Clinical Movement Analysis Society

– UK and Ireland

Clinical Movement Analysis Standards

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Contents

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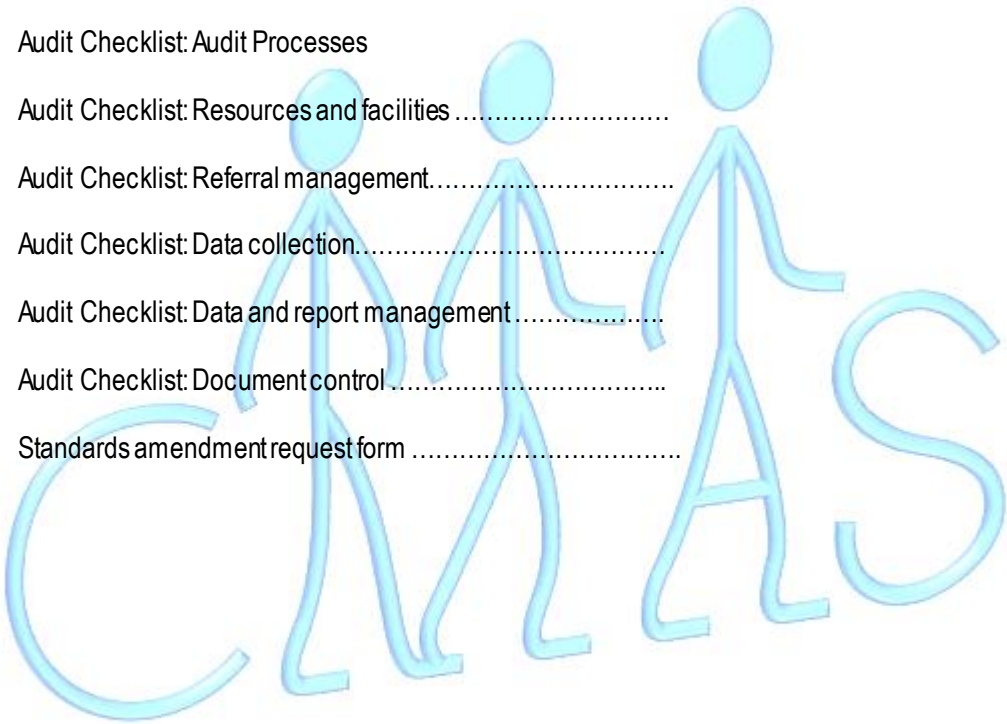
Audit Documents:



Introduction

CMAS aims to promote quality in the provision of movement analysis services by the development of standards relating to clinical gait analysis services. The implementation of these standards will be monitored by auditing and accrediting clinical gait analysis laboratories.

This document details the standards developed by the Standards Working Group of CMAS. The initial work was carried out from March 2002 up to February 2004. During 2004-7 the implementation of audit was explored, revealing the need for further changes to the standards. This work was started in late 2007 and completed during 2008, when a complete revision of the standards was launched. Standards will continue to be reviewed at regular intervals with revisions being made where needed.

The first 15 gait laboratories were accredited to the CMAS standards in April 2011.

Conformity to a standard allows accuracy or quality to be judged by auditing the processes against a checklist of key points stated in the agreed audit checklists. Details of the procedures carried out locally will be detailed in a protocol. The protocols should be sufficiently detailed to act as a guideline for all staff performing the stated task. Examples of protocols will be shared within the community of accredited laboratories.

A clinical gait analysis laboratory will be required to maintain its own set of written protocols conforming to the associated standards for the procedures relevant to that laboratory, or as stand-alone protocols where indicated in the list in the clinical gait analysis procedure document. Standards contain references to protocols where appropriate. **Where signatures are required these can be electronic.**

The scope of the standards deliberately excludes areas where local or national policies apply. These areas include:-

- Health and Safety
- Infection Control
- Patient Confidentiality
- Financial Issues
- Waiting time targets

- Patient consent procedures
- Communication/correspondence policies and record access
- Human resources
- Professional body requirements
- Local statutory training
- **Information Governance**

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Helen Evans (Derby Gait Lab) 2019

STANDARD: Resources and Facilities	
1. Staffing	
Mandatory Requirements	1 Each laboratory should have a list of current staff employed.
	2 Each laboratory should have at least one current member of CMAS.
	3 Staff should have current registration with the Health and Care Professions Council (HPCP - UK staff only) / appropriate Medical Council; or alternatively will be under the supervision of a named practitioner with current registration.
	4 The laboratory must keep a log for each staff member containing, a) The identity of any professional registration body, along with the registration number b) Evidence of gait laboratory induction training for new staff, which should be signed by the trainer, who should be competent (see e) c) Annual update of repeatability measures (where applicable). d) Evidence of participation in on-going in-service training activities, which should be signed by the trainer, who should be competent (see e) e) List of individual competences in patient history taking, clinical examination, data collection, data interpretation, scope of clinical recommendations. f) This should be signed by the lab manager.
	5 Repeatability testing is required for each test carried out by the clinical movement analysis service where clinical or technical judgement is required during data collection or processing:- a) Clinical judgement would include the use of simple measurement equipment (e.g. a goniometer) or the accurate placement of markers or electrodes. b) Technical judgement during processing would include labelling markers, event detection, knee varus/valgus correction. c) Examples of tests for which repeatability data are not currently applicable include video filming, plantar pressure and oxygen consumption.
	6 Repeatability testing should be performed as follows:-

