



SITE PLANNING OVERVIEW

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i. SCOPE:

This overview covers all CyberKnife® System models. Please contact Accuray for more detailed site planning information for your specific model.

ii. OVERVIEW:

This overview was written to provide general information to our distributors, customers and their contractors in the design and construction of their CyberKnife Robotic Radiosurgery System suite. The information in this guide is meant to provide a starting point of general information, upon which site-specific information can be added.

Each customer will be provided with both remote and onsite site planning assistance.

Accuray's goal during the site planning process is to help our customers achieve both a timely and trouble-free CyberKnife System installation.

iii. REGULATORY NEEDS:

In the United States, Accuray is available to assist our customers with their CON (Certificate of Need) or OSHPD (Office of Statewide Health Planning and Development) processes, if they are applicable to their state. The Accuray Sales representative will act as the contact for the CON process, and the Site Planner for the OSHPD process.

Internationally, Accuray, or our distributor, is available to assist our customers with any regulatory needs that they may have.

The customer is responsible for all permits and meeting all requirements relating to local, state and national codes, regulations, registration and ordinances affecting the site planning, site preparation, construction, system installation and system maintenance.

All Accuray customers are responsible for all reports and submissions to any governing body related to radiation surveys, radiation safety and physics reports.

In the United States, the customer is responsible for meeting any requirements of HIPAA (Health Insurance Portability & Accountability Act of 1996) which may affect the design of the CyberKnife suite, or the control of any patient data.

Please refer any other questions of a regulatory nature to your Accuray Sales representative, Site planner or Regulatory personnel.

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1 SYSTEM COMPONENTS, DESCRIPTIONS and SITE PLANNING CONSIDERATIONS

1.1 Treatment Room (also known as the Vault or Bunker)

The Treatment Room typically contains the following components:

Accuray Supplied:

Treatment Manipulator (Mounted to the floor)

Description: A six-axis manipulator used for positioning and pointing the Linear Accelerator (LINAC) for patient treatment.

Site planning considerations: The manipulator is bolted to a floor frame that is embedded in the floor concrete during the pre-installation process. A cable pull box will need to be installed behind the floor frame, with conduits running from the pull box to the Equipment Room (details will be shown on the *Site-Specific Drawings*). The movement of the manipulator and LINAC within the room dictates room space requirements, including horizontal distances between finished walls and vertical distances between the finished floor and finished ceiling. See *Section 3: Room Specifications* for more information.

Linear Accelerator (LINAC) (Mounted to the Treatment Manipulator):

Description: The LINAC delivers the radiation treatment to the patient and is a compact 6MV LINAC at various MU/min outputs, depending upon country regulatory approvals governing system configuration and system configuration as purchased by customer. Please refer to your sales agreement.

Site planning considerations: Typically, there are only shielding considerations. Please see *Section 2: Radiation Shielding Guidelines*.

Interchangeable Secondary Collimators

Description: Collimators are in diameters of 5.0, 7.5, 10.0, 12.5, 15.0, 20.0, 25.0, 30.0, 35.0, 40.0, 50.0, and 60.0 millimeters.

Site planning considerations: These twelve collimators, plus additional solid and pinhole collimators, weigh approximately 20 pounds each (9.07 Kg) and require adequate storage shelving or drawers. Please plan for a total weight of at least 280 pounds (127 Kg). Alternate storage may be available depending upon system options available for customer's location.

Treatment Manipulator Teach Pendant (Mounted to wall):

Description: This is a hand held panel used to manually control the Treatment Manipulator. It is installed somewhere convenient on a wall near the Manipulator.

Site planning considerations: A conduit will need to be installed from the pull box behind the Treatment Manipulator through the concrete floor to the wall and then up the wall to a single gang electrical box on the wall, located at 48 inches (1.22 meters) above finished floor. A cover with at least a one inch (25 millimeters) center hole should be provided for the box. Accuray will provide and install the wall mounted bracket over the box on the wall at the time of the system installation.

Image Detectors

Description: The detectors are used along with the X-ray Sources to correctly position the patient for treatment and to monitor patient positioning during treatment.

Site planning considerations: The detectors are positioned near the head end of the couch. Hardware used to determine the positioning of the detectors will be installed by Accuray during the pre-installation process.

X-ray Sources (Quantity=2) (Mounted to ceiling cap):

Description: The X-ray Sources are used as part of a larger system to track patient positioning. They are attached to the ceiling cap, via unistruts, above the imaging detectors.

Site planning considerations: The unistruts and related hardware used to support the X-ray Sources will be supplied by and attached to the ceiling cap by Accuray personnel during the pre-installation process. For a steel ceiling cap, the customer's contractor will need to weld adaptor plates (supplied by Accuray) to the steel ceiling. For vaults with ceiling caps 12 feet (3.66 meters) or higher Accuray will install an extension kit for the unistruts that includes side bracing. Conduits [6 inches (150 millimeters) or 4 inches (100 millimeters)] from each X-ray Source to the X-ray Generators will need to be installed by the customer. Details will be shown on the *Site Specific Drawings*. Because the Accuray system installers will need to adjust the location of the unistruts and because the X-ray Sources and/or cables may need to be changed out during the lifetime of the CyberKnife System, it is necessary for Accuray to have access to these areas through the ceiling. While a fixed ceiling may work in some areas of the Treatment Room, a drop down ceiling (or at least large access panels) is needed around the X-ray Source unistruts. The cables going to the X-ray Sources will need to be routed down from the ceiling or from the inside of the side wall of the soffit – so appropriate 4 inch (100 millimeter) grommets or openings should be planned for.

