Protocol for ORAU Medical Screenings for Citizens Living Near the Kingston Fly Ash Spill Of December 22, 2008

The purpose of the medical screening is to provide concerned residents of Roane County with targeted medical testing to screen for adverse health effects potentially related to the fly ash spill.

The screening examinations have been designed by the medical toxicologists (Seger, Benitez, and Williams) from the Tennessee Poison Center at Vanderbilt University Medical Center in consultation with Michael Kosnett, MD, a medical toxicologist, and Lee Newman, MD, a pulmonologist with the University of Denver Health Sciences Center in Denver, CO.

The selection of specific evaluations is based on the analysis of the coal ash performed by the Tennessee Department of Environment and Conservation performed on January 6-7, 2009 on residential property in the spill area. (Column one on the Matricies) These tests were chosen based on a comparison of the constituents of the coal ash and normal values for soil in the surrounding area.

The protocol is intended to ensure consistency of approach in the medical evaluation of the participants.

This protocol is not intended to dictate the clinical practice of medicine.

This protocol is not intended to substitute for periodic health maintenance/disease screening examinations by the participant's person physician. However, a secondary benefit may be the assessments contribution to general health information.

Provisions for follow up examinations are provided for in the ORAU-Vanderbilt contract. The need and scheduling of these will be determined after the first round of testing in completed. Possible follow up is envisioned at six month and one year which would be one year and 18 months after the spill.

Based on the exposure matricies (attached), the following examinations will be offered:

Health History/Questionnaire - attached
Physical Examination- follows
Spirometry
Chest x ray with interpretation
Routine urinalysis
Complete Blood Count (CBC)
Blood Chemistry to include:

Chemistry Panel
Sodium
Potassium
Chloride

Bicarbonate (sometimes reported as CO_2)
Glucose
Blood Urea Nitrogen
Creatinine
Aspartate Transaminase
Alanine Transaminase
Alkaline Phosphatase
Total Bilirubin

Biological Monitoring tests will include:

Test	Specimen Type	CPT Code
Aluminum	Serum	82108
Arsenic	Whole Blood	82175
Arsenic	Urine	82175
Barium	Urine	83018
Beryllium	Urine	83018
Chromium	Serum	82495
Cobalt	Whole Blood	83018
Copper	Serum	82525
Nickel	Serum	83885
Selenium	Serum	84255
Thallium	Urine	83018
Vanadium	Urine	82570, 83018

Note: Uranium values initially reported by TDEC are erroneous, so testing for uranium exposure is not recommended.

Participants will have all testing completed prior to their physical examination by the medical toxicologists. Participants will receive results at the time of their physical examination. A summary of the results and the findings of the examination will be sent in a letter to the participant by the Vanderbilt physicians.

Medical Surveillance Matrix – Kingston Coal Ash Project

Coal Ash Constituent	Concentration (Mean, range) mg/kg[1]	Estimated RME child oral dose[a] (mg/kg/d)	Estimated Pica Child oral dose[b] (mg/kg/d)	Estimated RME Adult oral dose[c] (mg/kg/d)	Comparison Dose (e.g. ATSDR MRL or EPA RfD) (mg/kg/d)	LOAEL (mg/kg/d)[2]	Adverse Effects Observable at/near LOAEL	Medical Surveillance for exposure at/near LOAEL	Biological Monitoring tests for exposure near LOAEL	Reference Range	Biological $T_{1/2}$	Comment
Aluminum	14,109 (1000 – 22,000)	0.18	4.4	0.02	1.0[3]	100[4]	neurological developmental deficits	Physical exam	a. serum Al b. urine Al	a. 1 – 10 µg/L[5] b. 1 – 25 µg/L	a. Hours (after acute exposure); Days to years (after chronic exposure.)	
Arsenic[6]	75 (26-100)[7]	0.0006[8]	0.014	0.00007	0.005[9]	0.05[10]	a. GI (N,V,D)[11] b. parasthesias c. anemia/ leukopenia	Physical exam CBC Chem panel	Urine Arsenic (sum of Inorg As, MMA, DMA)[12]	ND -19 µg/L[13]	2 – 3 days	Recent (≤ 3d) seafood meal may elevate urine levels of DMA

a. RME ingestion 200 mg/d of ash containing mean concentration of constituent by a 16 kg child
b. Pica ingestion 5000 mg/d of ash containing mean concentration of constituent by a 16 kg child
c. RME ingestion of 100 mg/d of ash containing mean concentration of constituent by a 70 kg adult

