

CANADIAN ASSOCIATION OF RADIOPHARMACEUTICAL SCIENTISTS

Newsletter



April 2020

www.RadiopharmacyCanada.com

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In this edition:

What is our response to the COVID-19 generated crisis?

The editorial highlights the impact of the pandemic on radiopharmaceutical operations and the measures taken to reduce the risks. This section provides an overview of radioisotopes supply as presented by the [World Council of Isotopes \(WCI\)](#).

Regulatory Affairs

2020 arrived with a series of changes on guidance documents that have an impact on radiopharmaceuticals. We note:

- Implementation of submission in eCTD format, including Drug Master Files and Clinical Trial Applications;
- Changes pertaining to Drug Establishment Licenses; and
- Changes to GUI-0024 referring to the application for a certificate of a pharmaceutical product and good manufacturing practice certificate

Progress on Isotope Technology Development

CARS notes the participation of Dr. Mihaela Ginj - the radiopharmacy operations lead at Toronto General Hospital - as an observer to the latest technology development for Mo-99 production by BWXT.

The **Isotopes Supply** section provides you with the latest updates on the impact of the current situation on the delivery of medical isotopes

Most of the scientific events have been cancelled and postponed. However, the scientific community transitioned to virtual meetings and online learning classes. Follow the latest news on the [Professional Development](#) and [Scientific Events](#) sections.



What is our response to the COVID-19 generated crisis?

Editorial

COVID-19 stopped the world in its track; it made everyone rethink what they are doing, how they are doing it and more. It focused everyone's attention on healthcare systems around the globe. Analysts, biostatisticians, and medical professionals generated predictive data in an attempt to estimate the course of the pandemic and its impact on routine activities.

Less acknowledged, the production and delivery of radiopharmaceuticals is affected by the impact on imaging and radiotherapeutical operations in the nuclear medicine departments.

As of April 13th, CARS did not receive information on potential shortages of imaging agents or radioisotopes. Supply of radionuclides have over the last couple of weeks become more complicated due to less transport options, resulting in frequent delays. However, most of the research projects and clinical trials not related to COVID-19 have been postponed all over Canada. On the production side, the isotope production centres adapted manufacturing shifts to avoid potential contamination with the virus. Management adopted protocols to limit traffic within facilities, making sure to maintain the core-production of radiopharmaceuticals with minimal disruptions. We would expect that once regular operations are reinstated, the imaging procedures will scale up as a measure to reduce the backlog.

The shortage of PPE and essential medical supplies raises questions on the potential review of operational inventories in general. We are looking forward to receiving your input regarding the operational issues that you encounter during these times, especially those being related to servicing your accelerator or facility, availability of spare parts, the response from your regular vendors, or lack of routine reagents and chemicals.

All major suppliers of Mo-99 generators issued reassuring messages regarding their response to the crisis. The [latest newsletter](#) issued by the [World Council of Isotopes](#) provides an overview of the current status on isotopes supply.

[CARS forum](#) is open for discussions to all members about COVID-19.

CARS would like to acknowledge the effort of those who work in the healthcare system. Thank you to those behind the scenes: production teams, QC specialists and all members of the radiopharmaceutical community who work on keeping the operations ongoing.



Submissions in eCTD format

The eCTD format is implemented for the following Clinical Trial regulatory activities:

- Pre-Clinical Trial Application Consultation Meeting (PRE-CTA)
- Clinical Trial Applications (CTAs) with either a 7 day administrative or a 30-day default performance standard
- Clinical Trial Applications - Amendments (CTA-As) with a 7 day administrative or a 30-day default performance standard
- Clinical Trial Application - Notification (CTA-N)

The submission of Clinical Trial Application in eCTD format is not yet mandatory.

Effective January 1st, the submission of Master Files in eCTD format is also applicable.

- New Type I Master Files - Drug Substance
- New Type II Master Files - Container Closure Systems and Components
- New Type III Master Files – Excipients
- New Type IV Master Files - Drug Product

Health Canada provides support to those preparing for their first eCTD format regulatory transaction and advises the applicants to hold a pre-eCTD submission technical meeting.

If you have already started a submission process in eCTD format and you are willing to share the experience with the CARS community, contact us. We will open the topic for discussions within the [Forum](#).

Drug Establishment License

On April 1st, the updated Guidelines on Drug Establishment Licences (GUI-0002) is published and supersedes the 2011 version. Three main changes are noted:

The removal of references to drug establishment license fees; now included in a standalone document.

