Occupational Health Clinics for Ontario Workers

Centre de Santé des Travailleurs(ses) de l'Ontario

Preventing Occupational Disease through the Designated Substance Codes for Exposure Measurement, Respiratory Protection and Medical Surveillance

A submission regarding the Ontario Ministry of Labour's Consultation on Proposed Changes to Ontario Regulation 490/09 – Designated Substances and the Requirements for Medical Surveillance, Respiratory Protection and Measuring

July 6, 2015

Executive Summary:

The Occupational Health Clinics for Ontario Workers Inc. (OHCOW) has extensive experience with designated substance assessment and control programs, including devising strategies for collecting exposure information, specifying what needs to be included in a control program and developing and delivering medical surveillance programs. OHCOW also has extensive clinical experience with workers who have suffered illness or injury due to exposures to various designated substances. Based on our experience, and the review of materials supplied by the Ministry of Labour (MOL), we are providing the following observations and recommendations regarding the "Consultation on Proposed Changes to Ontario Regulation 490/09 – Designated Substances and the Requirements for Medical Surveillance, Respiratory Protection and Measuring".

1. Our experience indicates that the current status of designated control programs in Ontario has deteriorated through neglect over the years since they were first initiated – we recommend that the MOL reinstate the deployment of occupational nurses, physicians and hygienists to audit control programs to ensure they meet the regulatory requirements.

2. We agree with the MOL that all workers working in workplaces subject to a designated substance program should fall under the provisions of such a program whether or not they are third party contractors, construction workers, or any worker as defined by the Occupational Health and Safety Act.

3. We agree with the proposal to update the code for measuring designated substances. However, we recommend that it include the requirement to conduct such sampling using appropriate sampling strategies (as defined in current occupational hygiene practice) – allowing for a range of qualitative to quantitative techniques as outlined in the hierarchy of exposure assessment.

    3.1. We recommend that the reporting of exposure data be centralized to ensure consistent data collection (the MOL?, CAREX?) to form the basis of valid and reliable personal exposure records.

    3.2. We have particular concerns regarding the measurement of non-monomeric isocyanates and would recommend that their measurement be required in the regulation.

4. We also concur with the strategy of using the CAN/CSA-Z94.4-11 – "Selection, Use, and Care of Respirators" as the pattern to establish appropriate respiratory protection programs.

5. Given the general approach of the proposed codes for measuring and prescribing respiratory protection for exposures to the designated substances, we recommend that this approach also be applied to the chemical agents listed in O.Reg 833, Control of Exposure to Biological or Chemical Agents.

6. In general, while we endorse the changes to the specific medical surveillance codes, we have a number of concerns about the outdated bases for the recommendations in the supporting documentation produced by Holness et al (2010):

6.1. The proposal to not use low-dose CT scans for high risk workers is outdated; since the time the Holness et al. review was written, the cited organizations have reversed their position – therefore, we recommend this issue be revisited and would endorse the authors' recommendation to find some mechanism that could respond to the evolving nature of the evidence for these techniques.

6.2. The suggestion that isocyanate biological monitoring is not yet mature is no longer true – again, we recommend that this issue be reconsidered given the current availability of valid techniques.

6.3. While we commend the reductions in the blood lead and urine mercury levels, we note that the current literature shows that health effects are associated with exposures resulting in blood lead and urine mercury levels lower than the proposed criteria; also, there is evidence to show an increase of genetic mutations in workers exposed to cumulative levels of vinyl chloride below current OEL levels.

6.4. While the use of a recent X-ray is commendable for reasons of reducing radiation exposure, we recommend, however, that the X-ray be re-read in light of the designated substance exposure information.

6.5. As per the principles outlined by L' Institut national de santé publique du Québec in their 2011 publication, "Reference Framework for Screening and Medical Surveillance in Occupational Health"; workers undergoing any medical tests/exams, must be made aware of all the screening benefits and disadvantages (including economic and quality of life implications) prior to consenting to participate in the medical surveillance program. We recommend that this type of informed consent be required for every occasion that a medical surveillance activity take place.

7. We suggest that the model on which the designated substance control programs were initially established is aging and in need of update – we recommend that the MOL consider the model of the Ontario Health Study and the use of e-health records to modernize the medical surveillance programs (both "active" and "passive"). We note that "passive" monitoring using Sentinel Health Events (Occupational) as screening criteria could be extended to cover substances listed in O.Reg 833 for which we have evidence of association with specific health outcomes.