	a) Laboratories should conduct an assessment of repeatability for each test every two years. (It is acceptable to perform a subset of tests where relevant e.g. a limited number of muscles for EMG or a reduced set of clinical examination measures). b) Repeat data collection of a single subject should be carried out at least once by all those performing that function in routine clinical practice. A single round of data collection should be completed within a period of 6 weeks. In labs where fewer than 4 staff are used then members of staff should perform sufficient repeats to give at least 4 datasets for comparison. c) All the repeatability data for the different assessors should be processed by the same person, where processing is required. d) In addition one set of data (a minimum of 5 trials) should be processed independently by all those responsible for data processing. e) All repeatability studies should report in the same units as the original measurements. Labs should set pass/fail thresholds/criteria in advance of conducting a repeatability study and report results against those criteria. Recommended thresholds are given below and labs should justify any marked deviation from these recommendations. f) Any failure to meet the criteria should be addressed by re-education or protocol refinement and the repeatability exercise (or a subset where appropriate) repeated.
	7 Gait laboratory induction training should include, a) Training on all local protocols (signed record) b) Shadowing of established staff until local staff are satisfied (signed record) c) The training records of new members of staff must show evidence of their repeatability by comparison with at least 1 member of the existing staff team before the new member of staff works independently.
	8 It is necessary to have a skill mix within the staff team, including clinical, technical and scientific expertise. This should include at least one member of staff with a clinical and one with a technical background.
Recommendations	1 A minimum of two staff should be employed to run a laboratory.

	2 For staff training/induction a) All staff should have attended a recognized gait course e.g. ESMAC, GCMAS, SIAMOC etc b) Co-operation between laboratories is encouraged for senior staff for peer supervision. c) New staff are encouraged to visit other laboratories as part of their induction training. d) Interim repeatability testing may be required by staff after a break or who assess patients less frequently.
	3 For repeatability testing a) Laboratories should consider using subjects with a gait pathology wherever possible, however local ethics committee advice may be required. b) For larger datasets laboratories should report results as variance components expressed as standard deviations. The use of indices such as CMCs or ICCs alone would therefore not be acceptable. c) More thorough investigations of inter and intra rater repeatability are recommended on a less frequent basis. These repeatability studies should allow the calculation of both inter- and intra-assessor variance components. Use of a Gait Reliability Profile in which these results are represented in a bar chart representing the variability in different gait variables is preferred. (Further information is available from Richard Baker's paper available on the website).
	4 Guideline thresholds for repeatability error (or rms error of a kinematic trace) are given below. It should be noted that the target threshold may vary between tests. a) Kinematic data — 5 degrees intra-assessor b) Kinematic data — 5-10 degrees inter-assessor c) Kinematic data — 2 degrees for processing (e.g. event detection) d) Clinical examination — 10-15 degrees depending on the test

Useful references on repeatability measurement:

Fosang AL, Galea MP, McCoy AT, Reddihough DS, Story I. Measures of muscle and joint performance in the lower limb of children with cerebral palsy. Dev Med. October 2003, vol./is. 45/10(664-70), 0012-1622.

Fosang A, Baker R. A method for comparing manual muscle strength measurements with joint moments when walking. Gait & Posture, Dec 2006,vol./is. 24/4(406-11), 0966-6362.

McDowell BC, Hewitt V, Nurse A, Weston T, Baker R. The variability of goniometric measurements in ambulatory children with spastic cerebral palsy. Gait & Posture, Oct 2000,vol./is. 12/2(114-21), 0966-6362

McWhirk LB, Glamzman AM. Within-session inter-rater reliability of goniomeric measures in patients with spastic cerebral palsy. Pediatric physical therapy, 2006, vol./is. 18/4(262-5), 0890-5669

Mutulu A, Livanelioglu A,Gunel MK. Reliability of goniometric measurements in children with spastic cerebral palsy. Medical science monitor: international medical journal of experimental and clinical research,July 2007, vol./is. 13/7(CR323-9), 1234-1010

McGinley, JL, Baker, RJ, Wolfe, R and Morris, ME. The reliability of three-dimensional kinematic gait measurements: A systematic review. Gait & Posture 2009, vol 29, p 360 – 369

Useful references for EMG repeatability:

French, H. P., Huang, X., Cummiskey, A., Meldrum, D. & Malone, A. 2015. Normalisation method can affect gluteus medius electromyography results during weight bearing exercises in people with hip osteoarthritis (OA): A case control study. *Gait Posture,* 41**,** 470-5.

Malone, A., Meldrum, D., Gleeson, J. & Bolger, C. 2011. Reliability of surface electromyography timing parameters in gait in cervical spondylotic myelopathy. *J Electromyogr Kinesiol,* 21**,** 1004-10.

Norcross, M. F., Blackburn, J. T. & Goerger, B. M. 2010. Reliability and interpretation of single leg stance and maximum voluntary isometric contraction methods of electromyography normalization. *J Electromyogr Kinesiol,* 20**,** 420-5.

2. Equipment

Clarification of Terminology

System Orientation: These are the tests described by the manufacturers. Laboratories should have copies of manufacturer's guidelines detailing requirements for system orientation.

