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October 27, 1977

Steven Witt, **Esq.**
Office of the Solicitor
U.S. Department of Labor
Occupational Safety and Health Admin.
3rd and Constitution Avenue, N.W.
Washington, D.C. 20210

Re: Proposed Beryllium Standard -
Kawecki Berylco Industries, Inc.

Dear Mr. Witt:

I am enclosing a copy of the post hearing brief of Kawecki Berylco Industries, Inc.

Sincerely,

Tyson W. Coughlin

/pjd

Enclosure

#21

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UNITED STATES DEPARTMENT OF LABOR--
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Proposed Occupational Safety and Health Standard for Occupational Exposure to Beryllium (Federal Register, October 17, 1975)

OSHA Technical Data Center--
Docket No. H005

Post-Hearing Brief
For
Kawecki Berylco Industries, Inc.

Ballard, Spahr, Andrews & Ingersoll
United Engineers Building
30 South 17th Street
Philadelphia, PA 19103

TABLE OF CONTENTS

On October 17, 1975, the Secretary of Labor published a notice proposing to adopt a new occupational health standard for beryllium. The new standard would replace the current National Consensus Standard which, with certain modifications, has been in existence since 1949, the year it was developed by the Atomic Energy Commission.

In February 1976, Kawecki Berylco Industries, Inc. ("KBI"), one of the two primary producers of beryllium metal and beryllium alloys, filed written comments to the proposed standard. These comments pointed out that, as applied to the Company's operations, the new standard was unworkable. The comments suggested that the standard be withdrawn and reexamined de novo.

In preparation for the hearing on the new standard, which commenced on August 16, 1977, KBI filed the written testimony of seven witnesses together with four exhibit books.* This evidence (1) outlined the historical background of the current beryllium standard and the monitoring technique traditionally used to determine concentration levels, (2) emphasized the stringent nature of the current standard, (3) described the operations of

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* The Company has filed a fifth exhibit book as a post hearing submission.

KBI and the beryllium concentration levels associated with those operations, (4) stated KBI's conclusion that it is not feasible to comply with the proposed standard, and (5) stated KBI's further conclusion that imposition of the proposed standard will not significantly improve working conditions at KBI's plants.*

The hearing extended for a three week period during which oral testimony was presented by witnesses on behalf of the OSHA Staff, the National Institute for Occupational Safety and Health (NIOSH), the United Steelworkers of America, the Oil Chemical and Atomic Workers Union ("OCAW"), KBI, Brush Wellman, and various secondary processors. In addition, a number of individuals presented their views.

KBI's oral and written evidence was submitted in the belief that the object of the hearing was to enable the Secretary to decide whether any change in the current standard is necessary; if so, whether the proposed standard is appropriate; and if not, what would be an appropriate standard. The purpose of the hearing should heve been to inform the Secretary, not to support or defeat the proposal.

As it turned out, rather than being a forum for the

* By prearrangement the development of information regarding the carcinogenic nature of beryllium was left to Brush Wellman, the other primary producer.

gathering of information and exchange of views, the hearing was an adversary proceeding, at least as far as the proponents of the new standard were concerned. The Secretary should consider much of the evidence presented by the OSHA and NIOSH Staffs in light of this attitude.

The witnesses presented by the OSHA Staff clearly thought it was their function to advocate the adoption of the proposed standard. As stated by the head of the standard setting section of OSHA, the Staff's role is to "prepare the Department's testimony in support of the proposal, prepare to be cross-examined, and assist the Solicitor's Office in preparing its own cross-examination of adverse expert witnesses".*

In a similar vein, the NIOSH witnesses argued in defense of OSHA's position on toxicity and monitoring. The zeal of their advocacy was revealed when the Director of NIOSH interceded without justification to abort the presentation of an analysis (prepared for Brush Wellman) that would have discredited NIOSH's principal epidemiologic study (T. 1079-1109).**

Consistent with the attitude that no one should be permitted to impugn the proposal, KBI and Brush were precluded from developing for the record the reasoning behind the various provisions of the proposed new standard (T. 36-38; 100). To this day no one has said what they are designed to accomplish.

We bring these matters to the attention of the Secretary

* Affidavit of Grover Wrenn - KBI Exhibit Book V, Tab 2.

** This study, identified as "Bayliss III," is discussed in Section 2 of Part D of this brief.

at the outset so that she may recognize that the OSHA and NIOSH Staffs are far from impartial in this proceeding. In view of their obvious partiality, we take the position that the OSHA and NIOSH Staffs cannot, consistent with the requirements of fairness and due process, continue to advise the Secretary on an ex parte basis. If the Secretary chooses to hear their side, fairness dictates that she also hear our side.*

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* In this regard we are told that the OSHA Staff reviews, analyzes and summarizes the record for the Secretary and in addition develops a final standard for the Secretary's consideration (T.101). We are further advised that we axe not entitled to a copy of the Staff's summary or recommendation (T.lO1-102; 3100-3103), and of course we have no opportunity to correct any misunderstandings or rebut any improper inferences on the part of the Staff.

A. INTRODUCTION

As the Secretary knows, under the Occupational Safety and Health Act the burden of proof is on those proposing a change from the National Consensus Standard.* This burden would extend not only to the question: is a change necessary to improve working conditions? But also to the question: will the proposal produce the desired improvements?

In the instant proceeding the burden of proof is singularly heavy because the existing standard is rigorous and long established and is generally conceded to have accomplished its purpose, the elimination of beryllium disease. We do not maintain that because the standard is of long standing it should not be modified under any circumstances. We do, however, contend that, before deciding that a change is needed, the Secretary should carefully weigh the historical background of the current standard, which is founded in good industriai hygiene practice calculated to assure healthful working conditions. This is particularly appropriate here, where many highly respected authorities believe that the current standard is working well and does not need change.

* The Act requires the Secretary to articulate the reasons for any departure from a National Consensus Standard (Section 6(b)(8)). The Act further directs that a standard be based on "the best available evidence" (Section 6 (b)(5)) in a factual record, the decision being subject to review under a "substantial evidence" test (Section 6(f)).

In the record the Company has set forth its belief that the current standard is satisfying the statutory objective of assuring healthful working conditions to the extent feasible. The limits on concentrations and exposures under the present standard appear to be the lowest feasible for primary producers such as KBI. Nothing will be gained by imposing lower limits that cannot be complied with. In the vernacular, a further reduction would be going from zero to one-half of zero.

If the Secretary, nevertheless, feels that a change is warranted, it should bear a logical relationship to the current National Consensus Standard. Change should be by way of evolution, not by way of drastic and extensive revision. Only in this fashion can continuity be maintained with the air sampling records that have been compiled by the primary producers over many years.* To render such data valueless (which is what the new standard would do) does not further the purpose of the Act.

The changes proposed by the OSHA Staff are so drastic as to constitute a brand new and much more rigorous standard. It is our position that the record does not justify such a revolutionary proposal as a matter of administrative judgment and does not sustain OSHA's burden of proof as a matter of law. We say that the record is deficient on several points, but most seriously and fatally deficient as to feasibility. We contend that the pro-

* This data is specifically designed to disclsse any correlations that may exist between exposure levels and disease, to pinpoint operations involving high concentrations, and to facilitate corrective action.

posed standard (considering both its provisions and its omissions) is so vague and uncertain as to violate the U.S. Constitution (Fifth Amendment). An order promulgating the new standard on this record would be an abuse of the Secretary's power under the Act and a violation of KBI's constitutional rights.

However, as stated in our comments, our principal objective is not to argue legal points but rather to persuade the Secretary to give the entire matter the additional study it so badly needs. The Vice-chairman of KBI spoke to this point at the hearing as follows:

> "I cannot urge too strongly that the proposed standard deserves reevaluation in a setting where the parties can exchange views as to the significance of data and studies and can work toward a mutual understanding of the technology, the economics, and the measurement of compliance. This would clearly be in the interests of the parties directly concerned and the public at large."*

* Lowry, W.T. p. 17.

B. The Proposed Standard Is Entirely Different From The Current Standard And Impossible To Comply With

1. Background - The problems of measuring fluctuating concentrations of airborne particulates

To demonstrate the nature and effects of the proposed standard it is first necessary to discuss the principles of industrial hygiene as they apply to the measurement of particulate concentrations in manufacturing plants. As early as 1936 Drinker and Hatch in their text entitled "Industrial Dusts"* recognized that dust concentrations in industrial atmospheres vary from hour to hour and from day to day. They noted that "The ultimate lung injury represents the integrated effect of dust over a long period of exposure," and pictured the task of the indcstrial hygienist to be the measurement of the average concentration over a period of time which would encompass the full cycle of variation. Dr. McDonald Wrenn testified that these principles are still valid today, and that "because of the random nature of dust concentrations, single values--whether for a single day or a single operation — give inadequate guidance. to the exposure producing the chronic biological response." (Wrenn, W.T. (written testimony) p. 9-10).

Drinker and Hatch (p. 87-88) also recognized that there is variability associated with the sampling instruments and the analysis used to measure particulate concentrations, and that

* Industrial Dusts, Drinker and Hatch (1936) - KBI Exhibit Book 11, Tab 1.

the combination of these variabilities - variability in the industrial atmosphere as well as in the method of measurement - presents difficult statistical problems. These statistical problems have been analyzed by NIOSH in connection with the Joint Standards Completion Program of NIOSH and OSHA. As stated by NIOSH:

> "The variability of occupational environmental data (differences between repeated measurements at the same site) can usually be broken into three major components: 1) random errors of the sampling method, 2) random errors of the analytical method and 3) variability of the environment with time. The first two components of the variability are usually known in advance and are approximately normally distributed. However, the environmental fluctuations of a contaminant in a plant usually exceed the variability of known instruments (often by factors of 10 or 20)."*

While NIOSH found the first two components (random errors in sampling and analysis) to be normally distributed, it concluded that the third (fluctuation of the environment) "is better described by a log-normal distribution", i.e. a distribution which "is generally positively skewed (long 'tail' to the right indicating a larger probability of very large concentrations than for normally distributed data)."**

NIOSH further concluded that one of the conditions conducive to this log-normal distribution is the extent to which "the concentrations lie close to a physical limit (zero concentration)" - as is the case in beryllium plants.

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* Statistical Methods for the Determination of Noncompliance with Occupational Health Standards, NIOSH (1975) p. 3-4 - KBI Exhibit Book y, Tab 9.

** Ibid., p. 3.

Finally, in another publication (Exhibit 78) NIOSH recognized that the fluctuation in airborne concentration3 must be taken into account in deriving a figure that is truly representative of the concentrations to which workers are exposed. As NIOSH puts it:

> "The word 'sampling' is used very commonly, but sometimes the full implications of the word are not realized. To sample means to measure only part of the universe and from the measurements taken infer things about the totality of the universe. In doing so, the variation with time encountered adds to the error. This variation is of two kinds: the intraday variability, that is the variability within a day of measurement; and the interday variability, the variability between days. Generally they can be lumped together and called temporal variability. The important thing is that these two sources of error be considered."

