

Canadian Leadership Needed Now More Than Ever

Strengthening Canada's Global Role in the Isotope Supply Chain to Double Production by 2030





The market data included in this report can be accredited to MEDraysintell Nuclear Medicine (part 1) – Marketed Radiopharmaceuticals – Edition 2021, <u>www.medraysintell.com</u>.

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About the CNIC

The Canadian Nuclear Isotope Council (CNIC) is a not-for-profit organization consisting of representatives from various levels within the Canadian health sector, nuclear industry and research bodies, convened specifically to advocate for our country's role in the production of the world's isotope supply.

A secure supply of a diverse portfolio of isotopes is essential to maintaining and improving our standard of living. Isotopes are used every day to verify the safety of our roadways, discover and develop natural resources, test industrial products, and support research in mental health and aging. Isotopes are critical in the health care sector, where they are used to diagnose and treat diseases and sterilize medical supplies.

The CNIC serves as a voice in safeguarding the continued availability of isotopes, ensuring our public policies are risk-informed and science-based, and support the highest levels of public health and safety. Leveraging existing infrastructure and expertise will have a significant positive impact on human health across the globe, keeping hospitals clean and safe while expanding Canada's leadership role in the global community by supporting new and innovative treatments.

We thank our members for their commitment to the CNIC.



Learn more about the CNIC on our website <u>canadianisotopes.ca</u>

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Executive Members

GENERATION



INNOVATIONS



isotopes for



Canadian Leadership Needed Now More Than Ever

Introductory message from the Chair

Canada has been a leader in the research, development, and production of medical isotopes for decades, contributing to the fight against cancer and transforming patient experiences.

Through our world-class nuclear expertise and achievements, Canada is paving the way in medical imaging, cancer therapy, disease prevention, and medical device sterilization, all using medical isotopes. With these advancements in modern medicine, the demand for critical isotopes is on the rise. As a result, the global market for medical isotopes offers a significant opportunity for Canada to maximize its production capacity and demonstrate its leadership.

In 2019, the Canadian Nuclear Isotope Council (CNIC) published its first landmark report, Isotopes: Global Importance and Opportunities for Canada, which outlined the importance of having a reliable supply and future market trends for medical isotopes. This report will offer an updated overview of the Canadian and global markets for widely used and emerging medical isotopes. Beyond that, this report will also demonstrate how isotopes offer new hope to cancer patients around the world. Using minimally invasive procedures, nuclear medicine provides patients with fewer treatments, fewer hospital visits, and shorter recovery times than traditional cancer treatments. For patients who were previously considered palliative, radiopharmaceuticals using medical isotopes are beginning to provide a new range of treatment and diagnostic options, and most importantly, hope.

Canada has provided reliable access to medical isotopes like cobalt-60, yttrium-90, xenon-133, irridium-192 and iodine-125 for decades. Historically, Canada was also one of the largest producers of molybdenum-99 in the world prior to the retirement of the National Research Universal Reactor (NRU), which was operated by Atomic Energy of Canada Limited (AECL) and then Canadian Nuclear Laboratories (CNL) at Chalk River. Now, Canada has become a major player in the development and innovation of emerging isotopes like lutetium-177 and actinium-225. Canadian companies are also expanding their operations using these medical isotopes to



provide reliable and robust production of next generation radiotherapeutic treatments. Canada is also able to support nearly the entire production supply chain for these and many other isotopes. At all stages of the production pipeline, Canada has the infrastructure and expertise necessary to return as a global leader in medical isotopes.

As this report will show, the global market for nuclear medicine has grown over the last several years despite the international disruptions, and supply chain challenges due to the COVID-19 pandemic. The market is now projected to grow quickly to between \$14 billion and \$33 billion US by 2031, with therapeutic products representing the majority share. However, Canada can only take advantage of these optimistic figures if the right policy, financial, logistical, and infrastructure supports are in place to allow our medical lsotope Ecosystem to thrive.

Canada is a leader in the fight against cancer and disease, but our work isn't nearly done. It's a time to make a renewed commitment to improving patient experiences and developing new treatments. Considering the rising global demand for medical isotopes, Canada faces a critical juncture to build on our progress, capabilities, and expertise and outline a bold vision for the future. By implementing the recommendations outlined in this report, we believe Canada can be positioned to double its production of medical isotopes by 2030.

With hundreds of therapeutic radiopharmaceuticals in the pipeline, and many expected to reach the market in the coming years, this is an exciting time for patients, physicians, researchers, and the wider isotope industry alike.



In Straged

James Scongack Chair, Canadian Nuclear Isotope Council

Key learnings



Canada has been a leader in the global supply of isotopes for decades, providing reliable access to important isotopes for medical use like Co-60, I-125, Y-90, Xe-133, Ir-192 and Mo-99. Canada is also guiding innovation in the development and application of highly promising emerging medical isotopes, such as Lu-177 and Ac-225.

Through key partnerships between Canada's research facilities, isotope producers and irradiators, and the international isotope community, we are contributing to new isotope production techniques and applications, advancing clinical trials, and increasing the supply of critical isotopes dispensed to patients around the world.









Canada's Isotope Ecosystem supports almost the complete supply chain for the production, processing, and delivery of a wide spectrum of medical isotopes. Canada's fleet includes power reactors, linear accelerators, research reactors, and two dozen low- to highenergy cyclotrons. Canada hosts several shielding processing facilities and a network of organizations that provide necessary infrastructure, specialized equipment and goods and services to the isotope producers and users. Canada is also home to a growing number of radiopharmaceutical companies that manufacture life-saving isotope products for patients.

The global nuclear medicine market reached \$5.6 billion US in 2020. Despite the pandemic, the global market grew market seven per cent in 2021 to reach \$6 billion US.*





It is estimated that the nuclear medicine market will see 15 per cent growth per year until 2026.* By 2031, it is projected that the market will reach between \$14 billion and \$33 billion US. The higher market projection is based on an estimation that therapeutics will represent around 75 per cent of the \$33 billion market.*

*Source: MEDraysintell Nuclear Medicine (part 1) – Marketed Radiopharmaceuticals – Edition 2021, www.medraysintell.com

For over 120 years, the global nuclear medicine market has undergone exponential growth in response to the advent of new medical isotopes, nuclear technologies, and production techniques. Breakthroughs in research and cancer treatments have led to surges in demand for medical isotopes. Most recently, demand is increasing in response to the emergence of many promising therapeutic products in the mid-2000s.



