

# **Protocol for the Submission, Review and Approval of CT Designation Requests**

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## **Purpose of the Protocol**

The purpose of this protocol is to set out the process that Local Health Integration Networks (LHINs), the Ministry of Health and Long-Term Care (ministry), and Health Service Providers (HSPs) must follow when submitting, reviewing and/or recommending the approval of CT designation requests/business cases.

## **2. Application and Scope**

This protocol applies to the ministry, the LHINs, and the HSPs. The protocol applies to requests for the designation of new or replacement CT scanners.

## **3. Applicable Legislation, Memorandum of Understanding, Management Board Directive, Agreements, etc.**

### **Public Hospitals Act (PHA)**

Hospitals may be classified as Group M hospitals pursuant to subsection 32.1(1) of the *Public Hospitals Act* (PHA). Group M hospitals, in accordance with clause 1(1)(m) of Regulation 964 to the PHA, may charge and accept payment from other hospitals for the performance of CT scans. The classification of a hospital under Group M is site specific.

The authority of the Minister of Health and Long-Term Care (Minister) to assign hospitals to classes and grades under s.32.1 of the PHA has been delegated to the Assistant Deputy Minister, Health System Accountability and Performance Division.

### **Healing Arts Radiation Protection Act (HARPA)**

Under the *Healing Arts Protection Act* (HARPA), the Minister has the authority to designate a hospital or class of hospitals that can install or operate a CT scanner and the number of CT scanners that a hospital may install and operate. The Minister has delegated his power under s. 23 (2) of HARPA to the Assistant Deputy Minister, Health System Accountability and Performance Division.

On July 1, 2011 amendments to the X-Ray Safety Code, Regulation 543 under HARPA came into force, which include the definition of a CT scanner as meaning, “an X-ray machine that is a computerized tomography system or subsystem and that is able to generate a volumetric representation of the human body using a multitude of X-rays at a multitude of orientations, and includes any such device regardless of its common name or brand name or any other way it is referred to, including, without limiting the generality of the foregoing, a computerized tomography scanner or a computerized axial tomography scanner.” The term “CT scanner” as used in this protocol has the same definition.

Pursuant to section 3 of the HARPA, the hospital also requires written approval from the Director of X-Ray Safety before the installation of the CT scanner can be initiated.

### **Health Insurance Act**

Regulation 552 of the *Health Insurance Act* (HIA), subsection 9(6) states: "Subject to subsection 11(1), an insured person is entitled to receive computerized axial tomography scanning services in a hospital graded, under the PHA, as a Group M hospital without paying any charge to the hospital for such services."

## **4. Process – Roles and Responsibilities**

### **Role of the Local Health Integration Network (LHIN)**

The LHIN will review each CT designation request, and will provide a letter of support to the ministry (LHIN Liaison Branch/LLB) outlining the rationale for recommending (or not) that the specific CT designation request be approved.

### ***STEP 1 – Hospital / Provider Submission***

#### **CT Scanner Designation Request - Proposal Components**

The hospital's business case requesting designation under the HARPA for its new CT scanner(s) should be **submitted to the LHIN Chief Executive Officer (CEO) at least 60 business days before a decision is required to allow for LHIN and ministry review.** The request must be signed by the hospital CEO, or designate with signing authority.

The business case should use the template provided in Appendix IV and must address the following:

#### **Note:**

Requests should be submitted no more than 12 months prior to the anticipated planned installation of the CT equipment.

#### **A. Overview & Current Status**

- Outline the rationale for developing the business case. A brief environmental scan should be included.
- List the individual CT scanners currently operating at the specific hospital site (a separate list may be attached to the business case). Please include:
  - Name of device
  - Date installed
  - Number of slices (i.e. 8, 16, 32, 64), if relevant
  - Total number of CT scanners per hospital site as listed on ministry's website: [http://www.health.gov.on.ca/en/common/system/services/hosp/group\\_m.aspx](http://www.health.gov.on.ca/en/common/system/services/hosp/group_m.aspx)

- Provide the total number of CT scanners at that specific hospital site after the installation of the new CT equipment.
- For each scanner, also indicate the purpose:
  - Research
  - Clinical
  - Hybrid (e.g. SPECT CT)
  - Dental
- Include a brief description of the new CT scanner being installed:
  - Make
  - Model
  - Number of slices
- Include a brief description of the sponsoring hospital, including programs/services available, overall bed numbers, catchment area, etc.
- **A brief cover letter from the hospital should also be included:**
  - confirming that the hospital will have a balanced operating budget, or that it has a LHIN approved plan in place to reach a balanced operating budget in the same fiscal year that the CT scanner is expected to become operational;
  - confirming that there are no additional base budget implications with respect to the purchase and operation of the new CT scanner; and
  - confirming that the CT scanner will be purchased with previously secured funds.

