From: John Schmuck [John_Schmuck@Cameco.com]
Sent: Tuesday, April 05, 2011 1:48 PM
To: Burrows, Ronald
Cc: Josh Leftwich; Kari Toews; Rhonda Grantham; John McCarthy
Subject: Crow Butte Lung Study Clarification
Attachments: Cameco Lung Study Characterization 4.4.2011.docx

Ron - During the public meeting with the NRC on March 17, 2011, the NRC requested additional information on the classification of the Crow Butte uranium product into DWY. We have prepared the attached clarification for your consideration.

thanks. .john

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Cameco Crow Butte Lung Study Clarification   April 4, 2011

During a public meeting with the NRC on March 17, 2011 additional information on the classification of the Crow Butte uranium product into DWY was requested. The following information provides a description on the methods used for determining the classification of the material.

A simulated lung fluid study conducted on the Crow Butte uranium product by the Innovation and Technology Development Research Centre. The Research Centre followed published methods in performing this experiment [Ansoborlo et al. 1999]. The study was run for 100 days and was followed up with X-ray fluorescence (XRF) measurement of the residual material left on the filter.

Table 1 shows the fraction of uranium remaining on the filter (retention fraction) at each sample time based on ICP Mass Spectrometer analysis. Standard errors on these results vary from 5% to 10%, with the higher errors occurring later in the testing, near the 100 day mark. Table 2 shows the summary of the XRF results taken at the end of the experiment. It is important to note that though the ICP-MS indicated that between approximately 1% and 8% (± 10%) of the uranium remained undissolved at 100 days (Table 1), it was later shown through the XRF analysis that the majority of that material was dissolved uranium that had been reabsorbed by the filter. This means that within experimental error there is essentially no material remaining undissolved at 100 days.

By definition, the solubility classes of days, weeks and years are based on the amount of material retained in the lungs at specified times. Specifically, the retention times, or clearance half times, for the classifications are as follows:

	Clearance Half Time (d)
Type D	up to 10
Type W	10 – 100
Type Y	greater than 100

The method that was used to determine the DWY classification is to fit a curve to the dissolution data and use the fit parameters from that curve to classify the material into DWY. Table 3 shows the 3-parameter fit results following the method by Kalkwarf in NUREG-1428. It is again important to note that this fit was performed based on the results of Table 1 and the fraction assigned to retention times (T values) greater than 100 days should be reassigned to the time from of 10-100 days as subsequent analysis showed no measureable material remaining after 100 days, within error. This is a conservative assignment because some of that material absorbed onto the filter could have been dissolved before day 10, however we are assuming all of the absorbed material was dissolved after day 10. Table 3 shows the parameters of the fit and the subsequent DWY classification. The f values represent the fraction of material with the given dissolution half-time (the T value). The dissolution half time determines which classification grouping the corresponding fraction is classified as, e.g. a T1 value of 4.6 means that fraction (f1) is class D. The mean square deviation (as a percent), or average error, for each fit is also shown in Table 3.