X-ray Generators (Quantity=2) (Mounted to floor):

Description: These two cabinets supply high-voltage power to the X-ray Sources.

Site planning considerations: The Generators may be located in the Treatment, Equipment, or Control Rooms. For service reasons, we recommend placement within the Equipment Room if adequate floor area is available and total cable length to the X-ray Sources is less than 80 feet (24.4 meters). If not, they can be placed in the Treatment or Control Rooms. They can be placed in a closet or large cabinet as long as service access and adequate cooling are planned for. Please refer to the *Site-Specific Drawings* for more information.

Treatment Couch (Mounted to floor):

Description: The Treatment Couch is used to position the patient for treatment using automatic patient positioning technology. The maximum patient load capacity of the Treatment Couch is 350 pounds (159 Kg). It includes a couch top, head base plate, hand control pad, and display.

Site planning considerations: During the pre-installation process, Accuray will install the cable conduits for the couch. During installation, Accuray will drill and anchor the couch to the floor.

Emergency Components:

Description: There is an Emergency Power Off (EPO) switch (quantity=1) installed within the Treatment Room, located near the Treatment Room door. There are Emergency Motion Off (EMO) switches (quantity=4) installed within the Treatment Room, one near the center of each wall.

Site planning considerations: Accuray supplies the switch mechanisms, pushbuttons and labels – the customer supplies the boxes, covers, conduits, wiring and installation. All boxes are single gang electrical boxes, placed 48 inches (1.22 meters) above the finished floor. All covers should be single gang stainless steel with a 7/8 inch (22.3 millimeters) hole punched in the center. Plastic covers are not recommended as they can easily crack.

Accuray Supplied (optional equipment):

Accuray supplies a wide array of options for the CyberKnife system. Availability of these options depends upon the local regulatory clearances and space limitations of the customer's proposed CyberKnife space.

Please consult your sales agreement for those options that have been purchased. Your site planner can help plan your space to make best usage of these options.

Customer Supplied (required):

Phone:

This phone is used for routine, service and emergency communication.

Sink:

The sink is needed for hand washing, patient clean-up and mask preparation.

Patient Positioning Lasers:

Please see *Section 5.7: Patient Positioning Lasers*

Hands-free Patient Intercom:

Please see *Section 5.8: Intercoms*

Closed Caption TV (CCTV) Cameras:

Please see *Section 5.9: Closed Caption TV (CCTV)*

Adequate storage:

For secondary collimators, QA and commissioning tools and equipment, patient masks, body immobilization devices, etc. The customer (primarily the Physicist) can provide recommendations on what storage may be needed. The *Site-Specific Drawings* will show areas of the Treatment Room where it is generally acceptable to install sinks and cabinets.

1.2 Control Room

The Control Room can be configured in many ways, depending upon the site layout and desire of the customer. Typically, it includes the following equipment:

Accuray Supplied:

Treatment Delivery Workstation (Placed on a desktop or countertop):

Description: This console consists of a computer, LCD flat panel monitor, keyboard and mouse.

LINAC Control and EPO (Emergency Power Off) Panel (Placed on a desktop or countertop):

Description: These two control boxes sit side-by-side on the Control Room countertop, within easy reach of the operator. Their overall measurements are 15 inches wide x 10 inches deep x 6 inches high (381 x 254 x 152 millimeters).

Emergency Component:

Description: There is a Door Override Key switch (quantity=1) for bypassing the Treatment Room door interlock. It is used during system testing and calibration. Note: Accuray supplies the key, switch mechanism and label – the customer supplies the single gang electrical box, single stainless steel cover with a 7/8 inch (22.3 millimeters) hole in the center, conduits, wiring and installation.

NOTE: There may be other workstation components installed in the Control Room depending upon options ordered.

Customer Supplied (required):

Phone with long distance access:

The phone is used for routine, service and emergency communication. Accuray will need the phone number prior to installation.

Hands-free Main Intercom:

See *Section 5.8: Intercoms*

Closed Caption TV (CCTV) Monitoring System:

See *Section 5.9: Closed Caption TV (CCTV)*

Customer network data port with Internet access:

This is needed by Accuray during system installation and service activities.

Emergency Components:

“X-ray On” light positioned above the Treatment Room door. The customer supplies all materials related to this light, with the exception of the 24v to 120v relay which is supplied by Accuray. The CyberKnife System supports the use of multiple lights driven off of various system signals. If more than one light is desired, please contact your Accuray Site Planner for more information.

A physics conduit port (Dosimetry tube) into the Treatment Room:

This is used for running QA and Commissioning tools and equipment cables between the Control Room and Treatment Room. It is typically a 4 inch (100 millimeters) conduit that runs from the top of the Control Room desk to the lower wall of the Treatment Room at a 45 degree angle, both vertically and horizontally, with access boxes and/or doors on either end.

NOTE: For site planning considerations for the Control Room, please see *Section 3: Room Specifications*.