**THE HOSPITAL WILL BE RESPONSIBLE FOR ALL OPERATING AND CAPITAL COSTS (INCLUDING RENOVATIONS)**

**Note:**

1. If this request is related to the replacement of an existing CT scanner, **indicate whether or not the equipment to be replaced will be de-commissioned before the new equipped is installed**, or if the older CT scanner will remain installed and available for use/continue to operate.

2. If a hospital wishes to install and operate CT equipment at off-site premises, the hospital must first ensure that the off-site premises have been approved under s. 4(2) of the PHA for use for hospital purposes. Subsection 4(2) states: “No institution, building or other premises or place shall be operated or used for the purposes of a hospital unless the Minister [of Health and Long-Term Care] has approved the operation or use of the premises or place for that purpose.” Once this approval is received by the hospital, a request for designation under HARPA to install and operate the CT equipment may be put forward.

**B. Strategic Analysis**

- Provide an impact analysis for both the hospital and the LHIN to verify that the hospital’s CT implementation plan is consistent with the service provision goals outlined in the LHIN Integrated Health Services Plan (IHSP).

- Describe any impact on existing community service providers (e.g. Independent Health Facilities [IHF]), as well as other nearby hospitals that may provide CT services. This impact analysis should include the requesting hospital and the LHIN in general.
- List key assumptions and any dependencies which exist with other projects or initiatives.
- Describe the proposed “reach” of CT services to other communities within the district, county, and/or region.

### C. Resource Analysis

- List all start-up, one-time capital, and base operating costs.
- Conduct a cost/benefit analysis that includes a multi-year financial plan addressing the sources of funding for both capital and operating costs. For operating costs, this should include a description of the hospital’s current financial position, sustainability of resources and the hospital’s ability to maintain a balanced budget position, as required in its Hospital Service Accountability Agreement (H-SAA).
- Include an analysis of the health human resources impact, impact on other services, and utilization management strategy.
- Describe the hospital’s fundraising strategy for capital and one-time start-up costs, and outline the impact on the hospital’s current cost-share ratio.

### D. Capital Component

In planning for the space for the proposed CT scanner(s), the hospital must meet the requirements of *CSA Z8000 – Canadian health care facilities*, including the OASIS principles and all applicable codes and standards.

In addition, as part of its business case, the hospital must respond to the following questions:

- 1) Will the proposed CT scanner project limit the future growth potential/vision for the facility and/or its site(s) (e.g. master plan)? ☐ yes ☐ no
- 2) Does the hospital require any funding beyond hospital/Foundation resources to fund the equipment and/or any required construction and/or renovations? ☐ yes ☐ no
- 3) If the hospital is in the planning or construction phase of an approved major project, does the proposed CT scanner project:
  - a) impact the major project (e.g. schedule, budget, etc.)? ☐ yes ☐ no
  - b) negatively impact the hospital's Local Share plan? ☐ yes ☐ no

- 4) Will the CT scanner(s) be installed into existing internal space that requires reconfiguration/ renovation such that the hospital must acquire a building permit, as per the *Ontario Building Code Act*? ☐ yes ☐ no
- 5) Will new/modular construction, as per the *Ontario Building Code Act*, be required to accommodate the CT scanner(s)? ☐ yes ☐ no
- 6) Will there be any physical impacts to adjacent clinical patient areas (e.g., clinical programs, departments)? ☐ yes ☐ no

**Note:**

If the hospital responds “yes” to any of the above questions, LLB will lead discussions between the LHIN and the ministry, as required, to determine whether the proposal will or will not be regarded as a capital project, subject to the ministry’s capital review and approvals process.

If it is determined that the proposal involves adding additional buildings or facilities to a hospital and is subject to the ministry’s capital review and approval process, the Health Capital Investment Branch will lead the capital approval process and coordinate any necessary approvals under subsection 4(3) of the *Public Hospitals Act* (PHA). Refer to the ministry approval protocol for requests under Section 4 of the PHA for additional information.

