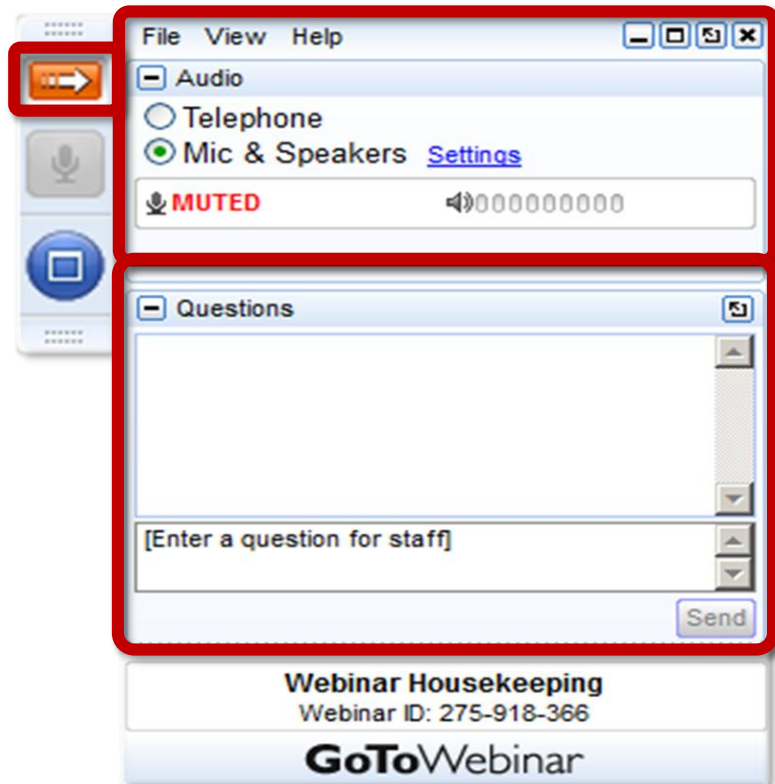


# Achieving Gold Seal Accreditation for Your IVF Lab



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



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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

