Every patient deserves the GOLD STANDARD ...

Reproductive Laboratory Checklist

CAP Accreditation Program
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# Reproductive Laboratory Checklist

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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-LAB Solutions. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory’s activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

SUMMARY OF CHECKLIST EDITION CHANGES
Reproductive Laboratory Checklist
07/28/2015 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged:
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements
None

REVISED Checklist Requirements

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INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a reproductive laboratory.

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

ANDROLOGY AND EMBRYOLOGY

QUALITY MANAGEMENT AND QUALITY CONTROL

GENERAL ISSUES

Inspector Instructions:

- How does your laboratory monitor embryology clinical outcomes?

RLM.01000 Unusual Laboratory Events Phase I

There is a written policy for reporting unusual or abnormal events to the supervisor, laboratory director, or physician.

REFERENCES

**REVISED** 04/21/2014

RLM.01200 Monthly QC Review Phase II

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
✓ Records of QC review with follow-up for outliers, trends, or omissions

REFERENCES

RLM.01250 Clinical Outcome Review

Phase II

The laboratory at least annually reviews embryology clinical outcome in relation to all data collected.

NOTE: The laboratory must keep statistical records and review the clinical outcome in relation to this data. The frequency of these reviews should be appropriate to the size of the laboratory and the number of patient cycles, but must be recorded at least annually.

Evidence of Compliance:
✓ Records of statistical data AND
✓ Records of data review by the laboratory director, designee or QM committee

REFERENCES

REQUISITIONS, SPECIMEN RECEIPT, AND RESULTS REPORTING

Inspector Instructions:

- Sampling of specimen collection and handling policies and procedures
- Sampling of patient records for all necessary collection information
- Patient instructions
- Sampling of patient reports

- Posted collection instructions

- What is your course of action when you receive unacceptable specimens?

RLM.01800 Specimen Collection/Handling

Phase I

There are written patient instructions for collection and prompt delivery of a semen sample to the laboratory.

NOTE: Patients must be provided with specific instructions for collection and prompt delivery of a semen sample to the laboratory. This should be written in simple terms in a language readily understood by the patient. Elements should include the need to abstain from ejaculation for 2-7 days before collection of the specimen, avoidance of lubricants and other contamination, completeness of collection, use of the supplied container, maintenance of sample temperature, and prompt delivery. Instructions must be posted in the collection room. Collection instructions should be distributed to off-site physician offices that refer specimens.
Semen specimens are accompanied by the following collection information, and records are maintained on the following.

1. Method of collection
2. Type of specimen container
3. Days of abstinence
4. Collection or transport problems (e.g. incomplete specimen, exposure to temperature extremes)
5. Time of specimen receipt and analysis
6. Identity of patient was confirmed and by whom

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.02100 Liquefaction Phase I

All semen specimens are given sufficient time for liquefaction before testing.

Evidence of Compliance:
✓ Written policy defining criteria for liquefaction

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.02200 Specimen Handling - Pre-analytic Phase I

Semen specimens are mixed thoroughly before testing.

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.02300 Specimen Characteristics - Analytic Phase I

All characteristics of the semen specimens are noted and reported (e.g. gelatinous clumps, viscosity, contaminants, erythrocytes, abnormalities of liquefaction).

NOTE: Macroscopic and microscopic characteristics of the semen specimens must be noted and reported, in accordance with the WHO laboratory manual for the examination and processing of human semen (i.e. fourth or fifth edition).

Evidence of Compliance:
✓ Written policy defining characteristics to be included in the report

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.02400 Reporting Phase II

Patient results are reported in a legible, easy-to-interpret format that clearly delineates the clinical significance of the results.
GENERAL QUALITY CONTROL

Inspector Instructions:

- Sampling of quality control policies and procedures
- Sampling of QC records

- How do you determine when quality control is unacceptable and when corrective actions are needed?

- Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

RLM.02800 QC Phase II

For qualitative tests, a positive and negative control is included with each run of patient specimens.

Evidence of Compliance:
✓ QC records showing positive and negative control results

REFERENCES

**REVISED** 04/21/2014

RLM.02900 QC Handling Phase II

Control specimens are tested in the same manner and by the same personnel as patient samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient/client testing - this does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled, recognizing that pre-analytic and post-analytic variables may differ from those encountered with patient/clients.

Evidence of Compliance:
✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES

RLM.03000 QC Confirmation of Acceptability Phase II

The results of controls are reviewed for acceptability before reporting results.
NOTE: It is implicit in quality control that patient test results will not be reported when controls do not yield acceptable results.

Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Evidence of corrective action taken when QC results are not acceptable

REFERENCES

RLM.03100 QC Data Phase II
Quality control data are organized and presented so they can be evaluated daily by the technical staff to detect problems, trends, etc.

REFERENCES

RLM.03125 QC Corrective Action Phase II
There is a record of corrective action when control results exceed defined acceptability limits.

NOTE: Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing samples, depending on the circumstances.

REFERENCES
# CULTURE MEDIA

**Inspector Instructions:**

| READ | • Sampling of test procedures for reagent handling (including media preparation/modification)  
<table>
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<th></th>
<th>• Sampling of in-house culture media QC records and manufacturer QC records</th>
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| OBSERVE | • Sampling of culture media (expiration date, condition, contamination)  
|      | • Appropriate environment for culture media preparation |
| ASK | • How does your laboratory evaluate the quality of contact material?  
|      | • What is your course of action when culture media does not meet QC requirements? |
| DISCOVER | • Follow a shipment of new culture media from receipt, examination and QC (if applicable). Determine if practice follows laboratory procedure. |

*Additional requirements are in the REAGENTS section of the All Common Checklist.*

**RLM.03500 Media Preparation/Modification**

*There are written procedures for media preparation and modification.*

*NOTE: All media preparation/modification must be performed with sterile technique, in a location and environment appropriate for media preparation. The laboratory has a responsibility for ensuring that any media purchased, prepared or modified is sterile and capable of supporting culture of gametes and embryos.*

**REFERENCES**


**RLM.03600 Media Handling**

*There are written criteria for media storage conditions and expiration.*

**REFERENCES**


**RLM.03700 Media QC**

*The laboratory has a written procedure for quality control of media.*
NOTE: Culture media must be able to support the viability of gametes and/or the growth of embryos. Media must be evaluated using a bioassay system such as the one or two cell mouse embryo culture assay or a sperm motility assay. If culture media or protein supplements are modified or prepared in-house, records show that they have been tested on site. Commercial media must be used within the labeled expiration period. Records of quality control testing using an appropriate bioassay system must always be supplied by the manufacturer and retained for quality control records. The media quality control procedure must include records of the acceptability of the receiving conditions for transported commercial media.

