2020 MAY 29

145-CNNO-20-0020-L

Ms. Haidy Tadros
Director General
Directorate of Nuclear Cycle and Facilities Regulation
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

OPERATIONS
Office of the Vice-President & CNO

Dear Ms. Tadros:

Feedback on Proposed Updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3

The purpose of this letter is to provide feedback on the proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, in response to the CNSC's, 2020 March 12 invitation to provide feedback [1].

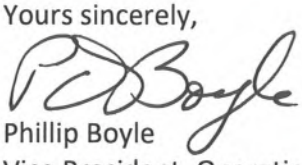
Please see attached a letter from our external counsel, Hicks Morley Hamilton Stewart Storie LLP, submitted on behalf of Canadian Nuclear Laboratories (CNL) (Attachment A).

Attachment A is supported and supplemented by the following enclosures, which are all contained within the attachment:

- Enclosure 1 – Feedback on Proposed Updates to REGDOC-2.2.4, Fitness For Duty, Volume II: Managing Alcohol and Drug Use, Version 3, prepared by Hicks Morley
- Enclosure 2 – Case Law Update, prepared by Hicks Morley
- Enclosure 3 – Expert Report of DriverCheck – Dr. Melissa Snider-Adler
- Enclosure 4 – Expert Report of Dr. Leo Kadehjian

If you require further information or have any questions regarding this submission, please contact Mr. Shaun Cotnam, CNL Chief Regulatory Officer, at 613-639-1353.

Yours sincerely,



Phillip Boyle
Vice President, Operations
Chief Nuclear Officer
Site Licence Holder – Chalk River Laboratories
Phone: personal information redacted
Email: personal information redacted

© Canadian Nuclear Laboratories

Attachment (1)

References:

[1] Canadian Nuclear Safety Commission, Email from cnsc.info.ccsn@canada.ca to cnsc.info.ccsn@canada.ca, *Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3*, 2020 March 12.

c.	R. Clarke (CNSC)	L. Forrest (CNSC)	G. Lamarre (CNSC)	K. Murthy (CNSC)
	B. Torrie (CNSC)	cnsc.forms-formulaires.ccsn@canada.ca		
	N. Caloren	C. Clark	S. Cotnam	J. Gilbert
	W. Graydon	S. Karivelil	L. Nel	M. Odesse
	T. Purcell	R. Swartz	C. Williams	D. Wood
	>CR CNSC Site Office	>CR Licensing		

© Canadian Nuclear Laboratories

Attachment A

Letter from Hicks Morley to CNSC on behalf of Licensees (Bruce Power, Ontario Power Generation, New Brunswick Power and Canadian Nuclear Laboratories) re: Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3

Attachment A

Hicks Morley Hamilton Stewart Storie LLP
77 King St. W., 39th Floor, Box 371, TD Centre
Toronto, ON M5K 1K8
Tel: 416.362.1011 Fax: 416.362.9680

HENRY Y. DINSDALE
henry.dinsdale@hicksmorley.com
Direct: 416.864.7067

Toronto
Waterloo
London
Kingston
Ottawa

File No. 3917-66
May 29, 2020

VIA EMAIL

Mr. G. Frappier
Director General
Directorate of Power Reactor Regulation

Ms. H. Tadros
Director General
Directorate of Nuclear Cycle and Facilities Regulation

Canadian Nuclear Safety Commission
280 Slater Street, P.O. Box 1046, Station B
Ottawa, ON K1P 5S9

Dear Mr. Frappier and Ms. Tadros:

Re: Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3

We are counsel to Bruce Power ("BP"), Canadian Nuclear Laboratories ("CNL"), New Brunswick Power Corporation ("NBP") and Ontario Power Generation ("OPG") (collectively, the "Licensees") with respect to the implementation of REGDOC-2.2.4., *Fitness for Duty, Volume II: Managing Alcohol and Drug Use* (the "REGDOC").

On November 30, 2018, CNL [1], NBP [2] and OPG [3] each requested that the CNSC incorporate oral fluid testing into the REGDOC's testing regime. BP wrote to the CNSC with the same request on December 3, 2018 [4].

In January, 2019, the Licensees proposed additional changes to the REGDOC. First, in response to an inquiry from the CNSC about the cut-off levels for "point of care [collection] and laboratory based oral fluid testing" [5], the Licensees identified their intention to conduct point of collection screening by urine testing [6]. The Licensees also proposed to the CNSC that two additional minor changes be made to two of the appendices of the REGDOC [7 (a)-(c)].

After additional discussions between the CNSC and industry representatives, [8-9], on March 20, 2019, the CNSC wrote to each of the Licensees seeking additional information in respect of the above-noted requests. It listed a series of specific questions for the Licensees' attention in an "Enclosure 1" [10 (a)-(d)].

On June 28, 2019, the Licensees jointly responded to the questions posed in Enclosure 1, enclosing various material including a proposed amended REGDOC, a Legal Brief and two Expert Reports [11 (a)-(d)]. On July 19, 2019, the Licensees jointly provided the CNSC with an updated proposed amended REGDOC to correctly identify the proposed cut-off level for Oral Fluid Cannabinoids for immunoassay laboratory-based drug screening [12].

On March 12, 2020, each of the Licensees received an email from the CNSC, in which it invited feedback on proposed updates to the REGDOC [13]. This invitation confirmed that the consultation period was only open to feedback on the specific changes in the current update, which are highlighted in a draft version 3 of the REGDOC ("REGDOC V3") [14].

The purpose of this correspondence is to provide the Licensees' joint feedback on certain of the specific changes in the REGDOC V3. In particular, this letter briefly identifies those changes in respect of which feedback is provided. For full information in respect of such feedback, it will be necessary to review the following four substantive enclosures:

(i) Feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, prepared by Hicks Morley [15];

(ii) Case Law Update, prepared by Hicks Morley [16];

(iii) Expert Report of DriverCheck – Dr. Melissa Snider-Adler [17]; and

(iv) Expert Report of Dr. Leo Kadehjian [18].

The Feedback, Case Law Update and Expert Reports make reference to jurisprudence, studies, articles and other publications, which are listed with full citations. To the extent the CNSC would like copies of any of the cited material, we would be pleased to provide copies under separate cover.

Specific Changes in respect of which Feedback is provided

1. *B5: Oral fluid immunoassay screening*
   B6: Oral fluid GC-MS and LC-MS/MS confirmation

   Table B5 provides the oral fluid analysis drug panel and the associated cut-off values to be used for immunoassay screening.

   Table B6 provides the oral fluid analysis drug panel and the associated cut-off values to be used for GC-MS and LC-MS/MS confirmation.

2. *6. Alcohol- and Drug-Testing Processes*

   Testing methodologies

3. *6.2 Drug-testing process*

   For urine drug testing, licensees shall use a laboratory accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA). For oral fluid drug testing, licensees shall use a laboratory accredited by SAMHSA or a laboratory that meets ISO/IEC 17025.

4. *6.2.1 Point of collection testing*

   Licensees may choose to utilize point of collection testing (POCT) as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral-fluid-based laboratory test.

   If licensees choose to utilize POCT, a protocol shall be established and documented. Non-negative results shall be verified by laboratory immunoassay screening and confirmation testing.

   The licensee shall compare negative POCT results with laboratory-based results on an anonymous and aggregate basis for quality assurance purposes.

   Licensees who decide to conduct POCT shall select devices that are:

   1. Health Canada certified or approved by the Department of Justice Canada for roadside use;

   2. independently evaluated by qualified laboratory personnel on an initial and annual basis to ensure that the devices meet forensic standards such as specificity, sensitivity and accuracy;

   3. calibrated to the extent possible with the urine or oral fluid drug testing cut-off levels established in appendix B (see table B2 for urine immunoassay or table B5 for oral fluid immunoassay)

   POCT devices shall not be used in pre-placement or follow-up testing circumstances.

If you require further information or have any questions regarding these submissions, please contact the individual Licensees.

Yours truly,

Henry Y. Dinsdale

Enclosures

c: Hicks Morley: D. Jozefacki
BP: M. Burton, L. Mahoney and J. Martelli
OPG: J. Vecchiarelli and H. Arthurs
NBP: B. Plummer and C. DeLong
CNL: S. Cotnam and N. Caloren

References

1. Canadian Nuclear Laboratories Letter, P. Boyle to H. Tadros, November 30, 2018, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, VII: Managing Alcohol and Drug Use*, 145-CNNO-18-0035-L, e-Doc# 5725125

2. New Brunswick Power Letter, B. Plummer to G. Frappier, November 30, 2018, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, VII: Managing Alcohol and Drug Use*, TU 06374 PICA 18-100, e-Doc# 5738361

3. Ontario Power Generation Letter, S. Granville to G. Frappier and H. Tadros, November 30, 2018, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, VII: Managing Alcohol and Drug Use*, N-CORR-00531-19432, e-Doc# 5735130

4. Bruce Power Letter, M. Burton to G. Frappier and H. Tadros, December 3, 2018, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, VII: Managing Alcohol and Drug Use*, NK21-CORR-00531-14839 / NK29-CORR-00531-15560 / NK37-CORR-00531-03118, e-Doc# 5729839

5. CNSC Email, S. Karkour to R. Manley et. al, December 11, 2018, *Request for Information Re. Industry Request to Use Oral Fluid Testing,* e-Doc# 5731460

6. Ontario Power Generation Email, R. Manley to S. Karkour, January 9, 2019, *REGDOC-2.2.4, Fitness for Duty, Volume II – CNSC Staff Questions Re: Oral Fluid Testing,* N-CORR-00531-19509, e-DOC# 5756694

7. (a) Canadian Nuclear Laboratories E-mail, S. Cotnam to H. Tadros, January 17, 2019, *REGDOC-2.2.4, Fitness for Duty, Volume II - Managing Alcohol and Drug Use, Version 2 - CNL 's Suggested Changes to Appendices*, 145-CNNO-19-0002-E, e-Doc# 5765611

   (b) Ontario Power Generation E-mail, R. Manley to G. Frappier and H. Tadros, January 18, 2019, *REGDOC-2.2.4, Fitness for Duty, Volume II - Managing Alcohol and Drug Use, Version 2 - Suggested Changes*, N-CORR-00531-19524, e-Doc# 5850965

   (c) (c) Bruce Power Letter, M. Burton to G. Frappier, January 18, 2019, *REGDOC-2.2.4, Fitness for Duty, Volume II -Managing Alcohol and Drug Use, Version 2 - Suggested Changes to Appendices*, NK21-CORR-00531-14925/NK29-CORR-00531-15669/NK37-CORR-00531-03151, e-Doc# 5768205

8. CNSC-Industry Meeting Minutes, February 22, 2019, *REGDOC-2.2.4 CNSC-Industry Meeting 22FEB2019 Agenda and Minutes*, e-Doc# 5795152

9. CNSC-Industry Meeting Agenda, March 6, 2019, *REGDOC-2.2.4 CNSC-Industry Meeting March 6, 2019*, e-Doc# 5825987

10. (a) CNSC Letter to Bruce Power, G. Frappier and H. Tadros to M. Burton, March 20, 2019, *Use of Oral Fluid Testing in the Implementation of REGDOC-2.2.4., Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions,* e-Doc# 5841221

    (b) CNSC Letter to Canadian Nuclear Laboratories, H. Tadros to S. Cotnam, March 20, 2019, *Use of Oral Fluid Testing in the Implementation of REGDOC-2.2.4., Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions*, e-Doc# 5846981

    (c) CNSC Letter to New Brunswick Power, G. Frappier to B. Plummer, March 20, 2019, *Use of Oral Fluid Testing in the Implementation of REGDOC-2.2.4., Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions*, e-Doc# 5844035

    (d) CNSC Letter to Ontario Power Generation, G. Frappier and H. Tadros to S. Granville, March 20, 2019, *Use of Oral Fluid Testing in the Implementation of REGDOC-2.2.4., Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions,* e-Doc# 5839242

11.(a) Canadian Nuclear Laboratories Letter, S. Cotnam to H. Tadros, June 28, 2019, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions*, 145-CNNO-19-0026-L

(b) New Brunswick Power Letter, B. Plummer to G. Frappier, June 28, 2019, *NB Power Response to Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions*, TU 06374 PICA 18-1004

(c) Ontario Power Generation Letter, S. Granville to G. Frappier and H. Tadros, June 28, 2019, *Use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, and Proposed Revisions*, CD# N-CORR-0-531-19788

(d) Bruce Power Letter, M. Burton to G. Frappier, June 28, 2019, *Bruce Power provides additional information regarding use of oral fluid testing in the implementation of REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use*, NK21 -CORR-00531 -15196 / NK29-CORR-00531-15982 / NK37-CORR-00531-03229

12. Ontario Power Generation Email, Jack Vecchiarelli to Suzanne Karkour, July 19, 2019, *RE: Request for Clarification Re: REGDOC-2.2.4 Volume II submission*

13. Canadian Nuclear Safety Commission Email from CNSC.Info.CCSN@canada.ca to CNSC.Info.CCSN@canada.ca, March 12, 2020, *Subject: Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version* 3

14. REGDOC-2.2.4: Fitness for Duty, Volume II: Managing Alcohol and Drug Use, version 3

15. Feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, prepared by Hicks Morley, May 29, 2020

16. Case Law Update, prepared by Hicks Morley, May 29, 2020

17. Expert Report from DriverCheck – Dr. Melissa Snider-Alder regarding REGDOC 2.2.4 Fitness for Duty, Volume II : Managing Alcohol and Drug Use, version 3, May 27, 2020

18. Expert Report from Dr. Leo Kadehjian regarding REGDOC 2.2.4 Fitness for Duty, Volume II : Managing Alcohol and Drug Use, version 3, May 28, 2020

Enclosure 1

Feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, prepared by Hicks Morley

FEEDBACK ON PROPOSED UPDATES TO REGDOC-2.2.4, FITNESS FOR DUTY, VOLUME II: MANAGING ALCOHOL AND DRUG USE, VERSION 3

[Enclosure 1]

[Reference 15]

May 29, 2020

Hicks Morley Hamilton Stewart Storie LLP

77 King Street West, 39th Floor
Box 371, TD Centre
Toronto, Ontario M5K 1K8

Henry Y. Dinsdale
Tel: personal information redacted
LSO No.: 29838G
E-mail: personal information redacted

Dianne E. Jozefacki
Tel: personal information redacted
LSO No.: 63706E
E-mail: personal information redacted

PURPOSE

1. This Brief provides the joint feedback of Bruce Power, Canadian Nuclear Laboratories, New Brunswick Power Corporation and Ontario Power Generation (collectively, the "Licensees") to specific changes in the CNSC's current update to REGDOC 2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, which are highlighted in a draft version 3 ("REGDOC V3"). The Licensees do not comment upon all of the proposed changes in the REGDOC V3.