The relevance of this background information on the problems of measuring fluctuating concentrations of airborne particulates will become clear in later sections of this brief. At this point it is sufficient to note (1) that concentrations in KBI's plants are characterized by intraday, interday, intermonth and even interquarter variations and (2) that the proposed new standard, by failing to take these variations into account, imposes a ceiling which KBI could not possibly comply with.

2. The primary production of beryllium and its alloys is associated with wide variations in the concentration of airborne beryllium

KBI and Brush produce beryllium and its alloys by batch processes involving powder technology and high heat. The process at KBI's Hazelton beryllium metal plant was described by Mr. Schoenly, the plant manager, as follows:

> "... at some point in the manufacturing sequence, finely divided pure beryllium powder must be made through impact attritioning, or in our ball mill, and which then must be sized, sampled, blended, stored and loaded into a die. And we are moving - handling - thousands of pounds of beryllium powder through the plant each month... we are dealing with a batch process - a non-continuous operation which requires stopping, starting, emptying and filling." (Schoenly W.T. p. 4)

At its Reading plant, the Company reduces beryllium oxide (which has the consistency of face powder) with carbcn in the presence of copper to produce beryllium copper master alloy (Velten W.T. p. 2). The operation takes place in arc furnaces. Ten tons of beryllium in the form of beryllium hydroxide and beryllium oxide powder are processed each month (Velten W.T. p. 8).

The principal source of airborne beryllium in the Hazelton and Reading plants is the fine powder that is used in great quantities in the basic manufacturing processes. As observed by Mr. Schoenly:

> "Finely divided particles are difficult enough to contain but add to this the handling of a batch process and one has created a real set of engineering problems especially at low concentrations. The problems can be summed up in one word - variability." (Schoenly W.T. p. 4).

The record is clear that dust concentrations in KBI's plants vary over an 8 hour period, from day to day, and over longer periods. For example, in analyzing KBI's Job Analysis Sheets Mr. Schoenly found that monthly time weighted average concentrations for the same job varied as much as 240% (Schoenly W.T., p. 11). On a quarterly basis he found variations of up to 450% (Schoenly W.T. p. 10).* Dr. McDonald Wrenn found that these variations are log normally distributed. The average geometric standard deviation for all occupations was 1.9 at Hazelton and 2.2 at Reading.** Some occupations had considerably higher GSD's.

The handling of finely divided powder in batch operations and the wide variations in particulate concentrations associated with such operations differentiate the beryllium industry from industries that produce on a continuous basis. In our plants something different is going on each day, and the levels of concentration vary on a daily basis.***

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* The difference between the "low" and "high" concentrations within a quarter on KBI's Job Analysis Sheets also illustrates the point. See KBI's Job Analysis Sheets in KBI Exhibit Book III and IV.

** Remarks about NIOSH Technical Information Publication, McDonald Wrenn, p. 2 - KBI Exhibit Book V, Tab 10.

*** Such variations are characteristic of the industry. More than a decade ago it was reported that:

> "Dust concentrations vary over an 8-hour period, from day to day, and with the season. The magnitude of this variation is more pronounced at facilities with numerous, complex sources, but variations exist in all cases."

Beryllium, Its Industrial Hygiene Aspects, Stokinger (1966) p. 303 - KBI Exhibit Book 11, Tab 2.

At this point we refer the Secretary back to Section 1 of this part of our brief, where we discussed the statistical problems of measuring fluctuating concentrations. When that section and the authorities cited in it are read in the light of the wide fluctuations encountered in primary beryllium plants, one would expect an up-to-date standard to take cognizance of the measurement problems. The current standard takes them into account., but the proposed new standard ignores them, as the following paragraphs will show. This failure, i.e. the failure to take interday variations into account, is the root of most of the proposed standard's flaws.

3. The current standard and how it handles fluctuaticg concentrations

The current beryllium standard of two micrograms per cubic meter of air (2 ug/m^3) is one of the most stringent particulate standards in existence. It is two thousand times more stringent than the standard for vinyl chloride (Wrenn, W.T., p. 15), and 50 times lower than the standards for lead and for cadmium (T. 364-365). It is comparable to 1.6 parts per billion, .0016 parts per million or 0.000000165 (Schoenly W.T., p. 2). Reputable experts, including OSHA's witness Harry F. Schulte, have speculated as to whether the limit is too strict and have seriously considered raising it. In this connection Mr. Schulte wrote:

> "The existing [beryllium] standard does require very careful attention to design and operation of ventilation and other controls. Relaxation of the air concentration standards by two to five times does not greatly reduce the stringency of the

> control measures required. There is no great incentive to seek this degree of relaxation. The concentration standards have been met in practice and are demonstrably feasible. It is unlikely that these numbers will decrease appreciably in the future while standards for many other materials have decreased and will probably continue to decrease. In the future the beryllium concentration may not appear so out-of-line with other toxic substances as it has in the past."*

The standard was set in **1949** by the Atomic Energy Commission, which recognized the problems of measuring fluctuating concentrations, and provided that the concentration to which an employee was exposed should be computed on the basis of numerous samples taken over a three month period. The result was called a daily weighted--or time weighted--average. If this average exceeded the standard **(2** ug/m^3) **,** the employer was required to submit plans for corrective action and provide respiratory protection. The objective of the **2** microgram limit was to control long term average exposures in order to prevent the chronic form of beryllium disease.**

As further protection against excessive long-term exposures, the standard provided that if the time weighted average for

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* Beryllium, The Criteria Document, Schulte (1973) - KBI Exhibit Book V, Tab 4.

** The **2** ug/m^3 value was arrived at through a comparison of the atomic weight of beryllium with the atomic weight of other known toxic metals and their maximum allowable concentrations. The resulting figure of **4** micrograms per cubic meter of air was then halved to provide a 100% margin for error. Basis of the Presently Used Maximum Allowable Concentrations. For Control of Beryllium Disease, Eisenbud (1961) - KBI Exhibit Book I, Tab **2**,

any quarter exceeded 5 ug/m^3, the operations in question should be halted until corrective action could be taken. This provision, like the 2 microgram provision, was directed at chronic beryllium disease.

The AEC contract* provisions embodying the 2 microgram and 5 microgram limits were as follows:

> "If the result of the daily weighted average concentration computed on a quarterly basis for any occupation exceeds 2 ug/m^3, but is less than 5 ug/m^3, the Contractor will submit plans for necessary corrections for Commission approval and provide all personnel exposed in this area with approved personal respiratory protective equipment. If the daily average concentration exceeds 5 ug/m^3, the operation in question will be halted until the necessary improvements can be accomplished. A daily average concentration exceeding 2 ug/m^3 will not be permitted to exist for a period exceeding 60 days except with the specific approval of the Commission. This approval will be granted only in the event that satisfactory procedures for reducing the concentration to below 2 ug/m^3 have been accepted by the Commission."

To prevent the acute form of beryllium disease, the AEC established a "peak" concentration of 25 ug/m^3, which was addressed--not to the time weighted average---but to single samples.** In this regard the AEC contract read:

> "In the event that a single air sample shows a concentration in excess of 25 ug/m^3 within the operating area but is less than 100 ug/m^3 (and this is to be confirmed within 10 days of the

* KBI Exhibit Book I, Tab 1.

** The peak value of 25 mg/m^3 was arrived at through the study of exposure values as related to the development of the acute disease. (T. 2149-2152).

time at which such a sample was obtained), all exposed individuals will be provided with personal respiratory protection approved by the Commission and the Commission will be notified of steps being taken to eliminate the high concentration. If the concentration exceeds 100 ug/m^3 in a single sample (and this is to be confirmed within the above time limit), operations will be halted and the necessary corrections made to reduce the air-borne concentrations at this single point to below 25 ug/m^3. In no case will concentrations above 25 ug/m^3 be permitted to exist for a period exceeding 60 days without the specific approval of the Commission. This approval will be granted only if steps have been undertaken which can be expected to provide a satisfactory reduction in air concentration."

While no time limit with respect to the 25 microgram value was spelled out in the AEC contract, the maximum duration for exposures to concentrations of this magnitute "was generally understood to be not more than 30 minutes".* The reason for limiting the permissible duration to 30 minutes is set forth by Breslin as follows: "By simple arithmetic, it may be shown that the duration of 25 ug/m^3 is limited to 38 minutes in a period of 8 hours if the average daily exposure of 2 ug/m^3 is to be maintained, and that would be allowable only if there were no other exposure to beryllium throughout the work day".**

The method prescribed by the AEC for determining the time weighted average concentrations associated with a particular

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* Beryllium, Its Industrial Hygiene Aspects, supra, p. 235-236; See also Beryllium, The Criteria Document, Schulte (1973), supra.

** Beryllium: Its Industrial Hygiene Aspects, supra, page 256.

job made allowance for the different concentrations associated with different operations (the intraday variation) and also for the fluctuation in concentrations from one day to another (the interday variation). The first step in the process was a study to determine what operations a worker was called on to perform and how much time he spent on each operation. The results of this study were entered on an AEC form called a job analysis sheet. The job analysis sheet for a vacuum furnace operator shown on the next page is typical:

JOB ANALYSIS SHEET

OPERATOR Vacuum Furnace Operator 1 MEN/SHIFT 3 SHIFTS/DAY 3 MEN/DAY

OPERATION OR OPERATING AREA	TIME OF OPERA (MINS)	PER SHIFT	TIME PER SHIFT (MINS) (T)	NO OF SAMP. LES	CONCENTRATION μg/M³ LOW	HIGH	(C) AVGS.	AV GE CONC M³. TIMES TOTAL TIME (T > C)
BZ Cleaning and removing billet from furnace	13	3	39	4	7.6	22	15	590
BZ Weighing furnace charge	6	3	18	4	3.5	17	6	110
BZ Charging furnace	a	3	6	5	1	37	19	110
CA Vacuum furnace area			351	11	0.6	4.1	1.7	600
CA Sprnt salt area			45	9	0.3	2.2	0.9	41
CA Lunch room			30	4	0.7	0.5	0.4	12
CA Locker room, before shift			10	5	0.7	0.6	0.4	4
CA Locker room, after shift			15	5	1.5	4.8	2.7	41

* Adjusted to two significant figures.

ΣT 510

$\Sigma (T \times C)$ 1500

$\frac{\Sigma (T \times C)}{\Sigma (T)} =$ 2.9 $\mu g/M^3 =$ _____ TIMES THE MAXIMUM ALLOWABLE CONCENTRATION

FIG. 9.23. Job analysis sheet. (Courtesy U.S.A.E.C. Health and Safety Laboratory.)

In filling out the job analysis sheet, the various operations performed by the vacuum furnace operator were listed in Column 1. The time spent on each operation was shown in Column 4. At least three samples for each operation were taken during the quarter (Column 5) and these samples were averaged to produce an average concentration for the operation in question (far right of Column 6). The average concentration for each operation was then multiplied by the time spent on the operation to produce an average exposure (microgram-minutes) for each operation (Column 7). These average exposures were then added together and divided by the total time for the shift (see bottom of page) to give the time weighted average concentration for the quarter year.*

The AEC contract provisions outlining the foregoing procedure were as follows:

> "In order to insure adequate sampling of breathing air concentrations, the following or equivalent procedures approved by the Commission should be followed:
>
> Each separate plant operation will be broken down into its primary components and the average time per day required for the accomplishment of each component and fhe number of times it is repeated will be determined. A minimum of three breathing-zone samples will be taken to evaluate the exposure arising from each such job component, in addition to an adequate sampling of the general air so that a complete overall exposure may be arrived at for each plant operator.

