

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

**CERTIFICATE OF NEED APPLICATION
BY
THE UNIVERSITY OF VERMONT MEDICAL CENTER INC.
TO
REPLACE ITS FIXED PET/CT SYSTEM**

Dated May 4, 2016

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SECTION I PROJECT OVERVIEW

A. Description of Project

The University of Vermont Medical Center Inc. (“UVM Medical Center”) hereby submits this Certificate of Need (“CON”) application in accordance with 18 V.S.A. Section 9440(c)(5), seeking expedited review and approval of a \$2.68 million project (the “Project”) to replace its fixed PET/CT system and to make the necessary renovations to house the equipment. Specifically, this application seeks approval of the following:

- (1) Replacement of UVM Medical Center’s only PET/CT system with a Philips Vereos PET/CT system for a cost of \$2,370,000¹; and
- (2) Facilities renovations for the PET/CT exam room, located on McClure 1, at a cost of \$172,000, related construction contingency expenses of \$38,880, design/bidding contingency expenses of \$22,360, furnishings, fixtures and equipment at a cost of \$27,000², architectural/engineering fees of \$56,033, and permitting fees at a cost of \$3,358.³

The total cost of the Project, which is \$2,689,631, will be covered by available working capital, without the need for additional borrowing.

B. Project Rationale

The Project does not involve any new program or service, the expansion or modification of any existing service or program, or the construction of any new health care facilities.

The Project involves only the routine replacement of UVM Medical Center’s existing PET/CT system, consistent with sound business practices, as well as minor facilities renovations necessary to house the equipment. The existing PET/CT equipment was installed in 2009, is fully-depreciated, does not feature the latest enhancements in updated image quality, and does

¹ This amount includes a reduction to the purchase price of \$380,000 as a result of the trade-in of UVM Medical Center’s existing PET/CT equipment.

² The cost for furnishings, fixtures and other equipment includes the cost of IT connections and replacement of the radio system in the room.

³ Permitting fees are limited to the CON application fee.

not have the necessary technology to meet current federal requirements for limiting radiation exposure.

UVM Medical Center's existing PET/CT system relies on outdated analog imaging technology. The new PET/CT system that UVM Medical Center proposes to acquire, the Philips Vereos system, uses digital photon technology to replace the traditional analog photomultiplier tubes. This new technology results in: (a) significant improvements in image quality, (b) lower amounts of radioactive radiopharmaceuticals⁴ administered to patients prior to the exam, and (c) lower radiation exposure from the CT scanner itself.

The Project is needed to enable UVM Medical Center to continue to provide high-quality tertiary-level care for the treatment of cancer and certain cardiovascular diseases where PET/CT serves as an essential diagnostic tool. Replacing UVM Medical Center's existing seven-year-old PET/CT system with the Philips Vereos system will provide numerous patient care benefits, as explained in greater detail below.

C. Consistency with CON Criteria and Standards

The proposed Project meets the statutory criteria set forth in Section 9437 of the Vermont Certificate of Need law, and is consistent with the Health Resource Allocation Plan published on July 1, 2009 ("HRAP") and the applicable HRAP CON standards, as explained in detail in Parts IV and V of this Application.

SECTION II DESCRIPTION OF UVM MEDICAL CENTER'S PET/CT SERVICES

A. Description of PET/CT Imaging

Overview of PET/CT Technology

PET/CT combines the unique functional, biochemical and physiologic information provided by a Positron Emission Tomography (PET) scan with the anatomic/morphologic information provided by a Computed Tomography (CT) scan.

A PET scan is a test that uses a special type of camera and a radioactive chemical (i.e., a radiopharmaceutical administered intravenously to patients) to look at organs in the body. PET scans are used to evaluate cancer, check blood flow and see how organs are functioning. During

⁴ Radiopharmaceuticals are drugs that carry a limited degree of radioactivity. Prior to diagnostic testing, these drugs are administered to the patient to assist with visualizing the structures of the body.

a PET scan, the radioactive chemical collects in certain cells that are using a lot of energy, such as a cancer cell, so that anomalies can be detected and treatment decisions can be informed.

Although PET scan pictures visualize cancers and other abnormalities, the pictures show only the location of the radioactive chemical and therefore they must be paired with a CT scan to develop a detailed image that can be relied upon for diagnostic and treatment purposes. A CT scan uses X-rays to make detailed pictures of structures inside the body (i.e., images of the liver, pancreas, kidneys, lungs, heart, blood vessels, bones and the spinal cord). To create the image, a CT scanner sends X-ray pulses through the body. Each pulse lasts less than a second and takes a picture of a thin slice of the organ or area being studied. The different pictures or “slices” taken during the CT scan can be reformatted in multiple planes, and can also generate three-dimensional images which can be viewed on a computer.

A fixed PET/CT system works by simultaneously combining the two images with complete precision. Instead of taking separate CT and PET exams (where the patient’s anatomy could change alignment in the time between exams), technologists perform one complete exam during a single patient visit. This fused system imaging can improve patient outcomes and provide more effective overall patient care, because physicians can more quickly and accurately view the locations of lesions. By detecting disease earlier and more accurately, PET/CT can help to reduce unnecessary patient surgeries, reduce unnecessary diagnostic procedures and reduce some biopsies.⁵

Essential Tool for the Diagnosis and Treatment of Cancer and Neurological Diseases

PET/CT imaging is highly beneficial in the management of cancer. The anatomical image generated by the simultaneous CT scan acts as a “map” showing doctors precisely where the cancer is located in one fused image. It is also used to manage patient therapies by monitoring response to a specific regimen (e.g., chemotherapy or radiation therapy) and providing real-time feedback on its efficacy. This can help to reduce or avoid ineffective treatments. PET/CT can also help to predict the prognosis for surgical procedures and eliminate those that will not be beneficial for the patient.