1.3 Equipment Room

The Equipment Room is typically located adjacent to or close to the shielded walls of the Treatment Room and is intended to hold the bulk of support equipment needed for the CyberKnife System. The distance from the Equipment Room to both the Treatment and Control Rooms is limited by the maximum cable lengths allowed between system components.

Accuray Supplied:

Controller (for the Treatment Manipulator) (Floor mounted)

Modulator (Floor mounted)

Computer Rack (Floor mounted)

Power Distribution Unit (PDU) (Floor mounted)

Chiller (Floor mounted)

NOTE: The chiller, which is self-contained, does not require a chilled water source for operation.

NOTE: The equipment in this room can sit either on the floor (on their rollers) or anchored to the concrete slab as required by OSHPD or other seismic requirements.

Accuray Supplied (optional):

NOTE: Depending upon system configuration and options ordered, there may be slight differences or additions to the equipment mentioned above. Your site planner can help to design the best layout for the equipment.

NOTE: There are operating and service clearances around this equipment. Please refer to the *Site-Specific Drawings*.

Customer Supplied (required):

Main Power Disconnect:

Please see *Section 4.1: Power Requirements*.

Air Conditioning Unit:

Please see *Section 4.2: Environmental Requirements*.

Junction Box (sometimes referred to as Customer Interface Box (CIB)):

This needs to be a simple electrical wall box, approximately 12 inches wide by 12 inches tall by 4 inches deep (300 millimeters wide by 300 millimeters tall by 100 millimeters deep) with an 18 to 20 point terminal strip inside. On one side of the terminal strip is the wiring from the EPO's, EMO's, Key switch, Door switch, and "X-ray On" light circuitry. All of this wiring is run by the electrician. On the other side of the terminal strip is the wiring that goes to the emergency circuitry (ESCC) within the CyberKnife System. This cable is run by Accuray.

Cable Management System:

We typically recommend a triple-tier J-hook style cable system to run around the perimeter of the room, with the lowest point of the J-hooks either at 75 inches (1900 millimeters) or 12 inches (300 millimeters) above the finished floor. Please see the *Site-Specific Drawings* for the required location in your Equipment Room and for our latest recommendations in material. Other types of cable management systems can work as well – please consult your Accuray Site Planner.

Network Drops:

Two CAT-6 connections to the facility network are needed. One connection is for CT data sets to be transferred to the CyberKnife System via the customer network. The other connection is for the firewall.

Please see *Section 5.4: Information Technology Needs* of this document for more information, or Accuray's *IT Guide* (Part Number 025168)

Phone:

This is needed during system repair.

Customer Supplied (optional):

Power Conditioner (Voltage Stabilizer):

Please see *Section 4.1: Power Requirements*.

NOTE: For additional site planning considerations for the Equipment Room, please see *Section 3: Room Specifications*.

1.4 Treatment Planning Room(s)

The Treatment Planning Room(s) can be located anywhere, and configured in many ways, depending upon the site layout and desire of the customer. It's important that this room be ready for equipment install and setup prior to system installation. Typically, the Treatment Planning Room includes the following equipment:

Accuray Supplied:

Treatment Planning System (Placed on a desktop or countertop):

A certain number of these workstations will come standard with the CyberKnife System (please consult your sales agreement). These are normally located in a Treatment Planning Room or Physicist's office. However, they can be located in the Control Room or any other location that has direct access to the CyberKnife System network, facility network or internet. Additional units can be purchased by the customer.

Color Laser Printer (Item 20 - placed on a desktop or countertop):

The printer is normally located near the main Treatment Planning System.

Accuray Supplied (optional):

NOTE: There may be optional workstations related to treatment planning that can be purchased. Please refer to your sales agreement.

Customer Supplied (Required):

Network Drops:

Minimum of four needed; eight recommended. If the remote workstation or printer is less than 328 feet (100 meters) in network cable run distance from the Equipment Room, then an independent CAT-6 network cable can be run between the location of the remote workstation and the Equipment Room. If the network cable run distance is more than 328 feet (100 meters), then the remote workstation or printer will need access to the facility's network, and an IP address will need to be assigned.

Please see the *Section 5.4: Information Technology Needs* of this document, or *Accuray's IT Guide* (Part Number 025168), for more information.

2 RADIATION SHIELDING GUIDELINES

Initial Site Planning:

Primary barrier thicknesses will likely be between 48 and 60 inches (1219 to 1524 millimeters) of standard density concrete (2.4 g/cm³ nominal density), depending upon workload, limits, occupancy factors and local regulations. In general, all walls are considered primary barriers with a 5% use factor.

For initial site planning, we recommend using 60 inches (1524 millimeters) on all primary barriers with adjacent public areas. We recommend using 42 inches (1067 millimeters) on all secondary barriers, including the ceiling.

In the Conventional Gantry LINAC Vault layout, the CyberKnife System can be configured to limit the treatment beams to only the primary barriers designed for the LINAC. In such an installation, the rest of the walls are considered as secondary barriers and will likely require about 42 inches (1067 millimeters) of shielding.

For specific shielding guidelines, please contact your Accuray site planner.

NOTE: The customer is ultimately responsible for determining the proper shielding for the Treatment Room.

