

Check the box to the left of the statement <u>ONLY</u> if the conditions described are verified accurate!

SITE REGULATORY READINESS CHECKS

Site RSO (Radiation Safety Officer) identified: (Print RSO Name)
☐ Site RSO contact information provided: (Phone) (E-Mail)
☐ ABT has been provided a copy of the BG site Radioactive Materials License via Fax:
ABT Molecular Imaging Inc. / (865) 982-0411 / Attn: Mr. Chuck Underwood
☐ All site occupancy permits, local code requirements, or required regulatory systems (For example, ventilation system monitors and area monitors) are in place enabling full access and operation of the Biomarker Generator Systems
Access to an appropriate sink in the BG area has been established for potential decontamination purposes by the ABT Commissioning Engineers between the hours of 8 AM to 8 PM including the weekends for the scheduled commissioning process period.
SITE GENERAL READINESS CHECKS
Site facility issues contact identified for the purpose of interfacing with the ABT Commissioning Engineers regarding facility issues that may develop and/or need to be addressed during the commissioning process: (Print Facility Issues Contact Name)
☐ Site facility issues contact information provided: (Phone) (E-Mail)
☐ Site material handling contact identified for the purpose of interfacing with the ABT Supply Chain Management and Commissioning Engineers regarding the receiving of parts and materials that may be needed during the commissioning process: (Print Materials Handling Contact Name)
Site materials handling contact information provided: (Phone) (E-Mail)
☐ Unfettered access to the Accelerator & CPM/QCM Room (or any BG Systems Support/Utility Rooms) will be granted to the ABT Commissioning Engineers between the hours of 8 AM to 8 PM including the weekends for the scheduled commissioning process period.
Access to the functional Restroom Facilities will be available to the ABT Commissioning Engineers between the hours of 8 AM to 8 PM including the weekends for the scheduled commissioning process period.

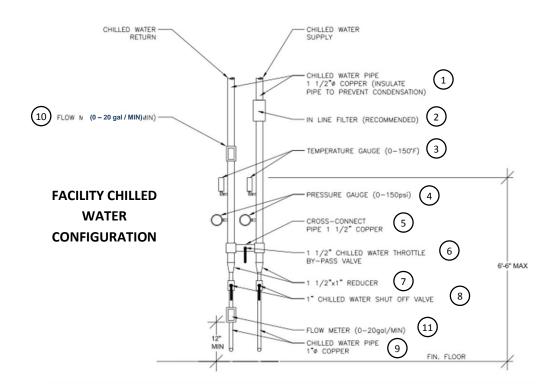


☐ Accelerator & CPM/QCM Room final finish has been applied to the floor and any trenches
☐ Accelerator & CPM/QCM Room interior finished Ceiling installed at a height of ≥9.0 feet (≥2.7432 m)
☐ Accelerator & CPM/QCM Room final wall finish has been applied
☐ Accelerator & CPM/QCM Room Lighting installed and operational
Other Site Construction efforts that may require power cycling of the electrical mains feeding the Biomarker Generator Systems are complete and no power interruptions are planned or expected during the scheduled commissioning process period
Other Site Construction efforts that may require cycling of the Facility Chilled Water system feeding the Biomarker Generator Water-To-Water Heat Exchanger are complete and no chilled water interruptions are planned or expected during the scheduled commissioning process period
Other Site Construction efforts that may require work within the Accelerator & CPM/QCM Room (or any BG Systems Support/Utility Rooms) are complete and no commissioning process interruptions are planned or expected during the scheduled commissioning process period
☐ The As-Built Facility Layout is per the ABT Facility Layout Drawing that was developed for the site from floor plans provided to ABT.
SITE HVAC / AIR HANDLING SYSTEM READINESS CHECKS
\square Biomarker Generator Room Ambient Temperature 70°F \pm 2°F (21°C \pm 1°C)
☐ Biomarker Generator Room Relative Humidity <45% Non-Condensing
\Box Biomarker Generator Room HVAC System is capable of maintaining the required temperature and humidity conditions with a Biomarker Generator Net Heat Load of 3,150 Watts (=~11,000 BTU's = ~1 Ton HVAC Requirement)
SITE CHILLED WATER SYSTEM READINESS CHECKS
☐ Facility Chilled Water Supply Temperature 45° F \pm 5° F (7° C \pm 3° C)
Facility Chilled Water System is capable of maintaining the required Facility Chilled Water Supply Temperature with a Biomarker Generator Heat-Exchanger Net Heat Load of 70,000 BTU/hr (20.5KW)



