

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VII

901 NORTH FIFTH STREET
KANSAS CITY, KANSAS 66101

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ENVIRONMENTAL PROTECTION
AGENCY-REGION VII
REGIONAL HEARING CLERK

BEFORE THE ADMINISTRATOR

IN THE MATTER OF)
)
University of Kansas Medical Center,) PREHEARING EXCHANGE
)
Respondent.) Docket No. RCRA-07-2006-0261
)
)
Proceedings Under Section 3008(a) and (g))
of the Resource Conservation and Recovery)
Act as amended, 42 U.S.C. 6928(a) and (g))

UNIVERSITY OF KANSAS MEDICAL CENTER'S PREHEARING EXCHANGE

Pursuant to the Prehearing Scheduling Order issued on March 17, 2007, and in accordance with the requirements of 40 C.F.R. §22.19, Respondent, University of Kansas Medical Center, ("KUMC") respectfully submits the following Prehearing Exchange.

I. Respondent's Fact Witnesses

1. Dr. James Voogt, Vice Chancellor for Research

On March 15-17, 2006, Dr. Voogt had overall responsibility for the laboratory chemicals used in the laboratory identified in the EPA complaint as Lied 3025. Dr. Voogt will testify that chemicals in the laboratory are the property of KUMC and he will discuss how the chemicals are used in the laboratory. He will say that the chemicals identified in the laboratory were unused and were suitable for their original purpose. He will also testify that at the time of the inspection, no decision had been made to dispose of any specific chemicals. He will also testify that the disposal decision would have (had it not been for the inspection) been made after he and Dr. Bryan Petroff

had gone through the chemicals to determine what chemicals Dr. Petroff needed when he took over the laboratory.

2. Dr. Lynwood Yarbrough, Professor of Biochemistry and Molecular Biology

On March 15-17, 2006, Dr. Yarbrough was responsible for the laboratory identified in the EPA complaint as Wahl East 4022. Dr. Yarbrough will testify that chemicals in the laboratory are the property of KUMC and he will discuss how the chemicals are used in the laboratory. He will testify that the chemicals identified during the inspection that were in the laboratory were unused and were suitable for their original purpose. He will also testify that at the time of the inspection no decision had been made to dispose of any specific chemicals. He will also testify that a new researcher was expected to be hired to take over the laboratory and that Dr. Yarbrough expected that the new researcher would evaluate the laboratory chemicals and decide which to keep and which to submit for disposal.

3. Mr. Rich Grabbe, Senior Laboratory Coordinator

Mr. Grabbe will testify that at the time of the inspection, March 15-17, 2006, he occupied the laboratory identified in the EPA complaint as Wahl East 4025. He will state that although he occupied the laboratory, he did not do any research in the laboratory. He will testify that in response to a question by the EPA inspector, he told her that he intended to evaluate the chemicals and see whether someone in his department could use them. If they could not, he told her that he would submit the chemicals for disposal. He will testify that to the best of his knowledge, all chemicals identified in the inspection were unused and suitable for their original purpose.

4. Mr. John Finley, Assistant Vice Chancellor for Compliance

Mr. Finley will testify that he is the Assistant Vice Chancellor for Compliance for Kansas University Medical Center and that he is intimately familiar with KUMC's compliance program.

Mr. Finley will testify that he was present during the closing conference held by the EPA inspector, Ms. Dedriel L. Newsome. Mr. Finley will testify that he understood Ms. Newsome to recommend the expeditious disposal of the maximum amount of those chemicals that she had identified in her inspection as being problematic. He will also testify that as a result of the discussion with Ms. Newsome, a decision was made that if KUMC could not quickly determine that the identified chemicals could be reused immediately, they would be disposed of.

5. Mr. Edward Phillips, Vice Chancellor of Administration

Mr. Phillips will testify that he is the Vice Chancellor of Administration for Kansas University Medical Center. Mr. Phillips will testify that he was present during the closing conference held by the EPA inspector, Ms. Dedriel L. Newsome. Mr. Phillips will testify that he understood Ms. Newsome to recommend the expeditious disposal of the maximum amount of those chemicals that she had identified in her inspection as being problematic. He will also testify that as a result of the discussion with Ms. Newsome, a decision was made that if KUMC could not quickly determine that the identified chemicals could be reused immediately, they would be disposed of.

6. Dr. Curtis Klaassen, Chair, Department of Pharmacology, Toxicology, and Therapeutics (Dr. Klaassen will also serve as an expert witness).

Dr. Klaassen will testify that at the time of inspection, March 15-17, 2006, he was responsible for the laboratory chemicals present and used in the room identified in the EPA complaint as Briedenthal 2015. He will testify that the chemicals in the laboratory were unused and were suitable for their original purpose. He will also testify that at the time of the inspection, there had been no decision to dispose of any specific chemical in the laboratory. He will further testify that any disposal decision would have come (had it not been for the results of the inspection) just before October 2006, when the laboratory was going to be moved to a new building on campus. Dr.