* Drinker and Hatch (p. *85)* outlined a similar approach: "The best procedure is to determine the dustiness during different stages of the operation and, with the aid of a time study, to break down the operator's day according to the time spent during each step. From this data one calculates the average dust exposure of the machine operator..."

On the basis of these samples, a daily average exposure will be computed for each operation. The average will be weighted with time by multiplying the average concentration for each job component times the amount of time spent by the operator each day in accomplishing the component. The sum of all of these products divided by the total time per day will yield the time weighted average concentration.

A minimum of four (quarterly) such evaluations will be performed each year for each operator."

It will be noted that the AEC contract called for a combination of general air and breathing zone samples. The difference between the two types of samples is described by Breslin as follows:

"In a chemical plant, more than half and sometimes as much as nine-tenths of a worker's time is spent in a few areas monitoring the process and occasionally adjusting the process equipment. His exposure in these circumstances can be estimated with reasonable accuracy by measuring the general air (GA) concentrations in these areas.*

A GA sample is one that is collected at a location, maintained in one position during the sampling period, and selected to represent environmental conditions over a working area."

* * *

"Another type of expcsure occurs when a worker performs some task in which he comes into close contact with the process material. This will occupy only a small fraction of his time in chemical operations, but the reverse is true in machine-shop operations, In either case it may represent an important part of his average daily exposure. Consider activities such as drum filling or dumping, cleaning a filter press,

* The concentration levels in these areas are minimal - see KBI DWA figures - KBI Exhibit Book III and IV.

> charging a furnace, collecting a control sample from the process, operating a machine tool, or any one of a hundred maintenance tasks that require dismantlement of, or entrance to, equipment. At jobs such as these, dust concentrations are apt to be greater, often by a substantial amount, than in the general air. Therefore these activites contribute to the average daily exposure far out of proportion to their duration. Also, if concentrations in excess of 25 ug/m^3 occur, they are likely to be found at these jobs.
>
> Concentrations at these jobs are measured by breathing-zone (BZ) sampling. The sampling device is held in the vicinity of the worker's breathing area for the duration of the task.... The sample should be taken as close to the worker's nose as possible, short of interfering with his freedom of movement."*

As a matter of practice both the general air and breathing zone samples were collected by means of high volume samplers having flow rates of from 8 to 18 cubic feet per minute (Wrenn, W. T. p. 8; T. 2159; Beryllium; Its Industrial Hygiene Aspects, supra, p. 304-309).**

The AEC standard was adopted by other agencies and was codified by the American National Standards Institute, Inc.

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* Beryllium, Its Industrial Hygiene Aspects, supra, 298-299.

** Breslin in Beryllium: Its Industrial Hygiene Aspects (page 312-313) recognized the availability of lapel samplers having flow rates of 1.5 liters (.05 cubic feet) per minute, He concluded that the lapel samplers "should usefully supplement other air-sampling instrumentation... (particularly) in the measurement of exposures that cannot be determined by conventional means" such as the exposures of maintenance personnel. He recognized, however, that "the Lapel sampler does not indicate the circumstances of short-term, high-dust concentrations".

("ANSI") in 1970.* The ANSI codification, in turn, was adopted as the National Consensus Standard under the Act in 1971.**

Several points with respect to the AEC standard warrant emphasis:

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* ANSI Standard Z37.29(1970) - RBI Exhibit Book I, Tab 3. In promulgating the standard ANSI emphasized the industrial hygiene approach stating:

> "Acceptable concentrations are not precise values sharply dividing what is hazardous from what is safe under the particular circumstances and therefore are not appropriate for use as legal requirements.
>
> "These standards are to be considered guides for good industrial hygiene practices and should be applied and interpreted by persons with a full understanding of the basis and limitations of the information from which the standard has been developed."

Also ANSI carried forward the suggestion developed in the 1960's that the 2 microgram standard take into account only respirable particles - i.e. particles less than 5 microns in diameter which, are small enough to enter the smallest lung passages. Larger particles, which - depending on the operation - can constitute in excess of half the total airborne beryllium, were excluded.

** There can be no doubt that the ANSI standard was adopted as the National Consensus Standard. The Code of Federal Regulations, as it existed at the time (see KBI Exhibit Book I, Tab. 4), specifically identified the source as being the "American National Standards Institute, 237 series". While the Act required that the standard be adopted without change, and, indeed OSHA intended to adopt ANSI without modification (T. 116), through inadvertence or misunderstanding the National Consensus Standard converted the 5 ug/m^3 limit applicable to the time weighted average into a "ceiling" related to the 25 ug/m^3 peak value (Wrenn W. T. p. 12-13).

1. The AEC standard was an industrial hygiene standard designed to improve working conditions. It concentrated on monitoring exposures, detecting sources of high concentrations, and taking remedial action. The emphasis was on stimulating the employer to eliminate hazards as they were discovered and thus gradually reduce both the average concentration and the peak concentrations. This is in marked contrast to the proposed standard which emphasizes the convenience of compliance sampling for the purpose of issuing Citations.

2. The AEC standard not only prescribed maximum permissible concentrations; it also specified the method of determining whether the concentrations in the plant did or did not exceed the prescribed limits;

3. The AEC standard adopted the traditional solution to the problem of variability in industrial atmospheres by specifying a time weighted average calculated over a quarter year. It thereby took into account both intraday and interday variability;

4. The AEC standard adopted an industrial hygiene approach under which excessive concentrations called for remedial action rather than punitive action. The maximums set forth in the standard functioned as guides for the industrial engineer. They were not hard and fast limits;

5. The AEC standard recognized that the significant exposures occur at certain tasks (generally of short duration) in which the worker comes into close contact with the process material. It, therefore, required the frequent sampling of these particular tasks to determine when and where corrective action was necessary;

6. In surveying plants the AEC sampled specific operations with high volume samplers and calculated daily weighted averages using job analysis sheets. The purpose of these surveys was "to check the data obtained by the plant staff members."*

The point we are emphasizing is that the AEC standard was responsive to the same concern which motivated the passage of the Act, i.e., concern for the employees' health. The AEC standard established limits that were logically related to health, the limits on average concentrations for chronic disease and the

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* Health Protection In Beryllium Facilities Summary of Ten Years of Experience, Breslin (1958), p. 29, 30, 39 - KBI Exhibit Book 11, Tab 4.

With respect to these same procedures as applied to the survey of plants producing uranium metal, the AEC noted that a three man team could "normally survey three huge plants... in approximately a work week. In these plants, daily weighted exposures of more than 600 personnel performing more than 100 different jobs [were] determined." Standard Procedures For Assessing Average Daily Air Contaminant Exposures. Klevin and Harris (1955), p. 7 - KBI Exhibit Book 11, Tab. 30.

peak limit for acute disease. It also told the employer how to monitor his operations in order to bring the concentrations below the prescribed limits and improve working conditions.

As we will show in the next section of this brief, the draftsmen of the proposed new standard have lost sight of the industrial hygiene objectives. They have discarded the detailed monitoring and sampling techniques developed by the AEC and adopted a different sampling method which makes things much easier for the compliance and enforcement people but is of little value to the industrial hygiene engineer. To make matters worse, there is no correlation between the two techniques. An employer monitoring by the AEC sampling technique might find his operations within the permissible concentrations only to be told by an OSHA inspector that his (the inspector's) sampling technique shows a violation. This is not just a lawyer's hypothesis. It is what actually happen to KBI, as described in our initial comments.

We believe this point to be of great importance to the Secretary. Her objective under the Act should be to improve working conditions, not to issue Citations for violations. We urge the Secretary to give careful consideration to the industrial hygiene benefits that will be sacrificed if this new standard is adopted.

4. The proposed new standard eliminates the provisions of the old standard with variability and makes other drastic chang

The proposed standard changes all essentials of the AEC standard. First it eliminates the provisions dealing with interday variability by changing the period for determining the average concentration from quarterly to daily. This is accomplished by permitting the issuance of Citations on the basis of a single day sample. As stated in Appendix B to the proposal: "Measurements taken for the purpose of determining exposure... are best taken such that the average 8-hour exposure may be determined from a single sample or two 4-hour samples." If there were any doubt about what this means, it has been laid to rest by OSHA's witness Bolt, Beranek and Newman, Inc. ("BB&N"). BB&N (presumably on OSHA's instructions) interpreted the proposal as requiring a determination of exposure from "measurements performed over the course of a worker's single (assumed to be typical) workday." (BB&N Economic Impact Statement, p. 47).*

In addition, the proposed standard reduces the limit on peak concentrations by 80% (from 25 to 5 micrograms) and the limit on average exposures by 50% (from 2 to 1 micrograms). These reductions would be substantial standing alone. However, they are

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* OSHA has been sampling KBI's plants and issuing Citations on the basis of a single day sample. See KBI Exhibit Book I, Tab 9 and KBI Exhibit Book III, Tab 3.

actually much more drastic than they appear at first glance because both are accompanied by changes in the method of determining compliance. In the case of the peak limit, not only is the permissible concentration reduced, but the maximum duration of the concentration is shortened by 50% (from 30 to 15 minutes)." In the case of the average limit, not only is the permissible average concentration reduced, but also, as we have seen, the averaging period is shortened from 90 days to one day.

Finally, the new standard permits the use of lapel samplers and thereby eliminates the sampling of tasks of short duration and high exposure, the tasks which pose the greatest threat to the health of the employees and which should be of the greatest concern to the Secretary under the Act.**

The overall effect of these changes, in conjunction with the provisions of the Act, is to transform an industrial hygiene standard designed to provide guides for action into a legal

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* The proposal states that "no employee may be exposed to an airborne concentration of beryllium in excess of 5 micrograms per cubic meter of air ($5ug/m^3$) as averaged over a maximum sampling time of 15 minutes." The introduction of an averaging concept is hopelessly confusing - see KBI Comments p. 37-38.

** The lapel (sometimes referred to as "personal") type sampler is a low volume portable device worn by the employee with its orifice clipped on to his shirt front. The appeal of the lapel sampler to OSHA is its convenience. The inspection officer does not have to follow the employee during the performance of his daily tasks as is required with the AEC - high volume method. He simply clips the lapel sampler to the employee and "lets him loose." Because of their low flow rate, the accuracy of the lapel samplers is questionable for sample durations of less than 10 or 15 minutes (T. 381-382; 1964).

standard that must be met 100% of the time to avoid fines and other legal penalties,*

The record does not offer explanations for the proposed changes. We know that in 1972 the AEC standard was put forth by NIOSH, without change, as the recommended permanent standard for beryllium.** We also know that since 1950 the American Conference of Governmental Industrial Hygienists ("ACGIH") has annually published the 2 ug/m^3 standard, without change, as its assigned threshold limit value for beryllium.*** But we don't know of

* Under the Act (Section 9(a), if the Secretary believes an employer has violated a standard she "shall with reasonable promptness issue a citation". Any employer who has received a citation for a serious violation "shall be assessed a civil penalty of up to $1,000 for each such violation" (Section 17(b)). Any employer who repeatedly violates a standard "may be assessed a civil penalty of not more than $10,000 for each violation" (Section 17(a)). Any employer who fails to correct a violation within the period permitted "may be assessed a civil penalty of not more than $1,000 for each day during which such failure or violation continues" (Section 17(d)).