3 ROOM SPECIFICATIONS

3.1 Treatment Room

3.1.1 Treatment Room Size Specifications

The room size requirements for the CyberKnife System are categorized as follows:

- **Recommended Size:**
 - Ideal amount of space for the CyberKnife System to operate
 - Provides ample space for a sink, counters and storage cabinets
- **Minimum Size:**
 - Minimum size that will fully accommodate the CyberKnife System
 - Provides minimal space for a sink, counters and storage cabinets
- **Absolute Minimum Size:**
 - Absolute minimum amount of space to accommodate the CyberKnife System
 - Provides little to no additional space for a sink, counters and storage cabinets

NOTE: Using any of the absolute minimum dimensions could possibly limit the number of current and future system options and upgrades. Please check with your sales representative or site planner if you have any questions.

3.1.1.1 Physical Requirements:

Floor Space:

Recommended:

21 feet by 22 feet (6.4 meters by 6.7 meters) of floor space between finished walls for all CyberKnife Systems. This size of room will provide ample space for a sink, counters and storage cabinets.

Minimum:

18 feet by 19 feet (5.5 meters by 5.8 meters) of floor space between finished walls for all CyberKnife Systems, with the longer dimension (19 feet or 5.8 meters) running parallel to the couch top. This size of room will allow for minimum space for a sink, counters and storage cabinets.

Absolute Minimum:

16 feet by 19 feet (4.88 meters by 5.8 meters) of floor space between finished walls. This size room will allow for little to no space for a sink, counters and storage cabinets.

NOTE: The CyberKnife System equipment within the Treatment Room does not take up the entire floor area of the 18 feet by 19 feet (5.5 meters by 5.8 meters) or 16 feet by 19 feet (4.88 meters by 5.8 meters), but does use the majority of space within this area depending upon the configuration of the system. The Accuray customer *Site-Specific Floor Plan* drawing will show the customer where it is safe to install sinks, cabinets and other pieces of customer supplied equipment within the room.

NOTE: The center of the Treatment Manipulator must be at least 66 inches (1676 millimeters) away from any wall, column or other obstruction, in order to allow the manipulator to freely move during system operation.

NOTE: The room dimensions mentioned above only include the floor space of the actual Treatment Room and do not include any floor space dedicated to a maze walkway or the swing path of a direct-shielding door.

Ceiling Cap Height:

Recommended:

11 feet or greater (3.35 meters or greater) height between finished floor and rough ceiling cap (whether concrete or steel). This will allow for plenty of room for HVAC, lighting, etc. to be located between the finished ceiling and the ceiling cap.

Minimum:

10 feet (3.05 meters) between floor and rough ceiling cap.

Absolute Minimum:

9 feet 2 inches (2.8 meters) between floor and rough ceiling cap.

Finished Ceiling Height:

Minimum (within Treatment Manipulator Operating Area):

9 feet 10 inches (3 meters) height between the finished floor and the finished ceiling within the Treatment Manipulator operating area [13 foot (3.97 meter) diameter circle centered on isocenter]. Please see the *Site-Specific Clearance and Elevation drawing* for representation of this circle.

Absolute Minimum (within Treatment Manipulator Operating Area):

9 feet (2.743 meters) height between finished floor and finished ceiling within the Treatment Manipulator operating area [13 foot (3.97 meter) diameter circle centered on isocenter]. Please see the *Site-Specific Clearance and Elevation drawing* for representation of this circle.

Minimum (over Treatment Manipulator and other areas depending upon options purchased):

9 feet (2.743 meters) height between finished floor and finished ceiling outside of the Treatment Manipulator operating area, directly over the back of the Treatment Manipulator and over some optional equipment. Please see the *Site-Specific Drawings* for representation of this area.

3.1.1.2 Minimum Door Clearance:

For rigging in equipment from the shipping truck to inside the Treatment Room, door clearances for the rig path need to be:

Recommended:

48 inches wide by 84 inches tall (1219 by 2134 millimeters).

Minimum:

43 inches wide by 84 inches tall (1092 by 2134 millimeters).

NOTE: There are some floor space clearances required for rigging in the Treatment Manipulator and some options. Accuray can help to assess suitability of the rigging path.

3.1.2 Recommended Equipment Orientations within the Treatment Room

Because of the flexibility of orienting the CyberKnife system within a vault, Accuray will help to determine the best orientation for your site based on:

- Ease of patient loading
- Exact system configuration
- System clearances
- Shielding considerations
- Ease of access to sinks and cabinets
- Customer preferences

Please contact your Site Planner or Drafter if you have any questions during the design process.

3.2 Control Room

Minimum Floor Space:

100 square feet (9.3 square meters), with enough counter space for at least 2 people and 3 to 4 workstations. This room should be large enough to easily accommodate four to five people during any training and Go-Live activities.

Recommended Location:

The Control Room should be located within eyesight of the Treatment Room door, and should be positioned away from public view as much as possible.

Minimum Door Clearance:

For moving workstations into the Control Room, any typical door clearance is acceptable.

NOTE: If the Equipment Room is located off of the Control Room, any doors into the Control Room must meet the same minimum door clearance as the Equipment Room.

3.3 Equipment Room

Recommended Floor Space:

160 square feet (15 square meters) if the X-ray Generators are located in the Equipment Room.

145 square feet (13.5 square meters) if the X-ray Generators are located outside of the Equipment Room.

