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Nuclear Management Company, LLC

L-HU-05-012
10 CFR Part 26 Appendix A

June 3, 2005

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

Monticello Nuclear Generating Plant
Docket 50-263
License No. DPR-22

Prairie Island Nuclear Generating Plant, Units 1 and 2
Dockets 50-282 and 50-306
License Nos. DPR-42 and DPR-60

REPORT OF UNSATISFACTORY BLIND PERFORMANCE TESTING RESULTS

In accordance with 10 CFR Part 26 Appendix A, Subpart B, section 2.8(e)(4), Nuclear Management Company, LLC (NMC) hereby reports unsatisfactory blind performance testing results from MEDTOX Laboratories for the Fitness For Duty (FFD) Program Performance Data for Corporate, Monticello Nuclear Generating Plant (MNGP), and Prairie Island Nuclear Generating Plant (PINGP).

On March 4, 2005, MNGP received an unsatisfactory blind specimen test result. Specifically, a blind specimen submitted as positive for 6-acetylmorphine (6-AM) was reported by the laboratory as negative. This result constituted a false-negative result. An NMC investigation into the extent of condition identified thirteen (13) additional unsatisfactory 6-AM blind specimen test results dating back to December 6, 2003. Of these, ten (10) were PINGP blind submittals and three (3) were MNGP blind submittals. As detailed in the enclosed MEDTOX corrective action letter, use of a gas chromatography/mass spectrometry (GCMS) qualitative screening process for 6-AM caused the failure to identify the specimens as positive for 6-AM.

MEDTOX has implemented corrective actions to prevent recurrence. Effectiveness of these corrective actions was demonstrated through retesting of all available (11) previously reported negative blinds for 6-AM under a quantitative limit of detection GCMS process. Each of the retested specimens yielded results positive for 6-AM.

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Likewise, blind specimens with 6-AM submitted subsequent to implementation of corrective actions have yielded expected results. NMC additionally retested all available true-donor specimens under the enhanced process obtaining negative 6-AM results.

NMC has entered the identification of unsatisfactory blind specimen results into its Corrective Action Program and developed additional corrective actions to ensure timely processing of unsatisfactory results. NMC will recognize the requirement to describe the actions taken to correct program weaknesses in the MNGP/PINGP Fitness for Duty (FFD) Program Performance Data Report for the period ending June 30, 2005 in accordance with 10 CFR 26.71(d). NMC has previously briefed NRC about this matter.

This letter makes no new commitments or changes to existing commitments.

Edward J. Weinkam
Director, Regulatory Services
Nuclear Management Company, LLC

Enclosure

cc: Commissioner, Minnesota Department of Commerce

ENCLOSURE

MEDTOX CORRECTIVE ACTION LETTER

5 Pages Follow

MEDTOX®
LABORATORIES, INC.

May 4, 2005

Mr. Randy Cleveland
Nuclear Management Company
700 - 1ST Street
Hudson, WI 54016

Dear Mr. Cleveland:

This is a follow-up letter to our correspondence dated April 5, 2005 regarding results of external blind QC samples submitted to MEDTOX Laboratories by NMC divisions over the last year.

As you are aware, NMC submitted several blind QC samples containing codeine, morphine and 6-Acetylmorphine to MEDTOX between December of 2003 and March of 2005. These specimens were processed as routine specimens utilizing the following procedure: initial screening was performed by immunoassay and all specimens presumptive positive for opiates were analyzed by GCMS. The GCMS confirmation procedure provides quantitative results for codeine and morphine and is used as a qualitative screen for 6-AM by monitoring appropriate ion fragments and ratios. When the qualitative results indicate that 6-AM may be present, the specimen is quantitatively confirmed by a second GC/MS procedure. This protocol meets the requirements of 10 CFR Part 26, Section 2.7(f)(5) which states, "Confirmatory tests for opiates shall include a test for 6-monoacetylmorphone (MAM) if the screening test is presumptive positive for morphine." The rule is not specific with regard to detection thresholds.

