



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 14, 2022

Amber George, Administrator
AGeorge@cpicteam.com

Exempt from Review – Replacement Equipment

Record #: 3936
Date of Request: June 20, 2022
Facility Name: Cardinal Points Imaging of the Carolinas Wake Forest
FID #: 210270
Business Name: Pinnacle Health Services of North Carolina, LLC
Business #: 1432
Project Description: Replace radiology equipment at the diagnostic center
County: Wake

Dear Ms. George:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the digital radiography system to replace the existing x-ray equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell
Chief

cc: Radiation Protection Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



June 20, 2022

Ms. Micheala Mitchell  
Chief, Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, NC 27603

RE: Request for No Review Determination for Acquisition of Replacement Diagnostic Imaging Equipment at Cardinal Points Imaging of the Carolinas Wake Forest/ Wake County

Dear Ms. Mitchell:

Pinnacle Health Services of the Carolinas, LLC (doing business as Cardinal Points Imaging of the Carolinas or CPIC), intends to acquire replacement medical diagnostic equipment at its existing diagnostic center (CON #J-11048-15) located at 839 Durham Road in Wake Forest. CPIC requests a determination that acquisition of this replacement equipment at this location does not constitute acquisition of a “major medical equipment” pursuant to NCGS 131E-176(14)(o), and will not otherwise be subject to certificate of need (CON) review.

At this time, CPIC plans to replace existing x-ray equipment at the Wake Forest diagnostic center with one (1) digital radiography (DR) system. As shown on the attached documentation, the acquisition cost of the replacement DR system is \$103,428. Including the Wake County 7.25% sales tax rate plus an allowance for shipping and installation, the total cost of the replacement diagnostic imaging equipment at Wake Forest is approximately \$115,927 (\$103,428 + \$7,499 + \$5,000).

CPIC does not need to upfit space within the existing Wake Forest diagnostic center in order to accommodate this replacement diagnostic imaging equipment. The

radiography room currently has lead lining that is sufficient for the replacement DR equipment.

*NCGS 131E-176(14)(o) states "Major medical equipment. - a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than two million dollars (\$2,000,000). In determining whether the major medical equipment costs more than two million dollars (\$2,000,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section. Beginning September 30, 2022, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.*

Based on the information provided in this letter, CPIC requests a determination from the Division of Health Service Regulation that acquisition of this replacement diagnostic imaging equipment will not constitute acquisition of a "major medical equipment" at CPIC Wake Forest pursuant to NCGS 131E-176(14)(o) and will not otherwise be subject to CON review.

I appreciate your attention to this matter. Please contact me at 919.332.3695 regarding any questions concerning this request.

Sincerely,

*Amber George*

Amber George  
Administrator

Attachments: Equipment Cost Documentation  
CPIC Wake Forest Certificate of Need J-11048-15

# STATE OF NORTH CAROLINA

*Department of Health and Human Services  
Division of Health Service Regulation*

## **CERTIFICATE OF NEED**

for

**Project ID #J-11048-15**

**FID #090950**

**ISSUED TO:** Pinnacle Health Services of North Carolina, LLC  
d/b/a Raleigh Radiology Wake Forest  
5029 Falls of the Neuse Road, Suite 210  
Raleigh, NC 27609

Pursuant to G.S. 131E-175, the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to G.S. 131E-189 for any of the reasons provided in that law.

**SCOPE:** Acquire 3D mammography equipment to replace existing mammography equipment and establish a new diagnostic center/ Wake County

**CONDITIONS:** See Reverse Side


**PHYSICAL LOCATION:** Raleigh Radiology Wake Forest  
839 Durham Road, Suite A  
Wake Forest NC 27587

**MAXIMUM CAPITAL EXPENDITURE:** \$415,339

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** February 1, 2016

This certificate is effective as of the 6<sup>th</sup> day of October, 2015

  
Shelley Carraway, Chief

**CONDITIONS:**

1. Pinnacle Health Services of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.
2. Pinnacle Health Services of North Carolina, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.
3. Pinnacle Health Services of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Healthcare Planning and Certificate of Need Section, Division of Health Services Regulation September 15, 2015.

**TIMETABLE:**

Occupancy/Offering of Service \_\_\_\_\_ January 1, 2016



Radon Medical, LLC

384 Peachoid Road Phone: (864) 487-0450  
 Gaffney, SC 29341 Fax: (864) 487-9955  
<http://radonmedicalimaging.com/>

Date 8/23/2021

Quote Number 00003632

Expiration Date 11/23/2021

Address Information

Bill To Name Cardinal Points Imaging of the Carolinas  
 Bill To 839 Durham Road  
 Wake Forest, NC 27587  
 United States

Ship To Name Cardinal Points Imaging of the Carolinas  
 Ship To 839 Durham Road  
 Wake Forest, NC 27587  
 United States

Quote Line Items

Quantity	Product Code	Product	Line Item Description	Options	Options Pricing	Price
1.00	DM-FMT	FMT - Floor Mounted Tube				\$51,428.00
1.00	COL-SIEMENS-M2	Siemens Manual Collimator (ML03)				
1.00	DM-CM50	DM-CM50				
1.00	DM-AEC-INT-2ION	AEC kit with interface board and two (2) Ion Chambers				
1.00	TUBE-VR14-90	Varian RAD 14 Tube - 90° cable arms, 0.6x1.2mm FS, 300kHU, 150kVp, 12° target, 3" anode				
1.00	DM-CAB-HV-40	40' Generator High Voltage Cables, 150 kVp				
1.00	DM-EV800	Del Medical EV800 Elevating Table with Four-Way Float Top				
1.00	DM-TRAY-1417	Grid Cabinet w/ 14x17" Detector Tray				
1.00	DM-TBL-REMOTE	Table top hand control, controls all table functions (elevation and four-way float of top)				
1.00	GRID-103-10-34	103 Line, 10:1 Ratio, 34-44" Grid				
1.00	DM-VS300	Del Medical VS300 Wall Stand				
1.00	DM-TRAY-1417	Grid Cabinet w/ 14x17" Detector Tray				
1.00	DM-VS-OVHGRP	Overhead Patient Handgrips				
1.00	GRID-103-10-40	103 Line, 10:1 Ratio, 40-72" Grid				
1.00	710CW	Canon CXDI-710C Wireless Digital Detector				\$52,000.00
1.00	VCOMP-RM/UPG-WLS	Room Component Bundle for Canon CXDI- Wireless Digital Detector				
1.00	CNTRLSTN-WRU	Wireless Room Upgrade Control Station Bundle				
1.00	App2day	Applications Training 2 day				

