



**ELIGIBILITY REGULATIONS FOR THE FEMALE CLASSIFICATION
(ATHLETES WITH DIFFERENCES OF SEX DEVELOPMENT)**

(Published on 23 April 2018, coming into effect as from 1 November 2018)

In the case of queries regarding these regulations, please contact the IAAF Medical Manager (Doctor):

IAAF Medical Manager
Health and Science Department
International Association of Athletics Federations
6-8, Quai Antoine 1er, BP 359, MC 98007 Monaco Cedex
Email: medical.confidential@iaaf.org

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1. INTRODUCTION

1.1 The IAAF Council has approved the issue of these Regulations further to Competition Rule 141 to address the eligibility of athletes with differences of sex development to compete in the female category of competition in certain track events. These Regulations reflect the following imperatives:

- (a) To ensure fair and meaningful competition in the sport of athletics, competition has to be organised within categories that create a level playing field and ensure that success is determined by talent, dedication, hard work, and the other values and characteristics that the sport embodies and celebrates. In particular:
 - (i) The IAAF wants athletes to be incentivised to make the huge commitment and sacrifice required to excel in the sport, and so to inspire new generations to join the sport and aspire to the same excellence. It does not want to risk discouraging those aspirations by having unfair competition conditions that deny athletes a fair opportunity to succeed.
 - (ii) Because of the significant advantages in size, strength and power enjoyed (on average) by men over women from puberty onwards, due in large part to men's much higher levels of circulating testosterone,¹ and the impact that such advantages can have on sporting performance, it is generally accepted that competition between male and female athletes would not be fair and meaningful, and would risk discouraging women from participation in the sport. Therefore, in addition to separate competition categories based on age, the IAAF has also created separate competition categories for male and female athletes.
- (b) The IAAF also recognises, however, that:
 - (i) Biological sex is an umbrella term that includes distinct aspects of chromosomal, gonadal, hormonal and phenotypic sex, each of which is fixed and all of which are usually aligned into the conventional male and female binary.
 - (ii) However, some individuals have congenital conditions that cause atypical development of their chromosomal, gonadal, and/or anatomic sex (known as differences of sex development, or **DSDs**, and sometimes referred to as 'intersex').
 - (iii) As a result, some national legal systems now recognise legal sexes other than simply male and female (for example, 'intersex', 'X', or 'other').
- (c) The IAAF respects the dignity of all individuals, including individuals with DSDs. It also wishes the sport of athletics to be as inclusive as possible, and to encourage and provide a clear path to participation in the sport for all. The IAAF therefore seeks to place conditions on such participation only to the extent necessary to ensure fair and meaningful competition. As a result, the IAAF has issued these Regulations, to facilitate the participation in the sport of athletes with DSDs.

- (d) There is a broad medical and scientific consensus,² supported by peer-reviewed data and evidence from the field,³ that the high levels of endogenous testosterone circulating in athletes with certain DSDs can significantly enhance their sporting performance. These Regulations accordingly permit such athletes to compete in the female classification in the events that currently appear to be most clearly affected only if they meet the Eligibility Conditions defined below.
- (e) These Regulations exist solely to ensure fair and meaningful competition within the female classification, for the benefit of the broad class of female athletes. In no way are they intended as any kind of judgement on or questioning of the sex or the gender identity of any athlete. To the contrary, the IAAF regards it as essential to respect and preserve the dignity and privacy of athletes with DSDs, and therefore all cases arising under these Regulations must be handled and resolved in a fair, consistent and confidential manner, recognising the sensitive nature of such matters. Any breach of confidentiality, improper discrimination, and/or stigmatisation on grounds of sex or gender identity will amount to a serious breach of the IAAF Integrity Code of Conduct and will result in appropriate disciplinary action against the offending party.
- 1.2 These Regulations operate globally, regulating the conditions for participation in Restricted Events at International Competitions. As such, the Regulations are to be interpreted and applied not by reference to national or local laws, but rather as an independent and autonomous text, and in a manner that protects and advances the imperatives identified above. In the event that an issue arises that is not foreseen in these Regulations, it shall be addressed in the same manner.
- 1.3 All cases arising under these Regulations will be dealt with by the IAAF Health and Science Department, and not by the National Federation of the athlete concerned, or by any other athletics body, whether or not the athlete concerned has yet competed in an International Competition. Each National Federation is bound by these Regulations and is required to cooperate with and support the IAAF in the application and enforcement of these Regulations, and to observe strictly the confidentiality obligations set out below.
- 1.4 These Regulations will come into effect on 1 November 2018, and will apply both to cases that arose prior to that date and to cases arising after that date. They are binding on and must be complied with by athletes, National Federations, Areas, Athlete Representatives, Member Federation Officials, and all other Applicable Persons. They will be subject to periodic review, and may be amended with the approval of the IAAF Council from time to time following such review to take account of any new evidence and/or relevant scientific or medical developments.
- 1.5 Defined words and defined terms used in these Regulations (starting with capital letters) have the meaning given to them in Appendix 1 to these Regulations, or (if not listed in Appendix 1) have the meaning given to them in the IAAF Constitution and/or the IAAF Competition Rules.

2. SPECIAL ELIGIBILITY REQUIREMENTS FOR RESTRICTED EVENTS AT INTERNATIONAL COMPETITIONS

- 2.1 The special eligibility requirements set out in clause 2.3, below, apply only to participation by a Relevant Athlete in the female classification in a Restricted Event at an International Competition. They do not apply to any other athletes, or to any other events, or to any other

competitions (although if a Relevant Athlete does not meet the Eligibility Conditions then she will not be eligible to set a World Record in a Restricted Event at a competition that is not an International Competition).

