39. Project Related Utilization and Financial Information.

Unit of Service Delivery	Projected Utilization		
	FY2017	FY2018	FY2019
Proton Therapy Facility:			
• Estimated Patients	448	670	808
• Average Revenue Per Patient	$54,568	$54,660	$54,654
Project related Total Revenue*:	$24,446,456	$36,622,495	$44,160,242

*Represents technical fee revenue only; excludes professional fee revenue.

40. Project-Service Related Revenues

Proton Therapy Facility:	First Three Years After Project Completion		
	FY2017	FY2018	FY2019
A. Inpatient Services	-	-	-
B. Outpatient Services	$28,963,150	$43,439,509	$52,398,589
C. Total Patient Services Revenue	$28,963,150	$43,439,509	$52,398,589
D. Allowance for Bad Debts & Free/Reduced Care	$2,178,885	$3,265,370	$3,958,631
E. Contractual Allowances[1]	-	-	-
F. Net Patient Service Revenue	$26,784,265	$40,174,139	$48,439,958
G. Other Revenue	-	-	-
H. Total Net Revenue	**$26,784,265**	**$40,174,139**	**$48,439,958**

[1] The OP services revenue is based on assumed payer rates, and is net of any contractual allowances.

41. Project-Service Related Expenses; (duplicative of #40)

42. Project-Service Related Expenses

Proton Therapy Facility:	First Three Years After Project Completion		
	FY2017	**FY2018**	**FY2019**
Revenue:			
Professional fee revenue	2,337,809	3,551,644	4,279,717
Technical fee revenue	24,446,456	36,622,495	44,160,242
Total Revenue:	26,784,265	40,174,139	48,439,958
Expenses:			
Salary & Benefit	8,169,863	9,294,556	10,232,867
Variable Costs	949,468	1,449,437	1,783,392
Program Expenses	2,744,036	6,818,039	7,281,046
Variable Cost Contingency	1,736,337	2,306,203	2,479,731
Fixed Cost Contingency	192,388	196,235	200,160
Fixed (overhead costs)	1,923,876	1,962,354	2,001,601
Financing Cost	1,015,000	770,570	520,029
Depreciation	8,011,244	8,061,244	8,111,244
Total Operating Expenses:	24,742,212	30,858,638	32,610,070
Income from Operations:	**2,042,053**	**9,315,501**	**15,829,888**

Above schedules reflect the following ramp up assumptions:

Year 1 (2017) 50% utilization
Year 2 (2018) 75% utilization
Year 3 (2019) 90% utilization

45. List of Major Equipment

Item	Description	New or Replacement	Fair Market value
Proton Therapy Total System Equipment	Consists of accelerator, gantries and associated systems and simulators	New	$59,300,000

Question 57. Describe the alternative methods (different equipment, floor plans, shared services etc.) that have been explored, and explain how it was determined that the project as submitted represents the least costly and/or most effective method to provide the service in question. If the total project cost is > $2 million, attach a copy of reports concerning alternatives studied in terms of service to be provided, budget impact cost effectiveness, etc. Compare the cost effectiveness of the selected alternative to the "do nothing" option.

Response:

Proton therapy equipment systems are classified as being large footprint/large scale or small footprint/small scale. The composition of a large scale model is typically a single proton accelerator that distributes proton beam to three to five treatment rooms. All of the proton therapy treatment centers in the US and globally that are treating patients utilize a large scale proton therapy system. Large scale proton therapy vendors include Hitachi, IBA, Mitsubishi, Optivus, Sumitomo, and Varian. Small scale proton therapy systems typically consist of a single proton accelerator that distributes proton beam to one or two treatment rooms. These systems are new entrants to the market and are targeted to market areas that cannot support large scale capacity or to customers who cannot assume the capital burden of a large scale system. The small scale vendors consist of either new entrants or large scale vendors who are developing compact models. The new entrant small scale vendors in the US market are Mevion and ProTom International. The large scale vendors who are developing a compact solution include IBA and Sumitomo.

When evaluating vendors, we considered several factors that are critical to quality and the success of the Sibley Proton Therapy Center. The following provides an example of these critical factors.