In 2013, therapeutics represented just six per cent of the total nuclear medicine market but grew to 20 per cent by 2019, demonstrating the fast growth of this sub-set of the market.

With hundreds of radiopharmaceutical products in the pipeline, many of which expected to reach the market, the demand for therapeutic radiopharmaceuticals is expected to grow by 32 per cent annually until 2031.





With many mergers and acquisitions of smaller nuclear medicine companies, there are now just seven companies around the world that control 65 per cent of the global nuclear medicine market.* The remaining 35 per cent is shared by other radiopharmaceutical companies, public institutions, and government-controlled companies.

Canada's Isotope Ecosystem is distinct from the wider nuclear industry and the broad health care system. It needs an environment with sufficient investment and political and logistical support to allow businesses producing isotopes to prosper.



Medical isotope terminology



MEDICAL ISOTOPES

Used in the practice of medical science to treat, characterize, and diagnose disease. Medical isotopes are generated by adding a sub-atomic particle to a stable isotope so that it becomes unstable.

TARGET

A stable isotope encapsulated in non-reactive material. A target is the starting material needed to irradiate and produce a medical isotope.

PARTICLE ACCELERATOR

Uses electromagnetic fields to propel charged particles like protons and electrons at high speeds, causing them to collide with a target and generate energy. The target absorbs the energy and particles and becomes radioactive. The target is then processed to isolate the new isotope and the residual target material is reused.

CYCLOTRON

A type of particle accelerator which repeatedly propels a beam of charged protons in a circular path. The stable targets are bombarded by the protons, causing a nuclear reaction, and making the stable isotope targets radioactive.

NUCLEAR REACTOR

A large reactor with the primary purpose of producing nuclear energy, which has been outfitted with the capacity to produce isotopes. Targets are inserted into the reactor's core, where they are exposed to highenergy neutrons during power generation. The targets absorb a neutron and become radioactive, and can then be extracted from the reactor core during a planned outage.



HALF-LIFE

Isotopes are continually undergoing radioactive decay to become stable. One half-life is the time it takes for half of the unstable atoms to undergo radioactive decay. Half-lives range from minutes to days, which can pose challenges in producing, processing, and transporting isotopes in a timely fashion so as to be useful in treating patients.

Radioisotopes are matched to different applications depending on their radioactive properties.



DIAGNOSTIC APPLICATIONS

Isotopes are used to diagnose, characterize, and stage illnesses by helping physicians visualize phenomena inside the body, noninvasively. Isotopes are used in Single Photon Emission Computed Tomography (SPECT) imaging, and Positron Emission Tomography (PET) scans.



THERAPEUTIC APPLICATIONS

Isotopes provide effective treatments for a variety of illnesses like cancer. This includes Brachytherapy, Radioembolic therapy, Targeted Internal Radionuclide Therapy (TIRT) and External Beam Radiation Therapy (EBRT).

THERANOSTIC APPLICATIONS

Emerging isotopes are being used for "theranostic" purposes (THERApeutic +DiagNOSITIC), meaning that they can be used to both diagnose and treat illnesses.









The historic development of global nuclear medicine

The first use of a medical isotope occurred in **1901**, using radium-226 to cure a tuberculosis patient of previously untreatable skin lesions. This success elicited immediate interest from the medical community and research into potential medical applications for other isotopes ensued. Over the next 15 years, scientists discovered that sealed sources of Ra-226 could be used to treat throat, cervical, prostate, and breast cancers. In **1931**, the cyclotron was invented and allowed medical isotopes to be produced on demand for the first time. As a result, sealed sources of isotopes remained the only effective treatment for cancer other than surgery until the advent of chemotherapy in the **1940s**.

By the **late-1940s**, scientists began to explore new ways to use isotopes to treat cancer. Rather than implanting a sealed source at the disease site, physicians developed External Beam Radiation Therapy to point a beam of cobalt radiation at the site externally to treat a tumour deep within the body. This procedure quickly gained attention for its ability to treat cancer in a minimally invasive way.

In the **1960s**, diagnostic imaging using gamma cameras spurred the creation of a new branch of nuclear medicine. The cameras could record dynamic images of the location of radioisotopes in the body, allowing physicians to visualize processes such as blood flow, iodine biodistribution, and glucose metabolism. Using diagnostic imaging, physicians could effectively assess and monitor thyroid function and illnesses like cardiovascular disease and cancer.

Research in the **1980s** found that brachytherapy using iodine-125 could effectively control the spread of earlystage prostate cancer, with fewer side effects than conventional treatments. Popularity of I-125 brachytherapy surged and led to growing demand for new isotopebased therapies. At this time, research emerging from national laboratories and universities allowed for the new breakthroughs in isotope applications.

Lock-and-key principle:

In the **1990s**, a new device for radioembolic therapy of liver cancer was designed using yttrium-90. The device, the microsphere, offered an effective treatment to a

disease that typically has a poor prognosis. With the growing success of isotope technologies, new investments were made around the world, allowing for an expanding global network of isotope producers and the creation of new radiopharmaceutical companies.



By the **early-2000s**, Canada was a major producer and global exporter of medical isotopes. Canada had become an important player on the global stage as a large-scale source for several key isotopes. In the **mid-2000s**, the market for therapeutic radiopharmaceutical products emerged and quickly began to grow. In **2013**, therapeutics represented just six per cent of the total nuclear medicine market compared to diagnostics, but has grown to represent 20 per cent in **2019**, demonstrating the fast growth of this sub-set of the market. With hundreds of companies globally with radiotherapeutics still in pre-clinical stages, many of which expected to reach the market, it is expected that the market will experience unprecedented levels of growth and offer new opportunities for investment.

In the **late-2010s**, the market also began to experience many mergers and acquisitions of smaller companies, which has concentrated the market in fewer hands. Now, seven companies around the world control 65 per cent of the global nuclear medicine market, while the remaining 35 per cent is shared by other radiopharmaceutical companies, public institutions, and governmentcontrolled companies.

MEDICAL RADIOISOTOPES

TARGETING MOLECULE

TUMOR-SPECIFIC RECEPTOR



more than 80% of the Co-60 sources in the marketplace today.

Canada's role in medical isotopes through the years

Canada has been a major global supplier and a leader in the research, production, and innovation of isotope technologies for decades.

