

CMLA

Commission for Motion Laboratory Accreditation, Inc

Applicant Manual

Introduction:

The purpose of this manual is to provide guidance to Applicant in completing the Accreditation Application successfully and efficient.

This guide is designed to help the Applicant understand questions that may seem ambiguous and we are seeking to provide you with clarification. This guide is not a recipe for passing criteria. Each Laboratory is unique. There is no single “correct” answer for any individual question. For example, based on passed reviews, we have found many ways to assess motion capture system precision, some very simple and some more sophisticated, both demonstrating an appropriate mechanism to receive credit for that particular criterion.

We do not believe this Manual will answer all your questions. The CMLA Board of Directors encourages you to contact us individually or through the general forum on the website <http://www.cmlainc.org/forums/viewforum.php?f=1> with any questions you might encounter.

Table of Contents

Introduction.....	3
Part 1: Administration & Personnel	4
Part 2: Equipment.....	15
Part 3: Data Processing/Data Management/ Reporting.....	21
Glossary.....	28

Part 1: Administration and Personnel

Minimal Acceptable Dataset

0- Completed and signed affidavit Affidavit

Each statement of the affidavit must be checked (affirmed) and a signature provided by a member of the departmental team listed in Question 2

1- Statement of Laboratory’s scope, purpose and mission is provided. Stated purpose indicates that the Laboratory is involved in clinical work. Part1Q1

Stated purpose must indicate that Laboratory is involved in clinical work and information is used for patient care.

2- Completed Table of Laboratory personnel included in application. Part1Q2

All aspects of each question must be included for each person listed as personnel. If any personnel have specialty certifications including but not limited to fine wire certifications, PT or MD specialty certifications other than licensure (ABPTS), technical certifications (such as Microsoft certifications), etc. should be included.

Name & Credentials	Job Title	CPR or BLS	Clinical Job Responsibility	% FTE	Years Exp. in Gait Analysis	Certifications	Medical Specialty	State of License	License Number
Jim Bone, MD	Director	CPR	i-iv,vii,viii	.5 clinical .5 research	11	Fine Wire EMG	Ortho.	AL	0112

3- Appendix A is included – current CPR or BLS certificates of all staff with direct patient contact provided. Part1Q2c

CMLA defines direct patient contact as face-to-face interaction with the patient as part of clinical care (clinical or technical). All personnel listed in the Table of Laboratory personnel with the following clinical job responsibilities (i-v) are considered to have direct patient contact. Individuals who perform these duties must have a current CPR or BLS certificate as of the date of the application. Evidence of CPR or BLS certificates must be provided. Each person must have a certificate.

Job duties considered direct patient contact:

- i. physical examination
- ii. marker placement
- iii. electrode placement (surface EMG)
- iv. invasive procedures (fine-wire EMG)
- v. data collection

Statement of certificates without verification is not acceptable.

Waiver: If applicant provides a letter with Chief of Staff signature from a JC accredited institution which states CPR or BLS is not required, then this criterion for that individual is waived

4- Appendix B is included – current licensure verifications of all medical /clinical staff provided. Part 1 Q2

All physicians (MD, DO), podiatrists, chiropractors, physical therapists, occupational therapists, or other medical/clinical personnel listed in the Table of Laboratory personnel who require licensure for professional practice must have a **current license as of the date of the application**. Evidence of indicated licensure and verification from appropriate state Board of Medicine, Board of Physical Therapy, etc. is required. Statement of licenses without verification is not acceptable.

5- Laboratory demonstrates that clinical assessments and evaluation are being conducted by or under the supervision of a clinician with credentials/licensure which includes assessment/evaluation within the scope of practice for the population being served. Part 1 Q2

All personnel listed in the Table of Laboratory personnel indicated as having physical examination clinical job responsibility must demonstrate appropriate licensure. Current licensures for physical therapists and physicians are acceptable. Clinicians whose scope of practice does not include physical evaluation (physical therapist assistants, physical therapy aides, etc.) are not acceptable. Non-licensed personnel who perform physical examination (kinesiologists, students) must be conducted under the supervision of a clinician with appropriate credentials. Description of the supervision should be included in answer to Part 1 Question 3.

6- Laboratory demonstrates that any invasive procedures performed (including but not limited to fine wire placement) are being conducted by or under supervision of a clinician whose licensure/credentials include such procedures within the scope of their clinical practice. Part 1 Q2

All personnel listed in the Table of Laboratory personnel indicated as performing invasive procedures within their clinical job responsibility must demonstrate appropriate credentials, experience, and/or training. If a training course in the area has been attended, verification of course completion should be included in Appendix B. Clinicians whose scope of practice does not include fine-wire placement (physical therapists, physical therapist assistants, physical therapy aides, etc.) are not acceptable. Non-licensed personnel who perform fine-wire placement (kinesiologists, students) must describe that clinical assessments, evaluations, and invasive procedures are conducted under the supervision of a clinician with appropriate credentials. Description of the supervision should be included in answer to Part 1 Question 3.