Minimum Floor Space:

145 square feet (13.5 square meters) if the X-ray Generators are located in the Equipment Room.

130 square feet (12 square meters) if the X-ray Generators are located outside of the Equipment Room.

NOTE: No side of the Equipment Room should be less than 7 feet (2.1 meters) long, in order to provide adequate installation and service access to the equipment. This rule changes to 10 feet (3.05 meters) for Equipment Rooms with the Minimum Floor Space.

Fixed Rule about Floor Space:

Additional floor space must be built into the Equipment Room for any customer-supplied equipment such as transformers, power conditioners (voltage stabilizers), floor mounted air conditioning units, data and server equipment, phone equipment, storage cabinets, etc. Service access and regulatory requirements must be considered when planning for adequate space around each piece of Accuray or customer-supplied equipment.

Recommended Location:

Due to limited cable lengths between most equipment, the Equipment Room should be located adjacent to the Treatment Room, and as close to the Treatment Manipulator as possible.

NOTE: As a rule of thumb, the maximum cable length run from the Treatment Manipulator pull box to the Equipment Room pull box should be no more than 30 feet (9.1 meters).

Fixed Rule about Location:

System operators must be able to access the Equipment Room during patient treatment. The equipment in the Equipment Room (with the exception of the X-ray Generators) can not be located in the Treatment Room, nor can they be located in a room that is entered into by going through the Treatment Room, nor can they be located on a different floor from the Control Room.

Minimum Finished Ceiling Clearance:

7 feet (2.135 meters) between finished floor and finished ceiling.

Minimum Door Clearance:

3 feet wide by 7 feet high (.914 by 2.134 meters) for rigging the equipment into the Equipment Room, door clearances for the rig path need to be a standard.

NOTE: The Equipment Room door(s) must be lockable, so that the room can not be accessed during treatment by anyone other than the operators.

3.4 Treatment Planning Room(s)

Workspace:

Enough workspace for two or more workstations and a desktop color laser printer. Accuray will attempt to show the exact number of purchased workstations on the customer *Site-Specific Drawings*. Otherwise, we will show a generic setup. Please contact your Accuray Site Planner for additional information.

Recommended Location:

The Treatment Planning Room should be located within 328 feet (100 meters) network cable run length to the Equipment Room. This will facilitate better I.T. connection speeds, as it will allow direct connection between the workstations located in this room and the CyberKnife System internal network.

Locating the Treatment Planning Room at a further location will require connecting the workstations and printer to the facility network and may significantly slow down the transfer speed of treatment plans. Please see the I.T. section of this document, or Accuray's *IT Guide* (Part Number 025168) for more information.

4 ELECTRICAL AND ENVIRONMENTAL REQUIREMENTS

4.1 Electrical

Power Requirements:

The power input requirements are dependent upon the CyberKnife Power Distribution Unit (PDU) supplied with the CyberKnife. Accuray will help to assess your exact power needs and work to match your power to our system. We can supply a step-down transformer for some circumstances.

The Main Power Disconnect typically needs a 36 inch square (914 millimeter square) exclusionary area directly in front of it for regulatory requirements. We recommend that it be located next to the door of the Equipment Room, with the Junction Box located between the Main Power Disconnect and the door. The customer is responsible for the Disconnect box, fuses and all conduits and wiring from the original power source to the box. Accuray will supply and run the power cable from the Disconnect Box to the CyberKnife System PDU.

The Main Disconnect can be located on an outside wall of the Equipment Room, as long as it remains within the cable limitations of the PDU. Accuray can help to locate the best position.

Power Conditioner (Voltage Stabilizer):

A power conditioner will be required of the customer if the input voltage can not be regulated to within +/- 5% phase to phase. Please see *Section 5.6: Power Conditioners* for more information.

Uninterruptable Power Supply (UPS):

An external UPS for the CyberKnife System is not needed as there is one built into the system that will power the Treatment Delivery workstation for about twenty minutes. The Treatment Delivery workstation will power itself down within this time to safeguard important data.

4.2 Environmental

Treatment Room:

The Treatment Room should be kept between 50° F and 85° F (10° C and 30° C), twenty-four hours per day, seven days per week, with a range of 30 to 70% relative humidity.

The heat generated by the equipment in the Treatment Room is generally about 4,700 BTU/h or 1.4 Kilowatts

Control Room:

There are no special requirements with regard to the CyberKnife System in the Control Room.

Equipment Room:

Because the CyberKnife System is kept running at all times, the Equipment Room must be kept between 50° F and 75° F (10° C and 24° C), with a range of 30 to 70% relative humidity, twenty-four hours per day, seven days per week.

The heat generated by the equipment in the Equipment Room is generally 35,000 BTU/h or 10.2 Kilowatts.

Treatment Planning Room(s):

There are no special requirements with regard to the CyberKnife System for the Treatment Planning Rooms.

System Storage (Non-operating condition) Guidelines:

If the CyberKnife System must be stored for any length of time in a crated or uncrated condition, please follow these guidelines:

- 1) Store in an environmentally protected indoor area free from dust and any potential water damage
- 2) Make sure the area is temperature controlled between 40° F and 90° F (5° C and 32° C)
- 3) Assure the area is humidity controlled to less than 80%, non-condensing
- 4) Assure the area is locked to prevent against vandalism

NOTE: Approximately 400 square feet (37.2 square meters) is needed for storing a crated CyberKnife System.

