

CANADIAN ASSOCIATION OF RADIOPHARMACEUTICAL SCIENTISTS

Newsletter



July 2019

www.RadiopharmacyCanada.com

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Network

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Canadian Association of Radiopharmaceuticals Scientists continues the efforts on the development of an active community involved in the research, production and development of radiopharmaceutical compounds.

Starting with this edition we open our series on pan-Canadian facility presentations. The future editions, will guide you through Coast to Coast cyclotron and radiopharmacy facilities. Our journey starts with two of the newest ones: Nuclear Molecular Medicine (NMM) at the Health Sciences Centre located in St. John's, NL and Saskatchewan Centre for Cyclotron Sciences (SCCS) operated by Sylvia Fedoruk Canadian Centre for Nuclear Innovations, located on the campus of University of Saskatchewan, Saskatoon.

Your voice is heard, we are happy to let you know that we have started the project of generating a new CARS website. Soon, you will be surprised about the changes we are planning.

On the regulatory side, The United States Pharmacopeia (USP) has released new and revised standards, General Chapters on compounding nonsterile medicines (USP <795> *Pharmaceutical Compounding—Nonsterile Preparations*), and compounding sterile medicines (USP <797> *Pharmaceutical Compounding—Sterile Preparations*). New standards for compounding radiopharmaceutical drugs are addressed in USP <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*. Our team is working to provide the community with a comparative review of changes.

July Edition “*Proudly Canadian*”

The Canadian science was on the top of the pyramid this year at SNMMI held in June 22-26, 2019 in Anaheim, California US. With Canada as a highlighted country our teams represented the best of science in the industry. One example is Dr. Eric Price, Assistant Professor in the College of Arts and Science's Department of Chemistry, University of Saskatchewan. Dr. Price was selected by SNMMI as “*Ones to Watch*” rising star in the field of radiopharmacy and nuclear medicine.



Canadian Network of Cyclotrons and Radiopharmaceutical Facilities

Nuclear Molecular Medicine (NMM) at the Health Sciences Centre in St. John's, NL

The newly constructed Nuclear and Molecular Medicine (NMM) Facility, at the Health Sciences Centre, in St John's, NL, was built and designed for a dual purpose:

- 1) to bring clinical Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT) imaging to the province, and
- 2) to establish a center of research excellence for the development of cutting edge radiopharmaceuticals (RPS).

The team



Dr. Vincent Bouvet
Clinical Assistant Professor
Radiochemist



Julio Panama
Professional Associate Cyclotron
Engineer



Nina Chandler
Lead Radiopharmaceutical
Technologist



Dr. Bassem Elshahat
Clinical Assistant Professor
Medical Imaging Physicist



Craig Turk
Quality Assurance Manager



Dr. Douglas Abrams
Lead Radiopharmacist
RPS Manager

The facility currently houses the province's only cyclotron (IBA Cyclone 18/18, 150µA), 6 clinical *SPECT/CT* cameras including 3 state-of-the-art Siemens Intevo units and the first fully digital PET/CT scanner in Canada (GE Discovery-MI).

The clinical PET program is already operational, and RP production will soon commence with the synthesis of ^{18}F -FDG.

Infrastructure



The Radio Pharmaceutical Sciences (RPS) Program is a collaboration between the Memorial University of Newfoundland (MUN) and Eastern Health (EH). EH provides the critical infrastructure for the clinical program, while MUN provides the innovation to maintain a state-of-the-art program.

The Facility has attracted researchers and gave them access to one of the four new GMP production laboratories.



^{18}F Routine Clinical
Radiopharmaceutical Production



Research and Development



^{124}I / ^{123}I / ^{11}C / ^{13}N Clinical
Radiopharmaceutical Production



Prospected Product portfolio

Radionuclides	¹⁸ F	⁶⁸ Ga	¹³ N	^{123/124} I	¹⁷⁷ Lu	⁶⁴ Cu/ ⁸⁹ Zr	⁹⁰ Y	¹¹ C
Timeline	2020/2021	2021	2021	2021/2022	2022	2023	2023	2024
Targets	<ul style="list-style-type: none"> • FDG • FDOPA • NaF 	<ul style="list-style-type: none"> • DOTA-TATE • PSMA 	<ul style="list-style-type: none"> • NH₃ 	<ul style="list-style-type: none"> • MIBG • NaI 	<ul style="list-style-type: none"> • DOTA-TATE • PSMA 	<ul style="list-style-type: none"> • Immuno-PET 	<ul style="list-style-type: none"> • DOTA-TATE • PSMA 	<ul style="list-style-type: none"> • Neurodegenerative disease diagnostic