8. Finally, we recommend that the MOL update its guidance publications related the designated substances (i.e. "Designated Substances in the Workplace: A General Guide to the Regulations", and the specific guides for physicians conducting medical surveillance tests and exams) – we also offer OHCOW's assistance in bringing these publications up to date.

We believe our recommendations, if adopted, would contribute significantly to the future prevention of occupational disease in Ontario.

OHCOW Background and Experience with the Designated Substances:

The Occupational Health Clinics for Ontario Workers Inc. (OHCOW) is an inter-disciplinary team of health professionals committed to promoting the highest degree of physical, mental and social well-being for workers and their communities. At six clinics in Ontario, a team of nurses, hygienists, ergonomists, service coordinators and physicians see patients and conduct research to identify work-related illness and injuries; promote awareness of health and safety issues; and develop prevention strategies. First established in 1989, the clinics have seen thousands of individual patients and visited hundreds of workplaces – helping to identify unhealthy and unsafe conditions, and providing advice to workplace parties on the prevention of occupational diseases.

OHCOW deals directly with Joint Health and Safety Committees (JHSC's), unions, employers, individual workers and others, helping them to interpret exposure assessments; develop assessment strategies; directly evaluate exposures; deal with issues underlying the requests for assessments (e.g. worker symptoms and health conditions); address questions of toxicology; and provide practical recommendations regarding elimination, substitution and/or control measures.

OHCOW has considerable experience with designated substance assessment and control programs, including devising strategies for collecting exposure information, specifying what needs to be included in a control program and developing and delivering medical surveillance programs. In addition, OHCOW has extensive clinical experience with workers who have suffered illness or injury due to exposures to various designated substances.

Current Status of Designated Substance Control Programs:

O.Reg 490 requires workplaces to perform assessments, and, where the assessment indicates, the regulation requires the development of a control program. Generally these control programs require engineering, work practice and hygiene exposure controls; methods and procedures to measure workplace and worker exposures; personal exposure and medical records; and a training program which covers the health effects of the designated substance and the contents of the control program.

In OHCOW's experience, the activity level involved with control programs has declined over the years. In 1989, when OHCOW was first established, the Ministry of Labour (MOL) would send a team consisting of an occupational health nurse and an occupational hygienist (sometimes also an occupational physician and/or an inspector) to audit the workplace control programs. Once section 28(3) of the Occupational Health and Safety Act (OHSA) came into effect, making participation in the medical surveillance program subject to the worker's consent, the participation rate seemed to decrease. After 1995, when the MOL eliminated the occupational health nurse positions and redefined the role of occupational hygienists, the auditing of control programs ceased. Since then, OHCOW has witnessed many of the medical surveillance programs deteriorate through attrition and neglect. Requests for assistance with, and OHCOW's participation in, designated substance programs has declined significantly – the only exception being small workplaces who recently have been inspected and ordered to establish control programs.

With respect to exposure records, very seldom when doing an exam for a designated substance, will OHCOW receive an exposure record as defined by O.Reg 490. Again, in our experience, the monitoring of worker exposures seems to have decreased, and the amount of sampling done is not adequate to

produce representative exposure records. Furthermore, particularly in small workplaces, there is often a heavy reliance on personal protective equipment, with insufficient emphasis on engineering controls as required by the regulation. Furthermore, personal physicians, who are often selected by workers to perform the designated substance exam and clinical tests, are often unfamiliar with the requirements under the regulation with respect to tests, exams, exposure record reviews and required health education. In summary, from OHCOW's perspective of involvement in designated substance control programs, the quality of these programs has deteriorated significantly over the years since their inception.

Underlying Concepts and Possible Updates:

The original structure of the designated substance control programs included engineering/work practice/hygiene exposure controls, monitoring of exposures in order to produce personal exposure records and medical surveillance for early signs of occupational disease with a view of intervening to reverse or at least prevent the condition from progressing, and recognizing occupational disease when it occurred by notifying the WSIB. The data, if collected properly and managed well, could also be analyzed collectively to monitor the group and thus follow trends on a population basis (which can be more sensitive than on the individual basis). However, without a centrally coordinated system to manage the data and ensure the measurements, clinical tests, and medical exams are performed according to the prescribed methods and strategies, the benefits of a group analysis of the collected data is lost. This applies to each individual workplace, and, if the data from all workplaces with the particular control programs are pooled, could also apply across the economic sector/province. As medical surveillance participation rates declined and/or diffused from centrally administered programs to personal physicians without central organization, the possibilities for monitoring the quality and compliance of the programs are more and more difficult if not practically impossible.