In reviewing results for the specimens submitted within the indicated time frame, it was determined that there were several specimens that were reported negative for 6-Acetylmorphine. At the time of our initial correspondence, we had received information from the Medical Review Officer (MRO) identifying 11 specimens as blinds. All of the data for those specimens was retrieved and reviewed and a summary was provided in our previous letter. We requested, and were granted, permission to retest all blind specimens submitted during the identified time frame as a part of our internal investigation into the discrepancies. There were additional specimens identified as blinds for inclusion in the review and retesting process. In all, 18 samples were identified, original data reviewed and specimens were retested for 6-Acetylmorphine.

The results are summarized in the table below. Re-review of the initial results indicated that 4 were reported as positive, 4 appeared to be 'borderline' on the screen and were not processed for confirmation testing, 2 were present on the screen but were 'missed' (administrative errors), and 8 samples were negative on the initial GCMS screen. Outside of the administrative errors in two of the samples where the technologists failed to request the confirmatory test, it appears that the protocol was followed correctly as designed. Certifying scientists have participated in re-training corrective action to ensure that analytical batches are reviewed appropriately to ensure that administrative errors do not recur.

Sixteen of the 18 specimens were available for retesting. All of the specimens tested by the directed GC/MS confirmation method confirmed the presence of 6-Acetylmorphine. Quantitative results varied somewhat, indicating that there may have been some degradation of the specimens over time.

	Initial Results			Retest Results	
Accession #	Codeine	Morphine	6AM-SCRN	6AM Quant	Comments
L3081718	407	387	BORDERLINE	N/A	Disposed 1/21/05
L3349357	381	382	ADMIN	N/A	Disposed 2/25/05
L3631732	422	439	POS – 15	17	
L3840707	425	429	NEG	13	
L4362361	396	413	BORDERLINE	16	
L4604287	377	422	NEG	16	
L4669763	384	412	NEG	18	
L4736099	397	455	BORDERLINE	17	
L4754461	426	444	NEG	15	
L5103529	476	462	NEG	13	
L5220558	401	445	NEG	12	
L5685859	463	349	POS-11	11	
L3788063	453	468	NEG	13	
L4366126	382	392	BORDERLINE	13	
L5009504	427	430	NEG	11	
L5652844	445	391	POS-10	10	
L5779841	440	445	POS-14	13	
L5827391	425	425	ADMIN	13	

As a part of our internal investigation, the assay was challenged 3 different times with a series of internal blind samples spiked with codeine, morphine and 6-Acetylmorphine at 10, 15, 20, 25 and 50 ng/ml. Internal blind QC specimens go through the entire process from processing through testing, certification and reporting to ensure that they are handled in the same manner as routine specimens. All specimens in this cycle were properly identified and reported. Results from a prior set of internal blinds processed in January were also reviewed. Two sets of samples containing 6-Acetylmorphine at 10, 15, 20 and 25 ng/ml had been submitted; 1 of 2 samples spiked at 10 ng/ml was not identified on the GCMS screen and the remaining samples were properly identified.

From a technical perspective, the primary GCMS confirmation procedure was developed with codeine and morphine as target compounds for quantitative purposes and qualitative 6-AM monitoring. Codeine and morphine are excreted from the body as glucuronide conjugates which improves their solubility in urine. Since it is important to measure the total concentrations of codeine and morphine in the sample, the GCMS opiate assay incorporates an enzymatic hydrolysis step to 'free' the drugs from their conjugated form. The glucuronidase enzyme treatment can lead to small losses of 6-Acetylmorphine during the extraction procedure which may affect recovery of this analyte. These small losses will have a more significant impact when starting concentrations of 6-AM are low. The specific GCMS assay for 6-Acetylmorphine is optimized in a lower concentration range and does not include a hydrolysis step. It is also true that 6-Acetylmorphine is susceptible to decay during room temperature storage conditions, varying conditions during handling at the collection site and transportation to the laboratory.

