EPA want this data, they can ither request it in writing directly from the source or review it at the facility. As the Agency is well aware, ease of enforcement is not a legitimate grounds for requesting the reporting of data/information unless it is also necessary for purposes of determining compliance. As will be noted below, this data/information also duplicates data/information that must be reported under §60.487(b). The duplication of data/information should be avoided by EPA as much as possible. We recommend that §60.487(a) be deleted.

As to the specific information required under §60.487(b) we hav the following comments. As a general point, we are only commenting on the specific information requested on in §60.487(b) since the Agency has indicated that the forms and data requested therein are not requirements of the proposed standards. If, however, the Agency changes its mind on this issue, we reserve our right to subsequently submit comments on the example forms on pages 1158 and 1159.

The leakless valve data requested in §60.487(b)(2) is irrelevant for purposes of determining compliance with §60.482(f)(6). It is irrelevant the number of leakless seals that exist at a specific process unit. Accordingly, §60.487(b)(2) should be deleted.

The data requested in §60.487(b)(4) is irrelevant for purposes of determining compliance with §60.482(f). Compliance can be determined adequately by evaluating the data submitted as required by §§60.487(B)(3)(5) and (6). Accordingly, §60.487(b)(4) should be deleted.

In both §60.487(b)(7) and (8) the Agency has not requested the critical point of whether or not the pump/compressor leak was repaired similar to §§60.487(b)(5) and (6). If the Agency wants truly meaningful data it should consider adding a new provision that would requir this data.

to make the applicabl d ta vailable upon request. In this regard, we recommend that §60.486(c) be revised as follows:

> "(c) The following information pertaining to the design requirements for closed vent systems, enclosed combution devices, and vapor recovery systems required in §§60.482(a) and (b) shall be recorded and made available upon request by the Regional Administrator or delegate:
> (1) Detailed schematics, design specifications, and piping and instrumentation diagrams.
> (2) The dates and descriptions of any changes in the design specifications.
> (3) Periods when the enclosed combustion devices and vapor recovery systems required in §§60.482(a)and (b) are not functioning as designed and dates of start-ups and shutdowns.

§60.487 - Reporting Requirements

The requirements proposed in §60.487 set forth the detailed r - porting requirements a source must make to the Administrator on quarterly basis. As we commented above, the Administrator may require an owner or operator of an emission source, persuant to Section 114 to make reports where the information to be reported is relevant to ne of the purposes set forth in Section 114(a). In this regard, the r porting requirements set out in §60.487 must be relevant to determining whether a person is in violation of one of the standards, or for carrying out any provision of the Act. The Agency sets forth that the subject reporting is solely for the purpose of determining compliance with the NSPS. Accordingly, where the data/information requested is not relevant to ascertain a services compliance, the Agency will have exceeded its authority under Section 114 to require the reporting of such data/information.

Under §60.487(a), it is unclear what a "summary" of the recorded data/information in §60.486(b) would entail. Since this data must be r adily accessible by the source, it seems unreasonable merely for ease of enforc ment purposes to r quir a source to summariz this

(8) R asons for n n-repair of pumps and/or compressors within 15 days as r quired in §§60.482(a)(6) and/or (b)(5).
(9) Number of pumps, compressors, and/or valves not repaired pursuant to the delayed compliance time schedule of §60.482(h).
(10) Statement signed by the owner or operator stating whether all provisions of 40 CFR 60 Subpart VV had been fulfilled during the reporting quarter.

(b) The provisions of §60.8(d) do not apply to affected facilities subject to the provisions of this subpart.

(c) In the first report submitted as required in §§60.487(a), the report shall include a reporting schedule stating the months that quarterly reports shall be submitted. Subsequent reports shall be submitted according to that schedule unless a revised schedule has been submitted in a previous quarterly report.

C nclusion

Although the Agency has made substantial progress in addressing the numerous issues the chemical industry has raised on earlier drafts of the proposed fugitive emissions NSPS, we still have several reservations with the subject proposal. We still have reservations as to the inflexibility of several of the proposed requirements and it still is procedurally more burdensome than necessary for sourc s to expeditiously and cost-effectively identify and repair fugitive emissions. In this regard, CMA has presented several recommendations in these comments which we believe would further clarify and make more flexible the fugitive emissions NSPS program. We urge EPA to giv serious consideration to the CMA proposals and modify the proposed regulations to reflect the concerns expressed herein.