2. This Brief is supplemented and informed by the following substantive Enclosures:

   (a) Case Law Update, prepared by Hicks Morley [Enclosure 2];

   (b) Expert Report of DriverCheck – Dr. Melissa Snider-Adler [Enclosure 3]; and

   (c) Expert Report of Dr. Leo Kadehjian [Enclosure 4].

SPECIFIC FEEDBACK

3. The Licensees provide feedback to the CNSC on the following aspects of the CNSC's proposed changes to REGDOC-2.2.4 found in Version 3:

   (a) Tables B5 and B6 Oral Fluid Screening and Confirmation Levels

      (i) Oral fluid cannabinoid (or "THC") screening and confirmation levels of 5 ng/ml and 2 ng/ml, respectively, versus 10 ng/ml and 10 ng/ml

      (ii) Technical Impediments to a THC oral fluid screening cut-off of 5 ng/ml

      (iii) Oral fluid cut-off levels for testing other than THC

   (b) Section 6 Alcohol- and Drug-Testing Processes: Feedback on testing methodology

   (c) Section 6.2 Drug-testing Process: Feedback with respect to licensing requirements for urine analysis and oral fluid drug testing

   (d) Section 6.2.1 Initial Point of Collection Test (POCT) urine screening

      (i) Use of POCT urine screening as an initial cannabinoid screen to determine if oral fluid testing for THC is warranted

      (ii) Use of POCT devices for reasonable grounds testing

4. Each of these areas of feedback is discussed in more detail below.

(a) Tables B5 and B6: Oral Fluid Screening and Confirmation Levels

(i) Oral fluid THC screening and confirmation levels of 5 ng/ml and 2 ng/ml versus 10 ng/ml and 10 ng/ml

5. In their June 28, 2019 submissions to the CNSC, including as captured in the enclosed June 2019 Legal Brief and the enclosed June 2019 Expert Reports from Dr. Melissa Snider-Adler and Dr. Leo Kadehjian, and in the July 19, 2019 email submission to the CNSC enclosing an updated proposed amended REGDOC, the Licensees proposed to the CNSC 10 ng/ml screening and confirmation test cut-off levels for THC.

6. The CNSC's current update identifies screening and confirmation test cut-off levels for cannabinoids of 5 ng/ml and 2 ng/ml respectively.

7. The Licensees maintain their submission that the 10 ng/ml cut-off level is the most appropriate and legally defensible level and provide the following additional commentary in support of that submission.

8. As set out in the June 2019 Legal Brief, and discussed once again in the Case Law Update, Canadian jurisprudence requires that the Licensees' Fitness for Duty policies, which are to be promulgated pursuant to the REGDOC, be reasonable and constitutional. The REGDOC and the Fitness for Duty policies must balance the interests of the public, the CNSC (as Regulator) and the Licensees (as employers), with the interests of the individuals who are to be subjected to alcohol and drug testing.

9. In particular, to withstand legal scrutiny, current jurisprudence demands the testing methodology and cut-off standards found in the REGDOC and each Licensee's Fitness for Duty policy strike a reasonable balance between workers' individual rights and the objective of ensuring safety from an unacceptable risk of impairment in the workplace.

10. Given the legalization of cannabis in Canada[1], workers may assert that their individual rights include the right to legally consume cannabis while away from work, as workers are entitled to do with alcohol[2], without fear of repercussion in the workplace, provided that such consumption does not result in an unacceptable risk of impairment in the workplace.

11. Therefore, the REGDOC's testing methodology and established THC testing thresholds must effectively determine whether the concentration of THC in a worker's system exceeds a threshold which establishes a scientifically justifiable nexus between the presence of THC and the risk of current impairment.

---

[1] *Cannabis Act,* S.C. 2018, c. 16.

[2] See for example, *Fluor Constructors Canada Ltd. v. I.B.E.W., Local 424*, (2001) 100 L.A.C. (4th) 391 (Elliott) at para. 131 and *Provincial-American Truck Transporters v. Teamsters, Local 880*, [1991] O.L.A.A. No. 16 (Brent) at para. 26.

12. Identifying past use of cannabis, without sufficient correlation to risk of current impairment due to THC, will not strike the required balance. As is discussed in more detail below, the Licensees submit that the 10 ng/ml cut-off level reliably demonstrates a risk of current impairment while the 2 ng/ml cut-off level establishes a less compelling nexus between a positive test result and the likelihood of current impairment at the time of the test.

13. It was for this reason that the Licensees proposed the use of oral fluid testing, rather than urine analysis, for THC. Urine analysis for THC testing has been rejected as a reliable indicator of likely current impairment by courts and labour arbitrators. Relevant jurisprudence on this topic is set out in paragraphs 23-41 of the June 2019 Legal Brief.

14. In contrast, oral fluid testing has been accepted by adjudicators in Canada and other common law jurisdictions as a testing methodology that can be a reliable indicator of likely current impairment. Relevant jurisprudence in this regard is set out in paragraphs 42-55 of the June 2019 Legal Brief. It is also endorsed by the Licensees' Expert Witnesses in their June, 2019 Expert Reports and the Expert Reports forming part of these current submissions.

15. The CNSC must make a policy determination regarding the appropriate screening and confirmation cut-off levels for oral fluid THC testing. The Licensees' feedback is in respect of this point.

16. The Licensees have submitted and continue to submit that the appropriate cut-off level for both screening and confirmation of THC is 10 ng/ml. An understanding of this submission requires recognition of the Licensees' current fitness for duty measures and consideration of the testing concepts of sensitivity and specificity.

17. With respect to the current fitness for duty measures, any drug testing regime will be one of several defence in depth measures already in place at the Licensees' facilities to further ensure the safety of the public, workers, the facilities and the environment. These were generally set out in paragraphs 20-22 of the June 2019 Legal Brief.

18. Alcohol and drug testing will be but one of the measures used to promote and supplement existing measures to ensure fitness for duty in the workplace. The Licensees do not and should not rely solely upon alcohol and drug testing to ensure that workers attend work fit for duty. The reasonableness of the Licensees' testing processes, including the cut-off levels, will be assessed in this context.

19. The concepts of sensitivity and specificity are explained in detail in the Expert Reports of Dr. Snider-Adler (see pages 22-23) and of Dr. Kadehjian (see pages 3-4) enclosed with the Licensees' feedback submissions to the CNSC.

20. In essence, testing sensitivity describes the extent to which the test is effective at correctly identifying a positive result for individuals who have the condition for

which the test is being administered. A test that has a high sensitivity will identify a high percentage of those tested who have a THC level at the chosen cut-off level and will not generate a high percentage of false-negative results.

21. A test's specificity measures how often a test will correctly identify a negative test for individuals who do not have the condition for which the test is being administered. A test with a high specificity will therefore not generate a high percentage of false-positive results.

22. The Licensees have made extensive submissions based on Canadian jurisprudence in support of the proposition that the testing goal of oral fluid testing for THC must be to detect risk of current impairment.

23. It follows that the test to be preferred is one that will establish a reliable nexus between non-negative tests results and current impairment in respect of the individual being tested.

24. This compels one to the conclusion that the chosen testing level must be both highly specific (i.e. does not generate many false-positive results) and at a testing level that, once detected, demonstrates a high likelihood of current impairment.

25. Both Dr. Snider-Adler and Dr. Kadehjian opine that the 10 ng/ml cut-off level establishes a cut-off level that is highly specific.[3] Moreover, both Dr. Snider-Adler and Dr. Kadehjian opine that an oral fluid confirmation testing cut-off level of 10 ng/ml establishes a high likelihood of current impairment at the time of the test[4]. As Dr. Snider-Adler wrote in her Expert Report enclosed with this feedback:

> The timeframe of detection using a cut-off level of 10 ng/mL lines up with the timeframe of acute intoxication with cannabis. In other words, those who use cannabis have a period of acute intoxication, a time when they are experiencing the direct impact of the substance on their brain (the "high" or "inebriation") which can last approximately up to 12 hours. Therefore, there is a correlation with impairment from cannabis and a positive oral fluid test and based on a positive result, it can be concluded that there was a high likelihood of impairment in the workplace when an individual tests positive at or above 10 ng/mL.[5]

26. In contrast, a confirmation testing level of 2 ng/ml reflects a highly sensitive cut-off level, ensuring that there will be fewer false-negative test results. It will, however, be less specific. As such, this will result in a higher number of false-positives. Moreover, a testing cut-off level of 2 ng/ml establishes a less compelling nexus between a positive test result and the likelihood of current

---

[3] Expert Report of Dr. Snider-Adler at pp. 22-23; Expert Report of Dr. Kadehjian at pp. 3-4

[4] Expert Report of Dr. Snider-Adler at pp. 22-23; Expert Report of Dr. Kadehjian at pp. 3-4.

[5] Expert Report of Dr. Snider-Adler at p. 21.

impairment at the time of the test than is the case with a cut-off level of 10 ng/ml. This point was emphasized by Dr. Kadehjian in his Expert Report as follows:

> But lowering the screening cutoff [sic] accordingly extends the window of detection perhaps beyond the established hours during which there are clear and recognized safety-related psychomotor and cognitive deficits. Thus, it may be argued that effects of THC may have sufficiently subsided such that diminished risks of safety-related deficits exist. So there is a trade-off between analytical sensitivity to detect any recent use, vs. the sensitivity and specificity to detect sufficiently recent use with associated recognized safety-related deficits. Thus, to ensure that a positive screening result has sufficient clinical specificity, a long detection window should be avoided.[6]

27. These issues were clearly, and not surprisingly, the focus of the Court in the *TTC* case. In accepting THC oral fluid testing at a cut-off level of 10 ng/ml, the motion judge in the *TTC* case wrote:

> I am satisfied on the evidence that due to the high cut-off levels set out in the TTC Policy (which are higher than the cut-off levels proposed in the draft SAMHSA Guidelines) and the corresponding short windows of detection, the time periods when oral fluid samples test positive for drugs overlap with the time periods during which these drugs impair the psychomotor and cognitive abilities of the person tested. Therefore, there is a likelihood that the person who tested positive was impaired when tested.[7]

28. In light of the spectrum of defence in depth measures already in place to ensure the safety of the public, workers, the facilities and the environment, Canadian workplace drug testing jurisprudence, the legalization of cannabis and current drug testing science, the Licensees submit that the appropriate policy and science-based decision with respect to oral fluid THC testing is to set screening and confirmation cut-off testing levels that establish a test of high specificity with a compelling nexus between a non-negative confirmation test result and the likelihood of current impairment at the time of testing.

29. For these reasons, the Licensees' feedback is that that Tables B5 and B6 of the REGDOC be amended to set a THC screening cut-off of 10 ng/ml and a THC confirmation cut-off level of 10 ng/ml respectively.

(ii) Technical Impediments to a THC oral fluid screening cut-off of 5 ng/ml

30. As set out above, it is the Licensees' recommendation that the THC oral fluid screening and confirmation cut-off levels used in the REGDOC be 10 ng/ml and 10 ng/ml respectively. In the event that the CNSC makes the policy decision to

---

[6] Expert Report of Dr. Kadehjian at p. 3.

[7] *ATU Local, 113 v Toronto Transit Commission*, 2017 ONSC 2078 at para. 114.

impose a lower THC oral fluid confirmation testing cut-off level of 2 ng/ml, there are technical impediments to using the proposed correlated THC oral fluid screening cut-off level of 5 ng/ml.

31. Referencing pages 24 and 25 of Dr. Snider-Adler's Expert Report, it is the Licensees' understanding that screening at 5 ng/ml is not within the capabilities of the Quantisal oral fluid device. This device, which is the device used by the Dynacare laboratory in London, Ontario (the only laboratory that does workplace testing), is calibrated by the manufacturer to screen at either 4 ng/ml or 10 ng/ml. The device cannot screen at 5 ng/ml.

32. As noted at page 24 of Dr. Snider-Adler's Expert Report, while the Draeger DrugTest 5000 oral fluid POCT device has the ability to screen at 5 ng/ml for oral fluid THC, this device does not satisfy the requirements necessary for it to be an acceptable device pursuant to section 6.2.1 of REGDOC V3.

(iii) Oral fluid cut-off levels for testing other than THC

33. The Licensees have no objection to the oral fluid screening levels or confirmation levels for drugs other than THC included in REGDOC V3 (except for Methadone and Benzodiazepines discussed below). There are currently, however, practical problems with some of the oral fluid testing cut-off values contained in Tables B5 and B6 of REGDOC V3 (discussed at pages 23-26 of Dr. Snider-Adler's Expert Report).

34. Specifically, it is our understanding that the Dynacare laboratory in London, Ontario does not currently have the technical ability to test for certain drugs using oral fluid at the screening cut-off levels set out in Table B5, and at the confirmation cut-off levels set out in Table B6.[8] However, it is anticipated that the appropriate oral fluid testing capability for these drugs will be available in 2021. While awaiting this development in testing ability, the Licensees are content to employ urine analysis testing for this spectrum of drugs.

35. With respect to Methadone, the Dynacare laboratory currently tests oral fluid at the screening testing cut-off level of 50 ng/ml and a confirmation cut-off level of 20 ng/ml, as opposed the 20 ng/ml and 15 ng/ml represented in Tables B5 and B6 of REGDOC V3.

36. With respect to Benzodiazepines, the Dynacare laboratory current tests oral fluid at the confirmation cut-off level of 10 ng/ml as opposed the 3 ng/ml confirmation cut-off level represented in Table B6 of REGDOC V3.

37. It is the Licensees' understanding that the cut-off levels currently employed by the Dynacare laboratory for both Methadone and Benzodiazepines are effective in detecting relevant levels of the drugs and that the difference in effectiveness

[8] See pp. 25-26 of the Expert Report of Dr. Melissa Snider-Adler.

and accuracy between the levels found in Tables B5 and B6 of REGDOC V3 and those employed by Dynacare are minimal.[9]

38. The Licensees make the following specific recommendations:

    (a) that the screening level for oral fluid testing for Methadone in Table B5 be amended to 50 ng/ml;

    (b) that the confirmation level for oral fluid testing for Methadone in Table B5 be amended to 20 ng/ml; and

    (c) that the confirmation level for oral fluid testing for Benzodiazepines in Table B5 be amended to 10 ng/ml.