- Section 3 was revised to improve the clarity of the requirements that pertain to the Sterilization of Raw Materials and Packaging Material
- Section 6 has been revised to clarify that each DEL foreign building annex (for importers) is specific to one domestic building

The new document, *Fees in Respect of Drugs and Medical Devices Order*, provides clarification on the applicability of and how to comply with the associated requirements.



	<p>Management of Applications and Performance for Drug Establishment Licences (GUI-0127)</p> <p>On April 1st, Health Canada implemented the new policies (including the pause-the-clock policy), and additional application process improvements included in GUI-0127. The new guidance clearly explains the DEL submission process and provides a timeline of 250 days for processing.</p> <p>Directly related to the latest updates on Guidance documents pertaining to Drug Establishment License, Health Canada provided a revised Drug Establishment Licence Application Form and Instructions (FRM-0033). The new form reflects components of the new cost recovery regime. It includes updates to category "Prescription Drug List (PDL), Schedule G, Narcotics, and/or Drug containing Cannabis" which came into force October 2018.</p> <p>The guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024) was also revised. Changes include:</p> <ul style="list-style-type: none"> • Revised throughout for improved flow and clarity • Updated to reflect the new fees coming into effect April 1, 2020. <p>Source: Health Canada</p>
<p>Progress on the Development of Innovative Technologies</p>	<p>BWXT announced the successful completion of cold kits labelling with sodium pertechnetate extracted from the innovative technology of Mo-99 generators.</p> <p>Dr. Mihaela Ginja, the radiopharmacy operations lead at Toronto General Hospital, part of the University Health Network, observed some of BWXT's testing and labelling process. "I had the opportunity to spend half a day at BWXT and see several generators eluted and cold kits labelled and then tested," said Ginja. "I'm encouraged by this technology and its ability to fit into the existing radiopharmacy and nuclear medicine infrastructure. It allows me to be optimistic about a more diversified and reliable Mo-99 supply for nuclear medicine professionals and patients in North America."</p> <p>Source: BWXT</p>
<p>Isotopes Supply</p>	<p>On March 30th, a communication issued by Nuclear Medicine Europe (NMEu) emergency response team (ERT) informed its members that the cancellation of international flights had interrupted bulk shipments of Mo-99 from South Africa during the prior week.</p> <p>Late Update</p> <p>ERT held a teleconference on April 15th to discuss the impact of the COVID-19 pandemic on Mo-99 and other radioisotope production. All organizations reported that production operations continue normally within adjustments that have been taken against COVID-19, although production is being oriented to international flight availability. Radioisotope shipments from Europe have been more stable in recent weeks and continue via the reduced number of ongoing passenger flights.</p>



<p>Professional development</p>	<p>As the COVID-19 pandemic evolved, almost all scientific events and educational programs in our industry have been either cancelled, postponed or adapted to online learning platforms.</p> <p>IAEA is committed to supporting institutions operating in radiopharmaceutical and nuclear medicine industry affected by COVID-19.</p> <p>The IAEA invites the community to join the webinar “COVID-19 Pandemic: Supply of Medical Radioisotopes and Radiopharmaceuticals” on Thursday, April 23, 2020, 14.00 – 15.30 CET (Vienna time).</p> <p>The webinar series on Challenges for Nuclear Medicine Departments by COVID-19 brought together a panel of experts to discuss practical considerations such as:</p> <ul style="list-style-type: none"> • Site readiness • Prevention and hygiene • Patient scheduling • Patient management • Radionuclide therapies • Support to radiology departments • What to do if a team member is COVID-19 positive? <p>Recorded webinars are available on IAEA website.</p>
	<p>IAEA-KAERI-WCI e-Learning Course on Diagnostic and Therapeutic Radioisotopes and Radiopharmaceuticals application</p> <p>The course, recently announced by World Council on Isotopes, will take place during 6 - 31 July 2020 (4 weeks). This course will be organized by the International Atomic Energy Agency (IAEA) in cooperation with the Korea Atomic Energy Research Institute (KAERI) and World Council on Isotopes (WCI).</p> <p>The objective of this e-learning course is to strengthen the transfer of crucial knowledge and practical skills to technical professionals in the radiopharmaceutical field, and thus participants can build the skills needed to manage radioisotopes and radiopharmaceuticals for diagnostic and therapeutic applications in their home countries.</p> <p>The course will take place over 4 weeks, providing a kick-off meeting, closing meeting, lectures, discussions, Q&A, assignments, quizzes, and a final examination.</p> <p>Applications must be received by the International Atomic Energy Agency, P.O. Box, A-1400 Vienna Austria, no later than 15 May 2020. The final selection of course participants will be held jointly by the IAEA and communicated to KAERI and WCI. You can find details regarding the modules here.</p>