The Canadian Nuclear Safety Commission licenses the use and production of over 250 isotopes, many of which are used to manufacture radiopharmaceuticals to diagnose and treat illnesses. Canada pioneered the production and use of several isotopes, including molybdenum-99, cobalt-60, iodine-125, and yttrium-90, and new initiatives seek to establish Canada as a primary global supplier for many others.

In the 1940s, during the development of External Beam Radiation Therapy using cobalt-60, AECL's NRU research reactor here in Canada was selected to produce the Co-60 needed for the medical equipment. Following months of collaborative work between Canadian scientists and physicians, the first patient was treated at the Victoria Hospital in London, Ont., on Oct. 27, 1951.



A 1988 Canadian postage stamp commemorating the development of cobalt-60-based EBRT.



Since then, Canada has remained a leader in the commercial-level production of Co-60. This isotope requires an irradiation period of two to five years, so developing a new source of Co-60 requires a significant investment of time. As a result, few countries in the world produce it commercially. Canada is the world's largest producer of Co-60, providing over half the global demand for the isotope in just the Ontario Power Generation and Bruce Power reactors.

In Canada, irradiated Co-60 is then shipped from the Bruce Power and Pickering reactors to Nordion's processing facility in Ottawa, where it is converted into sealed sources and distributed globally for the sterilization of medical devices and treatment of food and consumer products at over 300 highly specialized facilities around the world. Canada also imports and processes irradiated Co-60 from abroad. When combining domestic production with import processing, Canada provides more than 80 per cent of the Co-60 sources in the marketplace today.

Canada is also a leader in the production of iodine-125 primarily for brachytherapy, which is used to treat solid tumours. In the 1990s, I-125 grew in popularity in response to the isotope's success in treating prostate cancer, and demand quickly outpaced global supply. In response, Canadian researchers at McMaster University developed a process to produce I-125 from xenon-124. For years, Canada has been the largest producer of I-125 in the world, producing over 60 per cent of the global demand at the McMaster University Nuclear Reactor and treating more than 70,000 cancer patients annually.

Historically, Canada was the leader in the production of molybdenum-99, the most widely used medical isotope in the world as the precursor to technetium-99m. Large-scale production of Mo-99 commenced at NRU in 1972, allowing Canada to become a major global supplier. By the 1990s, Canada's NRU Reactor at Chalk River established itself as an early major global supplier of Mo-99. By the early-2000s, Canada had become one of the largest producers and exporters of medical Mo-99, generating over 40 per cent of the global supply. Today, over 40 million imaging scans are conducted globally each year, including 1.1 million in Canada alone.

By 2005, 96 per cent of the world's Mo-99 was produced at only six aging research reactors, including NRU. Unfortunately, due to the lack of redundant supply and low competition, the supply chain for Mo-99 was extremely vulnerable to shortcomings, and unplanned outages left a massive shortfall. With just one producer operating, supply could not keep up with demand.

Today, there are several efforts to bring more Mo-99 production using new technologies, including Canada's CANDU power reactors. Ontario Power Generation's Darlington site began production of Mo-99 in 2023 with plans to expand production, allowing Canada to supply Mo-99 domestically once again.

In August 2022, the CNIC joined twenty leading international organizations as part of a joint Industry Statement touting the benefits of nuclear isotopes.

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Government progress

Since the release of the CNIC's 2019 report, *Global Importance and Opportunities for Canada*, some government progress has been made towards recognizing the prominent role that isotopes play in Canadian health care. While this is a step in the right direction, work still must be done to ensure that Canada's Isotope Ecosystem has adequate financial and regulatory supports in place. A Canadian Medical Isotope Ecosystem (CMIE) will help to advance new technologies.



All-party support for 'Made-in-Ontario' isotopes

On Nov. 2, 2021, now-retired MPP Bill Walker rose in the Ontario Legislative Assembly to champion a Private Members Motion in support of medical isotope production in Ontario. In his Motion, MPP Walker said,

"The Government of Ontario should recognize the supply of medical isotopes used to diagnose and treat cancer and sterilize medical equipment as a key strategic priority for the Province in its health, economic, export, inter-provincial, energy, research and infrastructure planning and policies as Ontario recovers from the COVID-19 pandemic, leveraging its existing strong foundation in nuclear technology, isotope production and supply chain, and cancer and health research to position itself as a global leader in supply of 'Made in Ontario' life-saving medical isotopes."

MPP Walker's motion was widely successful and received support from all parties present in the Legislature. The motion was a major win for the medical isotope industry and represented a major step forward in Ontario.

Progress towards the Strategic Innovation Fund

For three years, the CNIC and six of its members have championed an application to the Strategic Innovation Fund (SIF). The SIF is a program of Innovation, Science, and Economic Development Canada that is designed to support innovation by providing targeted funding to specific sectors for large-scale projects. Together, the Centre for Probe Development and Commercialization, TRIUMF Innovations, Bruce Power, BWXT Medical, Canadian Nuclear Laboratories, and McMaster University have entered a proposal to the SIF Stream-5 program to create a Canadian Medical Isotope Ecosystem (CMIE). The CMIE will create an environment for Canadian scientists to advance new technologies through the production pipeline, from the research laboratory to preclinical testing, and then to hospitals. The CMIE will also support a robust and redundant supply of three emerging isotopes, Lu-177, Ac-225, and Ga-68.

The CMIE project will also actively seek out collaborations with private sector partners in the biosciences, which will help our nation grow its knowledge base in this space and expand our advanced biomanufacturing capabilities. At the same time, the CMIE will work to leverage Canada's existing infrastructure to the fullest advantage.

Finally, the CMIE will contribute to Canada's economy. In the first five years, the five projects are projected to create nearly 500 highly skilled jobs in a range of sectors across the country. The CMIE seeks to establish Canada as a hub for pharmaceutical companies seeking to conduct clinical research with medical isotopes. This will attract substantial foreign investment to Canada.

While the SIF application has progressed over the last few years, CNIC urges the Government of Canada to immediately approve the SIF application to start building the CMIE. The isotope industry has several innovative, shovel-ready projects waiting in anticipation of this investment funding.



Canada's capabilities – Our unique advantage and production pipeline

Canada supports almost the complete supply chain for the production, processing, and delivery of many medical isotopes.

