Achieving Gold Seal Accreditation for Your IVF Lab

March 7, 2019
Webinar Housekeeping

- **Join audio:**
  - Choose “Mic & Speakers” to use VoIP
  - Choose “Telephone” and dial using the information provided
    Make sure to join audio choosing either the “Mic & Speakers” or “Telephone” option
  - Lines will be muted so please use your control panel to communicate. You may need to expand view if you can’t see the panel.

- **Questions/Comments:**
  - Submit questions via the Questions panel at any time.

- **Note:** Today’s presentation is being recorded.
Achieving Gold Seal Accreditation for Your IVF Lab

Sharon Hibbe, MPH, Business Development Manager-Lab, The Joint Commission
Ron Quicho, MS, MLT, Project Director, The Joint Commission
Marybeth Gerrity, PhD, MBA, Society for Assisted Reproductive Technology Liaison to The Joint Commission

March 7, 2019
Overview of Today’s Webinar

- Benefits of Accreditation from The Joint Commission
- Resources Available
- IVF Accreditation Process
- IVF Standards
- Highlights of the Survey Activity Guide
- Real World Considerations in IVF Lab Accreditation
Benefits of Joint Commission Accreditation
The Joint Commission

- Established in 1951
- Private, Not-for-profit
- Evaluating hospital laboratory services since 1979
- Evaluating freestanding laboratories since 1995
- Accredits more than 1,500 labs representing almost 2,000 CLIA numbers
- Accredit 43 IVF laboratories
- The Centers for Medicare & Medicaid Services (CMS) officially recognizes The Joint Commission Laboratory Accreditation program as meeting the requirements of CLIA
Eligibility for IVF Labs

- Located in the United States or its territories

- Testing for a minimum of four months prior to survey
Benefits of Joint Commission as opposed to other accreditors

- Achieve, maintain, and demonstrate consistent excellence in quality and safety
- Establishes a quality management system which reduces procedural errors and prevent errors from “going out the door”
- Designates the laboratory is qualified and competent
- Consistent evaluation results in continued improvements to laboratory operations
- Joint Commission accreditation instills confidence of quality and patient safety to customers and patients
What Sets Us Apart from Other Accreditation Organizations?

- Employed experienced surveyor cadre
- Unmatched survey process including unique tracer methodology
- Non-prescriptive standards
- National Patient Safety Goals
- SAFER matrix which helps identify risk levels
Exclusive Resources Available For Your IVF Lab
View the Standards

Request E-dition Trial Standards
- Free 90-day access
- Print capabilities
- Contact us at qualitylabs@jointcommission.org

Purchase Hardcopy or Electronic Manual (E-dition)
- www.jcrinc.com
- Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB)
- E-dition electronic copy
E-dition Service Profile

Embryology Chapters

Accreditation Requirements
- Accreditation Participation Requirements (APR)
- Document and Process Control (DC)
- Environment of Care (EC)
- Emergency Management (EM)
- Human Resources (HR)
- Infection Prevention and Control (IC)
- Information Management (IM)
- Leadership (LD)
- National Patient Safety Goals (NPSG)
- Performance Improvement (PI)
- Quality System Assessment for Nonwaived Testing (QSA)
- Transplant Safety (TS)
Sample Written Documentation Checklist

WRITTEN DOCUMENTATION CHECKLIST

This worksheet lists element of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard.

*(Note: Documentation can be on paper or in an electronic format)*

<table>
<thead>
<tr>
<th>ENVIRONMENT OF CARE (EC)</th>
<th>STANDARD AND EP</th>
<th>REQUIRED WRITTEN DOCUMENTATION</th>
<th>DATE LAST VERIFIED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC.01.01.01, EP 3</td>
<td>The laboratory has a written plan for providing a safe environment for everyone who enters the laboratory’s facilities. (See also EC.04.01.01, EP 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC.01.01.01, EP 4</td>
<td>The laboratory has a written plan for providing a secure environment for everyone who enters the laboratory’s facilities. (See also EC.04.01.01, EP 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC.01.01.01, EP 5</td>
<td>The laboratory has a written plan for managing the following: Hazardous materials and waste. (See also EC.04.01.01, EP 15)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC.01.01.01, EP 6</td>
<td>The laboratory has a written plan for managing the following: Fire safety. (See also EC.04.01.01, EP 15)</td>
<td></td>
</tr>
</tbody>
</table>
Prompts to Assess Your Compliance

**ENVIRONMENT OF CARE (EC)**

**PROMPTS TO ASSESS YOUR COMPLIANCE**

*Please Note:* Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standard compliance.