7- The Laboratory demonstrates that the data interpretation team includes at least one licensed clinician with demonstrated knowledge and expertise for treatment of conditions present in the population being served. Part 1 Q2

One licensed clinician (physician or physical therapist) with appropriate training and scope of practice must be among the personnel who have data interpretation listed as a clinical job responsibility.

8- The Laboratory demonstrates that personnel involved in clinical recommendations have appropriate licensure. Part 1 Q2

Appropriate and verified licensure must be present for personnel who have clinical recommendations listed as a clinical job responsibility. Non-licensed personnel (kinesiologists, students) may participate in clinical recommendations, but may not be the sole professionals that provide clinical recommendations. Clinical recommendations performed by individuals from non-clinical professions (engineering, biomechanics) are not acceptable.

9- The application indicates that the Laboratory captures & reports 3-D kinematics. Part 1 Q3a

Laboratory must state they collect 3-D kinematics. 2-D kinematics are not acceptable. The equipment list in Part 2 Question 2 Hardware will be assessed by the reviewers.

10- The application indicates that the Laboratory captures & reports 3 orthogonal components of force (kinetics). Part 1 Q3a

Laboratory must state they collect 3-D kinetics. 2-D kinetics are not acceptable. The equipment list in Part 2 Question 2 Hardware will be assessed by the reviewers.

11- The application indicates that the Laboratory measures & reports electromyographic muscle activity (EMG). Part 1 Q3a

Laboratory must state they collect surface EMG. The equipment list in Part 2 Question 2 Hardware will be assessed by the reviewers.

12- The application indicates that the Laboratory captures all components (kinematics, kinetics, & EMG) simultaneously. Part 1 Q3a

Laboratory must state they collect all data simultaneously. If the system has the capability to collect data simultaneously, but the applicant chooses not to, they must explain how the Lab assures that all data (EMG and kinematic/kinetic) are speed matched for interpretation. Evidence must be provided.

13- Documentation of volume of clinical cases provided. Part 1 Q3b

14- Documentation of diagnosis categories & percentages of clinical cases provided. Part 1 Q3b

Table must be complete for criteria to be passed. No minimum number of clinical tests is required.

Calendar Year	mmddyyyy - mmddyyyy	
Diagnosis	Number	Percentage
Diagnosis 1	Number	% of total
Diagnosis n	Number	% of total
Total	Total	Total

15- Documentation of referral process for clinical cases provided. Part 1 Q3c

Description of this process must be provided, and is a direct question (Part 1Q3c).

16- Description provided that clinical motion studies are performed following physician referral. Part 1Q3c

Description of the referral process must include indication that clinical studies are performed by physician referral.

17- Appendix C is included – Laboratory Referral Form. Part 1Q3c

Evidence is required. Referral (order) must be included. If facility uses an electronic medical record, a de-identified screen shot of the referral (order) must be provided. Statement that referral (order) form is electronic without evidence is not acceptable. Evidence for physician referral is assessed by review of the referral form to check for physician signature line.

18- Documentation of a mechanism for patient/family satisfaction. Part 1Q4a

This criterion asks for documentation. Direct evidence is not required. Description of this process must be provided, and is a direct question. For first time applications, a general hospital-wide survey is acceptable, but not desired. The survey example provided in Appendix D must contain at least one reference to identify the Motion Lab department. A description of “no method” in place and no plans to institute a mechanism would fail the criterion.

19- Documentation of a mechanism for referral source satisfaction. Part 1Q4b

This criterion asks for documentation. Direct evidence is not required. Description of this process must be provided, and is a direct question. A description of “no method” in place and no plans to institute a mechanism would fail the criterion. For first time applications, a general hospital-wide survey is acceptable, but not desired. The survey example is provided in Appendix D

20- Appendix D included – Surveys. Part 1Q4ab (16/18)

Survey instruments for Q4ab are included here.

21- Documentation of procedure manual, procedure protocols or operational definitions for physical examination or assessment as performed in the Motion Laboratory. Appendix E is included. Part 1Q5a(i)

22- Documentation of a procedure manual or procedure protocol for marker/target placement. Appendix F is included. Part 1Q5a(ii)

23- Documentation of a procedure manual or procedure protocol for EMG surface electrode placement as performed in the Motion Laboratory. Appendix G is included. Part 1Q5a(iii)

24- Documentation of a procedure manual or procedure protocol for EMG fine wire placement as performed in the Motion Laboratory. Appendix H is included. Part 1Q5a(iv)

25- **Documentation of a procedure manual or procedure protocol for data collection. Appendix I included.** Part1Q5a(v)

26- **Documentation of a procedure manual or procedure protocol for data reduction which includes an established verification system for target tracking and event identification. Appendix J is included.** Part1Q5a(vi)

This series of criteria have a core requirement to provide evidence of a protocol or procedure manual for each of six different components:

- (1) physical examination;
- 2) marker/target placement;
- 3) surface EMG;
- 4) fine wire EMG;
- 5) data collection
- 6) data reduction

The question explicitly asks for evidence so the written protocol must be included. Reference to a protocol, manual, or book without evidence of the appropriate sections from that reference is not sufficient to pass the criterion. **The main body “documentation” must include some description of how these references are configured, applied, adapted, and/or integrated into the routine practice of the applicant Laboratory.** Appropriate sections of a manual in the appendix alone are not sufficient to pass the criterion. Specifics for each criterion are indicated below.