Canada has a sophisticated, supportive supply chain, with key infrastructure and ongoing investments in research and skills-training. As a result, Canada has become a vital source for many international pharmaceutical companies.

In Canada's Isotope Ecosystem, a range of companies contribute their specialized services to the supply chain. Among the facilities that produce the isotopes, there's a powerful research reactor, CANDU power reactors that are outfitted for medical isotope production, and several high-power and linear accelerators. Additionally, Canada has a network of cyclotrons and associated processing facilities, which directly supply short-lived isotopes to local hospitals, regional health care systems, and research institutes and universities. Canada also hosts a network of companies that supply specialized equipment, goods, and services to the pipeline, such as products to support automation of processes, manipulation or transportation of isotopes. Lastly, the pipeline includes companies that manufacture products that incorporate isotopes and radioactive materials for end-users, including a growing number of radiopharmaceutical companies.

The companies within our Isotope Ecosystem offer worldclass infrastructure and expertise, securing Canada's status as a global leader in nuclear medicine. Each piece of the supply chain relies on several others, but this collaboration facilitates the delivery of life-saving medical isotopes across the country. Together, Canada's Isotope Ecosystem gives patients hope.



Highlighting strategic partnerships: Emerging technologies – supporting development

In Canada, key partnerships and collaboration have allowed for cutting-edge innovation in areas like target delivery systems, new approaches and technology to produce emerging isotopes, and strategies to resolve supply challenges. Together, members of Canada's Isotope Ecosystem are supporting the development of emerging medical isotopes in exciting new ways.

1. BRUCE POWER - ISOGEN - ITM

In early-2022, Bruce Power, ITM Isotope Technologies München (ITM) and Isogen (a partnership between Kinectrics and Framatome) completed the installation of an Isotope Production System (IPS) in Bruce Power's Unit 7, which became the world's first power reactor with the capability to produce Lu-177. Commercial-level production began in October 2022. Using the Isogen-designed IPS, enriched ytterium-176 targets are irradiated to produce non-carrier-added Lu-177. Then, the irradiated products are processed by ITM, a leading radiopharmaceutical biotech company in Germany. With its proprietary manufacturing methodology and industrial scale production capacities, ITM yields high-quality, pharmaceutical grade Lu-177 for medical use. Exporting the products overseas requires logistical supports and specialized transportation services to handle and ship radioactive materials, provided by Canada's network of companies that offer goods and services to support the production pipeline.



Importantly, Bruce Power entered into an historic partnership with Saugeen Ojibway Nation (SON) to market this supply of Lu-177. The partnership, named Gamzook'aamin Aakoziwin (which translates to 'We are teaming up to fight the sickness'), includes an equity stake for SON in addition to a revenue-sharing structure that provides a direct benefit to the SON and its communities.

As the global demand for Lu-177 increases, this partnership comes at the right time to provide a scalable source that will supply cancer-fighting isotopes to patients here in Canada and around the world. Bruce Power is looking to build on the success of the IPS to determine future opportunities for the system, such as producing Y-90.

2. BWXT MEDICAL – LAURENTIS ENERGY PARTNERS – ONTARIO POWER GENERATION

In 2021, a partnership led by Laurentis Energy Partners (a commercial subsidiary of Ontario Power Generation) and BWXT Medical, was formed with the goal of producing Mo-99 for the first time in a power reactor. The project has gained momentum and has since received regulatory approval from the Canadian Nuclear Safety Commission.

BWXT has built a facility in Peterborough, Ont., to manufacture and deliver Mo-99 components to OPG's Darlington Nuclear Generating Station using specialized tooling. This process has enabled the Darlington reactor to become the first and only commercial operating nuclear reactor to produce Mo-99. Thanks to the unique design of Darlington's CANDU reactors, medical isotopes can be removed while the reactor is online, and without interrupting



the reactor's operations. Then, once irradiated and extracted from the reactor, BWXT processes the Mo-99 and integrates it into Tc-99m for distribution to its generator.

The Tc-99m is distributed across North America for use in thousands of diagnostic imaging procedures. In February 2023, Laurentis Energy Partners and BWXT announced the successful installation of the system. Soon, the system will commence commercial-scale production of the isotope, helping to secure a domestic supply chain for the essential Mo-99/Tc-99m isotope pair.

3. MCMASTER UNIVERSITY - PROMATION NUCLEAR

In July 2021, McMaster University and Promation Nuclear, a leading Canadian manufacturer of tooling and automation solutions for nuclear applications, signed a Memorandum of Understanding (MoU) to collaborate to bring new medical isotope technology to the market.

Developed by McMaster, the technology at the centre of this MoU is used to process lower-grade Lu-177 into clinicalgrade Lu-177. This technology will enable expansion and diversification of the supply chain, while generating higher yields of the isotope and low waste volumes. With expertise in automation and meeting stringent quality standards, Promation will contribute specialty tooling and equipment to support the technology. Together, Promation and McMaster are working to enable more patient treatments and a lower environmental footprint for each target processed.



Market demand for medical isotopes

The global market for nuclear medicine reached over \$5.6 billion US in 2020, which was a slight decline from the previous year. The decline can be directly tied to the COVID-19 pandemic, resulting from restrictions on air travels and transportation. During these bottlenecks, the distribution of radiopharmaceutical products to hospitals became difficult. However, by the end of 2020, most of these bottlenecks had resolved and the situation returned to more normal conditions. The global markets grew by about seven per cent in 2021, reaching \$6 billion US.

It is now estimated that the market will see 15 per cent growth year-over-year until 2026, driven by increased availability of new treatment options. In the coming years, more patients around the world will gain access to the life-saving treatments Canadians have enjoyed for decades.

By 2031, the nuclear medicine market is projected to reach between \$14 billion and \$33 billion US. Much of this growth is expected in therapeutics, which is estimated to account for 75 per cent of the \$33 billion market. Among the isotopes used for therapy, the short list includes Lu-177 and copper-67, but there is increasing interest of other alpha-emitters such as Ac-225. As such, having solid supply networks for these isotopes in place is essential to capitalizing on the future growth projections for radiotherapeutics.

The future of nuclear medicine is in therapy. Historically, the interest of investors increases with the strong results of new therapeutic drugs. With new radiopharmaceuticals anticipated in a few short years, this is an exciting time for the nuclear medicine market. The conventional pharmaceutical industry is also increasingly interested in radiotherapeutics because of their higher profitability (compared to diagnostics) and larger markets.

