

**STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD**

CERTIFICATE OF NEED APPLICATION
by
THE UNIVERSITY OF VERMONT MEDICAL CENTER INC.
for
**PURCHASE OF 3T MRI SCANNER AND CONSTRUCTION OF ADDITION TO
HOUSE IT**
May 25, 2021

TABLE OF CONTENTS

SECTION I: DESCRIPTION OF THE PROJECT	1
A. Overview	1
B. Project Need	1
C. Project Description	8
D. Project Finances	10
SECTION II: CONSISTENCY WITH THE HRAP CON STANDARDS	12
SECTION III: CONSISTENCY WITH 18 V.S.A. § 9437	18
CONCLUSION	20
INDEX OF EXHIBITS	20

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SECTION I: DESCRIPTION OF PROJECT

A. OVERVIEW

The University of Vermont Medical Center Inc. (“UVM Medical Center”) submits this Certificate of Need (“CON”) application to the Green Mountain Care Board (the “Board”) pursuant to 18 V.S.A. § 9434(b)(1), (2). The application requests a CON approving the following:

1. Purchase of a new Philips Ingenia Elition 3.0T X Magnetic Resonance Imaging scanner (a “3T MRI”), for an equipment capital cost of \$1,936,635; and
2. Construction of an 825 square-foot addition at UVM Medical Center’s Orthopedic Specialty Center located at 192 Tilley Drive in South Burlington for a capital cost of \$2,143,557 (the “Project”).

The total cost of the Project will be covered by available working capital, without the need for borrowing.

A 3T MRI is a type of MRI scanner that operates using a stronger, three Tesla magnetic field. 3T MRI is used for scans requiring higher resolution, and is also the preferred imaging modality for certain patient populations. UVM Medical Center is the only provider of 3T MRI services in the Vermont and northern New York region.

UVM Medical Center needs an additional 3T MRI unit in order to provide timely and high quality radiology services to its patients. UVM Medical Center is using all of its existing MRI scanners to their fullest capacity, performing eighteen percent (18%) more MRI scans per machine annually than a suggested benchmark. Hours of operation and equipment productivity cannot be further optimized to meet patient demand. UVM Medical Center is currently unable to offer many patients timely access to MRI and 3T MRI services, which may result in delayed diagnosis and treatment of serious conditions such as cancer.

B. PROJECT NEED

The following describes the uses of MRI and 3T MRI; UVM Medical Center’s existing MRI capacity; and the analysis demonstrating that an additional 3T MRI is needed to provide timely and high quality patient care.

1. Uses of 3T MRI Imaging

MRI is a diagnostic imaging technology that uses magnetic fields and radio waves to produce two or three dimensional images of organs, soft tissues, bones, and other parts of the body. It is considered the most sensitive tool for non-invasive diagnosis of a number of conditions, which often gives physicians a better assessment than other imaging modalities such as X-ray, ultrasound, and computed tomography (“CT”).

Use of MRI also benefits patient safety. Unlike a CT exam or X-ray, MRI does not expose the patient to ionizing radiation, which has been shown to increase the risk of certain cancers. The Joint Commission advises hospitals “to reduce the exposure of the patient to ionizing radiation, [by using] other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level.”¹

A 3T MRI is a type of MRI scanner that operates using a stronger, three Tesla magnetic field. 3T MRI is used for scans requiring higher resolution; it can capture detailed images of tiny anatomical structures such as blood vessels, brain structures, and small bones. Studies show that 3T MRI scans provide significant diagnostic advantages for certain exams²:

- Prostate MRI: Imaging the prostate with a 1.5T scanner may require the use of an endorectal coil because of the small size of the prostate gland. The stronger 3T system signal makes it possible to image the prostate with an external surface coil instead.
- Functional MRI (fMRI): fMRI is a technique used to evaluate specific areas of the brain. 3T MRI is more sensitive to changes in blood flow in these areas.
- Arterial Spin Labeling (ASL): ASL is a technique used to assess blood flow perfusion, primarily to the brain. This test is much more effective at the higher 3T magnetic field.
- 3T MRI produces higher resolution vascular imaging, such that it can sometimes substitute for invasive interventional catheter studies.
- 3T MRI is best for rectal cancer staging among other small pelvic structures.

3T MRI is also preferred for pediatric patients, patients with multiple sclerosis, and seizure patients.

2. UVM Medical Center’s Existing MRI Scanners

UVM Medical Center currently owns and operates five MRI scanners, including one 3T MRI. As shown in the table below, these MRIs operate at least 16 hours a day on weekdays, and most MRIs also operate on weekends. The 3T MRI operates 16 hours each weekday, and 11.5 hours on both weekend days.

¹ *The Joint Commission Sentinel Event Alert*, Issue 47 (Aug. 24, 2011).