Medical surveillance, biological monitoring, and disease screening are a set of concepts which are often confused with each other. In order to sort these concepts, it is helpful to conceptualize the source-exposure-disease process by the following continuum:

Source → Path → Exposure → Absorption and distribution → Biological response →
→ Altered biological system function → Disease

Biological monitoring can be distinguished between two types, **biological exposure monitoring**, where the measurement of the chemical (or its metabolite) corresponds to the degree of exposure (and may or may not indicate a biological response is likely), and **biological response measurement** (a measurement of the biological consequence of the exposure). The value of biological exposure monitoring over air concentration measurements increases if there are pathways of exposure other than inhalation (e.g. skin absorption, and/or skin contamination leading to ingestion). For exposures that only have inhalation importance, there is generally no significant advantage to biological exposure measurements over air exposure measurements. **Screening tests** are clinical measurements which have been shown to predict the development of disease (hopefully at an early enough stage to allow for an intervention to reduce the risk of the screened individual developing the disease). **Medical surveillance** is an overall program which can use biological monitoring, screening tests, and medical examinations to monitor the health of individuals and groups of individuals (populations) for trends that might indicate the need for an intervention to prevent disease. Kudász and Hudák have written a very useful summary of the

definitions of various terms used ("Health screening and surveillance – OSHwiki", http://oshwiki.eu/wiki/Health_screening_and_surveillance (accessed July 3, 2015)).

Screening tests for occupational diseases can be evaluated much like other medical screening programs (e.g. cancer screening programs). Generally the tests can be evaluated based on evidence as to whether they are able to identify the disease at an early stage, whether this early detection provides a benefit to the individual being screened, and whether the costs and health/employment risks associated with the screening outweigh the benefits. Neil Johnston and Maritza Tennassee of the CCOHS developed a booklet titled "Biomedical Surveillance – A List of Questions" (1986) which was designed as a tool for health and safety activists to use to evaluate the strength of any particular proposed occupational surveillance system. L' Institut National de Santé Publique du Québec more recently has also published a helpful guide titled, Reference Framework for Screening and Medical Surveillance in Occupational Health (May 2011) which lists 11 criteria by which an occupational screening program can be evaluated (page 15). At least two of these criteria involve the informing of participants of the limitations and implications of the screening (e.g. possibility of false positives, the quality of life implications of false positives, possibility of false negatives, etc.). This aspect is not explicit in the old codes nor is it present in the proposed code for medical surveillance.

In the "Review of Medical Surveillance for the Designated Substances", by Holness et al. (2010), the authors state that:

> "In summary, there is a lack of evidence for most assessment components and tests being used in surveillance or screening programs. However, their use in case finding continues and it is in this context that many of the recommendations are made." (page 4-5)

Thus it is recognized that "most" of the components of the designated substance medical surveillance protocol do not meet current evidence based criteria to warrant their use in a surveillance program, rather the emphasis is on "case-finding" which is trying to identify workers with signs of developing an occupational disease largely for tertiary prevention purposes (e.g. notifying the WSIB and the workplace of the failure of the control program). Holness et al (2010) also made the observation that:

> "Many of the current practices in Ontario and other jurisdictions are based on traditional requirements. The question of moving from the traditional practices to those that are more evidence based requires a variety of input." (page 5)

In the spirit of this suggestion we would recommend the consideration of an electronic health record based surveillance system. An example of this would be the identification of individuals enrolled in a designated substance program who are participating in the Ontario Health Study. We understand that the Study has the ability to identify sub-groups for unique follow-up. Specifying a designated substance sub-population in the study would facilitate the monitoring of the individual, the workplace and the population of participating individuals and workplaces across the province exposed to the particular designated substance. The Study could be designed to prompt the examining physician to perform the required clinical tests and examinations, and could also provide a model health education module to facilitate the required health education component of the regulation and code. This would address some of the problems relating to the coordination and the quality of the tests and exams across individuals in the same workplace and across workplaces with similar programs throughout the province.