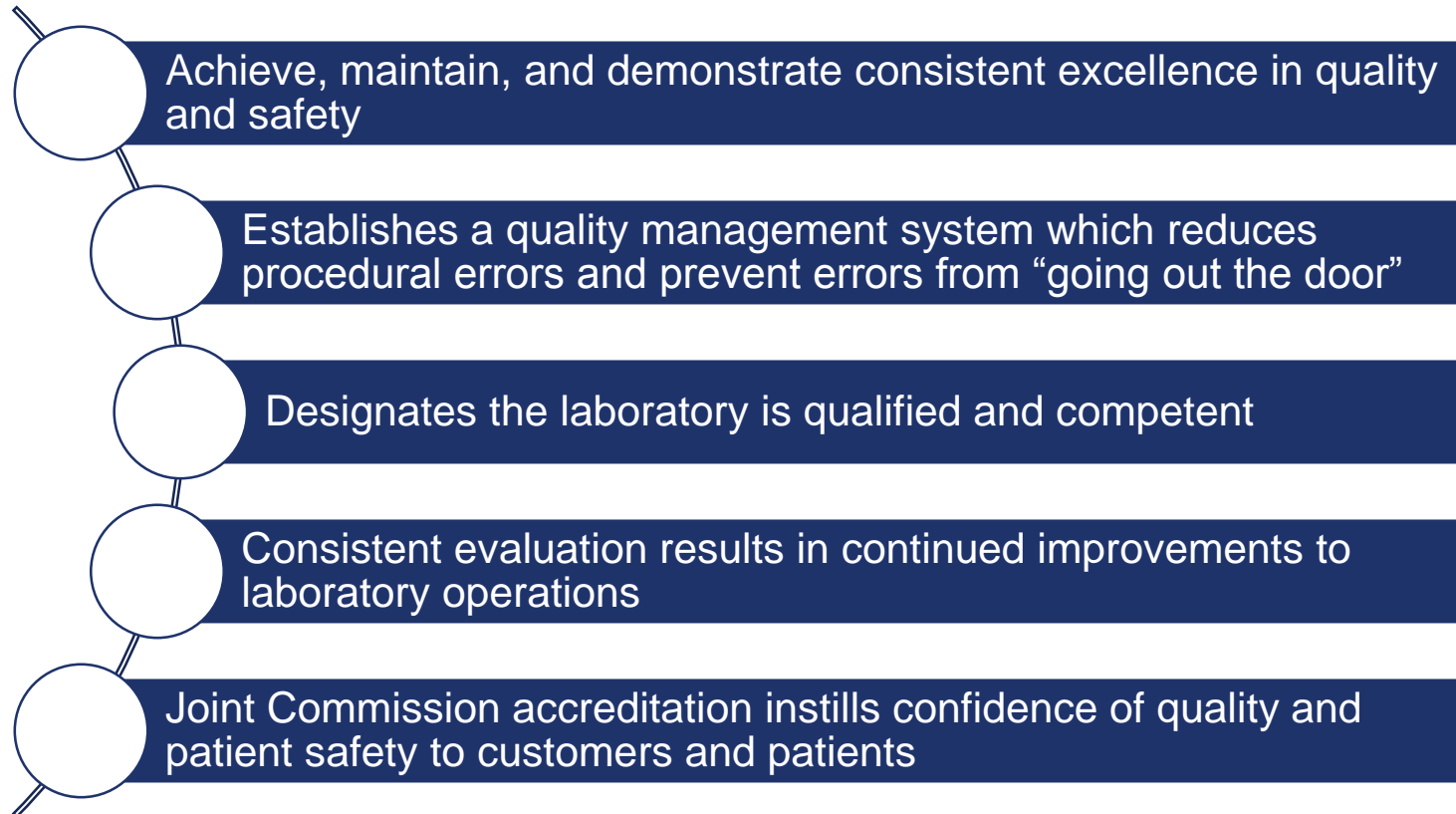


# Eligibility for IVF Labs

- 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





# 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](mailto:qualitylabs@jointcommission.org)



### E-dition® Laboratory Program

SKU# ELBSH

#### Site License

A site license provides access to all authorized staff of a single accredited organization. The site license allows all staff access to the product whenever they need it.

For large system orders, please contact us.

Download 'Renewal Instructions'

Software Program Type:	Laboratory
Software License Type:	Site License

## Purchase Hardcopy or Electronic Manual (E-dition)

- [www.jcrinc.com](http://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)

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**The Joint Commission**  
E-dition

[Print Content](#)

Effective Date: January 1, 2019

**Program: Laboratory : Laboratory : Embryology**

Standard Label	EP	Elements of Performance Description
APR.01.01.01	1	<p>The laboratory meets all requirements for timely submissions of data and information to The Joint Commission.</p> <p><b>Note 1:</b> The Joint Commission will impose the following consequence for failure to comply with this APR: If the laboratory consistently fails to meet the requirements for the timely submission of data and information to The Joint Commission, the laboratory will be required to undergo an Accreditation with Follow-up Survey. Failure to resolve this issue at the time of the Accreditation with Follow-up Survey may result in an accreditation decision change.</p> <p><b>Note 2:</b> The proposed consequences address only compliance with the requirement itself. They do not address the content of the laboratory's submissions to The Joint Commission. For example, if information in a laboratory's electronic application for accreditation (E-App) leads to inaccuracies in the appropriate length of the survey and a longer survey is required, the laboratory will incur the additional costs of the longer survey. In addition, if there is evidence that the laboratory has intentionally falsified the information submitted to The Joint Commission, the requirement at APR.01.02.01, EP 1 and its consequences will apply. (See also APR.01.02.01, EP 1)</p>
APR.01.02.01	1	<p>The laboratory provides accurate information throughout the accreditation process. (See also APR.01.01.01, EP 1; QSA.01.04.01, EP 1)</p> <p><b>Note 1:</b> Information may be received in any of the following ways:</p> <ul style="list-style-type: none"> <li>- Provided verbally</li> <li>- Obtained through direct observation by, or in an interview or any other type of communication with, a Joint Commission employee</li> <li>- Derived from documents supplied by the laboratory to The Joint Commission</li> <li>- Submitted electronically by the laboratory to The Joint Commission</li> </ul> <p><b>Note 2:</b> For the purpose of this requirement, falsification is defined as the fabrication, in whole or in part, and through commission or omission, of any information provided by an applicant or accredited laboratory to The Joint Commission. This includes redrafting, reformatting, or deleting document content. However, the laboratory may submit supporting material that explains the original information submitted to The</p>

# 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)*

ENVIRONMENT OF CARE (EC)			
	STANDARD AND EP	REQUIRED WRITTEN DOCUMENTATION	DATE LAST VERIFIED
	EC.01.01.01, EP 3	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)	
	EC.01.01.01, EP 4	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)	
	EC.01.01.01, EP 5	The laboratory has a written plan for managing the following: Hazardous materials and waste. (See also EC.04.01.01, EP 15)	
	EC.01.01.01, EP 6	The laboratory has a written plan for managing the following: Fire safety. (See also EC.04.01.01, EP 15)	