## ***STEP 2 – LHIN Review and Recommendation***

Once the business case is received by the LHIN, it should be assessed based on the following criteria:

- Are there any issues related to the strategic and/or the resource analysis that will require follow-up by the LHIN with the hospital?
- If required, has the hospital addressed the issues raised by the LHIN?
- Is the business case aligned with the LHIN IHSP, and with the LHIN strategic direction?
- Has the hospital confirmed base hours of operation?
- Are there any issues related to resource requirements (per hospital outline of necessary operating funding and/or relevant capital costs)? Is there sufficient availability of health human resources?
- Are there any other existing providers (Hospitals, Independent Health Facilities, and/or Specialty Clinics) currently offering CT scan services within five kilometres of the hospital requesting the new/replacement CT scanner designation?
- The LHIN will forward the business case to LLB, along with its recommendation and written confirmation that all of the criteria for approval outlined in this protocol have been met. If the LHIN recommends approval contrary to any of the criteria, a detailed

rationale will be required. If the LHIN does not recommend approval, a rationale for this recommendation will be required.

- The LHIN should forward the business case and its written advice to the ministry within **30 business days** of receipt of the hospital's business case.

### ***STEP 3 – Ministry Review***

LLB will coordinate the ministry's review of the business case and oversee the preparation of any necessary documents for approval consideration.

The ministry will review and provide a written response within approximately **45 business days** of receipt of the hospital's business case and the letter of support from the LHIN.

Additional time may be necessary to complete the approval process if:

- A. Additional information/clarification is required with respect to the hospital's business case, and/or
- B. Consultation with other ministry branches is needed.

### **X-Ray Inspection Services – Approval Process for Installation and Registration**

Under s.3 of the HARPA, the written approval of the Director of X-Ray Safety is required before the installation of any x-ray machines, including CT scanners.

The provider or delegate sends copies of its installation plan application to the X-Ray Inspection Service (XRIS), Health System Accountability and Performance Division.

Subsequently, the Director may issue a written approval for the installation of the CT equipment, in accordance with subsection 3(2) of the HARPA.

## **Appendix I: Replacement of a CT Scanner**

When a hospital is requesting the designation of CT scanners that will replace existing CT equipment, the following information must be provided to the LHIN:

- Rationale to support the replacement of the existing CT scanner.
- Any potential or existing capital implications (see capital component above).
- Confirmation with respect to whether the CT scanner(s) will be decommissioned, or if the existing CT equipment will remain installed and available for use/continue to operate.

## **Appendix II: CT Subsystem (Gamma Cameras)**

To request HARPA designation for a CT subsystem (e.g. SPECT CT or any other CT enhanced device), a hospital must provide the LHIN with a written statement, indicating that the equipment will not be used for diagnostic CT imaging and billing.

## Appendix III: Regional Cancer Program/Centre CT Scanners

The Capital Projects Office of Cancer Care Ontario (CCO) manages the provincial annual allocation for radiation treatment replacement, which includes the negotiation of provincial pricing agreements for the supply of scanners, maintenance of the provincial database for radiation treatment scanners, and the recommendation process for the annual allocation of funds (CCO website).

A Regional Cancer Centre/Program wishing to replace or purchase new CT scanners must submit a business case for new equipment and replacements must be identified in their five year equipment replacement strategy to CCO. CCO will then review the request and, if supported, will provide a letter of support to the local LHIN and to LLB.

The designations are site-specific to either the site of the hospital, or in some cases, the Regional Cancer Centre site (if located at a different address).

In order to comply with the requirements of *HARPA*, it is necessary to note the exact number of CT scanners to be designated within each request, as well as the total number and individual descriptions of the specific CT scanners that have previously received designation for installation and operation at this specific site.

- Information on regional cancer program and regional cancer centre locations can be found at the following website:  
<https://www.cancercare.on.ca/pcs/treatment/rcchospitals/>
- *HARPA* designation letters for regional cancer centres must ensure that CCO is appropriately copied on the letter

**Note:** It is the understanding of the ministry that the purchase and installation of the CT scanner is subject to the *Memorandum of Agreement* between CCO and the sponsoring hospital.

Under Section 3 of *HARPA*, written approval of the Director of X-Ray Safety is also required before the installation and operation of all CT scanners.

## Appendix IV: Business Case Template

(also available as an editable word document)

### **BUSINESS CASE TEMPLATE**

(To be completed by hospital)

#### **REQUEST FOR DESIGNATION UNDER THE *HEALING ARTS RADIATION PROTECTION ACT (HARPA)* TO INSTALL AND OPERATE CT SCANNERS / EQUIPMENT**

Hospital Name:

Mailing Address:

Contact name and Title:

Phone:

Email:

LHIN:

CT Scanner/Equipment (*new or replacement*)?