2.2 For these purposes:

- (a) A **Relevant Athlete** is an athlete who meets each of the following three criteria:
- (i) she has one of the following DSDs:
 - (A) 5 α -reductase type 2 deficiency;
 - (B) partial androgen insensitivity syndrome (PAIS);
 - (C) 17 β -hydroxysteroid dehydrogenase type 3 (17 β -HSD3) deficiency;
 - (D) congenital adrenal hyperplasia;
 - (E) 3 β -hydroxysteroid dehydrogenase deficiency;
 - (F) ovotesticular DSD; or
 - (G) any other genetic disorder involving disordered gonadal steroidogenesis;⁴
and
 - (ii) as a result, she has circulating testosterone levels in blood of five (5) nmol/L or above;⁵ and
 - (iii) she has sufficient androgen sensitivity for those levels of testosterone to have a material androgenising effect.⁶
- (b) **Restricted Events** are 400m races, 400m hurdles races, 800m races, 1500m races, one mile races, and all other Track Events over distances between 400m and one mile (inclusive), whether run alone or as part of a relay event or a Combined Event.

2.3 To be eligible to compete in the female classification in a Restricted Event at an International Competition, or to set a World Record in a competition that is not an International Competition, a Relevant Athlete must meet each of the following conditions (the **Eligibility Conditions**):

- (a) she must be recognised at law⁷ either as female or as intersex (or equivalent);
- (b) she must reduce her blood testosterone level to below five (5) nmol/L⁸ for a continuous period of at least six months (e.g., by use of hormonal contraceptives); and
- (c) thereafter she must maintain her blood testosterone level below five (5) nmol/L continuously (i.e., whether she is in competition or out of competition) for so long as she wishes to maintain eligibility to compete in the female classification in Restricted Events at International Competitions (or to set a World Record in a Restricted Event at a competition that is not an International Competition).

2.4 For the avoidance of doubt, there are no other special conditions that a Relevant Athlete must

satisfy in order to participate in the female classification in a Restricted Event at an International Competition (or to set a World Record in a Restricted Event at a competition that is not an International Competition).⁹ In particular, surgical anatomical changes are not required in any circumstances.

- 2.5 For the avoidance of doubt, no athlete will be forced to undergo any assessment and/or treatment under these Regulations. It is the athlete's responsibility, in close consultation with her medical team, to decide whether or not to proceed with any assessment and/or treatment.
- 2.6 A Relevant Athlete who does not meet the Eligibility Conditions (and any athlete who is asked by the IAAF Medical Manager to submit to assessment under these Regulations and fails or refuses to do so) will not be eligible to compete in the female classification in a Restricted Event at an International Competition (or to set a World Record in a Restricted Event at a competition that is not an International Competition). However, that athlete will be eligible to compete:
- (a) in the female classification:
 - (i) at competitions that are not International Competitions: in all Track Events, Field Events, and Combined Events, including the Restricted Events; and
 - (ii) at International Competitions: in all Track Events, Field Events, and Combined Events, other than the Restricted Events; or
 - (b) in the male classification, at all competitions (whether International Competitions or otherwise), in all Track Events, Field Events, and Combined Events, including the Restricted Events; or
 - (c) in any applicable intersex or similar classification that may be offered, at all competitions (whether International Competitions or otherwise), in all Track Events, Field Events, and Combined Events, including the Restricted Events.

3. ASSESSMENT OF CASES

3A. Opening a case

- 3.1 An athlete who is or believes that she may be a Relevant Athlete must advise the IAAF Medical Manager if she wishes to compete in the female classification in a Restricted Event at an International Competition, so that her case may be assessed in accordance with these Regulations. Her National Federation has the same obligation. She must do so as far in advance of the International Competition in question as possible (at least three months prior to the final entry date), and must provide the necessary information (or cooperate in the collection of the necessary information) and submit to the assessment described below to determine whether she is a Relevant Athlete and (if so) to demonstrate her satisfaction of the Eligibility Conditions.
- 3.2 In addition, the IAAF Medical Manager may investigate at any time (including, without limitation, through analysis of blood and/or urine samples collected from athletes who are competing or entered to compete in the female classification in a Restricted Event at an International Competition) whether any athlete who has not advised the IAAF Medical Manager in accordance with clause 3.1 may be a Relevant Athlete whose case requires assessment under these Regulations. The Relevant Athlete agrees to provide samples for this purpose, and also

agrees that any samples that she provides or has previously provided for anti-doping purposes and/or any anti-doping data relating to her may also be used for this purpose.

- 3.3 Only the IAAF Medical Manager may initiate an investigation under clause 3.2, and he/she may only do so when acting in good faith and on reasonable grounds based on information derived from reliable sources, such as (for example, but without limitation) the athlete herself, the team doctor of the National Federation to which the athlete is affiliated, results from a routine pre-participation health examination, and/or information/data (including but not limited to blood testosterone levels) obtained from the collection and analysis of samples for anti-doping purposes.
- 3.4 The dignity and privacy of every individual must be respected at all times. All breaches of confidentiality and all forms of abuse and/or harassment are prohibited. Such conduct will be considered a serious breach of the IAAF Integrity Code of Conduct and will be subject to sanction accordingly. In particular (but without limitation):
- (a) Any person or entity (including, without limitation, any other athlete and any Member Federation Official or other Applicable Person) that provides information to the IAAF Medical Manager for consideration under these Regulations is under a strict obligation:
 - (i) to ensure that the information is accurate and complete; and
 - (ii) not to provide any information in bad faith, to harass, stigmatise or otherwise injure an athlete, or for any other improper purpose.
 - (b) No stigmatisation or improper discrimination on grounds of sex or gender identity will be tolerated. In particular (but without limitation), persecution or campaigns against athletes simply on the basis that their appearance does not conform to gender stereotypes are unacceptable.
- 3.5 Each case will be investigated/assessed as quickly as is reasonably practicable in all of the circumstances. However, in no circumstance will the IAAF or the IAAF Medical Manager or any member of the Expert Panel be liable for any detriment allegedly suffered by the athlete or anyone else as a result of the length of time taken to complete the assessment. An athlete whose case is being investigated/assessed by the IAAF Medical Manager and/or the Expert Panel under these Regulations must cooperate fully and in good faith with the investigation/assessment (including, without limitation, by providing blood and/or urine samples upon request for analysis, and if needed, by submitting to medical physical examination), so that it can be completed as efficiently and quickly as possible. If in the IAAF Medical Manager's view the athlete fails to cooperate fully and in good faith, she may be declared ineligible to compete in the female classification in Restricted Events at International Competitions and to set a World Record in a Restricted Event at a competition that is not an International Competition pending satisfactory completion of the investigation/assessment.

3B. Appointment of athlete ombudsman

- 3.6 The IAAF Medical Manager and an athlete whose case arises for investigation and/or assessment under these Regulations (or her representative) may agree on the appointment of an independent ombudsman to assist the athlete in understanding and addressing the requirements of the Regulations.

3C. Case assessment

- 3.7 The IAAF Medical Manager will appoint a pool of independent medical experts from which a suitably qualified panel of experts (the **Expert Panel**) may be formed to review cases under these Regulations as they arise. It will appoint one of those experts to act as chair. The chair and other independent medical experts appointed by the IAAF to this pool as of the date of entry into force of these Regulations are identified in Appendix 2 to these Regulations.
- 3.8 The case will be assessed in accordance with the guidelines set out in Appendix 3 to these Regulations. The standard procedure may be summarised as follows:
- (a) There will be an initial assessment by a suitably qualified physician, involving an initial clinical examination of the athlete, and compilation of her clinical and anamnestic data, as well as a preliminary endocrine assessment.
 - (b) If it appears the athlete may be a Relevant Athlete, the IAAF Medical Manager will then anonymise the file and send it to the chair, who will convene an Expert Panel to determine whether further assessment is warranted as to whether the athlete is a Relevant Athlete.
 - (c) If the Expert Panel considers that further assessment is warranted, the athlete will then be referred to one of the specialist reference centres listed at Appendix 4 to these Regulations for further assessment, in order to reach a diagnosis of the cause of the athlete's elevated levels of blood testosterone, and to consider further the degree of the athlete's androgen insensitivity (if any).
 - (d) The report of the specialist reference centre will then be sent back to the Expert Panel for consideration.
- 3.9 The Expert Panel will review the report of the specialist reference centre along with the rest of the file, and will then send its recommendation in writing to the IAAF Medical Manager, who will forward it to the athlete (with a copy to the athlete's physician and the athlete ombudsman, if any):
- (a) If the Expert Panel considers that the athlete is a Relevant Athlete but that she has not (yet) met the Eligibility Conditions, it must explain in writing the reasons for its view. It should also specify what else the athlete must do to satisfy the Eligibility Conditions, should she wish to do so. In such a case, it will recommend that the athlete not be declared eligible to compete in the female classification in Restricted Events at International Competitions unless and until the IAAF Medical Manager decides that she has done what the Expert Panel considered remained necessary to satisfy the Eligibility Conditions.
 - (b) If the Expert Panel considers that the athlete is not a Relevant Athlete, or that she is a Relevant Athlete but that she has met the Eligibility Conditions, it will recommend that the IAAF Medical Manager confirm in writing to the athlete that she is eligible to compete in the female classification in Restricted Events at International Competitions (in the latter case, for so long as she continues to satisfy the Eligibility Conditions).

- 3.10 The IAAF Medical Manager's decision to adopt or not adopt any Expert Panel recommendation on behalf of the IAAF will be final and binding on all parties. It may only be challenged/appealed in accordance with clause 5.

3D. Continuing compliance

- 3.11 A Relevant Athlete will be solely responsible for continuing to comply with the Eligibility Conditions for as long as she wishes to compete in the female classification in a Restricted Event at International Competitions.

- 3.12 As part of its recommendation, the Expert Panel may specify particular means (e.g., further monitoring and/or reporting) to be used to enable a Relevant Athlete to demonstrate her continuing compliance with the Eligibility Conditions. In any event, unless and until a Relevant Athlete declares that she no longer wishes to be eligible to compete in the female classification in Restricted Events at International Competitions, the IAAF Medical Manager:

- (a) may require her to produce specific evidence of her continuing satisfaction of the Eligibility Conditions, such as laboratory reports (obtained by her personal physician) of the testosterone levels in blood samples collected from her periodically;
- (b) may monitor her continuing satisfaction of the Eligibility Conditions at any time, with or without notice, by any appropriate means, including (without limitation) by having samples of the athlete's blood (an 'A' sample and a 'B' reserve sample) collected and transported to an appropriate laboratory to determine her blood testosterone levels. The Relevant Athlete agrees to provide samples for this purpose, and also agrees that any samples that she provides for anti-doping purposes and/or any anti-doping data relating to her may also be used for this purpose;
- (c) may consult with the chair of the Expert Panel at any stage during this process as he/she considers necessary; and
- (d) may, if circumstances warrant, refer the Relevant Athlete back to the Expert Panel for further assessment.

- 3.13 If any of the following occurs:

- (a) the athlete refuses or fails to provide the evidence of her continuing satisfaction of the Eligibility Conditions requested by the IAAF Medical Manager;
- (b) the athlete refuses or fails to submit to the testing and/or other monitoring of her continuing satisfaction of the Eligibility Conditions that is directed by the IAAF Medical Manager; or
- (c) it is determined by the IAAF Medical Manager (following consultation with the chair of the Expert Panel, if necessary) that the athlete has failed to maintain her circulating blood testosterone levels continuously at a concentration of less than five (5) nmol/L;

then the athlete will not be eligible to compete in the female classification in a Restricted Event at an International Competition or to set a World Record in a Restricted Event at a competition that is not an International Competition until she demonstrates to the satisfaction of the IAAF

Medical Manager (in consultation with the chair of the Expert Panel, if necessary) that she is satisfying the Eligibility Conditions again, and in particular that she has maintained her circulating levels of blood testosterone below five (5) nmol/L for a new continuous period of at least six months.

- 3.14 If it is determined at any time that a Relevant Athlete has competed in the female classification in one or more Restricted Events at an International Competition while having blood testosterone levels of five (5) nmol/L or more, or that she set a World Record in a Restricted Event at a competition that is not an International Competition while having blood testosterone levels of five (5) nmol/L or more, then (without prejudice to any other action that may be taken) the IAAF may in its absolute discretion disqualify the individual results obtained by the athlete in such Restricted Events at that competition, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results.

