QUARTS
Quality for Assisted Reproductive Technologies in Switzerland

Requirements Specification for an

Accredited Laboratory

for Reproductive Medicine

of the

SGRM – Swiss Society of Reproductive Medicine

and the

AGER – Working Group for Gynaecological Endocrinology and Reproductive Medicine of the SGGG

Produced by the Accreditation Committee

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Version 3.5 is to apply mandatory starting from the 4th of March 2024.

Table of contents

Abbreviations

AGER	Arbeitsgemeinschaft für Gynäkologische Endokrinologie und Reproduktionsmedizin der Schweizer Gesellschaft für Gynäkologie und Geburtshilfe - Working Group for Gynaecological Endocrinology and Reproductive Medicine of the Swiss Society of Gynaecology and Obstetrics
ESHRE	European Society of Human Reproduction and Embryology
FIVNAT	"Fécondation In Vitro National". Swiss Register for Assisted Reproduction Laboratories; SGRM Committee
ISO 17025:2017	Accreditation Standard for Testing and Calibration Laboratories
ISO 15189:2022	Accreditation Standard for Medical Laboratories – Quality and Competence Requirements
ICSI	Intracytoplasmic Sperm Injection
IVF	*In-Vitro* Fertilisation
QMS	Quality Management System (= entirety of relevant documents)
UK-NEQAS	United Kingdom National External Quality Assessment Service
SGGG	Swiss Society for Gynaecology and Obstetrics
SGRM	Swiss Society of Reproductive Medicine

Names and definitions of human germ cells

Gametes	Sperm and unfertilised egg cells
Impregnated egg cell	Fertilised egg cell
Embryo	Fertilised egg cell from the cell division stage
Blastocysts	Embryo pre-implantation with a cavity (mostly from the 5th day of development)

Foreword to the first edition 2017

The specialist societies SGRM (Swiss Society of Reproductive Medicine) and AGER (Working Group for Gynaecological Endocrinology and Reproductive Medicine) of the SGGG (Swiss Society of Gynaecology and Obstetrics) took the Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, FMedG) and the Reproductive Medicine Ordinance (FMedV) as an opportunity to develop a quality label for reproductive medicine (QUARTS) and hereby presents the Requirements Specification of the module: Accredited laboratory for reproductive medicine.

IVF laboratories differ considerably from other laboratories to the extent that the current accreditation standards do not appear entirely suitable for demonstrating that the necessary quality standards are met. The accreditation standards of the International Standard Organisation (ISO) do not cover the particularities of IVF laboratories either. In addition, work within a reproductive medicine laboratory does not take place in an isolated manner, but rather it involves close, multifaceted exchanges with the clinical treatment providers of patients and couples.

The public expects the highest safety standards for fertility treatment. Externally monitored quality is valued highly and both specialist societies aim to meet this expectation by producing this Requirements Specification and the associated accreditation system.

This Requirements Specification is based on relevant document groups/standards that are relevant to the accreditation of IVF laboratories.

1.) Fortpflanzungsmedizinverordnung - FMedV (Reproductive Medicine Ordinance) - 1 September 2017
2.) ISO 17025:2017 "Accreditation Standard for Testing and Calibration Laboratories"
3.) ISO 15189:2022 "Accreditation Standard for Medical Laboratories – Quality and Competence Requirements"
4.) "Revised Guidelines for Good Practice in IVF Laboratories (2015)" of the European Society of Human Reproduction and Embryology (ESHRE)
5.) The Alpha consensus meeting on cryopreservation key performance indicators and benchmarks: proceedings of an expert meeting (2012)

The ISO standards set out the general framework conditions for work in laboratories whereas the ESHRE guidelines go beyond this and include issues specific to IVF. Both sets of standards cover quality management as well as the structures and processes required for the successful and safe operation of a laboratory. For the accreditation of an IVF laboratory, specific result parameters must also be met, which must be evaluated in close conjunction with the clinical treatment providers.

The original Requirements Specification for accreditation processes is available in English. The German translation is used solely for internal purposes.

1 General details of the laboratory

Requirement 1.1	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	4.1; 5.1; 5.4; 5.5	4.1, 5.1, 5.4.1	Art. 4; section c.
The laboratory provides the following structural information when applying for accreditation: • Name of the laboratory • Type of company (or part of which company) • Name of the manager of the basic clinical facility (practice, clinic) • Name of the laboratory manager • Name of the staff member responsible for accreditation (e.g. QM Officer) • Address and contact details of the laboratory (place, street, building number, email, telephone) • If available: Details of the certification of the basic clinical facility (practice, clinic) • If available: Details of the certification / accreditation of the laboratory			
Documents to be provided during the audit			
Extract from the commercial register			
Declaration of independence from the laboratory manager (exclusion of influence from third parties on the procedures and results of the laboratory)			
Certification and accreditation documents (if available)			

1.2 Impartiality / Ethical approach	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	4.1; 5.1	4.1, 5.1	Art. 4; section c.
The laboratory must show how impartiality / an ethical approach are ensured with regard to laboratory activities. All risks must be identified and eliminated / minimised.			
Documents to be provided during the audit			
Declaration of impartiality			
Risk assessment for impartiality			