1.00	INSTALL	Includes Standard Installation				
1.00	AH-Protection Plus	Protection Plus	1-Year Included			
1.00	1 Year Warranty	1 Year Warranty (Non Glass Parts, & Labor)				
1.00	OPTIONAL	**OPTIONAL ITEMS ARE NOT YET INCLUDED IN PURCHASE PRICE**				
1.00	Optional - Protection Plus	Protection Plus (Post Warranty)	Optional - \$4,000/ per year for years 2-5 of ownership.	Accept____ Decline____		
1.00	Optional	Optional-Additional 4 Year Point of Sale Service Agreement Post Initial 12 Month Warranty	Point of Sale Service Agreement years 2-5. \$6,000 per year.	Accept____ Decline____		
1.00	OPT-DM-CM65DR	Optional Del Medical CM Series DR 65kW, 800mA, High Frequency Three Phase Generator		Accept____ Decline____	\$11,035.00	
1.00	OPT-DM-CM-DSS	Optional Dual Speed Starter (3P, 400/480 models only) (CM Series)				
1.00	OPT-TUBE-VR60-90	Optional Varian RAD 60 Tube - 90° cable arms, 0.6x1.2mm FS, 400kHU, 150kVp, 12° target, 4" anode				
1.00	OPT-TUBE-SV150-40-80	Optional Siemens SV 150 40/80 C-100 Tube; 90° cable arms, 0.6x1.0mm FS, 600kHU, 150kVp, 12° target, 4 anode				

**Totals**

Prices quoted do not include shipping, applicable sales tax, or installation cost (unless noted)

**Grand Total**

**\$103,428.00**

Sales Contact: Kristen Johnson  
 Email: kjohnson@radonmed.com  
 PH: 919-353-8423

For any questions or concerns please do not hesitate to contact us at (864) 487- 0450.

**NOTE:** Please provide Tax Exempt Certificate if applicable. Otherwise, applicable sales tax will be included on the payment invoice.

Payment Terms: 70% down with order 30% upon install. Net 30 days

Any pre-owned equipment quoted is subject to the availability of equipment.

All glassware, as applicable, will be prorated over the life of the warranty.

**Signature on the last page of this document verifies acceptance of the quoted Equipment and/or Services agreement with all applicable terms and conditions.**

Product Code	Detailed Product Description
	Del Medical Floor Mounted Tube Stand <b>Item Features:</b> - Platform Tube Mount - Telescopic vertical column with tube support and operator controls - 10 ft. (305 cm) longitudinal rail standard - Focal Spot Travel - Transverse Travel 10.75 in. (27 cm)

DM-FMT	<ul style="list-style-type: none"> <li>- Vertical Travel 62.75 in. (160 cm)</li> <li>- Minimum ceiling height = 87 in. (221 cm)</li> <li>- Pressure activated 180° column rotation</li> <li>- ±180° tube rotation about the horizontal axis</li> <li>- Control buttons for the following actions: (located on the control handle)</li> <li>- Longitudinal lock, transverse lock, vertical lock, column rotation roll lock, all locks and automatic detent stops (both horizontal and vertical)</li> <li>- Centering detent aligns focal spot to image receptor</li> <li>- Electromagnetic locks</li> </ul>
COL-SIEMENS-M2	<p>Siemens Manual Collimator</p> <p>Item Includes:</p> <p>Lamellae close to the source to shield off extra focal radiation</p> <p>Additional pre-filters integrated in the collimator</p> <p>Bucky light generated by laser guarantees a sharp light line for all source to image distances</p> <p>Display of field sizes selectable: in or cm</p> <p>Rotation by +/-45° with a stop in 0° position by swiveling flange</p> <p>Tape measure integrated in a user-friendly way in the collimator</p> <p>Two foam protected accessory rails facilitate attachment of additional devices and further filters</p> <p>LED powered light field for better contrast and greater lifetime</p>
DM-CM50	<p>Del Medical CM Series 50kW, 630mA, High Frequency Three Phase Generator</p> <p>Item Features:</p> <ul style="list-style-type: none"> <li>- 150 kVp</li> <li>- Anatomical Programming with 768 programmable technique selections</li> <li>- One, two, or three point technique selection</li> <li>- Two Bucky Capability</li> <li>- Power Cabinet with Auxiliary Power Supply</li> <li>- Tube Protection Circuitry</li> <li>- Integrated service software assists in calibration and service</li> <li>- Self-diagnostic circuitry with error code recording for fast trouble shooting</li> </ul>
DM-AEC-INT-2ION	AEC kit with interface board and two (2) Ion Chambers
TUBE-VR14-90	Varian RAD 14 Tube - 90° cable arms, 0.6x1.2mm FS, 300kHU, 150kVp, 12° target, 3" anode
DM-CAB-HV-40	40' Generator High Voltage Cables, 150 kVp
DM-EV800	<p>Del Medical EV800 Elevating Table with Four-Way Float Top</p> <ul style="list-style-type: none"> <li>- 800 lb. (363 kg) patient load capacity</li> <li>- 86.5 (220cm) x 35.9 (91cm) fiber resin table-top</li> <li>- Height adjustment: 21.75 in. (55.25cm) to 33.77 in. (85.8cm)</li> <li>- Table top movement: +/- 21.25 in. (54cm) longitudinal, +/- 4.5 in. (11.4cm) transverse</li> <li>- Bucky travel: +/- 8.5 in. (22cm) longitudinal</li> <li>- Quiet duty motor with efficient elevating action</li> <li>- Recessed foot treadle lock controls for longitudinal and transverse, table top up/down movement</li> <li>- Integral collision safety sensors</li> </ul>
DM-TRAY-1417	<ul style="list-style-type: none"> <li>- Spring loaded blocks hold 14 x 17 wireless DR panel securely in place in either orientation</li> <li>- Standard on Universal Vet, option on all other systems</li> </ul>
DM-TBL-REMOTE	Table top hand control, controls all table functions (elevation and four-way float of top)
GRID-103-10-34	103 Line, 10:1 Ratio, 34-44" Grid
DM-VS300	<p>Del Medical VS300 Wall Stand</p> <ul style="list-style-type: none"> <li>- Slender Column Design</li> <li>- Electric Fail Safe locks only require power to move column</li> <li>- Ergonomic release handle</li> <li>- Lateral patient handgrips included (standard)</li> <li>- Height: 84 in. (213.4cm) (includes vertical travel)</li> <li>- Depth: 13.4 in. (34cm)</li> <li>- Width: 24.6 in. (62.5cm)</li> <li>- Weight (with receptor): 200 lbs (91kg)</li> <li>- 0.4mm front panel aluminum equivalency</li> </ul>
DM-TRAY-1417	<ul style="list-style-type: none"> <li>- Spring loaded blocks hold 14 x 17 wireless DR panel securely in place in either orientation</li> <li>- Standard on Universal Vet, option on all other systems</li> </ul>



