

cc

498

OAK RIDGE NATIONAL LABORATORY
OPERATED BY MARTIN MARIETTA ENERGY SYSTEMS, INC.
FOR THE U.S. DEPARTMENT OF ENERGY

POST OFFICE BOX 2008
OAK RIDGE, TENNESSEE 37831

June 27, 1990

707528

Mr. James A. Reafsnyder, Deputy Assistant Manager
Energy Research and Development
Department of Energy, Oak Ridge Operations
Post Office Box 2008
Oak Ridge, Tennessee 37831-6269

Dear Mr. Reafsnyder:

Results of Refractory Ceramic Fiber Research

As requested in your letter of May 24, 1990, the following are planned actions for (1) informing ORNL employees of hazards associated with refractory ceramic fibers, (2) reducing potential exposures to as low as reasonably achievable (ALARA), and (3) evaluating feasibility of substitute materials.

The research community at ORNL has been working closely with the Industrial Hygiene Section for several years with regard to ceramic fiber research. Both researchers and Industrial Hygiene staff members have been actively involved with American Society for Testing and Materials committees regarding ceramic research, and ORNL has cosponsored symposiums which focused on health and safety concerns associated with ceramic fibers. As a result, many research and craft personnel at ORNL are aware of the health hazards associated with airborne exposure to ceramic fibers. On January 9, 1990, a briefing was held for Environmental Safety and Health Upgrade Program divisional representatives to discuss current research findings on ceramic fibers and other man-made mineral fibers (MMMMF) which includes the subset of refractory ceramic fibers. In March 1990, an Energy Systems policy was drafted for the safe handling of MMMF and was forwarded to personnel in the Metals and Ceramics Division for review and comment. The policy is currently in the final stages of preparation; however, in order to ensure that all employees potentially exposed to ceramic fibers are fully informed of the recently released research results, the Industrial Hygiene Section will issue a bulletin to all ORNL personnel describing results of toxicological testing for refractory ceramic fibers by July 20, 1990.

The Energy Systems policy currently under development will outline requirements to maintain exposures to as low as reasonably achievable. The policy describes practices for medical evaluation, employee training, respirator usage practices, and other methods to reduce exposures. The Industrial Hygiene Section will review operations involving the use of refractory ceramic fibers and recommend engineering and administrative controls as appropriate. Practices described in the draft Energy Systems policy will be implemented for ORNL operations by August 1, 1990.

REPOSITORY Oak Ridge Ops Office (ORO)
COLLECTION Energy Programs Div. (ER-11)
BOX No. ACTIVE RECORDS GATHERED FOR HUMAN RADIATION EXPERIMENTS
FOLDER _____

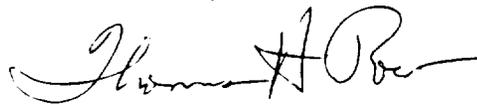
~~X-10 SITE OFFICE~~
LOG NO. 41534
FILE CODE 54866

1021762

An effort is currently underway to identify suitable, less toxic materials to replace Fiberfrax® and other suspect ceramic fibers. The Industrial Hygiene Section will continue to work closely with the Plant and Equipment Division and Metals and Ceramics Division to identify and evaluate possible substitutes. Results of those evaluations will be documented in a report by October 1, 1990.

ORNL management is committed to ensuring that all operations are conducted in such a manner to promote employee health and safety, and therefore will continue to monitor research activities associated with MMMF and take appropriate actions to reduce exposures to ALARA.

Sincerely,



Thomas H. Row, Director
Environmental, Safety,
and Health Compliance

THR:DLK:DTD:kc

cc: B. R. Appleton
D. T. Duncan
G. W. Oliphant
O. B. Morgan
J. O. Stiegler
J. H. Swanks
A. W. Trivelpiece - RC



Department of Energy

Oak Ridge Operations
P.O. Box 2001
Oak Ridge, Tennessee 37831-6269

Jim Cooke
"Reading File" Cop

May 24, 1990

Dr. Alvin W. Trivelpiece, Director
Oak Ridge National Laboratory
Martin Marietta Energy Systems, Inc.
Post Office Box 2008
Oak Ridge, Tennessee 37831-6255

Dear Dr. Trivelpiece:

RESULTS OF REFRACTORY CERAMIC FIBER RESEARCH

Enclosed is a notification by the Manville Corporation on the results of a toxicological evaluation of refractory ceramic fibers. Pursuant to Section 8(e) of the Toxic Substance Control Act, Manville reported to the EPA the occurrence of malignant tumors in the lungs of test animals exposed to airborne refractory ceramic fibers.