System checks: These are simple tests, performed on a daily basis, to examine sample measures of system performance. They do not attempt to assess the whole system.

Calibration: These are more extensive checks that are carried out less regularly. Calibration tests should be performed at least every six months.

Mandatory	1 Each piece of equipment should have a separate log, including a) record of equipment manufacturer, make and model. b) software and version numbers c) manufacturer's contact details. d) storage location of manufacturer's operational guidelines. e) list of all the relevant data collection procedures
	2 All equipment classed as a medical device and manufactured after 1998 should be CE marked.
	3 Each laboratory should have access to simple calibration equipment e.g.: a) a set of calibrated weights to a minimum of 25kg to represent the weight of their patient population b) calibrated scales c) one metal pole with markers attached.
	4 Each laboratory should examine all their equipment and assess whether they should be calibrated. Simple measurement tools should be inspected annually for accuracy and, where appropriate, safety. A standard reference measure, for example a fixed rule, should be used to spot check tape measures.
For 3D systems	
Mandatory	5 System orientation checks, relevant to the tests to be performed, should be carried out every day **that the system is used**. Results for these should be recorded to allow association with the

	specific patient records from that day.
	6 All system-specific tests prescribed within the manufacturers' guidelines should be performed.
	7 **System checks undertaken each day the system is used** should verify the orientation and synchronisation of the 3D system with any other measurement systems e.g. force plates. A pole test, or equivalent, could be used for this (see reference list).
	8 Calibration should include:- a) The absolute position of static markers in capture volume b) The relative marker position in capture volume during a dynamic test e.g. the distance between fixed markers through the whole volume
Recommended	9 Dynamic testing of absolute marker position is included in the calibration testing e.g. use of a SAMSA type rig (see reference list)
For Force plates (including video vector)	
Mandatory	10 **System checks undertaken each day the system is used** should include placing at least 25kg onto the force plate to check the accuracy of the vertical force measurement.
	11 **System checks undertaken each day the system is used** should include a check of the orientation of the ground reaction vector in all three planes. A pole test, or equivalent, could be used for this (see reference list)
Recommended	12 Calibration is performed to verify the absolute magnitude of the force in all three directions (see reference list)
	13 Calibration is performed to verify the accuracy of the centre of pressure measurement.
	14 Calibration is performed to assess the magnitude of drift of a static load measurement over time.
2D/video camera system	
Mandatory	15 2D cameras should be positioned in fixed locations corresponding to the appropriate anatomical planes.
	16 Where video vector technology is used daily system checks should be performed to verify the synchronisation and relative orientation between the video and the force plates. A pole test could

	be used for this.
Electromyography	
Recommended	17 Testing should be performed to measure any time delay between the EMG signal capture and other measurement systems where synchronisation may not be precise.
	18 Testing should be performed to investigate the frequency response of the EMG system to ensure that the band width is appropriate for the frequency content of the signals being recorded.
	19 Every 6 months the EMG/data capture system is checked by capturing a reference signal of known characteristics (e.g. from a signal generator).
Pedobarography	
Recommended	20 Testing should be performed to confirm that pressure measurements are accurate and the response is linear.
	21 Testing should be performed to ensure all measuring cells produce the same response and are accurate to within an acceptable tolerance.

References:-

Pole test methods

Baker R. The "Poker" test: a spot check to confirm the accuracy of kinetic gait data. Gait Posture. 1997;5(2):177-8.

Collins SH, Adamczyk PG, Ferris DP, Kuo AD. A simple method for calibrating force plates and force treadmills using an instrumented pole. Gait Posture. 2009 Jan;29(1):59-64.

Della Croce U, Cappozzo A. A spot check for estimating stereophotogrammetric errors. Med Biol Eng Comput. 2000 May;38(3):260-6.

Holden JP, Selbie WS, Stanhope SJ. A proposed test to support the clinical movement analysis laboratory accreditation process. Gait Posture. 2003 Jun;17(3):205-13.

Lewis A, Stewart C, Postans N, Trevelyan J. Development of an instrumented pole test for use as a gait laboratory quality check. Gait Posture. 2007 Jul;26(2):317-22.

Rabuffetti M, Ferrarin M, Benvenuti F. Spot check of the calibrated force platform location. Med Biol Eng Comput. 2001 Nov;39(6):638-43.

Force Plate Calibration

Browne J, O'Hare N. A quality control procedure for force platforms. Physiol Meas. 2000 Nov;21(4):515-24.

Cappello A, Lenzi D, Chiari L. Periodical in-situ re-calibration of force platforms: a new method for the robust estimation of the calibration matrix. Med Biol Eng Comput. 2004 May;42(3):350-5.

Cedraro A, Cappello A, Chiari L. A portable system for in-situ re-calibration of force platforms: theoretical validation. Gait Posture. 2008 Oct;28(3):488-94.

Cedraro A, Cappello A, Chiari L. A portable system for in-situ re-calibration of force platforms: experimental validation. Gait Posture. 2009 Apr;29(3):449-53.

Fleming HE, Hall MG, Dolan MJ, Paul JP. Quality framework for force plate testing. Proc Inst Mech Eng H. 1997;211(3):213-9.