² Retrieved from: <https://www.gehealthcare.com/feature-article/15t-compared-to-30t-mri-scanners>

Location	MRI Type	Current Operating Hours
MRI 1 (Main Campus)	1.5 T	Mon-Sun 7am - 7am (Open 24/7)
MRI 2 (Main Campus)	1.5 T	Mon-Fri 7am - 11pm
MRI 3 (Main Campus)	3.0 T	Mon-Fri 7am - 11pm; Sat-Sun 7:30am-7pm
Ortho MRI (Tilley Dr.)	1.5 T	Mon -Fri 7:30am - 11pm; Sat 7:30am-4pm
Mobile MRI (Fanny Allen)	1.5 T	Mon-Fri 7am - 10pm

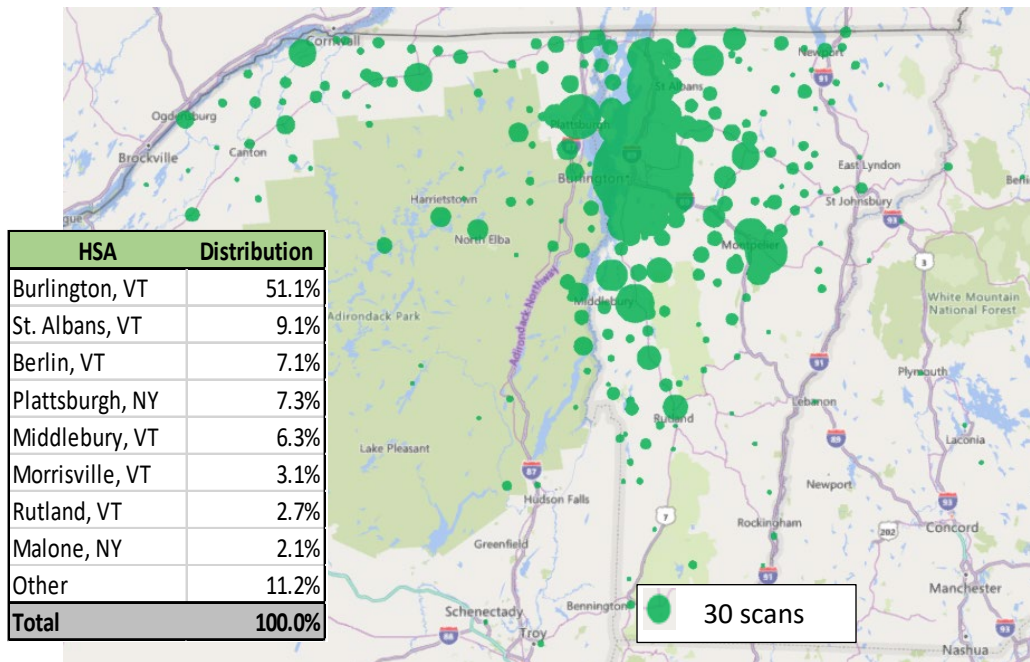
UVM Medical Center also rents time on a University of Vermont (“UVM”) 3T MRI. Increased use of the UVM unit is not a solution to the capacity shortfall detailed in the following discussion. This unit is dedicated to research, and its availability for UVM Medical Center’s general use is limited.

3. Demand Exceeds UVM Medical Center’s Existing MRI and 3T MRI Capacity

a. Demand for MRI and 3T MRI imaging has increased over the past decade, and will continue to grow.

UVM Medical Center is the only hospital in the Vermont and Northern New York region that has a 3T MRI scanner. Patients who need 3T MRI scans come to UVM Medical Center from throughout and outside the UVM Health Network’s general service area:

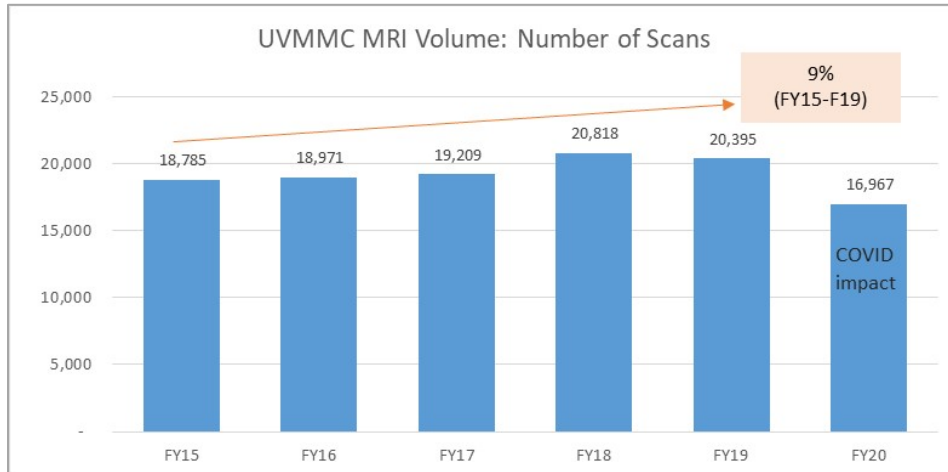
Map 1. FY20 UVMHC 3T MRI Volume by Patient Origin



Source: Epic FY20 MR3 data

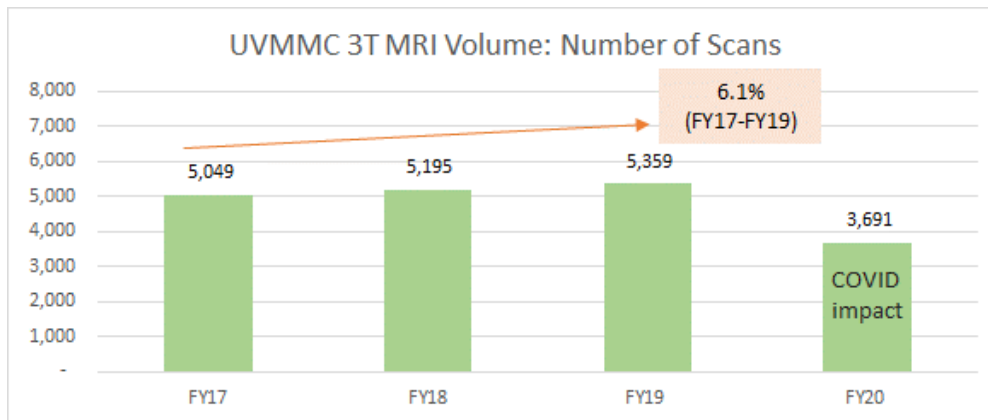
UVM Medical Center’s overall MRI volumes have grown steadily over the last 5-10 years, increasing 9% between FY15 and FY19 (see Chart 1). 3T MRI volume has also grown, increasing 6% from FY17 – FY19 (see Chart 2).