REFERENCES

RLM.03800 Contact Material QC Phase II
The laboratory tests and records the quality of contact materials using a bioassay.

NOTE: Materials pretested by the manufacturer with an appropriate bioassay system would not require further in-house testing. Records of testing performed by the manufacturer must be retained.

Evidence of Compliance:
✓ Written procedure for the testing of contact materials, including the acceptability criteria

REFERENCES

RLM.03900 Media QC Corrective Action Phase II
Records indicate corrective action when components do not meet quality control requirements after preparation or modification.

REFERENCES

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section must be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- Sampling of records for liquid nitrogen monitoring
- Sampling of alarm monitoring records
- Sampling of incubator monitoring records for gas concentration
- What is your laboratory's course of action when equipment failure occurs?
- What back-up options are available in the event of an electrical power outage?
- How does your laboratory monitor sterilizing devices?
- How is the alarm system monitored?

RLM.03910 Gas Mixtures Phase II
There are written criteria for use of gas mixtures.

REFERENCES

RLM.03915 Incubator Daily QC

**Checks of incubator function are recorded each day of use using an independent measuring device for gas concentrations in incubators.**

**NOTE:** In lieu of measuring daily gas concentrations, the laboratory may verify acceptable incubator culture conditions by monitoring and recording daily checks for pH. Alternatively, laboratories using premixed gas may retain the manufacturer's certificate of analysis as evidence of acceptable QC.

**REFERENCES**

RLM.03920 Incubator Acceptable Limits

**Acceptable limits of humidity, gas content, and/or pH are defined for incubators.**

**REFERENCES**

RLM.03930 Incubator Gas Failure

**The laboratory has written procedures to detect and prevent incubator gas failure.**

**Evidence of Compliance:**
✓ Written procedure for detecting and preventing gas failure (e.g. alarms or automated monitoring systems)

**REFERENCES**

RLM.03935 Emergency Power Back-up

**The laboratory’s incubator for embryos and gametes has emergency backup power, and it is tested at least quarterly.**

**Evidence of Compliance:**
✓ Record of generator testing

**REFERENCES**

RLM.03940 Liquid Nitrogen Levels

**The laboratory has a written procedure to monitor and maintain adequate liquid nitrogen (LN2) levels.**

**Evidence of Compliance:**
✓ Written procedure for monitoring LN2 levels AND ✓ Records of monitoring of LN2 levels at defined frequency

**REFERENCES**
1) Standards and technical manual reproductive cells and tissues. American Association of Tissue Banks, 2002
**Alarm Monitoring**

The alarms are monitored 24 hours/day (either remote or in the laboratory).

*NOTE: Alarm systems, if used, must be checked at least annually. Audible alarms are only effective if someone is able to respond and is trained to follow written procedures to correct the problem or take alternative measures.*

**Evidence of Compliance:**
- Written procedure for monitoring alarms **AND**
- Records of response to the alarm

**REFERENCES**

**Equipment Back-up**

The laboratory has a written procedure for implementing back-up capability (refrigerators, freezers, incubators, etc.).

*NOTE: If any unit begins to fail, a repair or replacement would probably not be able to be purchased and delivered soon enough to avoid loss of contents. It is therefore necessary to have an emergency procedure to provide backup units with adequate storage capacity to allow complete transfer of contents. The backup units must be tested at least annually to ensure their functionality if needed.*

Procedures for use of backup equipment, location, and contact personnel must be part of the procedure manual. If the backup plan involves using equipment at another laboratory or transferring specimens to another laboratory, there must be a written agreement between the laboratories.

**Sterilizing Device Monitoring**

All sterilizing devices are routinely monitored with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use with results recorded.

*NOTE: Chemical indicators that reflect sporicidal conditions may be used. One recommended method is to wrap the Bacillus stearothermophilus spore indicator strip in packaging identical to that used for a production run, and to include the test package with an actual sterilization procedure. This must be monitored with each sterilization cycle.*

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**RECORDS**

**Inspector Instructions:**
- Sampling of patients’ treatment cycle records for completeness
- Sampling of tracking records from source to final disposition
- Select a representative patient record and track progression through collection, processing, and administration of gametes and/or embryos. Confirm that the identity of the individual performing each step is recorded.
Result Recording

Laboratory records are generated for each individual patient’s treatment cycle and a copy is retained in the laboratory to include the following as applicable.

1. Results of oocyte retrieval
2. Semen analysis before and after processing
3. Outcome of insemination (e.g. fertilization)
4. Outcome of any culture (e.g. cleavage)
5. Relative timing of protocol events (incubation hours, etc.)

REFERENCES

Specimen Handling and Disposition

Laboratory records identify the person performing each step in the collection, processing and administration of gametes and/or embryos.

Evidence of Compliance:
✓ Patient records or worksheet identifying the person performing each step of the process

REFERENCES

Specimen Handling and Disposition

Records allow for the tracking of the disposition for gametes or embryos handled or stored.

NOTE: Records must allow for the tracking of tissues to their disposition to allow withdrawals/recalls to be directed appropriately and to allow problems in reproductive tissue recipients to be traced to their source.

REFERENCES

Reagent Records

Records of all critical reagents, supplies and equipment used in collection and processing of gametes and embryos, including lot numbers and expiration dates, are maintained and traceable for each product.

REFERENCES
1. U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm
ANDROLOGY PROCEDURES AND TESTS

SEmen ANALYSIS GENERAL

Inspector Instructions:

- Sampling of manual and automated semen analysis policies and procedures
- Sampling of patient records or worksheets
- Sampling of patient reports

- What is your laboratory’s course of action when specimens yield a low percent motility?

- Follow a semen analysis from requisition, collection information, testing, reporting and recording of result. Determine if practice follows laboratory procedure.