1.3 Confidentiality	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	4.2	4.2	Art. 4; section c.
Discretion and the confidential handling of all information held in the laboratory must be guaranteed.			
Documents to be provided during the audit			
Confidentiality declaration by all laboratory stakeholders			

2 Laboratory activities

2.1 Scope	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	5.3; 5.4; 7.2.2	4.3; 5.3.3; 6.7	Art. 4; section c.
The scope of application is defined by the laboratory on applying for the accreditation. As a general rule, the scope of application covers all activities performed by the laboratory as part of assisted reproduction. The scope of application is recorded on the accreditation certificate and published on the website of the specialist societies. The accreditation applies only to the procedures specified in the scope of the application. The laboratory can only state that it is accredited (e.g. on its website) for those procedures that are recorded within the scope of the accreditation certificate.			

Procedures to be selected for the scope of application: Basic activities of the ART Laboratory • Receipt and preparation of gametes for fertilisation • Fertilisation (IVF, ICSI) • Cultivation of the pre-implantation embryos (2PN, cleavage stage embryos, blastocysts) and preparation for embryo transfer. Cryopreservation and thawing of • Sperm • Egg cells • 2PN • Pre-implantation embryos • Ovarian tissue • Testicular tissue Specimen collection for PGT (Pre-implantation Genetic Testing) • Polar body retrieval, embryo biopsy, trophectoderm biopsy • Preparation of specimens for dispatch • Interface organisation with the molecular genetics laboratory Handling of specimens of seropositive patients Sperm diagnostics • Sperm analytics • Further tests as listed by the relevant IVF laboratory Donor sperm insemination Donor sperm banking
Documents to be provided during the audit
Declaration of scope of application
Stakeholder analysis

2.2 Establishing the procedure	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	5.5; 7.2.2	6.7	Art. 4; section c.
The laboratory has a document describing how new procedures are introduced. This ensures that new procedures can be introduced and included in the scope of application through the validity of the accreditation. The following applies in this respect: • Procedures that are already established based on corresponding publications, or in the form of commercial kits, can be introduced by the laboratory on the basis of the available data and following internal validation. Care is taken here to ensure that both the procedure *per se* and the reagents and materials used are evaluated and validated. • Procedures that are not yet established must undergo separate evaluation and validation measures by the laboratory.			
Documents to be provided during the audit			
Description of how new, already established procedures are introduced and tested.			
Optional – if relevant: Description of how procedures yet to be established are evaluated and validated in the laboratory on their introduction.			

3 Organisation of the laboratory

3.1 Laboratory management	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	5.2; 5.7; 7.2.2	5.2	Art. 4; section a. Art. 4; section c.
The laboratory manager has at least the following qualifications: • Academic qualification in a medical or scientific subject (e.g. Master's Degree, PhD, MSc) • At least 6 years of documented experience as an embryologist (with proof of further training and continuing education) • Transitional arrangement for laboratory managers with many years of experience but without an academic qualification as at 1.9.2017 in accordance with the recommendations of the Swiss Society of Reproductive Medicine • The statutory requirements for laboratory management are reserved Laboratory management tasks • Selecting procedures and materials, co-operating with competent authorities, responsibility for SOPs, for safety in the laboratory, for the QM system, for risk and prevention management, for the selection of laboratory staff, for induction, approval and continuing professional development and further education, for the introduction and monitoring of key performance indicators, for research projects, for the recording of clinical results and adverse events, for the selection of subcontractors and for communication.			
Documents to be provided during the audit			
Proof of qualification of the management			
Job description for managerial staff			

3.2 Laboratory staff	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.1; 6.2; 5.6	5.4.2; 6.2	Art. 4; section b. Art. 4; section c.
The laboratory staff have the necessary specialist skills: Completion of an apprenticeship with a biomedical or laboratory medicine connection or subject-related university degree. Internal training and further education in the field of embryology must be documented. The adequacy of the number and qualification of the laboratory staff in relation to the treatment frequencies must be demonstrated based on an appropriate concept. The responsibility for the following tasks must be defined, as well as the required skills and job description: • Technical/laboratory work • Administration • Training and education • Quality management (including management of the QMS, access to management) • Communication			
Documents to be provided during the audit			
Proof of laboratory staff qualifications			
Laboratory staff job descriptions for the afore-mentioned functions			
Organisational chart of the laboratory (stating the afore-mentioned tasks)			
Arrangements for substitutes			
Documentation of staff training and approval			

4 Quality management of the laboratory

4.1 QM system	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.1.1; 8.1.2; 8.2; 8.3	8.1; 8.2	Art. 4; section c.
The laboratory has established a QM system ("Knowledge management / Knowledge database"). The QMS contains all information and documents relevant for the laboratory for all methods and processes, including the documents required by this specification. If a laboratory has a valid certification according to ISO 9001, ISO 15189 or ISO 17025, the requirements of section 4 with exception of section 4.8 are met *per se*.			
Documents to be provided during the audit			
Description of the QM system			
Table of contents of the QM system			