Klaassen will testify that at the time of the inspection he did expect that some of the chemicals in the laboratory might end up not being reused, but that no specific chemicals had been identified for disposal. Dr. Klaassen will also testify that many of the chemicals that were disposed of as a result of this inspection were subsequently repurchased.

7. KUMC reserves the right to call all witnesses named by Complainant. Respondent further reserves the right to submit names of additional witnesses and to submit additional exhibits before the hearing of this matter, upon timely notice to the Administrative Law Judge and the Complainant.

II. Respondent's Expert Witnesses

1. Mr. Kevin Dirks

Mr. Dirks will testify that he is the Director of KUMC's Environment, Health and Safety Office. Mr. Dirks will identify the chemicals in the various KUMC laboratories and identify whether these chemicals are waste or useful product. Mr. Dirks will testify about the restricted access and protective measures concerning Building 25. He will further testify as to the restricted access to the laboratories. Mr. Dirks will also testify concerning the disposition of the identified chemicals as a result of the EPA inspection and that many of those chemicals were subsequently repurchased.

2. Dr. Curtis Klaassen, Chair, Department of Pharmacology, Toxicology, and Therapeutics (Dr. Klaassen will also serve as a fact witness).

Dr. Klaassen will testify that at the time of inspection, March 15-17, 2006, he was responsible for the laboratory chemicals present and used in the room identified in the EPA complaint as Briedenthal 2015. He will identify the chemicals in the various KUMC laboratories and identify whether these chemicals are waste or useful product. He will testify that the chemicals

in Briedenthal 2015 were unused and were suitable for their original purpose. He will also testify that at the time of the inspection, there had been no decision to dispose of any specific chemical in the laboratory. He will further testify that any disposal decision would have come (had it not been for the results of the inspection) just before October 2006, when the laboratory was going to be moved to a new building on campus. Dr. Klaassen will testify that at the time of the inspection he did expect that some of the chemicals in the laboratory might end up not being reused, but that no specific chemicals had been identified for disposal.

3. KUMC reserves the right to call all witnesses named by Complainant. Respondent further reserves the right to submit names of additional witnesses and to submit additional exhibits before the hearing of this matter, upon timely notice to the Administrative Law Judge and the Complainant.

III. Respondent's Exhibit List

A copy of each exhibit listed below is enclosed with KUMC's prehearing exchange.

- RX-1.** 45 Fed. Reg. 98, 33089, May 19, 1980, Identification and Listing of Hazardous Wastes
- RX-2.** 42 U.S.C. §6903(27), General Definitions
- RX-3.** 40 CFR 273.3 (d), Decision to Discard, Pesticides
- RX-4.** 40 CFR 261.3 (c)(3), Definition of Hazardous Waste
- RX-5.** 50 Fed. Reg. 14219, April 11, 1985, Definition of Solid Waste, Technical Corrections
- RX-6.** Final Rule 50 Fed. Reg. 636, Jan. 4, 1985, Definition of Solid Waste
- RX-7.** K.A.R. 28-31-4, Standards for generators of hazardous waste
- RX-8.** K.S.A. §65-3437, Application for permits,
- RX-9.** 42 U.S.C. §6928, Hazardous Waste Management, Federal Enforcement,

- RX-10.** 42 U.S.C. §6925, Permits for treatment, storage, or disposal
- RX-11.** 40 CFR §262.34(c)(1)(ii), Hazardous waste labeling requirements
- RX-12.** *American Mining Congress v. EPA*, 824 F.2d 1177 (D.C. Cir. 1987)
- RX-13.** *Safe Food v. EPA*, 350 F.3d 1263 (D.C.Cir. 2003)
- RX-14.** *Association of Battery Recyclers v. EPA*, 208 F.3d 1047 (D.C.Cir. 2000)
- RX-15.** *General Electric Co. v. U.S. EPA*, 53 F.3d 1324 (D.C. Cir. 1995)
- RX-16.** *Rollins Environmental Services, Inc. v. U.S. EPA*, 937 F.2d 649 (D.C.Cir. 1991)
- RX-17.** May 23, 2006, EPA Proposed Rule, Subpart K, “Standards Applicable to Academic Laboratories,” 71 Fed Reg. 29711 to 29752
- RX-18.** 5/4/2006 EPA Inspection Report
- RX-19.** EPA Inspection Photos (color)
- RX-20.** 3/30/2006 KUMC Response to EPA
- RX-21.** 12/26/2006 KUMC Purchase Orders
- RX-22.** 3/31/2006 KUMC Packing Slips
- RX-23.** 1/12/2007 Response to 11/27/2006 EPA Request for Additional Information University of Kansas Medical Center, Docket No. RCRA-07-2006-02
- RX-24.** 11/28/1990 Letter from EPA Assistant Administrator Don Clay to Ms. Kathleen Ream of the American Chemical Society
- RX-25.** 2/22/1989 Letter from Stephen L. Cochran, Acting Chief, Review Section to Mr. Raymond B. O’Day, Packard Instrument Company
- RX-26.** 5/16/1991 Letter from Sylvia K. Lawrence, Director of the Office of Solid Waste to Mr. Mark Schuly Pharmaceutical Services, Inc.
- RX-27.** 10/31/1985 Letter from Jack McGraw, Deputy Assistant Administrator to Mr. Carl Schaefer Director of Environmental Policy, Office of the Assistant Secretary of Defense
- RX-28.** EPA Guidance to Senior RCRA Policy Advisors Memorandum “Hazardous Waste Generated In Laboratories,” from Elizabeth Cotsworth, Director of the Office of Solid Waste, 8/16/2002