Isotope profiles and market potential

Canada is already a global leader in the research and production of several isotopes that are widely used by the medical community. Our domestic isotope industry is also beginning to make progress developing and innovating new ways to produce isotopes with therapeutic applications that offer significant promise and hope for patients.





Actinium-225

Type of radiation	Alpha-emitter
Half-life	9.92 days
Uses	Treatment of metastatic cancers.
Global market value	The current price of an Ac-225 dose and the significant gap between demand and supply limits its widespread use.
Global market growth projection	Growth projections are difficult to estimate but given the high demand and price of Ac-225, and significant gaps in supply, there are major opportunities for growth if production is increased. All alpha-emitters are expected to grow 35.7 per cent annually over the next five years, with North America as the largest market.

Actinium-255 is a "theranostic" isotope predominantly used to kill metastatic cancers. Ac-225 is combined with specific tumour-seeking targeting vectors and injected into the body to kill cancer cells while leaving healthy tissues unharmed.

Ac-225 is an emerging isotope, meaning that experts predict it will be needed for hundreds of upcoming, cutting-edge radiopharmaceuticals, which will cause demand to skyrocket. These products primarily target oncology or cardiology, are currently in clinical trials, and are widely anticipated by the medical community. These new drugs have high potential and are on track to reach the market before 2025.

In the global supply chain, Ac-225 has been dubbed the 'rarest drug on Earth.' The annual supply of Ac-225 from global sources enables an extremely limited number of treatments for patients. Globally, there are several different ways to produce Ac-225 that have been explored and, due to the interest in the isotope, significant advancements continue to be made. However, a secure supply chain for Ac-225 has yet to be established. Currently, global production is around 63 GBq, but the demand is at least 1,850 GBq.

Canada is among the most promising countries to fill this supply gap with our existing network of expertise. Canadian experts at Canadian Nuclear Laboratories (CNL) and TRIUMF are partnering to begin developing a domestic supply. CNL has also signed a Memorandum of Understanding with ITM Isotope Technologies Munich SE to explore industrialscale production of Ac-225, collaborating to manufacture the isotope and develop distribution pathways in the future. Lastly, BWXT and TRIUMF have also executed an agreement to produce high-purity Ac-225-based products for pharmaceutical companies.



Lutetium-177

Type of radiation	Beta- and gamma-emitter
Half-life	6.73 days
Uses	Targeted Internal Radionuclide Therapy for neuroendocrine tumours, prostate cancer, and other forms of cancer.
Global market value	\$85 million US in 2018
Global market growth projection	10.4 per cent annual growth, estimated to reach a value of \$138.2 million US in 2023. With new Lu-177-based treatments hitting the market, the market could reach \$350 million US in a few years.
Canadian market growth projection	10.9 per cent annual growth

Lu-177 is an increasingly popular medical "theranostic" isotope because it can attach to a targeting vector – a protein or peptide that has cancer-seeking abilities. Once it finds the tumour site, the beta particles it emits cause damage to the immediate area, shrinking the tumour.

The drug used to treat advanced metastatic prostate cancer is currently available to Canadians in B.C., Ontario and Quebec, and is expected to gain more widespread availability in the coming years. North America already accounts for the largest share (40 per cent) of the global market. Globally, the market for Lu-177 is growing quickly due to the new treatments for cancer that are driving growing demand for the isotope. As such, global demand may exceed available supply over the next few years.

In Canada, Lu-177 is generated from a different stable isotope, ytterbium-176. Canada's supply of Lu-177 is mostly sourced from McMaster University's reactor, while

some supply comes from particle accelerators such as TRIUMF and Canadian Light Source. More recently, Canadian medical isotope producers have moved to create a stronger domestic supply of Lu-177. Bruce Power, ITM Isotope Technologies Munich, and Isogen have partnered to use one of Bruce Power's CANDU power reactors to produce Lu-177, achieving commercial production in October 2022. McMaster University has also partnered with the Centre for Probe Development and Commercialization to manufacture Lu-177 for clinical use. Together, Canadian companies are working to provide a reliable, domestic supply of Lu-177.

As global demand for the isotope grows, facilities will need to be equipped to take on this challenging process and scale-up their production. The limited global supply of ytterbium-176 may also cause challenges as demand increases.



Molybdenum-99

Type of radiation	Gamma-emitter
Half-life	65.94 hours
Uses	Mo-99 is the precursor for Tc-99m for SPECT imaging to visualize internal processes and assess of cardiovascular disease, thyroid function, and the spread of cancer.
Global market value	Tc-99m market valued at \$2.6 billion in 2018.
Global market growth projection	9.9 per cent annual growth for Tc-99m, reaching a value of \$4.1 billion in 2023.
Canadian market growth projection	North America accounts for 45 per cent of the demand for Tc-99m diagnostics. In Canada, Tc-99m usage in expected to rise 10.6 per cent annually, reaching \$224.1 million in 2023.

Mo-99 is the most widely distributed isotope in the world, predominantly because it produces Technetium-99m, a nuclear fission by-product. In the 1970s, Tc-99m had emerged as the ideal SPECT imaging isotope due to its properties and easy production. An estimated 80 per cent of all nuclear medicine procedures are diagnostic, equating to well over 40 million imaging scans conducted globally each year. North America, particularly in the U.S., accounts for the largest global demand of Mo-99/Tc-99m, using 40 per cent of the world's supply. However, experts fear the supply chain could come under stress as new challenges face the industry and demand continues to increase. Time and time again, the world experiences shortcomings in supply, which reinforces the importance of additional diversity, competition, and redundancy in our supply of critical isotopes. Until recently, just six research reactors worldwide produced Mo-99, leaving the supply chain vulnerable to fluctuations. To that end, OPG's Darlington site has outfitted its CANDU power reactors to produce Mo-99 domestically, which will allow Canada to become a global leader in the production of this isotope once again.