Gill HS, O'Connor JJ. A new testing rig for force platform calibration and accuracy tests. Gait Posture. 1997;5:228-32

Hall MG, Fleming HE, Dolan MJ, Millbank SF, Paul JP. Static in situ calibration of force plates. J Biomech. 1996 May;29(5):659-65.

SAMSA Test rig

http://www.gcmas.org/samsa

3. Environment	
Mandatory	1 Facilities to have access for disabled patients, in line with the statement of purpose. 2 Facilities to have controlled access for security purposes during patient assessment. 3 The examination couch to have a firm surface and adjustable height to allow access for examiner. 4 A minimum 7 metre walking space is necessary for gait data collection. 5 Room temperature should be between 21 and 28°C to be suitable for the partially dressed patient. (Laboratories should have a thermometer to monitor this) 6 The environment should be quiet and non-distracting. 7 A designated area should be provided where the patient can both change and be examined in privacy. 8 Patient toilet facilities, including toilet for the disabled, to be available. 9 Adequate seating facilities available for patient and families. 10 Staff hand washing facilities to be provided. 11 Floor surface to be clean, be non-slip and level, free from obstacles 12 Examination couch and covers should be clean.
Recommendations	1 CMAS strongly recommends 10 metre walkways for new facilities

STANDARD: Referral Management	
Mandatory	1 Each laboratory should have a clear, current Statement of Purpose, including a) Test facilities available (equipment) b) Clinical expertise c) Level of reporting (i.e. gait description only, clinical opinion, treatment recommendations) d) Any exclusions (patients)
	2 Referrals should only be accepted if they are in line with the Statement of Purpose.
	3 Each laboratory should have an information sheet to send to patients referred for gait analysis. This should include the CMAS web address to allow patients to read the Statement of Purpose.
	4 Laboratories should have a written protocol defining the patient journey including referral, appointment and reporting.

STANDARD: Data Collection	
Mandatory	1 For each type of test performed there should be a written protocol including, a) key equipment required b) laboratory preparation - including system orientation and system checks c) patient preparation (including clothing) d) placement of any markers or electrodes e) minimum data sets f) data checks to be performed before the patient leaves g) standard file names and formats h) storage location for patient data (electronic and paper records)
	2 For each type of test performed there should be a standard recording method. Information should include, a) results of system orientation / or system checks b) results of calibrations performed c) results of any verification tests involving patient d) comments on compliance/co-operation e) indication of whether gait pattern is typical f) conditions recorded under (e.g. barefoot, shoes, splints, walking aids) g) staff involved in data collection h) problems encountered during data collection

	3 For clinical examination a) The protocol should specify patient posture and measurement method (photographs/pictures are recommended) b) Clinical examinations should be performed within a month of the gait analysis if the results are to be interpreted with the data collected. c) Any clinical examination data collected outside the gait laboratory, for interpretation with the gait data, should be collected using the same protocol and recording format as used in the lab. Assessors should have had their repeatability verified and documented. d) Clinical examinations should be performed or supervised by a member of staff with registration with the HPCP, GMC or equivalent. *Recommendations:-* e) CMAS recognises the limitations of clinical examination measures of spasticity and recommends that these values are interpreted with caution. f) Assessments of neurological patients should include a method of assessing and recording selective motor control g) The examination/filming of a patient standing should be included in the clinical examination of patients undergoing a gait assessment.
	4 For video/video vector analysis a) Standard recording methods should exist for recording spot check results (see Equipment Standard).
	5 For force plates a) Standard recording methods should exist for recording spot check results (see Equipment Standard). b) The written protocol should state how patients are aligned to avoid targeting of the plates. c) Circumstances when this does not apply should be identified in the protocol.

	6 For 3D movement analysis systems a) Standard recording methods should exist for recording spot check results (see Equipment Standard). b) The protocol should define how to deal with known artefacts. c) Sample video should be collected with all data collection
	7 For EMG a) The laboratory must be able to justify their protocol for electrode placement (e.g. by reference to the literature). b) The data collection protocol must include: i) details of patient and electrode preparation and electrode cleaning. ii) details of foot switch placement (where used) iii) details of how the EMG signals are checked and verified. This should include, • Verification of the signal gain to maximise signal amplitude without amplifier saturation on systems with adjustable gain. • Inspection of raw EMG signals • Definition of how to deal with known artefacts • Detail of how the outcome of any checks is recorded. c) EMG signals from surface electrodes should be captured at a frequency greater than 800Hz and this should be specified in the protocol. d) Sample video should be collected with all data collection
	8 For Energy consumption
	9 For plantar pressure measurement
	10 For functional tests/questionnaires -Appropriate validated tests should be used wherever possible.
	11 For dynamometry

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STANDARD: Data and Report Management	
1. Data Processing	
Mandatory	1 A clear written protocol is required describing the processing method for each type of test performed. The protocol should specify, a) The software required and version number. b) Signal processing requirements (e.g. filtering) c) Other processing parameters d) Definition of an acceptable data trial (including reasons for excluding data trials at the processing stage) e) Artefact correction techniques f) Any secondary processing tools
	2 A standard recording method should be used to record processing a) The method should have space to report any problems/artefacts b) A signature box/approval method should be provided to confirm completeness of data before reviewing and reporting. c) The software version number should be recorded.
	3 For 3D gait data a) Interpolation parameters should be stated in the protocol. b) The protocol should state method for identifying gait cycle events (e.g. initial contact, toe off) c) Details should be given of any post-collection corrections (e.g. varus wave correction)
	4 For force plates

