

MEMORANDUM

TO: All NCIC CTG Investigators

FROM: Dr. Ralph Meyer, Director, NCIC Clinical Trials Group

DATE: June 5, 2009 – **UPDATED JULY 15, 2009**

RE: Radioisotope Shortages

The NCIC CTG is aware of the shortages in the availability of radioisotopes that have resulted due to the temporary closure of the Chalk River manufacturing site. We appreciate the potential for substantial implications to the delivery of care to patients who are treated on or off of clinical trials. We recognize that each institution is developing its own priorities and that provincial Ministries of Health have also established guidelines.

In dealing with the potential shortage as this relates to NCIC CTG clinical trials, the following general principles apply:

1. Please see the attached summary for instructions related to MUGA cardiac testing and bone scans as these relate to specific trials that are led by the NCIC CTG.
2. From a clinical trials perspective the following priorities should be considered:
 - i) scans required for safety assessments;
 - ii) scans required for response assessment;
 - iii) scans required for eligibility;
 - v) scans required for assessments of late-effects.
3. In general, cardiac MUGA scanning can be replaced by echocardiography or, in patients who are off all therapy, deferred until the radioisotope shortage resolves.
4. With respect to bone scans, in general, patients considered for trials for metastatic cancer will remain eligible if other evidence of metastatic disease is detected. For adjuvant trials that require bone scanning as part of the assessment for eligibility, these patients will generally be considered as ineligible unless a bone scan is performed. However, there may be trial specifics that apply to this principle and the Physician Coordinator of the specific NCIC CTG trial should be contacted.
5. For any trial specific questions, please contact the Physician Coordinator for the respective trial.

6. With respect to Intergroup trials, and in the absence of guidance from the lead group, please follow the principles that have been established for trials that are led by the NCIC CTG. We will provide additional information to you as this becomes available.
7. As per the standard language of our protocol, the responsibility of treatment of subjects entered onto NCIC CTG clinical trials rests with the individual investigator. While the above principles regarding radioisotope scans should be adhered to as best is possible, we understand that individual patient circumstances and local priorities will influence the ability to perform radioisotope-related tests. When a protocol-mandated investigation is not performed because of radioisotope shortage please document this information both on the patient record, and where appropriate, on the case report form.

We will provide additional information to you as this becomes available.

Thank you for your cooperation.

Yours sincerely,

A handwritten signature in cursive script, appearing to read "Ralph Meyer".

Ralph Meyer, MD, FRCP (C)
Edith Eisenhower Chair in Clinical Cancer Research
Director, NCIC Clinical Trials Group
Professor, Department of Oncology, Medicine and
Community Health and Epidemiology, Queen's University

RM/tsj

Attachment (Isotope Shortage)

Isotope Shortage – NCIC CTG Led Studies (as of 10 July 2009) -- Updates are in red.

MUGA only required for Eligibility

Trials Affected	Action
BR.29 (only if significant cardiac history) I190 (only if significant cardiac history) MA.22 MA.29 MA.31 REC.2 (as per section 7 of the protocol)	Replace by ECHO

MUGA required for follow up – ON Therapy

Trials Affected	Action
BR.29 (only if significant cardiac history) MA.22 MA.29 MA.31 REC.2 (as per section 7 of the protocol)	Do MUGA if possible. If not possible, ECHO should be done. Return to MUGAs when possible.

MUGA required for follow up – OFF Therapy

Trials Affected	Action
MA.15 MA.21 (if the shortage causes delays by more than 3 months, an ECHO should be requested with return to MUGAs when possible)	Test can be deferred until supply deficiency resolves.

Bone Scan need for Eligibility – Metastatic Trial

Trials Affected	Action
MA.22 MA.31	If bone scan cannot be done and other criteria for metastatic disease are met, patient is eligible.

Bone Scan need for Eligibility – Adjuvant Trial

Trials Affected	Action
PR.12	Bone scan is a priority. If it cannot be done, default would be patient is not eligible (PCs to discuss).

Bone Scan need for response – On Therapy or at completion of therapy

Trials Affected	Action
MA.31	Scan is of priority. If it cannot be done, it should be performed asap once supply issue resolves. New symptomatic areas suggesting PD can be assessed by MRI or PET at investigator discretion.

Cont'd ...

Bone Scan need for response – OFF Therapy

Trials Affected	Action
PR.3 (if indicated) PR.7	Scan can be deferred until supply deficiency resolves