21. Physical Examination. Operational definitions of each component of the physical examination is required. For example, if a physical assessment consists of range of motion, strength, motor control, and spasticity, definitions of each of the four components must be included. Clinical procedure/protocol is included in Appendix E.

22. Marker/Target Placement. Including a chart and photos to organize/supplement the descriptions/locations is recommended. If a site describes that more than one marker set is used, it is necessary to describe each marker set and on what occasions the marker set is used. If a site uses virtual markers, the protocol for those locations must be described. Clinical procedure/protocol is included in Appendix F.

23. Surface EMG. **Main body should include a description of how the Laboratory staff verifies the electrode placement according to local anatomy.** A description with content that includes 1) guidelines for placement, 2) how anatomic placement is verified on an individual is recommended. The clinical procedure/protocol is included in Appendix G.

24. Fine Wire EMG. This must be different than Appendix G. Main body or protocol description should include the insertion technique not just the anatomic locations. Clinical procedure/protocol is included in Appendix H.

25. Data collection. Main body should include specifics on how the general motion/force plate/EMG capture process is customized to the specific Laboratory and the options that are chosen. Protocol description should include additional information for supplemental data collection processes that may occur (functional data, virtual markers, fine wire EMG, multi-segment foot model). If the site indicates routine capture of other components (from Part1Q3a) such as plantar pressures, or O2, a data collection protocol for each must be included to pass the

criterion. **Some description of protocol if markers fall off is recommended.** Clinical procedure/protocol is included in Appendix I.

26. Data reduction. The system for data reduction must be explicitly stated as it may be different than the product used for data collection (that is data collection Vicon Nexus, data reduction Vicon Workstation). Statement of software versions is required. **An established verification system for target tracking and event identification must be included. If different protocols are followed for filling gaps based on the number of gaps to fill, then each must be described.** Data processing for all aspects of routine data collection must be described (EMG, Muscle Lengths, Plantar pressures, O2, trunk kinematics). If normalization methods are used for data reduction, these must explicitly be described. If EMG data are post-processed beyond filtered raw data, the processing to final data format rectified, normalized, etc. must be indicated to pass criterion. Clinical procedure/protocol is included in Appendix J.

27- **Documentation of a process for data interpretation.** Part1Q5b

Description of this process must be provided, and is a direct question.

28- **Documentation of a process for clinical recommendations.** Part1Q5c

Description of this process must be provided, and is a direct question.

29- **Documentation of methods to achieve initial competency of personnel for each of the following areas is provided:** Part1Q6

- a. physical exam
- b. marker/target placement
- c. surface EMG placement
- d. fine wire EMG placement
- e. data collection
- f. data reduction
- g. data interpretation
- h. clinical recommendations

This criterion asks for a description. Direct evidence is not required. Initial competency refers to the methods used to establish the ability of new staff to execute the required task with a minimum level of proficiency. **To obtain complete credit for this criterion each of the areas (a-h) must be described, as requested in the question.**

Training manuals or protocols in each area may contribute to initial competence, but alone are not sufficient to pass this criterion (the presence of the protocols has already been assessed). Laboratories must describe a method by which new staff are trained in each of the requested areas. Methods may include job shadowing, supervised execution of the task, etc.

Minimum acceptable description must include a method to explain how the trainer determines when the trainee has reached the required proficiency to execute the task independently.

Data interpretation & clinical recommendations: **Discussion among individual interpreters during a case review session contributes to competency, but is not sufficient to pass the**

criterion for g & h. Applicants must describe a process beyond statement that are mentored by competent staff members. Inter-lab or intra-lab case reviews on a periodic basis or a description of a mentorship program of a number of observed interpretation session or guided interpretation is an example of an appropriate strategy.