5* IBA Synthera
¹⁸F/⁶⁸Ga



1* Ammonex
¹³N-NH₃



2* IBA Highmor
¹²³I/¹²⁴I



1* Synthra-¹¹C
¹¹C



1* basic science ASU



1* small animal
PET/CT Scanner

Clinical, Preclinical and Basic Science Projects

⁶⁸Ga-DOTA-TATE/¹⁷⁷Lu-DOTA-TATE

Collaboration with MUN Oncology Dpt. and MUN Radiology Dpt.

⁶⁸Ga-PSMA/¹⁷⁷Lu-PSMA/²²⁵Ac-PSMA

Collaboration with MUN Oncology Dpt. and MUN Radiology Dpt.

Collaboration with U de Sherbrooke Dpt. de Médecine Nucléaire et de Radiologie.

Collaboration with the Canadian Cancer Trials Group.

- Prostate Cancer Theranostics: Diagnostic and Treatment.
 - Oligometastatic Prostate Cancer: SBRT treatment planning.
- Tumor Response based on dose delivery, hypoxia and tumor size.

⁸⁹Zr-HER2-PET, ⁸⁹Zr-antiCD20-PET, ⁸⁹Zr-EGFR-PET.

Collaboration with MUN Oncology Dpt. and MUN Radiology Dpt.

- Synthesis optimization
- Side effects and full body biodistribution

¹⁸F-6-FDF

Collaboration with MUN Oncology Dpt. and MUN Radiology Dpt.

Collaboration with University of Dpt of Oncology, Biochemistry and Chemistry.

- Breast Cancer Recurrence:
- Glucose Transporter (GLUT2/5) Imaging

Insulin-like growth factor receptor (IGF1R) targeting

- Patient selection for IGF inhibitor therapy.

Cyclodextrin as a drug delivery system

- Small animal biodistribution and drug delivery quantification.



Canadian Network of Cyclotrons and Radiopharmaceutical Facilities

Saskatchewan Centre for Cyclotron Sciences (www.fedorukcentre.ca)

The Saskatchewan Centre for Cyclotron Sciences (SCCS) at the University of Saskatchewan (USask) is a state-of-the-art facility that supports innovation in nuclear imaging and therapy in living specimens: plants, animals and humans. Owned by the USask and operated by the Sylvia Fedoruk Canadian Centre for Nuclear Innovation (Fedoruk Centre), the SCCS is in close proximity to a hospital, medical school, veterinary college, the university's International Vaccine Centre, and the Canadian Light Source synchrotron, a national research facility of USask. SCCS provides organizations with access to specialized facilities and expertise to accelerate new nuclear medicine technologies.



The SCCS enables researchers to test better ways of diagnosing cancer, Parkinson's, Alzheimer's, and heart

disease; invent new detectors and targeted therapies; and apply nuclear imaging to advance agricultural sciences. Key goals are to:

- **Advance cutting-edge life sciences research in plants, animals and humans;**
- **Improve medical diagnoses and treatments through nuclear medicine;** and
- **Produce clinical-quality radiopharmaceuticals for regional hospitals.** Since 2016, the SCCS has provided medical isotopes for nuclear imaging scans of more than 5,000 Saskatchewan patients at Royal University Hospital, as well as for diagnosing cancer in Alberta and Manitoba.

Technical Capabilities



- The SCCS is a class II nuclear facility licensed to operate with a large range of radioisotopes including Ac-225, I-131, Cu-64, Bi-213, Ga-68, Cu-67, Zr-89, F-18, C-11, N-13, O-15, Mo-99, Tc-99m, Lu-177
- ACSI TR-24 cyclotron with four target stations. A duplex beamline allows the irradiation of liquid-gas targets and low power solid target at one branch and high power solid target station on the other
- Research production lab equipped with two COMECER hotcells with telemanipulators and automated target landing terminal and four mini Hotcells



- GMP production area equipped with COMECER hotcells, GE Fastlab and GE Tracer lab synthesizers and automated dispensing systems
- TRASIS synthesizers (miniAIO and AIO)
- QC labs with GMP testing equipment
- Radiochemistry Research Labs equipped with dose calibrators, UHPLC, HPLC, radioTLC