DM-VS-OVHGRP	Overhead Patient Handgrips for
GRID-103-10-40	
710CW	<p>Canon CXDI-710C Wireless Digital Detector</p> <p>Canon CXDI-710C Wireless Digital Radiography System is an advanced wireless digital radiographic device for a broad range of radiographic applications, including trauma, ICU and bedside imaging. The shape of the detector, which is identical to that of a conventional film cassette complying with ISO4090, enables digital radiography in the existing analog radiography configuration. The sensor with 125µm pixel pitch and CsI (Cesium Iodide) used for the scintillator produces high-resolution (approx. 9.5 MP) digital images within the effective imaging area (350 x 426 mm). The Canon CXDI-710C Wireless Digital Detector is lightweight, using new CFRP construction, weighing approximately 5.07 lbs (2.3kg) including battery pack and measures 14 in. x 17 in.</p> <p>In X-Ray Auto Detection mode, the CXDI-710C Wireless DR System can detect X-Rays at exposure and acquire images automatically, without the use of a typical generator interface.</p> <p>It features even further weight reduction over previous detectors in the Canon CXDI series and delivers greater operability than similar existing products as a result of improved water resistance (equivalent to IPX7) and the addition of new features (Standalone Mode and a READY switch). The CXDI-710C Wireless Digital Detector includes built in shock detection function which detects the shock applied to the detector unit and also the free fall of the detector unit. The data saved in the detector is transferred to the PC, can be output to .csv file and used for analysis.</p> <p>Includes: 2 - Battery Packs</p>
VCOMP-RM/UPG-WLS	<p>Bundle Package Includes:</p> <ul style="list-style-type: none"> <li>- Wireless Access Point</li> <li>- Power Injector for Wireless Access Point</li> <li>- Infrared Check-In Unit</li> <li>- Gigabit Ethernet Switch</li> <li>- Wall Holder for Canon CXDI-701C/710C and Grid</li> <li>- (1) Uninterruptible Power Supply</li> </ul>
	<p>Control Station for Canon Control Software NE</p> <p>PC Specifications:</p> <p>Intel i7 Quad Core CPU        8 GB High Speed RAM        250GB SSD Hard drive        DVD/RW Burner (SATA)        Microsoft Windows 10 Professional 64-Bit Operating System        Optical Mouse        Full Size Keyboard</p> <p>24" Medical Grade Touchscreen LCD Monitor</p> <p>Canon X-Ray Interface Unit</p> <p>Canon Battery Charging Unit</p> <ul style="list-style-type: none"> <li>- Charges two batteries at once</li> <li>- Quick charging, full recharge in &lt;3 Hours from zero</li> <li>- Indicator lights for when battery is charging and fully charged</li> </ul> <p>Canon Control Software NE</p> <p>Control Software NE Features:</p> <p>System Startup &amp; Quality Assurance</p> <ul style="list-style-type: none"> <li>- Standard Mode: No log-in required</li> <li>- Secure Mode: Operator log-in/password required (user authentication); autotime-out with log-in to last screen viewed</li> <li>- Warm-up time: None</li> <li>- Battery/Wi-Fi Monitor: Software to allow wi-fi strength monitor and battery monitor for CXDI- Wireless configurations.</li> </ul>

- Calibration Routine: Included; required once per year; configurable on-screen reminder message
- Display QA: SMPTE pattern included

#### Image Acquisition

- Programming: Unlimited anatomically programmed acquisition settings; user customizable to include annotation, orientation, patient demographics display location, and pre-selected basic and enhancement processing
- Reject/Retake: Reject, Retake, Un-Reject; Reject reason labeling with free or pre-set annotation; Reject log (.csv monthly file accessible to system administrator for rolling 12 months)
- Grid Suppression: Software-based grid suppression
- Protocol Pre-Pack: Allows for multiple APR views to be associated into one APR for easy grouping of views within a study.
- Auto-Stitch (v1.2): Multiple images can be stitched together within the software.