(b) Section 6 Alcohol- and Drug-Testing Processes: Feedback on testing methodology

39. In their proposed amendments to the REGDOC enclosed with their June 28, 2019 submissions to the CNSC, the Licensees sought an amendment to Section 6 to reflect anticipated emerging developments to testing methodologies. In particular, the Licensees sought the addition of the following language:

> *As alcohol and drug testing evolves, licensees may update their testing methodology subject to CNSC staff acceptance.*

40. This proposed language is not reflected in REGDOC V3.

41. However, Dr. Snider-Adler confirms that the scientific and technical guidelines for testing, laboratory accreditations and approved and recommended testing devices are continuing to evolve.[10] Indeed, with the legalization of cannabis the pace of this evolution is expected to increase.

42. Consequently it is both appropriate and practical for the approval process of testing mechanisms and regimes to be nimble so that Licensees can ensure that best practices are introduced without delay to fitness for duty alcohol and drug testing policies.

43. As a result, the Licensees seek an agile regulatory approach to responding to the evolution of alcohol and drug testing methodology and technology.

44. The Licensees recommend that section 6 of REGDOC V3 be amended to include the following:

> As alcohol and drug testing evolves, licensees may update their testing methodology subject to CNSC staff acceptance.

---

[9] Expert Report of Dr. Snider-Adler at p. 23.

[10] See pp. 10-16 of Expert Report of Dr. Snider-Adler.

(c) 6.2 Drug-testing process: Feedback with respect to licensing requirements for urine analysis oral fluid drug testing

45. REGDOC V3 establishes licencing requirements for laboratories that will be carrying out testing of oral fluid samples pursuant to the REGDOC. Specifically, REGDOC V3 mandates the following:

> 6.2 Drug-testing process
>
> For urine drug testing, licensees shall use a laboratory accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA). For oral fluid drug testing, licensees shall use a laboratory accredited by SAMHSA or a laboratory that meets ISO/IEC 17025.

46. To the best of the Licensees' knowledge and as outlined at pages 10-11 of Dr. Snider-Adler's Expert Report, there is currently only one laboratory in Canada which is accredited by SAMHSA for urine testing; the Dynacare Laboratory located in London, Ontario. There is therefore no flexibility with respect to the laboratory at which urine drug testing may be conducted.

47. The Dynacare Laboratory is not accredited by SAMHSA at this time for oral fluid testing nor, to the knowledge of the Licensees, are any other laboratories in Canada. Moreover, neither Dr. Snider-Adler nor the Licensees are aware of any Canadian laboratories that conduct oral fluid testing that have ISO/IEC 17025 accreditation for oral fluid testing.

48. The Licensees oppose sending oral fluid samples from their workers for testing to the United States, or any other foreign jurisdiction, for reasons of both cost and privacy.

49. Consequently, the Licensees recommend the REGDOC be amended as follows to address the fact that there is only one laboratory that is accredited by SAMSHA for urine testing and no laboratories accredited by SAMSHA or that meet ISO/IEC 17025 for oral fluid testing:

> 6.2 Drug-testing process
>
> For urine drug testing, licensees shall use a laboratory accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA) **or a laboratory that will conduct urine drug testing to the equivalent standards as required for SAMHSA accreditation for urine testing**. For oral fluid drug testing, licensees shall use a laboratory accredited by SAMHSA or **a laboratory that will conduct oral fluid testing to the equivalent standards as required for SAMHSA accreditation for urine testing or** a laboratory that meets ISO/IEC 17025.

(d) Section 6.2.1 Initial Point of Collection Test (POCT) urine screening

(i) Use of POCT urine screening as an initial THC screen to determine if oral fluid testing for THC is warranted

50. In their proposed revisions to the REGDOC enclosed with their June 28, 2019 submissions to the CNSC, the Licensees sought an amendment to the REGDOC that would permit the use of POCT urine analysis as an initial THC screen to determine whether additional oral fluid testing would be necessary. Specifically, the Licensees sought the following addition to section 6.2 of the REGDOC Version 2:

> *Licensees should establish a protocol for point of collection test (POCT) (urine) specimen collection and screening.*
>
> *Licensees should send urine specimens to an accredited laboratory to analyze and report results against the urine drug panel established in Tables B3 and B4 of Appendix B, in all cases with the exception of non-negative THC POCT (urine) screening for pre-placement, reasonable grounds, post-incident and random testing.*
>
> *Licensees should establish a protocol for oral fluid specimen collection to be followed in the event of a non-negative THC POCT (urine) screening for pre-placement, reasonable grounds, post-incident and random testing.*

51. In REGDOC V3, section 6.2.1 was added which provides as follows:

> 6.2.1 Point of collection testing
>
> Licensees may choose to utilize point of collection testing (POCT) as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral-fluid-based laboratory test.
>
> If licensees choose to utilize POCT, a protocol shall be established and documented. Non-negative results shall be verified by laboratory immunoassay screening and confirmation testing.
>
> The licensee shall compare negative POCT results with laboratory-based results on an anonymous and aggregate basis for quality assurance purposes.
>
> Licensees who decide to conduct POCT shall select devices that are:
>
> 1. Health Canada certified or approved by the Department of Justice Canada for roadside use
>
> 2. independently evaluated by qualified laboratory personnel on an initial and annual basis to ensure that the devices meet forensic standards such as specificity, sensitivity and accuracy

> 3. calibrated to the extent possible with the urine or oral fluid drug testing cut-off levels established in appendix B (see table B2 for urine immunoassay or table B5 for oral fluid immunoassay)
>
> POCT devices shall not be used in pre-placement or follow-up testing circumstances.

52. The Licensees interpret this amendment as permitting the use of POCT screening for THC as an initial screening tool to determine whether further oral fluid samples are required in the case of random drug testing and post-incident testing under the REGDOC. However, the Licensees are concerned about ambiguity in the amendment arising from the placement of the comma in the following phrase of paragraph 1 of section 6.2.1 of REGDOC V3:

> ...as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical **duties, pending** the medical review officer's report on the urine- or oral-fluid-based laboratory test.

53. Assuming that POCT urine analysis may be used as an initial screen for THC (thereafter only proceeding with oral fluid testing where the POCT test is non-negative), the Licensees ask that this be confirmed and recommend that the above-mentioned comma be removed.

(ii) Use of POCT devices in reasonable grounds testing

54. REGDOC V3 now includes in section 6.2.1 the following restriction:

> POCT devices shall not be used in pre-placement or follow-up testing circumstances.

55. Reasonable grounds testing will be used in circumstances where Licensees have additional information and observations that have led them to question a worker's fitness for duty. It is the Licensees' view that the information and observations that have led to the requirement for reasonable grounds testing should not be subordinated to the results of a POCT and that in those circumstances a worker should not be returned to a Safety-Sensitive or a Safety-Critical Position until the outcome of laboratory confirmation testing is known and communicated.[11]

56. The Licensees recommend that the current phrase in section 6.2.1 of REGDOC V3 be amended as follows:

> POCT devices shall not be used in pre-placement or follow-up **or reasonable grounds** testing circumstances.

[11] See Expert Report of Dr. Melissa Snider-Adler at p. 13.

Enclosure 2

Case Law Update, prepared by Hicks Morley

CASE LAW UPDATE

Re: Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3

[Enclosure 2]

[Reference 16]

May 29, 2020

Hicks Morley Hamilton Stewart Storie LLP

77 King Street West, 39th Floor
Box 371, TD Centre
Toronto, Ontario M5K 1K8

Henry Y. Dinsdale
Tel: personal information redacted
LSO No.: 29838G
E-mail:personal information redacted

Dianne E. Jozefacki
Tel: personal information redacted
LSO No.: 63706E
E-mail: personal information redacted

PURPOSE

1. This Case Law Update reinforces the legal foundation provided to the CNSC in the Legal Brief of Bruce Power, Canadian Nuclear Laboratories, New Brunswick Power Corporation and Ontario Power Generation (collectively, the "Licensees") dated June 28, 2019 (the "June 2019 Legal Brief"). The Licensees continue to rely on the June 2019 Legal Brief and jurisprudence cited therein.

2. This Case Law Update provides an update on relevant jurisprudence released since the June 2019 Legal Brief was filed. Specifically, it highlights for the CNSC's attention comments that adjudicators have made with respect to:

   - the continued scrutiny of alcohol and drug testing policies; and
   - the distinction between use and risk of impairment.

OVERVIEW

3. In their June 2019 Legal Brief, the Licensees requested amendments to the REGDOC-2.2.4., Fitness for Duty, Volume II: Managing Alcohol and Drug Use (the "REGDOC") primarily relating to testing for Tetrahydrocannabinol ("THC").

4. In their submissions, the Licensees outlined that Canadian jurisprudence requires that their Fitness for Duty policies, which are to be promulgated pursuant to the REGDOC, must be reasonable and constitutional. The REGDOC and the Fitness for Duty policies must balance the interests of the public, the CNSC (as regulator) and the Licensees (as employers), with the interests of the individuals who are to be subjected to alcohol and drug testing. In particular, they emphasized that to be lawful and withstand legal scrutiny, current jurisprudence demands that the testing methodology and cut-off standards found in the REGDOC and each Licensee's Fitness for Duty policy strike a reasonable balance between workers' individual rights and the objective of ensuring safety from an unacceptable risk of alcohol and drug impairment in the workplace.

5. Adjudicators have continued to follow the guidance in the foundational jurisprudence outlined in the June 2019 Legal Brief. In particular, the following recent decisions emphasize that alcohol and drug testing policies will be assessed on a reasonableness standard and that there must be a rational connection between the use of alcohol and drug testing, and its results, and an employer's interest in promoting safety.

RECENT CANADIAN JURISPRUDENCE

OPEIU and Cougar Helicopters Inc. (Random Drug and Alcohol Testing)[1]

6. In this arbitration decision dated December 9, 2019, the arbitrator considered the reasonableness of the employer's alcohol and drug policy only as it related to random drug testing.

7. The employer provided offshore passenger transfer and search and rescue support to the oil and gas industry offshore of the east cost of Canada. It implemented a revised alcohol and drug policy following the legalization of cannabis. The policy provided for the use of the "minimally invasive" oral fluid testing for all drugs, including cannabis.

8. At arbitration, the union only challenged random drug testing.

9. The arbitrator had no difficulty concluding that the employer operated a highly dangerous workplace and the positions at issue (including helicopter pilots) were highly safety-sensitive.

10. In assessing the reasonableness of the random drug testing aspect of the policy, the arbitrator applied the balancing of interests test set out in *Irving Pulp and Paper Ltd. and Communications Energy and Paperworkers Union of Canada Local 30* [2013] 2 S.C.R (discussed in the June 2019 Legal Brief). The arbitrator also noted that in *Irving,* permissible drug testing was done in circumstances where the employer had cause to believe the employee was impaired while on duty (through reasonable cause, post-incident or return to work testing).

11. The arbitrator then went on to find that in the case of random drug testing, the crux of the matter was whether the situation at this specific employer constituted an "extreme circumstance" that could justify random drug testing in the absence of evidence of a more generalized workplace substance use problem.

12. The arbitrator did not find it to be an extreme circumstance, and instead found that the privacy rights of employees outweighed the interests of the employer in conducting random drug testing. She went on to find that the comprehensive checks and balances implemented by the employer were sufficient to mitigate the risks of substance abuse and random drug testing was not necessary:

> While random testing by oral swab is much less intrusive than other means of testing, it still amounts to a removal of intimate bodily information, including DNA, without the consent of the employee. On balance, I find that this is an unjustified affront to the dignity and privacy rights of the affected employees, and that the protection of these privacy rights, in all of the circumstances, outweighs the Employer's legitimate interest in promoting safety. The Employer, through its practices, policies

[1] *OPEIU and Cougar Helicopters Inc. (Random Drug and Alcohol Testing), Re*, 2019 CanLII 125448 (CA LA) (Ashley).

> and procedures, accepted by the workforce, developed through its regimen of comprehensive checks and balances, pre-flight and in-flight, a system to significantly mitigate risks of substance abuse.[2]

Saskatchewan Health Authority and HSAS, Re.[3]

13. In this arbitration decision dated March 31, 2020, an arbitrator examined in great detail an alcohol and drug policy issued by the Saskatchewan Health Authority.

14. The arbitrator applied the principles from Canadian jurisprudence and emphasized the reasonableness approach. In doing so, he noted that alcohol and drug testing had to be for the detection of impairment in the workplace:

> "Reasonableness" is obviously an inherently elastic measure. In applying it arbitrators have used a "balancing of interests approach" between the legitimate interests of the employer and those of employees. With respect to alcohol and drug policies, the interest of an employer is to have a workplace where the safety of workers, clients, patients and others is not put in jeopardy by employees whose work performance, and even presence in the workplace, is or may be impaired by alcohol or drugs. The interest of employees is the protection of their personal dignity and privacy. Unjustified testing by urine, blood or breath sample, which the courts see as equally invasive, is a serious affront because it effects a loss of liberty and personal autonomy. An assessment or analysis of any unilaterally imposed alcohol or drug policy involves a careful balancing of these differing interests.[4]

15. Ultimately, the arbitrator found several issues with the policy, including that it did not properly delineate safety sensitive classifications, was overly broad in testing non-safety sensitive positions, was overly broad in its random testing (finding that such testing ought to have been limited to employees in safety sensitive positions who are subject to an agreed rehabilitative program), was overly broad in its post-incident testing, and overly broad in its disclosure requirements.

Canadian Pacific Railway Decisions

16. Recent decisions involving Canadian Pacific Railway in late 2019 further underscore the requirement that drug testing for cannabis in Canada test for risk of impairment, rather than for use. Members of the Canadian Railway Office of Arbitration & Dispute Resolution sent a clear message that a positive urine test that showed use, without more, is generally insufficient to suggest impairment and the testing provided little to no value in upholding discipline.[5]

---

[2] *Ibid* at para 109.

[3] *Saskatchewan Health Authority and HSAS,* Re, 2020 CanLII 25719 (SK LA).

[4] *Ibid.* at para. 45.