The following five checklist requirements are applicable to both automated and manual semen analysis.

RLM.03982 Report Disclaimer Phase I

If cell clumps or debris are observed during semen analysis, the laboratory indicates on the report that results may be inaccurate.

RLM.03984 Azoospermic Specimen Result Reporting Phase I

For azoospermic and post-vasectomy seminal fluid specimens, the laboratory clearly communicates the findings of the assay and either employs a concentrating technique on seminal fluid or includes a comment in the patient report indicating that a concentrating technique was not performed.

NOTE: Without a concentration technique, the presence of both motile and non-motile sperm may not be detected. The method for detection of motile and non-motile sperm and the laboratory findings must be clearly communicated on the patient report so that the clinician can interpret the results in context to the method performed. The decision on the method used and extent of testing to be performed should be made in consultation with the medical staff served.

The American Urological Association (AUA) Vasectomy Guideline recommends a careful evaluation of an uncentrifuged specimen and does not recommend centrifugation of the specimen for further assessment. The AUA Guideline also recommends reporting both the presence and absence of sperm and presence or absence of sperm motility on the patient report. If no sperm are seen in the uncentrifuged specimen, the guideline recommends reporting that the presence of sperm is below the limit of detection.
Evidence of Compliance:
✓ Patient report with concentration findings or appropriate comment indicating that
collection was not performed

REFERENCES
1) Evaluation of the Azoospermic Male. Fertil Steril. 2008; 90 (S74-7)

RLM.03986 Motility/Progression Evaluation Phase II

Sperm motility percent and progression are routinely evaluated within one hour of
collection.

NOTE: Exceptions must be noted on the final report.

Evidence of Compliance:
✓ Written procedure with requirement for motility evaluation AND
✓ Records indicating time of collection and evaluation AND
✓ Patient reports noting exceptions, when appropriate

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth

RLM.03988 Viability Testing Criteria Phase I

The laboratory performs viability testing on specimens with low percent motility (e.g. less
than 30%), or includes a comment that the decreased motility may be the result of non-
viable or non-motile sperm.

NOTE: Non-motile sperm may represent forms that were originally non-viable in the ejaculate,
or previously motile forms that have subsequently lost motility. Thus, viability assessment is
useful in making the distinction, and is commonly performed with a dye-exclusion method such
as eosin-nigrosin.

Evidence of Compliance:
✓ Written procedure for viability testing AND
✓ Patient records or worksheet with results of viability testing OR patient report with cautionary
verbiage

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth
2) Gunalp S, et al. A study of semen parameters with emphasis on sperm morphology in a fertile population: an attempt to develop

RLM.03990 Standard Temperature Range Phase II

The laboratory has established a standard temperature range for semen analysis
assessment, and deviations from this temperature are noted on the report.

NOTE: Specimen motility is temperature-dependent. Temperature ranges must be defined.

Evidence of Compliance:
✓ Written procedure with acceptable temperature range defined AND
✓ Records showing monitoring of temperatures

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth
AUTOMATED SEMEN ANALYSIS INSTRUMENTS

Varieties of systems are in use and some requirements may not apply to every system. The requirements are intended to check factors common to all automated systems. Inspectors should use individual judgment in applying the requirements to the particular type of system being used.

Inspector Instructions:

- Sampling of automated semen analysis policies and procedures
- Sampling of automated QC/calibration records (includes validation of calibration materials)

CALIBRATION AND QUALITY CONTROL

Several different methods may be used for calibration and quality control in the automated analysis of semen characteristics. "Calibration" techniques include use of:

1. Multiple analyzed sperm specimens,
2. Stabilized preparations of sperm cells (e.g. fixed or preserved),
3. Sperm surrogates (e.g. latex particles),
4. Digital images/videotaped sperm specimens.

NOTE: If stabilized control materials are used, they must represent different analytic levels (e.g. normal and high). Similarly, retained patient specimens must be of differing counts and/or motility, as applicable.

**REVISED** 07/28/2015
RLM.04100 Calibration Materials  Phase II

Calibration is verified with materials appropriate to the reportable range of the instrument, and verification is recorded.

NOTE: The quality control procedure for the automated instrument must include calibration and evaluation using defined limits of agreement with manually counted semen smears or stored digital images, as appropriate for the particular system. Laboratories must verify at least every six months that instruments are functioning correctly and are in control.

REFERENCES

**REVISED** 07/28/2015
RLM.04200 Daily QC  Phase II

The laboratory performs and records quality control for the automated instrument during each day of use, following the manufacturer instructions or using at least two levels of control at different concentrations.

REFERENCES
RLM.04300  Recalibration  Phase II

The laboratory has a procedure for recalibration of instrument parameter(s) when problems are encountered.

REFERENCES
2) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.04400  Calibration Material Validation  Phase II

The material used for calibration is validated using primary reference procedures (e.g. manual counts).

Evidence of Compliance:
✓ Written procedure identifying calibration materials and validation of materials used AND
✓ Records showing accuracy of calibration materials used to include manufacturer's certification/validation of commercial products OR in-house validation data

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press
2) Krause W. [Value of computer-assisted sperm analysis (CASA), reproducibility--online documentation--prognostic value]. [Article in German]. Fortschr Med. 1996;114:470-473

RLM.04500  System Control  Phase II

If a manual method is used as the system control for automated sperm counts, its accuracy is verified and recorded at intervals appropriate for laboratory volume.

REFERENCES

RLM.04600  Acceptable Limits - Controls  Phase II

Acceptable limits are established for the value of each quality control sample.

Evidence of Compliance:
✓ Records of defined acceptable limits for control range of each lot

**REVISED** 07/28/2015

RLM.04700  Sperm Concentration Range  Phase II

For automated sperm counts and motility, there is a written procedure to confirm that the concentration of the specimen is within the range appropriate for automated analysis.

REFERENCES

RLM.04900  Reportable Range  Phase II
Upper and lower limits of all reportable parameters on instruments are defined, and results that fall outside these limits are reported properly.

*NOTE:* Results that fall outside of these limits may be verified by repeating the test, using an alternative method or diluting/concentrating the specimen, as appropriate.

**Evidence of Compliance:**
- Written procedure defining the upper and lower reporting limits and verification of results
- Patient test verification records

**REFERENCES**

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**RLM.05000 Calibration Verification Criteria**

Phase II

There are written criteria for method calibration verification.