Facility Chilled Water Flow Rate capable of 10 gal/min (38L/Min) with a potential Biomarker Generator Heat-Exchanger induced 40 psi pressure drop (40 psi restriction) between the Facility Chilled Water Supply and Return Manifolds

☐ The maximum Chilled Water Supply pressure does not exceed 100 PSI



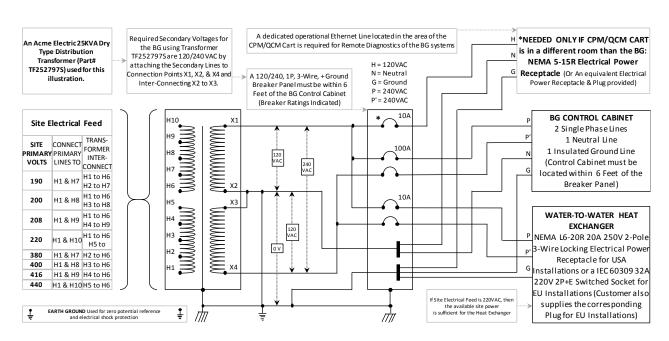
☐ Facility Chilled Water Supply Line is 1 ½ Inch Insulated (to prevent condensation) Copper. ①
☐ Facility Chilled Water Supply Line has an In-Line Filter. ②
\Box Facility Chilled Water Supply Line has a Temperature Gauge (~0-150°F). \bigcirc
\Box Facility Chilled Water Supply Line has a Pressure Gauge (~0-150 psi). \bigcirc
Facility Chilled Water Supply Line has a 1 ½ Inch By-Pass Line back to the Facility Chilled Water Return Line through a By-Pass Valve. 5 6
\square Facility Chilled Water Supply Line has a 1 ½ Inch to 1 Inch Reducer. \bigcirc
Facility Chilled Water Supply Line has a Shut-off Valve prior to the Chilled Water Supply Line termination point. 8
\square 1 Inch Copper Facility Chilled Water Supply Line is terminated with a 3/4 Inch NPT Female fitting. \bigcirc
☐ Facility Chilled Water Return Line is 1 ½ Inch Insulated (to prevent condensation) Copper. ①



\Box Facility Chilled Water Return Line has a Flow Meter (~0-20 gallons / minute). \bigcirc
\Box Facility Chilled Water Return Line has a Temperature Gauge (~0-150°F). \bigcirc
☐ Facility Chilled Water Return Line has a Pressure Gauge (~0-150 psi). 4
Facility Chilled Water Return Line has a By-Pass Connection Line back to the Facility Chilled Water Supply Line through a By-Pass Valve. 5 6
Facility Chilled Water Supply Line has a 1 ½ Inch by to 1 Inch Reducer.
Facility Chilled Water Return Line has a Shut-off Valve prior to the Chilled Water Supply Line termination point. 8
\Box 1 Inch Copper Facility Chilled Water Return Line has a Flow Meter (~0-20 gallons / minute). \bigcirc
☐ 1 Inch Copper Facility Chilled Water Return Line is terminated with a 3/4 Inch NPT Female fitting. (9)

SITE ELECTRICAL SYSTEM READINESS CHECKS

(REFER TO THE ELECTRICAL SYSTEM CONFIGURATION BELOW FOR ELECTRICAL READINESS CHECKS)