[5] *Canadian Pacific Railway and Teamsters Canada Rail Conference (MacDonald), Re* (2019), 142 CLAS 9 (Weatherill); *Canadian Pacific Railway and Teamsters Canada Rail Conference (Velanoff), Re* (2019),

17. In *Canadian Pacific Railway and Teamsters Canada Rail Conference (Velanoff), Re*, the grievor was subject to a post-incident test. The grievor tested positive on a urine test for cannabis but negative on an oral fluid swab drug test. The arbitrator noted the following:

> I have no difficulty arriving at the same conclusion reached by Arbitrator Weatherill, as have other arbitrators from this Office before him, that a urine drug test that uncovers traces of marijuana is not conclusive of impairment. As he succinctly put it "...that bit of evidence by itself in not enough to establish impairment, whereas the negative breath alcohol and oral fluid tests strongly indicate there was not". Apart from the stand-alone unreliability of the urine test as an indicator of impairment, it is noteworthy that Arbitrator Weatherill cited the contradictory results between the oral fluid test and the urine drug test as further support for his finding of insufficient evidence of impairment.
> …
> The grievor shall be reinstated to his employment, without loss of seniority, and with full compensation for his loss of earnings. … [6]

18. Similarly in *Canadian Pacific Railway and Teamsters Canada Rail Conference (Obenauer),* the grievor had a negative oral fluid swab drug test but a positive urine test. The arbitrator said the following of a urine test:

> As Dr. Rosenbloom attests, the THC content "leaches out for up to 30 days" which supports the finding that 21ng/ml of THC remained in the grievor's urine at the time he was tested. That result alone, as the CROA cases have determined, does not lead to a finding of impairment. There is no other evidence that the grievor demonstrated any physical signs that would lead to the conclusion that he was impaired at the time the incident occurred. Indeed, the grievor tested negative on the oral fluid tests. Accordingly, after consideration of the prevailing case law, particularly from this Office, and the expert evidence adduced in this case, I find that the Company has not met the onus of demonstrating that the grievor was in violation of CROR Rule G, as alleged in his Form 104 dismissal letter of April 8, 2019.[7]

Everitt v Homewood Health Inc.[8]

19. This is a decision from the Human Rights Tribunal of Alberta dated July 30, 2019. It briefly emphasizes that the focus of inquiry into an individual's use of cannabis will be on impairment, rather than use.

20. The complainant was a member of a building trade union and worked on safety-sensitive construction sites and the oil sands in Alberta. He alleged that

---

143 CLAS 2 (Moreau),; *Canadian Pacific Railway and Teamsters Canada Rail Conference (Obenauer), Re,* 2019 CarswellNat 10220 (Moreau).

[6] *CP Rail (Velanoff), ibid*, at paras 23 and 25.

[7] *CP Rail (Obenauer), ibid*, at para. 26.

[8] *Everitt v Homewood Health Inc.*, 2019 AHRC 36 (CanLII).

Homewood Health Inc., discriminated against him in the provision of services customarily available to the public when it refused to register him in the Rapid Site Access Program ("RSAP").

21. The RSAP was developed as a pre-qualification measure to facilitate workers getting onto job sites quicker, where such job sites included the requirement to pass a pre-access alcohol and drug test. Workers enrolled in the RSAP do not have to pass a pre-access test, but must agree to be subject to random testing while on the job site.

22. The complainant failed the drug test for registration in the RSAP – he tested positive for THC. He alleged that the cannabis was medicinal.

23. The evidence did not support that the cannabis was medicinal and therefore the adjudicator did not find any discrimination. In any event, given the levels of cannabis that the complainant was using (he tested at over 1200 ng/ml), the adjudicator held that the complainant posed an unacceptable "risk of impairment".[9]

IUOE, Local 793 v. Mammoet Canada Eastern Ltd.[10]

24. In this arbitration decision dated December 11, 2019, an arbitrator upheld the post-incident testing aspect of the employer's alcohol and drug policy (the only section being challenged).

25. Briefly for the purposes of this Case Law Update, the arbitrator made the following comments about the reasonableness assessment applicable to alcohol and drug policies:

> The balancing of interests approach recognizes that drug and alcohol testing is invasive to privacy rights and that testing requirements must achieve a balance of interests. In Irving Pulp, supra, Abella J. accepted at paragraph 49 and 50 that requiring an employee to undergo breathalyzer testing under the pain of discipline results in a loss of liberty and personal autonomy, which are at the heart of the right to privacy. It is unassailable that the same conclusion applies to the drug and alcohol testing at issue before me.[11]

26. The arbitrator also emphasized that the purpose of post-incident testing was to determine if the cause of the incident was the employee's drug or alcohol impairment.[12]

---

[9] *Ibid.* at paras. 73-76.

[10] *IUOE, Local 793 v. Mammoet Canada Eastern Ltd* , 2019 CarswellOnt 20596.

[11] *Ibid.* at para. 34.

[12] *Ibid.* at para. 50.

CONCLUSION

27. As stated in the June 2019 Legal Brief, to be effective and lawful, the REGDOC must establish requirements and guidance for the Licensees that will lead to Fitness for Duty policies that are legally defensible. Those policies must strike a reasonable balance between the Licensees' obligations to eliminate or minimize safety risks in the workplace related to fitness for duty, and the interests of workers to conduct their private lives in a society where our government has mandated that certain substances, like alcohol and cannabis, are legal.

28. As further emphasized in the above-noted case law, it continues to be the case that legally defensible policies must provide for alcohol and drug testing which are administered in appropriate contexts and that test for risk of current impairment.

Enclosure 3

Expert Report of DriverCheck – Dr. Melissa Snider-Adler

Melissa Snider-Adler, M.D., C.C.F.P.(AM), M.R.O., (AAMRO), D, A.B.A.M.

May 27, 2020 **PRIVILEGED AND CONFIDENTIAL**

Mr. Henry Dinsdale
Hicks Morley Hamilton Stewart Storie LLP
personal information redacted
Toronto, Ontario M5K 1K8

Dear Mr. Dinsdale:

Re: Bruce Power, Ontario Power Generation, New Brunswick Power and Canadian Nuclear Laboratories (the "Companies") re *REGDOC 2.2.4 Fitness for Duty, Volume II : Managing Alcohol and Drug Use, version 2*

I have been asked to provide an expert report in response to the Canadian Nuclear Safety Commission's (the "CNSC") invitation for feedback on proposed updates to *REGDOC 2.2.4 Fitness for Duty, Volume II: Managing Alcohol and Drug Use, version 3* (the "V.3 REGDOC").

Areas of Expertise

I am a physician licensed by the College of Physicians and Surgeons of Ontario, certified as a Diplomat of the American Board of Addiction Medicine and hold a Certificate of Added Competence in Addiction Medicine by the Canadian College of Family Physicians. I am also certified as a Medical Review Officer through the American Association of Medical Review Officers (AAMRO) in compliance with the U.S. Department of Transportation Alcohol and Drug Testing regulations.

I graduated Medical School at the University of Western Ontario in 1997 and completed my Family Medicine Residency at the University of Toronto in 1999, at the Toronto General Hospital. I began my practice in Addiction Medicine in 2000 and since then have worked in over nine clinics in a variety of communities across Ontario. I have over this time treated thousands of patients suffering from Substance Use Disorder, mainly Opioid Use Disorder with concurrent disorders and polysubstance use. Given the propensity of cannabis use in my population and the concurrent use of other substances such as cocaine, I spend a significant amount of time in my practice dealing with cannabis use, which includes cannabis for medical purposes, recreational cannabis use and cannabis use disorder. Additionally, I have significant experience managing

chronic pain, as there is a definitive link between opioid use disorder and history of chronic pain. Given the lack of ability for many of my patients to seek other medical help, I do manage acute pain, acute-on-chronic pain as well as chronic pain for many of my patients. At this time, I work in Oshawa, Ontario, currently offering care to approximately 200 patients with Substance Use Disorder and a variety of concurrent medical conditions.

I began working as a Medical Review Officer (MRO) in 2007 at DriverCheck Inc. DriverCheck Inc. was founded in 1996 and continues to provide comprehensive Alcohol and Drug Testing Programs to more than 6,500 companies spanning across Canada. I am presently the Chief Medical Review Officer for DriverCheck Inc., which involves MRO work, overseeing the other MROs at DriverCheck and consulting with companies who may have questions about their Alcohol and Drug Testing Programs. DriverCheck Inc. conducts over 300,000 drug and alcohol tests annually. DriverCheck Inc. also provides comprehensive Third Party Administrator Services (TPA), including test booking services, computerized random testing selection services, specimen collection services, mobile collection services and a host of occupational health services.

Given the difficulty employers have had dealing with cannabis for medical purposes, I helped to institute a medical cannabis review process at DriverCheck Inc. The Medical Cannabis Review Program (MCRP) began in 2018. Since its inception, I have been instrumental in reviewing cases and providing conclusions regarding fitness for duty with authorized cannabis and other prescription medications for employees working in safety-sensitive and risk-sensitive industries. This service has expanded to include review of employees who are prescribed opioids as well as treatment for opioid use disorder including methadone and buprenorphine.

I have spoken and lectured across Canada and the United States at hundreds of conferences, to health care professionals as well as various workplaces about substance use in the workplace, cannabis in the workplace, the impact of legalization of cannabis in the workplace, and opioid use disorder prevention and treatment.

As an expert in the field, I am often asked to provide expert opinions about drug testing and the workplace. I have testified as an expert at many arbitration hearings and court cases. I have provided written expert submissions and affidavits for court to a variety of employers across several different industries, including railway, oil and gas, aviation, construction, power generation/energy as well as to child custody courts for many different Children's Aids Societies across the country. I have been qualified as an Expert Witness for Addiction and as an Expert Witness for Drug Testing Interpretation in the Ontario Court of Justice as well as at numerous arbitrations across Canada.

I am an Assistant Professor at Queen's University Medical School Family Practice Residency Program and as such, am involved in Resident education and training in the field of Addiction Medicine.

For the last 17 or more years, I have been involved with the Methadone Program at the College of Physician and Surgeons of Ontario (CPSO). I conduct numerous Physician Peer Practice Assessments on behalf of the CPSO for physicians practising in the field of Addiction Medicine, as well as conducting assessments for the Inquiries, Complaints and Reports Committee (ICRC) of the CPSO. I was one of the Authors of the current Guidelines for Methadone practice in Ontario (Methadone Maintenance Treatment Program Standards and Clinical Guidelines 2011). I also act as an investigator and assessor for the College of Nurses of Ontario, assessing nurses with known or suspected substance use disorder. I am asked to give recommendations regarding their diagnosis and ability to return to work.

Please see my Curriculum Vitae, which can be found in Appendix A

Table of Contents

Questions to be Addressed in this Report

The following are a list of questions that I have been asked to address:

1. Proposed Revision: The Companies' alcohol and drug-related policy statements should prohibit reporting to work or remaining at work under the influence of, and prohibit bringing, keeping or consuming, cannabis-derived products.

    a. Please provide your opinion on the meaning and scope of the term "cannabis-derived products" in the drug testing context.

    b. To the extent you have such information and are at liberty to disclose it, please provide comment on the meaning and use of "cannabis-derived products" by other industries, and by other employers, in alcohol and drug testing policies.

2. Proposed Revision: For urine drug testing, licensees shall use a laboratory accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA). For oral fluid drug testing, licensees shall use a laboratory accredited by SAMHSA or a laboratory that meets ISO/IEC 17025.

    a. Please provide your opinion on whether Canadian laboratories have the proposed accreditations.

3. Proposed Revision: Point of Collection Testing

Licensees may choose to utilize point of collection testing (POCT) as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral-fluid-based laboratory test.

If licensees choose to utilize POCT, a protocol shall be established and documented. Non-negative results shall be verified by laboratory immunoassay screening and confirmation testing.

The licensee shall compare negative POCT results with laboratory-based results on an anonymous and aggregate basis for quality assurance purposes.

Licensees who decide to conduct POCT shall select devices that are:

i. Health Canada certified or approved by the Department of Justice Canada for roadside use;

ii. independently evaluated by qualified laboratory personnel on an initial and annual basis to ensure that the devices meet forensic standards such as specificity, sensitivity and accuracy;

iii. calibrated to the extent possible with the urine or oral fluid drug testing cut-off levels established in appendix B (see table B2 for urine immunoassay or table B5 for oral fluid immunoassay)

POCT devices shall not be used in pre-placement or follow-up testing circumstances.

a. You previously commented on the use of POCT testing in your June 26, 2019 Report. To the extent you have any additional comments in light of the manner in which the CNSC has proposed its use, please provide.

b. Please provide your opinion on the proposed specifications for POCT devices.

4. Proposed Revisions:

Oral Fluid immunoassay screening: Table B5 provides the oral fluid analysis drug panel and the associated cut-off values to be used for immunoassay screening.

Table B.6 Oral fluid GC-MS and LC-MS/MS confirmation: Table B6 provides the oral fluid analysis drug panel and the associated cut-off values to be used for GC-MS and LC-MS/MS confirmation.

a. In their June 28, 2019 Submissions, the Companies proposed a cut-off value to be used for immunoassay oral fluid screening and confirmation testing of 10 ng/ml for THC. The CNSC has proposed a screening cut-off of 5 ng/ml and confirmation cut-off of 2 ng/ml for THC. Where appropriate, please review and consider the concepts of specificity and sensitivity as they relate to these various testing cut-off levels and the relative efficacy of these various testing levels for the detection of risk of current impairment.

b. Apart from THC, please provide your opinion on the appropriateness of the identified cut-off levels for other drugs with reference, where available and appropriate, to scientific and other studies and reports.

c. Please provide your opinion on whether Canadian laboratories have the technical and scientific capabilities to perform the screening and confirmation tests at the proposed cut-off values.

Research Conducted and Materials Relied Upon

I have been provided with the following documents for review and consideration:

1. *REGDOC 2.2.4 Fitness for Duty, Volume II : Managing Alcohol and Drug Use, version 3*
2. Email from CNSC re: Invitation to provide feedback on proposed updates to REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3, March 12, 2020
3. M. Huestis, PhD. *Oral Fluid Drug Testing Practice: Report to the Canadian Nuclear Safety Commission*, RSP-673.2, Ottawa, 2019

4. International Organization for Standardization, ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories, Geneva, Switzerland

In addition to the scientific literature that I already had on file, I searched online scientific databases to identify new and updated literature and reports needed to form my opinions and conclusions. The scientific research I utilized and quoted is included as Footnotes.

As an expert, I agree to strict confidentiality. I understand that my role is to provide independent assistance, and as such, my opinions and conclusions are my own. My opinions are fair, objective, non-partisan, and related only to the matters that are within my areas of expertise. As an expert witness, I acknowledge my duty to provide an opinion and not to be an advocate for any party. I further acknowledge that my duty as an expert to provide evidence pursuant to the above principles prevails over any obligation which I may owe to any party by whom or on whose behalf I am engaged.