4.2 Management of specifications	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.3	8.2; 8.3	Art. 4; section c.
An appropriate version management system (title, date, version, scope/number of pages, person approving the document) and a controlled and traceable approval process (responsibility for drawing up, approving, reviewing/amending, archiving) ensure that every document in the QMS is current, correct, available and clearly labelled. The taking out of circulation and archiving of documents that are no longer valid is possible and controlled by the QMS.			
Documents to be provided during the audit			
Description of the version management and approval process for documents in the QM system (document management)			

4.3 Management of records	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.4	8.4	Art. 4; section c.
Records (documents of an evidence nature) are clear and traceable, collected in full, and archived in an accessible manner for a period to be defined. The legally prescribed retention periods are reserved. For patient-related records, data protection (confidentiality, property rights) and data security (fire, theft, water, data loss) are followed. Direct contact with patients is documented. This requirement applies both for paper documents and electronic documentation.			
Documents to be provided during the audit			
Description of the data protection (confidentiality within the laboratory and with respect to third parties)			
Description of the databases used, including data security			
Description of the management of records			

4.4 Laboratory strategy	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.2	5.5, 8.2.3	Art. 4; section c.
The laboratory management has formulated a strategy. This includes at least the following points: • Vision and aims of the laboratory • Commitment to "Good Manufacturing Practice" and "Good Clinical Practice" / to providing a good level of quality for the patients • Commitment that all staff shall meet the requirements of the QM system • Commitment to readiness for continual improvement • Commitment that all statutory and regulatory requirements shall be met.			
Documents to be provided during the audit			
Strategy paper of the laboratory			
Commitment of the management			

4.5 Error management / complaints / improvement / correction and prevention	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.9; 7.10; 8.6; 8.7	7.5; 7.7; 8.5; 8.6; 8.7	Art. 4; section c.
Error management (particularly non-compliance, organisational problems, emergencies, complaints, adverse events) is described and implemented. Correction management (particularly avoidance/prevention of recurrent errors, improvement measures) is described and implemented.			
Documents to be provided during the audit			
Description of the error management			
Description of the correction and prevention management			
Overviews (e.g. annual review) of the errors recorded			
Overviews (e.g. action plan and implementation results) of the defined corrective measures			

4.6 Risk management	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.5	5.6; 8.5	Art. 4; section c.
The risk management (including definition of a laboratory-specific risk catalogue, identification of risks, risk process analysis) is described and implemented.			
Documents to be provided during the audit			
Description of the risk management			
Risk analysis of procedures (also possible as an integrated part of the procedural SOP). Overviews (e.g. annual review) of the reporting of serious near misses in the CIRS (Critical Incident Reporting System)			

4.7 Internal Audits	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.8	8.8	Art. 4; section c.
Internal audits are established in the laboratory. Internal audits are carried out at least once a year on the basis of an audit plan. Every method / procedure is audited internally at least once every 3 years. In case of deviations, corrective measures are taken. An auditor for implementing internal audits should be independent (not from the same laboratory/same facility) and competent. The procedure should follow the instructions outlined in ISO 19011.			

Documents to be provided during the audit
Audit plan for the period up until the next accreditation audit
Audit reports since the last accreditation audit
List of internal auditors with qualification profile

4.8 Annual report/management review	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	8.9	8.9	Art. 4; section c.

The laboratory compiles an annual quality report (also: quality management review, management review). This report includes the following information:

- Evaluation of the aim(s) of the previous year
- Description of the met aim(s) for the current year
- Description and evaluation of the KPIs (Key Performance Indicators) of the previous year (KPIs 1-11) and of the year before the previous year (KPIs 12-15)
- Description of relevant changes (organisation, personnel, procedures) of the previous year
- Description of activities and improvements of the previous year
- Description of the risk analysis of the previous year and related activities

A form for writing the annual quality report is provided by the accreditation body on its website (www.doc-cert.com). The usage of this form is mandatory. Excluded are laboratories with a valid certification according to ISO 9001, ISO 15189 or ISO 17025. These laboratories can use their own form provided that the following requirements are met:

1) In the form it is mentioned that it has been designed to meet the QUARTS requirements specification (e.g. in the subtitle: evaluation of the quality system according to the QUARTS requirements specification V3.2 and ISO 9001:2015).
2) It covers all the basic chapters of the QUARTS form.
3) If in the form of the laboratory a chapter of the QUARTS form is covered, a reference to the corresponding QUARTS chapter must be made in brackets (e.g. QUARTS: 1.1 evaluation of the goals).
4) For the description and evaluation of the KPIs the QUARTS form “appendix KPIs” must be used.

The annual quality report must be signed by the laboratory manager.

Each year, the annual quality report is submitted to the accreditation body by the 30st of April for the previous year (01.01.-31.12.) and checked by the accreditation body for plausibility. If any irregularities are noted, the accreditation committee is informed and, if applicable, conditions are imposed on the laboratory.

Documents to be provided during the audit
For accredited laboratories: Quality reports since the last accreditation audit. For first accreditation audits the quality report of the previous year (01.01 – 31.12.) is provided. Laboratories that have just opened in the year of the accreditation audit or in the previous year follow the instructions below: • Laboratories that have opened in the previous year in the period from January until June hand in a quality report that covers the period July until December of the previous year. • For Laboratories that have opened in the previous year in the period from July until December or in the same year as the accreditation audit takes place there is no need to provide a quality report for the audit.