<table>
<thead>
<tr>
<th>PROMPTS</th>
<th>TIPS</th>
</tr>
</thead>
</table>
| *(EC.02.01.03)*  
Is the no-smoking policy up-to-date and enforced as written? | Review inventory and evaluate all hazardous materials or waste; also evaluate laboratory’s policy with managing such materials. |
| *(EC.02.02.01)*  
Have all hazardous materials and waste been identified and addressed in the spills and exposure plan? |
Resources: Continuous Compliance for Your IVF Lab

- **Leading Practice Library**
  Real-life solutions from accredited organizations

- **Perspectives**
  Joint Commission’s official monthly e-periodical

- **Intracycle Monitoring Resources**
  Tools to maintain peak performance throughout accreditation cycle

- **Laboratory Tools**
  - Proficiency Testing
  - CLIA Resources
  - IQCP Example

- **Standards Booster Paks™**

- **Targeted Solutions Tool™**
  Customized solutions to prevalent issues including hand hygiene, hand off communication

www.centerfortransforminghealthcare.org/
IVF Accreditation Process
IVF Laboratory Survey

- Initial surveys receive a 30-day notice

- Resurveys receive a 7-day notice
  (freestanding IVF laboratories)

- The accreditation cycle is every two years

- Resurveys will be conducted within 90-days prior to the accreditation expiration date
Survey Findings

Survey Analysis for Evaluating Risk™ (SAFER) Matrix

- Identifying and communicating risk levels associated with deficiencies cited during surveys
- Helps organizations prioritize and focus corrective actions
- Provides one comprehensive visual of survey findings
- www.jointcommission.org/topics/safer_matrix_resources.aspx

<table>
<thead>
<tr>
<th>Likelihood to Harm a Patient/Staff/Visitor</th>
<th>Immediate Threat to Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>LIMITED</td>
</tr>
<tr>
<td>MODERATE</td>
<td>PATTERN</td>
</tr>
<tr>
<td>LOW</td>
<td>WIDESPREAD</td>
</tr>
</tbody>
</table>
IVF Standards
Standards Development

1. Standards that apply across accreditation programs
   *(Leadership, Information Management, Infection Control, National Patient Safety Goals)*
   - Unified approach promotes consistency
   - Improves efficiency and synergy between laboratory and other clinical areas

2. Laboratory-specific standards
   *(Document and Process Control, Quality Assessment)*
Criteria for Standards Development

- Focus on standards that research and leading practice guidelines have shown to be effective in improving quality and safety

- In the eyes of the customer:

\[
\text{Value} = \frac{\Delta \text{in Quality & Safety}}{\text{Resources Consumed}}
\]
Highlights of Survey Activity Guide
Unique Issues with Laboratories

Non – Prescriptive requirements

- Multiple effective methods may exist
- Could stifle emerging practices
- Tracers are a system review process (rather than task verification)

Prescriptive requirements for IVF

- CLIA requirements
- Industry convention: SART Recommendations
- Unique Tracer approach: IVF Specific
Unique Issues with IVF

Licenses and Registrations

➢ CLIA specialties/subspecialties
  - Hematology: andrology
  - Chemistry: hormone assays, fructose, HCG

➢ Non CLIA Specialty: Embryology

➢ State license if applicable

➢ FDA registration: tissue storage and/or transport
Up-to-Date Best Practice in IVF

Alignment with SART specific requirements

- Embryology laboratory director, supervisor, and testing personnel
- Laboratory environment and equipment
- Policies and Procedures (*media preparation, insemination, chain of custody, informed consent*)
- Embryo transfer protocol
- Emergency planning
Standards Applicability Grid

Which Standards Apply?
- Standards Applicability Grid located in CAMLAB
- Electronic filtering by service in E-dition via Service Profile

<table>
<thead>
<tr>
<th>Standard Requirement Number</th>
<th>E2 Number</th>
<th>Blood Donor Center</th>
<th>Hematology</th>
<th>Immunohematology</th>
<th>Microbiology</th>
<th>Pathology</th>
</tr>
</thead>
<tbody>
<tr>
<td>APR.01.01.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.02.02.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.01.03.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.02.01.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.03.01.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.03.01.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>APR.03.01.01</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Embryology Andrology
Freestanding IVF Clinics

1. Emergency Management
2. Environment of Care
3. Infection Control
4. Information Management
5. Leadership
6. National Patient Safety Goals
Real World Considerations in IVF Lab Accreditation
It’s time for you to let us know your questions
Thank you for attending!

For additional information, please contact us at: qualitylabs@jointcommission.org
How to contact us

qualitylabs@jointcommission.org

Business Development
- For initial questions
- Discuss eligibility and timeline
- Access to trial standards
- Request for an application
- Pricing estimate worksheet
Appendix
Today’s Speakers

− Marybeth Gerrity represents the Society for Assisted Reproductive Technology (SART) which is dedicated to the practice of assisted reproductive technologies in the United States.

− Sharon Hibbe is a Business Development Manager for Laboratory Accreditation and Patient Blood Management Certification at The Joint Commission, assisting laboratories in the IVF accreditation process.

− Ron Quicho is a Project Director at The Joint Commission and works with standards and processes related to IVF laboratories.