30- **Documentation of methods to maintain competency of personnel for each of the following areas is provided:** Part 1 Q6

- a. physical exam
- b. marker/target placement
- c. surface EMG placement
- d. fine wire EMG placement
- e. data collection
- f. data reduction
- g. data interpretation
- h. clinical recommendations

This criterion asks for a description. Direct evidence is not required. Continued competency refers to the methods used to assess how staff maintain ability to execute the required task with a minimum level of proficiency. Declaring the proficiency standard in each area is optimal. **To obtain complete credit for this criterion each of the areas (a-h) must be described, as requested in the question.**

Demonstration of methods used to maintain competency may include educational programs or staff in-services that are performed with a designated routine frequency. Laboratories must describe a method and the frequency by which staff competency is assessed in each of the requested areas. Methods may include (but are not limited to) annual performance appraisals if competencies in the eight areas are addressed as part of routine job performance. Minimum acceptable description is a method and frequency for each area. **A statement of how many gait tests an individual performs in a given time-frame is not sufficient to pass the criterion.**

Data interpretation & clinical recommendations: **Discussion among individual interpreters during a case review session contributes to competency, but is not sufficient to pass the criterion for g & h.** Ideally, the laboratory describes a program with some type of standard routine assessment. Participation in inter-lab case reviews is one aspect of maintaining competency.

31- **Documentation of Quality Assurance Programs in at least two of the following areas within the past 3 years** Part 1 Q7a

- a. physical exam
- b. marker/target placement
- c. surface EMG placement
- d. fine wire EMG placement
- e. data collection
- f. data reduction

This criterion asks for a description of your Quality Assurance program. Direct evidence is not required. **A Quality Assurance Program is defined as a set of procedures performed at routine intervals for systematic monitoring and evaluation of a process** (the six processes listed above). Two of the six areas must be described. The interval of repetition of the must be at

least yearly, but may be more frequent. The purpose of such programs are to ensure that: 1) equipment is performing within specifications or 2) personnel are maintaining a pre-determined level of accuracy or reliability.

Routine educational programs (staff in-services, etc.) may contribute to competency and continuous quality improvement but do not constitute a quality assurance program. Examples of a quality assurance program may include, but is not limited to: monthly data collection of kinematics, kinetics, EMG of a typical subject; periodic measurement of camera or force plate accuracy with an external standardized device.

Calibration procedures or routine data quality checks on a per-patient basis do not constitute a quality assurance program.

32- **Documentation of methods to maintain consistency within personnel for each of the following areas:** Part 1 Q7b

- a. physical exam
- b. marker/target placement
- c. surface EMG placement
- d. fine wire EMG placement
- e. data collection
- f. data reduction
- g. data interpretation
- h. clinical recommendations

This criterion asks for a description. Direct evidence is not required. **Within personnel consistency refers to consistency within the same individual. For complete credit for this criterion each of the areas (a-h) must be described. Regardless if a single person or multiple individuals within a laboratory perform(s) a task [a-h], a method of assessment for consistency must be included to pass the criterion.**

Use of operational definitions or protocols in each area contribute to consistency, but are not sufficient to pass this criterion (the presence of the protocols has already been assessed). Laboratories must describe a method used to measure if the protocols, definitions, processes are executed as intended by the same individual on repeated assessment.

33- **Documentation of methods to maintain consistency between personnel for each of the following areas:** Part 1 Q7b

- a. physical exam
- b. marker/target placement
- c. surface EMG placement
- d. fine wire EMG placement
- e. data collection
- f. data reduction
- g. data interpretation
- h. clinical recommendations

This criterion asks for a description. Direct evidence is not required. **Between personnel consistency refers to consistency between different individuals responsible for the same task. For complete credit for this criterion each of the areas (a-h) must be described, as**

requested in the question. If a single person within a laboratory performs a task [a-h], the criterion is passed by default.

Use of operational definitions or protocols in each area contribute to consistency, but alone are not sufficient to pass this criterion (the presence of the protocols has already been assessed). Performing a task on a routine basis is not sufficient to indicate that consistency is maintained. Laboratories must describe a method of periodic protocol review as the minimal acceptable competency.

Consistency between personnel for aspects of job performance that are governed by an individual's licensure or are clinical in nature must be assessed between individuals with clinical background.

Data interpretation & clinical recommendations: **Discussion among individual interpreters during a case review session contributes to competency, but is not sufficient to pass the criterion for g & h.** Minimum acceptable description must include some method to assess interpretation & recommendations among different interpreters presented with the same data.

34- Documentation of Written Policies for adherence to: Part 1 Q8a

- Local Building Safety Codes. Appendix K is included.**
- Hazards Communication Program, including Material Safety Data Sheets available for potentially hazardous materials in work area. Appendix L included.**
- Emergency Medical Provision & First Aid Procedures. Appendix M included.**
- Age-Specific Patient Care Services Program for all personnel with direct patient contact (technical and clinical). Appendix N included.**
- Hospital and Departmental Infection Control Policies. Appendix O included.**

The question explicitly asks for evidence so the written policies must be included in each of the requested appendices. Reference to a protocol or manual without evidence of the appropriate sections from that reference is not sufficient to pass the criterion. Last date of approval for each policy must be included. The date of approval must be within three years of the date of application for 1st time applications and after the date of previous application if previous accreditation has been granted. **All sub-criteria must pass to achieve credit for the criterion.** Specifics are indicated below:

Local Building Safety Codes: **Minimum safety codes include fire, chemical contamination, severe weather, evacuation plan, utility failure, community disaster.**

If the laboratory resides in a satellite location from the main hospital there are other considerations. Date of building construction, and indication that building codes & building permits are followed is required. Applicants must also describe how security or notification systems are activated if this is not in the policy.

