

STEPS TO BECOMING A

**CERTIFIED
ISOPET®
REGIONAL
CLINIC**





Precision Radionuclide Therapy™

Next Generation Cancer Treatment for Animals

What is IsoPet®?

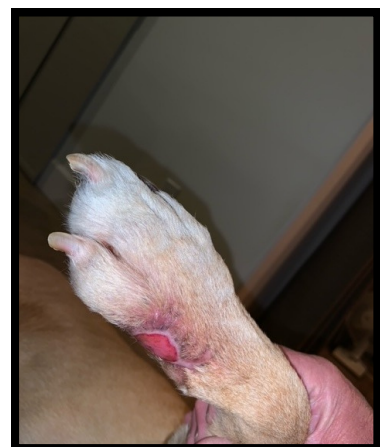
IsoPet® and our patented Precision Radionuclide Therapy™ (PRnT) represent innovative approaches in the treatment of cancer.

IsoPet® focuses on delivering targeted radiation to cancerous tumors while minimizing damage to surrounding healthy tissues.



Brew is an 11 yr old lab that came to us with an aggressive soft tissue sarcoma.

8 weeks after his IsoPet® treatment the tumor shrunk and Brew is currently a 3yr cancer survivor.



Welcome to the IsoPet® RAM Handbook

Let us guide you through:

- Amending an existing RAM* license
- Obtaining a new RAM* license
- Completing the IsoPet® Certification process

*Radioactive materials



Vivos Inc. is here to support you through each phase of the process of becoming a Certified Regional IsoPet® clinic:



Vivos will provide training and resources for your successful IsoPet® Certification.



Our dedicated team is available to support your staff through this entire process.

Become an IsoPet® certified clinic with these six easy steps!

1. Complete the IsoPet® online training modules
2. Amend or obtain a RAM license through the applicable state, with support from F.X. Massé*
3. Purchase and receive your IsoPet® Treatment Kit
4. Complete a Vivos supervised IsoPet® non-radioactive surrogate training (via remote video conference)
5. Complete a Vivos Inc. supervised IsoPet® low-activity radioactive surrogate training (via remote video conference)
6. Perform a Vivos Inc. supervised IsoPet® treatment at your clinic.

*Our partners, F.X. Massé Associates, Inc., are medical physics experts in radiation safety, shielding design, and regulatory compliance. They'll guide you seamlessly through each step.

We've developed a Certification Training Course to satisfy most regulatory training requirements.

- Authorized user (AU) training for new licensees consists of training modules, each with an accompanying quiz. Once each quiz is complete, the user will move to the next module.
- When all modules are completed, the veterinarian will receive a certificate of completion. This certificate can then be used in obtaining the RAM license.
- Supplemental reading material and regulatory templates are also provided and available to download for future reference on www.isopet.com

1. Complete the online training modules

Register at www.vivos.fxmasse.com, select IsoPet® Training and complete the modules for the Authorized User Training and Practical Use courses. Complete the require testing at the end of each module.

IsoPet® Training Modules

i.	Regulatory overview
ii.	Radioactivity
iii.	Interaction of Radiation With Matter
iv.	Radiation Detection and Measurement
v.	Radiation Biology
vi.	Shieling and Dosimetry
vii.	Radiation Surveys and Patient Release
viii.	Radiation Safety Program and Waste Management
ix.	Practical Use - IsoPet® Instructions for Use

2. Amend or Obtain a RAM License

i. Follow the 5 step procedure to amending your existing RAM license

or

ii. Follow the 6 step procedure to applying for your RAM license

3. Purchase your IsoPet® Treatment Kit

i. Contact the Vivos Inc. team to purchase everything needed for the surrogate training and eventual animal treatments

4. Complete the Supervised Non-Radiation Surrogate Training

i. The supervised surrogate training session by injections of non-radioactive gel into a chicken breast warmed to body temperature to ensure IsoPet® gelation. A ROA is to be present and the Instructions for Use to be followed.

5. Complete the supervised low-activity radiation surrogate training

i.

After receiving your materials handling license, complete a supervised training on a video conference by injections of low activity IsoPet® into a warmed chicken breast. A ROA is to be present and the Instructions for Use to be followed.

6. Final Training with Vivos team

i.

The final step is to complete your first IsoPet® animal treatment with members of the Vivos inc. team to ensure full compliance.