The main indications for PET/CT exams are for patients with suspected disease, documented malignancy or evaluation of response to treatment. The whole-body imaging capability of PET/CT is very effective for evaluating malignancy involving every organ system. PET/CT is also used to study the brain’s blood flow and metabolic activity, for the purpose of detecting nervous system problems such as Parkinson’s disease, multiple sclerosis, Huntington’s disease, and amyotrophic lateral sclerosis (ALS).

⁵ *Current Role of FDG PET/CT in Lymphoma*, Kostakoglu L. and Cheson B., *Eur J Nucl Med Mol Imaging* 2014; 41:1004 – 1027.

PET/CT for the Diagnosis of Cardiovascular Disease

PET/CT also serves as an advanced stress test for studying the heart. The test provides physicians with an image of the heart while resting and with increased blood flow, which is called “stress.” These images are then compared in order to learn more about the blood supply in a patient’s heart.

PET/CT combines PET and CT imaging technologies to check the health of the coronary arteries, which are the vessels that supply blood to the heart. Clinical studies have shown that PET/CT scans are more accurate than traditional stress tests (i.e., single-photon emission computed tomography or SPECT tests) that are widely used to diagnose heart conditions.⁶ The test works by taking detailed images of a small amount of “tracer” or “dye” that is injected into the bloodstream. The PET camera detects the tracer as it flows through the arteries to create images of the heart. A medication is then used to increase the blood flow through the heart (“stress”) and these images are compared to those taken before blood flow was increased.

The high image resolution of PET/CT provides a clearer picture of the heart than traditional stress tests and leads to a more accurate diagnosis of coronary disease. Because PET/CT provides for better diagnoses than traditional stress tests, it has been shown to produce fewer false positives for cardiac disease and thus leads to a decrease in the ordering of costly angiograms and bypass surgery for many patients.⁷

B. PET/CT Services Currently Offered at UVM Medical Center

PET/CT technology is essential in supporting the patient care, teaching and research missions of UVM Medical Center, the State’s only academic medical center and teaching hospital, and the regional referral center for complex tertiary-level care. PET/CT imaging serves as a critical diagnostic tool for the treatment of cancer and cardiovascular disease; it is used for numerous clinical trials; and it is used extensively for the education of Radiology and Cardiology physician residents and fellows, medical students, and UVM nuclear medicine students. Thus, the PET/CT system furthers UVM Medical Center’s mission to “to improve the health of the people in the communities we serve by integrating patient care, education, and research.”

UVM Medical Center started offering PET/CT services in September 2004, through a mobile PET/CT provider that stationed its unit at the Fanny Allen Campus parking lot on a part-time basis. Due to its location on the Fanny Allen Campus and its limited availability, the mobile unit could not be used for inpatients or for high-risk cardiac patients who required PET/CT imaging

⁶ *Diagnostic accuracy of rest/stress ECG-gated RB-82 myocardial perfusion PET: Comparison with ECT-gated Tc-99m sestamibi SPECT*, Bateman et al, J. Nucl Cardiology 2006; Volume 13; Number 1;24-33.

⁷ *Impact of Myocardial Perfusion Imaging with PET and RB on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management*, Merhige et al, J Nucl Med 2007; 48:1060-1076.

for stress testing but who needed to have their exams performed in close proximity to the hospital services on the Main Campus in case they needed emergent assistance.

In February 2009, the State of Vermont Department of Banking, Insurance, Securities and Health Care Administration (BISHCA) approved the Medical Center's acquisition of a fixed PET/CT system. In issuing the Certificate of Need for a fixed unit, BISHCA recognized that a fixed PET/CT system was more cost-effective than ongoing lease payments for a mobile unit and also that it was appropriate for UVM Medical Center to provide this service. After an extensive review process, BISHCA concluded as follows:

Because UVM⁸ is the only tertiary care facility in Vermont and has a robust cancer treatment program, this fixed technology is appropriate for UVM. UVM also has a close partnership with the University of Vermont's School of Medicine and its Vermont Cancer Center...regular availability of PET/CT with a fixed unit will allow UVM to enhance collaboration with other providers and pursue important research in the cancer field.

PET/CT is vital for cancer staging and improves cancer management for tumor diagnosis, disease staging and therapeutic response and disease recurrence.

PET/CT is also the best alternative for myocardial viability testing when MRI testing is not possible due to contraindications for patients with pacemakers, aneurysm clips and implanted metal devices.

PET/CT offers superior diagnostic capability [when compared to SPECT tests], results in fewer false positives, reduces the need for follow-up testing, which in turn, produces long-term savings for payers.

This project will serve the public good...will allow UVM, Vermont's only tertiary care hospital, to offer fixed PET/CT services to more patients, including certain high-risk inpatients and cardiac patients medically indicated for such services, who currently lack access to PET/CT services.⁹

UVM Medical Center's PET/CT service is part of its Nuclear Medicine Department, which is where all exams are performed that use radioactive substances for the diagnosis and treatment of disease. The PET/CT service operates on a full-time basis, Monday through Friday, 7:00 AM to 5:00 PM, and is staffed at all times by two licensed technologists: a nuclear medicine PET technologist and a CT technologist.