5 Laboratory results and key performance indicators

5.1 Key Performance Indicators	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.7	5.5; 7.3.7.4; 8.8.2	Art. 4; section c.
The laboratory has a database that enables an evaluation and statistical analysis of the relevant key performance indicators at least annually. Corrections in the database must be traceable. It must be possible to evaluate the following Key Performance Indicators (KPIs) by means of data input as a minimum: *See Appendix* The KPIs are regularly evaluated by the laboratory. Centres with at least 100 cases per trimester should perform the analysis every trimester. Longitudinal comparisons ensure that no systematic errors occur. KPIs with a denominator below 30 are not evaluated on a yearly basis. These KPIs are evaluated over a time period of 2 or 3 years and have to be discussed with the auditor separately. For appropriate KPIs, a limit figure is set by the specialist societies in accordance with the literature or national statistics (FIVNAT). If the laboratory does not meet this limit figure in a given year, actions for improvement shall be initiated. If the laboratory (together with its clinical facility) fails to meet the limit figure in at least two consecutive years, it shall appoint an external expert to carry out a joint quality audit. An evaluation of the individual laboratory staff members should be carried out and analysed. The annual analysis and any measures are communicated to the laboratory staff. *For all KPIs, the results of which are subject to influences from multiple factors, the auditor shall take the centre-specific circumstances into account and assess the outcome accordingly. Note for laboratories performing IVF-Naturelle: The KPIs defined in the appendix cannot be applied to IVF-Naturelle. A method for recording and monitoring the quality of IVF-Naturelle procedures must be demonstrated. The responsibilities for recording/monitoring and for any reactions must be clearly defined.			
Documents to be provided during the audit			
Description of the database			
Evaluation of the last complete annual cohort (max. 2 previous years)			
Any applicable action plan in case of deviations			

5.2 Quality assurance	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.7	7.3.7.1; 7.3.7.3; 7.3.7.4; 8.7	Art. 4; section c.
The laboratory takes part in at least one external quality assurance programme. This includes, for example ESHRE, SWICE or UK-NEQAS programmes.			
Documents to be provided during the audit			
Quality assurance concept (QA plan)			
Report / results of the quality assurance programme			

6 Safety in the laboratory

6.1 Room conditions	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.1; 6.3	6.3	Art. 4; section c.
The layout of the laboratory follows the requirements relating to the organisation of the work flow and safety. The following activities must be carried out in a separate space from the IVF area: • Changing clothing • Washing hands • Office work • Storage of gas cylinders The following activities must be carried out in a separate space or at a different time from the treatment cycles: • Preparation / cleaning of devices, cleaning and sterilization of materials			
Documents to be provided during the audit			
Layout plan of the laboratory with rooms allocated according to the activities			

6.2 Access regulations	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3	6.3	Art. 4; section c.
Only authorised personnel are granted access to the laboratory. Staff and visitors who are not authorised personnel must provide ID and their entry is documented and timed. The records are retained. Visitors are briefed by a laboratory staff member on the necessary conduct inside the laboratory and they sign a form regarding compliance with data protection (protection of patient data, protection of company data).			
Documents to be provided during the audit			
Access concept			
List of authorised persons			
Data protection declaration for visitors			
Documentation regarding access by unauthorised persons			

6.3 Emergency plan	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3	6.2; 6.3; 7.6	Art. 4; section c.
The protection of the laboratory staff, patients and biological material is assured by an emergency plan. This plan may also be part of a superordinate emergency plan (e.g. hospital). The power supply of relevant equipment (incubators, refrigeration systems) is assured in an emergency. A contact list of all laboratory staff and necessary persons in case of an emergency is kept in the laboratory and at a central coordination centre (part of the emergency plan). An alarm system is in place. Cooperation with a comparable nearby laboratory is agreed in writing, so that necessary treatments are not interrupted in case of an outage. A back-up solution is in place for the relevant equipment and systems in case of an outage.			
Documents to be provided during the audit			
Emergency plan			
Cooperation agreement with a nearby laboratory.			
List of replacement equipment (also in the central list of equipment)			

6.4 Occupational safety and Hygiene	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3	6.3; 6.4; 8.7	Art. 4; section c.

The laboratory meets the national, cantonal, regulatory and medical requirements for occupational health and safety. This concerns the height of the work surfaces (bench), the height of the microscope, the room temperature (heating and air-conditioning systems), the lighting conditions and work area per laboratory staff member. It also concerns hygiene (hand disinfection, surface disinfection, cleaning) and handling of hazardous biological materials (needle-stick injuries, sero-positive patients).

A current version of a hygiene plan is available for the laboratory. The specific features of a reproductive medicine laboratory (lighting, disinfection) must be taken into account in this.