Module 9 addresses the **Practical Use - IsoPet® Instructions for Use**. This includes practical use and radiation safety aspects specific to IsoPet® Precision Radionuclide Therapy (PRnT)™.

Module 9 is streamlined and designed for existing Authorized Users who are already familiar with the handling and use of unsealed radioactive materials.



If you already have a RAM license

FOLLOW THESE STEPS

- 1**
 - Identify your Authorized User (AU). This is the veterinarian listed on the granted RAM license who has specific training in the safe handling of sealed radioactive materials.
 - Existing AUs only need to complete Module 9: IsoPet®.

- 2**
 - Identify the location (space) within your facility where you will perform the IsoPet® procedure, which can be used in any area suitable for injections.

- 3**
 - Obtain the recommended materials and equipment for the safe use of IsoPet®. See inside back cover for the full list and contact FX Massé Associates with any questions.

- 4**
 - Send current RAM license, practice floor plan, physical address, and contact name to F.X. Massé Associates by email info@fxmasse.com or call 978-283-4888 (9 am to 5 pm ET), and they will draft the license amendment request on your behalf.

- 5**
 - F.X. Massé Associates will send you the completed license amendment application. The amendment will be submitted to the applicable state regulatory authority specified by F.X. Massé.

† The license is only a few pages, but the renewal content will be approximately 20 pages, including the ALARA, waste, dosimetry, radiation protection program policies, etc.

If you **DO NOT** have a **RAM license**

FOLLOW THESE STEPS

- 1
 - Identify your Authorized User (AU). This is the veterinarian to be listed on the RAM license who has specific training in the safe handling and use of unsealed and sealed radioactive materials. Complete the online training.
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- 2
 - Identify your Radiation Safety Officer (RSO). F.X. Massé Associates can provide a list of local consultants who can meet the requirements for a local consulting RSO.
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- 3
 - Identify the location (space) within your facility where you will perform the IsoPet® procedure, which can be used in any area suitable for injections.
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- 4
 - Obtain the recommended materials and equipment for the safe use of IsoPet®. See inside back cover for the full list and contact FX Massé Associates with any questions.
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- 5
 - F.X. Massé Associates will draft a RAM license application on your behalf using key information provided by your facility to them by emailing info@fxmasse.com If you have any questions, feel free to email or call 978-283-4888 (9 am to 5 pm ET).
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- 6
 - F.X. Masse Associates will send the draft RAM license application for review. Once the information is verified as correct, send your completed and signed application packet on company letterhead to the applicable state regulatory agency. Estimated processing times vary per state and can take 3-9 months.
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Vivos Inc. requires our Certified Regional Clinics to have the following in place:

Staffing Requirements

- Radiation Safety Officer (RSO): Responsible for all radiation safety aspects of the license
- Authorized User (AU): Responsible for administration of medical isotopes
- Veterinary Nurses and Technicians: Optionally train others as necessary.

Physical Space Requirements

- A designated storage refrigerator where radioactive materials are stored and prepared for treatment.
- Delivery location for arriving radioactive product(s).



Vista Veterinary Hospital in Kennewick, WA performing an IsoPet® treatment on a 10yr old Boxer with a spindle cell tumor.



As a certified IsoPet® clinic you will be required to purchase our IsoPet® Treatment Kit and Safety Supplies

IsoPet® Treatment Kit



- Vivos Peliter Chiller w/ Integrated Magnetic Stirrer
- Shielded IsoPet® Vial Holders
- Syringe shield
- 1 cc BD Luer-lock Syringes
- IsoPet® Instructions for Use
- Vivos Peltier Chiller Instructions for Use
- Training Aid for Use of Injection Guidance Form
- IsoPet® Guidance Table (Excel)

Radiation Safety Supplies



- Spill kit
- Unit dose carrier
- Signage
- Shielded sharps container
- Solid waste bin
- Wipes for wipe tests
- L-shield for unit dose preparation
- Templates for regulatory records

Together with F.X. Massé, the team at Vivos Inc. is dedicated to making the certification process as easy and timely as possible.

For over 50 years, F.X. Massé Associates, Inc. and their staff consisting of board-certified medical and health physicists, have been involved in licensing radioactive materials. To learn more about staff credentials, visit www.fxmasse.com/staff

F.X. Massé can be contacted as follows:

Hours: 9 am to 5 pm ET

Phone: 978-283-488

email: info@fxmasse.com



IsoPet® Precision Radionuclide Therapy (PRnT)™ is registered trademark of:

