From: Velichover, Einat <personal information redacted>
Sent: May 26, 2020 11:01 AM
To: Consultation (CNSC/CCSN)
Cc: Hunter, Lynda (CNSC/CCSN)
Subject: Consultation on draft REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use, Version 3
Attachments: Letter to Nuclear Safety Commission.pdf

Dear Members of the CSNC,
Please find attached Draeger Safety Canada's comments regarding the above noted draft.
If you have any questions regarding our comments, please don't hesitate to reach out.
Sincerely,

Einat Velichover
Business Development Manager
(Impairment Checks)

Cell: personal information redacted
Draeger Safety Canada Ltd
2425 Skymark Ave, Unit 1
Mississauga, ON, L4W 4Y6

May 25, 2020

VIA E-MAIL

From:
Einat Velichover
Draeger Safety Canada Ltd
[personal information redacted]

Attention: Lynda Hunter
Senior Human Factors Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, ON, Canada K1P 5S9

Re: **Public Commentary related to REGDOC 2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug Use***

Dear Ms. Hunter:

The purpose of this letter is to comment on REGDOC-2.2.4, version 3, which establishes requirements and guidance for managing worker fitness for duty with respect to alcohol and drug use, intended for high-security Canadian nuclear facilities.

General: Oral Fluid Testing

In meeting these requirements, it is now given in version 3 of REGDOC-2.2.4. that licensees may choose to use either urine drug testing or oral fluid drug testing, or a combination of both. The fact that licensees will be allowed to collect and test an oral fluid specimen as part of their drug testing programs is highly appreciated. The interest of more and more employers has shifted from urine testing alone towards a combination of different specimens to help maximize drug screening program efficiencies and return on investment. Each specimen offers particular strengths and weaknesses, and the use of multiple specimens in testing programs can complement each other.

Oral fluid is popular due to its easy, rapid collection, its non-invasiveness compared to urine or blood, the convenience of collecting a specimen anywhere, anytime, and the difficulty of adulteration. The main advantage of oral fluid, with its tighter window of detection, is that it gives an almost immediate result that would show a person's peak levels of intoxication at the time of the test on the job, since the presence of a parent drug can assist in the determination of an individual being 'under the influence' of a drug. It's a faster approach for more timely results.

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Developments in technology now allow immunoassay screening of oral fluid samples to be carried out onsite. Tests are commercially available, mobile and easy to use and, used on-site, can ensure sample collection without delay. The Dräger DrugTest 5000, is an oral fluid device developed by Dräger. It has been used globally for over a decade by law enforcement and workplace applications. The device is also approved by Canadian Society of Forensic Science and the Attorney General for use in criminal charges by law enforcement. Although the approval only includes THC and Cocaine, additional drugs can be monitored on the same hardware if desired by the Canadian legal system. Workplace customers using the Draeger DrugTest 5000 device can choose from 7 different drugs using the test panels for workplace applications.

Oral Fluid Immunoassay Screening

In the following text passages, the associated cut-off values to the oral fluid analysis drug panel given in Chapter B.5, Table B5, will be commented on in more detail. It must be mentioned that drugs present in oral fluid are often the parent drug rather than a metabolite and tests kits reflect those differences. Therefore, the oral fluid analysis panel and the associated cutoff values should be chosen accordingly.

<u>Oral fluid drug testing panel: Cannabinoids</u>

Setting the cut-off value for Cannabinoids at 5ng/mL – which is basically THC – seems to be a good decision. The detection time for THC in oral fluid is shorter than the detection time for the metabolite THC acid in urine; consequently, a lower initial test cutoff concentration enhances detection rates of marijuana use. Lower cutoff concentrations will increase the number of specimens that are identified as containing THC and, thereby, will increase the deterrent effect of the program and improve identification of employees using this substance.

<u>Oral fluid drug testing panel: Cocaine metabolite (benzoylecgonine)</u>

In table B.5 it seems that the cut-off value of 20 ng/mL is associated only with the primary inactive cocaine metabolite Benzoylecgonine (BE) and not with cocaine itself.

It is strongly to be recommended also to include cocaine. The inclusion of both cocaine and benzoylecgonine as test analytes will increase the number of specimens that are identified as containing these cocaine analytes and, thereby, will increase the deterrent effect of the program and improve identification of employees using this drug.

Consequently, the cut-off value of 20 ng/mL should be associated to cocaine and/or the cocaine metabolite (benzoylecgonine).

<u>Oral fluid drug testing panel: Methadone metabolite (EDDP)</u>

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In table B.5 it seems that the cut-off value of 20 ng/mL is associated only with the methadone metabolite EDDP and not with methadone itself.