Chart 1. Number of MRI scans at UVMMC



Source: Axiom MRI150m report for cost center 1320. Numbers above include volumes from 5 UVMMC MRIs.

Chart 2. Number of scans performed on 3T scanner (MR3)



Source: Radiology Department Internal Data

The main MRI volume growth drivers have been an aging population, and gradual volume shifts to MRI from other imaging modalities due to MRI’s superior performance for certain exams, and patient safety benefits over modalities that expose the patient to ionizing radiation.

Volume is also shifting to 3T MRI from other MRI units due to the superior performance of 3T MRI for certain exams. For example, UVM Medical Center is now the preferred UVM Health Network site for all prostate exams due to the fact that 3T imaging can be done without using an invasive endorectal coil. The number of 3T MRI prostate cases has grown from 13 cases per month in FY18 to 25 per month in FY2021.

The growth in MRI volume at UVM Medical Center results from appropriate and clinically efficacious use of this technology, rather than the overuse seen in some parts of the country. The Radiology Department follows evidence-based guidelines to make the most

appropriate imaging or treatment decision for each clinical condition, as well as additional procedures designed to prevent unnecessary or duplicative testing (see CON Standard 3.5). United States Department of Health and Human Services’ published data measuring imaging efficiency at UVM Medical Center suggests that these guidelines and procedures are effective to prevent overuse of MRI³ (see CON Standard 1.1).

According to national health system consultancy group Sg2, total MRI demand will continue to grow by 5.6% in the Burlington Hospital Service Area over the next five years.

b. UVM Medical Center is using all its MRI units to their fullest capacity.

The following analysis, which follows a methodology and uses benchmarks taken from a North Carolina Department of Health and Human Services study,⁴ shows that UVM Medical Center is using all of its MRI scanners to their fullest capacity.

- i) Current MRI volumes were adjusted to account for the different amounts to time needed to complete different types of MRI procedures:

Weighting System

Procedure Type	Base Weight	Inpatient Weight	Contrast Weight	Procedure Time Minutes
Outpatient/No Contrast/Sedation	1.0	0.0	0.0	30
Outpatient/With Contrast/Sedation	1.0	0.0	.4 (Add 12 minutes)	42
Inpatient/No Contrast/Sedation	1.0	.4 (Add 12 minutes)	0.0	42
Inpatient/With Contrast/Sedation	1.0	.4 (Add 12 minutes)	.4 (Add 12 minutes)	54

UVMMC MRI Volume after Adjustment:

MRI Type	FY19 MRI Vol Distribution	FY19 MRI Volume	FY19 Vol with IP and Contrast Adjustment
Outpatient / No Contrast/Sedation	46%	9,465	9,465
Outpatient / With Contrast/Sedation	39%	8,015	11,221
Inpatient / No Contrast/Sedation	7%	1,416	1,982
Inpatient / With Contrast/Sedation	7%	1,493	2,687
Grand Total	100%	20,389	25,356

³ HHS Hospital Compare Data, Use of Medical Imaging, [Find Healthcare Providers: Compare Care Near You | Medicare](#) (last visited April 18, 2021).

⁴ “State Medical Facilities Plan” 2020, North Carolina Department of Health and Human Services, retrieved from <https://info.ncdhhs.gov/dhsr/ncsmfp/2020/2020smfp.pdf>

ii) Adjusted Volume per machine was compared to the benchmarks below:

MRI Tiered Planning Thresholds

Acute Care Bed Service Area Fixed Scanners	Inpatient and Contrast Adjusted Thresholds	Planning Thresholds
4 and over	4,805	70.0%
3	4,462	65.0%
2	4,118	60.0%
1	3,775	55.0%
0	1,716	25.0%

UVMMC MRI Volume per machine compared to the benchmark:

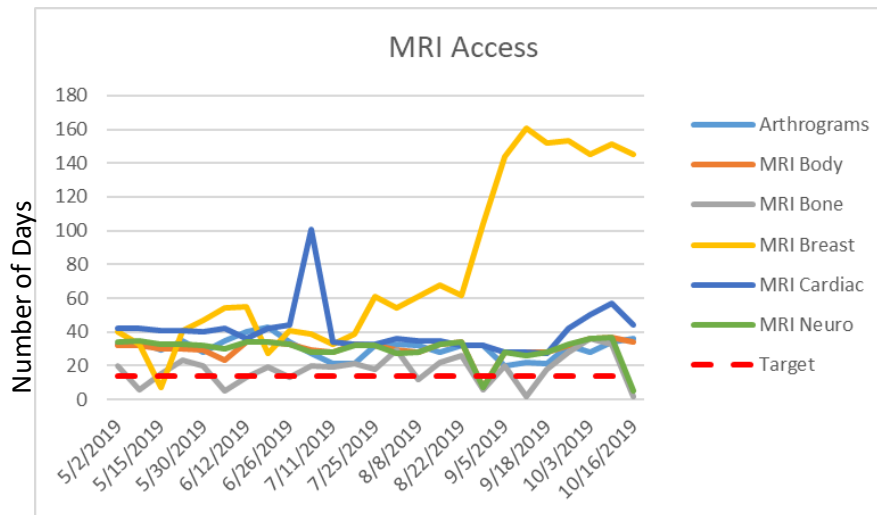
UVMMC MRIs (Fixed MRI = 1, Mobile MRI = 0.5)	FY19 MRI Vol. after Adjustments	FY19 MRI Volume per MRI	Benchmark
4.5	25,595	5,688	4,805