Hazards Communication Program with Material Safety Data Sheets: Evidence of policy required. Minimum acceptable data set includes evidence of a formal program that includes how staff know which hazards are present in their area and a method to locate material safety data sheets.

Emergency Medical Provisions and First Aid: Evidence of policies are required. **Minimum acceptable data set includes policies for individual medical emergencies, community**

disaster plan, radiation decontamination plan, and an emergency operation plan (shelter in place & patient/personnel evacuation plan).

Age-Specific Patient Care Services Program: See definition of program in glossary. Evidence of policy required. **Statement that indicates hospital does not require this is not acceptable to meet the criterion. If this program is not part of routine education, applicant must provide a copy of the self-directed program which the applicant utilizes.** All staff who encounter the family as part of their routine responsibilities must take part in this program. This includes but is not limited to support or administrative staff who greet patients, clinical staff and any technical staff that identify “data collection” as a job responsibility in Part 1 Q2 of the application.

Hospital and Departmental Infection Control Policies: Evidence of policy required. **If applicant states that they perform fine wire insertions, an additional infection control policy for fine-wire insertions must be included to pass the criterion.**

35- **Evidence of maintained competency for all personnel by annual training in the following areas. Appendix P included** Part1Q8b

- Local Building Safety Codes**
- Environmental Safety Procedures**
- Emergency Medical Provision & First Aid Procedures (demonstration of current CPR or BLS certification will suffice – see Appendix A)**
- Age-Specific Patient Care Services**
- Infection Control Procedures**

The question explicitly asks for evidence so human resources evidence must be provided. Information must include date that the training was last completed. This date must be within the last year of the date the application was submitted to meet criterion. (It must be up-to-date in all subsequent revisions.) Annual safety training modules sometimes have different names than those listed in this criterion. Applicant should indicate which modules contain the information listed above. **This data should be presented in Appendix P, not embedded in another appendix.**

36- **Documentation of current accreditation (including date of expiration) from agencies indicated. Appendix Q included.** Part1Q9

Evidence of each stated accreditation required with expiration date noted on supplied document is necessary to pass criterion. If none are indicated, criterion is passed by default.

Part 2: Equipment

- 37- **Dimensions and descriptions of current physical space or layout is provided. Appendix R is included.** Part2Q1

Provide a diagram (to scale). All equipment listed inPart2Q2 should be appropriately placed. A photograph by itself will not fulfill this criterion. Attach as Appendix R.

- 38- **Documentation of descriptions for all equipment in current use for routine data collection as described in Part I Question 3a.** Part2Q2

Submit the completed table as requested.

System description should include:

- a. Number of cameras, force plates, & channels of EMG
- b. Camera resolution
- c. Sample rate capability; sample rate used for data collection
- d. Analog data sample rate
- e. Marker size
- f. Electrode size
- g. Filters used and filter cutoff frequencies
- h. Size of fine wire needles and composition of fine wire
- i. Style of surface electrodes

Note: Include hardware components used for synchronization of systems.

Equipment Purpose	Manufacturer/ Company	Product Version/ Name	Model Number	Webpage reference*	System Description	Date of Purchase
Kinematics						
Kinetics						
EMG						
Synchronization of systems						
...						
Video System						
Energy Expenditure						
Plantar Pressures						
...						
All equipment for routine data collection						

- 39- **Capability to capture and report 3-D kinematics.** Part2Q2

Camera system and model number must be consistent with 3-D motion capture.

- 40- **Capability to capture and report 3 orthogonal components of force (kinetics).** Part2Q2

Force plate system and model number must be capable of measuring three orthogonal components of force, i.e., 3 forces/3 moments/center of pressure.

41- Capability to measure and report electromyography muscle activity (EMG). Part2Q2

System and model description must be capable of measuring and reporting EMG; provide brief description of any filtering that is used.

42- Evidence of system components for synchronization between kinematic, kinetic, and EMG measurement systems. Part2Q2

Description of equipment used to synchronize the three data capture systems (motion, Force & EMG). Be sure this is included in the table and three systems are indicated.

43- Documentation of calibration procedures for the motion capture system. Part2Q3

Describe calibration procedures in detail.