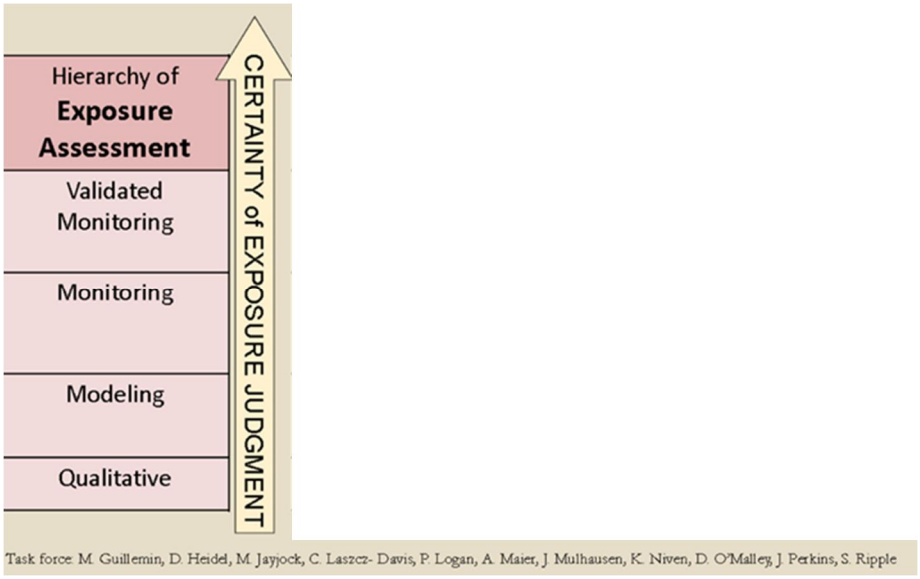
Some of the designated substances do not have an active medical surveillance program (e.g. arsenic and ethylene oxide). Instead they have a provision which allows for the evaluation of workers who are suspected (by themselves, their employer or their physician) to have a health effect due to exposure to a designated substance. This can be characterized as a "passive case-finding" system. A similar provision is found in O.Reg 833 section 8(1). In order to bring this type of case-finding "into the 21st century", one could use a system structure similar to the Ontario Health Study to passively monitor participants. For instance, one could monitor the healthcare system interactions of individuals exposed to a substance that is recognized in causing asthma or dermatitis for healthcare interactions relating to breathing or skin. Such a mechanism could also be extended to cover relevant substances in O.Reg 833 whose exposure has been associated with recognized Sentinel Health Events (Occupation) or SHE(O)'s (c.f. http://www.cdc.gov/niosh/topics/SHEO/). A system could then be designed to provide a prompting to investigate occupational exposures once a healthcare interaction which corresponded to a SHE(O) diagnosis was entered into the system. These prompts could be computer-generated protocols for including occupational exposure in the differential diagnosis and the etiology of the condition. The SHE(O) prompted guidance could also provide relevant medical management information in the context of workplace exposures. The establishment of a mechanism to transfer exposure information from the workplace to the medical records would enhance the capabilities of such a passive surveillance system. In essence this would provide a foundation for a reporting mechanism for occupational disease which could ultimately be built into an occupational disease registry.

Code for Measurement:

We believe, in general, it is wise to reference widely accepted methods that the field of occupational hygiene recognizes rather than specifying methods for the collection and analysis of airborne designated substances. That being said, however, in our experience there have been significant problems associated with the measurement of isocyanates. Often there are errors in selecting the proper method of sampling and analysis particularly in the cases of oligomers and blocked isocyanates. A common problem we have seen is a sampling strategy designed to only capture monomeric isocyanates when the source is predominantly oligomeric isocyanates. While this can be attributed to poor occupational hygiene practice, it is further abetted by the lack of any requirement to measure the exposure of non-monomeric isocyanates in the regulations (i.e. those not listed in table 1). Given the development in measuring oligomers, we would recommend these being included in the requirement for monitoring exposures and that the code for measurement apply also to such compounds.

As mentioned above, there is a concern regarding the lack of validity of the sampling strategies used to collect exposure data for the purpose of individual exposure records. As with the methods of collection and analysis of airborne designated substances, the field of occupational hygiene has developed standards of practice with respect to sampling strategies. The AIHA has published A Strategy for Assessing and Managing Occupational Exposures, 3rd Ed. (Joselito S. Ignacio and William H. Bullock, AIHA - American Industrial Hygiene Association (2006)) which is recognized as a minimum practice guide in developing strategies to assess exposures. The EPA also produced a booklet titled "Guidelines for Statistical Analysis of Occupational Exposure Data" (August 1994, www.**epa**.gov/opptintr/**exposure**/pubs/**stat**_guide_occ.pdf (accessed July 3, 2015)) which provides guidance for what is considered adequate data to characterize a worker's exposure.