As shown in the above table, UVM Medical Center performs around 5,700 adjusted scans per MRI machine, which is 18% more than the suggested benchmark for 4 and more scanners.

c. Patients wait too long for an MRI scan.

UVM Medical Center’s insufficient MRI capacity results in unacceptable scheduling delays. UVM Medical Center’s target wait time for an MRI scan is 14 days or fewer. As shown in the chart below, UVM Medical Center’s MRI wait times in the last six months of FY19 consistently exceeded the 14 days or fewer target, causing downstream delays in diagnosis and treatment.

The average wait time for an MRI scan is currently 4 weeks, and wait time for some types of scans requiring the 3T MRI is much longer. At the beginning of February 2021, UVM Medical Center was scheduling patients at high risk for breast cancer, whose annual screening is done using the 3T MRI, into May for breast scans on the 3T MRI. This backlog means patients with a higher risk of cancer could be significantly overdue for their annual screening.



As detailed below, the addition of the proposed new 3T MRI will allow UVM Medical Center to reduce the average wait time for all MRI scans to one week.

4. Incremental Volume Projections for the New 3T MRI Unit

To estimate the incremental volume for the new 3T MRI scanner, the following calculations were completed:

1. Estimate the total current demand (met and unmet) (Graph 1)
 - a. Unmet demand – UVM Medical Center has a 4 week wait time on average for an MRI scan, and a target wait time of 14 days or fewer; the unmet demand was therefore defined as 2 weeks’ worth of scans.
2. Project estimated demand using Sg2 growth rates for MRI Imaging in Burlington Healthcare Service Area (“HSA”) (Table 1)
3. Subtract current volume (FY19) from the estimated future volume (Table 2)

Graph1: Total estimated current demand:



**Backlog in excess of target wait time of 2 weeks.*

Table 1: Sg2 growth rate applied to estimated current demand:

Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Sg2 Growth Rate	1.7%	3.1%	3.9%	4.7%	5.6%
21,210	21,579	21,877	22,035	22,211	22,405

Table 2. Estimated incremental volume for 3T MRI over FY19:

	Year 1	Year 2	Year 3	Year 4	Year 5
Incremental Volume	1,184	1,482	1,640	1,816	2,010

Table 2 presents incremental volume that the new 3T MRI will absorb. Volume numbers in Table 2 were used in the financial assessment of this project. UVM Medical Center also expects, however, that at least 400 scans per year will be redirected to the new 3T MRI unit from UVM’s 3T MRI, which UVM Medical Center currently uses under the lease arrangement described in the above Section I(B)(2), as shown in the below Table 3.

Table 3. Estimated incremental volume for 3T MRI over FY19, including UVM 3T MRI volume:

	Year 1	Year 2	Year 3	Year 4	Year 5
Incremental Volume	1,184	1,482	1,640	1,816	2,010
Shift from UVM Research	400	400	400	400	400
Total Volume	1,584	1,882	2,040	2,216	2,410

In addition, the new 3T MRI will absorb some volume from other UVM Medical Center MRI units that are currently over-utilized, as detailed in the above Section I(B)(3). Since volume redirected from the UVM MRI unit, or other UVM Medical Center MRI units is not incremental to the organization, it is not included for purposes of the financial assessment.

The below Table 4 states the maximum capacity of a new 3T MRI based on proposed staffing and operating hours. There will be some capacity available to address spikes in demand, as well as to offer all patients more timely and convenient access to MRI imaging. UVM Medical Center anticipates that the new 3T MRI will allow the Medical Center to reduce the average wait time for all MRI scans to one week.

Table 4. Maximum capacity on a new 3T MRI scanner:

Capacity	Year 1	Year 2	Year 3	Year 4	Year 5
Days per Week	5	5	5	5	5
hours per day	10	16	16	16	16
Max Capacity / visits per year	2,340	3,900	3,900	3,900	3,900

C. PROJECT DESCRIPTION

1. Equipment

UVM Medical Center plans to purchase a Philips Ingenia Elition 3.0T X MRI System. Equipment will include the magnet assembly, support equipment for MRI procedures, and an uninterrupted power supply system (UPS) to power the equipment through completion of a scan in the event of a loss of normal power.

2. Facilities

UVM Medical Center plans to construct an approximately 825-square-foot addition to its Orthopedic Specialty Center located at 192 Tilley Drive in South Burlington to house the new 3T MRI. The existing facility is a two-story building with approximately 53,300-square-feet of outpatient clinical and office space.