*NOTE:* Criteria for determining the need for calibration verification typically include:

1. At complete changes of reagents, unless the laboratory can demonstrate that changing reagent lots does not affect either the range used to report patient test results or the control values,
2. When QC materials reflect an unusual trend or shift or are outside of the laboratory’s acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem
3. After major maintenance or service,
4. When recommended by the manufacturer,
5. At least every six months.

**Evidence of Compliance:**
- Written procedure defining method, frequency and limits of acceptability of calibration verification for each instrument/test system
- Records of calibration verification at defined frequency

**REFERENCES**
# MANUAL SEMEN ANALYSIS

## Inspector Instructions:

- Sampling of manual semen analysis policies and procedures
- Sampling of manual semen analysis QC records
- Sampling of stain QC records
- Sampling of patient reports (classification system noted)
- Sampling of patient records/worksheets

- Stained smear (uniquely identified, properly stained, free of precipitate, uniform cell distribution, recognition of reportable cell types)
- File of unusual slides
- Counting chamber condition

- What do you do if there is difficulty distinguishing leukocytes from other round cells when performing sperm counts using bright field microscopy?
- How is the sperm motility method in use verified?
- How do you ensure that morphologic observations are consistent among all personnel who report sperm differential results?
- How long does your laboratory retain slides?

## SPERM CONCENTRATION

### RLM.05100 Counting Chamber Quality

**Phase I**

The lines in the counting or motility chambers are bright, and the chambers are clean and free of scratches.

### RLM.05150 Cell Count Controls

**Phase II**

At least one cell count control specimen is analyzed, or a procedural control used, for each eight hours of patient testing.

**NOTE:** This requirement can be met with assayed liquid control material, a previously assayed patient sample, or a procedural control. (An example of a procedural control is correlation of the cell count with the cellularity of a stained slide prepared by a standard, validated method.) Liquid controls performed in a hemocytometer should be run in duplicate.

**Evidence of Compliance:**

- Written procedure for quality control of manual sperm counts **AND**
- Records of cell count or procedural controls at defined frequency

### RLM.05200 Semen Analysis Procedure

**Phase II**

For samples counted using a standard hemocytometer, each sperm sample is counted in duplicate.

**NOTE:** Defined limits of agreement between replicate counts must be established.
Evidence of Compliance:
✓ Written procedure requiring duplicate counts to include limits of agreement AND
✓ Records or worksheets reflecting duplicate counts and corrective action when limits of agreement are exceeded

SPERM MOTILITY

RLM.05900 Motility Microscopic Examination
The laboratory has written instructions for evaluating a sufficient number of separate and randomly chosen microscopic fields and sperm cells.

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.06000 Motility Quantification
Manual measures of percent sperm motility are quantified in a standardized manner.

NOTE: The laboratory must have a written method for determining and reporting sperm motility in its procedure manual that describes how sperm are assessed and counted (percent motility) and is based on a reference method, such as the World Health Organization (WHO) Standards (i.e. fourth or fifth edition).

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.06100 Forward Progression
Forward progression of sperm is evaluated.

Evidence of Compliance:
✓ Written procedure for evaluation of forward progression AND
✓ Patient reports or worksheets with results of forward progression

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.06200 Motility Method Verification
The sperm motility method is verified at least every six months (e.g. video tapes/digital images of specimens with known percent motility and/or specific motion quality).

Evidence of Compliance:
✓ Records of method verification

REFERENCES
SEmen Stained Smear - Sperm Differential

RLM.06300 Stain Usage

Stains are used to facilitate morphologic classification of cell types in semen (as opposed to performing differentials of unstained preparations).

Evidence of Compliance:

✓ Written procedure for the use of stains for cell classification

REFERENCES

RLM.06350 White Cell Confirmation Techniques

There is an additional procedure beyond unstained bright-field microscopy to ensure the accurate distinction of leukocytes from other round cells (e.g. Wright's or PAP stain, leukocyte alkaline phosphatase, myeloperoxidase).

NOTE: This requirement only applies to laboratories that differentiate leukocytes from other round cells on the patient report.

Evidence of Compliance:

✓ Written procedure for confirmation for cell differentiation

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press

RLM.06400 Stain QC

All stains are checked for contamination and reactivity each day of use.

Evidence of Compliance:

✓ Records of contamination checks on all stains

REFERENCES

RLM.06700 Morphology Classification

The sperm morphology classification method used is indicated on the report.

NOTE: Different classification systems have different reference intervals for normality. To improve the consistency and usefulness of reporting, CAP recommends the use of the WHO Standards (i.e. fourth or fifth edition) and the Kruger classification system, and discontinuing the use of older classification systems.

REFERENCES
2) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010). New York, NY: Cambridge University Press
RLM.06800  Slide Retention  Phase II

The slides are retained for at least seven days for future reference.

RLM.06900  Morphologic Observation Assessment  Phase II

The laboratory at least annually assesses morphologic observations among personnel performing microscopic morphologic classification of sperm and other cells, to ensure consistency.

NOTE: Suggested methods to accomplish this include:

1. Circulation of stained semen smears with defined specific qualitative abnormalities of sperm
2. Multi-headed microscopy
3. Use of published references
4. Digital images (e.g. from CD-ROM)

Evidence of Compliance:
✓ Written procedure defining the method and criteria used for evaluation of consistency AND
✓ Employee records of morphology assessment

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010), New York, NY: Cambridge University Press

RLM.07000  Sperm Morphology Reference  Phase I

There is a file of unusual slides or current atlas of sperm morphology available for training and reference.

REFERENCES
1) WHO laboratory manual for the examination and processing of human semen, most recent editions (i.e. fourth edition 1999 and fifth edition 2010), New York, NY: Cambridge University Press

RLM.07100  Stain Quality  Phase II

The stains used (Wright’s, Papanicolaou, eosin-nigrosin, peroxidase, etc.) and slide preparations are of sufficient quality to demonstrate the cellular characteristics for which they are designed.

NOTE: The stains used for semen analysis must be defined in the laboratory’s procedure manual.