Approximately 1,200 PET/CT exams are performed at UVM Medical Center each year, with inpatients accounting for about 15 percent of all exams and outpatients accounting for 85 percent

⁸ For consistency purposes, all references to "FAHC," UVM Medical Center's former name, have been changed to "UVM."

⁹ *Statement of Decision*, Docket No. 08-008-H, pp. 4 – 7.

of all exams. Of the 1,200 PET/CT exams performed each year, 64 percent of all exams are for the diagnosis and treatment of cancer, 34 percent are for cardiac scans, and 2 percent are for neurological diseases. The table below shows UVM Medical Center’s PET/CT volumes for FY 2006 through FY 2015.

PET/CT Volumes

<i>Fiscal Year</i>	<i>Annual Volume</i>
FY 2006	523
FY 2007	620
FY 2008	678
FY 2009	932
FY 2010	1,724 ¹⁰
FY 2011	1,551
FY 2012	1,066
FY 2013	1,301
FY 2014	1,395
FY 2015	1,193

While a few hospitals in the region offer limited PET/CT services through a mobile arrangement, UVM Medical Center is the only hospital in Vermont with a fixed PET/CT unit. UVM Medical Center is also the only hospital in Vermont to use PET/CT technology for cardiac testing.

Currently, the primary use of PET/CT for cardiac exams is for pharmacologic stress testing. As discussed above, stress testing is a procedure that provides information about how a patient’s heart works during physical stress and it is an important test for diagnosing coronary heart disease. There are two types of stress tests: (1) a pharmacologic stress test, where patients receive a medication or “stressor” to speed up blood flow in the heart; and (2) the traditional stress test, where patients run on a treadmill to speed up blood flow in the heart. The traditional treadmill test uses SPECT imaging, not PET/CT, to capture the patient’s blood flow before and after exercise, but this test is only available for those patients who are healthy enough for exercise.

¹⁰ Volumes increased upon UVM Medical Center’s acquisition of a fixed unit.

For those patients who cannot run on a treadmill to “stress” their heart (i.e., increase blood flow), medication must be used to increase blood flow. PET/CT has proven to be the superior imaging modality for pharmacologic stress testing, which is why UVM Medical Center uses it for this type of stress test. Recent peer-reviewed clinical journal articles concluded as follows:

PET MPI [myocardial perfusion imaging or stress testing] is more accurate for assessment of impaired coronary flow reserve compared with SPECT MPI, potentially reducing the demand for subsequent arteriography, percutaneous transcatheter intervention, and coronary artery bypass grafting, *with attendant cost savings*, while avoiding a negative impact on coronary events...[PET/CT cardiac stress testing] results in a >50% reduction in invasive coronary arteriography and coronary artery bypass grafting, *a 30% cost savings*, and excellent clinical outcomes at 1 y compared with SPECT.¹¹

Recent data indicate that almost **50%** of MPI studies are being performed by use of pharmacologic stress. Currently, Rb-82 PET perfusion imaging is performed almost exclusively with pharmacologic stress, because of the logistic challenges of obtaining image data in the immediate post-treadmill time limited by the short half-life of Rb-82. Our investigation provides evidence that *for patients who require pharmacologic stress, PET imaging may be preferable to SPECT*. In this study image quality was higher and the certainty of the interpretation was higher with gated PET MPI compared with gated SPECT MPI. Importantly, *PET proved superior in diagnostic accuracy to SPECT for the overall population, but also for both genders, for nonobese patients and for obese patients, and for identification of those patients with multivessel CAD* [coronary artery disease].¹²

The PET/CT unit is also used to further UVM Medical Center’s research mission to continually pursue better ways to prevent, screen for, diagnose and treat medical conditions through medical research. The following clinical trials are currently ongoing:

- *Motion Detection and Compensation in SPECT/CT or PET/CT*
- *Rate of Incidental Findings at Myocardial Perfusion Scintigraphy*
- *Specific Research Plan for Clinical Evaluation of PET Dementia Application Project*
- *Artifacts of Tail-Fit Scatter Correction in Rb82 3D PET Can Lead to Erroneous Interpretations*
- *Motion Detection in PET/CT Brain or Head and Neck Scans*

C. Need for Replacement of PET/CT

¹¹ *Impact of Myocardial Perfusion Imaging with PET and RB on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management*, Merhige et al, J Nucl Med 2007; 48:1060-1076.

¹² See *Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: Comparison with ECT-gated Tc-99m sestamibi SPECT*, Bateman et al, J. Nucl Cardiology 2006; Volume 13; Number 1;24-33.

Replacing UVM Medical Center's seven-year-old PET/CT scanner with up-to-date technology will produce several clinical benefits. Each benefit is discussed directly below.

1. Improved Image Quality

The Philips Vereos PET/CT system produces significantly higher image quality than UVM Medical Center's existing PET/CT unit, enabling improved lesion detectability and better anatomic detail. The Philips Vereos system also produces more detailed brain imaging and dynamic cardiac scans, as a result of the unit's digital system and faster CT scanning capability. For the treatment of cancer, as one example, the new unit's ability to better visualize small regions of uptake, which are indicative of cancer, will allow for easier detection of cancer and improved treatment decisions.

The superior image quality of the Philips Vereos system as compared to UVM Medical Center's existing PET/CT unit is evident in the images below. The image to the left is a full-body scan taken with the same model PET/CT used by UVM Medical Center; the image to the right is a full-body scan taken with the Philips Vereos PET/CT system.

Existing PET/CT Unit



Philips Vereos PET/CT



2. Patient Safety – Lower Radiation

The new PET/CT system will expose patients to less radiation from the imaging equipment itself and will also result in lower doses of radioactive pharmaceuticals being administered to patients prior to their exams.