A newly developed area includes three TEMA hotcells (equipped with automated dispensing system and integrated autoclave)



The Innovation Wing



- Facility for pre-clinical studies equipped with vivarium and cell culture labs
- Animal imaging capabilities such as MILab Vector 4PET CT in the image and Sofie PET Imager
- Radiopharmaceutical lab equipped with HPLC, UHPLC, Gamma Counter, Dose Calibrators

Currently being upgraded, the Innovation Wing is equipped with plant imaging detection system (BioPETx) and plant growth

chambers

Scientists from University of Saskatchewan and members of the industry use the SCCS state-of the art infrastructure to develop new imaging probes, therapeutic molecules and radioisotopes and advance new molecules to clinical trials. Some example of projects are:

Collaboration with USask Centre for Biologic Imaging Research & Development (C-BIRD), which is developing the next generation of molecular imaging agents for cancer diagnostics. The key product is Zr-89 DFO Nimotuzumab currently advancing to clinical trial. Other studies developed with **Dr. Humphrey Fonge** include Ga-68 PSMA.

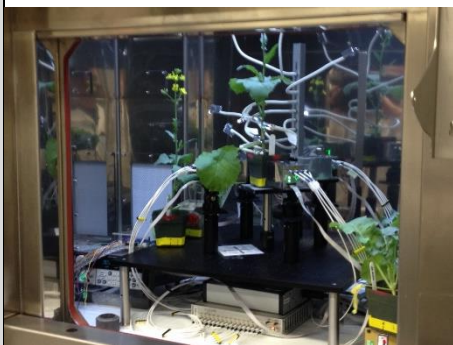
Ekaterina Dadachova's research group uses radioimmunotherapy to treat melanoma, pancreatic cancer and osteosarcoma. Her group pioneered its application for treatment of fungal and bacterial infections and HIV.

Dr. Chris Phenix Group designs PET radiotracers and probes and for imaging enzyme activity in plants, animals and humans. Dr. Phenix's works on:

- Cysteine Proteases developing probes and prodrugs inspired radiotracers.
- Glucocerebrosidase developing radioatracers to image synuclein,
- OIF to image uptake in llamas
- Probes to image Abscisic acid analogs for plant phenotyping with BioPETx

Dr. Eric Price (Canada Research Chair in Radiochemistry) develops more effective radiotracers for early detection of cancers and multi-drug resistant bacterial infections.

Fedoruk Centre facilitates the science beyond the radiopharmaceutical production and development. Key projects are led by **Dr. Steve Siciliano** which uses the SCCS to image microbial and root activity in soil ecosystems to help sustain the environment. He says that access to a cyclotron, synchrotron, and phytotron on campus, along with the BioPETx, provides plant and soil researchers with a combination of technology platforms that is unique in the world.



The BioPETx detector shown in the image is the first of its kind in Canada and used to study plants under various conditions and detect responses to stressors such as drought, infections, and insect infestations. In collaboration with the University of Regina, detection systems for studying root-soil microbial interaction are also being developed.

Visit <https://fedorukcentre.ca/facilities/saskatchewan-centre-for-cyclotron-sciences.php> to find out more about our facility.



NEWS

Regulatory	<p>The United States Pharmacopeia (USP) has released new and revised standards, General Chapters on compounding nonsterile medicines (USP <795> <i>Pharmaceutical Compounding—Nonsterile Preparations</i>), and compounding sterile medicines (USP <797> <i>Pharmaceutical Compounding—Sterile Preparations</i>). New standards for compounding radiopharmaceutical drugs are addressed in USP <825> <i>Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging</i></p> <p>The General Chapters have been published on June 01, 2019 and will become official on December 01 this year.</p> <p>A useful review of the impact of the new General Chapter USP <825> on the clinical practices was presented during the Annual Meeting of the American Pharmacist Association 2019 (APhA) held in Seattle, WA, March 22-25, 2019. The link below guides you towards the full presentation.</p> <p>https://aphameeting.pharmacist.com/sites/default/files/slides/RadiopharmRegUdate_HO.pdf</p>
Professional development	<p>Postgraduate Certificate Program in Radiopharmacy</p> <p>This postgraduate program enables natural scientists and pharmacists to assume responsibility for production and quality control of radiopharmaceuticals. The program is organized by ETH Zurich one of the world's leading universities for technology and natural sciences. The program is offered in cooperation with university of Ljubljana and Leipzig.</p> <p>The program provides essential knowledge in:</p> <ul style="list-style-type: none">• European Drug Legislation, Quality Assurance and GMP,• Radiopharmaceutical Chemistry,• Radiopharmacology and Clinical Radiopharmacy. <p>Graduates achieve the ETH degree "Certificate of Advanced Studies (CAS) in Radiopharmaceutical Chemistry/Radiopharmacy", which is recognized by the <u>European Association of Nuclear Medicine EANM</u></p> <p>You can find more information here:</p> <p>https://radiochem.pharma.ethz.ch/postgraduate-program/general-information.html</p>