As we discussed earlier, delay d compliance may in some instances occur after the fifteen day period after leak detection (i.e., next scheduled shutdown) or in a few limited instances by necessity after the next scheduled shutdown (i.e., CMA recommended regulatory language for discretionary extensions after the next scheduled shutdown). In order for EPA to have meaningful data to accurately appraise a sources compliance status new provisions should be added to ascertain the number of pumps, compressors, and valves not repaired by the next scheduled shutdown, and the number of valves, pumps, and compress rs not repaired consistent with a time schedule approved by the Regional Administrator after the next scheduled shutdown.

We recommend that §60.487(a) be revised, as follows:

> §60.487 Reporting requirements.
> Each Owner or operator subject to the provisions of this subpart shall comply with the following reporting requirements.
> (a) Quarterly reports shall include the following information:
> (1) Process unit identification.
> (2) Number of valves for which leaks were detected by the monitoring method specified in §60.485(a) during each month of the reporting quarter.
> (3) Number of valves not repaired within 15 days as required in §60.482(f)(4).
> (4) Reasons for non-repair of valves within 15 days as required in §60.482(f)(4).
> (5) Number of pumps for which leaks were detected during the reporting quarters as specified in §§60.482(a)(4) and (a)(5).
> (6) Number of compressors for which leaks were detected during the reporting quarter as specified in §60.482(b)(4).
> (7) Number of pumps and/or compressors not repaired within 15 days as required in §§60.482(a)(6) and/or (b)(5).

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Respectfully submitted,

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April 6, 1981

cc: [TO BE ADDED LATER]

Re Rinsky paper

long-term survival among patients with Stage III disease is 25 percent (two of eight). Among patients with Stage IV disease, 6 of 34 (18 percent) have survived overall; of the 23 patients with bone metastasis and bone marrow involvement at diagnosis — a group generally considered to have a particularly poor prognosis, 5 (22 percent) have survived. The survival of these five patients indicates that marrow "purging" may not always be needed.

There has been a price for survival — considerable treatment-related chronic toxicity. Six of the eight children have auditory injury affecting their hearing range[3] and wear hearing aids. Five patients have reduced glomerular filtration rates,[4] two of whom have chronic renal failure; one of them requires antihypertensive therapy. Apart from these handicaps, the eight children (now 6.3 to 12.4 years old; median, 8.2) are leading full and active lives, including normal school attendance.

This series is relatively small, but a comparable rate (71 percent) of response to this chemotherapeutic regimen plus surgery has been observed in a larger study by the European Neuroblastoma Study Group.[5] Previous reports state or imply that no progress has been made over the past 10 years in treating advanced neuroblastoma and that the number of survivors who are more than one year old at diagnosis is negligible.[6,7] We challenge these assertions. Our experience suggests that the median survival of patients in Stage III and IV has been extended. High-dose melphalan is probably an important component of this improved prognosis[5]; therefore, the long-term results at centers using more intensive "consolidation" regimens[8-10] will be awaited with great interest. Rather than adopt a negative attitude, those treating children with neuroblastoma should energetically search for better induction and consolidation regimens so that response rates can be improved.

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AIDS AND RENAL FAILURE

To the Editor: Rao et al. observed accelerated wasting and early death in patients with the acquired immunodeficiency syndrome (AIDS) who required maintenance hemodialysis for therapy of end-stage renal disease (April 23 issue).[1] The course appears to be more rapid than has been observed in patients with AIDS who do not have renal failure. This observation may indicate that patients with renal involvement have more extensive human immunodeficiency virus–related disease and therefore die sooner. However, it is also possible that hemodialysis accelerates the progression of AIDS. Normal immune stimulation of T helper cells may trigger replication of the AIDS virus.[2] Furthermore, patients receiving maintenance hemodialysis have an increased proportion of activated T cells in peripheral blood, as defined by expression of interleukin-2 receptors.[3] Whether such activation of T cells reflects long-term exposure to blood transfusions, infectious agents, or dialysis membranes or tubing, or is a manifestation of the uremic state itself, is unknown. Intravenous drug use, present in a high proportion of the patients studied by Rao et al., would also be associated with chronic immune stimulation. It might be interesting to see whether patients on long-term ambulatory peritoneal dialysis have increases in immune activation of T lymphocytes comparable to the increases observed in patients on maintenance hemodialysis. If increased T-cell activation is more marked in maintenance hemodialysis than in other forms of therapy of end-stage renal disease, survival of patients with this disorder and AIDS could be enhanced by an alternative therapy (such as long-term ambulatory dialysis, if feasible).

