

22 NOV 1977

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BSC  
7-011-011

November 17, 1977

Honorable Philip Lesser  
Administrative Law Judge  
Department of Labor  
Room 700  
1111 20th Street, N.W.  
Washington, D. C. 20036

Re: Rulemaking Proceeding on Proposed  
Standard for Occupational  
Exposure to Beryllium

Dear Judge Lesser:

At the close of the hearing on the Proposed Beryllium Standard, Brush Wellman Inc. and Kawecki Berylco Industries Inc. (the "industry") requested that you grant a period of six months for a post-hearing submission by the industry relating to certain epidemiological studies placed in the record by NIOSH and Dr. Thomas Mancuso. You set a ninety day period, but indicated a willingness to entertain a motion for further extension, if properly documented. You set December 1 as the date for filing the motion and December 9 as the final date for comments by other interested parties.

It has now become clear that, for reasons set forth in detail below, we will be unable to meet the December 12 date, and we therefore request an extension of approximately sixty days to February 12, 1978. We ask your indulgence for an early filing of the motion, and consideration and ruling on it in order that we may have a basis for planning the continuation of our work on the epidemiology.

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As you will recall, the industry experienced considerable difficulty throughout the course of the hearing in obtaining information concerning the epidemiology studies, a difficulty which severely hampered our ability to make an effective presentation. Finally, on September 6, 1977, after the conclusion of the direct presentation of evidence, we obtained from NIOSH a tape said to support the then most recent Bayliss study which was complete with birthdates of living members of the cohort and which made possible a detailed analysis. (Dr. Mancuso has not, even to this date, submitted materials which would provide the basis for such an analysis). Dr. Brian MacMahon and Dr. H. Daniel Roth, consultants to us, had informed us that it would be several months before they could complete an analysis and prepare meaningful reports. Based on their complete advice, and on the assumption that the Bayliss III report then in evidence and the September 6 tape which underlay it were the definitive Bayliss report and tape in this proceeding, we had requested the six-month extension.

Immediately after the close of the hearing, the industry and its consultants undertook two major efforts respecting the latest Bayliss study then in the record. First, it began an analysis of the September 6 tape in an unedited and uncorrected state, for the purposes of identifying anomalies and inadequacies in the data and of replicating or attempting to replicate the results reported by Bayliss. A report of this analysis, prepared by Dr. MacMahon, is now in draft form. The second effort, which involved the gathering of large amounts of data, had three aspects: (a) a thorough and painstaking review and checks of all material information on each of the 3070 members of the cohort, including name, race, sex, birthdate, and dates of commencement and termination of employment; (b) collection of additional data on the 3070, including job title and area of residence; and (c) identification of and gathering of data concerning individuals who may have been erroneously excluded from the cohort. The purpose of this effort was, and is, to provide a basis for evaluating the completeness and accuracy of the data which lies at the foundation of the study, and for analyzing the effect of any inadequacies discerned.

The data gathering effort is as yet incomplete, but preliminary results indicate that there are a large number of potentially significant errors in the 3070 tape

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and that many individuals, in fact several hundred, who should have been included in the cohort, were not included. We are working to get the best data possible on both those included in the cohort and those omitted from it. However, despite a major commitment of time by the staff of Kawecki Berylco Industries Inc., and the hiring of temporary help, the collection is not yet complete. We expect it to be so in two to three weeks, after which Drs. MacMahon and Roth will begin their analyses and evaluation.

Were it not for a major complication which has arisen since the hearing closed, we believe we could have made our final submission to the record by mid to late January, 1978. That complication initially arose on the evening of September 27, 1977, literally the final moment for the submission of post-hearing factual data, when NIOSH inserted into the record substantial new information including a computer tape several printouts and certain histological data relating to the Bayliss series of studies, together with certain printouts and a new report relating to Dr. Infante's epidemiology study of the Beryllium Case Registry. Even a quick review of these items reveals that they differ in material respects from the items submitted during the hearing. The Registry Study, for example, is changed from a negative finding to a positive finding. The Bayliss materials reflect yet another change in cohort size, a change in both the number of expected lung cancer deaths and the number of observed lung cancer deaths, and changes in several of the numbers which appear in the critical tables included in the Bayliss study submitted at the hearing.