Since ORNL is currently using refractory ceramic fibers as asbestos substitutes for high-temperature applications, we request that you develop an action plan to 1) inform the appropriate craft personnel of the research results, 2) maintain exposures as low as reasonably achievable, and 3) evaluate the feasibility of less toxic substitute materials. Please provide us with this action plan by June 23, 1990.

Sincerely,

James A. Reafsnyder
James A. Reafsnyder

Deputy Assistant Manager for Energy
Research and Development

ER-112:Cooke

Enclosure

1021764



Manville Technical Center

Hand Carried

February 14, 1990



Document Control Officer
Chemical Information Division
Office of Toxic Substances (WH-557)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Filing of Manville's 8E for the Refractory Ceramic Fiber Research on
February 24, 1989.

To Whom It May Concern:

On January 30, 1990, representatives from Manville Corporation and a team of pathologists reviewed the results of the 18-month interim sacrifice of rats and hamsters from the ongoing Chronic Oncogenicity Assay of Refractory Ceramic Fibers (RCF) being conducted at Research Consulting Company (RCC) in Geneva, Switzerland. As promised in the initial filing with your office, dated February 24, 1989, and pursuant to Section 8(E) of the Toxic Substances Control Act, Public Law 94-469, supplemental reports on results coming from interim sacrifices in this study will be provided to your office.

The draft report of the 18-month findings will be forwarded to you when received by Manville. Draft reports of the three-, six-, nine- and 12-, and 15-month findings in rats and hamsters have been sent previously to your office. As this status report is the result of a preliminary evaluation, the results presented should not be regarded as a final determination. Any review should take into account the fact that the report may be based on incomplete information.

In June of 1988, a two-year bioassay to determine the chronic biological effects of inhaled refractory ceramic fibers in rats and hamsters was initiated at RCC, Geneva. Groups of rats were exposed for six hours per day, five days a week to 30 mg/m³ of four different types of refractory ceramic fibers (RCF: 1) kaolin RCF; 2) zirconia RCF; 3) high purity RCF; or 4) "after service" (a kaolin based ceramic fiber, containing 27% crystalline silica that had previously been exposed to high temperatures).

Hamsters were exposed to only one type of RCF, i.e. kaolin RCF fibers. Positive controls (chrysotile asbestos, 10 mg/m³) and negative controls (filtered air) were included in both the rat and the hamster study. Interim sacrifices were carried out at three, six, nine, 12, 15, and 18 months after the exposure was initiated. This is a lifetime study and the final sacrifice will occur when 20% survival occurs in the RCF treated animals.

1021765

On December 4, 1989, three rats from each treatment group were sacrificed for the 18-month interim pathology assessment. The lungs of sacrificed animals were fixed in formalin, embedded in paraffin, sectioned, and stained for pathomorphological examination. No tumors were found in the lungs of any of the RCF treated or control animals. A thymic adenoma, thought to be spontaneous, was found in one asbestos exposed animal. To date, the only other tumor found in this study was an adenoma found at the 12-month sacrifice in a kaolin RCF exposed animal.

Microscopic examination revealed that all three of the 18-month rat lungs exposed to zirconia RCF, "after service" RCF, and asbestos had pulmonary change, grade 4 (Wagner Scale; McConnell et al., 1984¹). This change was characterized by slight to moderate collagen deposition and epithelialization, and moderate microgranulomas at the bronchiolo-alveolar junction, and macrophages in bronchioli and alveoli.

Two out of three of the kaolin RCF lungs had pulmonary change, grade 4; the other lung showed grade 5. One out of three of the high purity RCF lungs had pulmonary change, grade 4; the other two lungs showed grade 5. The latter change, grade 5, was characterized by slight to moderate collagen deposition, and moderate microgranulomas at the bronchiolo-alveolar junction in all rats. In addition, in the rats with pulmonary change, grade 5, interlobular linking of these lesions was noted. The severity of pulmonary change was not considered to be increased in any of the groups over that seen at the 12-month interim sacrifice.

On December 18, 1989, three hamsters from each study group (kaolin RCF treated, asbestos controls, and filtered air controls) were sacrificed for the 18-month interim pathology assessment. Lung pathology from these animals as well as from any animals that died spontaneously before 18 months were reviewed on January 30, 1990 at RCC, Geneva. The most significant findings were the occurrence of a total of 10 pleural mesotheliomas in the lungs of kaolin RCF exposed animals. This number includes the four mesotheliomas described in previous reports sent to your office. No tumors were found in either the asbestos exposed hamsters or in the filtered air breathing controls.