Recently, the occupational hygiene field has developed the concept of a hierarchy of exposure assessment allowing some flexibility in using qualitative exposure assessment techniques – especially relevant for small and medium enterprises (SME's) which may not have the expertise or resources to conduct quantitative exposure assessment that would meet the field recognized criteria:



Qualitative exposure techniques such a control banding allow workplaces to identify exposures and, based on use characteristics (amount used, toxicity, etc.), find the prescribed level of exposure control without having to take measurements. These qualitative systems can be used to generate semi-quantitative estimates of exposure which could be used to supplement exposure records. To compensate for the lower level of accuracy and validity of the less rigourous techniques, one could set the criteria for response much lower if using a technique with more uncertainty (e.g. the mere presence of a substance of concern would trigger prevention activities for qualitative methods of exposure assessment, whereas if one could demonstrate consistent statistical compliance with a valid sampling strategy, one could be exempt of certain provisions (e.g. move from "active" to "passive" surveillance)).

This hierarchical approach to exposure assessment could also be applied to the substances referenced in O.Reg 833 which in turn could feed into a "passive" surveillance system as suggested above.

Especially for isocyanates, it has been recognized that dermal exposure can be an important exposure route in developing isocyanate sensitization. As such, it would be reasonable to also assess and record dermal exposure. Again, using the hierarchy of exposure assessment, one could allow for some flexibility in choosing techniques to assess dermal exposure.

This approach to exposure assessment strategies and techniques would also help CAREX's efforts to build up a province-wide (or country-wide) occupational exposure database.

Code for Respiratory Protection:

While we find it rather unusual to be commenting on a conceptual presentation of the code rather than the exact proposed wording, in general we agree with the concept of following the CAN/CSA-Z94.4-11 - Selection, use, and care of respirators standard. In fact, it would be extremely helpful if this proposal were to be expanded to include the substances referenced in O.Reg 833 and also apply to occupational exposures to pesticides. Based on our own experience of characterizing a worker with leukemia whose exposure to benzene consisted mainly of the absorption of benzene through the skin from solvents which had benzene concentrations below the WHMIS reportable concentration (0.1%), we would suggest that dermal protective equipment should also be addressed.

Code for Medical Surveillance:

We would like to thank the MOL for providing the document by Holness et al (2010) which provides the rationale of the changes to the medical surveillance codes. The following comments will follow the order of the items discussed in this review document.

Lung Cancer Screening:

The review by Holness et al (2010) follows the American College of Chest Physicians (ACCP) in recommending against the use of low-dose CT scans to screen for lung cancer. However, it is important to note that this review was finished in 2010 and much has gone on since that time in the field of using CT scans for screening for lung cancer. As Holness et al, themselves state:

> "Thus, the recommendations based on current evidence may well change as new evidence becomes available. Ideally, a mechanism to allow ease of revision or modification of recommendations would be beneficial." (page 5)

In 2012, the ACCP with a number of other organizations published a guideline titled: "The role of CT screening for Lung Cancer in clinical practice - The evidence based practice guideline of the American College of Chest Physicians and the American Society of Clinical Oncology" (supplementary material to Bach et al. (2012), "Benefits and Harms of CT Screening for Lung Cancer - A Systematic Review", JAMA. 2012;307(22):2418-2429). This guideline reverses the previous position which Holness et al (2010) reference as justification for not including low-dose CT lung cancer screening. In the US the CDC has produced a list of organizations with their positions on lung cancer screening (http://www.cdc.gov/cancer/lung/pdf/guidelines.pdf). In Ontario, Cancer Care Ontario has published a guideline recommending CT screening for high risk populations (Roberts H, Walker-Dilks C, Sivjee K, Ung Y, Yasufuku K, Hey A, et al. Screening high-risk populations for lung cancer. Toronto (ON): Cancer Care Ontario; 2013 April 18. Program in Evidence-based Care Evidence-based Series No.: 15-10.). Thus, it would seem appropriate to reconsider this recommendation in light of the newer recommendations.