In recognition of the need to reduce harmful radiation exposure from CT scans, which produce many times the radiation of traditional x-ray machines to generate detailed, three-dimensional images, Congress recently passed legislation to mandate the installation of radiation safety features in CT equipment. The federal law, called the Protecting Access to Medicare Act of 2014,¹³ requires health care providers to use CT equipment that meets each of the attributes of the *National Electrical Manufacturers Association (NEMA) Standard XR-29-2013*, entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management” (the “NEMA CT Standard”). Failure to meet the NEMA CT Standard results in a 5 percent reduction in Medicare payments for the CT exam, effective January 1, 2016, and a 15 percent reduction in Medicare payments, effective January 1, 2017 and beyond.

Among other things, the NEMA CT Standard requires CT equipment to have the following technology:

- Radiation Dose Reporting: CT equipment must have a means of capturing both pre-exam and post-exam radiation dose information in an electronic format that can be loaded into the patient’s electronic medical record. Tracking radiation dosage at the individual patient level helps ensure patient safety by monitoring radiation exposure levels when additional diagnostic testing is needed.
- CT Dose Check: This technology notifies and alerts hospital staff, prior to starting a scan, if the estimated radiation dose from the scan will exceed pre-defined levels for patient safety. If the CT scanner alerts hospital staff that the proposed exam will exceed pre-defined thresholds, to continue the scan, the equipment operator must: (a) enter his or her user name into the system, (b) provide the diagnostic reason for exceeding the pre-defined threshold, (c) re-confirm the chosen CT protocol, and (d) provide a password before proceeding to the scan.
- Automatic Exposure Control: This technology is an operational mode that tailors a CT system’s radiation output to the specific body regions and parts being imaged in order to manage the radiation delivered to obtain the desired level of diagnostic quality.

¹³ H.R. 4302 (113th): *Protecting Access to Medicare Act of 2014*, Pub. L. 113-93, Sec. 218

UVM Medical Center's existing PET/CT unit does not meet the NEMA CT Standard requirements.¹⁴ The Philips Vereos PET/CT system is fully compliant with all NEMA CT Standard requirements and offers rapid scanning and reconstruction. In addition, due to the advanced technology of the Philips Vereos system's reconstruction software, radiation exposure from the PET/CT unit will be significantly reduced. The faster scanning times, in addition to increasing clinical efficiency and patient satisfaction, will also allow UVM Medical Center to reduce the dosage it administers to patients of radioactive pharmaceuticals by 40 percent, on average.

Thus, in addition to improving image quality for better diagnosis and treatment, the Philips Vereos PET/CT system will improve patient safety by reducing exposure to potentially harmful radiation.

3. Quantitative Myocardial Blood Flow (QMBF)

The Philips Vereos PET/CT system will enable UVM Medical Center to offer quantitative myocardial blood flow testing (QMBF), a cardiac test not currently available at UVM Medical Center due to the limitations of the existing PET/CT equipment.

QMBF allows for the detection of severe blockages that can sometimes be missed by nuclear stress testing, including PET/CT stress testing, as traditional stress tests rely on relative differences in regional blood flow. Severe blockages can lead to abnormalities in the entire heart, and since classic stress testing only looks at relative differences between *areas* of the heart, if the whole heart is affected by the blockage, it can be missed by the test because there will be no regional differences in blood flow.

QMBF using PET/CT imaging was FDA-approved over ten years ago. This test has gained widespread clinical acceptance and it is performed as part of a pharmacologic stress test. An abundance of research has demonstrated that QMBF improves the prediction of cardiac events and the determination of total cardiac disease burden.¹⁵ QMBF is so complete of an assessment that it has been shown to take the place of several cardiac exams that are usually ordered separately (including cardiac MRI, SPECT and Stress Echocardiography).

QMBF would offer the greatest benefit to the sickest patients who have the highest risk of mortality. For patients with multiple arterial blockages, QMBF has been shown to actually

¹⁴ Effective January 1, 2016, this has also led to a 5 percent reduction in UVM Medical Center's Medicare payments for PET/CT exams, pursuant to Section 218(a)(5)(A) of the *Protecting Access to Medicare Act of 2014*. All other CT scanners at UVM Medical Center, except for the PET/CT scanner, meet the requirements of the NEMA CT Standard.

¹⁵ *Quantification of Myocardial Blood Flow using PET to Improve the Management of Patients with Stable Ischemic Coronary Artery Disease*, Ohira et al, *Future Cardiol.* (2014) 10(5), 611 – 631.

prevent or lower the risk of death.¹⁶ Detecting severe cardiac disease has been a flaw of nuclear imaging, and that is where QMBF will help.

Another area where QMBF will help is for patients who have chest pain but no major blockages can be found on their noninvasive or invasive tests. Some of these patients (especially women with chest pain) are thought to suffer from diffuse plaque buildup in small arteries (microvascular disease). QMBF is the only minimally-invasive diagnostic test available to detect this condition.¹⁷ Diagnosing microvascular disease through a minimally-invasive PET/CT QMBF test will lead to more timely detection of the patient's condition (since more invasive approaches are typically reserved as a last resort) and the delivery of more timely patient care.¹⁸

SECTION III DESCRIPTION OF PROJECT COMPONENTS

As indicated above, the Project includes the purchase of the Philips Vereos PET/CT system, as well as related renovations. This is described directly below.