** Criteria for a Recommended Standard, Occupational Exposure to Beryllium, NIOSH (1972) - KBI Exhibit Book 11, Tab. 8.

The NIOSH Criteria Document specified the AEC standard after giving consideration to numerous animal studies reporting the induction of malignant growths in various animal species following exposure to beryllium. The Criteria Document also specified the use of high volume samplers for the collection of general air and breathing zone samples.

*** Indeed in 1975 the ACGIH grouped beryllium with substances "suspect of oncogenic potential for workers" but found that "present evidence indicates that the assigned TLV's are below the threshold response for inducing cancer in workers under ordinary conditions of employment." ACGIH Threshold Limit Values, 1975 - KBI Exhibit Book 11, Tab 7. The same TLV for beryllium was published by the ACGIH in 1976. ACGIH Threshold Limit Values, 1976 - KBI Exhibit Book 11, Tab. 22.

anyone who has been advocating the changes that the Staff is now defending with an advocate's zeal.

Why is the Staff taking this position? We can only speculate. One possibility is that the change from quarterly to daily averaging was a matter of convenience to permit OSHA inspections limited to a single day. But that assumes, as BB&N has stated, that the day is "typical" - an assumption that should not and cannot be made because of interday variability.

Another possibility is that the change was dictated by a desire to bring this part of the beryllium standard into line with other OSHA standards. But beryllium is different from other toxic materials in its historical perspective; the stringent nature of the current standard; and the pronounced variability caused by handling finely divided powder in a batch process. A standard to be applied to beryllium operations must take into account the nature of those operations.

When it comes to the change in the peak limit, we can only assume there has been a misunderstanding of the purpose of the peak limit in the AEC standard, plus a compounding of the error that was made when the 5 ug/m^3 value was transported from the ANSI standard into the National Consensus Standard (see p. 15 and footnote p. 22, supra). As now cast, the 5 ug/m^3 ceiling for 15 minutes would prohibit any dose in excess of 75 microgram minutes, whereas the 8-hour time weighted average of 1 ug/m^3 would permit a dose equal to 480 microgram minutes (T. 1864). There is

no logical relationship between these figures; nor is there any logical reason for changing the maximum duration from 30 to 15 minutes.*

We are fairly confident that the change permitting the use of lapel samplers, like the change to single day averaging, was designed to facilitate OSHA inspections. "Convenience" was a consistent theme running through the testimony of OSHA and NIOSH witnesses in this regard (T.353-354; 798; 842; 886). While convenience may be desirable, it cannot justify a change that is counter-productive in that it negates the process of task-by-task analysis which has heretofore been the cornerstone of industrial hygiene technique.

We can find no record support for the reduction of the limit on average concentrations from 2 ug/m^3 to 1 ug/m^3 other than handwritten notes made by an unidentified listener 'to a talk delivered by Harry F. Schulte at a symposium in Cleveland, Ohio.** But Schulte's experience has been limited to machine shops (T. 342, 361) - and the record is clear that the experience in machine shops cannot be extrapolated to the plants of the primary producers (T. 766-767; 1304). There is one other possible explanation for the recommendation to change from 2 micrograms to 1 microgram. That is that the Staff was under the impression that the primary

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* We can only guess that the 15 minute period relates to the fact that the accuracy of the lapel sampler is questionable for shorter periods (T.382; 1298).

** Reference 38 to the proposed standard - KBI Exhibit Book 11, Tab 15.

producers' operations are consistently below the 2 microgram level, which is not in fact the case.*

The hypothesis that the Staff was mistaken about the primary producers' ability to meet the current standard is bolstered by the fact that the preamble to the proposed standard misinterpreted reference works dealing with levels of exposure at primary plants. For example, the preamble says, "In one Ohio extraction plant exposure levels were recorded at or below 2 ug/m^3 over a seven-year period." But the 1961 study cited in support of this statement discloses numerous exposures far in excess of 2 ug/m^3 and says that "the data show a well defined upward deviation from the standards of safety which have been recommended hitherto. Exposure at peak concentrations up to 600 times the recommended levels have been recorded."**

We mention the misinterpretations and misunderstandings which appear to underlie the proposed new standard, not in a

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* See KBI's DWA figures - KBI Exhibit Book III and IV and conclusions of BB&N's Economic Impact Statement in this regard.

** Summary of the Results of Seven Years Experience In Investigating The Dispersion of Beryllium In The Air, Zielinski (1961) p. 86 - KBI Exhibit Book 11, Tab 34.

The Staff also cite the NIOSH Criteria Document in support of their conclusion that the current standard has been consistently met by the primary producers. But the Criteria Document states (p. V-3): "Employees were consistently exposed to daily weighted average exposures in excess of 2 ug/m^3."

spirit of criticism, but rather to illustrate two respects in which the record is inadequate:

First, the record does not show that the radical changes made by the proposal are rationally related to any problems encountered in the field or to any objectives established for the Secretary under the statute.

Second, to the extent that the record reveals anything about the assumptions and theories underlying the plan, it can be readily demonstrated that those assumptions and theories are in error.

These deficiencies in the record are not trivial. In our view they are fatal and can be corrected only by reexamination of the proposal in a setting conducive to a fair exchange of views among all parties concerned.

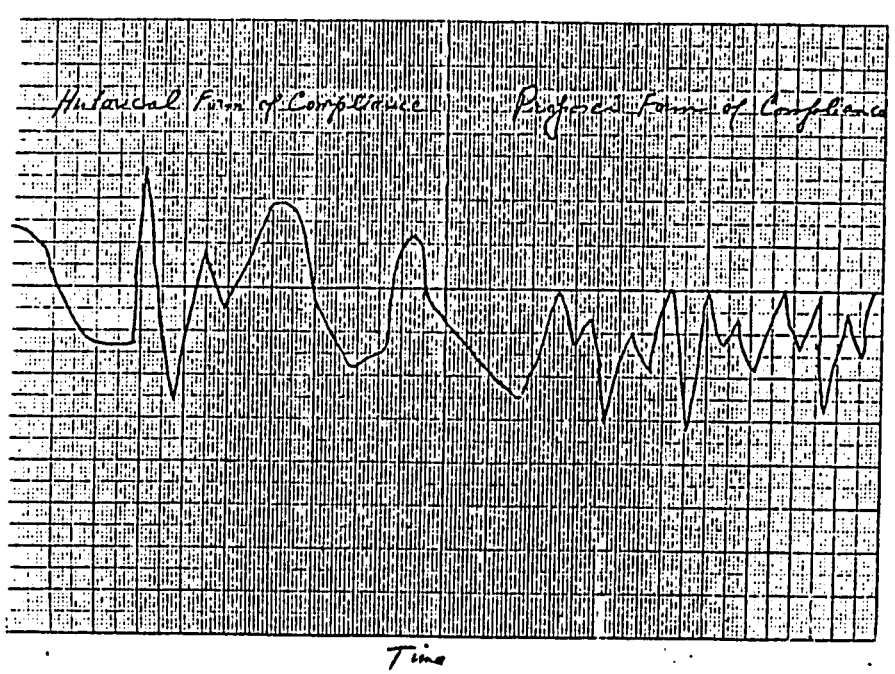
5. The cumulative effect of the changes embodied in the new standard is to make compliance impossible

The record does not provide a basis for quantifying the consequences of the changes being proposed by the Staff. For example, we don't know exactly the magnitude of interday variation (Geometric Standard Deviation) for the various occupations, and there has been no precise study of peak concentrations. Nevertheless, there is enough in the record to predict that the changes in sampling procedures alone would be sufficiently drastic so that both KBI and Brush would be hopelessly out of compliance and subject to a never ending series of Citations. This effect is magnified 100% when the 2 microgram figure is reduced to 1 micro-

gram. It is magnified again when lapel samplers are substituted for high volume samplers. We will explore the effects of the various changes in more detail below.

The change in the averaging period. The traditional approach to the statistical problem of measuring concentrations in an atmosphere unstable in time and space was to average concentrations over a period of time. In the case of the AEC beryllium standard, the averaging period was 90 days. According to OSHA witness Harry F. Schulte, the AEC procedure was, and is, "standard industrial hygiene practice" (T. 376).

The shortening of the averaging period from 90 days to one day changes the nature of the resulting figure, It is no longsr an average, an attempt to approximate the geometric mean; rather it is a ceiling applicable to each day. The following simplified graph submitted by Dr. Eisenbud (Exhibit 127) illustrates the point.



Both Dr. McDonald Wrenn and NIOSH have commented on the effect of such a change. Both agree that, as a result of the change, the employer must operate continuously far below the standard in order to have any degree of confidence that he will not be cited for violations. Dr. Wrenn calculated that, even if engineering controls were successful in reducing mean exposures at all operations to 0.14 ug/m^3, a plant sampled on a single day basis using lapel samplers "would be found out of compliance with the 1 ug/m^3 limit about one-half of the time". (Wrenn, W.T. p. 27). Be added that the effect is magnified where (as in the case of KBI plants) a facility has numerous operations.* He concluded:

> "In short, as presently envisioned; these standards are calling for a large but indeterminate reduction in the average exposure which depends actually on the size of the facility. The larger the facility, the larger the reduction in exposure would be required to have comfortable assurance of not being cited. This is essentially a self-defeating proposal which insures that the primary production facilities will not be able to meet any standard that OSHA promulgates. The crux of this matter is the single day provision with respect to compliance..."**

NIOSH's conclusions are essentially the same. It's publication states that "A GSD of 2.0 requires an action level as low as 0.115 of the standard!"*** The significance of this becomes

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* Remarks about NIOSH Technical Information Publication, supra, p. 3-4.

** Ibid, p. 4.

*** Exposure Measurement Action Level and Occupational Environmental Variability, NIOSH (1975), page 29 - KBI Exhibit Book V, Tab 8.

apparent when it is recalled that Dr. Wrenn found the mean value of the GSD at KBI's Hazelton plant to be 1.9 and at Reading 2.2.

Dr. Wrenn's calculation and NIOSH's statement mean that the innocent looking reduction in the averaging period from 90 days to one day has the practical effect of lowering the permissible average concentration about 90%, i.e. from 2 micrograms to 0.2 of a microgram using the old figure or from 1 microgram to 0.1 of a microgram using the new figure. In the modern phrase, there is "no way" that any beryllium plant is going to operate at levels such as these.