In the hygiene plan the following topics are regulated:

- Scope of the cleaning and disinfection measures. This also includes the choice of the cleaning and disinfectant agents, the cleaning and disinfection procedures as well as the frequency with which the measures are carried out. For the dosing safe dosing systems should be used. The handling of cleaning utensils should be described.
- Procedures for infectious material / patients
- Clothing, gloves, cosmetics, food
- Frequency of checks on the implementation of the measures formulated in the hygiene plan, including responsibilities

The personnel entrusted with cleaning and disinfection must be instructed in the hygiene plan and must be trained regularly. This also applies if external companies carry out cleaning and disinfection. Proof of training must be available.

The internal audits also check that the requirements regarding occupational safety and hygiene have been met.
Checks are carried out to ensure that laboratory staff have been vaccinated against hepatitis B. This vaccination is strictly recommended for the laboratory staff.
Furthermore, a plan for pandemic situations has to be available.

Documents to be provided during the audit
Audit report on occupational health and safety
Audit report on hygiene
Hygiene plan
Description of procedure for handling needle-stick injuries
Description of procedure for handling sero-positive patients

6.5 Gametotoxic components	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3	6.3; 6.4; 8.7	Art. 4; section c.

Gametotoxic components are minimised within the IVF laboratory. This applies to floors, surfaces, paints/varnishes, equipment and room air.
The laboratory provides concepts to demonstrate that this requirement is met.

Documents to be provided during the audit
Concept on the minimisation of gametotoxic substances in the laboratory and treatment area
Concept on local validation of room functions and equipment in the case of changes (initial use, renovation, conversions, after maintenance).

6.6 Equipment	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3; 6.4; 6.5; 7.5; 7.6	6.4; 6.6	Art. 4; section c.
The type and quantity of laboratory equipment must be appropriate for the type and frequency of treatment. A concept must be documented to this effect. Failure scenarios must be presented. This concerns the following equipment in particular: incubators; ICSI microscopes, stereo microscopes, heat sources, cryotanks, refrigerators, centrifuges, laminar-flow benches. Incubators for the embryo cultures are continuously monitored and have an emergency power supply. The gas supply is monitored. An emergency plan is available. All laboratory equipment must have a CE mark. If an item of equipment does not have a CE mark, its suitability for use in the IVF laboratory must be demonstrated in another way (validation, literature). An equipment logbook and operating instructions must be available and accessible for every item of equipment. For each item of equipment, it must be defined, how, when and on the basis of which specifications, maintenance, inspections and calibration are carried out. The decommissioning process is controlled and implemented accordingly. Decommissioned equipment must be labelled specifically as such.			
Documents to be provided during the audit			
List of incubators with associated validation reports, equipment logbooks and test reports			
Documentation regarding continuous monitoring and the emergency power supply (also possible through the building management system).			
Equipment lists with proof of validation, CE mark and operating instructions. Maintenance logbooks and, if applicable, proof of calibration for all equipment.			
Proof of calibration of test equipment and their metrological traceability			
Description of the decommissioning equipment process			
Commissioning process for newly installed equipment			

6.7 Air purity	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.3	6.3	Art. 4; section c.
Air purity is monitored regularly by means of particle measurements. An air purification system is present. The air quality must be measured periodically in accordance with a documented concept. The air quality must be GMP grade A in the workbench area and grade D in the other areas.			
Documents to be provided during the audit			
Test reports relating to air quality			
Maintenance reports for the air quality systems			

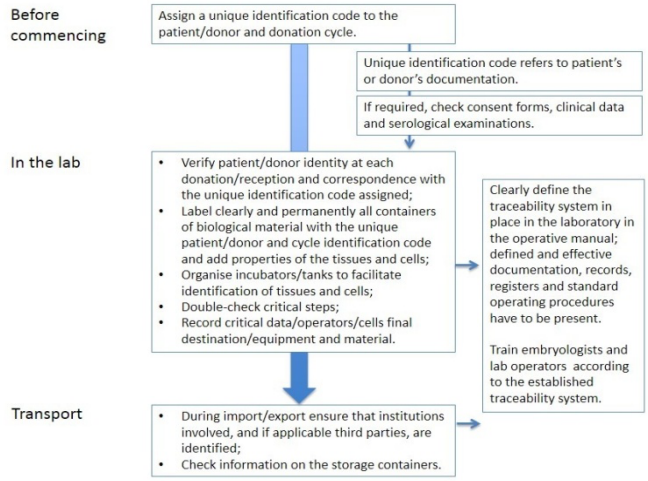
6.8 Storage	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.2; 6.3	6.2; 6.3	Art. 4; section c.
Storage following cryopreservation takes place outside the IVF laboratory. The liquid nitrogen (LN) level is continuously monitored. Personnel who handle LN and cryo products require special instruction on the use of the equipment, the work steps and the protective equipment. The safety of the personnel is ensured in rooms in which liquid nitrogen (LN) is present. A low-oxygen alarm and adequate ventilation are recommended.			
Documents to be provided during the audit			
Description of the continuous monitoring			
Proof of monitoring			

Description and proof of the special instruction
Description of the safety precautions in relation to risks associated with liquid nitrogen (LN)

7 Identification and traceability

7.1 Traceability	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.3; 7.4. 7.5	6.6; 7.2; 7.3.6	Art. 4; section c.

The identification of patients and germ cells/embryos and the traceability of all materials and products are controlled and described for all procedures.
The traceability includes the details of the staff and the time and location (for storage) of every relevant work step. The records must be retained as a minimum in accordance with the general statutory provisions for medical treatment data. A back-up system must be present. If cryopreserved cells or tissues are used, traceability back to cryopreservation and the process steps immediately prior to that must be ensured. The identity of both partners must be traceable in the case of cryopreserved embryos. The retention period is therefore extended to the period of cryopreservation.
Example from the ESHRE Guideline:



Documents to be provided during the audit
Description of the identification of patients and germ cells/embryos and their traceability.