A 1.5T MRI unit is already located at this outpatient site. The proposed Project will use existing MRI support spaces, which are adequate to support both the existing unit and the new 3T unit, including:

- Staff break / locker room
- ADA compliant male MRI bathroom and changing space
- ADA compliant female MRI bathroom and changing space
- MRI patient holding spaces
- MRI staff offices

The new addition will include the following features:

- **Architectural** – Please see the attached schematic level drawings for the proposed layout. The proposed addition will house a control room to be used for both the 1.5T MRI and the 3.0T MRI, a scanner room for the 3T MRI, and an equipment closet. An MRI RF galvanized steel shielding enclosure will be installed within the addition. The installation will also include an MRI RF galvanized steel shielding enclosure main front entrance door. The exterior of the addition will be constructed of brick and storefront window assemblies to match the existing facility.
- **Mechanical** – The new addition work will include necessary supplemental HVAC, plumbing, sprinkler systems, conduit, cabling, and duct work.
- **Electrical, Power, Lighting and Data** – New electrical, power and data are proposed for the addition to support the new equipment and spaces. All new lighting will consist of energy efficient LED devices. Convenience outlets will be installed as necessary.
- **Replacement Parking** – The new addition will displace three (3) existing parking spaces. UVM Medical Center proposes to add fourteen (14) new parking spaces along the northern edge of the existing parking lot for a net increase of eleven (11) spaces, which will provide some additional parking buffer on busy clinic days.

3. Operational Impacts and Human Resources

Starting in year 1, the new 3T MRI will be open Monday through Friday from 7am to 5pm. In year 2, the operating hours will be extended to 16 hours per day (Mon-Fri 7am -11pm).

Location	MRI Type	Current Operating Hours
MRI 1 (Main Campus)	1.5 T	Mon-Sun 7am - 7am (Open 24/7)
MRI 2 (Main Campus)	1.5 T	Mon-Fri 7am - 11pm
MRI 3 (Main Campus)	3.0 T	Mon-Fri 7am - 11pm; Sat-Sun 7:30am-7pm
Ortho MRI (Tilley Dr.)	1.5 T	Mon -Fri 7:30am - 11pm; Sat 7:30am-4pm
Mobile MRI (Fanny Allen)	1.5 T	Mon-Fri 7am - 10pm
NEW MRI (Tilley Dr.)	3.0 T	Mon-Fri 7am-5pm (Year 1) Mon-Fri 7am-11pm (Year 2 and beyond)

An additional 2.3 FTEs will be needed to support these hours of operation in year 1, and additional 2.3 FTEs will be needed starting in year 2.

Cumulative FTE Needs	Year 1	Year 2
Radiologist	0.3	0.6
Technologist	1.0	2.0
Medical Assistant	1.0	2.0
Total	2.3	4.6

D. PROJECT FINANCES

A financial analysis including a capital and depreciation schedule, 5-year incremental pro forma P&L, cash flow, and net present value calculation was performed. The findings are as follows:

1. Capital Expense for this project is approximately \$4.1M.

Capital Costs	
Facilities	\$ 2,143,557
Equipment	\$ 1,936,635
IT	\$ -
Other	\$ -
Total	\$ 4,080,192

Please note that equipment cost is pending best and final negotiation.

Facilities costs include:

Facility Costs	
New Construction	\$ 1,395,165
Site Work	\$ 146,900
Contingency	\$ 308,410
Related Project Costs	\$ 293,082
Total	\$ 2,143,557

2. The facilities portion of the capital expense will be depreciated over 20 years. The equipment cost will be depreciated over 7 years:

Depreciation Schedule	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y20	TOTAL
Facilities	\$ 107,178	\$ 107,178	\$ 107,178	\$ 107,178	\$ 107,178	\$ 107,178	\$ 107,178		\$ 107,178	\$ 2,143,557
Equipment	\$ 276,662	\$ 276,662	\$ 276,662	\$ 276,662	\$ 276,662	\$ 276,662	\$ 276,662		\$ -	\$ 1,936,635
IT	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -		\$ -	\$ -
Other	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -		\$ -	\$ -
Total	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840		\$ 107,178	\$ 4,080,192