We were informed by OSHA that at the time of submitting its post-hearing materials, NIOSH indicated it was willing to supply copies of the materials upon request to parties to the proceeding. Most of the computer printouts were too large and too thick to permit photocopying and the computer tape, of course, could be duplicated only on a computer. For all practical purposes, then, NIOSH was the only available source for working copies of the new NIOSH materials.

Accordingly, on September 30, 1977 we sent to two separate individuals within NIOSH identical requests for release of the data under the Freedom of Information

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Act. In a development not uncharacteristic of our prior experience in this matter, it appears that for reasons not necessary to detail, NIOSH failed to act on the request immediately. After the expiration of the time set by regulation for response, we contacted NIOSH, informed it of the delinquency and demanded action. Ultimately we did receive the data, but not until November 2, 1977. We passed the material information on to Drs. MacMahon and Roth who are now reviewing it. Their initial observations, which to date have been nothing more than examinations of the data and do not constitute analyses, indicate that there are a number of changes in the information on the tape which had not previously been apparent from our examination of the printouts and other data in the September 27 NIOSH submission. The addition of certain data concerning terms of employment is one significant example.

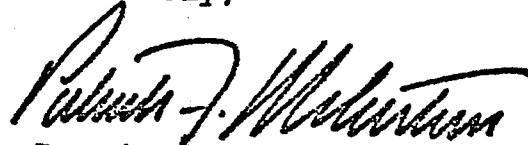
For obvious reasons, all of the work which we did in September and October was based upon the September 6 tape. Because we had planned our approach around that tape we have continued to use it as the basis for the work subsequent to November 2, while at the same time we are evaluating the impact of the November 2 tape on our continuing efforts. At the present time we believe that the appearance of the November 2 tape will require some data gathering and considerable analysis beyond that which would have been necessary to treat only the September 6 tape.

After reviewing the circumstances in detail with us, Drs. MacMahon and Roth have advised that in view of the extensive work which has yet to be done and of other commitments which they must meet, together with the approaching series of holidays, they cannot have final reports on the studies in question, primarily the Bayliss series of studies but also including the Mancuso and Registry studies, until early February, 1978. We believe that within the ensuing days we could assemble these reports, together with substantial backup data and a supplemental brief in one comprehensive submission which would provide the Assistant Secretary with a coherent explanation of the industry position on the epidemiology work in the record of this proceeding.

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Because of the delay occasioned by NIOSH's failure to respond to our Freedom of Information request for the latest tape and printouts in a timely fashion, it is already evident that we cannot under any circumstances meet the December 12, 1977 deadline with a meaningful submission. Under your original ruling other interested parties were to be furnished copies of this motion and were to provide their comments to you within eight days thereafter. Accordingly, we request that you solicit participants' views by Monday, November 28, 1977 and that you make a favorable ruling on this motion as soon as possible thereafter. Copies of this letter have been sent to the other participants.

Sincerely,



Patrick F. McCartan

cc: Messrs. Tyson W. Coughlin  
✓ Peter F. Infante  
William Lloyd  
Steven Witt  
Tom Hall



Telegram

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TLX ATTORNEYS CLV

ZCZC 003 DLY CLEVELAND OHIO DECEMBER 7

PMS DR. PETER F. INFANTE

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

P.O. BUILDING, ROOM 523

CINCINNATI, OHIO 45202

HONORABLE PHILIP J. LESSER

ADMINISTRATIVE LAW JUDGE

U.S. DEPT. OF LABOR

VANGUARD BUILDING, ROOM 700

1111 20TH ST., N.W.

WASHINGTON, D.C. 20036

DEAR JUDGE LESSER:



Telegram

WE ARE IN RECEIPT OF YOUR LETTER OF DECEMBER 5, 1977 WHICH DENIES OUR REQUEST FOR EXTENSION OF TIME TO SUBMIT POST HEARING MATERIALS, AND NOTE THAT YOU PLACE STRONG RELIANCE UPON REPRESENTATION OF OFFICE OF SOLICITOR CONCERNING CAPABILITY AND WILLINGNESS OF TECHNICAL DATA CENTER TO DUPLICATE CERTAIN MATERIALS IN EXPEDITIOUS FASHION. WE WISH TO SEEK RECONSIDERATION OF YOUR RULING FOR TWO REASONS, WHICH ARE, IN SUMMARY:

1. OUR REQUEST WAS BASED ONLY PARTIALLY UPON DELAY IN RECEIVING NIOSH POST-HEARING MATERIALS. EVEN WITHOUT THAT DELAY, WE WOULD, AS INDICATED IN OUR REQUEST, HAVE REQUIRED UNTIL MID TO LATE JANUARY 1978 TO PRESENT AN EFFECTIVE SUBMISSION. DETERMINATION OF WHETHER WE SHOULD OR SHOULD NOT HAVE OBTAINED NIOSH MATERIALS FROM OHSА DOES NOT ADDRESS THE ISSUE OF WHETHER THE JANUARY DATE WAS

SF-1201 (R5-69)

CDC 00033



Telegram

NECESSARY IN ANY EVENT.

2. EXPERIENCE OF BRUSH WITH OSHA TECHNICAL DATA CENTER WAS THAT IT HAD DUPLICATION EQUIPMENT ONLY FOR STANDARD SIZED DOCUMENTS. EVEN THEN, STAFF SHORTAGES AND BACKLOG AT TDC OFTEN REQUIRED BRUSH REPRESENTATIVES TO WAIT IN TURN AND OPERATE MACHINE THEMSELVES. COMPUTER PRINTOUTS, COMPOSED OF OVER 1800 PAGES OF WHICH BRUSH NEEDED TWO COPIES EACH, HAD PAGES TOO LARGE FOR NORMAL COPIER AND DESPITE EXTENSIVE CONTACTS WITH TDC OVER MANY MONTHS, BRUSH NEVER INFORMED THAT TDC HAD COPIER WHICH WOULD DUPLICATE. SAME TRUE OF COMPUTER TAPES. MORE IMPORTANTLY, WHEN BRUSH REPRESENTATIVES CONTACTED OSHA RE: NIOSH SUBMISSION OF SEPTEMBER 27, WERE NOT INFORMED THAT TDC OR ANY OFFICE IN OSHA COULD PROVIDE COPIES; RATHER WERE INFORMED THAT NIOSH WOULD PROVIDE COPIES. IT WAS BASED ON THIS REPRESENTATION OF

SF-1201 (RS-69)

CDC 00034



Telegram

OSHA THAT BRUSH WENT TO NIOSH, BELIEVING THIS TO BE, IN OSHA'S VIEW, THE ONLY POSSIBLE OR AT LEAST THE MOST EXPEDITIOUS ROUTE. BUT FOR SUBSEQUENT NIOSH DELAY, ROUTE CHOSEN WOULD HAVE BEEN EXPEDITIOUS. CERTAINLY BRUSH SHOULD NOT BE PENALIZED FOR SEEKING WHAT IT BELIEVED TO BE MOST EXPEDITIOUS ROUTE IN RELIANCE UPON OSHA STATEMENT.

ALSO CALL YOUR ATTENTION TO FOLLOWING FACTS: NIOSH CRITERIA DOCUMENT PREPARED AND TRANSMITTED TO OSHA IN 1972. PROPOSED OSHA STANDARD PUBLISHED ON OCTOBER 17, 1975. WRITTEN COMMENTS SUBMITTED ON FEBRUARY 2, 1976. HEARING COMMENCED AUGUST 16, 1977. BUT FOR SINGLE 45 DAY EXTENSION GRANTED TO INDUSTRY FOR WRITTEN COMMENTS (DECEMBER 16, 1975 - FEBRUARY 2, 1976) AND A SINGLE 1 WEEK DELAY IN HEARING DUE TO SCHEDULING PROBLEMS, ALL OTHER PASSAGE OF TIME

**Telegram**

DETERMINED BY OSHA. IN LIGHT OF EXTENDED TIME WHICH HAS PASSED,  
AT INSTANCE OF OSHA, SINCE OCTOBER, 1976, AND EVEN MORE SINCE  
1972, MINIMAL EXTENSION AT THIS TIME TO ALLOW COMPLETE ANALYSIS  
OF DATA ON CRUCIAL ISSUE IS REASONABLE.

CONFIRMING LETTER IN MORE DETAIL TO FOLLOW.

VERY TRULY YOURS,

PATRICK F. MCCARTAN

CC: DR. PETER F. INFANTE  
STEVEN WITT, ESQ.  
MARY-WIN O'BRIEN

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