7.2 Traceability training	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.2	6.2	Art. 4; section c.

The laboratory staff are specially trained on the necessary and correct documentation for traceability.
The correct documentation is checked during the internal audits.

Documents to be provided during the audit
Proof of training
Audit report with inspection report on the documentation

7.3 Witness systems	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.7	7.3.7	Art. 4; section c.
Certain critical work steps require the use of witness systems (e.g. the four-eye principle, electronic witness system). Witness systems must be used for at least the following procedures: • Team time out on egg retrieval (interface between the clinical team and laboratory team) • Team time out on embryo transfer (interface between laboratory team and clinical team) • Team time out on handover of native or processed sperm for planned insemination (interface between laboratory team and clinical team) • Team time out on receipt and handover of cryopreserved cells or tissues from or to external parties (interface between external party and laboratory team) • Handover of processed sperm for insemination in the case of planned IVF or ICSI (internal laboratory interface)			
Documents to be provided during the audit			
Description of the witness system used in the laboratory.			

7.4 Media, reagents and consumables including disposable products	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.6; 7.5	5.3.3; 6.6; 6.8	Art. 4; section c.
All media, reagents and consumables, including disposable products, used for the procedures have been tested and approved with respect to their suitability. The laboratory describes when certain test procedures are used for these materials. The quality of the relevant suppliers is checked and evaluated (including, for example, temperature checks during transport). If the requirements are not met, improvements are initiated and, if necessary, the supplier is changed. Batch management is implemented (including receipt, consumption, destruction)			
Documents to be provided during the audit			
Description of the use of the media, reagents and consumables.			
Supplier evaluation			
Description of batch management.			

8 Laboratory procedures

8.1 Procedural regulations and validation	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.1; 7.2.1	5.5	Art. 4; section c.
An SOP is available for every procedure for which the laboratory applies for accreditation (see section 2). The provisions of the ESHRE Guideline (previously validated standard) should be taken into account in the SOPs. Sections that are identical for several SOPs of one laboratory can be drawn up as separate documents. In such a case, the SOP refers to these documents. Changes to the SOPs must be traceable. If procedures are used that are not covered in the ESHRE Guideline or other standards, the laboratory must provide evidence to show that the procedure has been validated and should retain validation records.			
Documents to be provided during the audit			
SOP for every method/procedure to be accredited			
Validation records for standards that have <u>not</u> yet been validated			

8.2 SOP specifications	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.2.1	7.2; 7.3; 7.4	Art. 4; section c.
The procedural SOPs cover the following issues (only the relevant issues are to be covered by each procedure): • Background to the method • Responsibilities (person responsible, persons involved, qualification requirements) • Framework conditions [rooms, technology, subcontractors, environmental conditions (e.g. temperature, pH, osmolality, 02 concentration), environmental risks, information systems, interferences (e.g. LN2, surface contamination, virus carriers), customer requirements] • Procedural description with subdivision into pre-analytics, analytics and post-analytics (indication, patient information, informed consent, requirements, examination material, transport, incoming goods inspection, identification, reagents/consumables, individual work steps, documentation and records, witness systems, traceability) • Evaluation (measurement ranges and normal values, selection criteria, morphological criteria, result deviations and abnormal results, approval, findings, reports, errors and corrections) • Storage, disposal and cleaning • Quality assurance • Literature and specifications			
Documentation			
SOPs in accordance with the scope (section 2) for previously validated standards			
SOPs in accordance with the scope (section 2) and individual associated validation records for standards that have not yet been validated			

8.3 SOP update	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	6.1; 8.3; 8.4	8.3; 8.4; 6.2	Art. 4; section c.
The laboratory checks its procedures on a regular basis to ensure that they are up-to-date and correct. The laboratory has available a description of who is responsible for the monitoring and update of the procedural SOPs, and when and how the process of revision, presentation to the team, staff training and renewed approval is governed.			
Documents to be provided during the audit			
Description of how the procedural SOPs are monitored and amended (including any validation records).			

8.4 Reports / documentation of results	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.8	7.4.1	Art. 4; section c.
Reporting on laboratory activities must include all key features about the laboratory, sample and patients. The traceability of the results to the test process and metrological findings must be guaranteed. Biological reference ranges and clinical decision values must be provided, if required. Approval processes must be defined. Instructions regarding changes to findings must be documented in writing. A scenario for dealing with potentially false findings must be presented.			
Documents to be provided during the audit			
SOP on reporting findings / results documentation			

8.5 Laboratory information management	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.11	7.6	Art. 4; section c.
The laboratory must prove the reliability of information systems, if used. This refers in particular to the function, access options, stability and interfaces / data transfer from or to other systems. The responsibilities, data storage and data back-up together with a failure concept must be defined.			
Documents to be provided during the audit			
IT concept for ensuring reliable operations.			