3. Incremental Pro Forma Statement of Operations:

Incremental Pro-Forma: UVMHC 3T MRI Scanner Purchase

	Y1	Y2	Y3	Y4	Y5	5 Yr. Total
Incremental Volume						
# of MRI Scans ¹	1,184	1,482	1,640	1,816	2,010	8,132
Incremental Net Revenue²						
Facility Net Revenue	\$ 2,215,469	\$ 2,773,051	\$ 3,067,505	\$ 3,397,459	\$ 3,760,828	\$ 15,214,312
Professional Net Revenue	\$ 166,964	\$ 208,985	\$ 231,175	\$ 256,042	\$ 283,426	\$ 1,146,592
Total Revenue	\$ 2,382,433	\$ 2,982,036	\$ 3,298,680	\$ 3,653,501	\$ 4,044,254	\$ 16,360,903
Incremental Expenses						
Sub-Total Salaries/Wages and Benefits³	\$ 305,186	\$ 610,372	\$ 619,986	\$ 629,888	\$ 640,088	\$ 2,805,520
Physicians	\$ 144,956	\$ 289,913	\$ 289,913	\$ 289,913	\$ 289,913	\$ 1,304,606
Staff	\$ 160,230	\$ 320,460	\$ 330,074	\$ 339,976	\$ 350,175	\$ 1,500,914
Sub-Total Scanner Related Op. Expense	\$ 383,840	\$ 565,168	\$ 565,168	\$ 565,168	\$ 565,168	\$ 2,644,512
Depreciation & Amortization	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 1,919,200
Service Contract ⁴		\$ 181,328	\$ 181,328	\$ 181,328	\$ 181,328	\$ 725,312
Sub-Total Other Operating Expense	\$ 23,854	\$ 29,858	\$ 33,028	\$ 36,581	\$ 40,493	\$ 163,814
Medical & Surgical Supplies	\$ 9,465	\$ 11,847	\$ 13,105	\$ 14,515	\$ 16,067	\$ 64,998
Pharmaceuticals	\$ 14,389	\$ 18,011	\$ 19,923	\$ 22,066	\$ 24,426	\$ 98,815
Total Expenses	\$ 712,880	\$ 1,205,398	\$ 1,218,182	\$ 1,231,637	\$ 1,245,749	\$ 5,613,845
Incremental Savings						
Cost of Utilizing UVM Research Scanner ⁵	\$ 105,728	\$ 105,728	\$ 105,728	\$ 105,728	\$ 105,728	\$ 528,640
Incremental Contribution Margin						
Total Incremental Contribution Margin	\$ 1,775,281	\$ 1,882,366	\$ 2,186,226	\$ 2,527,592	\$ 2,904,233	\$ 11,275,698

¹ Based on a) Sg2 MRI imaging growth rate for Burlington HSA applied FY19 Volume b) Volume shift between UVM Research MRI and a new UVMHC 3T MRI c) MRI backlogs

² Reimbursement based on avg net revenue for an MRI scan (FY19)

³ In Year 1: 0.3 FTE for Radiologist, 1.0 FTE for Technologist and 1.0 FTE for Medical Assistant. In Year 2 the FTE doubles. Staff wages and benefits increase by 3% on an annual basis.

⁴ Service contract starts in Year 2

⁵ Cost savings due to volume shift from UVM Research scanner to new UVMHC 3T MRI

4. Net Present Value Summary shows a net present value of \$7.4M over 5 years:

Project only Cash Flow and Net Present Value (NPV): UVMHC 3T MRI Scanner Purchase

	Y1	Y2	Y3	Y4	Y5	5 Yr. Total
Contribution Margin	\$ 1,775,281	\$ 1,882,366	\$ 2,186,226	\$ 2,527,592	\$ 2,904,233	\$ 11,275,698
Depreciation	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 383,840	\$ 1,919,200
Capital Expense	\$ (4,080,192)					\$ (4,080,192)
Cash Flow	\$ (1,921,071)	\$ 2,266,206	\$ 2,570,066	\$ 2,911,432	\$ 3,288,073	\$ 9,114,706
Net Present Value	\$7,417,577					

SECTION II: CONSISTENCY WITH THE HRAP CON STANDARDS

The proposed Project is consistent with the Health Resource Allocation Plan published on July 1, 2009 (“HRAP”) and the applicable HRAP CON standards.

HRAP CON Standards

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 Vermont average.

While there are no published GMCB quality measures that relate to MRI, data collected and published by the United States Department of Health and Human Services (“HHS”) suggest that MRI utilization at UVM Medical Center is appropriate. HHS tracks the percentage of outpatients with low-back pain who had an MRI without first trying recommended treatments such as physical therapy, and advises that a high percentage may indicate unnecessary use of MRI. HHS data for 2018-2019 show that, on average, 39% of U.S. hospital outpatients with low-back pain had an MRI without first trying recommended treatments; the average for all hospitals in Vermont was 28.9%; and the average for UVM Medical Center was 21.4%.⁵

CON STANDARD 1.2: Applicants seeking to expand or introduce a specific health care service shall show that such services have been shown to improve health. To the extent such services have been the subject of comparative effectiveness research, an applicant shall show that the results of this research support the proposed project.

3T MRI is used for scans requiring higher resolution; it can capture detailed images of tiny anatomical structures such as blood vessels, brain structures, and small bones. Studies show that 3T MRI scans provide significant diagnostic advantages for certain exams,⁶ as detailed in the above Section I(B)(1).

CON STANDARD 1.3: To the extent neighboring health care facilities provide the services proposed by a new health care project, an applicant shall demonstrate that a collaborative approach to delivering the service has been taken or is not feasible or appropriate.

The UVM Medical Center is the only hospital in the Vermont and northern New York region that has a 3T MRI scanner.

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

⁵ HHS Hospital Compare Data, Use of Medical Imaging, [Find Healthcare Providers: Compare Care Near You | Medicare](#) (last visited April 18, 2021).

⁶ Retrieved from: <https://www.gehealthcare.com/feature-article/15t-compared-to-30t-mri-scanners>

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.

The Radiology Department at UVM Medical Center follows a quality assurance/quality improvement program consistent with the Joint Commission standards (PI 01.01.01: the hospital collects data to monitor its performance, compiles and analyzes data, and improves performance on an ongoing basis). The department collects, analyses and reports data in order to investigate and analyze risks or potential risks to patient safety and develop action plans to reduce identified risks. A Radiology Quality Committee charged with evaluating and improving the quality of care in the department meets bi-monthly. The Committee identifies and improves systems and processes that promote quality outcomes and patient safety; oversees monitoring activities intended to assess whether radiology services rendered were professionally indicated and performed in compliance with applicable standards of care; and reviews and recommends actions based on quality metric reports.