If the new CT equipment is replacing old/obsolete CT equipment, will the old equipment be decommissioned once the new CT is installed?

Will this equipment be located in a regional cancer centre (*Yes or No*)?

When is the hospital planning to install the new CT equipment?

What will be the total number of CT scanners designated at this specific hospital site once the new/replacement equipment is installed?

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### **A. OVERVIEW & CURRENT STATUS**

**1. Outline the purpose / rationale / reason for developing this business case at this time:**

(*response / comments*)

**2. Include a brief environmental scan:**

(*response / comments*)

3. List the individual CT scanners/equipment currently operating at each hospital site as listed on the ministry website. For each CT scanner, provide the information outlined below.

(A separate list may be attached to this document)

Name of hospital / hospital site	Total number of CT scanners at this site	Name of each device per specific hospital site	Number of slices (ie. 8, 16, 32, 64), if relevant	Date installed	Type (Research/ Clinical/Hybrid (eg. SPECT-CT) or Dental)

4. Attach a statement from the hospital which includes the following confirmation:

- The number of base hours of operation for the new/replacement CT equipment
- That the hospital will have a balanced budget (or LHIN-approved plan to balance) in that same fiscal year
- That there will be no additional base budget implications with respect to the purchase and operation of this new CT equipment
- That the CT equipment will be purchased with previously secured funds (ie. donation, etc)

5. Include a brief description of the sponsoring hospital which includes the following information:

- programs/services available
- overall bed numbers
- catchment area, etc

(response / comments)

6. Identify any “unique” factors that would make this proposal critical for the community / stakeholders.

(response / comments)

## B. STRATEGIC ANALYSIS

1. Provide impact analysis for both hospital and LHIN - to verify that the hospital's CT implementation plan is consistent with service provision goals outlined in LHIN's *Integrated Health Services Plan* (IHSP). Include target benefits, future success measures, dates for achievement, and critical deliverables, as appropriate.

(response / comments)

2. Describe any impact on existing community service providers (eg. Independent Health Facilities [IHF]) as well as other nearby hospitals that may provide CT services. This impact analysis should include the requesting hospital and the LHIN in general.

(response / comments)

**3. List key assumptions and any dependencies which exist with other projects or initiatives.**

(response / comments)

**4. Describe any infrastructure work (ie. renovations or new construction) which will be required to accommodate the new/replacement CT equipment.**

(response / comments)

**5. Describe the proposed “reach” of the CT services to other communities within the district, county, and/or region.**

(response / comments)

## **C. RESOURCE ANALYSIS**

**1. List all start-up, one-time capital, and annual operating costs.**

(response / comments)

**2. Conduct a cost-benefit analysis which includes a multi-year financial plan addressing the sources of funding for both capital and operating costs. For operating costs, this should include a description of the hospital's current financial position, sustainability of resources and the hospital's ability to maintain a balanced budget position, as required in its *Hospital Service Accountability Agreement (H-SAA)*.**

(response / comments)

**3. Include an analysis of the health human resources impact, impact on other services, and utilization management strategy.**

(response / comments)

## D. CAPITAL COMPONENT

**The hospital must clearly confirm that the following four conditions will be met:**

**In planning for the space for the proposed CT scanner(s), the hospital must meet the requirements of CSA Z8000 – Canadian health care facilities, including the OASIS principles and all applicable codes and standards.**

**As part of its business case, the hospital must respond to the following questions:**

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| 1) Will the proposed CT scanner project limit the future growth potential/vision for the facility and/or its site(s) (e.g., master plan)?  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| 2) Does the hospital require any funding beyond hospital/Foundation resources to fund the equipment and/or any required construction and/or renovations?   | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| 3) If the hospital is in the planning or construction phase of an approved major project, does the proposed CT scanner project:  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| a) impact the major project (e.g., schedule, budget, etc.)?  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| b) negatively impact the hospital's Local Share plan?  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| 4) Will the CT scanner(s) be installed into existing internal space that requires reconfiguration/ renovation such that the hospital must acquire a building permit, as per the <i>Ontario Building Code Act</i> ? | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| 5) Will new/modular construction, as per the <i>Ontario Building Code Act</i> , be required to accommodate the CT scanner(s)?  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| 6) Will there be any physical impacts to adjacent clinical patient areas (e.g., clinical programs, departments)?   | <input type="checkbox"/> yes | <input type="checkbox"/> no |

**Completed By (Print Name , Title, Organization):**

\_\_\_\_\_  
**Signature:**

\_\_\_\_\_  
**Date:**