1. **Alignment with the JHM Mission** – Do the missions of JHM and the potential partner align? Does the vendor understand the value of the JHM research and education missions?
2. **Proven Technology** – Has the potential vendor's proton system been tested and proven clinically? Does the integration of the component parts of the proton bean system, the accelerator, beam line, gantries, control systems, planning systems, operating systems, etc., result in a system solution that is safe, effective, and high quality for patient care?
3. **Advanced Development Pipeline –** Does the technology support the cutting edge advancements of scanning beam delivery where radiation delivery is "painted" rather than shaped with apertures, thus increasing efficiency and decreasing the required radiation management of these apertures? Does the technology support integrated image guidance? Will the technology support imaging of proton dose depth? Can the system deliver beam at all angles around the patient, thus not limiting the patients who can be treated with the technology? Is there a development path for a Multi Leaf Collimator?
4. **Financial Stability** – Is the vendor financially stable so as to support the long term demands of the partnership?
5. **Industry Longevity** – How long has the vendor been in the market? Is it the vendor's mission to be a long term provider and developer of proton therapy systems?

6. **In-House Proton System Expertise** – Has the vendor demonstrated expertise in proton system engineering and science?
7. **Service and Maintenance Capacity** – Does the vendor offer a service and maintenance program? Is the program provided by the vendor's experts or is this being outsourced from a sub-contractor?
8. **Development Partner** – Is the vendor interested in working with Johns Hopkins faculty to advance the functionality and quality of proton therapy systems?
9. **Cost** – What is the comparative cost for the solution required by Johns Hopkins? What is the comparative cost of annual service and maintenance?

Using the critical factors above, initial conversations were established with Industry experts who have historical knowledge of these vendors both domestically and globally. The results of these conversations narrowed the vendors for further due diligence to IBA, Sumitomo, ProTom International, Varian, and Mevion. Table 1 below provides an example of the evaluation matrix that was utilized to determine the best proton therapy vendor partner for the Sibley Proton Therapy Center. During the evaluation of cost, capacity, and capability, several important cost trends were apparent.

1. Small scale models may be less expensive simply because they are just that, smaller scale solutions. When evaluating cost and scale, large scale models may be less costly per treatment room than small scale models.
2. Technological advancement often drives an increase in cost, so lower costs may actually be the result of less advanced technology and less advanced capability.
3. The type of treatment room delivery has a direct impact on cost and capability. For example, a 360 degree rotational gantry treatment room can treat all patients and all sites. This gantry is the most cost costly type of treatment room delivery. A fixed beam treatment room is the least costly, but it is limited in the types of patients and sites that can be treated. When considering treatment room utilization, capability, and capacity, a higher cost alternative may provide improved flexibility and access for patients.
4. Annual maintenance cost for proton equipment is often quoted at 10-15% of the equipment cost.

Table 1: Evaluation of Vendors

	Sumitomo	ProTom International	IBA	Mevion/ Still River	Varian
Alignment with JHM Mission					
Proven Technology					
a. Clinical centers					
b. History of Effective Patient Treatment					
c. FDA Clearance					
Advanced Development Capability					
Financial Stability					
Industry Longevity					
In-House Proton System Expertise					
Service and Maintenance Capacity					
Development Partner					
Price					

Utilizing this evaluation methodology, Sumitomo was identified as the best vendor partner for the development of the Sibley Proton Therapy Center. Sumitomo has an established history of developing clinical proton therapy systems and innovating the proton therapy technology. In fact, the Sumitomo proton therapy system has been treating patients in Japan since 2001. Sumitomo is also best aligned with the Tripartite Mission of Johns Hopkins, and Sumitomo is committed to support Johns Hopkins in the advancement of clinical, research, and teaching applications of proton therapy.