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. (2005 State Health Plan, page 48).

The UVM Medical Center is a leading academic medical center providing graduate medical education based on a philosophy of evidence-based practice, which is committed to delivering high quality patient care using evidence-based protocols. Most physicians on UVM Medical Center's Medical Staff both practice and teach healthcare. UVM Medical Center providers make decisions regarding the appropriate and effective use of imaging with reference to the American College of Radiology's ACR Appropriateness Criteria®.

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 complies with Joint Commission requirements on Infection Prevention and Surveillance. Its Infection Prevention Team was established in 1984 and continues to strive to reduce and prevent healthcare-associated infections as part of the James M. Jeffords Institute for Quality and Operational Effectiveness. The team is led by the Hospital Epidemiologist and includes members certified in infection prevention. The team's infection prevention activities include 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

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.

UVM Medical Center has determined that locating the new 3T MRI in an addition to UVM Medical Center's Orthopedic Specialty Center is the most cost-effective option. As the Center already hosts a 1.5T MRI, the following sufficient support facilities are available at that site:

- Staff break / locker room
- ADA compliant male MRI bathroom and changing space
- ADA compliant female MRI bathroom and changing space
- MRI patient holding spaces
- MRI staff offices

The proposed architectural, supplemental mechanical HVAC, electrical and plumbing renovations are necessary and reasonable to accommodate the installation of the new Philips Ingenia Elition 3.0T X MRI system. 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.

UVM Medical Center is working with Efficiency Vermont to ensure that energy efficient design, systems and products are selected for the Project. UVM Medical Center anticipates using energy efficient LED lighting to meet general and clinical imaging illumination requirements. The new supplemental mechanical HVAC equipment will be commissioned in accordance with the FGI Guidelines and the standards set forth by the American Association of Healthcare Engineers, using the best available technology to reduce energy consumption while ensuring a comfortable environment for our patients and staff.

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

UVM Medical Center does not propose to build an entirely new facility, but rather to install the new 3T MRI in a small addition to its Orthopedic Specialty Center, which has adequate existing MRI support spaces.

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), 2018 edition.

UVM Medical Center is accredited by the Joint Commission, and required to follow the Guidelines for Design and Construction of Outpatient Facilities (the “FGI Guidelines”) as a condition of accreditation. The proposed Project will meet the 2018 FGI Guidelines. A table showing how the Project will meet each applicable Guideline is attached hereto as Exhibit 1.

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.

Although UVM Medical Center’s MRI investment strategies have developed over time, our capital budget submissions to the Board have included planned investments in MRI equipment for several years (with the exception of the FY21 budget, which was submitted with little detail due to the financial uncertainties attendant to the COVID-19 pandemic). Our FY22 budget submission, currently under development, will also include this investment.

CON STANDARD 3.5: Magnetic resonance imaging (MRI) 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 MRI 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 MRI utilization.

a) Capacity

The analysis detailed in the above Section I(B)(3)(b) shows that UVM Medical Center is using its existing MRI scanners in excess of their fullest capacity, exceeding a valid benchmark for scans per machine per year by eighteen percent (18%).

b) Appropriateness of Use

UVM Medical Center’s Radiology Department follows the American College of Radiology ACR Appropriateness Criteria, which are evidence-based guidelines to assist providers in making the most appropriate imaging or treatment decision for specific clinical conditions. In addition, the following systems and procedures are in place to prevent unnecessary or duplicative testing:

- Duplicate order check through the electronic medical record;
- Radiologist review to assure that the best modality for specific case is used;
- Decision support tools within the medical record to assist ordering providers in choosing the right test; and

- Insurance prior approval process to assure that payers agree with physicians on modality type to be used.

As discussed in the above response to CON Standard 1.1, HHH data suggests that UVM Medical Center's MRI utilization is appropriate, and these systems and procedures are effective to prevent overutilization.

c) Financial Incentives

UVM Medical Center has no financial incentives in place to encourage MRI utilization.

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 a tertiary/quaternary hospital serving approximately 1M people in Vermont and Northern New York. Its use of diagnostic imaging equipment, such as the Philips Ingenia Elition 3.0T X, is essential in the delivery of high quality patient care to our region. The purchase of this equipment, which is necessary because existing capacity is insufficient to meet current and projected future need for MRI services, will not directly drive health care cost reductions within the UVM Health Network or other health care settings. However, reduced MRI wait times, and increased patient access to higher resolution 3T MRI, can translate to cost savings as a result of earlier disease detection for oncology and neurology patients.

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).

As discussed in the above Section I, UVM Medical Center is the only hospital in Vermont and northern New York that provides 3T MRI services, and it cannot currently offer patients timely access to 3T MRI because its existing 3T MRI unit is operating in excess of its full capacity.

As previously discussed in response to CON Standards 1.1 and 3.5, the UVM Medical Center Radiology Department's established standards are effective to ensure appropriate use of MRI. UVM Medical Center will continue to follow these standards.

Please see the above Section I(C)(3) for discussion of personnel needed to support the proposed added 3T MRI services.

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.