Facts on Which the Report is Based

By way of background, I have been provided with the following factual information:

1. This matter arises in the context of a directive from the CNSC in the form of the REGDOC to the Companies to establish, implement and maintain clear fitness for duty policy statements regarding alcohol and drug use and abuse as a condition of license for all high-security sites.
2. Following the publication of Version 2 of the REGDOC on December 23, 2017 ("V.2 REGDOC"), the Companies asked that the CNSC make certain amendments to the V.2 REGDOC, including to incorporate oral fluid testing into the required testing regimes, specifically for THC, and urine-based Point of Collection Testing ("POCT") (in addition to other minor changes).
3. On March 20, 2019, the CNSC wrote to each of the Companies enclosing a series of requests for additional information that it required in order to complete its assessment of the proposed amendments to the V.2 REGDOC. It was with respect to those inquiries that my initial expert opinion was completed pursuant to the May 17, 2019 Expert Engagement Letter.
4. On June 28, 2019, the Companies provided answers to the CNSC's questions, and enclosed various supplementary material including my Expert Report dated June 26, 2019 (the "June 28, 2019 Submissions").

5. On March 12, 2020, the Companies received an invitation from the CNSC for feedback on proposed updates to the V.2 REGDOC, captured in highlighted text in the newly published V.3 REGDOC. In brief, the CNSC identified that the "proposed changes will allow for point of collection testing for oral fluid and urine, and oral fluid laboratory testing for all drug classes".
6. The V.3 REGDOC identified two new references in respect of which the CNSC had reference: (1) the Huestis Report; and (2) International Organization for Standardization, ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories, Geneva, Switzerland
7. The consultation period for feedback expires on May 30, 2020. The consultation period is only open to feedback on the specific changes in the V.3 REGDOC. Feedback that is beyond the scope of these changes will not be considered by the CNSC.

Answer to Question One:

1. Proposed Revision: The Companies' alcohol and drug-related policy statements should prohibit reporting to work or remaining at work under the influence of, and prohibit bringing, keeping or consuming, cannabis-derived products.
    a. Please provide your opinion on the meaning and scope of the term "cannabis-derived products" in the drug testing context.
    b. To the extent you have such information and are at liberty to disclose it, please provide comment on the meaning and use of "cannabis-derived products" by other industries, and by other employers, in alcohol and drug testing policies.

Cannabis-Derived Products

Cannabis is a plant that contains hundreds of biologically active chemical compounds. These compounds include cannabinoids, with the most commonly known being delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). They also contain terpenes and flavanoids; chemicals that are responsible for the aroma, flavors and colour of cannabis, and either support cannabinoids in producing desired effects or produce their own effects on the brain.

There are many products that are made using the components of the cannabis plant. The following chart is a detailed explanation of cannabis-derived products[1]

[1] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/about.html

Form	Description	THC potency
fresh or dried herbal material	Flowers and leaves from the cannabis plant	up to 30%
cannabis oil	Cannabis extract dissolved in oil. Can be used to make other forms (for example, edibles).	up to 3%
chemically concentrated extracts (for example, hash oil/shatter/budder/wax)	Highly concentrated cannabis extract dissolved in petroleum-based solvent (for example, butane). Shatter, budder and wax most highly concentrated.	up to 90%
physically concentrated extracts (for example, hash/kief)	Loose trichomes or pressed resin from the cannabis plant.	up to 60%
edibles	Foods and drinks containing extracts of cannabis	Depends on the amount of extract added
tinctures/sprays	Cannabis extract dissolved in a solvent, often alcohol. Can be used to make other products (for example, edibles).	varies
creams/salves/liniments	Cannabis extract preparation prepared with alcohol, oil or wax and applied to the skin.	varies

There are many policies that describe cannabis-derived products. These products may be described as "cannabis" which the Alberta Health Services Alcohol and Drugs Policy define in the policy[2] as:

> ***cannabis plant*** *(Cannabis sativa and Cannabis indica being the most popular varieties). Various products can be made from the parts of the entire cannabis plant including all extracts, edibles, oils, and dried flower or bud.*

Similarly, Canadian Pacific Railway Alcohol and Drug Procedures (revised September 1, 2019)[3] define cannabis as:

> *the use or consumption of cannabis from any source*

Cannabis-derived products are any products that contain any components of the cannabis plant regardless of whether they are obtained for the purpose of legal medical use, legal recreational use or illicit cannabis products. As described in the chart above, these may include anything from dried cannabis to oils to creams and sprays. Although some of the cannabis plant compounds are considered to have a greater impact on the brain, all of the compounds cross the blood-brain-barrier and play a role in brain function and chemistry. All of these compounds are therefore considered psychoactive ("affecting the mind or behavior"[4]).

---

[2] https://extranet.ahsnet.ca/teams/policydocuments/1/clp-prov-alcohol-drugs-HCS-232.pdf

[3] http://tcrcmwed.teamsters.ca/wp-content/uploads/sites/13/2019/08/HR-203.1-Alcohol-and-Drug-Procedures_July-23-2019.pdf

[4] https://www.merriam-webster.com/dictionary/psychoactive

Although not all policies that I have seen use the exact term "cannabis-derived products", to the best of my knowledge, and from what I have seen, the vast majority of workplace policies do include wording that would be synonymous with this term.

Answer to Question Two:

2. Proposed Revision: For urine drug testing, licensees shall use a laboratory accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA). For oral fluid drug testing, licensees shall use a laboratory accredited by SAMHSA or a laboratory that meets ISO/IEC 17025.

    a. Please provide your opinion on whether Canadian laboratories have the proposed accreditations.

Laboratory Accreditation

There is one laboratory in Canada which is accredited by the Substance Abuse and Mental Health Services Administration (SAMHSA) for urine testing; Dynacare Laboratory, London, Ontario ("Dynacare"). Although they have been conducting oral fluid testing for workplaces across Canada for many years (more than 20 years), and although they use the same principles for oral fluid testing as for urine testing (for which they are SAMHSA accredited), they do not have either of the required accreditations/certifications listed above for oral fluid testing. They are currently working towards applying for accreditation by SAMHSA for oral fluid drug testing, however, it is my understanding that this is not expected to be completed until mid to late 2021.

The delay is due to the need to wait for Immunalysis to provide the ability to screen the oral fluid swab most commonly used in Canada, Quantisal Oral Fluid Collection Device ("Quantisal"), at the cut-off levels that The Department of Health and Human Services (''HHS'') has established with their scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) allows federal agencies to collect and test an oral fluid specimen as part of their drug testing programs. The cut-off levels for oral fluid testing in the V.3 REGDOC mirror that found in the OFMG with a few exceptions (see more detail under **Proposed Cut-off Levels**). They are for the most part, different from what Dynacare is currently able to screen and confirm at.

In order for Dynacare to be accredited, as discussed below in the section "***Proposed Cut-Off Levels***" the ability to screen the tests at the different screening cut-off levels are first required. Immunaylsis must manufacture and produce the kits to use in screening the oral fluid samples at the new levels (which in some cases differ from what Dynacare can test at this time). There are many other steps that are required for accreditation that Dynacare must fulfill prior to applying for SAMHSA accreditation for oral fluid testing. These are similar to that required for accreditation by SAMHSA for urine testing. This similar and equally rigorous process required

by Dynacare (or any laboratory seeking accreditation to be able to conduct U.S. Federally Mandated oral fluid testing) does take time. It is my understanding that the laboratory has indicated that they will not be accredited for at least another year.

ISO/IEC 17025 accreditation is an important competency standard applied to testing and calibration laboratories around the globe. Laboratories accredited to this standard have demonstrated significant technical ability to reliably generate and reproduce accurate, precise and consistent data.

Laboratories with ISO/IEC 17025 accreditation for oral fluid testing have demonstrated significant technical ability, reliability and reproducibility of their data. This accreditation is a competency standard applied to testing and calibration of tests conducted at a laboratory. Although there is no doubt that having this accreditation helps to ensure that the tests are conducted to the highest standards, there are no laboratories in Canada that conduct oral fluid testing which have ISO 17025 accreditation for oral fluid testing that I am aware of. Dynacare, the only laboratory conducting workplace testing in Canada, does not have this accreditation. There are a few laboratories in the U.S. that are accredited, and based on the proposed revision, any oral fluid testing that the companies want to conduct would be required to be sent to the U.S. for testing until Dynacare is SAMHSA certified or ISO 17025 accredited for oral fluid testing.

The U.S. Department of Transportation ("DOT") is required to follow the Guidelines in developing drug testing programs for their regulated industries. In the OFMG it states that

> *"The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions."*

They further speak to the validity of oral fluid testing stating that:

> *"The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. Additionally, specimen volume is also much lower, saving time in collection and transport cost."*

It is my recommendation that the V.3 REGDOC consider the importance of oral fluid testing and the fact that the only current laboratory conducting workplace testing in Canada would not be able to meet these standards currently. The V.3 REGDOC could be modified to require the laboratory to conduct oral fluid testing to the same standards as required for SAMHSA accreditation for urine testing until the time that SAMHSA accreditation for oral fluid testing is completed.

Answer to Question Three:

3. Proposed Revision: Point of Collection Testing

Licensees may choose to utilize point of collection testing (POCT) as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral-fluid-based laboratory test.

If licensees choose to utilize POCT, a protocol shall be established and documented. Non-negative results shall be verified by laboratory immunoassay screening and confirmation testing.

The licensee shall compare negative POCT results with laboratory-based results on an anonymous and aggregate basis for quality assurance purposes.

Licensees who decide to conduct POCT shall select devices that are:

i. Health Canada certified or approved by the Department of Justice Canada for roadside use;

ii. independently evaluated by qualified laboratory personnel on an initial and annual basis to ensure that the devices meet forensic standards such as specificity, sensitivity and accuracy;

iii. calibrated to the extent possible with the urine or oral fluid drug testing cut-off levels established in appendix B (see table B2 for urine immunoassay or table B5 for oral fluid immunoassay)

POCT devices shall not be used in pre-placement or follow-up testing circumstances.

a. You previously commented on the use of POCT testing in your June 26, 2019 Report. To the extent you have any additional comments in light of the manner in which the CNSC has proposed its use, please provide.

b. Please provide your opinion on the proposed specifications for POCT devices.

My reported dated June 26, 2019 reviews urine POCT however oral fluid POCT is not thoroughly reviewed. I have no additional comments regarding urine POCT testing that were not touched upon in my original report. Oral fluid POCT will be discussed below given that it is necessary to understand the benefits and drawbacks of this type of testing.

Oral Fluid POCT - Health Canada Certified

Medical devices are defined by Health Canada as:

> *"The term Medical Devices, as defined in the Food and Drugs Act, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition."*

They further explain the following:

> *"The term "medical device" covers a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Some examples include pacemakers, artificial heart valves, hip implants, synthetic skin, medical laboratory diagnostic instruments, test kits for diagnosis and contraceptive devices."*

POCT devices used to detect whether someone has the presence of a substance in their oral fluid or urine may be considered a medical device. All medical devices in Canada require licensing through the Medical Devices Bureau (Bureau) of the Therapeutic Products Directorate, Health Canada in accordance with the *Food and Drugs Act and Regulations* and the *Medical Devices Regulations*.

The V.3 REGDOC specifies that the devices are required to be Health Canada certified or approved by the Department of Justice Canada for roadside use.

Although I completely agree with this recommendation, it is important to note that currently, the oral fluid POCT device recommended by Dr. Huestis in her report (Draeger DrugTest 5000) would not fit this criteria when referring to the other 5 ng/mL cut off level for THC as the test that is approved by the Department of Justice Canada for roadside use has a cut-off for THC of 25 ng/mL. The Draeger DrugTest 5000 is not Health Canada certified.

Oral Fluid POCT - Recommended Use

The V.3 REGDOC acknowledges that licensees may feel the need to utilize point of collection testing (POCT) "as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral-fluid-based laboratory test."

They further state that POCT testing should not be used in pre-placement or follow-up testing circumstances. However, I would add that for reasonable cause testing, relying on a result of a POCT (whether urine or oral fluid) and returning a worker to safety-sensitive or safety-critical duties based on the result of this, poses significant risk without having the result of the lab-based test. In the case of a reasonable cause test, the circumstances that led to the decision to test an individual should not be negated by a negative POCT test. False-negative results do occur with both urine POCT and oral fluid POCT. In situations with reasonable suspicion testing, a full investigation is generally conducted and this is not likely to be concluded prior to the availability of the POCT result. Awaiting a lab-based result (that has been reviewed by a Medical Review Officer) is highly recommended prior to returning an individual back to safety-sensitive or safety-critical duties.

It is my recommendation that the statement currently reading:

> *"POCT devices shall not be used in pre-placement or follow-up testing circumstances."*

Be changed to:

> *POCT devices shall not be used in pre-placement, follow-up or reasonable cause testing circumstances.*

Oral Fluid POCT - Lab Confirmation Recommendation

The V.3 REGDOC states that:

> *"Nonnegative results shall be verified by laboratory immunoassay screening and confirmation testing. The licensee shall compare negative POCT results with laboratory-based results on an anonymous and aggregate basis for quality assurance purposes."*

While I am in agreement with this, oral fluid POCT does not have the sensitivity that is required to be confident that all negative oral fluid POCT results are indeed negative. In other words, there is a higher risk than should be acceptable of false negative tests. If this is being used, it is my recommendation that all oral fluid POCT results (whether negative or non-negative) be confirmed at the laboratory.

The basis for my recommendation is as follows:

1. At the moment, with the criteria set out in the V.3 REGDOC (*"Licensees who decide to conduct POCT shall select devices that are: 1. Health Canada certified or approved by the Department of Justice Canada for roadside use"*), there are limitations for devices that can be used. There is one that is Health Canada certified, however this is not one of the devices that Dr. Huestis recommends in her report, and the sensitivity, specificity and accuracy may be questionable. There are two other devices being used by law enforcement and approved by the Department of Justice Canada however both are only approved for a cut-off level of 25 ng/mL for THC (Draeger DrugTest 5000 and SoToxa) of which SoToxa is not approved for any other drug testing outside of THC:

   > *"The inclusion of the SoToxa drug screener in the Order permits this equipment to be used by police at the roadside in a drug-impaired driving investigation. The SoToxa drug screener tests for the presence of THC in oral fluid."*[5].