<p>Our selection</p> <p>Upcoming scientific events 2019</p>	<p>World Molecular Imaging Congress (WMIC-2019) September 4-7, 2019 Montreal, Canada http://www.wmis.org/2019-wmic/</p> <p>WMIC 2019 provides a unique platform for scientists and clinicians to present and follow cutting-edge advances in molecular imaging.</p> <p>Annual Congress of European Association of Nuclear Medicine October 12 – 16, 2019 Barcelona, Spain (EANM 19) https://eanm19.eanm.org</p> <p>With more than 150 Sessions, the EANM Annual Congress is the most valuable Nuclear Medicine Meeting worldwide. Each year, more than 6,200 participants have the possibility to network, socialize and discuss the newest trends and findings in the field of Nuclear Medicine. The EANM is proud of receiving approximately 2,200 abstracts annually from all over Europe and overseas. 160 exhibiting companies, covering an area of 3,500 sqm present their newest technologies.</p> <p>IAEA- International Symposium on Trends in Radiopharmaceuticals (ISTR-2019), October 28-November 01, 2019, Vienna, Austria, https://www.iaea.org/events/istr-2019</p> <p>The International Symposium on Trends in Radiopharmaceuticals, ISTR-2019, will provide scientists and professionals working in the fields of production of radioisotopes and radiopharmaceuticals an international forum for discussing the most recent developments in the field. Various topics will be covered during the Symposium including development, production, and uses of diagnostic, therapeutic, and theranostic radioisotopes and radiopharmaceuticals, as well as regulatory and licensing issues related to their production. Education, certification and training methodologies will also be addressed.</p>
<p>Membership information</p>	<ul style="list-style-type: none"> • Our association welcomes new members from all areas of radiopharmaceutical development. Please feel free to share our information to your peers, colleagues and students. The CARS membership dues are presently \$50.00/year for full membership and \$20 for associate membership (technologists, research assistants). <p>Our Treasurer, Vincent is happy to assist you with the payment through etransfer at vincent.bouvet@easternhealth.ca</p> <ul style="list-style-type: none"> • 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 improve our presence to best represent your interest. We are considering the development of a new website and your feedback will be greatly appreciated. <p>Your Editor/Member-at-Large is happy to serve you, so please do not hesitate to contact Lidia at Lidia.Matei@usask.ca with suggestions and recommendations.</p> <p>Few key questions are:</p> <ol style="list-style-type: none"> 1. What do you expect to see on the website in the future? 2. What is your interest in the field of radiopharmaceuticals? 3. What message would you like to send to your peers in the community?



LETTER FROM THE EDITOR

Dear members:

Summer established itself with all the benefits: warm weather, vacation time, hiking, camping and BBQ.

We hope that you found our journey through the Canadian radiopharmaceutical facilities interesting. The purpose of this series is to create an overall picture of research and production sites and to build the structure of future collaboration as new sites are developed. It is great to see how fast this industry has grown in the last few years and now we can share the experiences among us. Only this way we will bring our knowledge to the highest level and reach the ultimate goal of addressing patients' needs and supporting those who are strong in their fights with life changing health issues.

In the fall edition (expected in mid- October) we will continue our series with two other facilities. I am confident that you will support this initiative and you will be happy to share your latest scientific developments, progress and interesting advancements with us. Please feel free to keep us updated and we will spread the word.

Be prepared for a surprise, we made progress towards a new concept of our website. Your feedback is welcomed, CARS executive team is committed to serve Member's needs and we will be happy to hear your suggestions.

As always please ensure your member information is up to date (email, mailing address, phone number(s)) and registration dues are paid up so that we keep you informed of activity in our radiopharma community. 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.

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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