MRI is an imaging technique designed to visualize internal structures of the body using magnetic and electromagnetic fields which induce a resonance effect of hydrogen atoms. An MRI scanner can be used to take images of any part of the body in any imaging direction. MRI provides better soft tissue contrast than CT and can differentiate better between fat, water, muscle, and other soft tissue than CT.⁷ The brain, spinal cord and nerves, as well as muscles, ligaments, and tendons are seen much more clearly with an MRI than with x-rays and CT. Furthermore, MRI can differentiate between white matter and grey matter and can be used to diagnose aneurysms and tumors. Because MRI does not use ionizing radiation, it is the imaging modality of choice when frequent imaging is required for diagnosis or therapy, especially in the brain.⁸

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.

3T MRI is used for scans requiring higher resolution; it can capture detailed images of tiny anatomical structures such as blood vessels, brain structures, and small bones. Studies show that 3T MRI scans provide significant diagnostic advantages for certain exams,⁹ as detailed in the above Section I(B)(1).

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

There are no known or perceived conflicts of interest with regard to the purchase of this replacement equipment either between UVM Medical Center and the vendor, the physicians and the vendor, or the physicians and UVM Medical Center.

⁷ “Radiation Emitting Products: MRI” retrieved from US Food and Drug Administration: <https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482765.htm>

⁸ “Magnetic Resonance Imaging” by National Institute of Biomedical Imaging and Bioengineering. Retrieved from: <https://www.nibib.nih.gov/science-education/science-topics/magnetic-resonance-imaging-mri>

⁹ Retrieved from: <https://www.gehealthcare.com/feature-article/15t-compared-to-30t-mri-scanners>

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

The proposed Project meets the statutory criteria set forth in Section 9437 of the Vermont Certificate of Need law.

§9437 Criteria

- 1. Proposed project aligns with statewide health care reform goals and principles because the project:**
 - A. takes into consideration the health care payment and delivery system reform initiatives;**
 - B. addresses current and future community needs in a manner that balances statewide needs, if applicable; and**
 - C. is consistent with appropriate allocation of health care resources, including appropriate utilization of services, as identified in the Health Resource Allocation Plan developed pursuant to section 9405 of this title.**

The new 3.0T MRI unit will enhance UVM Medical Center's ability to provide superior and timely diagnostic services to patients throughout the Vermont and northern New York region, promoting population health and improving outcomes. The main benefits impacting population health are:

- Potential cost savings and improved mortality rates with earlier detection for oncology and neurology patients.
- More precise capture of information for brain, vascular, musculoskeletal and small bone imaging for improved diagnoses and resulting treatments.
- The high-Tesla MRI can help in avoiding overtreatment and the risks of exposure to radiation after surgery, especially for oncology patients undergoing radiation therapy.

- 2. The cost of project is reasonable, because each of the following conditions is met:**

- A. The applicant's financial condition will sustain any financial burden likely to result from completion of the project;**

The Project's impact on UVM Medical Center's operating margin will be minimal. See Exhibit 2. Thus, the Project will not create an unsustainable financial burden, or adversely impact UVM Medical Center's financial health.

- B. The project will not result in an undue increase in the costs of medical care or an undue impact on the affordability of medical care for consumers. In making a finding, the Board 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; and**
 - (ii) Whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public.**

As previously discussed, the Project is needed to enable UVM Medical Center to offer its patients timely access to 3T MRI services. It will not result in any undue increase in the costs of medical care either systemically or for individual patients. UVM Medical Center will not raise its charges for any service as a result of this Project.

While the Project will not directly drive health care cost reductions within the UVM Health Network or other health care settings, reduced MRI wait times, and increased patient access to higher resolution 3T MRI, can translate to cost savings as a result of earlier disease detection for oncology and neurology patients.

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

As previously discussed, UVM Medical Center proposes to co-locate the new 3T MRI unit with an existing 1.5T MRI unit at its Orthopedic Specialty Center, which has adequate existing MRI support spaces. UVM Medical Center has not identified any less expensive alternative.

D. If applicable, the applicant has incorporated appropriate energy efficiency measures.

The Project incorporates appropriate energy efficiency measures, as previously discussed relative to CON Standard 1.10.

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

Please see the above Section I for discussion of how the Project will redress insufficient MRI capacity, which results in unacceptable scheduling delays, and downstream delays in diagnosis and treatment.

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.

Please see the above Section I for discussion of how the Project will redress insufficient MRI capacity, which results in unacceptable scheduling backlogs, and downstream delays in diagnosis and treatment.

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

The Project will not have an adverse impact on any UVM Medical Center service.

6. REPEALED

7. The applicant has adequately considered the availability of affordable, accessible transportation services to the facility, if applicable.

Special Services Transportation Agency (SSTA) shuttle service to the site is available free of charge, by reservation at least twenty-four hours in advance, from the University Mall at 155 Dorset Street in South Burlington. The University Mall is accessible by Green Mountain Transit bus (Red Line and Purple Line).

8. If the application is for the purchase or lease of new Health Care Information Technology, it conforms with the Health Information Technology Plan established under section 9351 of this title.

The Project does not involve the purchase or lease of new Health Care Information Technology.

9. The project will support equal access to appropriate mental health care that meets standards of quality, access, and affordability equivalent to other components of health care as part of an integrated, holistic system of care, as appropriate.

The Project has no relationship to mental health care access.

CONCLUSION

Based on the information contained in this application, and for all the foregoing reasons, UVM Medical Center respectfully requests expeditious approval of the application and issuance of a CON for the Project.

INDEX OF EXHIBITS

- Exhibit 1: FGI Guidelines Chart
- Exhibit 2: CON Financial Tables
- Exhibit 3: Floor Plans and Site Plan