The change in the peak limit. A similar statistical problem is presented by the reduction and change in the peak limit. Applying the NIOSH type of statistical analysis to single sample values recorded on KBI's job analysis sheets, Dr. Wrenn found that, even after engineering controls, at least 7 job classifications at Reading and 19 job classifications at Hazelton would not comply with the 5 ug/m^3 ceiling, assuming that high volume samplers were used for measurement (Wrenn, W.T. 28). Dr. Wrenn stated that "the proposed reduction of the peak value of 25 ug/m^3 to 5 ug/m^3 has as great an impact as any of the changes being contemplated." (Wrenn, W.T. 27). He concluded, that "It is not reasonable, nor is it fair that the industry be required to assume the responsibility (with respect to demonstration of compliance) for all the variability associated with beryllium concentrations in air".*

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* Wrenn, Recommendations, p. 1-2 - KBI Exhibit Book V, Tab. 10.

The change in the sampling device. Much of the hearing was taken up with the merits and demerits of lapel and high volume sampling, e.g. which sampler more nearly samples the breathing zone; what is the "outreach" of each device; how often are operation time studies performed; which sampler is more convenient; etc? Rather than becoming bogged down in these details, we refer the Secretary to the testimony of Mr. Richard Chamberlin, who has had extensive experience in monitoring beryllium exposures as consultant to both government and labor. Mr. Chamberlin recommended the high volume method of sampling (T. **1261**); he found no problem with placing the high volume sampler in the breathing zone (T. **1274**); he stated that the sampler is not subject to contamination in the hands of a trained technician (T. **1274-1275**); he found no problem created by the **"outreach"** of the high volume sampler (T. 1304); he opined that the high volume sampling method gives a better representation of the worker's exposure (T. **1276**); he noted that the lapel sampler is easily contaminated (T. **1278**); he stated that lapel samplers cannot measure short term exposures (T. **1298**); and he found the lapel sampler to be "consistently inconsistent" **(T. 1276-1277)**.*

What concerns us here is the effects of the proposed change. We start with the effect on the sample readings. As the

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* In addition, whereas the high volume sampler can meet the required precision of the proposed standard in the industrial atmosphere, the lapel sampler cannot. Analysis of the Comparability and Precision of Lapel and High Volume Samplers In Air Sampling For Beryllium, Equitable Environmental Health, Inc. p. **46**. Exhibit 32.B.6.

Secretary knows, there have been a number of studies comparing the readings obtained by the two sampling techniques (lapel and high volume). The 1973 NIOSH study* found that "monitoring with the personal [lapel] gross technique will give exposure levels at least: twice as high as those that would be obtained by utilizing the AEC method." In 1975, Brush Wellman, under contract to NIOSH, compared the lapel sampler with the high volume sampler when sampling on a single day basis.** The results of this study were reported by NIOSH in 1976*** and showed the lapel readings to be higher by at least a 3 to 2 ratio. Stearns-Roger pointed out that NIOSH, in analyzing the raw data, incorrectly took ratios of area averages, and that, when the study is corrected for this error, the relationship is somewhere close to 3 to 1.****

Dr. Wrenn also studied the two techniques and found the average ratio between the lapel readings and the AEC readings to be

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* Industrywide Study of Beryllium Production Facilities, NIOSH (1973) - KBI Exhibit Book I, Tab. 36.

** Analysis of the Comparability and Precision of Lapel and High Volume Samplers in Air Sampling for Beryllium, supra, p. 1.

*** Beryllium Sampling Methods, NIOSH (1976) - KBI Exhibit Book 11, Tab. 24.

**** The Technological and Economic Feasibility of Compliance with Proposed OSHA Standard For Exposure To Beryllium, Stearns - Roger p. 15-16.

3 to 1 at KBI's Reading plant and about 5 to 1 at the Company's Hazelton plant. He noted: "(1) The lapel technique generally gives higher results, (2) the lapel technique results are more variable, and (3) there appears to be a real difference between the ratio of results between the two [KBI] plants." (Wrenn, W.T. App. 1, p. 22.)

We do not know the reason why the lapel technique gives higher readings* (Wrenn, W.T. p. 25), but these various studies confirm the fact that the difference in readings exists.** We now turn to the question; what does this difference mean in the context of the standard?

First, the coexistence of two measurement techniques producing different readings means that there is a different standard, depending on which technique is used.*** If the lapel

* Susceptibility of the lapel sampler to contamination has been suggested as one reason (Wrenn, W.T. p. 25). This was also one of the reasons the NIOSH Criteria Document for the cotton dust standard rejected the use of personal samplers. See Affadavit of Grover Wrenn, p. 19-20 - KBI Exhibit Book V, Tab. 2.

** Breslin, who, in a study of a uranium facility, found a correlation between the two techniques when numerous samples were taken by the lapel technique and averaged, has suggested the need Lor further "careful investigation" (Exhibit 8 - Attachment IV, No. 9).

*** This fact is vividly illustrated by KBI's experience with a 1973 Citation at its Hazelton plant, On at least two occasions OSHA issued Citations for repeated violations on the basis of lapel single day readings for job classifications that were in compliance according to the time weighted averages of both the Company and Richard Chamberlin which were obtained using *AEC* techniques. See KBI Comments p. 10-21 and KBI Exhibit Book I.

sampler produces readings more than twice as high as the high volume samplers, then the standard is more than twice as strict if compliance is measured by the lapel device. If compliance is measured by the lapel device, the standard is also more vague and indefinite, because the lapel readings are more variable.

Secondly, when compliance is measured by lapel sampling, even the present standard is impossible to comply with. As observed by NIOSH in 1973, the lapel sampling method would impose upon the beryllium producers "undue hardships that cannot be supported from a medical standpoint. This is due to the fact that engineering feasibility does not yet exist to reduce worker exposure levels to 2 ugBe/m^3 as measured on a personal gross basis."* Earlier in the same study NIOSH formulated the same conclusion in different words:

> "Until such time as a relationship is established between the *AEC* method and personal sampling methods, and until such time as sampling methods for the collection of beryllium samples are standardized the environmental health standard of 2 ugBe/m^3 for beryllium cannot effectively be enforced."**

The cumulative effect of the changes. We have shown that the change in the averaging period has the practical effect of lowering the standard by as much as 90% (0.115 is approximately 10% of 1.0). The changes in the peak limit may well be equally

* Industrywide Study of Beryllium Production Facilities, NIOSH (1973), supra, page 18.

** Ibid, p. 17.

drastic. It is not clear to what extent these effects overlap, but, even if they overlap completely, the result would be a standard impossible to meet. If they are cumulative rather than overlapping, the result is still worse.

The other two changes, i.e. the use of lapel samplers and tho change from 2 micrograms to 1 microgram, have less sweeping, but nevertheless important, effects. The former would reduce the standard by as much as 80% and the latter by 50%. These results are cumulative and not overlapping. They are also cumulative with the results of the changes in the averaging period and the peak limit.

Conclusion. We have shown that there are at least four major differences between the new standard and the old, these being, the shortening of the averaging period, the change in the peak limit, the use of lapel samplers, and the reduction from 2 micrograms to 1 microgram. Any of these standing alone would require the Company to reduce the average concentration level in its plants by 50% or more in order to achieve compliance. The cumulative effect would require a reduction in excess of 90% - a manifest impossibility.

C. The Change From 2 Micrograms to 1 Microgram, Standing Alone, Is Not Technologically or Economically Feasible

There is nothing to be gained by laboring the point made above, namely that the cumulative effect of the changes introduced in the new standard is to produce an absurd result. We cannot, believe that the Secretary will accept this result; certainly na Court will accept it. Indeed, we find it hard to believe that those who drafted the new standard fully realized the consequences of the changes they were proposing. It seems more likely that the primary purpose of the new standard was simply to reduce the AEC average figure from 2 micrograms to 1 microgram and that the other changes were viewed as inconsequential.

It would be easy for the Secretary to amend the proposed standard to produce this result by leaving the averaging period, the ceiling limitation and the sampling technique unchanged and merely lowering the 2 microgram figure to 1 microgram. Such an amendment, which would retain The time-honored *AEC* monitoring procedures, would have much to recommend it. The AEC method of sampling is preferable to the single-day lapel method in at least the following respects:

(a) The *AEC* method measures intraday variations, which give guidance to the exposures producing the medical response (Wrenn, W.T. p. 9-10). It also measures the interday variations permitting a determination as to what is actually occuring in the plant;

(b) The exposures measured by the AEC method have been associated with medical responses over a long period of time.* A radical change in the method of measurement would destroy the value of this accumulated experience. As stated by Richard Chamberlin: "what I don't need is another set of figures" IT. 1277); and

(c) The AEC method monitors high exposure tasks whereas the lapel samplers cannot. As stated by Breslin "...an important advantage of the time-weighted average method over personal sampling [is] the identification and magnitude [sic] of specific sources of exposure to the individual worker. This information, needed for maintaining a safe work environment, is crucial to the plant official responsible for health protection and ought to be of some concern to the regulatory agency, as well."**

Because of these advantages, we feel that the Secretary will give real consideration to the simple solution of retaining AEC procedures and merely changing the limit on average concentrations. Accordingly, in this part of our brief (Part C), we

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* Industrywide Study of Beryllium Production Facilities, supra, p. 14.

** Exhibit 8 - Attachment IV, No. 9.

will consider whether such a solution would be feasible, either technologically or economically.

1. Despite diligent efforts, the Company is not now meeting the 2 microgram limit consistently in all jobs

The engineering principles for controlling airborne particulates are well known. They consist of local exhaust ventilation, engineering controls to reduce the escape of dust and fumes, automatic transfer of process material, special clothing, good housekeeping, carefully thought out work practices, and respiratory protection.* KBI has applied these principles to its operations at both its Reading and Hazelton plants.** Indeed, it is currently embarked on an engineering program at Reading which has been reviewed and approved by both OSHA and the Steelworkers.*** But, as observed by Dr. Wrenn, even with all the equipment in place "there is a constant fight to maintain levels of control on those jobs which are particularly difficult to ventilate properly, namely, those jobs which involve very large pieces of equipment, large mass transfers, and the need for human intervention during the process" (Wrenn, W.T. p. 20).

The problem areas were identified by BB&N as the vacuum melting process, the attritioning and powder handling areas, and

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* Schulte, W.T., p. 2; Health Protection in Beryllium Facilities Summary of Ten Years of Experience, Breslin - KBI Exhibit Book 11, Tab 4,

** Wrenn, W.T. p.20; Velten, W.T. p. 3-4; Exhibits 107-116; Lowry, W.T. p. 3.

*** See Reading Abatement Program - KBI Exhibit Book 111, Tab 4.

the arc furnace area (BB&N, ~~Economic Impact Statement~~ p. 16). They were described by Richard Chamberlin as those areas "involving powder technology, high heat and or attritioning."* In these areas, the problems are inherent in the nature of the operations. They cannot be solved simply by adding more controls or more ventilation. The equipment now in place has already lowered the concentrations drastically from those recorded in years past. The Company has reached the point of diminishing returns. Dr. Wrenn described the condition succinctly when he said:

> "In short because there are already numerous local exhaust points, hoods, enclosures, and ventilation which already maintain low concentrations, the addition of further controls of a similar nature (i.e., not as for example a completely enclosed or remotely operated system) should produce diminishing reductions in concentration levels per unit of effort, whether the effort is measured in dollars spent, cubic feet of air removed, or by some other yardstick." (Wrenn, W.T. p. 20).