#### Image Processing

- Basic Processing: Histogram analysis by automatic fixed region ROI or user adjustable ROI; grayscale conversion; adjustable brightness and contrast; 6 pre-set contrast enhancement curves; collimation edge detection and (black) masking with adjustable standoff; trim positioning and adjustment
- MTF Improvement: Preset and user-selectable/adjustable anatomical region-based filters, intensity levels
- Standard Processing: Preset and user-selectable/adjustable DEP (dynamic range adjustment), edge enhancement, noise reduction
- Preset and adjustable multi-frequency dynamic range adjustment; global edge enhancement
- Preset and user-selectable/adjustable dynamic range adjustment; noise reduction, local edge enhancement
- Security advancements allow for only select users to access full image processing protocols.

#### Data Output and Network Connection

- DICOM Print Format: Multi-format, user selectable pre-exposure and post-exposure formatting; selectable printing method (fixed ratio, life size, reduction, fit to film); queue viewable with priority and cancel capabilities; up to 2 DICOM printers may be specified at any one time, up to 4 DICOM printers may be configured - Study transmission: Selectable modes - after each image, after study end, post-study retrieval with resend individual or all image capabilities; queue viewable with priority and cancel capabilities; up to 2 storage devices may be specified at any one time, up to 4 storage devices may be configured
- CD Archive: Available as network selectable storage device with DICOMDIR (hardware not included)
- Network: Ethernet 10/100/1000 Base T, RJ45 standard
- Data Output: DX; DICOM 3.0 compliant, Print Management Service Class (SCU), Storage Service Class (SCU) and others
- IHE Profiles: Basic Security Profile option - User Authentication, Audit Log, Time Synchronization, Node Authentication

DICOM Modality Worklist for Canon CXDI Digital Radiography systems is a communications module for acquiring patient information and exam requirements from the HIS / RIS. The following features are available in this module:

#### Study Information Acquisition

- Study is configurable to include a wide variety of patient information such as name, sex, birth date, age, patient ID, accession number(s), referring physician, etc. - Find Mode is available and conforms to Modality Worklist SOP Class (MWL). - Patient information can be entered manually if the patient does not appear on the worklist.
- When used with a portable imaging unit, the worklist can be downloaded and stored in the control computer eliminating the need for network access at the patient's bedside. A barcode reader (not included) can be used to find and select the patient from the worklist.

#### Study Status Notification

- Supports Modality Performed Procedure Step SOP Class (PPS) with in progress, completed, or discontinued messages.
- PPS is available for both suite and portable imaging - Multi-accession imaging

#### Imaging Modes

- Manual imaging mode allows the user to individually select each view to be acquired
- Program imaging mode uses the study information sent by the HIS / RIS to pre-configure the exam(s) to be performed
- Images can be acquired in any order

- Additional views can added at any point in the exam
- The study can be ended without completing all views
- 100 views can be acquired for a single patient
- Exams and views can be customized to meet the needs of the facility \* Requires Program Imaging Mode Set Up and Implementation Fee

Optional DICOM tags can be defined, displayed, printed, and transmitted to PACS.

Pregnancy Status can be received from HIS / RIS and an alert displayed to inform the user of the pregnancy status.

Storage Commit function is available.

App2day	Applications Training - Two (2) Days/Eight (8) Hours of Technologist Training
INSTALL	Includes standard installation, M-F 8am-5pm, Non - Holidays.
AH-Protection Plus	Protection plus Covers panel for accidental damage which includes repairs. Does not cover the batteries or charger. \$5,000 per event deductible required. - Does not cover abuse, misuse, tampering, or Acts of God
1 Year Warranty	1 year parts and labor warranty, starting with first clinical use, during the hours of 8 AM to 5 PM Monday through Friday. Non-Holidays. Non-warranty after hour calls will be billed at time and one-half. (Glassware, Batteries not included)
OPTIONAL	<b>**OPTIONAL ITEMS ARE NOT YET INCLUDED IN PURCHASE PRICE**</b>
Optional - Protection Plus	Covers panel for accidental damage which includes repairs. Does not cover the batteries or charger. \$5,000 per event deductible required per replacement.'
Optional	Radon Medical Imaging Service Plan Contract Coverage Hours (Mon-Fri - 8am - 5pm) Includes Batteries, Glassware, & Protection Plus Coverage Parts and Labor PM coverage within contract hours Remote Log In (if applicable)
OPT-DM-CM65DR	Del Medical CM Series DR 65kW, 800mA, High Frequency Three Phase Generator <ul style="list-style-type: none"> <li>- 150 kVp</li> <li>- Digital Interface for integration with Digital Radiography systems</li> <li>- Anatomical Programming with 768 programmable technique selections</li> <li>- One, two, or three point technique selection</li> <li>- Two Bucky Capability</li> <li>- Power Cabinet with Auxiliary Power Supply</li> <li>- Tube Protection Circuitry</li> <li>- Dual Speed Starter</li> <li>- Integrated service software assists in calibration and service</li> <li>- Self-diagnostic circuitry with error code recording for fast trouble shooting</li> </ul>
OPT-DM-CM-DSS	Dual Speed Starter (3P, 400/480 models only) (CM Series)
OPT-TUBE-VR60-90	Varian RAD 60 Tube - 90° cable arms, 0.6x1.2mm FS, 400kHU, 150kVp, 12° target, 4" anode
OPT-TUBE-SV150-40-80	Siemens SV 150 40/80 C-100 Tube; 90° cable arms, 0.6x1.0mm FS, 600kHU, 150kVp, 12° target, 4 anode



### 1. THIS ADDENDUM.

(a) **SUPERSEDING EFFECT.** This Addendum is attached to and incorporated into the quotation (collectively the "Quotation") issued by Radon Medical Imaging Corporation-WV or Radon Medical, LLC (hereafter the applicable entity is referred to herein as Radon and/or "Company") to its customer ("Customer"). The Quotation (as modified by this Addendum) supersedes all previous bids, quotations, offers and dealings with respect to the services and/or equipment (collectively "the Products") set forth herein. The Quotation may be withdrawn by Radon at any time without notice and shall not bind Radon until signed by Customer and by an authorized representative of Radon.