5 OTHER SYSTEM IMPLEMENTATION CONSIDERATIONS

5.1 Pre-Installation Process

Shipping and Rigging:

The pre-install kit crate(s) are normally shipped to the site when the floor pit is ready – typically at least four to five weeks before construction is completed and the CyberKnife System is delivered. Accuray will schedule and pay for the shipment of the crate(s) to the customer location. We ask that the customer or their contractor receive the shipment and store it in a safe area until Accuray personnel arrive to unpack them and move the material into the CyberKnife System suite area.

Site Preparation:

The pre-install kit should be installed in the window of time between the completion of construction on the raw concrete vault (or demolition if renovating a vault) and the point just before finished walls and ceiling, and any ceiling work (HVAC, sprinklers, lighting, etc.) begin to be added.

Accuray will need access to the ceiling cap (concrete or steel) for anchoring (or welding for steel ceilings) our X-ray Source unistruts and plates, and any system options (please see *Site-Specific Drawings* for locations)

We will also need the floor pit completed and cleaned out of any trash and/or water. The rest of the inside of the vault should be as empty of material as possible to allow free movement of ladders, tools and equipment by Accuray. The conduits and pull boxes for the frame(s) will need to have been installed.

Tools and labor that Accuray will need the contractor to supply are:

- Ladder of sufficient height to do ceiling work (power lift for ceilings over twelve feet)
- Electricity for hand tools (typically 120VAC in the US, or equivalent internationally)
- Wet/Dry vacuum
- Portable lighting for safe work
- Hard hats, vests and safety glasses if required
- Basic cooling/heating as necessary if temperatures are extreme
- Dust ventilation, as required
- Additional labor (1 to 2 people) for a few minutes to help lift and install the floor frames onto the anchors

Accuray Pre-Installation Process:

During this process, Accuray (or an approved contractor) will complete the following:

- Locate Isocenter within the room and verify measurements to all walls
- Lay templates on the bottom of the floor pit to mark locations of anchors for all floor and ceiling installations (plates and unistruts)
- For ceiling work, Accuray will drill and place four blind concrete anchors for each plate, install the plates/unistruts and secure to the anchors. The unistruts will be cut to the proper length to support the X-ray Sources (to be installed during system installation)
- Accuray will drill and place anchors in the bottom of the floor pit for the floor frame(s). Accuray will install the frame(s) (with additional labor help as needed) onto the anchors and then level and secure to the anchors
- Accuray will then install any other needed material in the floor pit
- All floor installations will be marked to indicate where their level should end up in relation to the poured concrete floor. Some will be marked $\frac{1}{4}$ " (6 to 7 millimeters) above finished floor (assuming standard vinyl flooring – if non-standard flooring, such as ceramic tiles are installed then this number will change) and others marked *flush* with finished floor

Customer / Contractor Follow-up Work:

The contractor will be responsible for the following:

- Securing a connection between the rectangle conduit coming out of the back of the Treatment Manipulator floor frame and the contractor's pull box. The wall of the box around the conduit should be securely sealed so that concrete from the pit doesn't flow into the pull box.
- Pouring concrete into the pit as soon as possible to reduce the chance of the frames and other floor installations from accidentally being altered from their correct position.

The electrician will be responsible for the following:

- Installing the EPO, EMO, Door Override Key Switch and X-Ray On light relay (if needed). For the EPO, EMO and Door Override Key Switch, Accuray supplies the push buttons, switches and labels. The electrician supplies the single gang boxes, covers, conduits, wiring and installation.

Additional Site Work by Accuray:

After the pre-installation work is completed, Accuray will:

- Inspect and measure all cable conduits to make sure lengths are per the drawings
- Inspect the Equipment Room to make sure that all Power Distribution Boxes, pull boxes and other customer supplied equipment (HVAC, Power Conditioners, etc.) are in the locations per the plans
- Walk the rig route that the CyberKnife System will take to measure clearances and assure adequate staging area at the location the equipment will be taken off of the shipping truck.
- Be available to answer any questions.

5.2 CyberKnife Shipping and Rigging Considerations

5.2.1 CyberKnife System

Shipping and Rigging:

The CyberKnife System normally arrives on site around 7:00AM on the first day of the scheduled installation, typically a Tuesday. However, other days of the week and times can be scheduled according to what works best for the customer and Accuray.

Unless the contract calls for another arrangement, Accuray will schedule and pay for the shipment of the system crates to the customer location. The customer contract will determine whether the customer or Accuray is responsible for scheduling and paying for the rigging of the system from the shipping truck into the customer facility. The Accuray site planner can answer any questions the customer has on rigging responsibility.

If Accuray is responsible for the rigging, we will typically use our shipping company. Accuray will be responsible for the first \$8,000 of the rigging costs, which represents a typical rig job. The customer will be responsible for the remainder of the cost (this typically occurs if a crane or other special equipment is required). If the customer is responsible for the rigging, your Accuray site planner can help to get you in touch with the right contact person at our shipping company.

If you would like to arrange to have the rigging done by a local company, listed below is the manpower and equipment that will be needed for the rig-in:

Rig-in Manpower and Equipment Needed:

Manpower:

- One experienced rigger, two additional movers.
- Our installers will be present to help answer questions and assist with some work.