In sum, KBI's efforts at control have met with notable success,** yet the Company is still having difficulty in meeting the current standard with consistency in some operations.*** Its efforts to do so continue. As stated by the Company's Vice-Chairman, the process is "akin to trial and error" and "is never-ending."****

* Comments of Richard Chamberlain, p. 1 - KBI Exhibit Book 11, Tab 19.

** See KBI's DWA figures-KBI Exhibit Books III and IV.

*** BB&N, Economic Impact Statement, p. 36 - At these operations respiratory protection is supplied.

**** Lowry, W.T. p. 3.

2. If the limit were lowered to 1 microgram the Company would be in constant violation even with the best conventional controls

When the proposed standard was first published, KBI asked itself the question: can the average concentration be lowered to 1 microgram? It retained Catalytic, Inc., recognized environmental engineers, to answer that question. Catalytic's first assignment was to determine all conventional engineering controls that could be applied, without regard to cost, to the operations at the Company's Hazelton and Reading plants and the levels of concentration that would result. After a thorough study, Catalytic concluded that, even with these additional controls, the level of 1 microgram could not be met in the arc furnace area at Reading* and in certain jobs at Hazelton associated with attritioning and powder handling,** These findings, we reiterate, were based on AEC procedures and did not take into account any of the changes in the new standard other than the change from 2 micrograms to 1 microgram,

BB&N's conclusions were essentially the same. Assuming the use of AEC monitoring procedures, it found that, even with additional conventional controls, the primary producers would not

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* Catalytic was unable to determine the levels that might be achieved by the new electrolytic process which KBI hopes to substitute for the arc furnace.

** Catalytic Inc., Concept Report, Exhibit 31.F. 1.

be able to achieve 1 microgram with respect to five percent of their workforce (T. 421-427). In the case of KBI this finding related to the employees involved in attritioning, powder handling and the arc furnaces (T. 426).* Moreover, even with respect to the areas BB&N felt could be controlled, they stated:

> "Caution should be exercised in the use of this profile, because although a certain percentage of a workforce may be shown to be exposed to less than a specific exposure limit, the actual potential for exposure above the limit . . . cannot be indicated."**

These two studies - Catalytic and BB&N - show that if the 2 microgram limit were lowered to 1 microgram, even without giving effect to the other changes being proposed, KBI would be in constant violation of the Act with respect to some jobs - and could be in occasional violation with respect to others.

Richard Chamberlin's conclusions were consistent. Assuming AEC monitoring procedures, he said:

> "The nature of many of these operations such as those involving powder technology, high heat and/or attritioning, continue to present problems of control, and the 2 ug standard with a 25 ug ceiling may well be the lowest feasible limit."***

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* Neither Catalytic nor BB&N analyzed to determine the effect of the proposed reduction in the peak value to 5 ug/m3 (T. 426).

** BB&N Economic Impact Statement p. 27,

*** Chamberlin Comments, supra - KBI Exhibit Book 11, Tab 19, p. 1,

3. Even if the reduction to 1 microgram was technically feasible, the required investment would raise questions as to economic feasibility

The Catalytic study was not limited to the technical feasibility of achieving average concentrations as low as 1 microgram, it also projected the costs of installing and operating additional equipment and controls. In this process Catalytic examined the existing controls, reviewed the effects of changes in the past, and prepared a list of engineering changes which, in its opinion, could be expected to bring most of the jobs below the 1 microgram level measured by the AEC method. The estimated capital costs are **$6,008,000** at Reading* and **$4,650,000** at Hazelton.** Annual operating costs would be **$997,000** and $362,000 at these respective plants.

These figures do not answer the question of economic feasibility, they are merely the starting point. In order to address the feasibility question the Company would first have to ascertain whether the results projected by Catalytic are likely to be obtained, and, if so, whether these results would comply with

* This figure does not include an additional significant cost for the electrolytic cell designed to replace the arc furnace.

** Over a period approximating 18 years, KBI has already invested in excess of **$7,000,000** for in-plant air quality controls. Velten, W.T. p. **4**; Summary - KBI Exhibit Book I, Tab. **35.**

the standard. If there were no assurance of achieving compliance, there would, of course, be no economic justification for the expenditures.

Even if there was considerable assurance of achieving compliance, the Company still "would not simply embark on a program of spending millions of dollars at both plants in an effort to lower [its] concentration levels." (Lowry, W.T. p. 9). Rather the Company would analyze the operations in question from an economic point of view, and, where there was no reasonable prospect of recovering its investment, would abandon these operations (see Lowry, W.T. p. 7-9). The Vice-chairman of KBI noted that at the present time such an "economic analysis would be particularly critical at Hazelton which is, at best, a break even operation" (Lowry, W.T. p. 9). This means that Secretary must face the possibility that, even if the standard is amended to be technically feasible, it may still be so costly as to eliminate one of the two primary producers from a major part of the industry, thus conferring a monopoly on the other.

4. The economic uncertainties make it unlikely that the Company would commit itself to the required investment

The key to economic feasibility is the answer to the question: Can the Company reasonably expect to recover its investment through increased prices oyer a reasonable time? This answer, in turn, is dependent to a great extent on the period over which the investment is spread and on whether the market will

absorb the price increases necessary to provide the required return.

Investment period. The proposed standard does not contemplate a program such as outlined by Catalytic, which would take 'five or six years to accomplish. There is no provision for phasing in the new standard pari passu with such a program. On the contrary, the day the new standard went into effect, the Company would be subject to Citation and there would be no relief from Citations even if the program were accepted by OSHA as an abatement program. Such an immediate implementation of the standard is totally unrealistic, considering that the Company has long since passed the point where the installation of a simple system of ducts and fans will drastically lower the concentrations. As outlined by Mr. Lowry:

> "We are clearly at the stage of diminishing returns, where more costly and sophisticated controls successively produce smaller and smaller reductions in concentration. It takes time to design an abatement program, more time to implement it, and still more time to measure its effect. If our present plan for Reading runs its full course including the development and installation of electrolytic cells, we will not know the results until after 1981."*

Any Company management weighing the economics of a five or six year program would be reluctant to commit the funds at the beginning if it were told that it would receive no benefit from making the commitment; i.e. that even after making the commitment the Company would remain liable to citations and penalties.

* Lowry, W.T. 13-14,

Market Elasticity. We are told by BB&N that we should not be concerned with the investment that may be required by the new standard because the Company can simply pass any cost on to its customers. They (BB&N) tell us that the market will absorb any required increase in price because the demand for beryllium is inelastic; there are no substitutes for beryllium and users must buy beryllium regardless of price. Conceivably this holds true for some military and space applications of beryllium metal, but when it comes to industrial users of beryllium alloy (the bread and butter of the industry), the picture is entirely different.

Whereas BB&N's conclusions were based on supposition (T. 465-467), Mr. Graham P. Brown, an expert retained by KBI, undertook a market survey. He found that "real sensitivity to price is clear in the markets for beryllium copper and beryllium nickel" and that in these "product areas... which represent 65% of the market for beryllium alloys, price elasticity is evident." (Brown, W.T. p. 3). Mr. Brown's survey showed that if prices were increased to pass along the costs projected by Catalytic "within six months market degradation will be 7 to 8% and by the end of two years will probably reach 20%". (Brown, W.T. p. 4). Similarly, Joseph Healy, in comparing the Company's past costs with gross profit, concluded that "there appears to be no justification to assume that because costs might increase in the future, that any portion or all of such costs can necessarily be passed through to the customer . . . ." (Healy, W.T. p. 2.)

These predictions indicate that the Company could not be confident of recovering the investment required by the Catalytic program. This, in turn, makes it questionable whether the investment will be made in the first place.

Conclusion. The Company, as a responsible employer and manufacturer, will not make threats of shutting down. On the contrary, if the current standard is changed, the Company will make every effort to continue its operations in compliance with whatever limits are imposed. However, the doubts as to technology and economics engendered by Catalytic, Brown, and Healy are such as to lead to only one conclusion: The proposed change from 2 micrograms to 1 microgram is not feasible, even if AEC monitoring procedures are retained.

D. There Is No Medical Justification For Changing The Standard

The Staff has cited two medical reasons for changing the standard. First, the Staff maintains that despite "great reductions in beryllium exposure levels, an average of 10-12 new cases of beryllium disease have consistently been added to the [Beryllium] Registry each year since 1962." Second, the Staff has concluded that beryllium should be treated as posing a threat of cancer to man. The record is inadequate to support either point.

1. The record does not show that new cases of beryllium disease are occurring under the present standard

As far as beryllium disease is concerned, there is overwhelming evidence in the record and in the literature that the present standard is adequate. This was the testimony of Dr. Harriet L. Hardy who has studied beryllium disease since 1945. (Exhibit 8 - Attachment IV - Item 10). A similar opinion was expressed by Richard Chamberlain (Chamberlain Comments - KBI Exhibit Book 11, Tab 19, p. 2; T. 1279-1280); and by Merril Eisenbud (Eisenbud, W. T. p. 54). These conclusions are consistent with the literature:

> "The figure of 2 micrograms m^3 air for an 8-hour day was proposed in 1949. At this writing, there is no evidence that disease has rosulted following exposures at this level. Indeed, the figure may be too conservative, but the prognosis of the chronic disease is such that no one is inclined to propose that the level be raised." Beryllium Disease, Harriet L. Hardy, M.D. and John D. Stoeckle, M.D. (1959) - KBI Exhibit Book 11, Tab 3.

"Ten years of satisfactory experience in several installations, as documented in this report, is thought to be reasonable evidence that the stated exposure criteria are conservative. It may be anticipated that these criteria will be revised eventually. It would appear, however, that any revisions are more likely to be toward relaxation rather than greater restriction." Health Protection in Beryllium Facilities Summary of Ten Years of Experience, A. J. Breslin and W. B. Harris (1958). - KBI Exhibit Book 11, Tab 4.

"The in-plant figure of 2 ug/m^3 has no sound scientific basis, although it can be said that no animal experimental or human disease has been observed at this concentration. Data have been reviewed at yearly intervals, but there has been reluctance to make alterations in the standards. The level of 2 ug/m^3 is generally held to be conservative, probably over-conservative." Toxicity of Beryllium Compounds, Lloyd B. Tepper, Harriet L. Hardy, Richard I. Chamberlin (1961). - KBI Exhibit Book 11, Tab 5.

"The level of 25 ug/m^3 as an upper limit for transient peak exposure is designed to prevent acute disease and is based upon human experience and animal experiments. The Hygienic Guide (1956) for beryllium indicates that acute disease has been observed when air concentrations were 0.1 mg/m^3 and that most persons were affected at levels of 1.0 mg/m^3 value, it is evident that a safety factor of approximately four has been incorporated into the recommended short exposure limit. Experience has shown that no acute disease has arisen when peak exposures have not exceeded 25 ug/m^3." - Ibid.