3E. Costs

- 3.15 The IAAF will bear the costs of assessment and diagnosis of the athlete under these Regulations (including the standing costs of the Expert Panel and all costs of the doctors and experts involved in such assessment and diagnosis), as well as any costs incurred further to clause 3.12(b).
- 3.16 The athlete will bear the costs of her personal physician(s) and of any treatment prescribed for her by her personal physician(s), including any treatment required to satisfy the Eligibility Conditions, as well as the costs of providing the evidence of continuing satisfaction of the Eligibility Conditions requested by the IAAF Medical Manager in accordance with clause 3.12(a).
- 3.17 To ensure the independence of any athlete ombudsman appointed in accordance with clause 3.6, the IAAF and the athlete will share the costs of the athlete ombudsman equally.

3F. Athlete consent

- 3.18 Any athlete who wishes to compete in the female classification in a Restricted Event at an International Competition and/or to be eligible to set a World Record in a Restricted Event at a competition that is not an International Competition agrees, as a condition to such participation/eligibility:
- (a) to comply in full with these Regulations;
 - (b) to cooperate promptly and in good faith with the IAAF Medical Manager and the Expert Panel in the discharge of their respective responsibilities under these Regulations, including (without limitation):
 - (i) providing them with all of the information and evidence they request to determine whether she is a Relevant Athlete and (if so) to assess her compliance and to monitor her continuing compliance with the Eligibility Conditions, including (without limitation) submitting to testing in accordance with these Regulations;
 - (ii) ensuring that all information and evidence provided is accurate and complete, and that nothing relevant is withheld;

- (iii) providing appropriate consents and waivers (in a form satisfactory to the IAAF Medical Manager) to enable her physician(s) to disclose to the IAAF Medical Manager and the Expert Panel any information that the Expert Panel deems necessary to its assessment;
 - (c) (to the fullest extent permitted and required under all applicable data protection and other laws) to the collection, processing, disclosure and use of information (including sensitive personal information) as required to implement and apply these Regulations effectively and efficiently; and
 - (d) to follow the procedures set out in clause 5 to challenge these Regulations and/or to appeal decisions made under these Regulations, and not to bring any proceedings in any court or other forum that are inconsistent with that clause.
- 3.19 Upon request by the IAAF, the athlete will provide written confirmation of her agreement to the matters set out in clause 3.18, in such form as may be requested by the IAAF from time to time. However her agreement will be effective and binding upon her whether or not confirmed in writing.

4. CONFIDENTIALITY

- 4.1 All cases arising under these Regulations, and in particular all athlete information provided to the IAAF under these Regulations, and all results of investigations, examinations and assessments conducted under these Regulations, will be dealt with in strict confidence at all times. All medical information and data relating to an athlete will be treated as sensitive personal information and the IAAF Medical Manager will ensure at all times that it is processed as such in accordance with applicable data protection and privacy laws. Such information will not be used for any purpose not contemplated in these Regulations, and will not be disclosed to any third party save (a) as is strictly necessary for the effective application and enforcement of these Regulations; or (b) as is required by law.
- 4.2 The IAAF will not comment publicly on the specific facts of a case arising under these Regulations except in response to public comments made by the athlete or the athlete's representatives.
- 4.3 Each member of the Expert Panel will sign an appropriate conflict of interest declaration and confidentiality undertaking in relation to his/her work as a member of the panel.

5. DISPUTE RESOLUTION

- 5.1 Any breach of these Regulations by a National Federation or Area will be addressed in accordance with the relevant provisions in the IAAF Constitution. Any other breach of these Regulations amounts to a breach of the IAAF Integrity Code of Conduct and will accordingly be subject to investigation by the Athletics Integrity Unit under the IAAF Athletics Integrity Unit Reporting, Investigation and Prosecution Rules (Non-Doping) and possible prosecution before the IAAF Disciplinary Tribunal in accordance with the IAAF Disciplinary Tribunal Rules.
- 5.2 Any dispute arising between the IAAF and an affected athlete (and/or her Member Federation) in connection with these Regulations will be subject to the exclusive jurisdiction of the CAS. In

particular (but without limitation), the validity, legality and/or proper interpretation or application of the Regulations may only be challenged (a) by way of ordinary proceedings filed before the CAS; and/or (b) as part of an appeal to the CAS made pursuant to clause 5.3.

- 5.3 The affected athlete may appeal the following decisions (and only the following decisions) made under these Regulations to the CAS, in accordance with this clause 5, by filing a Statement of Appeal with the CAS and with the IAAF within thirty days of the date of communication of the written reasons for the decision (and the IAAF will be the respondent to the appeal):
- (a) a decision that an athlete is a Relevant Athlete who does not satisfy the Eligibility Conditions and so is not eligible to compete in the female classification in a Restricted Event at an International Competition or to set a World Record in a Restricted Event at a competition that is not an International Competition;
 - (b) a decision that an athlete who is asked by the IAAF Medical Manager to submit to assessment under these Regulations and fails or refuses to do so (or fails to cooperate fully and in good faith the investigation/assessment under these Regulations) is not eligible to compete in the female classification in a Restricted Event at an International Competition or to set a World Record in a Restricted Event at a competition that is not an International Competition;
 - (c) a decision that a Relevant Athlete has failed to continue to satisfy the Eligibility Conditions, with the consequences set out in clause 3.13; and
 - (d) a decision to disqualify results further to clause 3.14.
- 5.4 The CAS will hear and determine the dispute or appeal definitively in accordance with the relevant provisions of the CAS Code of Sports-Related Arbitration, provided that in any appeal the athlete will have fifteen days from the filing of the Statement of Appeal to file his/her Appeal Brief, and the IAAF will have thirty days from its receipt of the Appeal Brief to file its Answer. The law governing the dispute or appeal will be the IAAF Constitution and the IAAF Rules and Regulations (including these Regulations), with the laws of Monaco applying subsidiarily, and in the case of any conflict between any of the above instruments and the CAS Code currently in force, the above instruments will take precedence. The proceedings before the CAS will be conducted in English, unless the parties agree otherwise. Pending determination of the dispute or appeal by the CAS, the Regulations and the decision under appeal will remain in full force and effect unless the CAS orders otherwise.
- 5.5 The decision of the CAS will be final and binding on all parties, and no right of appeal will lie from that decision. All parties waive irrevocably any right to any form of appeal, review or recourse by or in any court or judicial authority in respect of such decision, insofar as such waiver may be validly made.