- RX-29.** 5/13/1981 Letter from Alan Corson, Chief Waste Characterization Branch to Mr. Steven C. Wittmer of Sharp & Dohme
- RX-30.** 8/8/2003 Memorandum from Ira Leighton, Deputy Regional Administrator to Bob Springer, Director Office of Solid Waste, "EPA New England Recommendations regarding the Regulation of Waste in Academic Laboratories (RCRA Docket-2003-0012)
- RX-31.** Monthly Hotline Report, August 1996
- RX-32.** Hotline Questions and Answers, August 1995
- RX-33.** 11/1999 EPA Project Fact Sheet, Project XL: New England Universities, EPA-100-FF-99-014
- RX-34.** Screen shot of Project XL, New England Universities Laboratories, <http://www.epa.gov/projctxl/nelabs/page6.htm>, (Apr. 15, 2007).
- RX-35.** March 2002, EPA "Report to Congress Evaluating the Consensus Best Practices Developed through the Howard Hughes Medical Institute's Collaborative Hazardous Waste Management Demonstration Project and the Need for Regulatory Changes to Carry Out Project Recommendations."
- RX-36.** 2003 RCRA Civil Penalty Policy
- RX-37.** Chapter III of the RCRA Orientation Manual
- RX-38.** Curriculum vitae, Dr. Curtis Klaassen
- RX-39.** Resume, Mr. Kevin Dirks

KUMC reserves the right to use any documents identified by Complainant. Respondent further reserves the right to submit additional exhibits before the hearing of this matter, upon timely notice to the Administrative Law Judge and the Complainant.

IV. KUMC's Response to the Proposed Penalty

1. *Count I*

KUMC believes that the penalty proposed by EPA for Count I is unreasonably high and, under the circumstances, entirely inappropriate. All but a few of the 721 containers of allegedly improperly stored "solid waste" were in fact useable laboratory chemicals. These chemicals were still in their original containers and were available for use by laboratory personnel. No decision had

been made to dispose of these chemicals. Therefore, these chemicals by definition are not “waste” and are not regulated under RCRA.

For the remaining chemicals, the extent of the deviation from the regulatory standard should be considered as “minor” instead of “major”. All but a few of the containers were not “waste” pursuant to RCRA, very few of the remaining containers did not have documentation of hazardous waste determinations, all containers were safely stored pending characterization, and some of the containers were properly labeled according to federal standards.

The potential for harm should also be considered “minor” in light of the security of the building in which the chemicals were stored, the high degree of training of research personnel, and the fact that much of the labeling was in conformity with federal standards.

Finally, KUMC believes the penalty is inappropriate because it is based on false assumptions. The penalty is based on disposition documents showing what chemicals KUMC disposed of after the inspection. EPA then concluded that those chemicals must have been improperly stored “waste”. But during the inspection outbriefing, the EPA inspector specifically told KUMC personnel that disposal of as many chemicals as possible would assist KUMC in avoiding a penalty. KUMC was merely doing what it believed the inspector wanted it to do.

2. *Count II*

KUMC believes that the penalty proposed by EPA for Count II is also unreasonably high and, under the circumstances, entirely inappropriate. Both the extent of deviation from the requirement and the potential for harm should be “minor” in light of the security of the building in which the chemicals were stored, the high degree of training of research personnel, and that much of the labeling was in conformity with federal standards.

V. Other Matters

KUMC believes that the most appropriate location for the hearing would be at the Regional Hearing Office for U.S. EPA Region VII, located at 901 North 5th Street, Kansas City, KS 66101. Both parties are located in Kansas City, Kansas and the Regional Hearing Office would be a mutually convenient location.

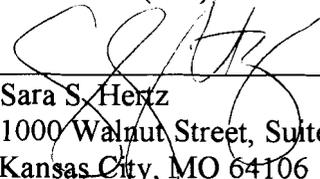
Respectfully submitted,

SPENCER FANE BRITT & BROWNE LLP

Date: 4/13/07



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**ATTORNEYS FOR RESPONDENT –
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CERTIFICATE OF SERVICE

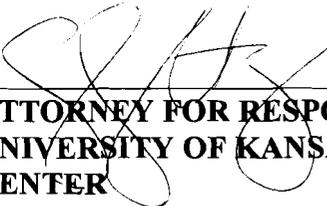
I hereby certify that on this 13th day of April 2007, a copy of this document was served by commercial delivery, upon:

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