Yttrium-90

Type of radiation	Beta-emitter
Half-life	64 hours
Uses	Radioembolic therapy to treat liver cancer and liver metastases.
Global market value	The entire microspheres market reached \$275 million US in 2020. Y-90 microspheres represented 98 per cent of this market.*
Global market growth projection	5 to 6 per cent annual growth estimated to reach a value of \$500 million US by 2031.*

Since the late 1980s, physicians have treated tumours using radioembolic therapy, where thousands of Y-90 microspheres are injected into a patient. The microspheres are small enough to travel through large arteries throughout the body, but small enough to block the small blood vessels that supply the tumour with blood. Though liver cancer typically has a poor prognosis, the use of Y-90 effectively improves patient health outcomes. Pioneered by Canadian company Nordion, most of the world's supply of Y-90 therapeutic microspheres were produced for nearly three decades at the NRU Reactor. Today, microspheres continue to be produced and used in Canada and exported around the world. However, Canada's supply of Y-90 is complex since the isotope is not currently generated here. Rather, the inactive material is exported internationally for irradiation before being re-imported to Canada, processed, and distributed to hospitals. Producers in Canada have recently begun to examine the feasibility of producing Y-90 domestically. Bruce Power signed an MOU with Boston Scientific in 2022 to explore producing the isotope in its CANDU reactors.

Establishing a domestic supply chain for Y-90 will offer new opportunities for medical research, development, and innovation, and provide liver cancer patients in Canada with widely available treatment options.



Cobalt-60

Type of radiation	Beta- and gamma-emitter
Half-life	5.27 years
Uses	High-Specific Activity Co-60 used for Gamma Knife brain surgery; Low-Specific Activity Co-60 used for medical sterilization.
Global market value	\$8.5 billion US in 2022 (for gamma sterilization).
Global market growth projection	8.8 per cent annual growth over the next five years.

Beginning in 1951, the first successful Co-60-based EBRT treatment in London, Ont., set the stage for Canada to become a global leader in the research, and development of Co-60.

Since then, the therapeutic applications of High-Specific Activity (HSA) Co-60 have evolved into Sterotactice Radiosurvery (SRS), an example of which is the Elekta Gamma Knife, used to treat brain cancer and other diseases of the head and neck. This procedure focuses 200 highenergy radiation beams to the area being treated, which allows for precisely localized tissue ablation. Gamma Knife surgery is also extremely precise and can destroy multiple metastases, which allows it to treat brain malignancies that typically would not respond well to conventional therapeutic methods. Finally, compared to traditional brain surgery, which requires long recovery times, Gamma Knife radiosurgery is usually a one-time, single-day therapy. As such, over the last 60 years, more than 35 million cancer patients have been treated with HSA Co-60. In addition to therapeutic uses, Low-Specific Activity (LSA) Co-60 has increasingly been used to sterilize about 40 per cent of the world's single-use medical devices. This includes equipment like implantable devices, bandages, sutures, tubing, masks and gloves, surgical gowns, and syringes. About 85 per cent of the world's LSA Co-60 is used for sterilization.

Global use of gamma sterilization is expected to grow in the coming years, partially in the aftermath of the COVID-19 pandemic, which exponentially increased the need for single-use medical equipment. Additionally, Canada's aging population will also drive an increase in demand for gamma sterilization domestically as our overall need for health care increases.

Worldwide, only five countries in the world currently produce Co-60, with Canada in a leadership position. As demand grows, Canada faces an opportunity to sustain and expand its leadership in Co-60 production.

Opportunities for Canada within the global market

Canada is already a global leader in isotope production, but there are many opportunities to leverage our leadership and technology to engage in emerging global market trends.

North America accounts for approximately 40 per cent of the global market, which shows there are significant opportunities for Canada to serve its own demand for medical isotopes. Canada must ensure it has a robust, continuous, and reliable supply of isotopes to provide hospitals and patients at home with life-saving treatment and diagnostic options.

Hundreds of new radiopharmaceutical products are in development, mostly targeting oncology, while others target cardiology, neurology, and infectious diseases. Of these, a substantial portion (close to 20 per cent) use Lu-177 or Ac-225. Establishing a solid supply network for these isotopes offers a lucrative opportunity for Canada to help fill this gap in the supply chain.

To protect Canada's supply of medical isotopes, we must pursue source redundancy and robust supply chains. Historically, we have seen several instances in which demand outweighs supply, leading to fluctuations and critical shortcomings. To protect Canadian patients and mitigate future shortages, it is critical to diversify our supply chains.

For example, Canada can supply the diversification of the Mo-99 supply chain as the precursor to Tc-99m. Though experts have determined the direct cyclotron production of Tc-99m proved to be feasible, this method is not economically realistic. There are just six aging research reactors around the world that produce Mo-99 at a commercial scale, which causes the supply chain to be vulnerable to fluctuations and shortcomings. Once a leader in Mo-99 production, Canada has imported much of its supply of the isotope for the last several years. With production of Mo-99 now happening at OPG's Darlington site, Canada can leverage its power reactor fleet to again become a significant producer and contribute to a redundant, diversified supply.

Canada also has an opportunity to export its expertise in isotope production techniques, supply chain technology, and innovation to the global market. Not only is Canada a global leader in the production of isotopes, but Canada is home to dozens of companies that provide goods or services to the industry, allowing radioactive products to be safely E.

North America accounts for approximately 40% of the global medical isotope market.

and efficiently manipulated, transported, and packaged. Without these companies, medical isotopes would not be able to reach end-users and patients across the country.

Canada's lsotope Ecosystem boasts a strong network of world-renowned companies that provide innovative technology to support strategic logistics within the supply chain. These specialist companies include ones that supply:

- Equipment, like shielding or specialist packaging.
- Logistical, regulatory, translation and commercialization support.
- Engineering design.
- Customized automation solutions for production processes and remote handling.
- Support for research and development.
- Source and target materials.

These value chain facilities are the backbone of the lsotope Ecosystem and enable medical isotopes to be produced and delivered to patients here in Canada. They offer the flexibility and support to facilitate the production of isotopes needed for future medical applications. To truly achieve redundancy and diversity in supply, Canada must ensure that its domestic supply chain is strong and resilient. In addition to securing additional sources for isotopes, this will also involve strategic investments in the entire value chain and production pipeline.

Canada possesses the unique capacity to develop and export this value chain expertise internationally, to connect patients with life-saving isotopes around the world. With world-class expertise in medical isotopes, Canada can maximize its position in the global industry by offering thought leadership and collaboration to producers around the world.