Appendix section 5.1 - key performance indicators	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
	7.7	8.8.2	Art. 4; section c.

The relevant key performance indicators are published in English only:

Inclusion criteria:

- woman's age ≤ 40 years*
- ejaculated sperm (excl. TESE/MESA)
- insemination of fresh oocytes
- more than 3 COC

**For frozen embryo transfers: woman's age ≤ 40 years at the time of the transfer*

Key performance indicators:

KPI	Key performance indicator	Calculation	Numerator (Number per year)	Denominator (Number per year)	Center Result (%)	Competency value	Excellence value
1.	ICSI damage rate	no. of damaged or degenerated x 100 no. of MII oocytes injected				≤10%	≤5%
2.	ICSI normal fertilization rate[e]	no. of oocytes with 2PN x 100 no. of MII oocytes injected				≥65%	≥80%
3.	IVF normal fertilization rate[d]	no. of oocytes with 2PN x 100 no. of COC inseminated				≥45-60%[d]	≥60-75%[d]
4.	Failed fertilization rate (IVF)	no. of cycles with no evidence of fertilization x 100 no. of stimulated IVF cycles				n.d.	≤5%
5.	Cleavage rate	no. of cleaved embryos on Day 2 or 3 x 100 no. of normally cultivated oocytes[a]				≥90%	≥95%
6.	Blastocyst development rate	no. of blastocysts x 100 no. of normally cultivated oocytes[a]				≥40%	≥60%
7.	Blastocyst cryosurvival rate	no. of blastocysts appearing intact x 100 no. of blastocysts warmed				≥90%	≥95%
8.	Implantation rate (cleavage stage)[b]	no. of sacs seen on ultrasound[c] x 100 no. of embryos transferred				≥25%	≥35%
9.	Implantation rate fresh (blastocyst stage)[b]	no. of sacs seen on ultrasound[c] x 100 no. of fresh blastocysts transferred				≥35%	≥60%
10.	Implantation rate cryo (blastocyst stage)[b]	no. of sacs seen on ultrasound[c] x 100 no. of cryopreserved blastocysts transferred[f]				≥35%	≥60%
11.	Successful biopsy rate	no. of biopsies with DNA detected x 100 no. of biopsies performed				≥90%	≥95%
12.	live birth rate cleavage stage-fresh	no. of live births x 100 no. of fresh Day 2-4 embryos transferred				n.d.	n.d.
13.	live birth rate cleavage stage cryo	no. of live births x 100 no. of frozen Day 2-4 embryos transferred				n.d.	n.d.
14.	live birth rate blastocyst fresh	no. of live births x 100 no. of fresh Day 5-6 blastocysts transferred				n.d.	n.d.
15.	live birth rate blastocyst cryo	no. of live births x 100 no. of frozen Day 5-6 blastocysts transferred[f]				n.d.	n.d.

ICSI= intracytoplasmic sperm injection; MII = metaphase II; PB = polar body; PN = pronucleus.

[a] Defined as oocytes with 2PN and 2PB on Day 1 with a maximum of 12 oocytes according to the current Swiss law.

[b] Based on total number of embryos transferred to all patients in the reference group, not just to those for whom an implantation occurred.

[c] Definition reached after discussion, as some felt that no. foetal heartbeat detected/no. embryos transferred was a more meaningful Indicator.
[d] Dependent on the average MII rate after the puncture, which is expected to be between 75-90%. It is recommended to calculate the overall MII rate of the centre (for example from ICSI cycles) for a better interpretation of this KPI.
[e] ICSI normal fertilization rate can be considered as a good key performance indicator if a laboratory performs ICSI compared to IVF insemination in more than 70% of the cases. For laboratories that perform ICSI only for lower quality sperm and therefore have a lower ICSI vs. IVF insemination rate, the ICSI fertilization rate might be lower.
[f] Blastocysts after trophoectoderm biopsy are not included in this KPI

Below key performance indicators for cryopreserved oocytes are defined. The presentation of these key performance indicators is voluntary.

Inclusion criteria:

- woman's age ≤ 40 years at the time of transfer
- ejaculated sperm (excl. TESE/MESA)
- more than 3 COC

Exclusion criteria:

- cryopreserved oocytes from external centres

Key performance indicators for cryopreserved oocytes:

KPI	Key performance indicator	Calculation	Numerator (Number per year)	Denominator (Number per year)	Center Result (%)	Competency value	Excellence value
1.	Oocyte cryosurvival rate	no. of morphologically intact oocytes[a] x 100 no. of oocytes warmed				70%	85%
2.	Fertilization rate	no. of oocytes with 2PN[b] x 100 no. of warmed MII oocytes injected				55%	70%
3.	Embryo development rate	no. of cleaved embryos on Day 2 or 3 x 100 no. of normally fertilized oocytes[a]				≥90%	≥95%
4.	Implantation rate (cleavage stage)[b]	no. of sacs seen on ultrasound x 100 no. of embryos transferred				No more than 10–30% (relative) lower than that for the comparable population of fresh embryos at the centre	
5.	Implantation rate (blastocyst stage)[b]	no. of sacs seen on ultrasound x 100 no. of blastocysts transferred				No more than 10–30% (relative) lower than that for the comparable population of fresh embryos at the centre	