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BENZENE AND LEUKEMIA

To the Editor: In the study on benzene and leukemia by Rinsky et al. (April 23 issue),* there were but nine cases of leukemia and four cases of myeloma. These are very small numbers on which to base conclusions, especially when the overall mortality has been as expected and the mortality due to malignant neoplasms has also been as expected.

Of special interest is the authors' Table 4, which lists the cases. Some had minuscule exposure, and one wonders what other malignant disease–causing agents they may have been exposed to during their lives. Of special interest is the fact that no employee first exposed after 1954 had leukemia or myeloma, even though hiring continued for 11 years and even though 7 of the 13 cases had the onset of disease within 20 years of first exposure. (Cases were followed through 1981, so there should have been some cases.) In the study, two subjects died within 3½ years of exposure.

Looking at the year of initial exposure of the 13 cases, one can see that 9 had first exposures before the end of World War II. One wonders about the measuring instruments in that situation.

Having spent some time studying childhood malignant disease more than 25 years ago, I am very sensitive to the tendency to observe clusters of cases sometimes living within short distances of each other. Statisticians have generally attributed these to chance, and there is no reason why that may not be true in the cases in this study.

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*Rinsky RA, Smith AB, Hornung R, et al. Benzene and leukemia: an epidemiologic risk assessment. N Engl J Med 1987; 316:1044-50.

To the Editor: The paper by Rinsky et al. on workers in rubber hydrochloride plants exposed to benzene reports a cohort study, a case–control study, and a risk assessment for leukemia in relation to benzene. Table 1, which uses data from that paper, indicates a discrepancy between the cohort and case–control studies. The case–

Table 1. Deaths from Leukemia, the Standardized Mortality Ratio (SMR), and the Predicted Odds Ratio, According to Cumulative Exposure to Benzene.

Cumulative Exposure (ppm-yr)	Deaths from Leukemia	Observed SMR	Predicted Odds Ratio*
0–40	2	1.1	1.3
40–200	2	3.2	4.5
200–400	2	11.9	43.8
>400	3	66	423

*From the risk-assessment model of Rinsky et al., using the midpoint of each exposure category (400 ppm-years for highest category).

control risk assessment predicts, in the higher-exposure categories, odds ratios much larger than the standardized mortality ratios observed in the cohort. A possible explanation for the discrepancy is that the exposure of the controls was much lower than that of all cohort members without disease. In support of this, it can be inferred from the paper that the mean cumulative levels of benzene exposure of the 1156 subjects without disease and the 90 controls were about 67 and 50 parts per million (ppm)-years, respectively.

It is reasonable to ask why the case–control study was done. A case–control study within a cohort is usually done to reduce the cost of determining the exposure of all cohort members without disease. However, this reason is not applicable here, since the exposure to benzene of all cohort members was known. Rinsky et al. offer several reasons for doing the case–control study, but all the objectives could have been met effectively by a cohort analysis of all the data.

The disparity between the mean exposure level of all cohort members without disease (67 ppm-years) and that of the 90 controls (50 ppm-years) requires explanation. It is probably not the result of selection due to matching, since this should have raised the level in the comparison series. The investigators may have reviewed the information on the benzene exposures of cases and controls, with the result that the average level of the controls, but not that of the cases, was lowered. If such a review explains why the control exposure levels were lowered by 26 percent, then the validity of the cohort study is questionable. Finally, if chance explains the difference between the cohort data and the case–control risk assessment, a risk assessment based on the entire cohort would be superior. Irrespective of the explanation, it would be appropriate to evaluate the data further. Although this might involve reevaluation of the benzene exposures of all cohort members, the results should clarify the relation between benzene and leukemia.

The Occupational Safety and Health Administration (OSHA) proposes to reduce the benzene standard of a 10 ppm time-weighted average to 1 ppm. A principal basis for this is the results of the rubber hydrochloride study. However, the magnitude of the dose–response relation in this cohort is uncertain. We, in a review supported in part by Texaco, Inc., and others have done risk assessments based on this study and estimate that exposure to 300 ppm-years of benzene would cause 50 to 80 excess leukemia deaths per 1000 workers so exposed.* The risk assessment of Rinsky et al. predicts 250.

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*Austin H, Delzell E, Cole P. Benzene and leukemia: a review of the literature and a risk assessment. Am J Epidemiol (in press).