Evidence of Compliance:
✓ Examples of each type of stained slide available for microscopic review by inspector, as applicable

BIOCHEMICAL TESTS

**REVISED** 07/28/2015

RLM.07400  Biochemical Tests - Daily QC  Phase II
For biochemical tests such as fructose, positive and negative controls are run with each assay, with results recorded and reviewed for acceptability.

Evidence of Compliance:
✓ Written procedure for QC AND
✓ QC records

REFERENCES

ANTI-SPERM ANTIBODY (ASA) TESTS

Inspector Instructions:

- Sampling of ASA policies and procedures
- Sampling of ASA QC records

**REVISED** 07/28/2015

RLM.07500 Heat Inactivation Phase II

Serum and follicular fluid specimens used for indirect ASA testing are heat-inactivated before use.

NOTE: Serum and follicular fluid specimens used for indirect ASA testing must be treated to inactivate complement.

Evidence of Compliance:
✓ Written procedure for pre-analytic treatment of specimens

REFERENCES
1) Keel BA, Webster BW. CRC handbook of the laboratory diagnosis and treatment of infertility. Boca Raton, FL: CRC Press, 19RLM.185

RLM.07600 Motility Testing Phase I

If the testing for ASA requires motile sperm, specimens are assayed with minimal delay and the motility assessed and recorded.

Evidence of Compliance:
✓ Patient records and worksheets showing time of collection and evaluation of motility

REFERENCES

RLM.07700 ASA Controls Phase II

For indirect antibody testing, positive and negative controls are run with each assay, with results recorded and reviewed for acceptability.

Evidence of Compliance:
✓ Written procedure for QC AND
✓ QC records

REFERENCES
1) Keel BA, Webster BW. CRC handbook of the laboratory diagnosis and treatment of infertility. Boca Raton, FL: CRC Press, 19RLM.185
SPERM PROCESSING FOR THERAPEUTIC INSEMINATION

Inspector Instructions:

- Sampling of therapeutic insemination policies and procedures (includes maintaining specimen identity)

RLM.07800 Specimen Handling - Therapeutic Insemination  
Phase II

Special handling requirements for insemination specimens are defined and followed (e.g. aseptic technique, processing with minimum delay), as necessary.

REFERENCES

RLM.07900 Sperm Preparation  
Phase II

There are written procedures for preparing sperm for insemination (e.g. gradient, swim-up techniques).

REFERENCES

RLM.08000 Specimen Handling  
Phase II

There is a system to verify and maintain the identity of the specimen throughout receipt, storage, processing, and disposition.

NOTE: All specimens must be labeled with a minimum of two identifiers.

Evidence of Compliance:
- Written procedure for maintaining specimen identity

REFERENCES

ANDROLOGY PERSONNEL

The laboratory should have an organizational plan, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files must contain diplomas or transcripts, references, competency assessments, health records, and continuing education records for each employee. Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (i.e. easily available to the inspector).

The section director of the andrology laboratory must have the appropriate training and background to assume responsibility for the overall operation and administration of the laboratory, including hiring competent personnel, formulating laboratory policies and protocols, and communicating regularly regarding patient progress and patient protocols as they affect laboratory aspects of treatment. The andrology section director must be accessible to the laboratory for on-site, telephone or electronic consultation as needed.
**Inspector Instructions:**

- Records of andrology section director/staff education and experience

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**RLM.08200 Personnel Qualifications**

Phase II

The andrology section director and all other personnel in the andrology laboratory meet the requirements described in the Laboratory General Checklist and the Team Leader Assessment of Director and Quality Checklist.

**NOTE:** The andrology section director must have two years experience in a laboratory performing andrology procedures. This experience should include quality management, quality control, inspection, accreditation and licensing procedures, as well as andrology procedures.

**Evidence of Compliance:**

- Records of qualifications including degree or transcript, certification, current license (if required) and work history in related field

**REFERENCES**


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**EMBRYOLOGY**

Embryology laboratories may have separate andrology facilities that are not accredited by the College of American Pathologists. However, if the embryology laboratory either processes sperm for therapeutic insemination, oocyte insemination, or performs any form of a semen analysis, it must complete requirements in the preceding SPERM PROCESSING FOR THERAPEUTIC INSEMINATION section and/or the ANDROLOGY section.

**Genetic testing on embryo biopsy specimens** must be performed by a CAP accredited laboratory or other laboratory meeting the reference laboratory selection criteria defined in the Laboratory General Checklist (GEN.41350).

If no embryology procedures are performed in the laboratory continue with the Cryopreservation of Sperm, Oocytes, and Embryos section.
OOCYTE AND EMBRYO HANDLING

Inspector Instructions:

- Sampling of policies and procedures for oocyte/embryo handling and embryo transfer
- Sampling of embryology records (time-out verification, embryo development stage, chain-of-custody documentation, catheter checks)
- Sampling of training and competency records
- Sterile technique environment
- How does your laboratory verify proficiency in its ability to assess the quality of embryos?
- Follow a patient procedure from handling, assessment, culturing and transfer of human sperm, oocytes and embryos. Determine if procedures and records are adequate.

CULTURE OF SPERM, OOCYTES, AND EMBRYOS

NOTE: If a sperm count and/or motility are performed as part of the sperm processing procedure, the laboratory must comply with the pertinent checklist items for sperm count, motility, and proficiency testing listed in the other sections of this checklist.

RLM.08290 Time-Out

A "time-out" is called and the following information recorded prior to initiation of each egg retrieval or embryo transfer procedure.

1. Patient's two identifiers
2. Planned procedure (e.g. egg retrieval or embryo transfer)
3. Written physician's order
4. Number of embryos to be transferred

NOTE: The "time out," or immediate preoperative pause, must occur in the location where the procedure is to be done with active participation of the appropriate members of the team. The time-out is an opportunity to confirm agreement of all team members present and to resolve any discrepancies prior to initiation of the procedure.

The procedures for egg retrieval and embryo transfer must explain the laboratory's role, the elements to be confirmed, and the method used for recording the time-out. The record of the time-out must demonstrate that all required elements have been verified.
Evidence of Compliance:
✓ Written procedure with steps to verify information AND
✓ Records of time-out verification for each procedure

REFERENCES

RLM.08300 Sterile Techniques
Sterile techniques are employed in the handling, assessment, culturing, and transfer of human sperm, oocytes and embryos.