	5 For EMG a) Each lab should have a protocol detailing the requirements for processing EMG (e.g. filtering techniques used, gait timing identification) b) For any laboratory reporting processed EMG information, raw data must also be stored for future inspection.
	6 For Energy testing
	7 For Plantar pressure measurement
	8 For Dynamometry

2. Normal Data	
Mandatory	1 A normal database **collected locally** is required for all the measurements being taken within the scope of practice of the laboratory. (This should include relevant aspects of the clinical examination such as range of motion, bony torsion)
	2 Data should be collected in conditions according to the written protocols of the laboratory.
	3 The normal database should include at least 10 subjects.
	4 There should be a written policy for including subjects within the normal database (e.g. excluding those with certain pathologies, obesity, outliers)
	5 Averaged data for kinematic and kinetic curves for normal reference range to be displayed +/- 1SD (Any other preferred method of showing variation, which must clearly labelled.)
	6 Reference values collected locally, for example normal clinical examination data, should be expressed +/- 1SD; any other preferred method of showing variation must be clearly labelled.
	7 Each laboratory collecting EMG data must have its own normal EMG database covering the muscles examined.
	8 Normal data to be checked for validity against published results. This process **can be a visual comparison and** should be documented.*
	9 Normal database to be checked after minor changes to protocols or equipment (data from one unimpaired subject should be checked against previous database). A new normal database is required where marker placements/processing models are changed.
	10 Details of each normal database should be kept in a file containing, a) Details of all subjects including: age, sex, date & assessors. b) Storage location of raw data files c) Published normal datasets for comparison

	d) The protocol used e) A printout of the collated data, indicating variability
Recommendation	1 Separate databases should be compiled for different ages and genders. a) (see Sutherland/Ranchos Los Amigos)
	2 Data collection should be conducted at a range of self-selected walking speeds.
	3 Laboratories conducting plantar pressure measurements should consider pictorial and/or numerical normative examples to aid interpretation.

*References:-

Normal gait data

Pinzone, O., Schwartz, M.H., Thomason, P. & Baker, R. 2014. The comparison of normative reference data from different gait analysis services. *Gait Posture,* 40**,** 286-90.

DH Sutherland et al (1988) "The Development of Mature Walking", *Mac Keith Press, Oxford*

J Perry (1992) "Gait Analysis – Normal and Pathological Function", *SLACK Incorporated, NJ USA.*

Ranchos Los Amigos book

Plantar pressure measurement

Bowen, T. R., Miller, F., Castagno, P., Richards, J., And Lipton, G. A method of dynamic foot-pressure measurement for the evaluation of pediatric orthopaedic foot deformities. J Pediatr Orthop 18, 6 (1998), 789–93.

Ledoux, W. R., And Hillstrom, H. J. The distributed plantar vertical force of neutrally aligned and pes planus feet. Gait Posture 15, 1 (2002), 1–9.

Lord, M., Reynolds, D. P., And Hughes, J. R. Foot pressure measurement: A review of clinical findings. J Biomed Eng 8, 4 (1986), 283–94.

Menkveld, S. R., Knipstein, E. A., And Quinn, J. R. Analysis of gait patterns in normal school-aged children. J Pediatr Orthop 8, 3 (1988), 263–7.

Wearing, S. C., Urry, S. R., And Smeathers, J. E. Ground reaction forces at discrete sites of the foot derived from pressure plate measurements. Foot Ankle Int 22, 8 (2001), 653–61.

Zhu, H.,Wertsch, J. J., Harris, G. F., And Alba, H. M. Walking cadence effect on plantar pressures. Arch Phys Med Rehabil 76, 11 (1995), 1000–5

3. Interpretation of Data and Reporting	
Mandatory	1 A written protocol is required to define reporting practice. This should specify the standard content of a report and circulation lists.
	2 The reporting process should include a) relevant clinical history b) a consideration of the consistency of the patient's gait pattern, supported by data c) conditions under which data were collected (e.g. barefoot) d) patient compliance/cooperation e) comments on whether data are typical for the patient f) any problems or artefacts identified g) any corrections applied during data collection and processing
	3 The report should be signed and dated by those taking responsibility for content of report. An electronic signature is permissible.
	4 The report should be consistent with the Statement of Purpose for the laboratory.
	5 The report should present clear evidence from the data collected for any treatment recommendations.
	6 Values quoted should be compared with reference normal data.
	7 Graphs should be plotted against a normal database.
	8 The normal comparison group used should be identified.
	9 When the results from validated functional tests or questionnaires are stated, references should be included.
	10 CMAS recognises the usefulness of EMG in clinical decision making. It is mandatory that any definitive statements about the activity level/ timing of an individual muscle within a muscle group are supported by EMG recording.

	11	Graph **trial numbers must be traceable within the laboratory records and are recommended to be labelled in the report**. Graphs should be labelled with date, units and walking condition. For mean profiles and consistency graphs, traceability of trials should be evident (e.g. Trials 1-4 for Barefoot consistency).
	12	Copy of the full report (electronic, film or paper) to be kept in the laboratory (including all raw data, forms and graphs).
Recommendations	1	Local jargon and terminology should be avoided.

