

FACTSHEET ON THE ACCREDITATION STANDARD FOR IVF LABORATORIES OF THE AGER / SGRM

Dear Colleagues,

According to article 4.1.c. of the Swiss Reproductive Medicine Ordinance (FMedV), biological reproductive medicine laboratories must implement a quality management system “based on the ISO standards ISO/IEC 17025:2005 or ISO 15189:2012”.

As the ISO standards cited are not specifically tailored to IVF laboratories and the word ‘based on’ in the legal text also allows for other QM systems, it has been left to the specialist societies in particular to establish specific, effective quality assurance requirements and offer these to the IVF centres on a voluntary basis.

The term “Accreditation” is not legally protected and can be freely used for competence recognition by specialist societies. Accreditation involves ensuring the quality of organisation, infrastructure, technical competence, processes and results.

In accordance with the resolution taken by their boards (SGRM on 26/10/2017, AGER on 2/11/2017), the SGRM and AGER have decided to develop their own quality label. The first module, an accreditation programme specifically designed for IVF laboratories, is in its pilot version. The ISO 15189 and 17025 as well as the ESHRE guidelines have been considered accordingly.

The aim of establishing this standard by own specialist hands is to meet the requirements of the FMedV article 4.1.c, while taking account of IVF specificities. Similar quality projects have been successfully carried out for example by the Swiss Society of Mastology (SGS) in cooperation with the Swiss League Against Cancer.

The other goals of this quality label are to lower costs of setting up and obtaining the accreditation compared to the above ISO standards, and reward more concrete benefits thanks to the specification. Unlike the general ISO standards stated above, the individual accreditation system can only focus on the specificities of ART (Assisted Reproductive Technology).

The public expects the highest safety and quality standards for fertility treatment. Externally monitored quality is valued highly and both specialist societies aim to meet this expectation by producing the Requirements Specification and the associated accreditation system. With the accreditation label from the specialist societies, laboratories can show their high level of quality and safety.

The boards of the AGER and SGRM are delegating members to the accreditation committee, whose role it is to define the standard and further develop it if necessary. The operational organisation of the

accreditation is assured by an independent certification/accreditation body (DOC-Cert AG, Kreuzlingen) in cooperation with the SGRM administration. Synergies with inspections of cantonal doctors and FIVNAT audits are planned to be used. Professional policy statements and contact with the authorities shall be carried out via the AGER /SGGG.

Participation in this accreditation programme for IVF laboratories is of course voluntary. Certification to ISO 9001 is not fail-safe proof of quality of a laboratory per se. However, several aspects of ISO 9001 are relevant and have been taken into account in the Accreditation specifications. By the end of January 2018, the Requirements Specification will be reviewed as part of a pilot accreditation procedure (external Auditor: Prof. Thomas Ebner, Austria) and by the accreditation committee.

The Swiss IVF centres will be informed about the further development of the project. The project will also be presented to members at the Annual General Meeting of the SGRM on 18 January 2018 in Zurich. If the project is approved by the accreditation committee and boards of the two specialist societies, the accreditation procedure can be duly rolled out as of 1 April 2018. The Requirements Specification for an IVF Laboratory: "Accredited laboratory for reproductive medicine of the SGRM (Swiss Society of Reproductive Medicine) and AGER (Working Group for Gynaecological Endocrinology and Reproductive Medicine of the SGGG)" Version 1.0 will be available during February 2018.

The accreditation committee is searching for members, please contact us if you are interested.

On behalf of the Project Committee

Dr. Fabien Murisier, President Accreditation Committee

Dr. Sabine Steimann, President AGER

Dr. Felix Häberlin, President SGRM