OHCOW has considered the guideline produced by the National Comprehensive Cancer Network (NCCN), "Clinical Practice Guideline in Oncology for Lung Cancer Screening" (Version 1.2016), because it includes occupational exposures to lung carcinogens as a risk factor included in the criteria. The organization has also developed a guide for patients to help them understand the risks and benefits associated with such screening (http://www.nccn.org/patients/guidelines/lung_screening/files/assets/common/downloads/files/lung_s

creening.pdf). This is particularly relevant to the Sarnia OHCOW Clinic, since it has been collaborating with Princess Margaret Hospital/University Health Network in Toronto on a screening study for asbestos-exposed workers since 2005. Thus we would endorse the comment made by Holness et al (2010):

> "A mechanism to provide for the evolving evidence with respect to both health effects and screening tests would be advantageous so program recommendations could be modified as new evidence is found." (page 5)

Acrylonitrile:

While we agree with the recommendation that lung cancer screening is not warranted for workers exposed to acrylonitrile, we have some concerns about the errors in the rationale for this recommendation. First of all, an IARC group 2B classification should not be interpreted as the "… epidemiology data show no evidence of carcinogenicity in humans" (page 17). Furthermore, the Sponsiello-Wang et al (2006) meta-analysis (which was produced by employees of the Philip Morris Products S.A. R&D, Product Risk Management department) is mistakenly referenced as showing:

> "While a 2006 meta-analysis examining acrylonitrile exposure and lung cancer did suggest an effect estimate of 1.25 (95% CI 1.10 to 1.43) after adjustment for the healthy worker effect (overall effect estimate 0.95 [95% CI 0.86 to 1.06]) (Sponsiello-Wang 2006)" (page 17)

In fact the article by Sponsiello-Wang et al (2006) says the opposite, namely, "Overall effect estimates were 0.95 (95% CI 0.86 to 1.06) and 1.25 (95% CI 1.10 to 1.43) before and after adjustment for the healthy worker effect, respectively." (page 257). A recent paper by an author from the US EPA (Kopylev, L. (2014), "Approaches to Calculation of Average Exposure in Analysis of Epidemiologic Cohorts Using Large Acrylonitrile Cohort as an Example" Open Epidemiology Journal, 7, 1-5.), found that:

> "With restricting the cohort to only those with enough latency for lung cancer, the cumulative exposure divided by the length of employment is a significant predictor of the lung cancer mortality, while cumulative exposure divided by the duration of exposure (average intensity) is not." (page 1)

Thus, we would disagree with the characterization of the evidence as suggesting that acrylonitrile is not associated with cancer, however, given the low relative risk (RR) for lung cancer, the risk is not high enough to warrant lung cancer screening as per the guidelines suggested by a Canadian group (Fitzgerald et al., "Eligibility for low-dose computerized tomography screening among asbestos-exposed individuals", Scand J Work Environ Health – online first. doi:10.5271/sjweh.3496, 2015) who suggest that (for asbestos) screening is not cost-effective for those with a RR of 5 but is effective for those whose asbestos exposure would be associated with a RR of 10 (non-smokers only). Thus, a relative risk of 1.25 would not justify sufficient risk to counterbalance the risks associated with the screening process (i.e. radiation and risks associated with the follow-up of a false positive test).

Again, we reiterate the suggestion that a "passive" health surveillance system appropriately programed to sentinel health events associated with acrylonitrile exposure would be the most efficient means of surveillance.

Arsenic:

We suggest that a "passive" health surveillance system appropriately programed to sentinel health events associated with arsenic exposure would be the most efficient means of surveillance.

Asbestos:

We assume that there are few, if any, workers in Ontario that are covered by O.Reg 490 and that most asbestos exposed workers in Ontario would fall under the application of O.Reg 278/05. We therefore reiterate the discussion above with respect to reconsidering whether or not low-dose lung cancer screening is appropriate to be offered to highly exposed asbestos workers (as per the criteria suggested by Fitzgerald et al (2015)).

Benzene:

We would like to commend the author of the benzene section of the review by Holness et al (2010) for the thorough treatment of the issues. As per our experience cited above, we would add that any history of exposure to solvents having a significant aromatic hydrocarbon content (not just toluene) should be considered as a possible risk especially for dermal absorption of benzene, even if benzene is not listed on the safety data sheet (because it is present in concentrations less than 0.1%).