APPENDIX 1 - DEFINITIONS

A1. Capitalised terms used in these Regulations have the following meanings:

Applicable Persons has the meaning given to it in the Integrity Code of Conduct.

CAS means the Court of Arbitration for Sport in Lausanne, Switzerland.

Differences of sex development (or DSDs) has the meaning given to that term in clause 1.1(b)(i).

Eligibility Conditions has the meaning given to that term in clause 2.3.

Expert Panel has the meaning given to that term in clause 3.7.

IAAF Competition Rules means the rules of competition of the IAAF, as amended from time to time. The current version is available at www.iaaf.org/about-iaaf/documents/rules-regulations.

IAAF Integrity Code of Conduct means the IAAF Integrity Code of Conduct, as amended from time to time. The current version is available at www.iaaf.org/about-iaaf/documents/rules-regulations.

IAAF Medical Manager means a medically qualified person within the IAAF Health and Science Department who is appointed by the IAAF to act on its behalf in matters arising under these Regulations or (in the absence of the IAAF Medical Manager) his/her nominee.

Regulations means these regulations setting out eligibility requirements for the female classification, as amended from time to time.

Relevant Athlete has the meaning given to that term in clause 2.2.

Restricted Events has the meaning given to that term in clause 2.2.

A.2 References to provisions of the Constitution or of any IAAF rules or regulations shall be deemed to include references to any successor provisions thereto as may be issued after the Effective Date.

APPENDIX 2 - LIST OF MEDICAL EXPERTS

	Name	Area of expertise
1	Prof. Martin Ritzen (SWE) (chair)	Pediatrics/endocrinology
2	Prof. Peter Lee (USA)	Pediatrics/endocrinology
3	Prof. Berenice Mendonca (BRA)	Endocrinology/genetics
4	Prof. Tsutomu Ogata (JAP)	Genetics
5	Prof. Zi-Jiang Chen (CHN)	Gynecology/polycystic ovary syndrome
6	Prof. George Werther/Prof. Jeffrey D. Zajac (AUS)	Pediatrics/endocrinology
7	Prof. Patrick Fenichel (FRA)	Gynecology/endocrinology
8	Prof. Angelica Lindén Hirschberg (SWE)	Gynecology/endocrinology
9	Prof. Myron Genel (USA)	Pediatrics/endocrinology
10	Prof. Ieuan Hughes (UK)	Pediatrics/endocrinology
11	Prof. Joe Leigh Simpson (USA)	Genetics/obstetrics/gynecology
12	Prof. Peggy Cohen-Kettenis (NED)	Psychology
13	Dr. Rinus Wiersma (RSA)	Pediatrics/surgery
14	Prof. Maria New (USA)	Pediatrics/genetics
15	Prof. David Handelsman (AUS)	Endocrinology/andrology

APPENDIX 3 - FRAMEWORK FOR ASSESSMENT OF CASES

1. This Appendix sets out an overall framework for the assessment of cases arising under the Regulations. The specific procedure to be adopted in each case will depend on the nature, timing and/or complexity of the case. For example, depending on the circumstances of the case, the Level 1 and Level 2 Assessments may be performed together, or the athlete may be referred directly to the Level 3 Assessment.

Level 1 Assessment – initial clinical examination and compilation of data and preliminary endocrine assessment

2. When a case first arises for assessment under the Regulations, the first step will normally be an initial clinical examination of the athlete and compilation of her clinical and anamnestic data, together with a preliminary endocrine assessment (together, the **Level 1 Assessment**), in order to (i) confirm that the athlete's blood testosterone level is 5 nmol/L or greater; (ii) gather information to assist in diagnosing the cause of her elevated level of blood testosterone; and (iii) gather information to assist in assessing whether the athlete is androgen insensitive (and, if so, to what degree).
3. To the extent that such information has already been gathered by the athlete's own physician, and is provided by that physician (having obtained the athlete's informed consent) to the IAAF Medical Manager for use in assessing the athlete's case under the Regulations, the IAAF Medical Manager will not repeat the process but will rely on that information, provided it appears adequate and reliable.
4. If not all of the necessary information has been gathered, however, the IAAF Medical Manager will refer the athlete to an appropriate examining physician, who should be a gynaecologist, endocrinologist or pediatrician with extensive experience of DSDs and other conditions leading to female hyperandrogenism. The examining physician should be familiar with the relevant literature, including (1) *American Association of Clinical Endocrinologists – medical guidelines for clinical practice for the diagnosis and treatment of hyperandrogenic disorders*, Goodman et al, *Endocrine Practice* 2001 Mar-Apr;7(2):120-34; (2) Lee et al, *Consensus Statement on Management of Intersex Disorders*, International Consensus Conference on Intersex, Pediatrics 2006; 118:E488-E500; and (3) Lee et al, *Global Disorders of Sex Development, Update since 2006: Perceptions, Approach and Care*, *Horm Res Paediatr* 2016;85:158-180.
5. Prior to conducting the Level 1 Assessment, the examining physician will explain to the athlete the purpose of the assessment, the nature of the testing to be conducted, and the potential consequences both for the athlete's health and for her eligibility under the Regulations. Where the athlete is a minor, the examining physician will provide such explanation to the athlete's parents or legal guardian(s). The examining physician will satisfy him/herself that the fully informed consent of the athlete (or athlete's parents or legal guardian(s), where the athlete is a minor) has been obtained before starting the Level 1 Assessment.
6. The athlete (or athlete's parents or legal guardian(s), where the athlete is a minor) will designate a physician to be the recipient of the results of the Level 1 Assessment on her behalf.
7. The examining physician will then take a full medical history and conduct a careful clinical examination of the athlete designed to ensure accurate assessment and diagnosis. The examining physician will assess the athlete in particular for clinical features associated with

pronounced and chronic cases of female hyperandrogenism. The IAAF Medical Manager may provide a check-list to assist in the collection of all potentially relevant information.