References:

Some ideas on impairment focused interpretation and reporting from Richard Baker are available from:

http://www.salford.ac.uk/health-sciences/research/research-programmes/gait-biomechanics/gait-analysis-downloads

STANDARD: Document Control		
Mandatory	1	Laboratory must have ready access to the latest version of the CMAS standards.
	2	The laboratory should have a list of all current protocols, clearly stating the **review** date, author and version number.
	3	The list should be signed by the head of department/service at each reissue of a protocol. The signature is then valid for two years, or until the protocol is replaced.
	4	Protocols should be readily available to all staff.
	5	The laboratory should have a list of all current recording forms/records, clearly stating the review date, author and version number.
	6	Blank forms should be readily available to all staff trained in their use.
	7	All protocols and recording forms should be reviewed every two years and the issue date updated accordingly.

	8 The laboratory should have a list of all the controlled storage locations, where current versions of any documentation can be found. Locations should be specified for, a) Local protocols b) Blank recording forms c) Completed recording forms e.g. patient notes, equipment/software logs, calibration results. d) Internal audit checklists. e) Internal and external audit reports 9 Controlled documents may be kept in paper or electronic format.
	10 All current documentation should be kept securely, with electronic documents kept under password and edit control and subject to backup procedures. 11 Copies must be kept of previous versions of all protocols and forms for at least 5 years after they are replaced.
	12 All completed patient records should have: a) Name, date, date of birth. b) Information to identify the patient and date of the assessment on each side of every page. c) All assessment documentation should include signature/initials (these can be electronic) to identify staff responsible for the data.

	13 Completion of forms: a) Standard forms may contain compulsory and optional sections if clearly indicated (e.g. highlight with **bold** or *italics*). b) Compulsory sections of standard forms must be completed in full. Where the data collection was impossible or inappropriate, compulsory fields should be struck through or marked as 'N/A'. c) Optional sections on standard forms should still be completed fully where appropriate but may be left blank where data collection was not required or inappropriate. d) Where no indications are given an entire form will be presumed compulsory. e) Patient responses on laboratory standard forms and other records originating outside the laboratory are excluded. f) Local clinical governance procedures may take precedence.
	14 All electronic patient data should be stored in a location which is supported by regular back up. 15 The time of storing data before archiving should be informed by local Information Governance procedures.
Recommendation	1 Printed documents should use a page numbering convention x/n, where x is the page number and n the total number of pages in the document, for example 2/7

STANDARD: Auditing the CMAS standards	
1. Management	a) The auditing of the CMAS standards will be overseen by the CMAS Standards and Accreditation Committee (SAC). b) The membership of CMAS SAC will be decided by the main CMAS committee. c) The activities of the CMAS SAC will be overseen by the main CMAS committee.
2. Auditors	a) A minimum of one internal auditor will be appointed by the laboratory itself. This person should be an appropriate professional but need not have experience of gait analysis. A second auditor will, however, be required if audits are performed by gait laboratory staff to prevent staff from auditing their own work. b) External auditors will be appointed by the CMAS SAC from another accredited gait laboratory. c) All auditors will have received guidance/training in audit from the CMAS SAC or another body where appropriate. d) All external auditors will be required to sign a confidentiality agreement before accessing patient records.
3. Audit method	a) External audits will be conducted using the checklists produced by CMAS. b) External audits will include an assessment of internal audit procedures. c) All boxes on the audit checklists should be completed. 'N/A' can be used at the discretion of the auditor. All areas of doubt should be referred to the CMAS SAC. d) The laboratories may use the same check lists for their internal audit. However, they are encouraged to expand the audit to cover local protocols in more detail.

4. Audit frequency	External audit: a) All the audit checklists will be subject to external audit at least once every two years. b) Under normal conditions external auditors will visit the laboratory twice in 2 years, as arranged by CMAS SAC. c) A laboratory with an established external and internal audit track record may apply to move to a 2-year external audit pattern. Acceptance is at the discretion of the CMAS SAC and will require the laboratory to submit internal audit records over the 2 year period. d) Consecutive external audits must be spaced by at least 6 months and no more than 2 years. e) The CMAS SAC can request additional external audits if there is any cause for concern. Internal audit: a) Internal audit will be performed at least 4 times in two years on a timetable drawn up by the laboratory. b) For laboratories on the 2-year external audit pattern, the internal audit timetable must be sent to CMAS SAC for reference (this should be provisionally agreed at the external audit and returned to CMAS SAC at this time). c) Consecutive internal audits must be spaced by at least a month. d) Internal auditors will cover all aspects of the laboratory's work over the 2 year cycle. (This means that a single audit need not cover everything. A laboratory could produce 4 checklists covering the whole process which are then used in rotation).