Appendix 71A – Summary of Johns Hopkins Medicine Quality Management Program

Appendix 71A

Johns Hopkins Quality Management Program Overview

Radiation therapy involves the delivery of ionizing radiation in the treatment of cancer patients. The goals of radiation therapy are to deliver maximum dose to the tumor while minimizing dose to healthy tissue. The success of achieving these goals is dependent on the accuracy of dose delivery, patient positioning, and tumor motion management. To manage and measure the accuracy in dose deliver, patient positioning, and tumor motion management each radiation therapy department is responsible for managing, maintaining, and advancing its own Quality Management Program (QMP). The goal of the QMP must be to ensure that radiation therapy procedures are consistent, accurate, and safe in the delivery and achievement of the prescribed radiation dose. The following provides an overview of the Johns Hopkins QMP, and the policies and procedures that have been developed and managed by Department of Radiation Oncology, Medical Physics.

Section 1: The As Low As Reasonably Achievable (ALARA) Program Overview

The principles of this program pertain to assuring optimal safety conditions under standard operating conditions and addressing misadministrations and recordable events. The policies will be followed strictly. This program will be reviewed annually to insure it is current and complements the Quality Management Program of the department.

The management of the Johns Hopkins Department of Radiation Oncology and Molecular Sciences is committed to the policy of ALARA (as low as reasonably achievable) for occupational doses. It is also the intent that all procedures involving radioactive sources or radiation producing machines be conducted in the safest manner possible. As the practices of the radiation oncology department are expanding to include state of the art techniques, each technique will be examined for safety. At all times the basic principles of time, distance and shielding will be utilized to minimize exposure. So that the department can continue to meet the goals of radiation safety as well as the principles of ALARA, radiation safety agenda items will be reviewed at least quarterly by the Department's internal Radiation Safety [1]Committee which is already established within the Radiation Oncology Department. The specifics for radiation safety agenda items to be considered by this committee are outlined below on the following pages.

It is recognized that a radiation safety program is in place for the entire Johns Hopkins Medical Institutions. The procedures listed in this document are not intended to replace any of the requirements put into place by the Radiation Safety Committee or Radiation Safety Officer of the medical institutions. The authorized user physician or his/her designee physician is a member of the Department's internal Radiation Safety Committee and is also a member of the Radiation Safety Committee of the Johns Hopkins Medical Institutions. The two committees will work together towards the common goal of ALARA. In addition, the radiation safety program shall comply fully and at all times with all of the requirements listed in the Code of Maryland Regulation 26.12.01.01including all Supplements to the Regulations.

[1] Formerly, the MAG/CDC committee had this function because its membership consisted of a Physician, physician resident, medical physicists, management, dosimetrists, nursing, and therapists, and registrars.

Section 2: Quality Assurance Program For External Beam Treatment Planning Overview

Treatment planning systems (TPS) are an essential and integral part of a radiation oncology department, providing the means to optimize radiation therapy treatments and determine parameters for radiotherapy equipment to deliver safe and effective radiation treatments. These systems may be used to simply calculate beam-on time, to determine simple beam arrangements for simple treatments, or to plan much more complex 3D-conformal or intensity-modulated radiotherapy. Because of the important role that treatment planning systems play in radiation therapy, it is imperative that a quality assurance program be setup to carefully review the performance of the planning systems and the treatment planning process.

The purpose of this document is to outline the policies and procedures for assuring the quality of the treatment plans generated in the Department of Radiation Oncology and Molecular Radiation Sciences at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; denoted as the Department in the ensuing text. This document is a supplement to the quality assurance measures for radiation treatment planning and dose calculations, as described in the Quality Management Program for External Beam Radiation Therapy (QMP-EBRT).

This guiding principle of this quality assurance program is to assure that equipment performance and procedure review are in accordance with the standards and recommendations set out by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO).

The primary resource document for setting up this QA program is the report of the AAPM Radiation Therapy Committee Task Group 53: Quality Assurance for clinical radiotherapy treatment planning (**Med. Phys**. **25** (1), October, 1998, pp. 1773). This document focuses on continuing quality assurance (as opposed to acceptance and commissioning), describing periodic quality assurance testing and quality assurance of the daily treatment planning process.

Section 3: Quality Management Program For External Beam Radiation Therapy Overview

Quality management (QM) in radiation oncology is embodied in the policies and procedures that ensure a consistent and safe fulfilment of the dose prescription specified by a qualified radiation oncologist. The purpose of this document is to outline policies and procedures for assuring that external beam radiotherapy equipment performs within the expected tolerances, and that procedures followed by the radiation therapy staff in the delivery of the prescribed dose meet all quality and safety expectations.