"The limits set by the Atomic Energy Comission in 1959, when strictly adhered to, have been so effective that no new cases of beryllium disease have been known to occur." The Toxicology of Beryllium, U.S. Department of Health, Education and Welfare, Herbert E. Stokinger (1972). - KBI Exhibit Book 11, Tab 6.

"The standard recommended in this document is similar to that adopted by the AEC in 1949 and the present OSHA environmental standard. It is felt to be feasible technologically for the control of worker exposure to beryllium and effective biologically for protection of the worker from

acute and chronic beryllium disease. Criteria for a Recommended Standard . . . Occupational Exposure to Beryllium, U.S. Department of Health, Education and Welfare (NIOSH) (1972) - KBI Exhibit Book 11, Tab 8.

The continued appearance of new cases added to the registry each year is explained by exposures at levels well above the current standard - generally from periods going back to the 1940's (T. 1774) Even where employment is very recent, there is always a history of exposure higher than 2 micrograms, most often from accidental exposure, which would not be eliminated by the proposed standard.*

As we said in our comments: "We know of no one with knowledge and experience in the field who is affirmatively contending that new cases of berylliosis will develop under the 2 microgram standard" - and no such witness came forth at the hearing.

2. The record does not create a suspicion of carcinoqenicity

We also noted in our comments our belief that the factor that might weigh most heavily in the Secretary's mind is carcinogenicity. We observed that the animal studies and epidemiological studies cited by the Staff were inconclusive. We questioned why the Staff had disregarded the 1972 NIOSH Criteria Document. We expressed our concern that beryllium was being "swept along" by vinyl chloride, which, as the Secretary knows, presented an emergency where "expert after expert recommended that this 'very

* For example, see the testimony of Dr. Nancy Sprince regarding a case involving a man first employed by KBI in 1970 (T. 1779).

virulent' carcinogen be restricted to the lowest detectible level". We pointed out that beryllium did not present an emergency which would prevent a careful reexamination of the proposed standard.

The voluminous record at the hearings supports these contentions. There was not a single expert outside the NIOSH staff and NIOSH's "side-kick", Dr. Mancuso*, who would say that beryllium is a carcinogen in man. Not a single case of human cancer was identified with beryllium. No one has yet pointed to even one employee of ours who has contracted cancer by reason of his exposure in our plants.

The fact of the matter is that it is NIOSH, and only NIOSH, who calls beryllium a human carcinogen. The Secretary is being asked to impose a standard which, even in its most lenient interpretation, threatens to disrupt an industry, abolish jobs and create hardship in the community, in reliance on NIOSH's epidemiologic study. We say that NIOSH's study is crucial because, we submit, without the NIOSH study there would be no finding of human carcinogenicity. The OSHA Staff's case on human carcinogenicity rides on the NIOSH study. If the Secretary rejects the study, the case falls.

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* We do not use the term "side-kick" lightly. As the Secretary knows, Dr. Mancuso has published two epidemiologic studies regarding the carcinogenicity of beryllium in man. Both are inconclusive. Approximately two weeks before the hearing, NIOSH suggested that Dr. Mancuso supply that agency with the underlying data for his old (1937-1948) cohort, and it -- NIOSH --would analyze and update the study (T. 291; 236-238). In light of NIOSH's treatment of its own study, as related below, it is not surprising that the updated Mancuso results correlate with NIOSH's final conclusions.

We contend that the Secretary should, and indeed must, reject the **NIOSH** study. In taking this position we are well aware of the statutory relationship between **OSHA** and **NIOSH** and the degree of confidence the Secretary is entitled to have in **NIOSH's** recommendations. But nothing in the statute or the cases directs the Secretary to accept **NIOSH** studies blindly. The ultimate judgment is to be exercised by the Secretary, not **NIOSH**. The Secretary must read a **NIOSH** document with the same critical appraisal she would apply to any other document in the record.

When the **NIOSH** study is read searchingly and critically in the light of the record, it does not stand up. The full analysis supporting this conclusion is being set forth in Brush's brief and need not be repeated here. We will limit ourselves to a short review of the development of the study to show that it cannot be accepted as the fruit of a dispassionate scientific investigation. Rather, it is the product of advocacy, contrived and adjusted to lend support to a pre-determined proposition.

The story of the new **NIOSH** study starts with the 1972 **NIOSH** Criteria Document. That Document considered all, or virtually all, the animal and epidemiologic studies of beryllium in existence at that time.

With respect to the animal studies, **NIOSH** stated:

> "An exact parallelism in the response of animals and man does not always exist. Animals respond toxicologically to beryllium with changes that are morphologically different from those observed in man. In the rat, epithelialization has ultimately resulted in development of an adenomatous tumor. The epithelial proliferation and

primary pulmonary cancer was induced in rats after long-term daily repeated exposures to beryllium sulfate at an average concentration of 643 ug/m^3 (55 ug/m^3 of beryllium) and has not been reproduced in man even after long periods of time and high exposure levels. In man, the granulomatous disease seems only to be progressive in this respect. Hence, the carcinogenic exposure-effect relationship observed in animals does not correlate to man. The human organism has not been observed to respond in the same manner as rats to beryllium exposure; therefore animal studies contribute only indirectly and provide no correlation of human exposure--effect relationship as they pertain to development of a recommended environmental standard."

With respect to the epidemiological studies, NIOSH stated:

"A retrospective cohort study of cause-specific mortality among 3,923 males employed in two beryllium plants during January, 1942 through December, 1967, was conducted. Comparison was made between the risk of death among beryllium workers with that expected on the basis of age-sex-calendar time of specific mortality rates for the general population of the United States (Tables VI to X).

"Mortality patterns, including mortality from respiratory tract cancer, revealed no significant departure from expectation in this population. Even when consideration was given to a lapsed time of ten years and of fifteen years after onset of employment, no evidence was demonstrated for an association between beryllium exposure and lung cancer induction in man. Likewise, no association was detected for intensity, duration, or calendar period of exposure to beryllium."

On the carcinogenic nature of beryllium, NIOSH concluded:

"The finding in animals that some beryllium compounds are carcinogenic was

> also considered; however, the cautious approach that must be taken in data interpretation between humans and experimental animals is supported by the evidence as reported by Bayliss.* His finding of no significant departure from expected causes of death from respiratory tract cancers in almost **4000** workers shows no evidence of an association between beryllium exposure and lung cancer induction in man.
>
> "Until more complete knowledge can be obtained through comprehensive long-term controlled studies relating contact with beryllium to the incidence of disease in man, experience with present exposure limits for beryllium must provide the basis for establishment of the standard recommended in this report."

The **NIOSH** Criteria Document concluded that the **2** microgram beryllium standard, which had operated successfully for more than twenty years, should remain unchanged unless and until the need for change was demonstrated by "comprehensive long term controlled studies relating contact with beryllium [at that level] to the incidence of disease in man." That was how things stood in **1972.**

The next chapter begins in September **1975,** with a request by OSHA for **NIOSH** to "update" the evidence regarding the connection between beryllium and human cancer. In response, Dr. Joseph Wagoner of **NIOSH** reviewed the literature and found only one new publication (admittedly inconclusive) since the date of the Criteria Document.

* This is a reference to **a 1972** study colloquially known as "Bayliss **II",** in which the author concluded that there was "no evidence of an association between beryllium exposure and lung cancer induction in man."

Considering the conclusions reached in the Criteria Document, one would have expected Dr. Wagoner's next step to be the commissioning of long term controlled studies as envisioned therein. But that is not what Dr. Wagoner did. He made no further studies and collected no further evidence; he simply issued an updated memorandum announcing his conclusion that beryllium is carcinogenic in man.* His only justification for this abrupt about face was his belief that three cases of bone cancer, which then appeared in the Beryllium Registry, were "striking" because of the rarity of this form of the disease. As we shall see, two of these three cases were subsequently deleted by corrections to the record. But by that time it was apparently too late to reverse the course of events that Dr. Wagoner's hasty and unverified memorandum had set in motion.

On September 23, 1975, on the basis of the Wagoner memorandum, a group of NIOSH personnel approved the "labeling" of beryllium as a "suspect human carcinogen,"** and on September 29, the Director of NIOSH informed the OSHA Staff of its conclusion that "beryllium in all likelihood represents a carcinogenic risk to man."*** On December 10, 1975, after publication of the proposed new standard and as a follow-up to his communication to the Staff, the Director of NIOSH, sent the then Secretary a copy of Dr. Wagoner's memorandum without change. None of these pro-

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* Wagoner Memorandum - KBI Exhibit Book 11, Tab 10.

** Craft. Memorandum - KBI Exhibit Book 11, Tab 11.

*** Finklea Memorandum - KBI Exhibit Book 11, Tab 13.

nouncements reflected an independent study or new evidence. They were simply the domino effect of Dr. Wagoner's pronouncement.

At this juncture, in the words of Dr. Vernon **Rose,** NIOSH set about making as neat a case for the government as possible as far as the "public record" was concerned.* Obviously, the most important step was to do something about "Bayliss II", the NIOSH study which had found no relationship between beryllium and lung cancer. Dr. Wagoner toolc on this task. In conjunction with Dr. Peter Infante of NIOSH, he prepared a paper reitering his view on carcinogenicity for presentation in Toronto, Canada. This paper dated October 30, 1975, presented no new evidence and again emphasized as **"striking"** the three bone cancers in the Registry.**

In February, 1976 Dr. Harriet Hardy informed the Staff that the notation of three bone cancers found in the Registry was an error. In fact there was only one.***

Undaunted, Dr. Wagoner continued to rework Bayliss II by eliminating the population at KBI's Hazelton plant and concentrating on the population at the Company's Reading plant (T. 1068). Since Wagoner's initial findings reported an insignificant number of cancer deaths at Hazelton (T. 1137-9), this change would predictably bias the result in favor of the conclusions already promulgated by NIOSH. **It** was, to say the least, self serving.

* Rose Memorandum - KBI Exhibit Book **11,** Tab 12.

** Evidence for the Carcinogenicity of Beryllium - **KBI** Exhibit Book Y, Tab 5.

*** Letter of Harriet Hardy - KBI Exhibit Book **11,** Tab 17.

The next change was just as bad. The first version of the new report (Bayliss 111, Public Version 1) defined the Reading cohort to exclude administrative and clerical personnel (T. 1075-1076). It turned out, however, that there were 6 lung cancer deaths in the administrative group (T. 1121-1122). The consequence was a reversal of the definition. The final version (Bayliss 111, Public Version 3) includes administrative and clerical employees, although surprisingly the size of the cohort has not changed (T. 2647-2648).

