High-Risk Health Technology (HRHT):

What HRHT Owners Need to Know

High-Risk Health Technology (HRHT) is specialized equipment used to diagnose, treat or rehabilitate patients that requires regular calibration, maintenance, repair, user training and safe decommissioning.

Because these technologies require specialized operation and ongoing technical oversight, they must be registered with the Bermuda Health Council. High-Risk Health Technology does not include implantable, disposable or single-use medical devices.

HRHT may include equipment used to:

Produce diagnostic images
Equipment such as X-ray, CT, MRI and PET scanners.

Deliver radiation or other forms of energy
To treat disease, such as linear accelerators used in cancer treatment.

Administer or remove medicines or fluids
Where there is significant risk to patient safety, such as dialysis machines.

Other complex procedures
Diagnostic or therapeutic procedures needing specialized operation, calibration and ongoing technical maintenance.

HEALTH COUNCIL
BERMUDA

How Is HRHT Determined?

The Council assesses equipment to decide whether it is High-Risk Health Technology by considering the following:

1. **Criteria Review**
   Equipment is assessed against the criteria in the Bermuda Health Council Act 2004.
2. **Intended Use**
   Whether the equipment is used to diagnose, treat or rehabilitate.
3. **Technical Characteristics**
   How specialized, complex and calibration-dependent the equipment is.
4. **Oversight Required**
   The level of regulatory oversight needed for safe operation. If met, it is classified as HRHT and must be registered.

Not sure if your equipment qualifies? Contact the Health Council.

Common Examples of HRHT

Include, but are not limited to:

- X-ray systems
- MRI scanners
- Mammography systems
- Linear accelerators
- CT scanners
- PET scanners
- Fluoroscopy equipment
- Dialysis machines

Questions or Concerns?

We're Here to Help.

Website
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E-mail
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Legislation

- Bermuda Health Council Act 2004
- HRHT Regulations 2024