A. Equipment

To meet its needs for high-quality imaging, UVM Medical Center plans to install a Philips Vereos PET/CT system in the PET/CT exam room on McClure 1 to replace its existing Philips Brilliance CT Big Bore Oncology system. The new PET/CT system will feature the digital PET system with digital photon counting technology; a 128-slice CT scanner; an ECG monitor; a dose reporting and notification system to comply with the NEMA CT Standard; and a sub-system power protection to provide temporary backup power in the event of a power failure.

The costs for the Philips Vereos PET/CT system, the IT connections, and the furnishings, fixtures and other equipment, are included in Table 1 of the CON Financial Tables. The quote from Philips for the equipment is also included as an attachment to this application.

B. Renovations

Only minor renovations will be required to house the new PET/CT equipment. The existing PET/CT suite, which is comprised of an exam room, a control room, an equipment room, pre-procedure and recovery areas, dedicated changing and toilet facilities, and a “hot lab” room, currently complies with all requirements in the 2014 edition of the Facility Guidelines Institute's *Guidelines for Hospitals and Outpatient Facilities* (the “FGI Guidelines”).

¹⁶ *The Role of PET Quantification in Cardiovascular Imaging*, Slomka et al, Clin Transl Imaging (2014) 2:343 – 358.

¹⁷ The invasive approach is to inject chemicals into the patient's arteries during a heart catheterization.

¹⁸ *Myocardial Blood Flow: Putting it into Clinical Perspective*, Schindler T., J. Nuclear Cardiology (2015) 1071 – 3518.

To accommodate the new equipment, modifications will need to be made to the existing mechanical and electrical infrastructure supporting the PET/CT equipment. This includes increasing the cooling capacity, the dehumidification capacity, and the uninterrupted power supply (UPS) capacity. Modifications to the high and low voltage pathways and cabling will also be needed. Additionally, the new PET/CT system requires more cabinetry for supporting equipment, which requires moderately expanding the size of the equipment closet that is located within the footprint of the existing PET/CT exam room.

No changes to radiation shielding will be required as a result of the PET/CT replacement. A radiation physicist has already conducted a review of the existing radiation shielding in the PET/CT exam room and determined that the existing shielding has more than sufficient capacity to accommodate the new PET/CT unit.

The facilities renovations will cost \$172,000 and will take approximately four weeks to complete. After the renovations are complete, installation of the new equipment, testing, physicist validation, and training will take another three weeks. During the seven weeks in which fixed PET/CT services are unavailable, UVM Medical Center will lease a mobile PET/CT unit. The mobile unit will be located at the Fanny Allen Campus parking lot, and the lease will cost approximately \$86,500. The cost of leasing the mobile unit is included in Table 3B of the CON Financial Tables.

Included as attachments to this CON application are the following sets of full-size (24 x 36 inch) drawings depicting the renovation work that will occur:

1. An Overall Floor Plan, showing the PET/CT exam room and adjacent support space; and
2. Schematic-level Drawings, prepared in accordance with GMCB requirements, depicting the proposed renovations and including the layout of the new PET/CT equipment.

SECTION IV CONSISTENCY WITH THE HRAP CON STANDARDS

The applicable CON Standards are **bolded** below followed by an explanation as to how the Project is consistent with each standard.

CON STANDARD 1.1: Applicants shall include published GMCB quality measures for services related to a specific application, for the applicant and other hospitals that report on that quality measure. The applicant shall demonstrate how the project will improve or assist in the improvement of the relevant quality measures, if the applicant's score is not above the national or the Vermont average.

UVM Medical Center is unaware of any GMCB published quality measures for PET/CT services. However, UVM Medical Center monitors the quality of its PET/CT services using a peer review process that is discussed in response to CON Standard 1.6 below.

The PET/CT program's accreditation by the American College of Radiology (ACR) was recently reviewed and renewed. The review included an assessment of images, dosing, quality control practices, and clinical protocols. In addition, continuing medical education and certification of technologists, physicists, and radiologists was reviewed by the ACR and found to meet or exceed ACR requirements.

CON STANDARD 1.6: Applicants seeking to develop a new health care project shall explain how the applicant will collect and monitor data relating to health care quality and outcomes related to the proposed new health care project. To the extent practicable, such data collection and monitoring shall be aligned with related data collection and monitoring efforts, whether within the applicant's organization, other organizations or the government.

UVM Medical Center's Nuclear Medicine Department (which includes the PET/CT service) monitors quality through internal and external means. Internally, the department uses a software application called "Peer Vue," which tracks peer reviews of radiologists' interpretations of diagnostic images. A peer review is a secondary read by another radiologist to confirm that the initial radiologist's interpretation of the image was accurate. In addition to acting as a double-read to ensure that no significant clinical findings are missed after the initial radiologist's interpretation, the peer review process can help identify trends with a given provider's reads and it also serves as an important training tool for Radiology residents.

The Peer Vue application also tracks quality reviews of exams performed by technologists. All reviews are followed and reported by supervisors and managers to ensure that exams are consistently being performed according to established protocols.

In addition to internal tracking of quality data, the Nuclear Medicine Department closely tracks its patient satisfaction scores. Patient satisfaction data includes measures relating to wait times, skill of staff, and courteousness and sensitivity of staff. Patient satisfaction surveys are sent out and reviewed on a quarterly basis.

The collection, reporting and monitoring of quality of care data, as discussed above, will continue in place upon the acquisition of the new PET/CT equipment.

CON STANDARD 1.7: Applicants seeking to develop a new health care project shall explain how such project is consistent with evidence-based practice. Such explanation may include a description of how practitioners will be made aware of evidence based practice guidelines and how such guidelines will be incorporated into ongoing decision making.

For its PET/CT services, UVM Medical Center follows evidence-based practice guidelines that have been adopted by the American College of Radiology. The American College of Radiology has developed the ACR Appropriateness Criteria®, which are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment

decision for a specific clinical condition.¹⁹ The ACR Appropriateness Criteria® consists of over 200 evidence-based guidelines, and employing these guidelines helps providers enhance quality of care and contribute to the most efficacious use of radiology.

The UVM Medical Center Nuclear Medicine Department is accredited by the American College of Radiology Positron Emission Tomography Accreditation Program, and its radiologists are all Board-certified in Radiology as well as their applicable subspecialties. In order to achieve and maintain its accreditation by the American College of Radiology, the Nuclear Medicine Department is required to demonstrate its adherence to the evidence-based guidelines during the course of ongoing assessments. The evidence-based guidelines, which are based on a comprehensive analysis of the best available data, assist physicians with clinical decision-making by giving guidance on when to select specific diagnostic exams for particular conditions and the risks and benefits of each exam.

Adherence to these guidelines will continue after the acquisition of the new PET/CT unit.

CON STANDARD 1.8: Applicants seeking to develop a new health care project shall demonstrate, as appropriate, that the applicant has a comprehensive evidence-based system for controlling infectious disease.

The UVM Medical Center Infection Prevention Team was established in 1984 and, as part of the James M. Jeffords Institute for Quality and Operational Effectiveness, continues to strive to reduce and prevent health care-associated infections. A knowledgeable and effective infection prevention team is an important component of a successful infection prevention and control program. UVM Medical Center has an experienced team with proven success in reducing health care-associated infections. The team is led by the hospital epidemiologist and includes members certified in infection prevention.

The team's infection prevention activities incorporate the following:

- Collection and analysis of infection data;
- Evaluation of products and procedures;
- Development and review of evidence-based policies and procedures;
- Consultation on infection risk assessment, prevention and control strategies, including activities related to occupational health, construction, and disaster planning;
- Educational efforts directed at interventions to reduce infection risks;
- Interpretation and implementation of changes mandated by regulatory, accrediting and licensing agencies;
- Application of epidemiological and quality improvement principles, including activities directed at improving patient outcomes;
- Participation in research projects; and

¹⁹ The evidence-based guidelines are available at: <http://www.acr.org/Quality-Safety/Appropriateness-Criteria>

- Ensuring compliance with Joint Commission requirements on Infection Prevention and Surveillance.

The efforts of UVM Medical Center's Infection Prevention Team have led to an infection rate of less than one percent for patients who are treated with diagnostic and interventional procedures.

CON STANDARD 1.9: Applicants proposing construction projects shall show that costs and methods of the proposed construction are necessary and reasonable. Applicants shall show that the project is cost-effective and that reasonable energy conservation measures have been taken.

The estimates for the renovations have been compared to recent imaging equipment replacement projects at UVM Medical Center and were found to be within an appropriate cost margin. Opportunities to improve upon energy conservation are somewhat limited due to the narrow scope of the renovations. Mechanical and electrical infrastructure changes are focused on the service requirements of the new PET/CT equipment and are largely reserved to the equipment room. Power and cooling requirements are guided by the requirements for proper operation of the imaging equipment and cannot be compromised. However, in an effort to optimize energy efficiency, the expanded equipment room will incorporate new HVAC controls as well as cooling supply improvements.

We should also note that the approach UVM Medical Center is following for this project – an adaptive reuse of existing space – yields the most cost-effective and reasonable construction option available, and is a better alternative than total demolition and reconstruction of the PET/CT suite.

Energy conservation measures are discussed in response to CON Standard 1.10 below.

CON STANDARD 1.10: Applicants proposing new health care projects requiring construction shall show such projects are energy efficient. As appropriate, applicants shall show that Efficiency Vermont, or an organization with similar expertise, has been consulted on the proposal.

As explained in response to CON Standard 1.9, opportunities to improve energy conservation are limited due to the narrow scope of the renovations and the power and cooling requirements of the new imaging equipment. However, improvements to equipment room HVAC controls will be employed to optimize energy efficiency. UVM Medical Center will also consult with the Burlington Electric Department²⁰ to obtain input on additional energy conservation measures that can be undertaken within the limited scope of the project renovations. Finally, UVM Medical Center anticipates using energy efficient LED lighting to meet general and clinical procedure illumination requirements.

²⁰ Efficiency Vermont does not provide consultative services to Burlington area businesses. Instead, the Burlington Electric Department provides these services.

CON STANDARD 1.11: Applicants proposing new health care projects requiring new construction shall demonstrate that new construction is the more appropriate alternative when compared to renovation.

The proposed project seeks to renovate existing space, not construct new space. As such, CON Standard 1.11 does not appear to be applicable to this application.

CON STANDARD 1.12: New construction health care projects shall comply with the Guidelines for Design and Construction of Health Care Facilities as issued by the Facility Guidelines Institute (FGI), 2010 edition.

At the outset, we should note that entities such as UVM Medical Center, which are accredited by the Joint Commission, are required to follow the Guidelines for Design and Construction of Health Care Facilities (the “FGI Guidelines”) as part of the Joint Commission accreditation process.

The existing PET/CT suite meets all current requirements in the FGI Guidelines, and the minor renovations associated with this project will not alter the suite’s compliance with the guidelines. Exhibit 2, attached hereto, contains a detailed table showing each relevant FGI Guideline for Positron Emission Tomography (Section 2.2 – 3.6.3) and a description of how the design of the current PET/CT suite is compliant with the FGI Guidelines.