Coke Oven Emissions:

Some of the rationale provided in Holness et al (2010) for discontinuing medical surveillance for workers with coke oven emission exposure is rather concerning. Just because an "exact causative agent" cannot be identified is not sufficient grounds to cease medical surveillance. We have already addressed the issue of lung cancer screening above, however, given the number of other health conditions associated with coke oven emission exposures, we do not find the rationale provided convincing. Perhaps the "passive" medical surveillance suggestion would be sufficient to screen for such exposures, however, we can also see benefits for regular "case-finding" surveillance of COE workers.

Isocyanates:

In contrast to ethylene oxide, OHCOW has quite a significant history of involvement in performing medical surveillance for isocyanate-exposed workers. As noted above, one of our concerns is that the exemption of oligomers from the exposure assessment requirements makes it difficult for the examining physician to understand the extent of the worker's exposure.

Holness et al (2010) seems to suggest that biological monitoring for isocyanates is not yet practical for workplaces, however, we would direct your attention to work that has been done in the UK which demonstrated its efficacy already in 2005 (http://www.hse.gov.uk/aboutus/meetings/iacs/acts/watch/051005/13annexe2.pdf). In 2015 the ACGIH adopted a BEI for 1,6-Hexamethylene Diisocyanate (HDI): 1,6,Hexamethylene Diamine (HDA) in urine – end of shift 15 µg/g creatinine; and, also notified their intention to add a BEI for Toluene Diisocyanates (TDI): Toluene Diamine (TDA) in urine – end of shift 5 µg/g creatinine.

The HSE has Benchmark Guidance Values (BGVs) for Isocyanate Metabolites in Urine – 1 µmol isocyanate-derived diamine/mol creatinine – for the metabolites of HDI, TDI and two other isocyanates:

MDI (Methylene Dianiline) and Isophorone Diisocyanate (Isophorone diamine) http://www.hsl.gov.uk/media/1589/isocyanate_metab.pdf.

We would suggest the question of biological monitoring for isocyanates should be revisited given the current state of practice.

Lead:

We would again commend the author of the lead medical surveillance review in Holness et al (2010) for having done a thorough job. As noted in the review:

> "The setting of a single medical removal level may also be justified on the basis of non-reproductive (and therefore not gender specific) outcomes such as neurocognitive effects (executive abilities, manual dexterity, peripheral motor strength) which may occur at blood lead levels as low as 0.86 umol/L (Schwartz et al. 2002) and renal dysfunction and hypertension which occur at levels as low as 0.48 umol/L (Kosnett et al. 2007)." (page 89)

Thus the removal level of 1.0 or 1.4 µmol/L can be viewed as not being sufficiently protective. In a February 2013 report Health Canada lends further support for this point:

> "Studies clearly document adverse health effects - including neurodevelopmental, neurodegenerative, cardiovascular, renal and reproductive effects - at blood lead levels below 10 micrograms per deciliter (µg/dL), the current Canadian blood intervention level. There is sufficient evidence that blood lead levels below 5 µg/dL are associated with adverse health effects. Adverse health effects have also been associated with blood lead levels as low as 1-2 µg/dL, levels that are present in Canadians, although there is uncertainty associated with effects observed at these levels." (page 4, http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/prms_lead-psgr_plomb/index-eng.php (accessed July 3, 2015))

While we applaud the improvement proposed for the lead medical surveillance program, we would also like to keep in mind that there is strong evidence for the presence of health effects at exposure levels which correspond to blood lead concentrations well below the newly proposed criteria.

Mercury:

The author of the section of the review dealing with mercury cites 0.175 µmol/L as the "lowest level at which increased excretion of urinary NAG has been reported" (page 106). However, Richardson et al (2009) noted:

> "Ellingsen et al. (2000) is the first study to clearly observe elevated U-NAG at levels of UHg as low as 10.5 µg/g creatinine." (page 34, from: "Mercury vapour (Hg^0): Continuing toxicological uncertainties, and establishing a Canadian reference exposure level", Regul Toxicol Pharmacol. 2009 Feb;53(1):32-8.)

10.5 µg/g creatinine is equivalent to 0.05 µmol/L (using the creatinine assumptions cited by Holness et al (2010)).

Other health effects at even lower levels have been noted by Beate et al (2010):

> "Out of the resulting correlations between concentration and effect, ROC-curves were calculated to determine best estimates of the cut-off-values in the bio monitors. For the parameters ataxia of gait and sadness cut-off values of 4.7 and 3.6 µg Hg/g crea in urine were calculated." (page 3530 from: Beate L, Stephan BO, Gustav D. Proposal for a revised reference concentration (RfC) for mercury vapour in adults. Sci Total Environ. 2010 Aug 1;408(17):3530-5.)