[a] based on intention to inject, at the time of ICSI. If the oocyte is judged to be suitable for injection, then it is considered to be morphologically normal for the purposes of this KPI.
[b] at time time of fertilization check (17 ± 1 h post insemination)

Appendix 17025:2017 / ISO 15189:2012 and FMedV - 1. September 2017	Cross-reference to ISO		
--	ISO 17025:2017	ISO 15189:2022	FMedV - 1 September 2017
Requirement 1.1	4.1; 5.1; 5.4; 5.5	4.1; 5.1; 5.4.1	Art. 4; section c.
1.2 Impartiality / Ethical approach	4.1; 5.1	4.1; 5.1	Art. 4; section c.
1.3 Confidentiality	4.2	4.2	Art. 4; section c.
2.1 Scope	5.3; 5.4; 7.2.2	4.3; 5.3.3; 6.7	Art. 4; section c.
2.2 Establishing the procedure	5.5; 7.2.2	6.7	Art. 4; section c.
3.1 Laboratory management	5.2; 5.7; 7.2.2	5.2	Art. 4; section a. Art. 4; section c.
3.2 Laboratory staff	6.1; 6.2; 5.6	5.4.2; 6.2	Art. 4; section b. Art. 4; section c.
4.1 QM system	8.1.1; 8.1.2; 8.2; 8.3	8.1;8.2	Art. 4; section c.
4.2 Management of specifications	8.3	8.2; 8.3	Art. 4; section c.
4.3 Management of records	8.4	8.4	Art. 4; section c.
4.4 Laboratory strategy	8.2	5.5; 8.2.3	Art. 4; section c.
4.5 Error management / complaints / improvement / correction and prevention	7.9; 7.10; 8.6; 8.7	7.5; 7.7; 8.5; 8.6; 8.7	Art. 4; section c.
4.6 Risk management	8.5	5.6; 8.5	Art. 4; section c.
4.7 Internal Audits	8.8	8.8	Art. 4; section c.
4.8 Annual report/management review	8.9	8.9	Art. 4; section c.
5.1 Key Performance Indicators	7.7	5.5; 7.3.7.4; 8.8.2	Art. 4; section c.
5.2 Quality assurance	7.7	7.3.7.1; 7.3.7.3; 7.3.7.4; 8.7	Art. 4; section c.
6.1 Room conditions	6.1; 6.3	6.3	Art. 4; section c.
6.2 Access regulations	6.3	6.3	Art. 4; section c.
6.3 Emergency plan	6.3	6.2; 6.3; 7.6	Art. 4; section c.
6.4 Occupational safety	6.3	6.3; 6.4; 8.7	Art. 4; section c.
6.5 Gametotoxic components	6.3	6.3; 6.4; 8.7	Art. 4; section c.
6.6 Equipment	6.3; 6.4; 6.5; 7.5; 7.6	6.4; 6.6	Art. 4; section c.
6.7 Air purity	6.3	6.3	Art. 4; section c.
6.8 Storage	6.2; 6.3	6.2; 6.3	Art. 4; section c.
7.1 Traceability	7.3; 7.4. 7.5	6.6; 7.2; 7.3.6	Art. 4; section c.
7.2 Traceability training	6.2	6.2	Art. 4; section c.
7.3 Witness systems	7.7	7.3.7	Art. 4; section c.
7.4 Media, reagents and consumables including disposable products	6.6; 7.5	5.3.3; 6.6; 6.8	Art. 4; section c.
8.1 Procedural regulations and validation	7.1; 7.2.1	7.3	Art. 4; section c.
8.2 SOP specifications	7.2.1	7.2; 7.3; 7.4	Art. 4; section c.
8.3 SOP update	6.1; 8.3; 8.4	8.3; 8.4; 6.2	Art. 4; section c.
8.4 Reports / documentation of results	7.8	7.4.1	Art. 4; section c.
8.5 Laboratory information management	7.11	7.6	Art. 4; section c.
Appendix	7.7	8.8.2	Art. 4; section c.

History of published Versions of the Requirements Specification

Version	Date published	Date coming into force	Replaces Version #	Approved by
1.2		2018-03	--	QUARTS Commission
2.0		2018-06	1.2	QUARTS Commission
3.0	2020-02-04	2020-08-01	2.0	QUARTS Commission
3.1	2020-02-14	2020-08-01	3.0	Doc-Cert AG
3.2	2020-07-08	2020-08-01	3.1	QUARTS Commission
3.3	2020-07-27	2020-08-01	3.2	Doc-Cert AG
3.4	2022-01-10	2022-01-10	3.3	QUARTS Commission
3.5	2024-03-04	2024-03-04	3.4	QUARTS Commission