CON STANDARD 3.4: Applicants subject to budget review shall demonstrate that a proposed project has been included in hospital budget submissions or explain why inclusion was not feasible.

The cost for this Project was included in UVM Medical Center’s approved capital budget, which was submitted to GMCB.

CON STANDARD 3.6: Computed tomographic (CT) scanning capacity shall not be increased until current capacity is in excess of valid state, regional and/or national benchmarks for medically necessary exams per year and sufficient additional need is demonstrated based on such benchmarks. An applicant proposing a project involving CT shall provide information on current use, document the effectiveness of the internal program utilized by the applicant to prevent overuse, and verify that the applicant does not have financial incentives in place to encourage CT utilization.

The project seeks to *maintain* UVM Medical Center’s existing PET/CT capacity by replacing existing equipment. The project does involve any increase to UVM Medical Center’s existing capacity.

UVM Medical Center has protocols in place to ensure appropriate use of PET/CT services and prevent over-utilization. All requests for nuclear medicine procedures, such as PET/CT, are reviewed by a radiologist specializing in both nuclear medicine and cross-sectional imaging. The radiologist will determine the appropriateness of the imaging procedure based on the

patient's vital signs and symptoms, as well as recent previous imaging procedures performed on the patient. If a different exam is more appropriate to answer clinical questions, the radiologist will contact the referring provider and discuss alternative imaging to obtain the most relevant clinical results. If the radiologist determines that the test ordered is the appropriate test, the radiologist will protocol the exam accordingly. In this way, appropriate utilization is ensured.²¹ Indeed, according to available data, Vermont has the sixth lowest utilization rate for PET/CT services in the United States.²²

UVM Medical Center hereby verifies that it does not have any financial incentives in place to encourage CT utilization.

CON STANDARD 3.7: Applicants proposing to replace diagnostic or therapeutic equipment shall demonstrate that existing equipment is fully depreciated, or the cost of the early replacement, including the cost of the remaining depreciation on existing equipment, is less costly than keeping the existing equipment.

The PET/CT equipment is fully depreciated.

CON STANDARD 3.19: An applicant seeking to purchase a piece of diagnostic or therapeutic equipment shall include an analysis of whether other health care system costs may be reduced through more effective interventions through the use of the equipment. As appropriate, hospitals shall provide scientific evidence supporting the migration of such equipment and technology outside of tertiary care facilities.

UVM Medical Center is Vermont's only tertiary care facility and it is appropriate for UVM Medical Center to continue to provide these needed services. As described in response to CON Standard 3.6 above, UVM Medical Center has adopted robust protocols to ensure appropriate utilization of PET/CT imaging. Moreover, for pharmacologic stress testing, PET/CT has been proven to be superior to traditional stress testing, both in terms of image quality and from an overall cost standpoint, with one recent study concluding as follows:

PET MPI [myocardial perfusion imaging or stress testing] is more accurate for assessment of impaired coronary flow reserve compared with SPECT MPI, potentially reducing the demand for subsequent arteriography, percutaneous transcatheter intervention, and coronary artery bypass grafting, *with attendant cost savings*, while avoiding a negative impact on coronary events...[PET/CT cardiac stress testing] results in a >50% reduction in invasive coronary arteriography and coronary artery bypass

²¹ In addition to UVM Medical Center's internal procedures to assure appropriate utilization, payers have utilization criteria for diagnostic imaging to restrict inappropriate utilization. Most insurers also require pre-certification before the exam can be performed, as an additional step to assure that they agree that the service is medically necessary and appropriate.

²² *Benchmark Report: PET Imaging*, 2012 IMV Medical Information Division, Inc.

grafting, *a 30% cost savings*, and excellent clinical outcomes at 1 y compared with SPECT.²³

CON STANDARD 3.20: Applications to purchase diagnostic or therapeutic equipment, or to expand facilities to accommodate major medical equipment purchases, shall address the appropriateness of such distribution as compared to population, the availability of appropriately trained personnel, an evaluation of patient need versus convenience, urgent versus non-urgent use, and appropriate protocol to reduce the risk of repetitive testing (both within the facility purchasing the equipment and within the health care system).

UVM Medical Center is *not* proposing to “*expand* facilities to accommodate major medical equipment.” Instead, the proposal set forth in this application simply seeks the replacement of outdated and depreciated PET/CT equipment with new equipment. No changes will occur related to the distribution of PET/CT equipment in Vermont or the availability of trained personnel.

UVM Medical Center already employs fully-trained physicians and technologists who can safely and efficiently perform these procedures. This application, if approved, will not require any changes in UVM Medical Center’s staffing of its PET/CT service.

As discussed in response to CON Standard 1.7 above, UVM Medical Center physicians use evidence-based guidelines in their clinical decision-making and quality assurance review to reduce the risk of repetitive testing and to determine which patients are suitable candidates for PET/CT imaging. Based on UVM Medical Center’s low rates of utilization, discussed above, we believe that these efforts have been and will continue to be successful.

CON STANDARD 3.22: For applications involving the purchase of diagnostic or therapeutic equipment, applicants shall establish, through the submission of evidence in the form of peer-reviewed or similar articles, the clinical efficacy of the diagnoses or procedures to be performed.