5. Audit Reporting	a) The results of any audit will be recorded and reported by the auditor. They will also be signed by the laboratory manager. b) All audit records will be kept for at least 5 years. c) Copies of internal audit reports will be held by the laboratory. d) For laboratories on the 2-year external audit pattern, copies of all internal audit reports must be sent to the CMAS SAC so that internal audit progress can be monitored. e) Copies of external audit reports will be sent to the CMAS SAC in order that accreditation can be renewed. f) At each external audit the auditor should discuss with the laboratory any changes required to the Statement of Purpose form.
6. Non-conformances	a) Problems or non-conformances raised at an audit will be documented and reported to laboratory staff by the auditor. The laboratory is then required to put a plan in place to deal with the problem with a realistic completion date agreed with the auditor. b) Progress of remedial actions to correct non-conformances should be monitored through the internal audit process with actions should be verified complete primarily by internal auditors. c) External audit should confirm this process is working correctly.

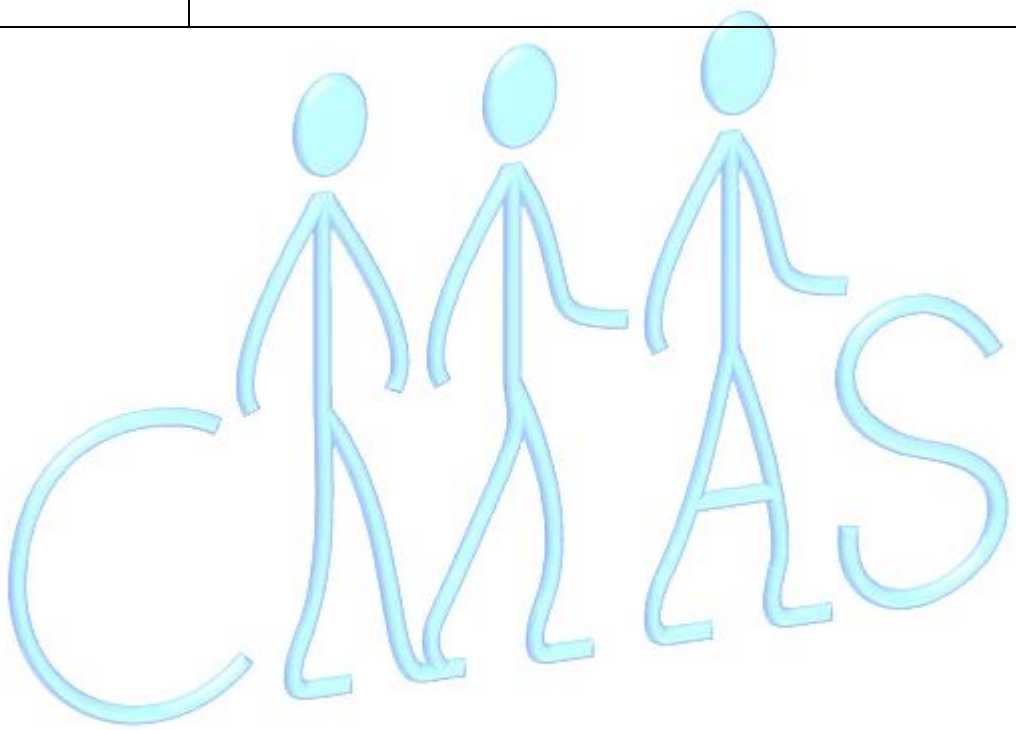
7. Dealing with problems	a) Both internal and external auditors will have direct access to the CMAS SAC if problems arise. b) If issues cannot be resolved by the CMAS SAC, the main CMAS committee may be contacted. c) An external audit will be deemed to have been failed if the laboratory has not dealt with the issues raised at the previous external audit. This will be classed as a major problem. d) All major problems will need to be discussed with the CMAS SAC. The implementation of the steps listed below will be managed by the CMAS SAC, and not by the individual external auditor. i) The laboratory will be required to put a plan in place to correct the failure within 6 months. At the end of that time a repeat external audit will be required at a charge of half the annual registration fee. ii) If the laboratory has still not dealt with the problem at the repeat audit then their accreditation will be suspended. iii) Restoration of a suspended accreditation will take two further external audits, covering the whole system. These will be charged at half the annual registration fee for each audit.

STANDARD: Accreditation to the CMAS standards	
1. Management	Accreditation will be overseen by the CMAS Standards and Accreditation committee.
2. Accreditation	Laboratories will be considered for accreditation after: a. A Statement of Purpose form has been completed and approved. b. Internal auditors have been appointed and trained and an internal audit mechanism is in place and functioning. c. Two successful external audits have been completed, at a spacing of at least 6 months, covering all the checklists. d. Receipt of the accreditation fee. Continued accreditation will only be considered after completion of successful external audit AND receipt of annual CMAS Standards accreditation fee. Full responsibility rests with the lab regarding payment of this fee. Accreditation is awarded to the laboratory on the basis of the Statement of Purpose form. After the initial submission, changes to the Statement of Purpose form will need to be approved by the external auditor, through the normal audit process. Laboratory accreditation will be considered to have lapsed 18 months after the most recent external audit. Two additional audits would then be required to restore the accreditation.
3. Dissemination	Accredited labs will receive a certificate from CMAS. A list of accredited labs will be made available through the CMAS website, along with the information contained in the Statement of Purpose form.

4. Changes to Statement of Purpose	Proposed significant changes to a laboratory's Statement of Purpose should be audited before acceptance, in particular introducing a new test or changing a reporting level. This is to ensure that appropriate steps are already in place; e.g. protocols, staff training, repeatability checks and normal data. A laboratory wishing to change its Statement of Purpose form should present the revised version at an external audit. The external auditor should then focus on the proposed changes as part of the audit.