Table1: Crow Butte Material Dissolution Kinetics

Sample No	CROW 2533-A	CROW 2533-B	CROW 2533-C	CROW 2537-A	CROW 2537-B	C ROW 2537-C	CROW 2538-A	CROW 2538-B	CROW 2538-C	CROW 2539-A	CROW 2539-B	CROW 2539-C	CROW 2540-A	CROW 2540-B	CROW 2540-C
U Total in 50 mg Sample (%)	74.12	74.04	74.24	73.51	73.44	73.26	76.7	76.78	76.81	74.44	74.45	74.42	73.12	73.18	73.1
U Total (mg)	37.06	37.02	37.12	36.76	36.72	36.63	38.35	38.39	38.41	37.22	37.23	37.21	36.56	36.59	36.55
Elapsed Time (d)	Retention (%)														
0	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
0.02	94.40	94.90	99.00	97.90	92.40	97.50	95.60	98.80	95.10	92.00	96.00	93.50	94.80	95.80	93.60
0.13	72.90	73.30	97.00	88.20	86.40	90.70	78.40	92.80	73.80	63.80	79.30	70.10	87.80	78.40	71.70
0.31	66.30	51.00	94.40	76.70	77.10	81.50	59.10	82.90	50.60	45.60	69.10	50.80	77.10	59.80	54.00
1	45.50	34.90	72.30	64.40	54.30	60.20	29.20	54.60	18.30	30.70	52.50	34.20	59.90	43.80	35.10
1.31	40.80	32.30	65.60	62.70	51.00	57.60	25.90	49.40	16.40	27.90	48.60	31.10	54.30	41.40	31.30
2	36.10	26.30	45.30	57.90	42.50	44.00	20.10	32.30	12.30	21.40	38.10	25.40	44.10	36.10	24.10
2.31	34.50	24.20	37.40	56.10	40.60	41.50	19.00	26.60	11.10	19.20	34.70	23.20	41.80	34.10	22.10
3	30.90	20.10	27.60	52.40	38.60	37.80	17.30	20.70	8.00	14.60	27.90	19.20	36.90	29.30	18.70
4	26.20	15.90	21.80	50.00	36.90	34.10	15.50	18.60	5.70	10.10	21.20	16.00	33.20	24.30	16.10
7	18.70	7.60	16.40	44.50	28.60	26.50	11.70	14.50	2.10	4.60	10.40	9.70	25.30	11.50	11.90
9	13.90	5.70	13.70	41.20	20.20	22.30	9.90	10.60	1.10	4.40	8.80	7.70	21.40	7.60	10.40
11	10.50	5.10	11.90	37.10	14.30	18.10	8.40	8.30	1.10	4.40	8.70	7.50	18.40	5.90	9.50
14	7.80	4.50	9.90	30.70	11.00	14.30	7.00	6.80	1.10	4.40	8.70	7.50	14.90	5.70	8.60
21	7.60	4.50	7.40	16.10	6.70	9.70	6.50	6.50	1.00	4.40	8.70	7.50	9.30	5.70	7.80
28	7.60	4.50	5.90	11.00	6.30	9.40	6.50	6.40	1.00	4.40	8.70	7.50	7.50	5.70	7.60
36	7.60	4.50	5.80	6.70	6.30	9.40	6.40	6.40	1.00	4.40	8.70	7.50	7.40	5.70	7.50
42	7.50	4.50	5.70	5.00	6.30	9.30	6.40	6.40	1.00	4.40	8.70	7.50	7.40	5.70	7.50
49	7.50	4.50	5.70	3.90	6.30	9.30	6.40	6.40	1.00	4.40	8.70	7.50	7.40	5.60	7.50
56	7.50	4.40	5.70	3.40	6.30	9.20	6.40	6.30	1.00	4.40	8.60	7.50	7.30	5.60	7.50
63	7.50	4.40	5.70	3.20	6.30	9.20	6.40	6.30	1.00	4.30	8.60	7.50	7.30	5.60	7.40
71	7.50	4.40	5.60	3.20	6.30	9.20	6.40	6.30	1.00	4.30	8.60	7.40	7.30	5.60	7.40
84	7.50	4.40	5.60	3.10	6.20	9.10	6.40	6.30	1.00	4.30	8.60	7.40	7.30	5.60	7.40
100	7.50	4.40	5.60	3.10	6.20	9.10	6.30	6.30	0.90	4.30	8.60	7.40	7.30	5.60	7.40

Table 2: X-Ray Fluorescence Results

Sample No	CROW 2533-A	CROW 2533-B	CROW 2533-C	CROW 2537-A	CROW 2537-B	CROW 2537-C	CROW 2538-A	CROW 2538-B	CROW 2538-C	CROW 2539-A	CROW 2539-B	CROW 2539-C	CROW 2540-A	CROW 2540-B	CROW 2540-C
U Total in 50 mg Sample, (%)	74.12	74.04	74.24	73.51	73.44	73.26	76.7	76.78	76.81	74.44	74.45	74.42	73.12	73.18	73.1
U in a Sample Initial (mg)	37.06	37.02	37.12	36.76	36.72	36.63	38.35	38.39	38.41	37.22	37.23	37.21	36.56	36.59	36.55
U in a Sample Calculated from Extracted U (mg)	34.3	35.4	35.04	35.62	34.43	33.3	35.9	36	38	35.6	34	34.5	33.9	34.5	33.8
U Residual on a Filter After the Completion Calculated (mg)	2.76	1.62	2.08	1.14	2.29	3.33	2.45	2.39	0.41	1.62	3.23	2.71	2.66	2.09	2.75
U Residual on a Filter XRF Analyses After the Completion (mg)	0.6	0.7	0.7	0.8	0.8	0.8	0.4	0.4	1.8	0.5	0.6	0.3	0.3	0.5	0.4
Difference	2.16	0.92	1.38	0.34	1.49	2.53	2.05	1.99	-1.39	1.12	2.63	2.41	2.36	1.59	2.35
Standard Error (%)	6	2	4	1	4	7	5	5	-4	3	7	6	6	4	6