(b) **NO COUNTEROFFERS.** Acceptance of this Quotation is expressly limited to its terms and conditions. Any additional or different terms or conditions contained in Customer's order or response hereto shall be of no force or effect and shall not be binding upon Radon.

(c) **RETURN OF GOODS.** All items are sold without return privileges. Returns may be granted in the sole and absolute discretion of Company and returns require Company's prior written authorization. Except where items were damaged in transit, Company approved returns must be in

clean factory packaging. All returns must be made by prepaid transportation unless otherwise specified by Company. Whole or partial credit for authorized returns will be based on the price listed on the original invoice.

## **2. SHIPMENT, DELIVERY, TESTING, AND ACCEPTANCE.**

(a) **DELIVERY INSTALLMENTS.** Radon reserves the right to deliver the Products in installments. All such installments shall be separately invoiced and paid for when due, without regard to subsequent deliveries. Delivery dates are approximate. If Customer requests a later delivery date, Radon may, at its option, deliver the products to a storage facility designated by Customer or, if Customer fails to designate a storage facility, to a storage facility designated by Radon, at Customer's sole expense and risk. At the time of such delivery to the designated storage facility, the Customer will immediately pay Radon all sums which would otherwise be due upon Acceptance as set forth in 2(e) below.

(b) **DELAYS IN SHIPMENT, DELIVERY, AND ACCEPTANCE.** Shipping, delivery and acceptance dates are estimated on the basis of prompt receipt of all necessary information and items from Customer. Should delivery or installation be delayed, in whole or in part, for any reason beyond Radon's control, Radon's time for performance shall be extended by the duration of the delaying cause. Radon shall not be responsible for nonperformance or delay in performance resulting from any cause or causes beyond its reasonable control, including without limitation the unavailability of materials or labor required for manufacture, assembly and installation, labor disputes, *force majeure*, and acts or omissions of governmental authorities. Radon shall not be liable for any damages or economic losses attributable to any such failures or delays. Customer shall have no right to cancel or rescind its order if the reason for the delay is solely limited to an excusable delay as defined in this section 2.b. and Customer and Radon shall cooperate with each other to minimize any adverse impact to Customer and/or Radon that results from such excusable delay.

(c) **TRANSPORTATION.** All shipments will be made F.O.B. shipping point by the method Company deems most advantageous. Transportation charges will be collected, or, if prepaid, will be invoiced to Customers and are not included in the prices shown on the Quotation. If the shipment is made at Customer's request via a method and/or carrier other than that which would normally be used, such shipments will be made F.O.B. shipping point. Title to the Product shall pass upon delivery to the Customer's Location or its designated storage facility.

(d) **SHIPMENT DISCREPANCIES.** Any errors in any shipment or requests for adjustments on concealed shortages involving cartons received intact must be reported to the Company within five (5) working days of receipt of the shipment.

(e) **ACCEPTANCE.** Unless otherwise set forth in this Quotation customer shall be deemed to have accepted the Products on the earlier of: (i) if Radon installs the Products, 5 days after Radon notifies Customer that it has completed installation and the Products is operating substantially in accordance with OEM published performance specifications; (ii) if Radon does not install the Products, 5 days after delivery of the Products to Customer; or (iii) the date Customer first uses the Products.

## **3. INSTALLATION AND SITE PREPARATION.**

(a) **BY RADON MEDICAL IMAGING.** If the Quotation requires installation by Radon, Company shall during regular working hours install the Products and connect the Products to safety switches and power outlets provided by Customer. If the Quotation includes installation, such installation will include on-site configuration of the installed Products and integration as per Radon (or the OEM Radon is a dealer/reseller for) published specifications and testing.

(b) **BY CUSTOMER OR OTHERS.** If the Quotation specifies that Customer will make its own installation of the Products, then the Customer shall be solely responsible for such installation, configuration, integration and testing and the subsequent operation of the Products. The customer must follow all Radon/OEM published guidelines and requirements for equipment/system installation and installation must be performed by qualified individuals qualified per Radon/OEM standards to do so. Failure to follow the above will void equipment warranty should problems occur.

(c) **CONDITION OF PREMISES.** In any event, the Customer shall provide free access to the installation site and suitable and safe space thereon for storage of the Products before installation. Radon assumes no responsibility for the fitness or adequacy of the premises, or for any damage or claim arising out of the condition of such premises. Regardless of who is installing the Products, the Customer shall provide all the items set forth in Section 16 below.

## **4. RELOCATION OF PRODUCTS.**

The customer must notify Radon prior to any relocation of Products. Failure to notify Radon (i) may be a violation of applicable software licenses applicable to Products; and (ii) unless such relocation is approved in writing by Radon, shall terminate all warranties of Radon and/or OEM.

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## **5. SOFTWARE.**

(a) The Products include certain components of software ("Software") that is either being sold or sub-licensed by the owner of the Software through Radon or is being separately licensed to Customer by the owner of the Software. Customer shall at all times comply with the terms of the license agreement for any Software. Radon shall have no liability or responsibility to provide, install, or configure any subsequent versions, updates, maintenance, releases, or other modifications or improvements to Software provided by the Software manufacturer.

All references to "**Software**" throughout this Quotation shall mean the computer software in digitally encoded machine readable "object code" form for which Customer has been granted a license pursuant to this Quotation. The term "**Documentation**" shall mean the Company's user guides or manuals for use of the Software and the documentation, if any, expressly listed elsewhere in this Quotation. For purposes of this Quotation the Products and the Software are collectively referred to as the "**System**."