The clinical efficacy of performing PET/CT imaging is well established, and is discussed throughout this application. For example, in analyzing the effectiveness of PET/CT imaging for diagnosis of cancer tumors, one recent peer-reviewed clinical study concluded as follows:

The success of an individualized treatment strategy depends largely on accurate diagnostic tests both at staging and during therapy. In this regard, positron emission tomography (PET) using fluorodeoxyglucose (FDG) with computed tomography (CT) has proved effective as a metabolic imaging tool with compelling evidence supporting its

²³ *Impact of Myocardial Perfusion Imaging with PET and RB on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management*, Merhige et al, J Nucl Med 2007; 48:1060-1076.

superiority over conventional modalities, particularly in staging and early evaluation of response.²⁴

CON STANDARD 3.23: In addition to proving need, applicants seeking to add or expand diagnostic or therapeutic equipment shall show that the equipment reduces costs and/or improves quality.

This application does not propose to “add” or “expand” diagnostic or therapeutic equipment. It only seeks to *maintain* UVM Medical Center’s existing PET/CT services, by replacing fully-depreciated equipment that no longer conforms to industry standards. As such, this CON standard is not applicable to this application.

CON STANDARD 3.24: An applicant shall disclose potential financial conflicts of interest between hospitals and physicians and an equipment purchase.

There are no potential financial conflicts of interests between UVM Medical Center and its physicians related to or created by the Project. As such, CON Standard 3.24 is not applicable to the proposal.

SECTION V CONSISTENCY WITH 18 V.S.A. § 9437

This Application demonstrates, and the GMCB should find, that the Project complies and is fully consistent with the statutory criteria set forth in 18 V.S.A. Section 9437

The statutory language contained in Section 9437 is **bolded** below followed by UVM Medical Center’s explanation of how the Project is consistent with each requirement.

1. The Application is consistent with the HRAP.

As indicated in Section IV, the Project is consistent with each of the HRAP CON standards and all other applicable provisions of the HRAP.

2. The cost of the project is reasonable, because:

A. the applicant’s financial condition will sustain any financial burden likely to result from completion of the project;

The Project will not create a “financial burden” for UVM Medical Center. The costs of the Project will be paid from available working capital without incurring additional debt. The only

²⁴ *Current Role of FDG PET/CT in Lymphoma*, Kostakoglu L. and Cheson B., Eur J Nucl Med Mol Imaging 2014; 41:1004 – 1027.

incremental cost of the Project is depreciation. Taking added depreciation into account, Nuclear Medicine services will generate a positive contribution margin and have a positive overall effect on UVM Medical Center's budget. Table 3C of the CON Tables shows that in FY 2017, the first full year of operation, the Nuclear Medicine Department will generate \$6,886,778 in excess revenue over expenses. Thus, the project will not create a burden on UVM Medical Center's financial condition.

B. the project will not result in an undue increase in the costs of medical care. In making findings under this subdivision, the commissioner shall consider and weigh relevant factors, including:

- i. the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges;**
- ii. whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public; and**

The Project involves simply routine equipment replacement and will not result in any increase in the costs of medical care. UVM Medical Center will also not raise its charges for PET/CT procedures as a result of the Project.

C. less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate;

Reasonable alternatives to replacing the PET/CT equipment are not appropriate or feasible. The only alternative to replacing the equipment at this time would be to delay its replacement. That would not be appropriate or satisfactory, nor would it be consistent with sound business practices for replacing major capital equipment that is nearing the end of its useful life and no longer conforms to federal guidelines for radiation exposure.

As the only tertiary-care hospital in Vermont, it is essential for UVM Medical Center to have up-to-date PET/CT imaging equipment to provide high-level care for cancer patients and cardiac patients. Replacing the seven-year-old imaging equipment now, before the equipment begins to experience significant downtime, will ensure that UVM Medical Center can: (a) continue to offer reliable and high-quality PET/CT imaging services with its one PET/CT unit, and (b) provide patients with the clinical benefits associated with modern PET/CT equipment (e.g., improved image quality, lower doses of radiation, and capability to perform QMBF as part of stress testing).

3. There is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide;

The need for this Project is demonstrated throughout this Application, and is specifically addressed in Sections I(B), II(A), II(B) and II(C), which are incorporated herein by reference.

4. The project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both;

The Project will enable UVM Medical Center to maintain the existing high quality of its PET/CT services and implement equipment technology enhancements, including better image quality and lower radiation, that will improve the quality of patient care, as explained throughout this Application, particularly in Sections I(B) and II(C), which are incorporated herein by reference.

5. The project will not have an undue adverse impact on any other existing services provided by the applicant;

The Project will not have a material impact on any other existing services offered by UVM Medical Center. All existing services will continue to be provided by UVM Medical Center.

6. The project will serve the public good;

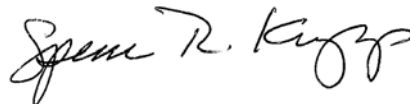
The Project will serve the public good in numerous ways, as stated throughout the application.

CONCLUSION

Based upon the information contained in this Application, UVM Medical Center respectfully asks that the Application be APPROVED expeditiously and that a CON for the project be issued.

Dated at Burlington, Vermont this 4th day of May, 2016

THE UNIVERSITY OF VERMONT MEDICAL CENTER INC.



By:

Spencer R. Knapp
Sr. V.P and General Counsel



And:

Steven J. Klein
Director of Legal Affairs &
Assistant General Counsel

INDEX OF EXHIBITS

- Exhibit 1: CON Financial Tables
- Exhibit 2: FGI Guidelines Compliance Chart with accompanying Floor Plans
- Exhibit 3: Equipment Quote
- Exhibit 4: CSI Division 16 Report & Comprehensive Budget