Barriers to unleashing Canada's future isotope potential

	INFRASTRUCTURE	Specialized infrastructure required.Leveraging current infrastructure while investing in new facilities.
	LOGISTICS	Radioactive decay poses logistical challenges.Limited shipping routes.
A B	MARKET ADOPTION	 Domestic clinical trials required. Health economics determine adoption potential. Physician education determines actual adoption.
<u></u>	ECONOMICS	Full cost recovery standard.New players add complexity.Minimal private sector investment.
N.S.S.	LABOUR AND TRAINING	 Availability of fully-trained staff. Retention and turnover. Recruitment and industry awareness.



Many isotopes are made-to-order and shipped to patients all over the world.

Infrastructure

- Isotopes require specific infrastructure to produce at commercial scale, such as a cyclotron, reactor, linear accelerator, or facilities to isolate or enrich. This equipment and infrastructure come with high barriers to entry. With high building costs and lengthy build times, commercial investors see high risk and long return times. Obtaining the necessary licencing and permits can be complicated and time-consuming for new players.
- Canada must balance between better leveraging its current infrastructure capacity, such as refitting CANDU power reactors to produce isotopes and refurbishing high power cyclotrons, while investing in new infrastructure and facilities.

Logistics

- Producing and transporting isotopes at the commercial-scale can be difficult due to radioactive decay, a continuous process that determines how long an irradiated isotope is effective. Due to radioactive decay, many isotopes must be "made-to-order," and transported quickly to patients across the world.
- Expanding or establishing shipping routes for radiopharmaceuticals is limited because there are only certain airlines and couriers that will transport radioactive materials, and only certain ports that will accept them.
- Shipments of certain isotopes, like Co-60, are often extremely large, with thousands or millions of curies moving at once. This requires specialized transport packages and logistical planning to achieve.



Market adoption

- Before an isotope can reach the market in Canada, adoption is constrained by certain requirements as designated by Health Canada. An isotope product must be approved through domestic clinical trials foreign trials are not considered relevant — before it can become commercially available.
- Health economics affect adoption because this determines how much a particular product is worth. The Canadian Agency for Drugs and Technologies in Health (CADTH) is the national organization that provides research and analytics to health care decision-makers on the optimal use of drugs or medical devices and their economic value. In Canada, certain conventional treatments are covered by government health care, so market adoption is heavily tied to how well a new drug can justify changing how the government finances the treatment of a particular illness.
- Final adoption of a product is driven by physicians and their level of familiarity with a new radiopharmaceutical. If physicians are educated about the benefits and uses of an isotope product, they will be more likely to offer the product to patients.

Economics

• Full-cost recovery has recently become the standard economic approach in the isotope industry since the Mo-99 crisis of 2009-10. Full-cost recovery ensures that isotopes are sold for realistic, competitive prices,

without relying on government subsidies. This economic model has encouraged more companies to enter the industry, which has driven new investment, partnerships and innovation.

- New players entering the isotope industry have
 resulted in a wider diversity of funding models for
 new ventures. Now, pieces of the isotope production
 pipeline belong to for-profit entities, some are publicly
 owned while others are privately funded, and some
 use a mixture of government funding. This diversity
 adds complexity to the standard economic approach,
 which could cause price uncertainty.
- Since government assistance can be sparse or tied to specific projects, funding for isotope-related projects also depends on private sector investment, but this is often minimal. Production of an isotope cannot begin without investment. However, isotopes may take several years to be commercially profitable on the market, which makes it difficult for private investors to justify an initial investment.

Labour and training

- Driven by the success of new therapies and growth in demand, the number of people directly and permanently involved in the isotope industry in Canada will need to increase by 33 per cent in the next three years to support the upcoming capital projects and production expansions. Otherwise, insufficient labour will delay or restrict future production.
- Canadian companies struggle with the availability of radiochemists, sub-contractors, and fully trained staff given that careers in the isotope industry require complex training, education, and experience. Turnover rates have also increased, up to 20 per cent in some cases, driven by competition and the ability to work from home for large international companies.
- Public awareness of careers in the sector is inconsistent, as people may not understand the medical isotope industry as a distinct entity from the pharmaceutical and nuclear industries. As a result, fewer people actively seek jobs in the industry, so job postings do not attract the attention they deserve.

The medical isotope industry is full of growth opportunities for Canada.

Key policy recommendations

To achieve the goal of doubling Canada's isotope production by 2030 and to unleash the potential of the sector, the CNIC makes the following key recommendations to various levels of Government:

1. Develop a national isotope strategy

Canadian Nuclear Laborator

The CNIC encourages the Government of Canada to develop a national isotope strategy in collaboration with the industry to build on Canada's unique foundation and leadership position. This strategy needs to be cross-functionally aligned with various government departments, priorities, and funding programs. This will ensure Canada's position can be advanced in an agile and integrated manner and be led by single Minister, included in future Mandate Letters, such as the Minister of Natural Resources or Minister of Innovation, Science and Economic Development.

This strategy development can be aided through the unifying umbrella of the CNIC and can be integrated with provinces through the Council of the Federation. A tangible first step to advance this recommendation would be a review of this opportunity through a Parliamentary Committee.

ODUCTION

This would aide in enabling industry research and support for all isotope-related activities, in domestic and global supply, distribution, and development of isotopes for medical and industrial applications. The strategy should also address interprovincial barriers and how to leverage Canada's existing infrastructure while guiding investment into new infrastructure to lead in global research and manufacturing.



2. Better data, better focus

There are currently 294 medical facilities licensed by the Canadian Nuclear Safety Commission (CNSC) to handle radioactive materials, including small dose isotopes, large sources or powerful irradiators like research reactors, and cyclotrons or electron accelerators. There is a need for a centralized national inventory for these facilities to detail the precise scope of their isotope usage for patient care and the number of treatments performed or the specific isotopes used.

This comprehensive inventory will allow Canada to have a unique position on the global stage to quantify isotope impacts globally and areas of focus required or strategic opportunities.

The current lack of comprehensive data makes it very difficult to quantify isotope impacts in Canada or have a sense of exactly where isotopes are being used in Canada or for what. The CNIC encourages the federal government to work with its regulators, Health Canada, Natural Resources Canada, Ministry of Innovation, Science and Economic Development and the isotope community to help address these gaps and provide a more fulsome understanding of the impact isotopes play every day in patient care and the economy.

There are currently 294 medical facilities licensed to handle radioactive materials in Canada.