44- Evidence that calibration occurs in accordance with manufacturer's recommendations for the motion capture system being used. Part2Q3

Manufacturer's calibration recommendations must be included. Provide detailed description of procedures, including how often calibration is performed and acceptable errors, as recommended by manufacturer. If manufacturer's recommendations are not described or description of the frequency routine calibration is performed by the applicant is not described or is not in accordance with stated manufacturer's recommendations for procedure, frequency, or acceptable error an explanation must be provided. The example calibration data that is within 6 months of the date of application is provided in Appendix S.

45- Documentation of methods to ensure accuracy (validity) of the motion capture system. Part2Q3

Provide detailed description of test(s) used to test validity of motion capture marker position, including frequency of performing these tests. Attach sample data that is within 6 months of the date of application in Appendix S. An example might be to collect data using a marker set on an object that produces known angles and linear distances.

46- Documentation of methods to ensure precision (repeatability) of the motion capture system. Part2Q3

Provide detailed description of test(s) used to test precision of motion capture marker position, including frequency of performing these tests. Procedures should include within and between day test-retest. Attach sample data that is

within 6 months of the date of application in Appendix S that also show repeatable kinematic curves for entire marker-set. Repeating the example accuracy test on multiple days or different sessions in a single day assesses the repeatability.

47- Appendix S is included. Part2Q3

The items to include in this appendix are: 1) calibration data; 2) accuracy data; 3) precision data.

48- Physical layout in Question 1 is consistent with the calibration volume described in Question 3. Part2Q3

Calibration volume should be consistent with the physical layout provided in Appendix R.

49- Documentation that calibration procedures are in place for all additional measurement equipment used for clinical analysis. Part2Q4

- 1. Force platform system
- 2. EMG system
- 3. All additional measurement systems as described in Part1 Question 3a.

Provide detailed descriptions of calibration procedures, including frequency of calibration and manufacturer's recommendations. Attach sample data that is within 6 months of the date of application in Appendix T. Please be sure to include calibration data for each system.

50- Evidence that calibration occurs in accordance with manufacturer's recommendations for each additional measurement system. Part2Q4

- 1. Force platform system
- 2. EMG system
- 3. All additional measurement systems as described in Part1 Question 3a.

Manufacturer's calibration recommendations must be included. Provide detailed description of procedures, including how often calibration is performed and acceptable errors, as recommended by manufacturer. If manufacturer's recommendations are not described or description of the frequency routine calibration is performed by the applicant is not described or is not in accordance with stated manufacturer's recommendations for procedure, frequency, or acceptable error an explanation must be provided. The example calibration data for each system: 1) force plates, 2) EMG; 3) each additional system must be within 6 months of the date of application. Example data is included in Appendix T.

51- **Documentation of methods to ensure accuracy (validity) for each additional measurement system.** Part2Q4

- 1. Force platform system
- 2. EMG system
- 3. All additional measurement systems as described in Part1 Question 3a.

Provide detailed description of test(s) used to test accuracy of each of the measurement systems listed, including frequency of performing these tests. Attach sample data that is within 6 months of the date of application in Appendix T.

52- **Documentation of methods to ensure precision (repeatability) for each additional measurement system.** Part2Q4

- 1. Force platform system
- 2. EMG system
- 3. All additional measurement systems as described in Part 1 Question 3a.

Provide detailed description of test(s) used to test precision of each of the measurement systems listed, including frequency of performing these tests. Attach sample data that is within 6 months of the date of application in Appendix T.

53- **Appendix T is included.** Part2Q4

The items to include in this appendix are: 1) calibration data; 2) accuracy data; 3) precision data for each system – force plates, EMG, all other measurement system.

54- **Evidence that marker set can characterize 3D kinematics of the lower limbs.** Part 2Q5

This criterion evaluates the marker set to assure that it is sufficient to characterize 3-D motion, not simply that a procedure is place. Information including a description of how the entire marker set (including virtual markers) is used to determine 3D joint kinematics is required. The marker set and model must include a description of how the technical coordinate system translates to an anatomical coordinate system to generate 3D kinematics. **A reference only is not sufficient to meet this criterion.**

55- **Evidence that the biomechanical model can utilize coordinate trajectories and ground reaction forces to calculate 3D kinetics of the lower limbs.** Part2Q5

This criterion evaluates how the 3D coordinate trajectories are integrated with the ground reaction force and inertial properties to generate 3D kinetics. A description of the model used (typically inverse dynamics) must be included. **A reference only is not sufficient to meet this criterion.**

56- Descriptions provided demonstrates that authors understand the strengths and weaknesses of the biomechanical model they are using. Part2Q5

The strengths and weaknesses of both the kinematic and kinetic components of the model must be explicitly provided to pass this criterion.

57- Description provided demonstrates that authors understand the potential sources of error in their calculations. Part2Q5

The potential sources of both the kinematic and kinetic components of the model must be explicitly provided.

Part 3: Data Processing; Data Management; Reporting

58- Description of kinematic & kinetic data reduction software provided. Part3Q1

Detailed description of data reduction software (manufacturer's and custom); version of manufacturer's software; and purpose of each respective type of software.