Thus, while we can commend the reduction of the removal criteria for urine mercury levels, as per our comments concerning lead, one needs to note that the scientific evidence shows health effects at exposures corresponding to urine mercury concentrations much lower than those prescribed and those cited in the review.

Silica:

The proposed addition to the silica medical surveillance code suggests that workers with exposures less than 0.025 mg/m^3 could have a reduced frequency of follow-up. It should probably be clarified whether this is a yearly average exposure or maximum.

Vinyl Chloride:

Holness et al. (2010) reference the commonly held opinion that there have been no cases of angiosarcoma related to vinyl chloride monomer at exposures below the OEL of 1 ppm (equivalent to a working lifetime cumulative exposure of 40 ppm-years). It has been brought to our attention that scientific reports published after the review by Holness et al. (2010), have indicated genetic alterations in workers whose cumulative exposure ranged from 10-40 ppm-yrs. Brandt-Rauf et al (2012) summarized their conclusions regarding this range of exposure:

> "Workers with 10-40 ppm-years of cumulative exposure have been found to have a statistically significantly increased occurrence of the mutant biomarkers at a rate which is actually not statistically different from workers with more than 40 ppm-years of cumulative VC exposure, whereas workers with less than 10 ppm-years of cumulative exposure did not have a statistically significantly increased occurrence of the mutant biomarkers compared to unexposed controls.[31] Thus, a risk assessment based on biomarkers might suggest a permissible exposure limit of 0.25 ppm as being more adequately protective of workers' health by preventing the occurrence of these cancer-related mutations." (taken from: Brandt-Rauf PW, Li Y, Long C, Monaco R, Kovvali G, Marion MJ. Plastics and carcinogenesis: The example of vinyl chloride. J Carcinog. 2012;11:5.)

Again, there is "newer" evidence published since Holness et al.'s review that health effects are associated with levels of exposure below those stipulated in O.Reg 490.

Post-Acute Exposure Medical Exams and Clinical Tests:

We commend the recommendations to explicitly offer post-acute exposure medical exams and clinical tests for benzene, isocyanates, lead and mercury.

Using X-rays Taken for other Purposes:

While the main goal of reviewing previous chest X-rays as opposed to exposing workers to further radiation is rooted in health protection, there is some concern that significant occupational findings may be missed. For many decades the International Labour Office (ILO) classification of radiographs of

pneumoconioses has been the gold standard used in the radiological evaluation of asbestos-induced lung fibrosis. Significant to this protocol is that information of exposure be considered when evaluating chest radiographs. Clinical and relevant history information, which includes occupational exposure, often guides the interpretation of tests. Without the knowledge of occupational exposure, the radiologist may not be looking for occupational disease or findings. In a systematic review of accuracy of evaluating test results, Loy and Irwig ("Accuracy of Diagnostic Tests Read With and Without Clinical Information: A Systematic Review", JAMA, 292:1602-9 (2004)) concluded that including clinical information (of which occupational exposure would be relevant) improves the accuracy of the diagnosis. Therefore, reliance on previous chest X-rays may not be sufficient and we recommend they be re-read taking into consideration the specific exposure.

Removal of Construction Exemption from Section 15 (O.Reg 490):

We were surprised to note that construction workers were exempted from the provisions that apply to other "third party workers". In the practices we have observed or been part of, all workers in a workplace with a control program were expected to comply with the provisions of the designated substance control program. Given that this is what we understood the regulation to require, it is good to know the regulation is catching up to "current practice". We would assume that corresponding changes would be made to section 14 also to make them consistent with the intent behind the changes to section 15.

MOL Designated Substances in the Workplace: A General Guide to the Regulations:

We believe that the latest version of the booklet titled: "Designated Substances in the Workplace: A General Guide to the Regulations" was printed in 2001. Given the valuable materials in the booklet for a workplace looking to apply the regulation to their situation, we would recommend that the booklet be updated. OHCOW would be willing to assist with such a project.

MOL Guides for Physicians Performing Designated Substance Medical Evaluations

In the 1980's the Ministry of Labour published a number of guidelines for physicians performing designated substance medical evaluations. We believe these publications had useful information for physicians that weren't familiar with the expectations in the regulation and the code(s). Again, we believe that these should be updated and OHCOW would be willing to assist with such a project.