Equipment:

- An 8,000 pound (3600 Kg) forklift with 8 foot (2.4 meter) fork blades
- One electric two-ton pallet jack
- One hand-operated genie lift (>300 lbs capacity)(136 kg)
- One J-bar
- Eight (8) four-wheel dollies and straps
- Two metal plates for crossing doorways
- Floor protection for the length of the route (masonite or lexan sheets 4 foot by 8 foot)(1.2 meter by 2.4 meter). The heaviest piece to move is the Treatment Manipulator at 2,850 lbs (1,293 Kg).
- Basic tools for uncrating the equipment
- Tarps to cover or “stage” the equipment if the weather is bad

NOTE: Because the rig-in typically starts at 7:00AM, the rigging equipment will need to be delivered either before 7:00 AM or the night before (preferred).

5.3 CT Scanners used for Patient Imaging

5.3.1 CT scanner Selection

The CyberKnife System has been designed to deliver patient treatment with sub-millimeter accuracy. In order to ensure this high level of patient care and treatment, the image data sets that are sent from the customer's CT scanner(s) to the CyberKnife System need to follow certain guidelines:

Minimum Requirements:

A minimum 4-slice CT scanner should be used for cases that aren't typically affected by patient breathing. This will assure reasonably short scan times, and high image quality.

Minimum Requirements:

A minimum 16-slice CT scanner should be used for cases where patient breathing or movement is involved. This will assure reasonably short scan times, high image quality, minimal fiducial movement, and minimum artifacts and movement due to patient breathing.

Minimum Requirements:

No more than 1.5 millimeter slice thickness must be used in order to maximize treatment accuracy.

NOTE: Variable slice thickness can not be used with the CyberKnife System.

Minimum Requirements:

Slice quantity: A maximum of 512 slices should be taken for Extra-Cranial (EC) cases.

NOTE: If your facility's CT scanner(s) can not meet any of the requirements listed above, or you have any questions about these guidelines, please contact your Accuray Account Manager or Site Planner for more information.

5.3.2 CT Overlay Kits

Each CT scanner used to supply image data sets to the CyberKnife System must have a flat overlay for the CT cradle, a 2 inch (51 millimeters) thick pad and a CIVCO base plate. These need to be present on the CT scanner at the time of system installation. They should be ordered well in advance of the installation, as lead times with the manufacturer can be as long as eight weeks.

Overlay tops are not needed for other modalities used during treatment planning, such as MRI, Angio or PET.

5.4 Information Technology Needs

IP Addresses:

A minimum of three needed for the CyberKnife System to connect to the customer network; one for the CyberKnife System firewall and one for the Log File Transfer Software, and one for the service technician in the control area. An IP Address will also be needed for any CyberKnife System workstation or printer that ends up residing outside of the CyberKnife System network (such as the facilities network or the internet).

Facility Network Ports:

Typically two are needed; one dedicated port in the Equipment Room near the equipment rack and one port in the Control Room that has (at least temporary) internet access.

Dedicated Network Ports:

For each System Workstation and printer that resides within 328 feet (100 meters) of cable distance to the Equipment Room, we require a dedicated Cat-6 network cable to be run from the System to the Equipment Room (near the equipment rack). This will allow the System to be directly connected to the CyberKnife System network. These typically reside in the Treatment Planning Room or physicist's office. Your Accuray site planner can help to define the number of Systems that fall into this category.

For more information, please see Accuray's Installation *I.T. Guide* (Part Number 025168). Your site planner can provide this document to you.

NOTE: The IT setup work must be completed ahead of system delivery.

5.5 Sulfur Hexafluoride (SF₆) Gas

The customer is responsible for supplying one cylinder of chemically pure SF₆ gas for use with the CyberKnife System.

Equipment Needed:

Bottle of SF₆ gas: At least 99.9% pure. About 20-30 inches (500 to 760 millimeters) long and 7 inches (180 millimeters) in diameter. Approximately 60 pounds (27.2 Kilograms) of gas. But, larger sizes will be fine.

Common Suppliers:

- 1) Concorde Specialty Gases, Inc. – (800) 818-5109 – www.concordegas.com
- 2) Air Liquide – (407) 548-5000 – www.airliquide.com
- 3) Praxair – (800) PRAXAIR (From within US) – (716) 879-4077 (From outside US) – www.praxair.com

NOTE: The SF₆ gas is needed prior to the start of the system installation, so it will need to be ordered at least one month ahead of time.

5.6 Power Conditioners

The customer is responsible for purchasing and installing a power conditioner if the input voltage can not be regulated to within +/- 5% phase to phase.

Equipment Needed

One power conditioner with voltage regulation.

Common Supplier

- 1) Transtector - (800) 882-9110 - www.transtector.com (they have a specific power conditioner identified for the CyberKnife System)

5.7 Patient Positioning Lasers

The customer is responsible for purchasing and installing the lasers for use with the CyberKnife System. While these lasers are not absolutely necessary, they are highly recommended.