8. For the preliminary endocrine assessment, urine and blood (serum) samples will be collected from the athlete under conditions prescribed by the IAAF Medical Manager, for analysis by a laboratory approved by the IAAF.
 - (a) The laboratory will analyse the athlete's urine for at least the following hormones and their urinary metabolites: testosterone, epitestosterone, androsterone, etiocholanolone, 5 α -androstenediol, 5 β -androstenediol, dihydrotestosterone and dehydroepiandrosterone sulphate.¹⁰
 - (b) The laboratory will analyse the athlete's blood (serum) to determine the concentration of testosterone.¹¹
 - (c) Depending on the circumstances of the case, to assist with diagnosis the IAAF Medical Manager may also decide to have the athlete's blood analysed for additional hormones/substances, including but not limited to dihydrotestosterone, luteinizing hormone, follicle-stimulating hormone, estradiol, prolactin, anti-mullerian hormone, inhibin B, 17-OH-Progesterone, dehydroepiandrosterone sulfate, delta 4 androstenedione, and/or sex hormone-binding globulin.
9. The laboratory's reports of the results of the above analyses, the report of the examining physician in respect of the initial clinical examination of the athlete, and the clinical and anamnestic data compiled, will be transmitted confidentially to the athlete's designated physician and to the IAAF Medical Manager.
10. The IAAF Medical Manager will review the results of the Level 1 Assessment to decide whether there is sufficient information for the Expert Panel to carry out the Level 2 Assessment. As part of this review, the IAAF Medical Manager may:
 - (a) arrange for the collection and analysis of one or more further urine and/or blood samples from the athlete to exclude the possibility that the athlete's results are the consequence of an exogenous administration of androgens;
 - (b) arrange for the collection and analysis of further blood and/or urine samples from the athlete in order to confirm the results obtained from the preliminary endocrine assessment and/or as an additional tool for diagnosis; and/or
 - (c) seek an advisory opinion on a confidential basis from such person(s) as he/she considers appropriate.

Level 2 Assessment – assessment by an Expert Panel

11. Once the necessary information has been gathered and a blood testosterone concentration above 5 nmol/L has been confirmed, the IAAF Medical Manager will send the file (in anonymised form) to the chair of the Expert Panel,¹² who will either review the case alone or choose at least three experts (which may include him/herself) from the list at Appendix 2 to review the case. A person may not sit on the Expert Panel for the case if he/she was involved in any prior medical examination of the athlete.
12. The Expert Panel (whether one person or more) will review the athlete's file to determine whether further investigation is warranted as to whether the athlete meets the following criteria (and so is to be considered a 'Relevant Athlete' for purposes of the Regulations):
 - (a) she has one of the following DSDs:
 - (i) 5 α -reductase type 2 deficiency;
 - (ii) partial androgen insensitivity syndrome (PAIS);
 - (iii) 17 β -hydroxysteroid dehydrogenase type 3 (17 β -HSD3) deficiency;
 - (iv) congenital adrenal hyperplasia;
 - (v) 3 β -hydroxysteroid dehydrogenase deficiency;
 - (vi) ovotesticular DSD; or
 - (vii) any other genetic disorder involving disordered gonadal steroidogenesis;¹³ and
 - (b) as a result, she has blood testosterone levels of 5 nmol/L or above; and
 - (c) she has sufficient androgen sensitivity for those levels of testosterone to have a material androgenising effect. To assess this third criterion, the Expert Panel will look at the results of the clinical examination and the data collected as part of the Level 1 Assessment in order to determine the nature and extent of the androgenising effect, with the benefit of any doubt on this issue being resolved in favour of the athlete.
13. The Expert Panel may make such enquiries or investigations as it considers necessary to carry out the required assessment effectively, including (without limitation) requesting further data or information from the athlete or the athlete's physician and/or obtaining additional expert opinion(s), in which case the IAAF Medical Manager will organise the collection and provision of such data or information to the Expert Panel. The athlete and her personal physician must cooperate and assist with that process.
14. If the Expert Panel considers that further investigation is warranted as to whether the athlete meets the criteria to be a Relevant Athlete, then the Expert Panel will recommend a full examination and diagnosis under level 3 (the **Level 3 Assessment**).
15. If the Expert Panel considers that further investigation is not warranted and that the athlete does not meet the criteria to be a Relevant Athlete, then the athlete will be eligible as far as the Regulations are concerned to compete in the female classification in Restricted Events at

International Competitions and to set World Records in competitions that are not International Competitions.

16. The IAAF Medical Manager will notify the athlete and her designated physician of the Expert Panel's view as soon as reasonably practicable. Where the Expert Panel considers that the athlete is not a Relevant Athlete because her elevated levels of blood testosterone were not caused by one of the conditions referenced above, it will be for her designated physician to follow up on any comments made by the Expert Panel as to the potential cause of her elevated levels of blood testosterone.