# Prompts to Assess Your Compliance

## ENVIRONMENT OF CARE (EC)

# PROMPTS TO ASSESS YOUR COMPLIANCE

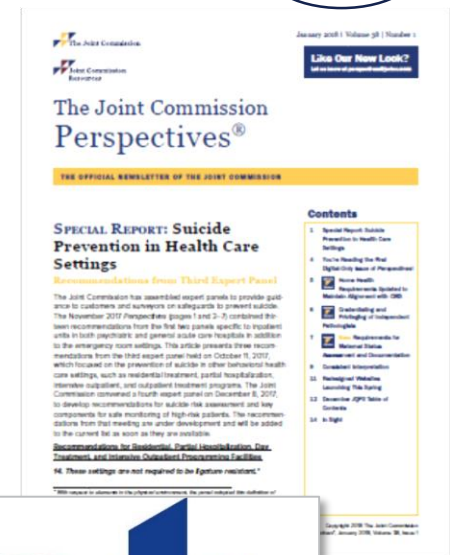
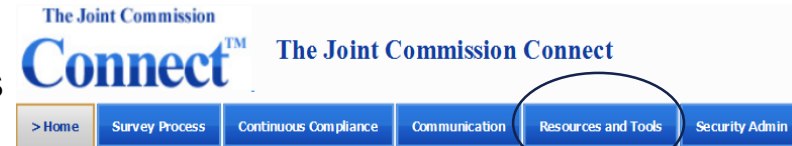
*Please Note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standard compliance.*

PROMPTS	TIPS
<p><b>(EC.02.01.03)</b> Is the no-smoking policy up-to-date and enforced as written?</p> <p><b>(EC.02.02.01)</b> Have all hazardous materials and waste been identified and addressed in the spills and exposure plan?</p>	<p>Review inventory and evaluate all hazardous materials or waste; also evaluate laboratory's policy with managing such materials.</p>

# 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/](http://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](http://www.jointcommission.org/topics/safer_matrix_resources.aspx)

		<i>Immediate Threat to Life</i>		
		LIMITED	PATTERN	WIDESPREAD
Likelihood to Harm a Patient/Staff/Visitor	HIGH			
	MODERATE			
	LOW			

# 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

Evidence  
Based

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

Value

- In the eyes of the customer:

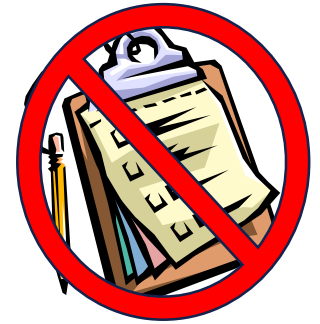
$$\text{Value} = \frac{\Delta \text{ in Quality \& Safety}}{\text{Resources Consumed}}$$

# Highlights of Survey Activity Guide

# Unique Issues with Laboratories

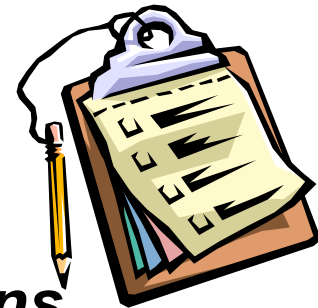
## Non – Prescriptive requirements

- 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 **Embryology Andrology**
- Electronic filtering by service in E-dition via Service Profile

**Embryology  
Andrology**

CAMLAB Update 2, January 2019  
 Shading indicates a change effective January 1, 2019, unless otherwise noted.

Standard Requirement Number	EP Number	Blood Donor Center	Chemistry		Clinical Cytogenetics	Diagnostic Immunology	Embryology	Histocompatibility	Hematology		Immunohematology	Microbiology			Molecular Biology	Pathology			Provider-Performed Microscopy (PPM)	Tissue Storage	Waived Testing
			Toxicology/Endocrinology/Routine Chemistry	Urinalysis	Clinical Cytogenetics				Immunogenetics	Hematology/Coagulation		Blood Transfusion	All Other Immunohematology	Bacteriology/Mycolabacteriology/ Mycology		Culture Set-up Only	Parasitology	Viridlogy			
APR.01.01.01	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
APR.01.02.01	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
APR.01.03.01	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
APR.02.01.01	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
APR.03.01.01	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
	3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
	4	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
	6	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
	7	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		

# 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](mailto:qualitylabs@jointcommission.org)

# How to contact us

[qualitylabs@jointcommission.org](mailto:qualitylabs@jointcommission.org)

## Business Development

- For initial questions
- Discuss eligibility and timeline
- Access to trial standards
- Request for an application
- Pricing estimate worksheet



Daniel Briggs  
Business Development Manager  
East



Sharon Hibbe  
Business Development Manager  
West

# 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.