Our evaluation of the GCMS opiate assay as a 6-AM screening method indicates that concentrations in the range of 10 – 15 ng/ml are approaching the 'threshold' of detection for 6-AM. When we operate near the 'threshold' in any assay, analytical variability predicts that some results will fall below the threshold, some results will be at the threshold and some results will fall above the threshold. The results of the NMC blind samples confirm that this is the case. If we consider the two 'administrative' samples as positives, six samples were positive (above threshold), four were 'borderline (at the threshold) and 8 were negative (below the threshold). The results are consistent with what would be expected when challenging the GCMS screen at the threshold.

Assay detection limits and day-to-day analytical variability are inherent aspects of any laboratory testing program. It is generally recommended that blind proficiency samples be targeted at concentrations sufficiently above the cutoff to minimize the effects of variability at the threshold while still challenging the accuracy of the assay. Rule of thumb is 200% of threshold; i.e. for an assay with a

cutoff of 10 ng/ml, proficiency samples would ideally be at least 20 ng/ml. The specimens submitted in this case were targeted in the range where variability at the assay threshold very likely impacted the results.

During our discussions, you have indicated that even though the language in 10 CFR Part 26 regarding detection thresholds for 6-AM is not specific, you believe it is the intent of the program to test for 6-Acetylmorphine at as low a concentration as possible. Identifying 6-AM at levels below 10 – 15 ng/ml requires that samples be subjected to the specific confirmation procedure for 6-AM without initial GCMS screening. To comply with your request, we have modified our internal protocol for specimens tested under the rule so that the GCMS screening step is bypassed and all morphine positive samples are tested in the quantitative 6-AM confirmation procedure and reported to limit of detection. This modification effectively eliminates the issue of borderline screening results. This change was effective April 6, 2005.

To ensure that no 'real' donor results were affected by the original testing protocol, we have also performed a retrospective data audit and directed 6-Acetylmorphine testing on all specimens reported positive for opiates in the previous 12 months. Results of all 6-AM testing were negative; results are presented in the table below.

Acount #	Accession #	Codeine	Morphine	Initial GCMS Screen Result	6-AM Confirmation Result
10148	L3944039	NEG	384	NEG	Negative
10148	L4200485	>3000	1443	NEG	Negative
10148	L4399031	NEG	592	NEG	Negative
10148	L4660845	NEG	394	NEG	Negative
10148	L4820606	NEG	446	NEG	Negative
10148	L5083065	NEG	536	NEG	Negative
10148	L5659472	1954	597	NEG	Negative
10539	L3972663	NEG	518	NEG	Negative
10539	L5573315	NEG	686	NEG	Negative
10539	L5723595	>3000	1222	NEG	Negative
10539	L5818026	203	521	NEG	Negative
10539	L5904244	>3000	2147	NEG	Negative
10539	L5936507	NEG	489 (X2)	NEG	Negative

In summary, our internal investigation has indicated that the root cause of the discrepant results reported for blind specimens is most likely the fact that the concentrations of the specimens submitted were in the range of 15 – 16 ng/ml, very close to the detection limits of the GCMS screening method utilized to monitor 6-Acetylmorphine. The variable results reported are consistent with assay behavior at the 'threshold' and a more sensitive assay is required to detect 6-AM 100% of the time in that range. As corrective action, we have modified the protocol to bypass the initial screening test and have reviewed the process with analysts and certifying scientists to ensure compliance.

We believe that these actions provide sufficient resolution to the issues under consideration. While the previous protocol for monitoring 6-Acetylmorphine complies with the requirements of 10 CFR Part 26, it does not provide adequate sensitivity for reporting results below 10 ng/ml.

We are also enclosing a copy of the summary of our internal corrective action activities in regards to this event. Please contact us if you have questions or require additional information or documentation.

Sincerely,

Jennifer A. Collins, Ph.D.
Laboratory Director
MEDTOX Laboratories, Inc.

Mitchell F. LeBard
Associate Director of Forensic Toxicology
MEDTOX Laboratories, Inc.