   To my knowledge, neither are Health Canada certified. Therefore, any oral fluid POCT that would fit the criteria set out in the V.3 REGDOC is of concern with respect to the sensitivity, specificity and accuracy of the results. A lab confirmed test would be necessary.

2. Dr. Huestis stated in her report that there are three oral fluid POCT devices that performed well: These include the following:

   i. Draeger DrugTest 5000 - would not fit the criteria standard of the V.3 REGDOC as described above unless using the THC cut-off of 25 ng/mL

[5] http://www.gazette.gc.ca/rp-pr/p2/2019/2019-07-10/html/sor-dors237-eng.html

ii. Alere (Abbott) DDS2 (renamed SoToxa) - only approved for 25 ng/mL by the Department of Justice Canada (not Health Canada certified)

iii. DrugWipe 5 - this is not Health Canada certified nor is it approved by the Department of Justice Canada

Even when considering the recommended oral fluid POCT devices, the sensitivity of the Draegar DrugTest 5000 ranges when looking at the studies from 50% [6] for cocaine and from 80.8% to 91%[7] for THC. A study by Logan et al (2015)[8] had an overall sensitivity of 93.8% when comparing to lab-based oral fluid testing (THC being 90.9%).

With respect to Dr. Huestis' recommendation about the Draeger DrugTest 5000 (which I agree would be the best performing oral fluid POCT device when considering all available devices) there are a few other concerns regarding this device:

a. The cut-off that is approved by the Depart of Justice Canada for THC testing is 25 ng/mL. The Draeger DrugTest 5000 however has the ability to test THC at 5 ng/mL which matches the current screening cut-off level in the V.3 REGDOC. This however is not the cut-off level that is approved by the Department of Justice Canada. To my knowledge, the Draeger DrugTest 5000 is also not a Health Canada certified medical device.

b. There are large discrepancies with the sensitivity of THC testing using the Draeger DrugTest 5000 when looking at the currently available literature. This may in part be due to differences in the studies with respect to what they are comparing the oral fluid test to. For example, when comparing a non-negative oral fluid result to a laboratory test at 10 ng/mL for THC versus that of 2 ng/mL, there is going to be a difference in the false negative rates. As well, some studies compare the results to a blood test, which would not be relevant for workplace testing (as we do not use blood tests).

c. Cocaine testing with the Draeger DrugTest 5000 may be problematic. At the moment, the cut-off level for cocaine testing is as follows: cocaine 20 ng/mL (which is consistent with the screening cut-off level used at the laboratory for cocaine) however the cut-off level for benzoylecgonine (the metabolite of cocaine) with the Draeger DrugTest 5000 is 200 ng/mL (whereas it is 20 ng/mL with the screen at the laboratory). With a screen test at the laboratory, if the combination of benzoylecgonine and cocaine equates to a quantitative level over 20 ng/mL, the screen would be presumptive positive and would go on for

---

[6] Vanstechelman S, Isalberti C, Van der Linden T, Pil K, Legrand SA, Verstraete AG. Analytical evaluation of four on-site oral fluid drug testing devices. J Anal Toxicol 2012;36:136–40

[7] Desrosiers NA, Lee D, Schwope DM, et al. On-site test for cannabinoids in oral fluid. *Clin Chem*. 2012;58(10):1418−1425. doi:10.1373/clinchem.2012.189001

[8] https://legislature.vermont.gov/Documents/2018/WorkGroups/House%20Judiciary/Bills/H.237/H.237~Trish%20Conti~VT%20Oral%20Fluid%20Drug%20Testing%20Study%202015~2-23-2018.pdf

further confirmation testing (where the cut-off level would be 8 ng/mL for either cocaine or benzoylecgonine). With the Draegar DrugTest 5000 however, unless cocaine itself is above 20 ng/mL and/or benzoylecgonine is above 200 ng/mL, the test will be falsely negative.

d. There are variations in the literature (as stated above) regarding the sensitivity for THC testing. Cannabis (THC testing) and cocaine account for more than 90% of all positive drug tests in Canada[9]. This is consistent with Quest Diagnostics Drug Testing Index 2018 data[10] which tracks millions of workplace drug testing each year since 1988 (both U.S. Federally mandated testing as well as U.S. general workplace testing). Given this, a lower sensitivity for the most commonly used substances in the workplace is concerning if they are not able to detect all individuals who have recently used these substances. This is a potential risk for safety-sensitive and safety-critical duties.

These above considerations are highly concerning as a false negative result for workplace testing, where the test is not sent to the laboratory for confirmation testing, can increase the risk in the workplace. With a lower sensitivity, there would be a higher rate of individuals with false negative results who should have tested positive (and would have tested positive with a lab-based test) and are at high risk of impairment due to recent use of a substance that was missed on the oral fluid screening POCT test.

3. At the moment, the only test that is Health Canada certified (StatSwab) is not one which Dr. Huestis listed to be recommended for use in the workplace when using oral fluid POCT testing.

In summary, it is my recommendation that if the licensee is going to use oral fluid POCT testing, that the following additions to the V.3 REGDOC should be considered:

1. Oral fluid POCT results should not be used to determine whether an employee should return to their safety-sensitive or safety-critical duties for reasonable cause testing
2. At all times, regardless of the result of the oral fluid POCT, a lab-based oral fluid test should be conducted and sent to the laboratory for confirmation testing.

Answer to Question Four:

4. Proposed Revisions:

Oral Fluid immunoassay screening: Table B5 provides the oral fluid analysis drug panel and the associated cut-off values to be used for immunoassay screening.

[9] DriverCheck stats 2019

[10] https://www.questdiagnostics.com/dms/Documents/Employer-Solutions/DTI-2019/quest-diagnostics-drug-testing-index-2019-press-release/quest-drug-testing-index-press-release-2019.pdf

Table B.6 Oral fluid GC-MS and LC-MS/MS confirmation: Table B6 provides the oral fluid analysis drug panel and the associated cut-off values to be used for GC-MS and LC-MS/MS confirmation.

a. In their June 28, 2019 Submissions, the Companies proposed a cut-off value to be used for immunoassay oral fluid screening and confirmation testing of 10 ng/ml for THC. The CNSC has proposed a screening cut-off of 5 ng/ml and confirmation cut-off of 2 ng/ml for THC. Where appropriate, please review and consider the concepts of specificity and sensitivity as they relate to these various testing cut-off levels and the relative efficacy of these various testing levels for the detection of risk of current impairment.

b. Apart from THC, please provide your opinion on the appropriateness of the identified cut-off levels for other drugs with reference, where available and appropriate, to scientific and other studies and reports.

c. Please provide your opinion on whether Canadian laboratories have the technical and scientific capabilities to perform the screening and confirmation tests at the proposed cut-off values.

Oral Fluid Testing - THC

When looking at THC testing in oral fluid, the test reflects the remnants of delta-9-tetrahydrocannabinol (THC), the psychoactive component of cannabis prior to it being metabolized, found in the oral cavity after cannabis use. These remnants remain in the oral cavity for a number of hours depending on the cut-off level used. The two cut-off levels that are available and used for workplace testing in Canada presently are as follows:

Screen 10 ng/mL	Confirm 10 ng/ml
Screen 4 ng/mL	Confirm 2 ng/mL

To fully appreciate the importance of both the cut-off levels for a screening test as well as that of the confirmation test, the differences between the two types of testing are discussed below.

Screen and Confirmation Test Differences

All tests (whether urine or oral fluid) sent to the laboratory for testing, undergo preliminary screening tests. The screening test is an immunoassay test. If this results in a presumptive positive at or above the set screening cut-off level, the specimen proceeds to confirmation testing.

For oral fluid testing, the set screening cut-off level is set by the manufacturer of the oral fluid device (Immunalysis) as it is their kits that are used for this process at the laboratory. The screening test assay has a cut-off screening level option of 10 ng/mL or 4 ng/mL for delta-9-THC in the oral fluid. If a tested oral fluid sample produces an absorbance (result) greater than the screen cut-off level selected, it is considered presumptive positive.

If a tested oral fluid sample produces an absorbance less than the specified calibrator absorbance (set cut off level) it is considered negative and is then reported to the Medical Review Officer as negative. No further testing would take place.

When an oral fluid test undergoes screening, the immunoassay screen picks up a number of structurally similar compounds. For THC testing, the screening test cross-reactivities are shown below for both a screen cut-off level of 4 ng/mL. The same chart is not available for a screen cut-off level of 10 ng/mL.

Table 3: Cross-Reactivity with Structurally Similar Compounds

Compound	Approx. ng/mL Equivalent to 4 ng/mL Δ^9 THC	% Cross-Reactivity
(-)Δ^9–THC	4	100
Cannabidiol	10,000	0.04
Cannabinol	8	50.0
(-)11-nor-9-carboxy-Δ9-THC	16	25.0
(+/-)-11-Hydroxy-delta9-THC	60	7.0

When using either a cut-off screen level of 4 ng/mL or 10 ng/mL, the assay has 100% cross-reactivity with delta-9-THC.

From the chart above you can see that when using a screening cut-off level of 4 ng/mL, cannabinol has a 50% cross-reactivity with the assay and 11-nor-9-carboxy-delta-9-THC (a secondary metabolite - this is the metabolite that is tested for in the urine) has a cross reactivity of 25%.

If any of these analytes are present in the oral fluid at concentrations at or above the set screening cut-off level (either 10 ng/mL or 4 ng/mL), the screen would be positive (i.e., the absorbance from the donor specimen will have exceeded the absorbance of the cut-off calibration standard).

Since the immunoassay has significant cross-reactivity with a number of analytes, they may also be present together in the specimen, each at concentrations below the set cut-off level and still produce a positive result as their combined cross-reactivity is enough to a generate an absorbance at or exceeding the cut-off calibration standard. In other words, the combination of the structurally similar components of cannabis exceeds the set cut-off level resulting in a presumptive positive screening result.

Once this occurs, the test goes on to confirmation testing. With oral fluid, the confirmation test is completed using LC/MS/MS (liquid chromatography/tandem mass spectrometry) testing. The confirmation test confirms only the presence of delta-9-THC (THC) in the oral cavity. The cut-off level for this is either 10 ng/mL or 2 ng/mL (as ordered based on the company request). This confirmation test will be positive if THC is present at or above the set cut off level. There is no "cross-reactivity" in confirmation testing, as it is very specific to the substance being tested.

The screen level is important as it helps to ensure that the sensitivity of the test is high. In other words, the screen helps to prevent false-negative tests from occurring.

Differences in Confirmation Cut-off Levels - 10 ng/mL vs. 2 ng/mL

As reviewed above, it is the remnants of the parent drug delta-9-tetrahydrocannabinol ("THC") left in the oral cavity that is detected by way of the oral fluid test. This is different than with many other substances where the metabolite (break-down product produced by the body) is tested. Essentially, after ingestion or inhalation (by way of vaporization or smoking) THC is left in the oral cavity for hours until degradation, absorption and breakdown to its metabolites (11-nor-9-THC being one of the main metabolites).

The higher the THC concentration, the longer the remnants linger in the oral fluid and therefore stay positive on an oral fluid test. At the same time, the higher the concentration of THC (the psychoactive component of cannabis), the more impairing the drug is and the longer the impairment is thought to last.

The factors that may influence the length of time one takes to clear the THC from the oral cavity include the following:

1. Quantity of THC (based on number of grams used and strength of the THC)
2. Route of administration
3. History of use of cannabis

Anizan et al. (2013)[11], looked at frequent and occasional cannabis smokers and measured the THC levels in oral fluid (among other markers that we do not use in practice) up to 30 hours after smoking 54 mg of THC. At 6 hours, frequent users had an average of 12 ng/mL of THC in oral fluid (with a range of 2.5 – 27.4) and occasional users of THC had a level of 8.3 ng/mL (with a range of 2.7 – 27.8). When using a cut-off level of 2 ng/mL, the timeframe for the last positive test was 24 hours with the vast majority only testing positive up to 13.5 hours. In frequent cannabis users, the last positive was 30 hours with the majority of individuals only testing positive up to 24 hours.

[11] Anizan, S., Milman, G., Desrosiers, N., Barnes, A. J., Gorelick, D. A., & Huestis, M. A. (2013). Oral fluid cannabinoid concentrations following controlled smoked cannabis in chronic frequent and occasional smokers. *Analytical and bioanalytical chemistry*, *405*(26), 8451–8461. doi:10.1007/s00216-013-7291-5

This is in keeping with other studies as well. Huestis and Cone (2004)[12] showed that within 12 hours of using cannabis, all of their subjects had THC levels below 1 ng/mL in oral fluid. Again, it is important to note the date of this study and the fact that less potent THC levels were used. The timeframes with the use of todays THC would therefore be longer (as THC concentration has increased significantly over the years).

These studies (along with Newmeyer et et., 2014[13], Niedbala et al., 2001[14] and Cone and Huestis, 2007[15]) help to conclude that with most people, using a cut-off of 2 ng/mL, we would expect to see positive tests for no longer than 24 hours for occasional cannabis users. It is possible for heavy, chronic, frequent users of cannabis to test positive in an oral fluid for slightly longer (30 hours) however these individuals would have prolonged impairment in comparison to occasional cannabis users.

With a cut-off for THC of 10 ng/mL, as was proposed by the Companies in their June 28, 2019 Submissions, we limit the timeframe of detection to less than 12 hours after use. After this time, the THC levels would decrease and fall below the confirmation cut-off level of 10 ng/mL.

Considering the data from Anizan et al. (2013)[16] described above, the median THC fell below 10 ng/mL less than 8 hours after use for frequent cannabis user and none were positive at 10 ng/mL or above at 21 hours. The timeframe was slightly shorter for occasional smokers: the average oral fluid quantitative level was below 10 ng/mL at 6 hours. Like frequent smokers, oral fluid levels of all occasional smokers fell below 10 ng/mL well before 21 hours.

In another study conducted by Toennes et al. (2010)[17,] 13% THC was used and measurements in the oral fluid were taken at different times after smoking cannabis. At 8 hours, most were at 10 ng/mL or below.

Most studies conducted prior to 2010 looked at lower THC percentages (6.8% or less) but essentially showed that at 8 hours, the levels were well below 10 ng/mL. Considering the strength of THC available today, on average, a positive oral fluid test for THC at or above 10 ng/mL relates to use of cannabis within approximately 12 hours (accounting for the increase in strength of THC in the average cannabis used today).