A. Scope and Purpose

The External Beam Quality Management Program (EB-QMP) is intended to assure that equipment performance and procedure review are in accordance with the standards and recommendations set out by the American College of Radiology (ACR) and American

Association of Physicists in Medicine (AAPM). Meeting these standards assures compliance with the expectations of the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), which has the role of auditing the quality of patient management. The directives set forth in this document are to be considered the minimum QA requirements of the external beam radiotherapy service at Johns Hopkins Hospital and affiliated clinics.

B. General Policies

General Policies are in place to ensure the dose prescription specified by a qualified radiation oncologist is communicated in a manner that ensures it is interpreted and administered accurately and unambiguously. Standard operation is to secure a written or electronic prescription prior to starting treatment. This written or electronic prescription may be on a standard greensheet if electronic record and verify is not to be used, or may be electronically recorded in the record and verify system. An electronically recorded prescription must be approved by an attending physician prior to treatment. A written or electronic prescription prior to the start of the treatment planning phase will assist in efficient and unambiguous preparation for treatment. The exception is to accommodate unforeseen emergency events where expedient treatment outweighs standard procedures.

C. Equipment Performance

The EB-QMP defines the quality assurance tests and testing frequency for equipment. This includes the linear accelerators and imaging equipment under the auspices of the Radiation Oncology Department used in the preparation and verification of treatment delivery. A Medical Physics Quality Assurance Office is established to oversee, manage and safeguard the data from the equipment quality assurance tasks performed by the staff.

D. Procedure Review

The EB-QMP also defines the procedures for reviewing the processes related to patient preparation, planning, and the delivery of treatments by the external beam radiotherapy service.

E. Resource Requirements

An effective QA program requires the chairman of the radiation oncology department and hospital administration assure that the necessary resources are available, including: personnel, QA test tools, equipment, and an allocation of adequate time for performing QA procedures.

Section 4: Quality Assurance Program For Medical Linear Accelerator Overview

The purpose of this document is to outline the quality assurance policies and procedures to be followed in order to maintain effective, efficient, and safe delivery of radiation therapy in the Department of Radiation Oncology and Molecular Radiation Sciences (denoted the Department) at John Hopkins. These policies are intended to satisfy all regulatory requirements of the Department of the Environment of the State of Maryland and to comply with the recommendations of the American Association of Physicists in Medicine, the American College of Radiology, and the Joint Commission on the Accreditation of Hospital Organizations.

The primary aim of this document is to assure that all radiotherapy linear accelerators accurately deliver the prescribed radiation dose to within $\pm$5% of the prescribed radiation dose. This document is a supplement to the quality assurance measures for radiation delivery equipment as described in the Quality Management Program for External Beam Radiation Therapy (QMP-EBRT).

A. Scope

The process of delivering radiation therapy to an individual patient is an extremely complex process in the simplest of cases. Correct operation of the radiation therapy delivery equipment is only one aspect of that process. This document only addresses the quality assurance on the medical linear accelerators (linac) and radiation delivery equipment.
Quality assurance (QA) of CT simulators, treatment planning equipment, record and verify systems, electronic portal imagers, multileaf collimators (MLC), and the individual patient treatment process are the responsibility of the Division of Medical Physics. The QA tasks of several of these subsystems have been established and are included as part of the comprehensive QMP. QA tasks for other equipment are under development, reflecting the evolving technologies being implemented in the department. These will be added to the QMP as a continuing quality improvement initiative.

Section 5: Quality Management Program for Stereotactic Radiation Therapy and Radiosurgery Overview

Quality management (QM) in radiation oncology is embodied in the policies and procedures that ensure a consistent and safe fulfilment of the dose prescription specified by a qualified radiation oncologist. The purpose of this document is to outline policies and procedures for assuring the stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) equipment performs within the expected tolerances; and, for reviewing and approving the procedures followed by the radiation therapy staff in delivery of the prescribed dose.