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[1] TDEC ash sampling, residential properties, January 6 – 7, 2009
[2] Lowest Observable Adverse Effect Level (noncancer)
[3] ATSDR intermediate duration oral MRL [ref 11]
[4] Animal chronic duration oral LOAEL
[5] ref 12, 13, 14
[6] Chemical speciation of the arsenic in Kingston coal ash was not available. However, the ash pH was neutral to slightly alkaline (pH 6.7 – 8.3) [ref 1], which may have favored formation of calcium arsenate (V), a moiety often associated with coal fly ash [ref 2,3,4]. Iron arsenate compounds may also have been present.
[7] Residential property sampling by TDEC, January 6 – 7, 2009 [ref 5]
[8] Assumes an oral relative bioavailability of 0.61 [ref 9]
[9] ATSDR acute MRL [6], and EPA Region VIII acute and subchronic RfD [ref 7]
[10] Human LOAEL, acute and subchronic [ref 6, 7]
[11] ref 6,7,8
[12] Urinary inorganic arsenic, monomethylarsonic acid, dimethylarsinic acid. Note that recent seafood ingestion may cause significant increase in DMA
[13] ref 10

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Barium	357 (180 – 1100)	0.0045	0.112	0.0005	0.2[15]	115	Renal function decrement	BUN, creatinine	Urine Ba	50th percentile 1.52 µg/L; 95th percentile = 7.48 µg/L[16]	< 1 week (initial phases of multicompartment model)[17]	
Beryllium	3 (1.5 -7.9)	0.00004	0.0009	0.000004	0.002[18]	0.56[19]	GI inflammation	History/Physical	Urine Be	95th Percentile < 0.14 µg/L[20]	2 – 8 wks[21]	
Chromium	25 (16 – 43)[22]	0.0002	0.005	0.00002	0.005[23]	0.77	Microcytic hypochromic anemia	CBC	a. Urine Cr b. Serum Cr	a. 50th percentile 0.12 µg/L; 95th percentile 0.70 µg/L[24] b. 50th percentile 0.15 µg/L; 90th percentile 0.26 µg/L[25]	a. 10 – 40hr[26] b. 10 – 40hr	Cr (III) is a dietary nutrient, typical adult intake ≈ 36 µg/d; skin contact may cause allergic contact dermatitis

[14] Lowest Observable Adverse Effect Level (noncancer)
[15] ATSDR intermediate duration oral MRL
[16] ref 15
[17] ref 29
[18] ATSDR chronic duration MRL (oral)
[19] ED10 (benchmark dose) for GI effects in dogs, [ref 16]
[20] ref 15
[21] ref 16
[22] ≤ 13% hexavalent Cr, per TDH
[23] Int. duration oral MRL; ref 17
[24] ref 18
[25] Plasma values shown, [ref 19], which approximate serum values
[26] ref 17

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Cobalt	13 (6.7 – 29)	0.0002	0.004	0.00002	0.01[28]	1.0	Polycythemia	CBC	a. Urine Co b. Whole Blood Co	a. 50th percentile 0.410 µg/L; 95th percentile 1.27 µg/L[29] b. < 1 µg/L[30]	a. 1-2 d	Prosthetic implants may be a source of elevated exposure
Copper	46 (25 -76)	0.0006	0.014	0.00007	0.01[31]	0.09	GI upset	History/Physical	Serum Cu	≈ < 2 mg/L[32]	2 – 4 wks[33]	Serum Cu incr. in pregnancy
Nickel	23 (13 – 37)	0.0003	0.007	0.00003	0.02[34]	50	Decreased wt gain during development	History/Physical	a. Urine Ni b. Serum Ni	a. 1 – 3 µg/L b. < 1µg/L[35]; < 2 µg/L[36]	a. 1 – 2d b. 1 – 2 d	Contact allergen
Vanadium	77 (42 – 150)	0.001	0.024	0.0001	0.003[37]	0.57	Decrements in renal function	BUN, Cr	Urine V	< 1 µg/L [38]	20h [39]	

[27] Lowest Observable Adverse Effect Level (noncancer)
[28] ATSDR intermediate duration MRL (oral)
[29] ref 15
[30] ref 20
[31] ATSDR intermediate duration oral MRL
[32] ref 26, 27
[33] ref
[34] EPA RfD oral, soluble nickel salts
[35] ref 21
[36] ref 22
[37] ATSDR intermediate duration oral MRL
[38] ref 25
[39] ref 25

Draft Medical Surveillance Matrix – Kingston Coal Ash Project. Exposure to airborne constituents