3. Secure and expand Canadian talent and expertise

Canada must build on existing expertise within the industry to drive future innovation in medical isotope production capabilities. At the same time, it must invest in the next generation of experts by supporting educational initiatives that bring bright young minds into the field, and support funding initiatives that enable researchers to develop and translate new medical isotope-based agents from the laboratory to the patient's bedside.

Through the Provincial-Federal Ministerial Forum of Ministers of Colleges, Universities and Training, the following opportunities in this area include:

- Collaboration between national labs, universities, and institutes to establish and expand multidisciplinary learning and training programs, co-op placements, post-graduate, and post-doctorate positions in career and research programs directly related to medical isotopes.
- Engagement with universities to establish a multi-disciplinary track that links medical isotopes, science, and engineering at undergraduate level in Canadian universities.

- Leveraging and partnering with the private sector to establish pre-employment training courses for technicians able to work in these specialized facilities, enabling people with appropriate skills to be identified before job-specific trainings begin.
- Greater engagement with students to the industry at an earlier age with the inclusion of more isotope and radiochemistry courses at the undergraduate level.

Leveraging and expanding existing programs at institutions at the federal (Canadian Nuclear Laboratories, National Research Council, Canadian Institutes of Health Research, etc.) and provincial (Fedoruk Centre, University of Saskatoon, TRIUMF, University of British Columbia, McMaster University, University Health Network, etc.) levels to develop an academic network focused on radiochemistry, radiochemical production, and the uses of radioisotopes would increase training capacity for professionals and trades while helping to draw undergraduate attention to the industry and its opportunities



4. Encourage partnerships with the Canada Infrastructure Bank

Canada has a strong and robust human and capital infrastructure to produce medical isotopes for diagnostic and therapeutic applications – with the proper support this can be leveraged to position Canada as the leader in the next generation of nuclear medicine.

Canada possesses a strong foundation of infrastructure, including existing CANDU reactors, cyclotrons, and accelerators, a sophisticated supply chain, and leading research institutions. To build upon this foundation, Canada must declare its supply of isotopes as a key element of strategic national infrastructure using the Canada Infrastructure Bank and/or similar provincial and federal mechanisms. In doing so, we will enable public-private partnerships and allow the isotope industry to access the same funding tools as other major infrastructure projects.

5. Increase Canada's international competitiveness

Canada is presented with significant opportunities to enhance our competitiveness in a challenging economic environment that has been impacted by inflation, supply chain constraints, and labour shortages. At the same time, there are opportunities to attract international investment into our medical isotope sector. By expanding existing funding programs offered through organizations such as Business Development Canada and Export Development Canada to encompass medical isotopes, Canada will encourage international investment and sector growth.

To encourage international investment and sector growth, expanding existing funding programs is key.

6. Provide matching funding programs for the Canadian medical isotope sector

As a world leader in the supply of medical isotopes, Canada is poised to be a country where research and development of new innovative cancer diagnostics and treatments are more easily advanced. Such a market advantage will attract international investment. This too will benefit Canadian cancer patients and researchers who are on the frontline of fighting cancer. With additional funding support from the federal government, companies in Canada will have additional resources earlier in the process, which will be critical to attracting the private investment needed to overcome inertia and the commercialization challenges faced when bringing innovative new treatments to market.

To overcome this challenge, specific funding programs should be created to help Canada leverage its infrastructure advantage and strong network of universities, institutes, national labs, researchers, clinicians, and entrepreneurs to position our country as a global leader in medical isotope innovation. These funding programs should be of a similar nature to those currently being explored to advance Net Zero technologies, in so far as they provide new matching funding options for isotope innovation.

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Specifically, these funding programs would also include designating Canada's isotope community as a key focus area within the Strategic Innovation Fund (SIF). Encouraging industry, such as pharmaceutical companies, to invest in the Canadian Medical Isotope Ecosystem with funding or financial incentives can directly provide jobs and better health outcomes for cancer patients. Other programs and research tax incentives, such as the Life Sciences Innovation Fund and Canada Foundation for Innovation grants, should also place specific consideration on isotopes. With specific and targeted funding programs, Canada can encourage larger pharmaceutical companies to develop products here in Canada and help overcome the commercialization challenges currently faced by Canadian isotope companies.

> Investing in the isotope industry means job creation and better health outcomes for cancer patients.

7. Establish a National Isotope Advisory Caucus

Canada and a national isotope strategy can benefit from an independent council comprised of national and international experts to assist government in managing the program in prioritizing critical needs in technology development and infrastructure needs, as well as research and isotope development. To do this, the government should establish a National Isotope Advisory Caucus.

The caucus could also provide advice on the development and execution of the several educational programs associated with isotope production and use. It could consist of representatives from both the public and private sectors, and include diverse representation from across the isotope sector. Although the council may draw upon industry experts, it must be independent of commercial or academic influence while representing the collective needs to benefit national interests.

> The recommended National Isotope Advisory Caucus will represent the collective needs of the industry.









isotopes for HOPP

Canadian Leadership Needed Now More Than Ever



Conclusion

As this report shows, Canada has occupied a leadership position in the global medical isotope industry for over 70 years. Countries around the world depend on Canada for its expertise and guidance in medical imaging, disease prevention and sterilization, and cancer therapies. In the coming years, there will be several opportunities for Canada to expand its position in the global isotope supply chain, to capitalize on the exponential market growth projected while stabilizing and securing economy enabling supply.

With decades of experience as a continuous, reliable supplier of isotopes like cobalt-60 and iodine-125 to name a few, and once producing the majority of global need of molybdenum-99, Canada is uniquely positioned to become a leader in the development and application of other isotopes. For instance, isotopes like lutetium-177 and actinium-225 can be used to provide cancerfighting treatment options. Though rare, these isotopes are projected to increase in demand as new products progress through clinical trials. Given that the market for these isotopes is expected to fuel much of the international market growth, there is a significant opportunity for Canada to maximize the potential of its domestic supply chain.

If Canada is to continue as a leader on the international stage, it is imperative to pursue innovative solutions to existing supply issues. While we celebrate the achievements and progress of Canada's medical isotope industry, we must continue to collaborate to ensure that gaps in the supply chain are resolved and that Canada can rely on a continuous domestic supply of critical isotopes. In doing so, we will ensure that medical isotopes can continue to offer hope to patients in Canada and around the world.



Strengthening Canada's global role in the isotope supply chain to double production by 2030



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