To the Editor: In his editorial on new scientific evidence and public health imperatives (April 23 issue),[1] Dr. Ashford stated that "another example is the reanalysis of the National Cancer Institute data on human exposure to formaldehyde,[2] which now indicates a clear risk of cancer to humans." The authors of the study of humans exposed to formaldehyde[2] concluded that "these data provide little evidence that mortality from cancer is associated with formaldehyde exposure at the levels experienced by workers in this study." Since substantial numbers of health workers are exposed to formaldehyde, it would be of considerable interest if Dr. Ashford could provide the evidence that indicates "a clear risk of cancer to humans."

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To the Editor: The editorial by Ashford sounds a false alarm about the state of public health regulation today. Far from "waiting for the bodies to fall," federal agencies long ago adopted the "preventive public health policies" that Professor Ashford now pleads for. The Supreme Court's decision in the benzene case accepts this approach by authorizing OSHA to "risk error on the side of overprotection rather than underprotection."[1] The essence of the court's ruling is that this principle must be applied within realistic limits, so that instead of seeking "to eliminate completely and with absolute certainty any risk of serious harm," regulators must fairly evaluate all the available scientific data and "make a rational judgment about the relative significance of the risks" involved.[1] Federal agencies have recognized that prudence, rather than an ill-conceived rush to judgment, is crucial to sound public health regulation and have had no difficulty implementing the vital risk assessment and policy-making disciplines contemplated in the benzene decision.[2-4] In fact, OSHA has already regulated asbestos[5] and ethylene oxide[6] as carcinogens and will shortly prescribe stricter limits for formaldehyde.[7]

The report by Rinsky et al. on a much-studied cohort of benzene workers, which Professor Ashford cites as "better science" requiring an immediate "governmental response," actually illustrates the pitfalls of reacting uncritically to a single publication. Indeed, it fails to meet the standard of scientific excellence to which he subscribes. During OSHA's public hearings on benzene last summer,[8] major shortcomings in the paper by Rinsky et al. were uncovered, including selective use of the available data on industrial hygiene; substantial underestimation of exposures, particularly during the 1940s, at the work stations where the excess cases of leukemia occurred and where workers were known to have died from the acute blood-poisoning effects of benzene[8]; and failure to account for the prolonged, heavy exposures to benzene that many of the workers in this cohort experienced at work stations excluded from the analysis.[9,10]

There is nothing to be gained and much to be lost by fomenting a crisis atmosphere based on a flawed analysis that greatly exaggerates the level of risk, especially since average benzene exposures in the petroleum industry and elsewhere have for some time been reduced to levels comfortably below the 1-ppm limit OSHA has proposed.[11] Instead, Professor Ashford should recognize, as the American Petroleum Institute does, that the best way to improve health protection against the hazards we face today — occupational and otherwise — is to insist on a thorough scientific review of all the available data, focusing on the question of what exposures pose significant risks.

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The above letters were referred to the authors of the articles in question, who offer the following replies:

To the Editor: Dr. Bader is concerned that our analysis rests on only nine deaths from leukemia and four from multiple myeloma and may therefore represent merely a description of a random "cancer cluster." That conclusion is highly unlikely, because of the close association of the cases with an experimentally proved carcinogen[1-3] and the demonstrated strong, internally consistent dose–response relation. Similar features are characteristic of series of cases of other chemically induced cancers, such as mesothelioma in asbestos workers[4] and hepatic angiosarcoma in vinyl chloride workers.[5] Dr. Bader is correct in noting that no cases of leukemia developed in our series among workers first exposed to benzene after 1954. The most likely explanation for this finding is a reduction in cumulative exposure; relatively few workers were hired after 1954, and among those workers, total lifetime exposure was kept low by decreases in production and progressive diminution in exposure standards.

Austin et al. are concerned by what they perceive as "discrepancies" between the risk estimates derived from our case–control and standardized mortality ratio analyses. Given the different nature of these two analyses, such concern is misplaced. The standardized mortality ratio study is intended simply to delineate overall patterns of mortality. It provides a poor basis for ascertainment of an exposure–response relation, because each dose category within the cohort is a distinct subset with a different duration of follow-up, a different proportion of deaths, and different age distributions. In addition, the standardized mortality ratio uses an external population for comparison — namely, the entire population of the United States. By contrast, the case–control study provides an elegant means for modeling cumulative dose while controlling for age, duration of follow-up, and other potential confounders and effect modifiers. *Furthermore, it employs an internal comparison group.* All that said, however, the apparent discrepancy noted by Austin et al. is largely an artifact of their manner of representing our data. They arbitrarily chose to derive risk estimates by using the midpoint of each of our exposure categories. A more appropriate procedure, given the stated highly skewed distribution of the cumulative exposures, would have been to use the person-years weighted average exposure for each category. With that approach, more highly concordant risk estimates would have been obtained.