In addition to the tumors, microscopic examination of the kaolin RCF exposed hamster lungs revealed pulmonary change, grade 4 (Wagner Scale; McConnell et al., 1984¹) in all three hamsters sacrificed at 18 months. This change was characterized by slight to moderate collagen deposition and epithelialization, and moderate microgranulomas at the bronchiolo-alveolar junction, and macrophages in bronchioli and alveoli. Collagen deposition was also noted in the pleura of all three hamster lungs.

Microscopic examination of the asbestos exposed hamster lungs at 18 months revealed pulmonary change, grade 5 in all three hamsters. This change was characterized by slight to moderate collagen deposition, and moderate microgranulomas at the bronchiolo-alveolar junction in all hamsters. In addition, interlobular linking of these lesions was noted. Negative control hamsters had no lung lesions.

The terminal sacrifice of rats and hamsters will occur when the percent survival has reached 20%. This is expected to occur in early March 1990 for the hamsters and sometime after August 1990 for the rats. We will continue to provide your office with supplemental and final reports on the RCF inhalation research being conducted at RCC. The current MSDSs for products containing refractory ceramic fibers have been revised to reflect these new findings and letters have been sent to notify Manville employees and customers of the potential health risk involved. Manville is currently requiring that anyone in a Refractory Ceramic Fiber work area wear a respirator irrespective of exposure levels until more scientific information is available about the possible health effects of this product.

Document Control Officer (EPA)
February 14, 1990
Page 3

Should you like to discuss the preliminary results of this study, please do not hesitate to contact
ME.

Sincerely,



William B Bunn, M.D., J.D.
Senior Director
Health Safety and Environment Department

cc: Vanessa Vu (EPA)
R. Anderson
G. Chase
T. Hesterberg
R. Batson
D. Goldberg

¹McConnell, E.E., Wagner, J.C., Skidmore, J.W., and Moore, J.A. A comparative study of the fibrogenic and carcinogenic effects of UICC Canadian chrysotile B asbestos and glass microfibre (JM 100). In "Biological Effects of Man-Made Mineral Fibers." Volume 2, World Health Organization, 1984.

1021767

May 24, 1990

Dr. Alvin W. Trivelpiece, Director
Oak Ridge National Laboratory
Martin Marietta Energy Systems, Inc.
Post Office Box 2008
Oak Ridge, Tennessee 37831-6255

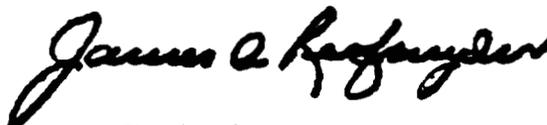
Dear Dr. Trivelpiece:

RESULTS OF REFRACTORY CERAMIC FIBER RESEARCH

Enclosed is a notification by the Manville Corporation on the results of a toxicological evaluation of refractory ceramic fibers. Pursuant to Section 8(e) of the Toxic Substance Control Act, Manville reported to the EPA the occurrence of malignant tumors in the lungs of test animals exposed to airborne refractory ceramic fibers.

Since ORNL is currently using refractory ceramic fibers as asbestos substitutes for high-temperature applications, we request that you develop an action plan to 1) inform the appropriate craft personnel of the research results, 2) maintain exposures as low as reasonably achievable, and 3) evaluate the feasibility of less toxic substitute materials. Please provide us with this action plan by June 23, 1990.

Sincerely,



James A. Reafsnnyder
Deputy Assistant Manager for Energy
Research and Development

ER-112:Cooke

Enclosure

JWCooke:6-0737:jwp:4-9254:5/22/90:LIBRARY/0016.jp

memorandum

DATE: March 26, 1990

REPLY TO

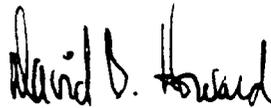
ATTN OF: SE-333:Brantley

SUBJECT: REFRACTORY CERAMIC FIBER RESEARCH RESULTS

TO: Those on Attached List

On February 14, 1990, the Manville Corporation notified the EPA about the results of a toxicological evaluation of refractory ceramic fibers. Pursuant to Section 8(e) of the Toxic Substances Control Act, Manville reported the occurrence of malignant tumors of the pleura (lung lining) among test animals exposed to airborne refractory ceramic fibers. Refractory ceramic fibers are currently being utilized in ORO high temperature applications as asbestos substitutes.

