

**GUIDANCE FOR MAXIMIZING SUPPLY OF
TECHNETIUM-99M (TC-99M) DURING A SHORTAGE**

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I. INTRODUCTION:

At the February 13, 2009 Federal-Provincial/Territorial Workshop on Contingency Planning for Medical Isotope Shortages, interest was expressed in having guidance from medical professional associations and the nuclear medicine community at large on how to maximize the supply and utilization of Tc-99m during a substantial or extended medical isotope shortage.

The Government of Ontario, advised by the Ontario Isotope Working Group, prepared draft guidelines as part of its Medical Isotope Supply Disruption Plan.

The following guidance is based in large part on the guidelines in the Ontario plan as well as input from the Ad-Hoc Group of Experts on Medical Isotopes, which was created in December 2007, to provide advice to Canada's Minister of Health. This guidance is being provided as advice to provinces and territories and the health care community in developing strategies to manage patient care until such time as supply can be re-established and returned to normal levels. These recommendations should not be interpreted as a substitute for the personal judgement of a health care practitioner.

Health Canada is willing to work with health care partners to address regulatory requirements for these strategies, where they are required.

II. GUIDANCE:

1) Modify scanning technique, adjust patient scheduling and optimize the available activity of the generators

- Coordinate and schedule procedures based on generator delivery and available activity. For example, procedures that require higher doses, such as cardiac procedures, should be performed at the beginning of the generator life.
- Scan outside of normally scheduled hours of operation to maximize generator activity, including on weekends where generator delivery is available on weekends.
- Reduce the dose of isotope used and scan the patient for a longer period. This will require corresponding adjustments in patient scheduling to accommodate longer scanning times per patient. There is no safety hazard to the patient or reduction in the quality of the scan using this modified technique.

- Seek appropriate regulatory approval from Health Canada to use alternate radiopharmaceuticals to replace Technetium labelled products.
- Where this is possible, consider shipping eluted generators from central radiopharmacies to smaller facilities at the beginning of the second week of use, where they may be more useful because they cannot conveniently receive Tc-99m.

2) Prioritize patients to direct available supply to more urgent needs

- Prioritize patient scans to direct available Tc-99m to those with more urgent medical need: expedited scans for newly-diagnosed breast cancer and paediatric cancer patients according to the list below. Where possible, use alternate diagnostic procedures for cardiac, and adult cancer bone scans, as described in sections 3 and 4. Alternatively, schedule high dose procedures immediately after generator delivery to maximize available activity.

Priority Needs for Tc-99m
Sentinel lymph node biopsy to help stage patients newly diagnosed with breast cancer with specific reference to the status of cancer spread to axillary lymph nodes and melanoma.
Any bone scan for newly diagnosed or established paediatric cancers since there is no alternative to Tc-99m bone scans for the paediatric patients in the event of a shortage.
Any bone scan for staging newly diagnosed cancer patients when immediate treatment decision will be affected - only when alternatives are not possible.
Benign skeletal abnormalities: <ul style="list-style-type: none"> A. Infection and/or fracture associated with a hip or knee prosthesis. B. Fracture in elderly patients or occult fracture in paediatric patients where a plane film x-ray is inconclusive: CT may be helpful if no contraindications. C. Osteomyelitis in paediatric or adult patients. D. Assessment of child abuse.
Myocardial perfusion imaging for those patients who do not have immediate access to alternative cardiac imaging (see section on alternatives for cardiac imaging).
Renal scans for transplants or acute renal failure where alternative scans are either not applicable or available, such as in paediatric nuclear medicine examinations.
Paediatric nuclear medicine examinations, since the alternatives are usually more irradiating.
Detection of pulmonary embolism in pregnant women.
Patients with a contraindication to contrast media for MRI and CT scan.

3) Shift to alternate diagnostic modalities, nuclear and non-nuclear

- For the patients not listed in the above priority list, consider shifting patients to alternate scanning methods (e.g. stress thallium/echocardiogram, CT or MRI) depending on the type of disease in order to further conserve the use of Tc-99m. See table below.
- Seek appropriate regulatory approvals where required to use alternatives. Health Canada can provide assistance in this regard.

Alternatives to Tc-99m	
Nuclear Medicine Test – Organ Scans	Alternative
Liver scan	CT, MRI, Ultrasound
Renal scan	IV Pyelogram, 24hour creatinine clearance, Ultrasound
Lung scan for suspected pulmonary embolism	CT scan, if no contraindications
Cardiac Imaging (ACUTE)*	Alternative
UA/NSTEMI (no early cath)	Stress thallium/echocardiogram*
STEMI (thrombolytic therapy, no cath)	
ACS, coronary anatomy, unclear significance	
Preoperative Risk Assessment : <ul style="list-style-type: none"> • Intermediate risk surgery, intermediate preoperative risk predictor. • High risk surgery, poor exercise tolerance. 	
Cardiac Imaging (ELECTIVE)*	Alternative
Cardiomyopathy, unknown aetiology	Rest or Stress thallium/echocardiogram
Evaluation of Chest Pain Syndrome <ul style="list-style-type: none"> • Intermediate to high pretest probability • Low risk chest pain at rest • New onset heart failure with chest pain syndrome 	Stress thallium/echocardiogram*
Consideration of ICD, Biventricular Pacemaker (whether elective or acute, will depend on clinical circumstance)	Echocardiogram/MRI
* Thallium suppliers require one week's notice to ramp up production of Thallium-201 if it is expected to replace Tc-99m; Thallium-201 is approved by Health Canada for myocardial perfusion for the diagnosis and localization of myocardial infraction	

Cancer Imaging	Alternative
Adult cancer patients being followed with established bone metastases or in whom bone metastases are suspected	X-ray, CT or MRI

4) Use of PET nuclear imaging isotopes as alternatives, where available

- It may also be possible to use PET isotopes as alternatives, where they are available.
- PET scans using F-18 FDG can supplant some Tc-99m uses for cancer imaging. There are currently five authorized manufacturers of F-18 FDG in Canada.
- PET scans using Sodium F-18 can be considered as an alternative to Tc-99m for bone scans and potential other uses, provided that appropriate regulatory approvals are in place. Clinical trials on the use of Sodium F-18 as an alternative medical isotope are currently underway; authorization is granted by Health Canada after the review of the Clinical Trial Application.
- Prioritization and further guidelines for the use of PET or other imaging alternatives may need to be considered.

5) Review of Guidelines

These guidelines will be reviewed in six months from November 2009. The review will be carried out to determine if refinements are necessary, based on current practices and input received.