

Public 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 250 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. The Isologic cyclotron facilities are home to negative ion cyclotrons designed to produce 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, GMP radiopharmaceuticals.

At the present time, Isologic's cyclotron (PET) processing facilities are primarily used to produce Fluorine-18 (F-18), which is then incorporated into the radiopharmaceutical [F-18]-FDG (fluorodeoxyglucose) using automated synthesis protocols. The various radioisotopes used in our SPECT facilities include Technetium-99m (Tc-99m), Indium-111 (In-111), Gallium-67 (Ga-67), and Iodine-131 (I-131) for the diagnosis and treatment of thyroid cancer. In addition to this, both PET and SPECT facilities provide Gallium-68 (Ga-68) labelled radiopharmaceuticals using Germanium-68 (Ge-68) based generators. Cyclotron-produced F-18 is also utilized for research purposes, particularly the development of novel molecular imaging agents.



How are radioisotopes turned into radiopharmaceutical products?

Once the radioisotopes have been created by the cyclotron, they are delivered to synthesis units housed in many hot cells and to produce radiopharmaceuticals for medical imaging and research. In the case of Fluorine-18 (F-18), it would likely be bound to trace commonly used to image cancer patients for diagnosis, treatment planning, or clinical trials.

Most of the chemistry work is done in sealed, lead-lined "hot cells." The lead protects staff from the radiation.



Currently the only radioisotope produced using the cyclotrons is F-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, 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 or living nearby ISOLOGIC facilities?

No. Cyclotrons and radiopharmaceutical processing facilities have been built and operated worldwide since the 1930s and are 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 at 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 put our staff, patients or community at risk.

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 material 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 ISOLOGIC's PET and SPECT facilities.

Isotope	50% non-radioactive
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 quantity of radioactivity remaining after production and processing will quickly decay to background levels at which time the products can be safely 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, Toronto, Ottawa, Montreal, Saskatoon, Calgary, Edmonton 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 50mL, about the same size as a double 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 regulates 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 all 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 license renewals ensure the regulator reviews the entire operation on a regularly 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](#)

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 [Frank Maiorino](#), VP Commercial.