REQUIRED BIOMARKER GENERATOR ELECTRICAL SYSTEM CONFIGURATION

ABT HEAT EXCHANGER SITE ELECTRICAL CONNECTION READINESS CHECKS

☐ Electrical Power for the BG Water-To-Water Heat Exchanger is adjacent to the Facility Chilled Water Supply & Return Line Terminations



☐ Electrical Power for the BG Water-To-Water Heat Exchanger is provided via a NEMA L6-20R 20A 250V 2-Pole 3-Wire Locking Receptacle for USA Installations or a IEC 60309 32A 220V 2P+E Switched Socket for EU Installations (Customer also supplies the corresponding Plug for EU or other type Installations)
☐ The Water-To-Water Heat Exchanger Electrical Power Voltage is 200-240VAC and capable of sourcing 10 Amps
ABT CONTROL CABINET SITE ELECTRICAL CONNECTION READINESS CHECKS
☐ BG Control Cabinet Electrical Power connection point is located on the wall within 6 feet of the planed BG Control Cabinet location
☐ BG Control Cabinet Electrical Power connection point has provisions for attaching 2-Single Phase Lines, 1-Neutral Line, and 1-Ground Line.
☐ BG Control Cabinet Electrical Power connection point 2-Single Phase Lines are capable of sourcing 100 Amps.
\Box The Voltage between the 2-Single Phase Lines is 220–240VAC and capable of maintaining the voltage unde a 100 Amp current load.
☐ The Voltage between each Phase Line and the Neutral Line is 110-120VAC.
☐ The Voltage between Neutral Line and the Ground Line is 0V.
☐ Electrical Power for the BG Control Cabinet has a Disconnect capability and is located in the same room as the BG Control Cabinet.
☐ 100 Amp Circuit Protection is incorporated in the Electrical Power feeding the BG Control Cabinet.
ABT CPM (CHEMISTRY PROCESS MODULE) SITE ELECTRICAL CONNECTION READINESS CHECKS
☐ Electrical Power for the CPM Cart is located at the planned CPM Cart location. If the CPM Cart is to be located in the Accelerator Room against the Accelerator Shielding as per the standard BG System footprint, then disregard this readiness check.
☐ Electrical Power for the CPM Cart is provided via a NEMA 5-15R Power Receptacle (An equivalent Electrical Power Receptacle for EU or other type Installations can be used as long as the Customer supplies the corresponding Plug).
If the CPM Cart is to be located in the Accelerator Room against the Accelerator Shielding as per the standard BG System footprint, then disregard this readiness check.



☐ The CPM Cart Electrical Power Voltage is 110-120VAC and capable of sourcing 10 Amps. If the CPM Cart is to be located in the Accelerator Room against the Accelerator Shielding as per the standard BG System footprint, then disregard this readiness check.
☐ A dedicated static IP address and operational Ethernet Line is located in the area of the CPM/QCM Cart for Remote Diagnostics of the Biomarker Generator systems by ABT Technical Personnel.
SITE COMPRESSED GASES READINESS CHECKS
☐ Hydrogen Gas Cylinder (For Ion Source) has a Minimum Purity of 99.9999%.
☐ Ion Source Hydrogen Gas Cylinder has a CGA350 Outlet Fitting or a Hydrogen Gas Cylinder adaptor for a CGA350 Regulator has been acquired. ABT Supplies a CGA350 Regulator / ABT number 100-36-4241.
Ion Source Hydrogen Gas Cylinder Size is no less than a 0.15 ft 3 (0.43 L) Lecture Bottle and no more than a 35 ft 3 (1000 L) Cylinder. ABT recommends a 35 ft 3 (1000 L) Hydrogen Gas Cylinder Size.
☐ Ion Source Hydrogen Gas Cylinder Pressure ≥2000 psi (13.8 MPa).
☐ Argon Gas Cylinder (For Target Argon Manifold) has a Minimum Purity of 99.999%.
☐ Target Manifold Argon Gas Cylinder has a CGA580 Outlet Fitting or an Argon Gas Cylinder adaptor for a CGA580 Regulator has been acquired. ABT Supplies a CGA580 Regulator / ABT number 100-36-3834.
☐ Target Manifold Argon Gas Cylinder Size is 300 ft³ (8500 L).
☐ Target Manifold Argon Gas Cylinder Pressure ≥2500 psi (17 MPa).
☐ Argon Gas Cylinder (For CPM/QCM Cart) has a Minimum Purity of 99.999%.
☐ CPM Cart Argon Gas Cylinder has a CGA580 Outlet Fitting or an Argon Gas Cylinder adaptor for a CGA580 Regulator has been acquired. ABT Supplies a CGA580 Regulator / ABT number 100-36-4080.
☐ CPM Cart Argon Gas Cylinder Size is 300 ft³ (8500 L).
☐ CPM Cart Argon Gas Cylinder Pressure ≥2500 psi (17 MPa).