---

[12] Huestis, MA, Cone, EJ; Relationship of Δ9-Tetrahydrocannabinol Concentrations in Oral Fluid and Plasma after Controlled Administration of Smoked Cannabis. *J Anal Toxicol* 2004; 28 (6): 394-399. doi: 10.1093/jat/28.6.394

[13] Newmeyer, Matthew N., et al. "Cannabinoid disposition in oral fluid after controlled cannabis smoking in frequent and occasional smokers." *Drug testing and analysis* 6.10 (2014): 1002-1010

[14] Niedbala, S,. Kardos, KW., Fritch, DF., Kardos, S., Fries, T., Waga, J., Robb, J., Cone, EJ.; Detection of Marijuana Use by Oral Fluid and Urine Analysis Following Single-Dose Administration of Smoked and Oral Marijuana. *J Anal Toxicol* 2001; 25 (5): 289-303. doi: 10.1093/jat/25.5.289

[15] Cone, EJ., and Huestis MA.,. "Interpretation of oral fluid tests for drugs of abuse." *Annals of the New York Academy of Sciences* 1098.1 (2007): 51-103.

[16] Anizan, S., Milman, G., Desrosiers, N., Barnes, A. J., Gorelick, D. A., & Huestis, M. A. (2013). Oral fluid cannabinoid concentrations following controlled smoked cannabis in chronic frequent and occasional smokers. *Analytical and bioanalytical chemistry*, *405*(26), 8451–8461. doi:10.1007/s00216-013-7291-5

[17] Toennes SW, Ramaekers JG, Theunissen EL, Moeller MR, Kauert GF. Pharmacokinetic properties of delta-9-tetrahydrocannabinol in oral fluid of occasional and chronic users. J Anal Toxicol. 2010;34(4):216–21.

In summary, when the confirmation cut-off for THC is set at 2 ng/mL, as the CNSC has proposed, the detection timeframe is approximately 24 hours. If there is a positive test at or above 2 ng/mL, this is indicative of use of cannabis within the last 24 hours. After this time, the THC levels would decrease to fall below the cut-off level for the vast majority of individuals using cannabis.

When the confirmation cut-off for THC is set at 10 ng/mL, the detection timeframe is shorter and indicative of use of cannabis within 12 hours prior to the test.

The timeframe of detection using a cut-off level of 10 ng/mL lines up with the timeframe of acute intoxication with cannabis. In other words, those who use cannabis have a period of acute intoxication, a time when they are experiencing the direct impact of the substance on their brain (the "high" or "inebriation") which can last approximately up to 12 hours. Therefore, there is a correlation with impairment from cannabis and a positive oral fluid test and based on a positive result, it can be concluded that there was a high likelihood of impairment in the workplace when an individual tests positive at or above 10 ng/mL.

Cannabis Impairment

Cannabis impairment is discussed in detail in my Expert Report dated June 26, 2019. When considering impairment however it is important to consider all forms of impairment; acute intoxication, residual impairment, impairment from withdrawals from substances, and long term cognitive changes occurring from substances that result in chronic impairment.

To briefly review, Grotenhermen (2003)[18] examines the evidence of acute impairment from oral ingestion of cannabis which has been shown to last up to 12 hours even in the face of lower potency THC. When looking at more recent studies, where the cannabis THC strength still does not equate to what individuals are using today, we see increasing time of impairment with strength of THC (Hunault et al., 2014[19] found that in an occasional user, smoking high potency 14% THC has prolonged acute subjective and objective effects in comparison to previously reported studies using lower potency cannabis). There are numerous studies and conclusions that lead to the consideration that those using cannabis do have impairments that exceed the acute intoxication phase.

The Occupational and Environmental Medical Association of Canada's Position Statement on Cannabis use in safety-sensitive workplaces states:

> *"It is recognized that the timing and duration of cannabis impairment is variable and that more research is needed in this regard. To provide practical guidance, until definitive evidence is available, it is not advisable to operate motor vehicles or equipment or engage*

[18] Grotenhermen, F. (2003). Pharmacokinetics and pharmacodynamics of cannabinoids. Clinicol Pharmocokinetics, 42(4),328-360

[19] Hunault, C.C., Böcker, K.B.E., Stellato, R.K., Kenemans, J.1., de Vries, 1., & Meulenbelt, J. (2014). Acute subjective effects after smoking joints containing up to 69 mg delta-9-tetrahydrocannabinol in recreational users: a randomiazed, crossover clinical trial. Psychopharmacology 231(24), 4733.

in other safety-sensitive tasks for 24 hours following cannabis consumption, or for longer if impairment persists."

Given that there is strong evidence that there is a risk of impairment after THC use that often lasts up to 24 hours at minimum, whether using a cut-off level of 2 ng/mL, there will be detection of individuals who have used cannabis and are at risk for impairment.

Sensitivity and Specificity of Oral Fluid Cut-off Levels

To answer the question and provide insight for question 4 a. it is first important to define sensitivity and specificity. Sensitivity measures how often a test will correctly identify a positive result for individuals who have the condition that is being tested for. A test that has a high sensitivity will identify almost all individuals who have the disease/condition/state and will not generate a high false-negative result. If a test has a 95% sensitivity, it will correctly identify (a positive test) 95/100 people who have the disease/condition/state. There will however be 5 people who will test negative, but were missed (or should have tested positive).

Specificity on the other hand, measures how often a test will correctly identify a negative test for people who do not have the disease/condition/state. A test with a high specificity will therefore not generate many false positives (people who do not have the disease/condition/state and should have tested negative).

With respect to oral fluid testing, the purpose is to identify individuals who have used a substance and are likely impaired. Oral fluid testing narrows the window of detection and with these tighter timeframes, it is possible to understand when the individual used a substance. With this knowledge, if an individual used a substance 8-12 hours before the test, and we know that impairment is highly likely at the time of the test, we would say that the oral fluid test was positive and there is a high likelihood of impairment.

Putting all of this together, and considering oral fluid testing and sensitivity and specificity, we can better understand whether or not the test will accurately identify all of those who may be impaired (not missing any individuals who are impaired - meaning the test has a high sensitivity) without picking up some individuals who are not impaired (avoiding falsely identifying someone who is impaired - meaning a test with a high specificity).

When using a cut-off of 2 ng/mL, the sensitivity will be very high. Meaning, that any individuals who have used cannabis in the last 24 hours, and could therefore potentially be at risk of impairment, will have a positive test. In other words, using 2 ng/mL has a high sensitivity and low rate of false negatives. However when using a cut-off level of 2 ng/mL, we may not be able to state for certain that everyone who tests positive is definitively impaired. There is most certainly a risk of impairment when cannabis is used within 24 hours; however, with our current knowledge and lack of definitive information pertaining to impairment for each individual person (as it is complicated and dependent on too many factors unlike alcohol), the timeframe of residual impairment is variable. When speaking in terms of specificity then, with the use of a

confirmation cut-off level of 2 ng/mL, we cannot necessarily confirm that the specificity would be 100% without any false positive tests.

With respect to 10 ng/mL, the sensitivity would not be as high as when using a confirmation cut-off level of 2 ng/mL. Meaning, that there may be individuals who test negative, who are indeed impaired. On the other hand, with respect to specificity, the specificity would be exceptionally high, in that, all individuals who test positive are most certainly impaired. A positive test would therefore indicate that the individual is at very high risk of impairment as this indicates very recent use of cannabis.

Proposed Cut-Off Levels

The chart below outlines the cut-off levels suggested by Dr. Huestis in her report *Oral Fluid Drug Testing Practice: Report to the Canadian Nuclear Safety Commission,* the cut-off levels listed in V.3 REGDOC, and the oral fluid cut-off levels currently used across Canada for workplace testing.

SUBSTANCE	Dr Huestis SCREEN LEVEL (ng/mL)	REGDOC SCREEN LEVEL (ng/mL)	Dynacare Current SCREEN LEVELS (ng/mL)	Dr Huestis LEVEL TO CONFIRM (ng/mL)	REGDOC LEVEL TO CONFIRM (ng/mL)	Dynacare Current LEVEL TO CONFIRM (ng/mL)
amphetamines	50	50	50	25	25	**50**
Benzodiazepines	10	10	10	3	3	**10**
THC	4	**5**	4 or 10	2	2	2 or 10
cocaine*	20	20*	20	8	8	8
opioids**	30	30	**40**	15	15	**40**
6-AM	4	4	***	2	2	**4**
Methadone	20	20	**50**	15	15	**20**

The cut-off levels that differ are **bolded and underlined**

* the REGDOC only specifies screening of benzoylecgonine (BZE), however with oral fluid cocaine and BZE will be screened which is recommended by Dr Huestis in her report

** this includes codeine, morphine, hydrocodone, hydromorphone, oxycodone and oxymorphone

*** the screen for 6-AM is not currently available. Immunalysis is working on this as per the SAMHSA OFMG but currently this is not available

Apart from THC, with respect to the appropriateness of the identified proposed cut-off levels for all other substances , I am in agreement with all of the cut-off levels when considering the timeframe of detection as well as the timeframe of impairment from these substances.

When individuals are using illicit, medically authorized or unauthorized amphetamines (including amphetamine, methamphetamine and MDMA,), cocaine (cocaine and Benzoylecgonine the metabolite of cocaine), opioids (including codeine, morphine, 6-AM, oxycodone, oxymorphone, hydrocodone and hydromorphone), benzodiazepines and methadone, it is imperative that a drug test will have the ability to detect use during the timeframe of impairment from these substances.

Dr. Huestis reviewed the target analytes in oral fluid and I do certainly agree with the overarching comments regarding the need to maintain a screen test that is sensitive enough to avoid false negative tests, and yet one that does not commonly detect non-impairing related medications or substances. The confirmation levels must be also set at a level that detects those using the substance in the timeframe where impairment would impact safety at work. Overall the screen and confirmation levels suggested by Dr. Huestis in her report have credibility, are appropriate and are closely mirroring that set out in the OFMG.

There are however, a few logistical concerns with the proposed cut-off levels listed in V.3 REGDOC.

1. **THC Screen at 5 ng/mL**

The cut-off levels for screening tests are set by the manufacturer (Immunalysis) of the kits that screen the oral fluid tests (using Quantisal Oral Fluid Device). The only available screening levels, as per the chart above, are 4 ng/mL and 10 ng/mL. The ability to screen at 5 ng/mL does not exist for the screening of Quantisal. It is not anticipated that Immunalysis will develop the ability to screen at 5 ng/mL, as this is not in keeping with the OFMG set cut-off levels for THC in oral fluid (which is a screen at 4 ng/mL and confirm at 2 ng/mL). Dynacare does not use any oral fluid tests that have the ability to screen at 5 ng/mL. It is plausible that there are other laboratories in the U.S. that use other oral fluid testing kits where they are able to screen at 5 ng/mL, however I am not aware of any laboratories that have that cut-off level.

As discussed above, the Draegar DrugTest 5000 oral fluid POCT has the ability to screen at 5 ng/mL (although this would not fit the criteria and standard set-out for an acceptable device by the V.3 REGDOC which is discussed above). This level cannot be matched at the laboratory.

Dr. Huestis states that following recommendation in her report regarding the oral fluid test for THC:

> *"For laboratory oral fluid screening and confirmation, a 4 ng/mL screening cutoff and a 2 ng/mL confirmation cutoff matching the SAMHSA proposed guidelines and the cutoff utilized by the COAA, CODC, Syn Lab, and the London, Ontario Dynacare Laboratory is recommended."*

It can only be assumed that V.3 REGDOC has proposed a screen cut-off level of 5 ng/mL in order to match that used by the recommended POCT for oral fluid (Draegar DrugTest 5000). Other than to stay consistent with this device (which again is neither Health Canada certified, nor is the test at 5 ng/mL one that is approved by the Department of Justice Canada), there are no studies that I am aware of looking specifically at a screening cut-off of 5 ng/mL, nor is this screening cut-off level available in Canada.

2. **Ability to test at the proposed cut-off levels**

There are many cut-off levels (both screen and confirmation) proposed in V.3 REGDOC that Dynacare cannot currently test at (aside from THC which is reviewed above). The chart below outlines the screening and confirmation test cut-off levels for oral fluid testing listed in the U.S. Department of Health and Human Service's Mandatory Guidelines for Federal Workplace Drug Testing Programs (Oral Fluid Mandatory Guideline - OFMG). U.S. DOT testing will require the laboratories to test at these levels; however they do not test for benzodiazepines or for methadone and as such, this is not included in the OFMG.

The chart below only outlines the OFMG cut-offs that differ from what Dynacare is currently testing at. It is important to note these levels, as Dynacare will be able to screen and confirm at these cut-off levels in the chart below (as this will be required for all U.S. Federal testing such as U.S. Department of Transportation testing):

SUBSTANCE	Dynacare Current SCREEN LEVELS (ng/mL)	Oral Fluid Mandatory Guideline SCREEN LEVELS (ng/mL)	Dynacare Current CONFIRMATION LEVEL (ng/mL)	Oral Fluid Mandatory Guidelines CONFIRMATION LEVEL (ng/mL)
amphetamines	50	50	50	25
cocaine	20	15	8	8
Codeine	40	30	40	15
morphine	40	30	40	8
oxycodone/ oxymorphone	40	30	40	15
hydrocodone/ hydromorphone	40	30	40	15
6-AM	***	4	4	2

From this, one can see that, other than the screen of THC at 5 ng/mL (vs. 4 ng/mL in the OFMG), and the cocaine screen at 20 ng/mL (vs. 15 ng/mL in the OFMG), the remainder of the screen and confirmation cut-off levels recommended in V.3 REGDOC are the same as those of the OFMG. The concern at the moment is that the laboratory is not able to currently screen or confirm at some of the levels.

In summary, the following are a list of cut-off levels that the laboratory is unable to test at currently:

Screen

THC (V.3 REGDOC proposed 5 ng/mL only 2 ng/mL or 10 ng/mL available)

* ***Opioids*** (V.3 REGDOC proposed 30 ng/mL only 40 ng/mL available)

* ***6 -AM*** - the screen for 6-AM is not currently available. If the test screens positive for any opioids, Dynacare will confirm whether or not there is the presence of 6-AM at the confirmation cut off level of 4 ng/mL). Immunalysis is working on this as per the SAMHSA OFMG but currently this is not available

Methadone (V.3 REGDOC proposed 20 ng/mL only 50 ng/mL available)

Confirmation

* ***Amphetamines*** (V.3 REGDOC proposed 25 ng/mL only 50 ng/mL available)

Benzodiazepines (V.3 REGDOC proposed 3 ng/mL only 10 ng/mL available)

* ***Opioids*** (V.3 REGDOC proposed 15 ng/mL only 40 ng/mL available)

* 6-AM (V.3 REGDOC proposed 2 ng/mL only 4 ng/mL available)

Methadone (V.3 REGDOC proposed 15 ng/mL only 20 ng/mL available)

The discrepancies that will resolve once Dynacare is set to screen and confirm at the OFMG cut-off levels are shown with a star (*) to the left of the test. This however, as stated earlier, is not expected to be available until mid 2021.