Evidence of Compliance:
✓ Written procedure detailing use of appropriate sterile techniques at each step

RLM.08400 Oocyte Maturity/Embryo Quality
There are written criteria for evaluation/assessment of oocyte maturity and embryo quality prior to insemination and embryo transfer respectively.

NOTE: Procedures should include description of oocyte and embryo quality and maturity. The stage of embryo development at transfer must be recorded.

REFERENCES

RLM.08450 Embryo Quality Assessment Verification
The procedure of embryo transfer includes verification of the laboratory’s proficiency to assess the quality of embryos (e.g. participation in a commercial proficiency testing or inter-laboratory comparison program).

RLM.08500 Insemination - Oocyte Maturity
There are written criteria for insemination relative to oocyte maturity.

NOTE: Procedures must be defined for instances of immature and/or atretic oocytes.

REFERENCES

**REVISED** 07/28/2015

RLM.08600 Sperm Number/Volume
There are defined criteria for volume and number of sperm used for insemination of each egg.

NOTE: There are written procedures for estimation of sample parameters for concentration, motility and morphology along with techniques for insemination with respect to count and motility for both normal and male factor patients.

REFERENCES

RLM.08700 Disposition of Oocytes
There is a written procedure for the immediate disposition of oocytes with an abnormal number of pronuclei.
NOTE: Embryos with abnormal numbers of pronuclei should not be transferred.

REFERENCES

RLM.08800 Oocyte Examination Phase II
There is a defined period for examination of oocytes for fertilization.

REFERENCES

RLM.08900 Re-Insemination Criteria Phase II
The laboratory has written procedures for re-insemination, using either in vitro fertilization or intracytoplasmic sperm injection.

NOTE: Procedures for re-insemination of oocyte and/or micromanipulation should include time frame for re-insemination, criteria for use of initial sample, time frame for re-examination of these oocytes, and the hierarchy for their use at embryo transfer.

REFERENCES

RLM.09100 Micromanipulation Phase II
The laboratory has a program to ensure that micromanipulation procedures are performed at an acceptable level.

NOTE: This would include fertilization of oocytes, survival following zona hatching and pregnancy rates using micromanipulated embryos.

Evidence of Compliance:
✓ Written procedure to assess ongoing performance, including criteria defining the acceptable levels of performance AND
✓ Records of evaluation of individuals performance OR evaluation of fertilization rate statistics for each embryologist OR records of another documented method approved by the laboratory director AND
✓ Records of corrective action when acceptable level of performance are not achieved

RLM.09150 Embryo Biopsy/Specimen Preparation Training Phase II
There is a written program to train personnel and evaluate competence in the performance of embryo biopsy and specimen preparation.

Evidence of Compliance:
✓ Records of training and competency

EMBRYO TRANSFER PROCEDURES

RLM.09200 Embryo Culture Timeline Phase II
There are written procedures for the length of time that embryos are cultured before transfer.

REFERENCES
RLM.09300 Embryo Quality/Status

The laboratory records the status and quality of embryos before transfer.

*NOTE: It is suggested that, whenever possible, photographic records be retained.*

**REFERENCES**

RLM.09400 Chain-of-Custody

The identity of the patient specimen (sperm or embryos) is checked against the identity of the patient prior to transfer or insemination and this identification is recorded.

*NOTE: There must be an established chain-of-custody for all reproductive gametes or embryos that are transferred back to a patient. This includes records of the patient specimen identification (ID), as well as the patient's ID. When it is not possible for the laboratory staff to check the patient's ID, then this check should be performed and recorded by a nurse, physician, or other health care provider before transfer.*

**Evidence of Compliance:**
- Written procedure defining chain-of-custody for patient and patient specimen ID prior to transfer or insemination

RLM.09500 Catheter Check

The laboratory records a check of the catheter for any embryos left after transfer.

**REFERENCES**

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**EMBRYOLOGY PERSONNEL**

**Inspector Instructions:**

- Records of embryology section director education and experience
- Back-up personnel policy

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**EMBRYOLOGY SECTION DIRECTOR**

RLM.10166 Embryology Section Director Qualifications

The section director of the embryology laboratory has proper qualifications through education and experience to provide direction and administration of the laboratory.

*NOTE: The section director of the embryology laboratory must have at least 2 years of experience in a laboratory performing in vitro fertilization or assisted reproductive technologies-related procedures. Section directors of embryology laboratories who are not physicians or qualified doctoral scientists, but who were functioning as embryology directors on or before July 20, 1999 are considered in compliance with the personnel requirements in the Laboratory General Checklist, as long as they meet all other requirements. Effective January 1, 2006, all new laboratory directors must hold HCLD (High Complexity Laboratory Director), ABB-ELD (American Board of Bioanalysis Embryology Laboratory Director), or equivalent certification.*
If the laboratory is also performing testing for the purpose of diagnosis (e.g. semen analysis, hormone assays), the laboratory director must meet the personnel requirements defined in the Team Leader Assessment of Director and Quality Checklist.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, certification, current license (if required) and work history in related field, as applicable

REFERENCES
1) United States general accounting office. December 1989, p 17, 7d

**RLM.10250 Assisted Reproductive Technology (ART) - Personnel Qualifications**

**Phase II**

Embryology laboratory personnel performing assisted reproductive technology (ART) procedures must have appropriate education and records of training.

**NOTE:** Embryology laboratory personnel must have records of training for each of the ART laboratory procedures performed. An embryologist must have a minimum of a bachelor's degree in a chemical, physical, biological, medical technology, clinical or reproductive laboratory science from an accredited institution. Embryologists performing ART laboratory procedures prior to January 1, 2012, are considered in compliance with this requirement, as long as there is recorded training for the ART laboratory procedures performed and the embryologist meets the laboratory's defined personnel qualifications. If embryology personnel are also performing testing for the purpose of diagnosis (e.g. diagnostic semen analysis, hormone analysis), the embryologist must also qualify under the testing personnel requirements defined in the Laboratory General Checklist.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field, as applicable

REFERENCES

**RLM.10253 Embryology Training/Evaluation**

**Phase II**

There is a written program to train and evaluate personnel in their competency to perform embryology, including micromanipulation and other assisted reproductive technology techniques.