SITE RADIATION MONITORING AND PROTECTION READINESS CHECKS

Radiation Level Survey Meter equivalent to a Ludlum Model 14C with a 202-241 Meter Face and a Model 44-38 Gamma Detector is on-site and available for the ABT Commissioning Engineers during the scheduled commissioning process period.
Radiation Level Survey Meter will be within calibration for the scheduled commissioning process period.
☐ Radiation Contamination Survey Meter equivalent to a Ludlum Model 12 with a Model 44-9 GM Pancake Probe is on-site and available for the ABT Commissioning Engineers during the scheduled commissioning process period.
\square Radiation Contamination Survey Meter will be within calibration for the scheduled commissioning process period.
☐ Neutron Radiation Level Meter equivalent to a Ludlum Model 12-4 Neutron Dose Rate Meter is on-site and available for the ABT Commissioning Engineers during the scheduled commissioning process period.
☐ Neutron Radiation Level Meter will be within calibration for the scheduled commissioning process period.
SITE SUPPORT EQUIPMENT READINESS CHECKS
Refrigerator for storage of perishable consumables is available
\square Freezer for the storage of perishable consumables is available
☐ Radioactive Waste storage for used DSCs, activated O-18 Water from the Accelerator, used Target Windows, etc. is on-site
☐ Radioactive Waste Container for used gloves, Kimwipes, etc. is on-site
☐ Sharps Container for needle, razor blade, etc. disposal is on-site
☐ Ultrasonic Cleaner for cleaning activated Target Bodies is on-site
☐ L-Block for shielding personnel cleaning/rebuilding Targets is on-site
☐ Acetone, ACS Grade for cleaning targets is on-site
☐ Chloroform, ACS Grade for cleaning targets is on-site



☐ Methanol, ACS Grade for cleaning targets is on-site
\square Water, HPLC Grade for Chemistry processes and target cleaning is on-site
☐ Disposable Exam Gloves for contamination protections are is on-site
☐ Charles River Endosafe Unit for pyrogen testing is on-site
☐ Charles River Endosafe calibration reference standards are on-site
☐ Charles River Endosafe sample analysis cartridges are on-site
☐ Charles River LAL low endotoxin grade water (4 each, 1 L bottles) is on-site
☐ MCA unit is on-site
☐ Calibration Sources for MCA (Cs-137 @ 0.1 uCi & Na-22 @ 0.1 uCi) are on-site
☐ Dose Calibrator suitable for 511 KeV isotopes is on-site
☐ Calibration Sources for Dose Calibrator (Cs-137 @ 200 uCi & Co-57 @ 10 mCi) are on-site
☐ Shielded Syringe Carrier similar to a Biodex 001-179 (2 each) are on-site
Radiac Wash or equivalent for decontamination is on-site
SITE READINESS NOTES:

THANK YOU FOR COMPLETEING THE BIOMARKER GENERATOR SITE READINESS CHECKLIST!