With respect to benzodiazepines, it is my recommendation that the CNSC consider changing the cut-off levels for benzodiazepines to match that which the laboratory can currently test at. The reason for this is that, otherwise oral fluid testing will not be able to be conducted by the Companies if the samples are to remain in Canada. Additionally, when an individual is using benzodiazepines, the test will detect many of the metabolites (or breakdown products), many of which are also active metabolites (having action in the brain), and prolong the detection in the

oral fluid. Although there is certainly an argument for lower testing levels in order to lengthen the timeframe of detection, the laboratory in Canada is not able to test at these levels currently.

With respect to methadone, individuals who are prescribed methadone take this medication daily or near daily (with occasional missed doses especially for individuals who are not stable with respect to their treatment and substance use disorder). Methadone has a very long half-life and will be picked up for all individuals prescribed methadone even with the lower levels that the laboratory can currently test at. It is my recommendation that, similar to benzodiazepines, the CNSC consider changing the cut-off levels to match what the laboratory is able to test at. This will not sacrifice any detection of individuals taking methadone.

I am hopeful that this report answers the questions you posed with clarity. If you require any further information or explanation, please do not hesitate to contact me.

Sincerely,

Melissa Snider-Adler, MD, CCFP(AM), MRO (AAMRO), DABAM
Chief Medical Review Officer, DriverCheck Inc.
Addiction Physician, South Oshawa Clinic
Assistant Professor, Queens University School of Medicine, Department of Family Medicine
Methadone Program Peer Assessor, CPSO
Phone:personal information redacted
Fax: personal information redacted
Email:personal information redacted

Enclosure 4

Expert Report of Dr. Leo Kadehjian

Dr. Leo J. Kadehjian

Biomedical Consulting

personal information
redacted
Palo Alto, California 94306

personal
information
redacted

May 28 ,2020.

Mr. Henry Dinsdale
Hicks Morley Hamilton Stewart Storie LLP
Toronto, Ontario, CANADA

Mr. Dinsdale,

In response to your letter dated May 19, 2020, below are my responses to the questions you have posed regarding proposed changes to REGDOC 2.2.4 Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3.

1.(a). My opinion on the meaning and scope of "cannabis-derived products" in the drug testing context.

Within the context of the safety-driven REGDOC prohibitions of reporting to work, remaining at work under the influence of, and bringing, keeping or consuming cannabis-derived products, the term cannabis-derived products" in my opinion represents those materials whether natural or synthetic that are derived from the cannabis plant that contain psychoactive THC or are similar in behavioral effects to THC. This would include cannabis plant material other than hemp with demonstrated minimal THC content (i.e. <0.3%). This would also include THC-containing products intended for smoking, vaping or in edible formulations. This would also include synthetic formulations such as Sativex which contains synthetic THC, and other psychoactive synthetic derivatives of THC.

1.(b). Comment on how this term may be used and/or interpreted by other industries or employers in their alcohol or drug policies

I have no information on whether or how this term may be used and/or interpreted by other industries or employers in their workplace alcohol and drug policies.

2(a) Comment on Point of Collection Testing (POCT)

I have previously commented extensively on the use of POCT testing in my prior June 26, 2019 report. Since then I have maintained active review of the peer-reviewed published analytical and toxicology literature and nothing therein has led me to alter my opinions. I remain supportive of the use of POCT as a screening tool.

I understand that the REGDOC does not mandate the use of POCT devices for urine or oral fluid drug testing, but rather simply allows the licensees to choose whether they wish to utilize POCT devices as a screening tool or to assess the risk of having a worker return to safety-sensitive or safety-critical duties, pending the medical review officer's report on the urine- or oral fluid-based laboratory test.

As I read and interpret the first one-sentence paragraph under REGDOC Version 3, 6.2.1 Point of Collection Testing, one situation where the use of a POCT is being contemplated, is pending MRO review of a urine or oral fluid laboratory test result. This language obviously implies that the laboratory result was confirmed positive and thereby would be reported to the MRO, thus requiring MRO review. I would advise against interposing a POCT test pending MRO review and report of a laboratory-confirmed positive test result. In my opinion, the laboratory-confirmed positive test result demonstrates a potential safety risk that should not be at risk of being overridden by a subsequent potentially "negative" POCT test. That is not to say that POCT tests are not accurate or reliable, but a "negative" POCT test result after a confirmed positive laboratory result can never be taken to mean "no drug in the specimen" nor "no drug use". Given the critical safety-sensitive issues in the nuclear power industry, the concerns resulting from a confirmed laboratory test result should not easily be dismissed, even temporarily, pending a medical review officer's report, by an interposed potentially "negative" POCT test result. If my reading of this paragraph misinterprets the policy intent, then the language in this paragraph should be more clearly articulated.

The proposed changes in REGDOC Version 3 also include the certification of POCT devices by various agencies including certification by Health Canada or approved by the Department of Justice Canada for roadside use.

I cannot comment on the specific expertise with which these agencies have to make assessments of the scientific and clinical performance of various POCT devices. The device performance criteria for roadside use with associated potential criminal penalties may be different than those required for a safety-based workplace drug testing program. However, I agree that any such devices be vetted through an agency that does have the demonstrated qualifications and experience to rigorously assess such devices. One such agency would be the U.S. FDA which has been the agency with the responsibility and long expertise to determine the performance of these devices.

I agree that any POCT devices selected be independently evaluated by qualified laboratory personnel both in an initial evaluation as well as on an ongoing basis at least annually, and also whenever a new lot of devices is obtained. These evaluations should include both spiked and actual clinical specimens with concentrations both above and below the stated cutoffs.

I agree that the devices need to be calibrated with established standards at the stated cutoffs. Furthermore, such calibration should be performed in compliance with the POCT manufacturer stated procedures.

3(a) Comment on the proposed REGDOC Version 3 which includes a change to the screening and confirmation THC cutoffs in oral fluid from 10 ng/mL screening and confirmation, to 5 ng/mL screening and 2 ng/mL for confirmation.

Before addressing the choice of screening and confirmation cutoffs, it must be remembered that the gatekeeper in determining whose specimen is identified as demonstrating an increased risk of safety-related impairment is the screening cutoff. Confirmation testing is simply to demonstrate with high specificity that the screening assay accurately identified the drug and/or metabolite in question and to quantitate the drug and /or metabolite concentration.

One must also recognize the distinction between analytical sensitivity and specificity and clinical sensitivity and specificity. Analytical issues reflect the accurate determination of the concentration of drug and/or metabolite in a specimen. Clinical issues reflect the accurate determination of the test result to demonstrate an increased risk for safety-related performance. So the analytical accuracy at a 5 or 10 ng/mL cutoff is distinct from whether an accurate analytical result at a given cutoff accurately reflects a donor presenting an increased safety risk.

Regarding analytical sensitivity and specificity of the screening assay, anytime a screening cutoff is lowered analytical sensitivity is naturally expected to increase. That is, lowering the oral fluid screening cutoff to 5 ng/mL from 10 ng/mL will identify those additional subjects whose oral fluid THC concentrations lie between 5 and 10 ng/mL at the time of specimen collection. This could be a very small number of specimens relative to the total number of positive specimens and thus lowering the cutoff may not have a significant impact on sensitivity. But lowering the screening cutoff accordingly extends the window of detection perhaps beyond the established several hours during which there are clear and recognized safety-related psychomotor and cognitive deficits. Thus, it may argued that effects of THC may have sufficiently subsided such that diminished risks of safety-related deficits exist. So there is a trade-off between analytical sensitivity to detect any recent use, vs. the sensitivity and specificity to detect sufficiently recent use with associated recognized safety-related deficits. Thus, to ensure that a positive screening result has sufficient clinical specificity, a long detection window should be avoided.

It is hard to know what the effect will be absent knowing the oral fluid concentrations observed within the population being tested. It is true that subjects who test positive at 10 ng/mL or above will at some later point in time have concentrations between 5 and 10 ng/mL, but when they may no longer present significant safety risks. I maintain my recommendation for a 10 ng/mL screening cutoff for THC, which is consistent with that recommended by the EWDTS (European Workplace Drug Testing Society) and even lower than that in the Australia–New Zealand Standard (15 ng/mL). That said, use of a 5 ng/mL cutoff may still be acceptable from a safety standpoint. I note that the proposed 5 ng/mL cutoff does not exactly comport with that recommended in the Huestis report (4 ng/mL) but does match the cutoff for the Draeger POCT device.

With regards to analytical specificity, i.e. correctly identifying specimens below the stated cutoff as "negative", specificity failures then can result in an otherwise "negative" specimen being incorrectly identified as "positive". Such failures are termed "false positives". That is not to say that the specimen was drug-free or that there has not been drug use. Granted such incorrect identifications are completely undesirable for any testing program. But further confirmation testing can resolve any of the incorrect analytical identifications.

But the issue goes beyond analytical accuracy to whether the test correctly identifies those creating a workplace safety risk, i.e. the accuracy of the clinical interpretation of the test result. So what is important overall is that a confirmed positive result have high positive predictive value that the donor is presenting an increased workplace safety risk. I have originally and continue to recommend the use of 10 ng/mL screening cutoff for THC in oral fluid to have high positive predictive value that the use of impairing cannabis has occurred sufficiently recently to be associated with the known periods of performance deficits of cannabis users. There have been no new peer-reviewed published studies since my previous June 26, 2019 report to convince me to alter my opinion. Granted using a lower screening cutoff will allow the detection window to be extended. In pharmacokinetic drug elimination terms lowering the cutoff from 10 to 5 is what would be expected after an additional half-life of drug elimination from oral fluid, i.e. after each half-life drug concentration is reduced by one-half. Given the relatively slow elimination of THC from the body, this additional half-life could extend the window of test positivity to periods where the risk of safety-related performance deficits may have diminished.

Thus, to ensure that a positive screening result accurately identifies those subjects who have used cannabis recently within the time frame associated with performance deficits I continue to recommend a 10 ng/mL cutoff. This provides assurance to donors that they will not be identified when there maybe little risk of safety-related performance deficits.

As clearly stated in the REGDOC Version 3, I agree that in the initial phases of the implementation of oral fluid testing, a sufficient sampling of "negative" specimens be submitted for confirmation testing so as to have a more accurate assessment of the THC concentrations observed within the licensee's population.

I understand that the Commission has considered the report by Dr. Marilyn Huestis dated March 2020. I have reviewed this report. I note that the Huestis report recommendations for the screening cutoff for THC is 4 ng/mL for laboratory based testing, and 5 ng/mL for POCT testing using the Draeger Drug Test 5000 device. My review of the Huestis report indicates that these cutoffs do not appear to be impairment risk based. The POCT cutoff appears to be based simply on what the device's capabilities are. The 4 ng/mL cutoff recommendations appears to simply be based on what SAMHSA and other organizations have chosen. I note that other organizations have chosen higher screening cutoffs of 10 and 15 ng/mL. As REGDOC Version 3 indicates the proposed oral fluid screening cutoff for THC is 5 ng/mL and thus is the same whether screening by laboratory-based or POCT-based testing.

The Huestis report also indicates a very short detection window of only 2-3 hours for occasional users at a 10 ng/mL cutoff. However, my review of the literature demonstrates that after controlled dosing, numerous occasional use subjects did have positive test results well beyond 2–3 hours, to 6 hrs or even slightly longer. Given that it may be argued by some that the likelihood of a risk of safety-relative deficits may not extend beyond several hours after cannabis use, it is important that a cutoff be chosen such that the window of detection does not extend far beyond that where there is recognition of safety-related performance deficits.

The emphasis should be on detection of use associated with likely increased safety risks and not on overall sensitivity to detect any use. In this regard, in my opinion, a 10 ng/mL screening cutoff is appropriate.

3(b) The appropriateness of the screening cutoffs for other drugs

I have assumed the question again refers to the oral fluid screening cutoffs.

For drugs other than THC, there is less data on which to make conclusive decisions about appropriate screening cutoffs associated with an increased risk of safety-related impairment. Based on the literature available, I have made recommendations for oral fluid screening cutoffs for the drugs amphetamines (50 ng/mL), cocaine (50 ng/mL), opiates (50 ng/mL), benzodiazepines (10 ng/mL), and methadone (50 ng/mL) for increased safety-related impairment risk. These cutoffs have been based on the temporal connections between the period of oral fluid test positivity and the period of recognized safety-related performance deficits. The cutoffs I have recommended do not differ in any clinically significant way from those in REGDOC Version 3 or in the Huestis report, and do comport with those from some other drug testing agency recommendations. For cocaine, opiates, and methadone my recommended screening cutoffs are different and more conservative (i.e. resulting in a slightly shorter window of detection) (cocaine metabolite 50 ng/mL vs. 20 ng/mL, opiates 50 ng/mL vs. 30 ng/mL, and methadone 50 ng/mL vs. 20 ng/mL). That is, having slightly higher cutoffs means a shorter window of detection ensuring that those testing positive have used the drug sufficiently recently to have increased risks of safety-related impairment. I note that the Huestis report did not specifically demonstrate that the recommended cutoffs were chosen because of a temporal association with known periods of safety-related impairment, but rather simply noted the cutoffs complied with those suggested by other groups, agencies and laboratories.

I note that modern technically competent laboratories should be able to provide whatever screening and confirmation cutoffs are deemed appropriate for safety-related workplace drug testing policies. I do not believe that the laboratory should be limiting the choice of cutoffs for safety-based workplace drug testing programs. Granted, POCT testing may have greater technical limitations in meeting safety-based workplace drug testing programs' desired oral fluid screening cutoffs. Safety-based workplace drug testing programs' wishing to utilize POCT devices may have to accept any cutoff limitations that exist with the use of such devices.

That said, I do not have any strong arguments to make for or against the specified cutoffs in REGDOC Version 3 for the drugs other than THC.

I am prepared to respond to any questions you may have.

Dr. Leo Kadehjian