(b) **SOFTWARE LICENSE:**

Subject to the terms and conditions of this Quotation, Customer is granted a non-transferable, non-exclusive, perpetual license ("**License**") to use

the Software as delivered to Customer only on the Equipment at the locations (the "Locations") where initially installed. Customer may permit the Software to be used at the Locations for the benefit of, or by, physicians and radiologists who are not employees of Customer and for the benefit of health care clinics, physician groups and other similar entities to be used by such individuals and entities; provided that in all such cases: (i) the use is only to the extent necessary to ensure that such individuals and entities may properly perform their professional medical responsibilities to patients; (ii) Customer ensures that such non-Customer personnel comply with the terms of this Quotation with respect to maintaining confidentiality and non-disclosure of the Software; and (iii) Customer ensures that such non-Customer personnel have been trained in the operation of the Software. Any demonstration Software provided to Customer by Company and/or Owner at no charge ("Demonstration Software") shall be subject to this Quotation, however, such Demonstration Software shall not be utilized by Customer for clinical use, or for more than 60 days, and in no event beyond Customer's first clinical use of the System.

(c) **TERMINATION OF LICENSE:** Company may terminate the License granted under this Quotation if Customer: (1) fails to perform any material obligation under this Quotation which is not cured within thirty (30) days after written notice of default from Company; (2) breaches any obligation under this Quotation involving Customer's license to the Software or involving the proprietary rights of Company and/or Owner; (3) ceases to do business as a going concern; or (4) has its assets assigned by law.

(d) **USE RESTRICTIONS; COPYRIGHT:** Customer shall not, and shall not allow or permit its employees, representatives or agents to: (i) sell, assign, lease, sublicense, transfer or disclose to any third party, or allow any third party to use, the Software or the Documentation, or (ii) copy or otherwise reproduce the Software (or any portion thereof) except as necessary for Customer's use, testing, backup and archival of the Software in accordance with the terms and conditions of this Quotation.

(e) **CUSTOMER SOFTWARE MODIFICATIONS:**

If Customer causes changes to be made to the Equipment, Software or Documentation without the prior written consent of Company and/or OEM Company represents, Customer shall indemnify and hold Company and the OEM Company harmless against damages, costs and expenses (including, without limitation, reasonable attorney's fees and costs of suit) resulting from the defense and settlement of any claim by a third party.

## **6. PAYMENTS.**

(a) **TIME OF PAYMENT.** Upon acceptance of the Quotation, the Customer shall pay to Radon the down payment and subsequent payments at the intervals indicated in the Quotation. The customer shall pay any final balance of the purchase price for the Products upon Acceptance of the Products.

(b) **SALES AND EXCISE TAXES.** Customer shall be solely responsible for and shall pay to Radon all sales, use, excise, and occupation taxes, and similar taxes, which may be due to any state or other political subdivision in respect of the sale of the Products. If tax exempt, the Customer is responsible for providing Radon with a tax-exempt certificate.

(c) **DEFAULT IN PAYMENT.** Customer shall pay a finance charge of 1.5% per month, not to exceed the rate allowed by law, on any sums which are not paid by Customer when due. If Customer shall fail to pay any amount when due or shall otherwise default, Radon may, in addition to any other remedies Company may have in law or in equity, without notice to Customer, enter any premises in which the Products may be found and render it inoperable or remove it, and suspend, defer or cancel shipments and orders under this or any other Radon Quotation and/or suspend performance on any service agreement. Customer disputed sums/payments which are later mutually agreed to be valid and owed to Radon or found by a mutually approved and/or legal authority to be valid and owed to Radon will be treated as afore-described.

(d) **SECURITY INTEREST.** Customer grants to Radon a security interest in the Products to secure payment of all sums due hereunder, and shall, as Radon may from time to time reasonably request, deliver such promissory notes, security agreements, financing statements, leases and rental agreements covering the Products as requested by Radon to evidence and secure Customer's obligations. Customer hereby grants to Radon an irrevocable power of attorney to execute and file such instruments or documents on behalf of Customer, for purposes of protecting Radon's security interest. Company or its representative may enter upon Customer's premises at any reasonable time upon consent of Customer to inspect the Products and the Software until the payments due under this Agreement have been paid in full. The Products remain personal property, even if attached to realty or other property, until all amounts due to Company under this Agreement have been paid in full.

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If Customer fails to make payments when due, Company may take possession of the Products and the Software and Customer shall pay 5% per month of the aggregate payments due under this Quotation from the date of delivery of such Products and Software. Company may apply any payments previously made to this charge and retain any balance as liquidated damages.

## **7. RISK OF LOSS:**

Risk of loss or damage to the Products, shall pass to Customer upon delivery of the Products to the Customer's location or storage area.

## **8. WARRANTY AND LIMITATION THEREON; CUSTOMER RESPONSIBILITIES; DAMAGES LIMITATIONS.**

(a) **HARDWARE WARRANTY.** Radon only warrants to Customer, as set forth in the Quotation, that hardware components of Products shall be free from defects in material and workmanship under normal use and service and shall be fit for the ordinary use for which designed if operated by a trained and competent operator and properly serviced and maintained. Radon's obligation under this warranty is limited to correction, without charge for parts or labor, of any defect which, is reported to Radon during the warranty period, and which Radon determines in the exercise of reasonable judgment impairs the ordinary use of the Products.

(b) **OEM WARRANTY.** The Original Equipment Manufacturer ("OEM") determines the start date of hardware, software, licenses, etc. that may carry a warranty as described in the Quotation. Warranties that start from date the equipment is shipped to Radon carry a reasonable time for

Radon to install and for Customer to accept the Product/Systems. Delays in installation beyond the original scheduled date which are determined to be the responsibility of the Customer will result in the Product/Systems warranty beginning while the Products/Systems are in storage (at Radon or a designated site). Radon will not be responsible for warranty starting prior to installation / acceptance or expired warranty resulting from delays or other circumstances outside of Radon's control.