It is recommended that operating contractors be tasked to develop an action plan to 1) inform the appropriate crafts person of the research results, 2) maintain exposures as low as reasonably achievable, and 3) evaluate the feasibility of less toxic substitute materials.



David B. Howard, Director
Safety and Health Division

Attachment:

Ltr. Manville to EPA,
dtd. 2/14/90

cc w/attachment:

R. R. Nelson, SE-30
H. W. Hibbitts, SE-30
Robert Barber, EH-34, Germantown

1021770

Addressees - Memorandum Dated March 26, 1990
Subject: REFRACTORY CERAMIC FIBER RESEARCH RESULTS

Action
4/3 *Martha - Action*

Robert J. Spence, Y-12 Site Manager, DP-81
Marianne M. Heiskell, K-25 Site Manager, DP-85
Raymond J. Hansen, Acting FMPC Site Manager, DP-84
James A. Reafsnyder, Deputy Assistant Manager for Energy Research and Development, ER-10
Lynda H. McLaren, Contracting Officer Representative for Analysis Corporation, ER-112
K. Dean Helms, CEBAF Site Manager, ER-13
G. H. Carr, Director, Engineering Services Division, CE-51
Wayne A. Hampton, Director, Project Management Division, CE-52
Lester K. Price, Director, Technical Services Division, EW-93
Stephen H. McCracken, Acting WSSRAP Project Manager, CE-541
Eugene W. Gillespie, Portsmouth Site Manager, EO-221
David R. Allen, Paducah Site Manager, EO-222
Paul J. Plaisance, Project Manager, Strategic Petroleum Reserve Project Management Office, PR-61

*Call Brantly
why are we allowing
them to continue*

*Martha's site to
J. Infor
he*

*Assign
to Cooke
Jim see me
on this Martha
2) Hu
3) Fine*
4-13-90

SS

Dr. Alvin W. Trivelpiece, Director
Oak Ridge National Laboratory
Martin Marietta Energy Systems, Inc.
Post Office Box 2008
Oak Ridge, Tennessee 37831-6255

Dear Dr. Trivelpiece:

RESULTS OF REFRACTORY CERAMIC FIBER RESEARCH

Enclosed is a notification by the Manville Corporation on the results of a toxicological evaluation of refractory ceramic fibers. Pursuant to Section 8(e) of the Toxic Substance Control Act, Manville reported to the EPA the occurrence of malignant tumors in the lungs of test animals exposed to airborne refractory ceramic fibers.

Since ORNL is currently using refractory ceramic fibers as asbestos substitutes for high-temperature applications, we request that you develop an action plan to 1) inform the appropriate craft personnel of the research results, 2) maintain exposures as low as reasonably achievable, and 3) evaluate the feasibility of less toxic substitute materials. Please provide us with this action plan by June 13, 1990.

Sincerely,

James A. Reafsnyder
Deputy Assistant Manager for Energy
Research and Development

ER-112:Cooke

Enclosure

DATE
RTG. SYMB.
INITIALS

JWCooke:6-0737:jwp:4-9254:5/22/90:LIBRARY/0016.jp

memorandum

DATE: March 26, 1990

REPLY TO

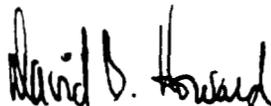
ATTN OF: SE-333:Brantley

SUBJECT: REFRACTORY CERAMIC FIBER RESEARCH RESULTS

TO: Those on Attached List

On February 14, 1990, the Manville Corporation notified the EPA about the results of a toxicological evaluation of refractory ceramic fibers. Pursuant to Section 8(e) of the Toxic Substances Control Act, Manville reported the occurrence of malignant tumors of the pleura (lung lining) among test animals exposed to airborne refractory ceramic fibers. Refractory ceramic fibers are currently being utilized in ORO high temperature applications as asbestos substitutes.

It is recommended that operating contractors be tasked to develop an action plan to 1) inform the appropriate crafts person of the research results, 2) maintain exposures as low as reasonably achievable, and 3) evaluate the feasibility of less toxic substitute materials.



David B. Howard, Director
Safety and Health Division

Attachment:

Ltr. Manville to EPA,
dtd. 2/14/90

cc w/attachment:

R. R. Nelson, SE-30

H. W. Hibbitts, SE-30

Robert Barber, EH-34, Germantown

1021773