Airborne Constitutent	Post ash spill, 24 hr average values ($\mu g/m^3$)	Background values, or regional levels prior to ash spill	National Ambient Air Quality Standard	ATSDR MRL (for inhalation)	TLV	LOAEL (noncancer)	Adverse Effects Observable at/near LOAEL or ambient levels	Medical Surveillance for exposure at/near LOAEL or ambient levels	Biological Monitoring tests for exposure at/near LOAEL or ambient levels	Comment
Fine Particulates[1] (PM10 PM2.5)	PM10 (Jan 1 – 10, 2009): range 6.1 – 76.2;[2] (May 28 –June 27,2009) : ≈ range 15 – 30 [3] PM2.5 (Dec 31, 2008 – Feb 3, 2009): range ≈ 3 – 28 [4] (May 28 – June 27, 2009): range ≈ 7 – 24 [5]	PM10 Roane Co. 1993 – 1998 annual average ≈ 60 [6] PM2.5 Roane Co. 2008 annual mean ≈ 13 [7]	PM10: 150 (24h avg) PM2.5: 35 (24h avg)[8]; 15 (annual avg)[9]	N/A	N/A	No threshold identified. Effects detected at /near ambient levels in USA[10]	Exacerbation of asthma, COPD, decrements in airflows; increase in cardiovascular morbidity (e.g. ischemic heart disease) and mortality[11]	Medical history	Spirometry	Cited health endpoints have low specificity

[1] Per TDH: "Kingston Fossil Plant coal fly ash is a 50/50 Central Appalachian/Powder River Basin blend that averages 8.2% PM2.5 and 31.2% PM10 (personal communication, Steven C. Strunk, TVA, March 17, 2009)."
[2] Tetratech/EPA. Final Comprehensive CERCLA Report, Revision 0, Kingston Fossil Plant Fly Ash Response. EPA Contract No. EP-W-05-054; Feb 20, 2009
[3] TVA Kingston PM10 Ambient Air Network Sampling Results 30 day history (from graphical data) http://tva.gov/kingston/air/jun27/Charts_PM25_06_27_2009.pdf [accessed July 20, 2009]
[4] TVA Fossil Plant on-site measurements (from graphical data) http://tva.gov/kingston/air/KIF_TEOM_FRM_24hrPM2%205_chartr1.pdf [accessed July 20, 2009]
[5] TVA Kingston PM2.5 Ambient Air Network Sampling Results 30 day history (from graphical data) http://tva.gov/kingston/air/jun27/Charts_PM25_06_27_2009.pdf [accessed July 20, 2009]
[6] US EPA (from graph) http://www.epa.gov/cgi-bin/broker?_service=data&_debug=0&_program=dataprog.maptest_08.sas&parm=81102&stfips=47
[7] US EPA. (from graph) http://www.epa.gov/cgi-bin/broker?_service=data&_debug=0&_program=dataprog.maptest_08.sas&parm=88101&stfips=47
[8] To attain this standard, the 3-year average of the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area must not exceed 35 $\mu g/m^3$ (effective December 17, 2006).
[9] To attain this standard, the 3-year average of the weighted annual mean PM2.5 concentrations from single or multiple community-oriented monitors must not exceed 15.0 $\mu g/m^3$
[10] US EPA. Integrated Scientific Assessment for Particulate Matter. First External Review Draft. December 2008. ISA: EPA/600/R-08/139
[11] US EPA, 2008 ibid.
also: Dominici F et al. Fine particulate air pollution and hospital admission for cardiovascular and respiratory disease. JAMA 295:1127-1134; 2006.
Liu L et al. Acute Effects of air pollution on pulmonary function, airway inflammation, and oxidative stress in asthmatic children. Environ Health Persp 117:668-674; 2009
Dales R et al. Acute effects of outdoor air pollution on FEV1: a panel study of schoolchildren with asthma. Eur Resp Journal 2009. Epub ahead of print: doi 10.1183/09031936.00138908

MEDICAL SURVEILLANCE MATRIX
Acronyms, Abbreviations and Symbols

Al	Aluminum
As	Arsenic
ATSDR	Agency for Toxic Substances and Disease Registry
Ba	Barium
Be	Beryllium
BUN	Blood Urea Nitrogen
CBC	Complete Blood Count
Co	Cobalt
Cr	Chromium, Creatinine
Cu	Copper
d	Day
DMA	Dimethylarsinic Acid
ED	Benchmark Dose
EPA	Environmental Protection Agency
GI	Gastrointestinal
H	Hours
kg	Kilogram
L	liter
LOAEL	Lowest Observed Adverse Effect Level
mg	Milligram
MMA	Monomethylarsonic Acid
MRL	Minimal Risks Level
N, V, D	Nausea, Vomiting, Diarrhea
ND	None Detected
Ni	Nickel
pH	Power of Hydrogen
RfD	Reference Dose
RME	Reasonable Maximum Exposure
$T_{½}$	Biological half-life
TDEC	Tennessee Department of Environment and Conservation
TDH	Tennessee Department of Health
U	Uranium
V	Vanadium
wks	Weeks
wt	Weight
µg	microgram