**NOTE:** For laboratories performing embryology, there must be a training program for new personnel, using animal model systems or nonviable human oocytes.

Evidence of Compliance:
✓ Records of training and competency

REFERENCES

**RLM.10255 Off-Site Embryology Section Director Visits**

**Phase II**

For laboratories that do not have an on-site embryology section director, there must be records of visits from the embryology section director at a minimum of once per quarter.

**NOTE:** If the laboratory performs andrology testing, state and federal requirements for director visits must be followed, which may be more stringent.

REFERENCES
RLM.10260  Oversight Responsibility  Phase II

For laboratories that do not have an on-site, full time embryology section director, or the medical director is also the embryology section director, there is a designated on-site individual qualified as an embryology supervisor, to provide oversight of daily activities and assist with troubleshooting or other unusual situations.

NOTE: The intent is to ensure that the laboratory continues to function properly in the embryology section director's absence and to ensure that resources are available to quickly assist with unusual problems to minimize any adverse impact on patient care.

REFERENCES

RLM.10265  Embryology Supervisor  Phase II

Embryology supervisors must have at least one year of supervisory experience in all aspects of embryology performed by the laboratory or a minimum of 60 cycles over a period of not less than six months.

NOTE: Technical supervisor certification is highly recommended. If the laboratory performs andrology testing, personnel requirements defined in the Laboratory General Checklist must be followed.

RLM.10832  Back-up Personnel  Phase II

The laboratory has a policy to provide back-up laboratory personnel as needed, to ensure timely embryology services.

NOTE: Staffing levels must be appropriate for the size and volume of the program. If routine staffing of the laboratory does not provide sufficient back up for laboratory personnel, the laboratory must have a policy describing how patient care needs will be met for its laboratory services in the event of a staffing shortage or emergency. The laboratory director is responsible to ensure that the qualifications of each individual are adequate for the duties to be performed.

REFERENCES

CRYOPRESERVATION OF SPERM, OOCYTES, AND EMBRYOS

Inspector Instructions:

- Sampling of cryopreservation policies and procedures (includes labeling and tracking of specimens)
- Current inventory records
- Sampling of specimen storage, retention, retrieval and disposition policies and procedures
- Sampling of record storage and retention policies and procedures
How does your laboratory ensure specimen identity and integrity?

How does your laboratory ensure viability and measure recovery rates?

If responses to the above questions indicate problems or concerns, further evaluate the laboratory’s corrective actions and resolutions

Follow the records of randomly selected cryopreserved sperm and embryos from receipt, preparation, storage and use. Determine if inventory procedures are functioning correctly.

RLM.11500  Cryopreservation  Phase II

The laboratory has a written procedure(s) for cryopreservation of sperm, oocytes, and/or embryos.

REFERENCES

2) Lasalle B, Testart J. Human embryo features that influence the success of cryopreservation with the use of 1,2 propanediol. *Fertil Steril.* 1985;44:645-651

RLM.11525  Specimen Handling  Phase II

Procedures are adequate to verify specimen identity and integrity throughout the entire cryopreservation process.

NOTE: All specimens must be labeled with a minimum of two identifiers.

Evidence of Compliance:
✓ Written procedure for maintenance of specimen integrity/identity throughout the process

REFERENCES

RLM.11600  Specimen Labeling/Tracking  Phase II

The laboratory has a reliable method for labeling and tracking of cryopreserved specimens.

Evidence of Compliance:
✓ Written procedure for specimen labeling and tracking requirements

REFERENCES
1) American Association of Tissue Banks. Standards for tissue banking, 1997

RLM.11700  Record Retention  Phase II

Records of all patient specimens, donor specimens, and patient/donor matches are retained and easily accessible.

Evidence of Compliance:
✓ Written record retention policy

REFERENCES
1) American Association of Tissue Banks. Standards for tissue banking, 1997

RLM.11800  Duplicate Record Storage  Phase II
Duplicate records are maintained in a separate area from the originals, and there is
evidence that all copies of the records are reconciled at least annually.

**NOTE:** Laboratories that use computer-based record systems must demonstrate that the records
are backed up when changes are made to the inventory database. The back-up media must be
stored in a location separate from the primary records. In this context, "separate" means that in
case of fire or other disaster in the laboratory, the back-up records would be preserved (or readily
taken to safety).

**REFERENCES**

**RLM.11900 Specimen Retrieval**  
**Phase II**

**Procedures are adequate to ensure that cryopreserved patient specimens can be easily retrieved.**

**RLM.12000 Inventory**  
**Phase II**

**Records are available for the current inventory of all specimens that have been stored in its cryobanks.**

**REFERENCES**
1) American Association of Tissue Banks. Standards for tissue banking, 1997

**RLM.12100 Lost Inventory**  
**Phase II**

**There is a procedure to investigate inventoried samples that cannot be located in the bank.**

**RLM.12300 Viable Recovery Rate**  
**Phase II**

**The laboratory has a program to ensure that cryopreservation is capable of providing viable recovery rates.**

**Evidence of Compliance:**

✓ Written procedure or written quality indicator detailing process to verify viable recovery rates, including thresholds for acceptable performance **AND**

✓ Records including data and evaluation of post-thaw recovery rates **AND**

✓ Records of corrective action when thresholds are not achieved

**REFERENCES**
1) American Association of Tissue Banks. Standards for tissue banking, 1997

**RLM.12400 Specimen Storage/Long-Term Disposition**  
**Phase II**

**There is a written procedure regarding the length of storage, informed consent and long-term disposition of cryopreserved gametes or embryos.**

**NOTE:** Good practice dictates that the consent form for all procedures is on file and readily available to the laboratory staff.

**REFERENCES**
3) American Association of Tissue Banks. Standards for tissue banking, 1997
4) Disposition of Abandoned Embryos, *Fertility and Sterility,* Vol. 82, Suppl 1, September 2004 (Disposition of abandoned embryos)
REPRODUCTIVE TISSUES

Inspector Instructions:

- Sampling of reproductive tissues policies and procedures (includes labeling, tracking, quarantine, storage)
- Applicable FDA registration
- Sampling of tissue storage records
- Sampling of donor eligibility determination records

- Quarantined donor tissues

- How are you informed of an adverse reaction to implanted tissue?
- What is your laboratory’s course of action prior to using non-FDA-cleared/approved reagents and supplies?