(c) **WARRANTY SERVICE.** RADON'S SOLE OBLIGATION IN RESPECT OF ANY WARRANTY CLAIM SHALL BE, AT RADON'S OPTION, TO REPAIR OR REPLACE THE PRODUCTS DURING RADON'S NORMAL WORKING HOURS, SO AS TO PLACE THE PRODUCTS IN GOOD WORKING CONDITION. When Customer calls for warranty service and demands same day service, Radon will reasonably attempt to provide such service within normal working hours. If Radon is not able to accomplish such work within normal working hours, Customer will be charged for the overtime hours in accordance with Radon's standard policy on overtime rates. Radon will not cover any loss, damage or expense relating to the following: (i) any equipment or Software other than the Products identified in the Quotation; (ii) the replacement of any disposable, consumable, or supply items; (iii) any service or repair necessitated as a result of: (A) a change of design, specification or instruction provided by Customer or its representative; (B) Customer's failure to fulfill any of its obligations or responsibilities hereunder; (C) the failure of anyone other than Radon or its service contractor to comply with written instructions, manuals, or recommendations that Radon provides to Customer.

(d) **CUSTOMER RESPONSIBILITIES.** Radon's warranties shall terminate if Customer: (i) fails to notify Radon in a timely manner that any unusual operating peculiarity appears; (ii) fails to operate the Products in a safe and competent manner and in compliance with operation manuals provided with the Products; (iii) fails to regularly and properly service and maintain the Product; (iv) combines of any component of the installed Products with any other equipment or software that is incompatible with the Products; (v) alters or improperly stores, handles, uses or fails to maintain any part of the Products; (vi) has design or manufacturing defects in any item of a third party; or (vii) needs any repair, service or replacement necessitated as a result of: (A) relocation of the Product; (B) external source power supply, (C) failure to maintain proper environmental conditions; (D) neglect, abuse, misuse or failure to follow operating instructions; or (E) casualty of any nature.

(e) **LIMITATION OF LIABILITY -- EXCLUSION OF IMPLIED WARRANTIES.** The warranties in this Section are expressly in lieu of any other warranties, express or implied, including any implied warranty of merchantability or fitness for particular purpose.

(f) **CONSEQUENTIAL AND OTHER LOSS OR DAMAGE.** IN NO EVENT SHALL RADON BE LIABLE, BY REASON OF ANY TORT, BREACH OF CONTRACT OR WARRANTY, OR OF ANY ACT OR OMISSION ON ITS PART RELATING DIRECTLY OR INDIRECTLY TO THE SALE OR INSTALLATION OF THE PRODUCTS, FOR PROSPECTIVE, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, INDIRECT OR SPECIAL DAMAGES, ECONOMIC LOSS, LOSS OF PROFITS OR DAMAGES RESULTING FROM LOSS OF USE OF THE PRODUCTS, EVEN IF RADON IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES. IN NO EVENT SHALL RADON'S LIABILITY TO CUSTOMER (WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE) ARISING OUT OF OR RELATING DIRECTLY OR INDIRECTLY TO THE TRANSACTION CONTEMPLATED BY THE QUOTATION EXCEED THE AMOUNT ACTUALLY PAID BY CUSTOMER TO RADON PURSUANT TO THE QUOTATION.

## **9. SERVICE CONTRACT.**

Radon shall have no liability or responsibility for providing maintenance, service, repair, replacement or otherwise to provide any services with respect to the Products following completion of installation, except for covered warranty work, unless Customer and Radon have entered into a separate service contract.

## **10. CHANGES IN PRODUCTS.**

Radon and/or OEM for which Radon is a dealer/reseller may change the construction or design of the Products so long as the general function of the Products are not thereby altered. In the event such change occurs, Radon shall document any such change and provide a copy of such document to Customer setting forth the change and verification that the general function of the Products was not altered in any material way."

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## **SOFTWARE CHANGES:**

Improvements, modifications, alterations, derivative works and enhancements ("**Changes**") to any of the Equipment, Software or Documentation, including but not limited to those made by the Customer with authorization of Company and/or Owner, those made by Company and/or Owner at the request of the Customer, or those made by Company and/or Owner on behalf of Customer, shall be the sole and exclusive property of Company and/or Owner. Notwithstanding the foregoing, Customer remains solely responsible for any liability associated with Changes that were made without Company's and/or Owner's authorization.

## **11. INDEMNIFICATION**

Each party agrees to indemnify the other from any and all claims, liability, loss, judgment, settlements, costs and expenses for injury or death of any person, or injury to any property, resulting from any negligent or willful act or omission of the indemnifying party, its agents, employees, servants, students, staff members, contractors with respect to obligations assumed under this Agreement.

## **12. NOTICES.**

All notices and requests in connection with this Agreement shall be given or made upon the respective parties in writing and shall be deemed to be given as of the day such notice or request is deposited in the U.S. Mail, postage prepaid, certified or registered, return receipt requested, addressed as follows:

COMPANY: Radon Medical Imaging

384 Peachoid Road  
Gaffney, SC 29341

CUSTOMER: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**13. ENTIRE AGREEMENT.** This Quotation constitutes the entire and only agreement between the parties hereto, and any prior agreement, representation, affirmation of fact and course of prior dealings, promise or condition in connection herewith or usage of the trade not incorporated herein shall not be binding on either party. No assignment, waiver, alteration, or modification of any of the provisions hereof shall be binding unless in writing and signed by a specifically authorized representative of both parties.

**14. GOVERNING LAW; DISPUTES.** The law of the State where the product is installed, or the service is provided will govern any dispute between the parties. EACH PARTY EXPRESSLY WAIVES ALL RIGHTS TO A JURY TRIAL IN CONNECTION WITH ANY DISPUTE ARISING UNDER THIS AGREEMENT. Disputes (other than collection matters) arising under or relating to this Quotation will be submitted to the American Arbitration Association ("AAA") office located closest to the largest metropolitan area of the State where the product is installed or the service is provided for binding arbitration in accordance with the AAA's Commercial Arbitration Rules. The cost of the arbitration, including the fees and expenses of the arbitrator, will be shared equally, with each party paying its own attorneys' fees. The arbitrator will have the authority to award damages only to the extent otherwise available under this Quotation.