Austin et al. are also concerned by a "disparity" between the mean level of exposure to benzene of all cohort members without disease (67 ppm-years) and that of the 90 controls (50 ppm-years). This apparent discrepancy is easily explained. The appropriate procedure for tabulating doses in a case–control incidence study requires that cumulation of the controls' exposure be truncated at the time of death of each corresponding case.[6] For all other members of the cohort, dose continues to accumulate until cessation of exposure. Austin et al. have overlooked this methodologic point, and thus the two average doses cited by them are not comparable.

We are reassured that a separate risk assessment undertaken recently by Austin et al. produced overall findings quite similar to ours.[7] Both studies demonstrate an elevated risk of leukemia with cumulative exposure to benzene, both derive similar dose–response curves, and both indicate that there is a substantial risk of leukemia at exposure levels below 10 ppm.

Mr. O'Keefe states that during public hearings on benzene held by the U.S. Department of Labor in 1986, "major shortcomings" were uncovered in our research. O'Keefe fails to note that with our cooperation, he and his staff scrutinized each datum in our analysis. They found only minor discrepancies among thousands of coded work histories and exposure measurements. We subsequently corrected each of these errors, and the corrections are included in our published report. Correction of those errors actually increased our estimates of leukemia risk slightly. Furthermore, the environmental measurements were reviewed by the company in whose plants the study was undertaken. The company took no exception to our characterization of exposures, and they rejected the notion that we had substantially underestimated exposure.[8]

We are pleased to note that on September 1, 1987, OSHA announced a reduction in the standard for permissible occupational exposure to benzene from 10 to 1 ppm.

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To the Editor: Despite assertions to the contrary by Mr. O'Keefe, federal (regulatory) agencies have *not* adopted preventive health policies. OSHA waited 15 years (until 1986) to regulate asbestos as a carcinogen — and then suspended the new standard for non *asbestiform fibers. This could hardly be called a preventive approach,* since thousands of asbestos workers died because of the delay. OSHA also failed to establish a short-term exposure level.

Ethylene oxide was only recently regulated because OSHA was sued; OSHA has still refused to define a short-term exposure level for ethylene oxide that would be required for adequate protection. What Mr. O'Keefe would probably call an ill-conceived rush to judgment is what those concerned with public health would recommend as a prudent measure. Sufficient evidence to justify a standard is, like beauty, in the eye of the beholder.

Decisions about whether to regulate can be in error because of uncertainties about the nature and extent of the risk or about the economic and technological feasibility of regulatory controls. One type of error is committed when, because of insufficient evidence, society fails to regulate an activity that turns out to be harmful. Another type of error is committed when society regulates an activity that turns out not to be harmful and resources are needlessly expended. Aversion to making these two types of errors reflects differing values regarding the nature of the mistakes made and the extent, prevalence, or magnitude of the mistakes.

In my opinion, reliance on scientific conventions of causality for public health purposes is simply too costly in terms of human life. To dignify a decision not to regulate or a decision to wait for more evidence, under the mantle of its being scientific, is to do a disservice to both science and public policy. Furthermore, it obscures the value judgments made.

With regard to the regulation of chemicals over the past 17 years, I cannot think of a single regulated substance for which the evidence has not grown more convincing with time or for which a reversal in regulatory policy occurred. Sooner or later, the tip of the

iceberg reveals the iceberg. We are very far from ill-conceived rushes to judgment. On the contrary, the regulatory agencies have sometimes been dragged kicking and screaming into action necessary for fulfilling their statutory mandates. In the meanwhile, workers and citizens are harmed.

An example is the evolution of science regarding the carcinogenicity of formaldehyde. The National Cancer Institute (NCI) study in 1986 asserted that there was "little evidence that mortality from cancer is associated with formaldehyde exposure at levels experienced by workers in this study." In a later publication[1] the same authors concluded that

> Despite small numbers, the dose-dependent association of nasopharyngeal cancer with exposure to formaldehyde and particulates deserves further investigation through case-control studies, where the influence of formaldehyde and particulates may be evaluated with more statistical power than by standard cohort studies.

