Facility Disclosure

About ISOLOGIC

Isologic Innovative Radiopharmaceuticals (ISOLOGIC) is a nationwide radiopharmaceutical company, dedicated to nuclear medicine and the science of Radiopharmaceutical production. Our commitment to these fields extends to the communities we serve. We have over 170 team members focused on serving our customers and their patients. We utilize our significant experience, expertise and networks in Nuclear Pharmacy to provide our customers and patients with reliable; safe and high-quality radiopharmaceutical products and services. These radiopharmaceuticals are primarily used for Positron Emission Tomography (PET) and Single-photon emission computed tomography (SPECT) scans and assist doctors in diagnosis and treatment planning for patients with cancer and other serious diseases.

What is a cyclotron?

A cyclotron is a machine that is used to produce radioactive materials. The machine accelerates particles (such as hydrogen ions) to a very high speed and directs them into a target where a controlled reaction forms a radioactive isotope or radioisotope. The Isologic Cyclotron Facilities are home to negative ion cyclotrons designed for the production of short-lived positron-emitting radioisotopes such as Fluorine-18. The facilities also house a suite of hot cells and clean rooms dedicated to the production, processing and quality assurance of sterile, clinical grade radiopharmaceuticals.

At the present time, Isologic's cyclotron (PET) and SPECT processing facilities are primarily used for the production of fluorine-18 which is then incorporated into the radiopharmaceutical [F-18]-FDG (fluorodeoxyglucose) using automated synthesis protocols, and the processing of various radioisotopes used for SPECT such as Tc-99m (Technetium), In-111 (Indium), Ga-67 (Gallium), and I-131 (Iodine) for the diagnosis and treatment of thyroid cancer.

[F-18]-FDG is used in the clinic for imaging various disease states by Positron Emission Tomography (PET), while the other radioisotopes such as Tc-99m and I-131 are used in Single-Photon Emission Computed Tomography (SPECT). Cyclotron-produced F-18 is also utilized for research purposes, particularly the development of novel molecular imaging agents.

For example, in order to make Fluorine-18 (F-18), which is by far the most common isotope used for PET imaging, the beam is directed onto a target containing water enriched with the non-radioactive isotope Oxygen-18 (O-18).

How are radioisotopes turned into radiopharmaceutical products?

Once the radioisotopes have been created by the cyclotron, chemistry techniques are used to incorporate them into radiopharmaceuticals for medical imaging and research. In the case of Fluorine-18 (F-18), it would likely be bound to tracers

commonly used to scan cancer patients for diagnosis or treatment planning, or they may be used in research or clinical trials.

Most of the chemistry work is done in sealed, lead-lined "hot cells". The lead lining shields the radiation so that staff handling the radioactive material do not receive any radiation exposure.

Currently the only radioisotope produced using the cyclotrons is Fluorine-18.

In the SPECT facilities, set quantities of radioisotopes are received at the facility and incorporated into the drug that is required for the respective patient diagnostic or therapeutic procedure. In this case, the chemistry takes place inside vials kept in thick lead or tungsten pots. Individual patient doses are drawn from the vials into syringes for direct patient injection. All the work is done following Good Manufacturing Practices (GMP) and using specialized tools behind shielding to minimize radiation exposure to staff.

Are there any risks to individuals working at ISOLOGIC facilities or living nearby?

No. Cyclotrons and radiopharmaceutical processing facilities have been built and operated worldwide since the 1930s and are considered to be a clean and safe nuclear technology. It is important to note that the cyclotron cannot operate or produce radioactivity without electrical power. Unlike a nuclear reactor, a cyclotron can simply be shut off like a light bulb. For the SPECT facilities, only a limited quantity of radioactive material is available at any given time as it is not produced by these facilities. These radioisotopes are received in set, specific amounts on a regular basis. The ISOLOGIC facilities have also been designed to ensure radiation exposure to any adjacent areas is kept below normal background levels. For example, although the cyclotron unit itself is relatively small, much of the space in the facility is taken up by extra thick concrete and lead walls.

Staff members who work at ISOLOGIC have received specialized training to work safely with radioactive material. The facilities also contain several safety monitoring systems, security features, and interlocks which are tested on a regular basis. Special ventilation and filter systems guard against accidental releases of radioisotopes outside the facility and were designed to ensure that even in a worst-case scenario, there would be no measurable risk to the public. Emissions from all our cyclotron facilities and iodine manufacturing are monitored continuously.

Since ISOLOGIC began operations in 2014, there have been no facility releases at levels that would be significant to our staff, patients or community.

Does the facility produce radioactive waste?

ISOLOGIC produces very little radioactive waste. All radioactive isotopes have "half-lives," which is the time it takes for half of a given sample of a radioactive materials to undergo radioactive decay. This means that after one half-life, half of the material is no longer radioactive. Most isotopes produced from a cyclotron have very short half-lives; for F-18, the half-life is just under 2 hours. The table below shows how much of a sample would still be radioactive after a certain amount of time has passed for our most common radioisotopes in both ISOLOGI’s PET and SPECT facilities.

Isotope	Half-life (50%)
Fluorine-18 (F-18)	110 minutes
Technetium-99m (Tc-99m)	6 hours
Iodine-131 (I-131)	8 days

Due to the short half-lives, any quantities of radioactivity remaining after production and processing will quickly decay to background levels and the products can then be safety discarded through standard chemical waste streams.

The short half-lives also mean that bulk quantities of radiopharmaceuticals, such as F-18 cannot be stored for future use and must be produced daily. The number of isotope production accelerators in Canada, such as cyclotrons, has almost doubled in the last 10 years. There are several other cyclotrons operating in Toronto as well as in Hamilton, London, Ottawa, Montreal and Vancouver.

Is the radioactive material transported safely?

The volume of radioactivity produced by the cyclotron is relatively small in scale. A typical production run of F-18 amounts to a volume of less than 20mL, about the same size volume as an espresso coffee. Our SPECT products are shipped in shielded syringes for individual patients (referred to as “unit dose”) and typically hold less than 2 ml per syringe or in small capsules (similar in size to vitamin capsules) for I-131. The radiopharmaceuticals are transported from ISOLOGIC facilities in shielded containers and cases that meet all international standards. Anyone packaging or transporting radioactive material is also required to have specialized training in accordance with Transport Canada and other federal regulations.

Who has oversight for ISOLOGIC facilities and its products?

As a company that produces and uses radioactive materials, ISOLOGIC requires licensing through the Canadian Nuclear Safety Commission (CNSC). The CNSC has regulated the production and use of all nuclear material in Canada since 1946. They are mandated to ensure the safety of staff, public and the environment.

The design of the entire ISOLOGIC facilities, including safety considerations for staff and the general public, has been reviewed and approved by the CNSC. They also review and approve the Radiation Safety program, policies and procedures. As a part of their oversight program, periodic inspections of the facilities are performed by CNSC staff members. Regular reports are also made by ISOLOGIC to the CNSC, and licence renewals ensure the regulator reviews the entire operation on a scheduled basis.

For more information on the CNSC visit: www.nuclearsafety.gc.ca

Where can I get more information on radiation and radiation safety in Canada?

The Canadian Nuclear Safety Commission has excellent educational resources about radiation and radiation safety in Canada at the following links:

- Introduction to Radiation
- CNSC Videos
- CNSC Site on Cyclotrons

Disclosures

Any significant events will be posted for public disclosure on the CNSC website for Event Reporting: Class II Nuclear Facilities and Nuclear Substance Processing Facilities .

Contact Us

If you have questions about ISOLOGIC, please contact Christine Henault, Senior Vice President, Sales and Marketing