Level 3 Assessment – assessment by a specialist reference centre

17. Where the Expert Panel refers a case for a Level 3 Assessment, the purpose of that assessment will be (a) to reach a diagnosis of the cause of the athlete's elevated levels of blood testosterone; and (b) to consider further the degree of the athlete's androgen insensitivity (if any). The assessment will take place as soon as possible after notification to the athlete and her designated physician, at the specialist reference centre listed in Appendix 4 of the Regulations that is located closest geographically to the athlete's habitual place of residence, unless the athlete prefers for legitimate reasons to be examined in another specialist reference centre on the list (or another reference centre not on the list but accepted by the IAAF). The costs of the Level 3 Assessment, including the athlete's travel costs, will be borne by the IAAF.
18. If the athlete is permitted to continue to compete in the female classification in one or more Restricted Events at International Competitions while her case is assessed, the Level 3 Assessment will take place on an expeditious basis, and the IAAF Medical Manager may impose a deadline for this purpose.
19. Prior to conducting the Level 3 Assessment, the examining physician will explain to the athlete the purpose of the assessment, the nature of the testing to be conducted, and the potential consequences both for the athlete's health and for her eligibility under the Regulations (where the athlete is a minor, the examining physician will provide such explanation to the athlete's parents or legal guardian(s)). The athlete will provide her fully informed written consent to the examination in accordance with applicable laws. Where the athlete is a minor, parental or legal guardian consent will be obtained.
20. The specialist reference centre will conduct a full examination on the athlete and will carry out a diagnosis of the athlete in accordance with best medical practice. In cases of DSDs, the diagnosis will further be made in accordance with the recommendations for diagnostic evaluation set out in the Consensus Statement on Management of Intersex Disorders (and update paper) cited above. The Level 3 Assessment will normally include the following different types of test: physical, laboratory (including urine and blood analysis and appropriate genetic testing for mutations in the genes involved in the conditions at issue), imaging, and psychological assessment.
21. Following completion of the Level 3 Assessment, the results (including the athlete's diagnosis and any prescribed medical treatment) will be transmitted confidentially by the reference centre to the athlete's designated physician and to the IAAF Medical Manager.

Recommendation by the Expert Panel

22. The IAAF Medical Manager will forward the results of the Level 3 Assessment (in anonymised form) to the Expert Panel, so that the Expert Panel may conduct a further comprehensive review of the athlete's case and make an informed decision as to whether she meets the criteria to be a Relevant Athlete. As part of that review, the Expert Panel will consider all of the information in the athlete's file, as well as any written submission or other evidence that it may request (via the IAAF Medical Manager) from the athlete, and any further expert opinion(s) that it considers necessary to obtain (on an anonymised basis). If the Expert Panel has any concerns about the adequacy of the evidence provided by the athlete on any particular point, and it could in theory be possible for her to address those concerns, it must give the athlete a fair opportunity to try to address those concerns before it comes to a final view.
23. The Expert Panel will only recommend that the athlete be treated as a Relevant Athlete if it is satisfied that she meets all of the criteria set out at paragraph 12 of this Appendix. In this analysis, the benefit of any doubt shall be resolved in favour of the athlete.

APPENDIX 4 - IAAF-APPROVED SPECIALIST REFERENCE CENTRES

Centre	Expert	Address
Stockholm (SWE)	Prof. Martin Ritzen	Dept. of Women's and Children's Health, Paediatric Endocrinology, Karolinska University Hospital, Stockholm
	Prof. Angelica Lindén Hirschberg	Dept. of Gynecology and Reproductive Medicine, Karolinska University Hospital, Stockholm
Nice (FRA)	Prof. Patrick Fenichel	Service d'endocrinologie et médecine de la reproduction, Hôpital de l'Archet, CHU de Nice, BP 3079, 06202 Nice cedex 03
Hershey, PA (USA)	Prof. Peter Lee	Dept. Pediatrics, Penn State College of Medicine, Hershey, Pennsylvania
Melbourne (AUS)	Prof. George Werther	The Royal Children's Hospital, 50 Flemington Road, Parkville, Victoria 3052, Melbourne
	Prof. Jeffrey D. Zajac	Dept. of Medicine, The University of Melbourne, Austin Health & Northern Health, Studley Road, Heidelberg, Victoria 3084, Melbourne
Tokyo (JAP)	Prof. Tsutomu Ogata	National Research Institute for Child Health and Development, Tokyo
Sao Paulo (BRA)	Prof. Berenice Mendonca	Unidade de Endocrinologia do Desenvolvimento e Laboratório de Hormônios e Genética Molecular, Disciplina de Endocrinologia, Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo, Sao Paolo
London (GBR)	Professor Sarah Creighton Professor Gerard Conway	University College London Hospitals, Elizabeth Garrett Anderson Wing

End notes

¹ A survey of published, peer-reviewed studies reporting concentrations of serum testosterone measured by mass spectrometry methods indicates that (i) women (including elite female athletes) without DSDs have serum levels of testosterone of between 0.12 and 1.79 nmol/L (95% two-sided confidence limit); (ii) women with polycystic ovary syndrome have serum levels of testosterone with an upper limit of 3.1 nmol/L (95% one-sided confidence limit) and 4.8 nmol/L (99.99% one-sided confidence limit); and (iii) the normal range of serum testosterone levels in men is 7.7 to 29.4 nmol/L (95% two-sided confidence limit). Meanwhile women (including female athletes) with DSDs covered by these Regulations can have serum levels of testosterone above 5 nmol/L and well into (or even above) the normal male range. See Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews (publication pending).