There should be three lasers; two cross-hair lasers with the centerline located 36 1/4 inches (920.75 millimeters) off the finished floor, on either side of isocenter, and one sagittal laser located 90 inches (2286 millimeters) off the finished floor, at the foot of the patient couch, with the laser pointed down the centerline of the couch top. The positions are called out on the Accuray *Site-Specific Drawings*.

Equipment Needed

Two cross-hair lasers and one sagittal laser.

Common Suppliers

- 2) LAP - (800) 498-2674 - www.lap-laser.com
- 3) Gammex – (800) 426-6391 - www.gammex.com
- 4) Diacor – (800) 342-2679 - www.diacorinc.com

NOTE: The lasers are installed and aligned after the CyberKnife System has been installed. Typically they are installed prior to system Go-Live.

5.8 Intercoms

Comprised of a microphone and speaker.

The customer is responsible for purchasing and installing the intercom for use with the CyberKnife System.

Equipment Needed

One intercom base station for Control Room and one intercom hands-free speaker in the Treatment Room.

Common Suppliers

- 1) Aiphone - (800) 692-0200 - www.aiphone.com
- 2) Nutone – (888) 336-3948 - www.nutone.com

NOTE: The intercom needs to be installed prior to the CyberKnife System installation.

5.9 Closed Caption TV (CCTV)

This is usually comprised of a quad multi-plex monitor, used for viewing the patient in the Treatment Room from at least four different angles, along with cameras located in the Treatment Room.

Accuray recommends a minimum of four cameras, with at least two of them having pan/tilt/zoom capabilities (recommend that all four have this capability).

Two cameras should be located at or on the finished ceiling, and the other two located at isocenter height, approximately 36 inches (914 millimeters) above finished floor to center of lens. If there is a maze walkway, it's suggested to have a fifth camera focused on the walkway.

Impact-resistant dome cameras recommended for the lower cameras. Camera monitor, pan/tilt/zoom control, keyboard and speaker to be located in the Control Room. Camera locations and quantity are to be determined by the customer (typically the Physicist). The camera manufacturer, type and capabilities are to be selected by the customer. The customer is responsible for purchasing and installing the camera system for use with the CyberKnife System. Please provide details to the Accuray Site Planner for approval of clearance and serviceability.

Equipment Needed

Four cameras and suitable viewing station.

Common Suppliers

- 1) General Electric - (888) 437-3287 - www.gesecurity.com
- 2) Panasonic – www.panasonic/business/security.com
- 3) Samsung – www.samsungsecurity.com
- 4) Nuvico – (866) 523-1700 - www.nuvico.com

NOTE: The camera system needs to be installed prior to the CyberKnife System installation as it is used during system testing and calibration.

5.10 Quality Assurance and Commissioning Tools and Equipment

For a current list of required and recommended QA Tools, please consult Accuray's Physics Essentials Guide.

These tools will need to be onsite prior to the start of the CyberKnife System installation.

Listed below are our current recommendations:

Accuray provides the following equipment with the CyberKnife® System:

Equipment	Used For
Accessory flange (also called a birdcage)	Holding a diode detector or a Baldwin-Farmer type ion chamber at a fixed distance from the radiation source
Head and neck phantom with Ball-cube film cassettes (includes a starter pack of radiochromic film inserts)	E2E tests for 6D Skull Tracking, Fiducial Tracking, and Xsight Spine Tracking
Automated QA (AQA) phantom (includes a starter pack of radiochromic film inserts)	Daily QA
AQA test film analysis software	Daily QA
Pinhole laser collimator for fixed collimators	Laser Alignment check
Front distance pointer	Distance measurement
Initial supply of radiochromic films for use with head and neck phantom and AQA phantom	E2E and Daily QA (about a 3 month supply)
End-to-End (E2E) test film analysis software	All E2E tests
Other equipment may be supplied depending upon purchased options	

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Table 12: Accuray-provided QA and Commissioning Equipment

The following is a list of recommended user-supplied equipment for commissioning and QA required for the CyberKnife® System:

Equipment	Suggested Vendors	Used For
3D water phantom with 0.1 mm measurement accuracy • Minimum 300x300x300 mm scan region	• PTW • Wellhofer	• Beam data collection • Regular QA of beam data
At least one calibrated Baldwin-Farmer type ion chamber with 6 MV build-up cap	• Per country-specific calibration protocol	• Absolute dose calibration • LINAC output measurements • Delivered dose measurements
Calibrated electrometer	• Various	• QA and beam data collection procedures involving ion chambers and/or diode detectors
Micro ion chamber	• Standard Imaging Exradin A16 • PTW 31016 • Other equivalent	• Delivered dose measurements
Stereotactic diode detector	• PTW 60012 • Sun Nuclear Edge Detector	• Beam data collection • Regular QA of beam data
Reference diode detector	• Diode detector with approximately the same sensitivity as the stereotactic diode detector above	• Beam data collection • Regular QA of beam data
Phantom with: • plugs and holes for ion chamber and/or film inserts and/or TLDs • accurately known dimensions for structural features, insert pieces or fiducial marker locations • inhomogeneities (for Monte Carlo Dose Calculation option)	• Stereotactic Dose Verification Phantom from Standard Imaging (“Baby Blue”) • Tissue-equivalent slab phantoms with fiducials – multiple vendors	• Delivered dose verification • Geometric accuracy verification of CT scanner

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Table 13: Customer-provided QA and Commissioning Equipment