59- Description of EMG data reduction software provided. Part3Q1

Detailed description of data reduction software (manufacturer's and custom); version of manufacturer's software; and purpose of each respective type of software. Include description of software use for filtering, rectifying, creating an envelope and/or quantifying the EMG signal.

60- Description of how processing errors are identified and corrected is provided. Part3Q1

For kinematics only, include description of filling trajectory gaps, managing occluded markers, etc.

61- Description of how gait events are identified is provided. Part3Q1

Detailed description of how gait events are identified.

62- Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction in kinematic and kinetic data. Part3Q1

Detailed description of strengths and weaknesses of kinematic and kinetic data reduction software.

63- Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction of EMG data. Part3Q1

Detailed description of strengths and weaknesses of EMG data reduction software.

64- Description of control kinematic and kinetic dataset complete. Part3Q2

- Facility & Date(s) of data collection provided.
- Description of marker set provided.
- Type and Model of motion capture system provided
- Type and Model of force plate system provided

Detailed description of parts 1-4 must be provided. If presently using a different motion

capture system from the one used for control dataset describe how you have validated commensurability of the two systems.

65- Description of control EMG dataset complete (including facility & date of data collection). Part3Q2

Detailed description of control EMG dataset including facility & date of data collection is required. **Providing only a reference is not sufficient.** If you collected your own dataset and are presently using a different EMG system from the one used for the original control dataset describe how you have validated commensurability of the two systems.

66- Suggested table provided and complete with data as requested. Part3Q2

All requested demographic data of control dataset must be presented in a table.

67- Description of data averaging, number of gait cycles per patient, and assignment of standard deviation provided. Part3Q2

Provide all information requested.

68- If control data taken from the literature or manufacturer, description of methodology for verification of consistency and validity of data with current clinical system is provided. Part3Q2

Detailed description of method to verify consistency is necessary.

69- Documentation of control kinematic and kinetic data provided. Appendix U included. Part3Q2

Appendix U must be complete.

70- Documentation of control EMG data provided. Appendix V included. Part3Q2

Appendix V must be complete.

71- Documentation of control temporal-distance parameters provided. Appendix W is included if necessary. Part3Q2

Appendix W must be complete.

72- **Data set includes a physical examination relevant to the condition being evaluated.** Part3Q3

- Passive Range of Motion Examination**
- Lower Extremity Alignment (Transverse/Coronal Plane)**
- Muscle Testing of Relevant Muscle Groups**
- Assessment of Selective Motor Control**

Detailed description of all subcomponents of criterion must be provided.

73- **Comprehensive kinematic data set provided.** Part3Q3

- Conditions of Testing Identified**
(e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.)
- Clear Identification of Right/Left sides**
- Clear Identification of Gait Cycle**
- Clear Identification of Y-axis label**
- Anatomic/Planar Orientation of Plots**
- Normative Data Included on Plots and Clearly Identified**
- Temporal-Distance parameters included**
- Type of Depicted data clearly identified**
(representative trial, multiple trials, mean of multiple trials, etc.)

Detailed description of all subcomponents of criterion must be provided.

74- **Comprehensive kinetic data set provided.** Part3Q3

- Conditions of Testing Identified**
(e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.)
- Clear Identification of Right/Left sides**
- Clear Identification of Gait Cycle**
- Clear Identification of Y-axis label**
- Anatomic/Planar Orientation of Plots**
- Normative Data Included on Plots and Clearly Identified**

Detailed description of all subcomponents of criterion must be provided.

75- **Comprehensive EMG data set provided.** Part3Q3

- Clear Identification of Right/Left sides**
- Clear Identification of Gait Cycle**
- Normative Data Included on Plots and Clearly Identified**
- Clear Identification of Type of processing, if appropriate**
- Muscles or Muscle Abbreviations clearly identified**

Detailed description of all subcomponents of criterion must be provided.

76- **Comprehensive clinical history data set provided.** Part3Q3

- Identification of chief complaint or reason for study
- Documentation of pertinent past medical history
- Documentation of pertinent past surgical history
- Documentation of current orthotic, prosthetic, assistive device use

Detailed description of all subcomponents of criterion must be provided.

77- **Comprehensive clinical/interpretive report provided.** Part3Q3

- Anatomic and/or Problem List Organization of Report
- Identification of Clinically Important Deviations/Abnormalities
- Identification of Possible Specific Treatment Options Based on Deviations/Abnormalities
- Names, profession, signatures of interpreters included. At least one of interpreters has a medical practice license.

Detailed description of all subcomponents of criterion must be provided. Do not blind medical/clinical practice signatures.