² See, for example, Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews (publication pending); Auchus (2017) *Endocrinology and Women's Sports: The Diagnosis Matters*, 80 LAW & CONTEMP. PROBS., no.4, 2017, p.127; Allen (2016) *Hormonal eligibility criteria for 'includes females' competition: a practical but problematic solution*, Horm Res Paediatr 85:278–82; Bermon et al (2015), *Women with Hyperandrogenism in Elite Sports: Scientific and Ethical Rationales for Regulating*, J Clin Endocrinol Metab Jan 14:doi:10.1210/1.2014-3603; Ritzén et al (2015), *The regulations about eligibility for women with hyperandrogenism to compete in women's category are well founded. A rebuttal to the conclusions by Healy et al.*, Clin Endocrinol 82:307–8; Sanchez et al (2013), *The New Policy on Hyperandrogenism in Elite Female Athletes is not about "Sex Testing"*, J Sex Res, February, 50:112-115; Wood & Stanton (2012), *Testosterone and Sport: Current Perspectives*, Horm Behav January; 61:147-155; Ballantyne et al (2012), *Sex and gender issues in competitive sports: investigation of a historical case leads to a new viewpoint*, Br J Sports Med, 46:614-617; Gooren (2011), *The significance of testosterone for fair participation of the female sex in competitive sports*, Asian Journal of Andrology 13, 653-654; Hercher (2010), *Gender Verification: A Term Whose Time Has Come and Gone*, J Genet Counsel, 19:551-553; Handelsman and Gooren (2008), *Hormones and sport*, Asian Journal of Andrology, 10, 348-50; Hipkin (1992), *The XY female in sport: the controversy continues*, Br J Sp Med, 27:150156. Cf Healy et al (2014), *Endocrine profiles in 693 elite athletes in the post-competition setting*, Clinical Endocrinology, 81:294-305; Sonksen et al (2014), *Medical and Ethical Concerns Regarding Women with Hyperandrogenism and Elite Sport*, J Clin Endocrinol Metab:doi:10.1210/jc.2014-3206; Sonksen (2016), *Determination and regulation of body composition in elite athletes*, Br J Sports Med, 2016;0;1-13; doi:10.1136/bjsports-2016-096742. See also Huang and Basaria (2017), *Do anabolic-androgenic steroids have performance-enhancing effects in female athletes* Mol Cell Endocrinol. 2018 Mar 15;464:56-64.

³ Peer-reviewed data from the IAAF World Championships in Daegu (2011) and Moscow (2013) indicate that women in the highest tertile (top 33%) of testosterone levels performed significantly better than women in the bottom tertile (bottom 33%) in the following events: **400m hurdles** (top tertile, with mean T concentration of 1.94 nmol/L, outperformed bottom tertile, with mean T concentration of 0.43 nmol/L, by 3.13%; **400m** (top tertile, with mean T concentration of 7.39 nmol/L, outperformed bottom tertile, with mean T concentration of 0.40 nmol/L, by 1.50%; and **800m** (top tertile, with mean T concentration of 3.28 nmol/L, outperformed bottom tertile, with mean T concentration of 0.39 nmol/L, by 1.60%): Bermon and Garnier (2017), *Serum androgen levels and their relation to performance in track and field: mass spectrometry results from 2127 observations in male and female elite athletes*, Br J Sports Med 2017;0:1-7, additional material at <http://bjism.bmj.com/content/51/17/1309>.

In addition, female athletes with DSDs causing serum testosterone concentrations in the normal male range performed on average 5.7% better when their serum testosterone levels were unrestricted, compared to when their serum testosterone levels were suppressed below 10 nmol/L: Bermon (2017), *Androgens and athletic performance of elite female athletes*, Curr Opin Endocrinol Diabetes Obes 2017;24:246–51.

⁴ These Regulations do not apply to any other conditions (including, without limitation, polycystic ovary syndrome), even if such conditions cause the individual to have blood testosterone levels above the normal female range. If, as a result of an assessment conducted under these Regulations, it is established that an athlete has any other condition, she may be recommended to obtain appropriate medical assistance, but her participation in the sport of athletics will not be restricted in any way by these Regulations.

⁵ For purposes of these Regulations, references to testosterone in blood are to total testosterone in serum or plasma, and all measurements of circulating testosterone levels must be conducted by means of gas or liquid chromatography coupled with mass spectrometry using a validated method.

⁶ A woman who has androgen insensitivity syndrome (AIS) is completely (CAIS) or partially (PAIS) insensitive to testosterone, thereby eliminating (CAIS) or reducing (PAIS) the physiological effect of that testosterone. An athlete with CAIS is not a Relevant Athlete. An athlete with PAIS will only be a Relevant Athlete if she is sufficiently androgen-sensitive for her elevated testosterone levels to have a material androgenising effect. The benefit of any doubt on this issue will be resolved in favour of the athlete.

⁷ For example, in a birth certificate or passport.

⁸ As noted above (see endnote 1), the available data on serum testosterone levels in men and women indicate that the upper limit of the normal female range (including elite female athletes) is 1.79 nmol/L (95% two-sided confidence limit), the upper limit for women with PCOS is 3.1 nmol/L (95% one-sided confidence limit) and 4.8 nmol/L (99.99% one-sided confidence limit), and the lower limit of the normal male range is 7.7 nmol/L (95% two-sided confidence limit). Therefore, a concentration of 5 nmol/L is an appropriate decision limit for purposes of these Regulations.

⁹ The standard eligibility conditions set out in the IAAF Competition Rules will continue to apply to all athletes, including Relevant Athletes seeking to participate in the female classification in a Restricted Event at an International Competition. Nothing in these Regulations will be deemed to permit, excuse or justify non-compliance with any of the standard eligibility conditions, including (without limitation) the anti-doping rules.

¹⁰ If the athlete has had urine samples tested for such substances as part of anti-doping testing, she will provide the IAAF Medical Manager with the results of such testing.

¹¹ Due to circadian and cyclic fluctuations in the blood levels of testosterone, the blood sample(s) should be collected (a) between 8 am and 10 am; and (b) (where the subject menstruates) between the third and the eighth day of the menstrual cycle. Interaction with certain other medications has to be taken into account, especially if the patient is taking estrogens and/or progestagens or glucocorticosteroids. A wash-out period from these treatments should therefore be considered prior to investigation.

¹² If the case involves a suspected violation of the anti-doping rules, the IAAF Medical Manager will instead, or also (as appropriate), send the file to the IAAF Athletics Integrity Unit.

¹³ These Regulations do not apply to any other conditions (including, without limitation, polycystic ovary syndrome), even if such conditions cause the individual to have testosterone levels in her blood above the normal female range. However, such conditions may have implications for the athlete's health, and diagnosis can often help to improve the conditions, avoid metabolic disorders, and possibly reduce the risk of later cardiovascular events and gynaecological cancers. A serious underlying medical condition should always be suspected if the onset of symptoms is fast and/or intense. In such cases, the possibility of an androgen-secreting tumour should always be investigated. All relevant information should be provided to the athlete's personal physician to determine the appropriate treatment (the Expert Panel may make recommendations in this regard).