Table 3: 3-Parameter Curve Fitting Results and DWY Classification

Sample Number	f1	f2	f3	T1	T2	T3	MSD (%)	D	W	Y
CROW 2533-A	45.41	47.15	7.44	0.14	2.98	393491550	1.7	93	7	
CROW 2533-B	53.50	42.19	4.30	0.13	2.10	7.019E+09	0.7	96	4	
CROW 2533-C	87.23	7.63	5.14	1.49	14.58	123891016	3.1	87	13	
CROW 2537-A	34.08	64.36	1.56	0.22	11.16	242015638	1.8	34	66	
CROW 2537-B	43.55	50.59	5.87	0.30	4.89	688967288	2.0	94	6	
CROW 2537-C	47.98	43.05	8.97	0.55	4.98	1.556E+09	1.2	91	9	
CROW 2538-A	72.54	21.09	6.37	0.27	3.29	115028268	0.4	94	6	
CROW 2538-B	81.43	12.38	6.20	0.90	5.36	822162027	1.4	94	6	
CROW 2538-C	76.82	22.27	0.91	0.23	1.86	19317409	0.5	99	1	
CROW 2539-A	52.58	43.20	4.22	0.09	1.46	7.842E+09	0.4	96	4	
CROW 2539-B	23.44	68.15	8.42	0.07	1.65	2.836E+10	0.6	92	8	
CROW 2539-C	52.88	39.75	7.37	0.12	1.74	2.232E+10	0.3	93	7	
CROW 2540-A	45.67	47.09	7.24	0.42	5.03	94634910	1.6	93	7	
CROW 2540-B	42.78	51.96	5.26	0.13	2.54	1.686E+09	1.1	95	5	
CROW 2540-C	49.99	40.81	9.20	0.13	1.46	213.001	0.7	91	9	

In Table 3 all the samples have a very high fraction of material in class D, with the exception of sample CROW 2537-A. A review of the dissolution kinetic shows that at day 9 roughly 60% of the material had been dissolved. In this case, the low D percentage is likely due to uncertainty in the fitting process.

Table 4 shows the data from Table 3 and the subsequent annual limit on intake (ALI) and derived air concentration (DAC). The final ALI and DAC values were calculated by taking a weighted sum of the percent contribution of each solubility class within a sample multiplied by the default ALI and DAC for that solubility class, from 10 CFR 20.

Table 4: ICRP 30 Classification and Dosimetric Quantities for Crow Butte

Sample Number	Type D (%)	Type W (%)	Type Y (%)	ALI (µCi)	DAC (µCi/ml)
CROW 2533-A	93	7	0	0.99	4.86E-10
CROW 2533-B	96	4	0	0.99	4.92E-10
CROW 2533-C	87	13	0	0.97	4.74E-10
CROW 2537-A	34	66	0	0.87	3.68E-10
CROW 2537-B	94	6	0	0.99	4.88E-10
CROW 2537-C	91	9	0	0.98	4.82E-10
CROW 2538-A	94	6	0	0.99	4.88E-10
CROW 2538-B	94	6	0	0.99	4.88E-10
CROW 2538-C	99	1	0	1.00	4.98E-10
CROW 2539-A	96	4	0	0.99	4.92E-10
CROW 2539-B	92	8	0	0.98	4.84E-10
CROW 2539-C	93	7	0	0.99	4.86E-10
CROW 2540-A	93	7	0	0.99	4.86E-10
CROW 2540-B	95	5	0	0.99	4.90E-10
CROW 2540-C	91	9	0	0.98	4.82E-10
Average				0.98	4.8E-10

The results show that the average ALI for this material is 0.98 µCi and the average DAC is 4.8 µCi/ml. These values are slightly lower than the default class D values, but still have a very high degree of solubility.

It is important to note and clarify that data in the original report (Table 1A and 3A under NRC submission (ML102640194) dated 3/16/2011), was based directly on the dissolution kinetics table, e.g. the fraction of material that had dissolved in the first 10 days (percentage of class D material) was determined using the formula "100% - fraction remaining on day 11". However, after the most recent discussions with the NRC it was clarified that use of the fitting parameters is the preferred method. Therefore, the DWY classification results in Table 4 above have been updated to reflect this change. It should be noted that the final result, an ALI of 0.98 µCi and DAC of 4.8 µCi/ml is the same as the original submission.

As a further point of clarification, the 2-parameter fit results shown in the original submission are used only as inputs to ICRP 66 based internal dosimetry models, which require the F1, T1 and T2 values. These fits were not used in determining the DWY classification. For determining DWY classifications, the 3-parameter fit following Kalkwarf was used.

References

Ansoborlo, E.; Hengé-Napoli, M.H.; Chazel, V.; Gibert, R.; Guilmette, L.A. *Review and Critical Analysis of Available In Vitro Dissolution Tests*, Health Physics, 77(6): 638-645; 1999.