**15. SUCCESSORS AND ASSIGNS.**

The terms, provision, covenants and conditions contained in this Agreement shall apply to and inure to the benefit of and be binding upon the parties hereto, their heirs, executors, administrators, legal representatives, successors and assigns.

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**16. CUSTOMER REQUIREMENTS FOR INSTALLATION.**

As part of the installation and operation of the System, Customer is responsible for all, but not limited to, the following:

1. As applicable to radiation producing equipment, submitting a Shielding design to the appropriate Federal, State, Local or other requiring Government Agency and getting approval for installation of equipment from said Agency.
2. Ensure that all Federal, State, Local or other requiring Government Agency requirements are met prior to and after installation of equipment, including but not limited to, shielding design and post installation radiation survey.
3. An employee from Radon will need to survey current installation site prior to scheduling of this job to ensure that appropriate power and electrical runs are available for equipment installation and all network requirements are met as required for system communication and remote service access purposes.
4. Radon will supply equipment layout and specifications upon request. Any deviation from Radon's specifications must be approved by Radon. Ensuring that the users of the System are advised and understand that the System is an aid in the practice of healthcare and is not a substitute for professional judgment.
5. Provide appropriate power and electrical runs for equipment.
6. Installing and maintaining any dedicated modems and phone lines necessary to support the Equipment and the Software.
7. Provide all network cables, drops, etc. for network communications required.
8. Have a network speed of at least 100Mbps on the segment that Company's server and client workstations will be connected to or a dedicated 10Mbps segment specific the System.
9. Providing and maintaining an appropriate network connection to any device supplied at the site by Company.

10. Installing and maintaining any "firewalls" and other security protocols and devices that are adequate to ensure that unauthorized third parties cannot access or manipulate data within the System. Customer will make every reasonable effort to prevent and correct any problems arising from such other equipment, software, hardware, firmware and interfaces or malicious activity by persons known or unknown. If Customer's System is accessed by unauthorized third parties, whether such access is internal or external, Customer is solely responsible for all costs of restoring Customer's network and the System, and for any data loss or corruption. Any service from Company required or requested in order to repair or restore the System will be charged to Customer at Company's then-current service rates.
11. Installing and maintaining remote connections, including communications necessary to support the System (equipment, software and all other related components) required for remote support and maintenance. If remote connections are not available at the site and system evaluation cannot be performed remotely, travel charges will occur at Radon's current rate if Radon is required to come on-site to trouble shoot or resolve a system problem.
12. The supervision, management and control of its use of the System, including but not limited to ensuring that proper controls are in place to validate data and results obtained through the use of the System.
13. Regularly backing up the System and archiving data as may be necessary to meet Customer's backup needs and to protect against unanticipated data loss. Customer is required to maintain and document these backup procedures and provide said documentation to Company's or Company's service contractor's Technical Support upon request.
14. Maintaining the site and environment (including temperature and humidity control, incoming power quality, and fire protection system) in a manner consistent with manufacturer's recommendations and documentation. Customer will maintain documentation of such site and environmental conditions where the System is located and provide such documentation to Company's or Company's service contractor's Technical Support upon request.
15. Assuring that, at all times, properly qualified and appropriately licensed personnel use the System in the manner specified by Company and the manufacturer.
16. Assuming full responsibility for the safety and any consequence of lack of safety of the System in possession or control of the System
17. Appoint and have available a System Administrator during the entire installation process available for training, and thereafter, have a System Administrator designated who possesses the skills to properly conduct day-to-day administrative activities for the System.
18. Making domain and system administrative privileges available to Company's technicians (if applicable). If this is not possible, a Customer representative with such privileges must be available at all times during the installation, and thereafter if required by Company in order to service the System.
19. Making sure that all of the client workstations are communicating with the System's server;
20. Expeditiously communicating installation dates to any third party vendors whose cooperation is necessary to complete installation (for example, Broadband service providers, other related system vendors, etc.).

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21. Expeditiously communicating Company's Interface Specifications (e.g., standard HL7 Specifications) to any third party vendors whose cooperation is necessary to complete interface testing (for example, RIS vendors) and confirming said communications to the appropriate Company representative (typically the project manager) in a timely fashion.
22. Placing service calls and requests to Company when appropriate as specified by Company or the manufacturer's then-prevailing protocols.
23. Making the System available without restriction for service in accordance with a mutually acceptable service appointment schedule.
24. Proper electrical current for operation of the Products will be brought to the safety switches and outlets by Customer and the Customer will supply all of the necessary conduits, wiring, unistrut steel or similar supports in the ceiling and walls, plumbing, carpentry, construction work and rigging, and all other site preparation and installation accessories which may be required for making the installation.
25. If any certificates or other approvals of any governmental authority are required to be obtained for the installation, the same shall be procured by Customer at Customer's expense before the scheduled delivery date.
26. If trade unions prevent installation by Radon employees, Customer shall make all required arrangements with trade unions to permit completion of the installation, the additional cost of which shall be paid by Customer.



Radon is pleased to submit the above quotation for the Products. By signing this Quotation, you acknowledge and agree that you have read and understand, and agree to be bound by the prices quoted, all of the terms and conditions stated including without limitation, referenced addendums or attachments and further subject to final approval and acceptance by Radon on or prior to quotation expiration date.

**CUSTOMER**

\_\_\_\_\_  
**Authorized Customer Signature**

\_\_\_\_\_  
**Date of Acceptance**

**RADON**

\_\_\_\_\_  
**Authorized Radon Signature**

\_\_\_\_\_  
**Date of Acceptance**