<p>Scientific events 2020</p>	<p>Scientific Events</p> <p>Current status of industry scientific events:</p> <p>Annual Conference of Canadian Association of Nuclear Medicine that planned to be held in Ottawa, April 23-25, 2020, will now take place in between October 8 - 10 , in Ottawa at the Brookstreet Hotel.</p> <p>The Annual Meeting of SNNMI 2020, initially scheduled for June 13-16, 2020 in New Orleans, Louisiana is currently uncertain. In a release posted on April 13th the SNNMI announced that the Board of Directors is looking to find alternatives for virtual scientific meetings. The New Orleans Convention Centre is currently closed and converted into a field hospital. In the meantime, SNNMI has created a detailed contingency plan for an interactive virtual meeting that is both informative and appealing, including continuing education, scientific abstracts, posters, exhibits and networking.</p> <p>18th Workshop on Targetry and Target Chemistry (WTTC18) The Local Organizing Committee Team of WTTC 18 is monitoring the coronavirus situation, and presently expects that WTTC18 can go ahead as planned in August. The new deadline for abstract submission is May 22, 2020</p> <p>The Fedoruk Centre, in partnership with the and the University of Saskatchewan and with Tourism Saskatoon support from the World Council of Isotopes (WCI) and IAEA will organize the 11th International Conference on Isotopes in Saskatoon in between June 19-23, 2022. The local organizing committee welcomes you to attend. More details will follow.</p>
<p>Membership information</p>	<p>Our association welcomes new members from all areas of radiopharmaceutical development. Please feel free to share our information with your peers, colleagues and students.</p> <p>The Executive Committee of CARS has decided in a meeting held on March 18, 2020 to waive the annual membership fees for professionals with interest in radiopharmaceutical sciences for a short period.</p> <p>You are welcome to register via CARS website, and you will have the opportunity to join our community and participate actively in discussions on our forum.</p> <p>Your input adds value to our community. Our association is looking to improve the communications between its executives and members. Currently, we dedicate the efforts to enhance our presence and to best represent your interests.</p> <p>Your Editor/Member-at-Large is happy to help you, so please do not hesitate to contact Lidia on her email at lidia.matei@fedorukcentre.ca with suggestions and recommendations.</p>



LETTER FROM THE EDITOR

Dear CARS members,

Because of our current situation, we have interrupted our journey through Canadian Cyclotron Facilities for this edition. We will return to the topic. Meanwhile, feel free to explore our [Community](#) section on the CARS website, and you will have an overview of the Canadian network of radiopharmaceutical facilities. If your facility is not listed, please contact us, and we will update the information within the shortest delay.

Lots of things happened since our last edition of CARS Newsletter. To resume a few;

- The refreshed CARS website is now active. You are welcomed to explore it and join our group discussions on the [Forum](#). The new site is designed to accommodate active discussions and information exchange.
- A pandemic has impacted our lives, and most of us try to adjust to the “*new normal*” of our professional (and personal) activities. We discovered that we have to make decisions that we have never made and that we have to adapt to situations that never would have occurred normally.

While clinical research and lab activity is impacted, we discovered that we now have the time to work on new projects or to catch up on document revisions. I hope that this work will lead to successful results in all of us.

Call for Contents

Your editor/member-at-large invites you to submit your articles, achievements or published work that you would like to bring attention to.

As always, please ensure your member information is up to date (email, mailing address, phone number(s)). We also encourage you to reach out to us with recommendations to help you get the most out of your membership. Our motivation is to provide value for our members and share best practice guidance to our radiopharmaceutical community.

Meanwhile, please stay safe and healthy.




Thank you for being a member of the Canadian Association of Radiopharmaceutical Scientists!

Sincerely,
Lidia Matei

Editor/Member-at-Large (CARS)



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 @Radiopharmcan
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 [linkedin.com/groups/12050884](https://www.linkedin.com/groups/12050884)