78- **The laboratory demonstrates that treatment recommendations (including appropriate referrals) are made consistent with the clinician's licensure guidelines.** Part3Q3

This criterion is about the presence of the signature line and about scope of practice and training of the individuals signing the report. Do not blind or de-identify this information. Solo signatures by physical therapists, kinesiologists, biomechanists or engineers together or in isolation are not acceptable for content that includes surgical and/or medical treatment recommendations. Reports that have a physical therapist, kinesiologist, biomechanist or engineer **and** a physician signature are acceptable.

79- **Documentation of data management for raw data provided.** Part3Q4

- Location
- Back-Up
- Security
- Confidentiality
- Duration

80- **Documentation of data management for processed data provided.** Part3Q4

- Location
- Back-Up
- Security
- Confidentiality
- Duration

81- **Documentation of data management for video data provided.** Part3Q4

- Location**
- Back-Up**
- Security**
- Confidentiality**
- Duration**

82- **Documentation of data management for clinical history/questionnaires provided.** Part3Q4

- Location**
- Back-Up**
- Security**
- Confidentiality**
- Duration**

83- **Documentation of data management for physical examination provided.**
Part3Q4

- Location**
- Back-Up**
- Security**
- Confidentiality**
- Duration**

84- **Documentation of data management for clinical files provided.** Part3Q4

- Location**
- Back-Up**
- Security**
- Confidentiality**
- Duration**

For items 79-84 describe in detail back-up procedures, whether done electronically or in hard-copy for each component of data.

Each subcomponent of the criterion must be present to achieve credit for the entire criterion. Many of the processes are the same for each component (raw-clinical files), but each must still be described. As electronic medical records are now in place for most (if not all) facilities, the data management for the EMR should be described. Data elements that are stored electronically and those in hard-copy form must be described in full.

85- **Documentation of written policies regarding back-up procedures, security measures, and patient confidentiality in the following areas. Appendix Y included and complete.** Part3Q4

- Information Systems.**

- Protected Health Information**
- Medical Records or Health Information Systems**

This criterion requires evidence so the written policies or a cover page of the policy must be provided and included in Appendix Y. The cover page of the policy must include: name, brief summary of the policy purpose, and date of approval (last date of approval for each policy must be included). The date of approval must be within three years of the date of application for 1st time applicants, and after the date of previous application. If policies at the institution have different names from those indicated above, but include the proper content, applicant must indicate which policies correspond to the above areas.

86- Evidence of maintained competency for all personnel by annual training in the following areas. Appendix Z included and complete. Part3Q4

- Information Systems.**
- Protected Health Information**
- Medical Records or Health Information Systems**

Complete record of competency for each staff member listed in Part 1 Question 2 must be presented in Appendix Z. Evidence includes verification of the date of last completion for each staff member and must be within one year of the date of application. Annual training modules for different facilities have different titles. Applicants must describe which components of their annual training correspond to the above requirements.

Glossary

Age-Specific Patient Care Services Program: A program for establishing and verifying that all staff that have routine patient contact or deliver direct clinical care are competent to provide care that is appropriate to a patient's culture, age and developmental level. The program objective is to educate and/or verify staff knowledge in population specific: cultural sensitivities, developmental skills, safety, reactions to health-care experiences, and appropriate staff interactions/interventions.

Competency: A set of defined behaviors that provide a structured guide to proper performance of a task. The ability to execute a required task properly with a minimum level of proficiency.

Initial Competency: The set of defined behaviors, guides, and mechanisms used to assure new staff are able to execute a required task properly (a defined level of accuracy).

Continued Competency: The set of defined behaviors, guides, and mechanisms used to assure all staff maintain ability to execute a required task properly (a defined level of accuracy).

Consistency: the extent of agreement or uniformity of measurement when a task is repeated on more than one occasion.

Within-Personnel: Agreement or uniformity when the task is repeated by the same individual. Also known as intra-rater agreement

Between Personnel: Agreement or uniformity of measurement when the same task is performed by different individuals. Also known as inter-rater agreement.

Direct Patient Contact: Any staff who encounters the patient or the family as part of their routine tasks. This may or may not include direct physical contact.

Documentation: Description of the process or procedure without direct proof that this is the process that actually occurs.

Evidence: Proof or verification of stated licensure, certificates, calibrations or data requested in application. Statement of the above is not sufficient. Corroboration is required via scanned documents or verifications from a licensing board.

Minimal acceptable data: The least set of provided information that is sufficient to pass any single criterion or sub-set thereof.

Operational Definitions: A set of written procedures followed to maintain consistency in the performance of a task.

Protocol: A system of rules or procedures to be followed for accomplish a test correctly

Quality Assurance Program: A systematic process to determine if a service or piece of equipment is meeting specified requirements. A program or protocol repeated on a regular basis to assess functioning of a method of data collection or equipment.

Scope of Practice: The procedures, actions and processes an individual is permitted to perform based on licensure. The scope of practice is usually defined by the specific Board of Licensure in a particular state. Each state or area jurisdiction has governing laws and regulations that describe requirements for education and training.