It is strongly to be recommended also to include methadone. Research has shown that EDDP cannot be observed in all oral fluid specimens being positive for methadone (Gray et al, 2011). Therefore, focusing on the detection of EDDP in oral fluid might lead to negative results although the drug itself, methadone, would be detectable in the sample.

Consequently, the cut-off value of 20 ng/mL should be associated to methadone and/or the methadone metabolite EDDP.

Oral fluid drug testing panel: Amphetamines

In table B.5 it seems that the cut-off value of 50 ng/mL is associated to "Amphetamines", including amphetamine and methamphetamine. It is important to consider that Amphetamine and methamphetamine are chiral molecules, so both molecules do exist in two different versions, the d-version and the l-version, which have different chemical properties. In both cases the d-version (=d-enantiomer) has greater biological activity than the l-enantiomer. For that reason, it is to be recommended to specify in table B.5 that the drug panel includes d-amphetamine and d-methamphetamine, with associated cut-off values of 50 ng/mL.

Oral fluid drug testing panel: Benzodiazepines

In table B.5 it seems that the cut-off value of 10 ng/mL is associated to either a single unspecified drug of the benzodiazepine family, or to a sum of two or more benzodiazepines.

If the cut-off value is associated to one drug of the Benzodiazepine family, it would be recommended to specify that drug in the same way as it was done in table B.5 for the opiates.

The specified benzodiazepine could be diazepam as one of the most commonly prescribed drugs, associated to a cut-off value of 10 ng/mL or 15 ng/mL.

Oral Fluid GC-MS and LC-MS/MS confirmation

Oral fluid drug testing panel: Benzodiazepines

In table B.6 it seems that the cut-off value of 3 ng/mL is associated to either a single unspecified drug of the benzodiazepine family, or to a sum of two or more benzodiazepines.

It would be recommended to specify the benzodiazepines, in the same way as it was done in table B.6 for the opiates.

Such a specification of the Benzodiazepines was already made for the urine LC-MS/MS confirmation analysis, see table B.3.

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If the commission has any questions for us or has any interest in further discussing the above comments, we welcome hearing from you.

Sincerely,

Dräger. Technology for Life

Dräger is an international leader in the fields of medical and safety technology. The family-owned company was founded in Lübeck, Germany, in 1889. Over the past five generations, Dräger has evolved into a publicly traded, worldwide group. The company's long-term success is based on the four key strengths of its value-driven culture: customer intimacy, professional employees, continuous innovation and a commitment to outstanding quality.

"Technology for Life" is the guiding philosophy. Whether in the operating room, in intensive care or emergency response services, Dräger products protect, support and save lives. Draeger Safety Canada and Draeger Medical Canada have operated in Ontario for over 30 years. Draeger currently supports workplace and law enforcement with diagnostic equipment nationally.

Draeger Safety division: Emergency response services, law and regulatory enforcement and industries such as mining, manufacturing, water treatment and power generation, where there are many safety-sensitive positions, trust in Dräger's integrated hazard management, in particular for personal protection and plant safety. This includes: respiratory protection equipment, fire training facilities, stationary and portable gas detection systems, professional diving equipment, as well as alcohol and drug detection technology.

Dräger also offers its customers extensive services and develops customized solutions, training concepts, and workshops.

Dräger has more than 14,500 employees worldwide and is currently present in more than 190 countries. The company maintains sales and service subsidiaries in over 50 countries. Its development and production facilities are based in Germany, Chile, China, the Czech Republic, India, Norway, South Africa, Sweden, the United Kingdom, and the USA.

Please visit www.draeger.com for more information.

Expert Background:

Dr. Stefan Steinmeyer

For 18 years, Stefan Steinmeyer has been working for Dräger, headquartered in Lübeck, Germany, within the Product Management Group, dealing with breath alcohol measurement devices and drug testing systems. He was part of product development teams and deeply involved in market research, and gained numerous user contacts in the course of operator trainings, product demonstrations, and clinical and field evaluations.

Stefan Steinmeyer studied chemistry of nutrition, and started to work in the field of forensic toxicology to prepare his PhD work. Therefore, he is well experienced in drug research and forensic scientific work. He is author of several relevant scientific papers and presentations, and is a member of national and international scientific organizations, including GTFCh, TIAFT, EWDTS.

Einat Velichover

For the past 3 years, Einat has been the Business Development Manager for impairment diagnostics at Draeger Safety Canada. She manages both workplace and law enforcement diagnostic portfolio. Einat managed the roll out of the Dräger DrugTest 5000 screening system, the first roadside oral fluid drug screening device approved for use by Canadian law enforcement. She works regularly with CSFS, DOJ, DDC, ATC, RCMP, Federal and provincial governments. Einat has completed the University of Indiana, The Robert F. Borkenstein Courses on The Effects of Drugs on Human Performance and Behavior and Alcohol and Highway Safety.