Appendix 1: Required protocols	

	• A protocol defining the patient journey including referral, appointment and reporting.
	• For each type of test performed, protocols for:
	  • data collection
	  • data processing
	  • reporting practice
	• A normal data protocol.



Appendix 2: Required records	

	• A statement of purpose form for the laboratory.
	• Patient records.
	• A log containing details of all staff members and internal auditors.
	• A log containing details of all equipment.
	• A log containing details of all protocols and forms.
	• For each type of test performed there should be standard methods for:
	  • recording data collection.
	  • recording data processing.
	  • reporting.
	• Staff repeatability records for tests requiring clinical or technical judgement.
	• A normal database for tests.
	• Calibration or inspection records for key equipment.
	• External audit records.
	• Internal audit records.

Clinical Movement Analysis Society –

UK and Ireland

Statement of Purpose Form

Name of Laboratory	
Address	
Telephone number	
Email	
Website	

Please provide a brief description of your laboratory – history, location, etc. Also describe main activities – clinical/teaching/research (maximum 150 words).

Host Institution

NHS Trust	☐
University/Academic	☐
Private Company	☐
Other...(please specify)	

Named Staff

	Name	Email	Phone
Main contact			
Clinical Lead			
Technical Lead			

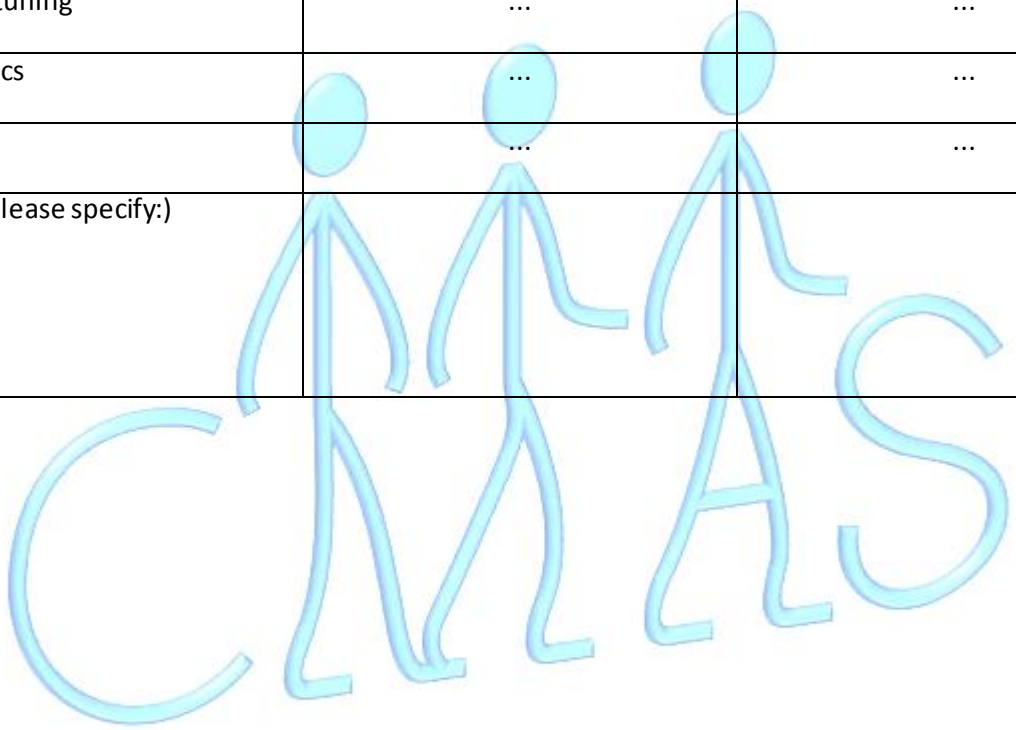
Staffing

	Employed by laboratory	***Available for consultation***
Orthopaedic Surgeon	☐	☐
Rehabilitation Consultant	☐	☐
Paediatrician	☐	☐
Neurologist	☐	☐
Physiotherapist	☐	☐
Sports Scientist	☐	☐
Bioengineer (Clin Sci)	☐	☐
Clinical Technologist	☐	☐
Orthotist	☐	☐
Prosthetist	☐	☐
Podiatrist	☐	☐
Others (please specify:) (use Enter to expand)	☐ ☐	☐ ☐

Clinical Expertise

- indicate a major interest in an area, minor interest or if you would not accept a referral (excluded)

	Adults	***Children***
Cerebral Palsy	...select	...select
Neuromuscular disorders	...	...
The Foot	...	...
Orthopaedics	...	...
Spinal injuries	...	...
Stroke	...	...
Orthotics	...	...
Orthotic tuning	...	...
Prosthetics	...	...
Sports	...	...
Others (please specify:)		



Testing Available

	Level of Reporting
Clinical exam	...select
Orthogonal video filming	...

Force plate	...
Video vector technology	...
3D movement analysis	...
Detailed foot movement analysis	...
Electromyography	...
Plantar pressure measurement - barefoot	...
Plantar pressure measurement – in shoe	...
Energy cost measurement (oxygen/HR)	...
Balance assessment	...
Upper limb assessment	...
Other (please specify:)	... ...