Thus we see that the new study (Exhibit 13 F), which NIOSH has put forward as a sound basis for drastic regulatory action, has been at least twice adjusted in ways that can be interpreted only as deliberate efforts to reach a desired result. But this is not all that is wrong with it. The study is replete with clerical errors (T. 1185-1186; 2642-2644) and errors of significance. For example:

(a) When corrected for erroneous employment termination dates, it shows excess lung cancer deaths among short term employees as compared with long termers (T. 1188-1196). These deaths must be related to a factor other than beryllium (T. 2654);

(b) If administrative and clerical personnel, who clearly have the least exposure to beryllium, are removed from the cohort, there is no statistical significance to the difference between the observed and expected deaths i.e. there are no excess cancer deaths in the group with the

greatest exposure (T. 2651; 2653-2654). Even when administrative and clerical personnel (with their crucial six deaths) are included, the results of the study are "just barely" statistically significant (T. 2651); and

(c) Of the 46 people who died of lung cancer two had been employed for two days, another for five days and a third for 17 days (T. 2648). Of the 32 deaths listed as having been employed five years or less, "17 of those individuals were employed less than three months, 24 were employed less than six months and 30 were employed less than a year" (T. 2653). It doesn't make sense to conclude that a few weeks or months of exposure are more carcinogenic than years or decades. As stated by Dr. Roth:

> "What you are speaking about are individuals - picture this for a moment - that were employed less than a year, and in most cases were employed less than six months, and in five cases were employed less than a month, and these individuals go away from the plant for 15 years or even 25 years, and it is among these individuals that you see the greatest significance or the greatest relative risk." (T. 2653.)

This is only a partial list of the errors and problems that vitiate the revised study. For a more comprehensive critique, we refer the Secretary to the comments of Brush and the evidence that will be forthcoming by December 12, 1977. However, on the basis of the foregoing analysis alone, we submit that - in the words of Dr. MacMahon -- the twice reworked study "should not be permitted to influence regulatory decisions" (T. 2684).

In taking the position that the Secretary should reject the NIOSH epidemiologic study we have not overlooked the proposed generic cancer standard. The adoption of that standard would not affect our position because that standard deals with the quantum of trustworthy evidence necessary to justify a finding of carcinogenicity, whereas we are challenging, not the quantum of **NIOSH's** evidence, but its trustworthiness, in legal terms, its reliability. There is nothing in the proposed generic standard that would require the Secretary to rely on **a** meretricious document, and that is what has been submitted in this case.

E. Tightening The Standard Will Not Improve Working Conditions

Implicit in any change in a standard is the assumption that it will improve the workers' environment, that it will, in the words of the statute, assure "healthful working conditions." That is what the statute is all about. But in the instant case there is no evidence that the new standard will produce any lower concentrations or healthier conditions than are already being developed under the existing standard.

As stated by the Vice-chairman of KBI, the proposed standard, as far as the primary producers are concerned, "will not accomplish anything that is not being accomplished under the present standard . . . [because] under the present standard our efforts are directed at reducing concentrations to the lowest possible levels . . . . In every case we are seeking to come as close to zero as possible." (Lowry, W.T. p. 12).

This view was confirmed by Richard Chamberlin who testified:

> "I don't claim to be capable of engineering something that would go to two and not to one and would go to one and not go to two. What I am saying is . . .anytime an industrial hygienist develops a control for an operation, that its ultimate goal is to make that zero." (T. 1299).

The fact is that the present standard is fulfilling the statutory objective of healthy working conditions. Admittedly beryllium is toxic when not under control, but this fact was recognized more than a quarter of a century ago, and modern plants

have controls of great sophistication and effectiveness. There are no increased rates of mortality or morbidity associated with beryllium employment today. The record on this point is clear:

> "Present evidence indicates that the assigned [beryllium TLV is] below the threshold response for inducing cancer in workers under ordinary conditions of employment." - 1975 ACGIH*
>
> "There are no known cases of human beryllium disease with or without cancer at documented levels at or near the present TLV." - Harriet Hardy**
>
> "halving a small number, 2 ug/m^3, accomplishes nothing health-wise." - Stokinger***
>
> "I personally have not seen a chronic beryllium disease where exposure above the present 2 ug standard or very high peaks had not occurred." - Chamberlain****
>
> "In at least one well controlled, well monitored Beryllium research laboratory with levels close to the present permissable limit has after 25 years shown no illness and especially no cancer of any site." - Harriet Hardy*****

Notwithstanding these endorsements, we do not propose to rest on our oars. There are always refinements and improvements to be made, as our present 5 year program at Reading demonstrates.

* American Conference of Governmental Industrial Hygienists, 1975 - KBI Exhibit Book 11, Tab 7,

** Dr. Harriet Hardy, Comments, letter of July 11, 1977, Exhibit 8, Attachment IV - No. 10.

*** Dr. Herbert Stokinger letter of December 12, 1975 - attached written testimony of Brush Wellman, Inc.

**** Chamberlin, Comments, letter of January 28, 1976 - KBI Exhibit Book 11, Tab 19,

***** Dr. Harriet Hardy, Comments, supra.

OSHA can assure that these improvements will be made by enforcing the present standard. It does not need additional leverage.

All that would be accomplished by tightening the standard is to eliminate any realistic prospect of compliance; to take from the primary producers any confidence that their plants can be operated in accordance with law; and to face the employees with a future of working under continuous notification of violation even though there will be no threat to their health. Those are not the results the statute was intended to produce.

F. Adoption of the Proposed Standard Would Be Arbitrary, Capricious and Unreasonable

The record points to one overriding conclusion: to wit, if the new standard were adopted and enforced as proposed by the Staff, the primary producers would face an endless series of citations with no foreseeable means of compliance. This may be acceptable to OSHA, but is is not contemplated by the Act. The Act speaks in terms of "feasible" standards. The concept of feasibility presupposes that a conscientious company can do business without being in violation. In the words of the Supreme Court:

> "[e]very precaution should be taken that orders issue. . . only when it appears that obedience is within the power of the party being coerced by the order." (emphasis added) Maggio v. Zeitz, 333 U.S. 56, 69 (1966).

There are indications in the record that the OSHA Staff does not accept the Supreme Court's admonition that orders must not command the impossible. As viewed by the Staff, there is considerable advantage to a standard that can't be compiled with. It permits the Staff to put pressure on employers by issuing Citations and then bargaining as to what the employer must do to clear himself by way of an abatement program. The system works even better when (as here) there is no moratorium on Citations

during the process of abatement.* If OSHA has second thoughts about an abatement program, it can reopen the bargaining by the simple device of issuing more Citations for the conditions the program is designed to correct. This is what Mr. Grover Wrenn, head of OSHA's standard setting section, called "leverage." (T. 126.) As he put it, OSHA "is in a better position to monitor the employer's coming into compliance after having cited initially for non-compliance." (T. 126.)

Mr. Wrenn's in terrorem approach to the administration of standards cannot be squared with the Act or the decisions of the Courts. The Secretary should reject any effort to justify an impossible standard on the grounds that it gives the enforcement people a more effective bargaining position.

We recognize that the Act has been described as "technology forcing" legislation. But any assumption that a technological breakthrough is in the offing "cannot be based on 'crystal ball'" inquiry." Portland Cement Assoc. v. Ruckelshaus, 486 F.2d 375, 391 (D.C. Cir. 1973). As stated by the District of Columbia Circuit Court:

> "Congress does not appear to have intended to protect employees by putting their employers out of business - either by requiring protective devices unavailable under existing

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* The head of OSHA's standard setting section testified that, even though an employer is conscientiously pursuing an abatement program, under the wording of the new standard, he is nevertheless subject to Citation (T. 123). Additionally, the new standard requires respiratory protection under certain circumstances and still permits the issuance of Citations while the protection is in use (T. 124).

technology or by making financial viability generally impossible." Industrial Union Department v. Hodgson, 499 F.2d 467, 478 (D.C. Cir. 19742..

The record in the instant proceeding establishes that the primary producers are reaching the limit of conventional control. (Wrenn, W.T. p. 21; T. 1267.) The only technology that would produce a plant capable of operation without Citation under the new standard would be a completely enclosed and remotely controlled system (referred to in the record as a "glove box" system). But, as everyone (even BB&N) agrees, a glove box system is not economically feasible. (BB&N, Economic Impact Statement, p. 117.)

The Secretary must face the fact that if she commands the primary producers to operate so that no employee will ever be exposed to a concentration above 1 microgram on any single day, she will, in fact, be commanding an impossibility. It cannot be done. No witness in this proceeding said that it could be done.

The Secretary should also carefully consider the alternatives that are open to an employer who has been commanded to do the impossible. One is to operate under continuous Citation for legal violations while making continuous investments in abatement programs. But, as noted by KBI's Vice-chairman, "What would we say to lending institutions and investors about the prospects of a company that was continually required to make investments in a plant without any assurance that the plant could ever comply with the applicable legal standard?" (Lowry, W.T. p. 11.) Or, indeed,

what would OSHA do about "an employer who was trying hard, but, through no fault of his own, falling short of an unattainable goal?" (Lowry, W.T. p. 11.)

The other alternative is obvious: go out of business. No responsible employer would threaten to do this, but any thoughtful analysis shows that it is likely to happen, later if not sooner. If the Secretary issues the standard as proposed, she must recognize that she may well be sounding the death knell of this industry.

* * *

This brief is addressed to the Secretary, and its primary objective is to convince her that the proposed standard is ill-conceived, impossible to comply with, unwise and unsound from an administrative point of view. However, we are also enjoined to apprise the Secretary of the legal infirmities that we would urge upon a reviewing court in the event the proposed standard were promulgated. These fall in the general categories of vagueness (to the point of a constitutional violation), arbitrariness, capriciousness, and unreasonableness. They can be summarized as follows:

1) The command of the standard is unconstitutionally vague because it does not say how compliance will be measured. The substance of the command differs radically depending on what measure of compliance is applied. In addi-

tion, there are many uncertainties in the wording of the standard, the most important being the uncertainty as to the meaning of new peak limits.

2) The standard taken as a whole exceeds the authority granted to the Secretary under the Act because it is not feasible within the meaning of the Act and because it will not improve working conditions.

3) The changes in the averaging period and the peak limit are arbitrary and capricious in that there is no evidence as to what they were intended to accomplish.

4) The change permitting the use of lapel samplers is unreasonable because it sacrifices good industrial hygiene practice merely on the gounds of convenience.

5) The reduction from 2 micrograms to 1 microgram is unreasonable because there is no evidence that it is needed, or that it is feasible, or that, if feasible, it would improve working conditions.

6) The failure of the standard to provide a moratorium on Citations during the abatement proce s is arbitrary and capricious and cannot be justified on grounds of expediency.

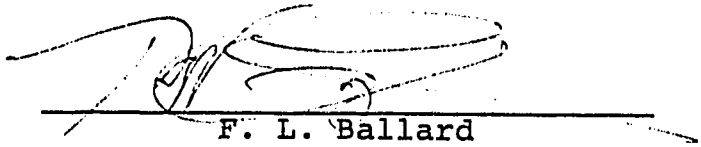
7) The medical evidence does not support any change in the standard.

8) The evidence on technology would not support any major change in the standard. Indeed, it shows that the standard is already at the lowest feasible level.

9) The economic evidence would not permit any change in the standard entailing substantial increased costs.

Wherefore, the Secretary should reject the proposed standard in toto.

Respectfully submitted,



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