A. Scope and Purpose

The SRT/SRS-QMP is intended to assure that equipment performance and procedure review are in accordance with the standards and recommendations set out by the American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM). Meeting these standards assures compliance with the expectations of

the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), which has the role of auditing the quality of patient management. The directives set forth in this document are to be considered the minimum QA requirements of the stereotactic radiosurgery and stereotactic radiotherapy services at The Johns Hopkins University/Hospital, Department of Radiation Oncology and Molecular Radiation Sciences. This document pertains to conventional as well as robotic linac-based SRS/SRT.

B. General Policies

General Policies are in place to ensure the dose prescription specified by a qualified radiation oncologist is communicated in a manner that ensures it is interpreted and administered accurately and unambiguously. Standard operation is to secure a written or electronically approved prescription prior to starting treatment.

C. Equipment Performance

The SRT/SRS QMP defines the quality assurance tests and testing frequency for equipment. This includes the linear accelerators, robotic manipulators and radiographic equipment used in the preparation and verification of treatment.

D. Procedure Review

The SRT- SRS-QMP also defines the procedures for reviewing the processes related to patient preparation, patient specific QA, planning, and the delivery of treatments by the external beam SRS/SRT service.

E. Resource Requirements

An effective QA program requires that the chairman of the radiation oncology department and hospital administration assure that the necessary resources are available, including: personnel, QA test tools, equipment, and an allocation of adequate time for performing QA procedures.

Section 6: Quality Assurance Program for the Tomotherapy Delivery System Overview

This procedure verifies TG51 calibration delivery of a known dose to rotational isocenter of the Tomotherapy gantry at the center of a 5 cm longitudinal (IEC-Y) field width at a nominal depth (1.5 cm) of maximum dose. All data are entered into the TG51 calibration worksheet and Argus QA system.

Quality management (QM) for the Tomotherapy Delivery System is presented in this separate section because of its unique process for delivering linac derived radiation therapy. This uniqueness includes a helical type dose delivery system and a megavoltage computed tomography imaging system. The purpose of this document is to outline policies and procedures for assuring the Tomotherapy equipment performs within

the expected tolerances; and, for reviewing and approving the procedures followed by the radiation therapy staff in delivery of the prescribed dose.

Section 7: Quality Management Program for Brachytherapy Overview

The brachytherapy service provides a variety of procedures aimed at curative or palliative treatment of cancer patients. These procedures include fractionated high dose-rate (HDR) after-loader treatment using interstitial, intra-cavitary, intraluminal, and superficial applicators, low dose-rate (LDR) permanent or temporary implant of encapsulated radio-isotope sources, and a variety of un-encapsulated radio-isotopes that are targeted to specific organs. This wide range of procedures makes for a dynamic service but also necessitates a complex set of rules and procedures to assure patient and personnel safety, and treatment efficacy. The Quality Management Program (QMP) addresses the unique needs of each procedure by defining rules and documentation requirements specific to each procedure. The QMP also addresses safety and efficacy needs that are common to all procedures utilized in the brachytherapy section. The QMP has provisions to allow introduction of new procedures, both established and investigational. The QMP also has provisions to provide over-sight and evaluation of its efficacy, and modification as needed.

A. Philosophy

The primary goal of the brachytherapy QMP is to assure safe and effective treatment for our patients. The second goal is to assure safety for all Johns Hopkins personnel and the general public. A third goal is to foster an environment that will allow evaluation of current protocols and lead to improved therapies for the future. The fourth goal of the QMP is to provide a process that is productively and financially efficient.

B. Purpose

The purpose of the QMP is to provide a high degree of confidence that radioactive material or radiation from radioactive material requiring a written directive is administered as directed by the physician authorized user.

C. Patient Procedures Included in the Quality Management Program

Any therapeutic application of brachytherapy radiation dose including:

- HDR after-loading
- Temporary or permanent implant of encapsulated radioactive material
- (RAM)
- Injection or ingestion of non-encapsulated RAM.
- After-loading of non-encapsulated RAM(e.g. GliaSite)
- Intravascular after-loading of encapsulated RAM