- Follow the records of donor tissue identification through receipt, preparation, storage, issuing, acceptance and disposition. Determine that procedures and records ensure adequate tracking of all tissues.

RLM.12411  Tissue Program  Phase II

The authority, responsibility and accountability of the reproductive tissue program are clearly defined.

NOTE: This includes donor testing and reproductive medically related procedures.

Evidence of Compliance:
✓ Written policy defining authority, responsibility and accountability for program

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12444  Regulatory Document Availability  Phase II

For US laboratories, the following documents are readily available, and there is evidence of their use in policy and procedure development.

1. Latest version of applicable sections of 21CFR
2. Current FDA guidelines
3. Latest version of applicable state and local laws

REFERENCES

RLM.12455  FDARegistered  Phase II
The laboratory is registered with the FDA.

NOTE: Laboratories that recover, process, store, label, package, or distribute any reproductive tissue, or screen or test the tissue donor must register with the FDA annually and update their current product listing.

REFERENCES
2) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12466 Record Retention Phase II

Donor records are maintained at least 10 years after the date of transfer or distribution, disposition or expiration, whichever is latest.

Evidence of Compliance:
✓ Written record retention policy

REFERENCES
2) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12477 FDA-Cleared/Approved Reagents/Supplies Phase II

Whenever available, reagents and supplies used in the collection, processing and cryopreservation of reproductive tissues are cleared/approved by FDA for human use.

NOTE: The use of reagents or supplies that are not FDA-cleared/approved must be either approved by the institution’s Institutional Review Board as part of a trial, covered under an investigational new drug or device exemption, or previously validated in the scientific literature.

Evidence of Compliance:
✓ Written procedure for the internal review and approval of non-FDA-cleared/approved reagents and supplies AND
✓ Records showing FDA approval of reagents and supplies, as applicable AND
✓ Records for the internal review of non-FDA-cleared/approved reagents and supplies, as applicable

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12499 Donor Tissue Labeling/Tracking Phase II

Each donor tissue is assigned a unique identification code that relates to the tissue donor and to all records pertaining to that tissue, with maintenance and tracking of this identifier throughout receipt, storage, issuing of the product, and disposition.

NOTE: The labeling number and information may not contain the donor’s name, social security number, or medical record number, unless the donor tissue is for autologous or directed donation. An institution may choose to use a unique identification code for autologous and directed donations.

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12510 Donor Tissue Labeling Requirement Phase II

Donor tissues are labeled in accordance with intended use, i.e. 1) Use in case of urgent medical need; 2) For autologous use only; 3) Not evaluated for infectious substances; or 4) Directed donor.
NOTE: The tissue label must contain a distinct identification code, description of the type of tissue, expiration date (if any), warnings (if any); the name and address of the establishment that made the eligibility determination and makes the tissue available for distribution may either appear on the label or accompany the tissue.

For laboratories subject to US regulations, the warnings are those required by FDA regulation Title 21; 1271.60(d), 1271.65(b)(2) or 1271.90(b).

Donor tissues stored for autologous use only must be prominently labeled as such.

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12521  Donor Tissue Quarantine

Reproductive donor tissues are placed in quarantine until completion of the donor eligibility determination.

NOTE: Units in quarantine status must be easily distinguishable from units available for release and distribution. If units in quarantined status are shipped outside of the laboratory, the quarantined status must be clearly indicated.

Evidence of Compliance:
✓ Written procedure for quarantine of tissues including storage, release and distribution AND
✓ Records of quarantined tissues

REFERENCES
2) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12532  Donor Records

Donor records contain a summary or statement to indicate that all communicable disease testing was performed, including tests performed and results, and a statement containing the name and address of the laboratory making the donor eligibility determination.

NOTE: If the donor was determined to be ineligible, a statement with a reason for ineligibility must be included.

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12543  Release From Quarantine

There is a written procedure to release reproductive tissues from quarantine that includes a review of records by a supervisor or other designated individual.

NOTE: There must be a mechanism to ensure that quarantined units, units from deferred donors and units on which testing is incomplete are not inappropriately released. The disposition of these units must be controlled and recorded. Records must allow for an audit for compliance with the release from quarantine.

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12554  Reproductive Tissue - Ineligible Donors

For reproductive tissues from donors determined to be ineligible, tissues are stored in a separate area and specifically labeled as a biohazard, and/or subject to other procedures to prevent improper release.
NOTE: Donor tissues may be used only under limited circumstances when results of any screening or testing performed indicate the presence of relevant communicable disease agents and/or risk factors or clinical evidence of disease agents. If these products are stored for use they must be labeled as a biohazard, and the physician must be notified of the results. Physically separate does not necessarily indicate that a separate dewar (LN2 storage tank) is needed. Storage may be maintained in a separate basket or section of the dewar.

Evidence of Compliance:
✓ Written procedure for storage and labeling of ineligible donor tissues

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12565 Reproductive Tissue Shipping Requirements Phase II

If reproductive tissues are shipped to another laboratory or received from another laboratory outside of the facility, detailed information is provided for the following.

1. Unique identifier ID code on the container, not to include the donor’s name, and/or SSN or medical record number, unless the units are designated for autologous or directed donation
2. Statement that donor is eligible or ineligible
3. Summary of records (disease testing, name and address of lab making the eligibility determination, statement of reasons for ineligibility if determined)
4. Statement on specimen quality and number of samples shipped
5. Quality control data on freeze/thawing of the specimen, including detailed thawing technique to be used with each specimen

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm

RLM.12587 Donor Infection/Adverse Events Investigation Phase II

There are written procedures for investigating donor infections or adverse events after reproductive donor tissues are received or implanted.

NOTE: Possible tissue-transmitted infections and other adverse events must be investigated and reported to the reproductive tissue source facility when appropriate. If the reproductive tissue source facility notifies the user facility about a donor’s infection or reactive infectious-disease test, procedures are required for quarantining tissue or notifying the tissue recipient when appropriate.

Evidence of Compliance:
✓ Records of investigation of tissue-transmitted infections or adverse events AND
✓ Records from source facility recalls indicating action taken

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration http://www.fda.gov/cber/tiss.htm