Further analysis of the NCI data by Sterling and Weinkam[2] reveals a clearly increased risk of lung cancer. At congressional hearings in 1986, the Director of the NCI, in commenting on the earlier work, testified that "in association with particulates, there is an association between formaldehyde and nasopharyngeal cancer, which clearly has to be followed up."[3]

The irony concerning the criticisms of the adequacy of the science is that the scientific evidence is essentially there. OSHA has just decided to reduce the permissible exposure level for benzene to 1 ppm. It waited far too long. Let there be a better governmental response to the new realities.

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THE EC–IC BYPASS STUDY

To the Editor: The recent discussion (March 26 issue)[1-4] of the extracranial–intracranial (EC–IC) arterial bypass study is very timely. I would like to speak to one statement in the editorial: "The conclusions of the EC–IC trial are valid for the population of patients studied."[1]

The population that underwent surgery included patients who had only one episode of the transient ischemic attack. Most neurosurgeons who are experienced with the bypass procedure would not accept for surgical consideration any patient with a single transient ischemic attack. There is no discussion in the original report of the randomized study[5] about how many of the patients who underwent surgery were in this ordinarily nonoperative group. Subsequent reports by the authors of the randomized study have never clarified this issue.

Regardless of whether the randomization of the patients was proper or not, the mere fact that patients with one transient ischemic attack were included in the study negates the concept that the conclusions of the EC–IC trial are valid for the population of the patients studied.

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To the Editor: The Special Reports in the *Journal* of March 26 on the validity of the international randomized trial of extracranial–intracranial arterial bypass, first published in the *Journal* in 1985,[5] induce some thoughts about the findings. Specifically, the implication of the findings for a better understanding of the pathogenesis of ischemic stroke is of interest.

The results are fully consistent with the hypothesis that ischemic strokes are largely embolic in origin. The relations among transient ischemic attacks, completed strokes, and atherosclerotic plaques of the internal carotid artery were well established before the study was done.

Emboli from ulcerated plaques or occlusive lesions of the internal carotid artery or middle cerebral artery would presumably lodge in a brain vessel distal to the anastomosis, whose only effect could then be to improve marginal or collateral circulation to the periphery of the territory where the infarct occurred.

Is it too simplistic to assume that in the case of the carotid lesions, a natural bypass already exists — the circle of Willis?

One of the postulates of the study was that lesions of the middle cerebral artery would be especially suitable for bypass surgery. In fact, the existence of such lesions generally indicates more severe, widespread atherosclerotic disease, with the attendant risk of stroke from embolism originating in the internal carotid artery or aorta or death from coronary heart disease.

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*The EC/IC Bypass Study Group. Failure of extracranial–intracranial arterial bypass to reduce the risk of ischemic stroke: results of an international randomized trial. N Engl J Med 1985; 313:1191-200.

To the Editor: The *Journal* is to be congratulated for its complete handling of the controversy surrounding the EC–IC operation.[1-4] However, we strongly disagree with the conclusions of both the neurosurgeons[5] and the Editor,[3] who seems to have been impressed by the neurosurgeons' arguments and to cast a shadow on the proper interpretation of such trials. We agree that generalizability is strengthened when most eligible patients are randomized, but we insist that the results should stand unless or until an even better study repudiates them. In the meantime, those who insist on using this now-discredited operation should not expect third-party reimbursement until they provide credible (i.e., well-controlled experimental) evidence that contradicts the EC–IC study.

The called-for retrospective review of the outcome in the nonrandomized patients would be as worthless as any uncontrolled historical survey. It would be impossible to sort out selection factors from treatment effects. Some patients selected for operation rather than randomization might do worse than those randomized, because the more threatened patients were treated surgically, and some might live longer because their good condition made them attractive surgical candidates. Whichever predominated, the result would be uninterpretable, as demonstrated by several published comparisons of survival of randomized and nonrandomized patients who seemed to have the same prognosis.[7-9] If surgeons have reservations about the validity of randomized controlled trials because their patients were not entered, the problem is easily solved by including all eligible patients in future studies that have the prior approval of those surgeons.

In our experience, patients readily accept randomization when their physicians are convinced of its validity. When told of the results of the trial and the lack of any evidence favoring surgery, they would prefer randomization to an operation based on surgical judgment alone. As suggested by one of us,[5] the study could be paid for with the money saved by operating on only half as many patients. In the meantime, there is no acceptable evidence that the