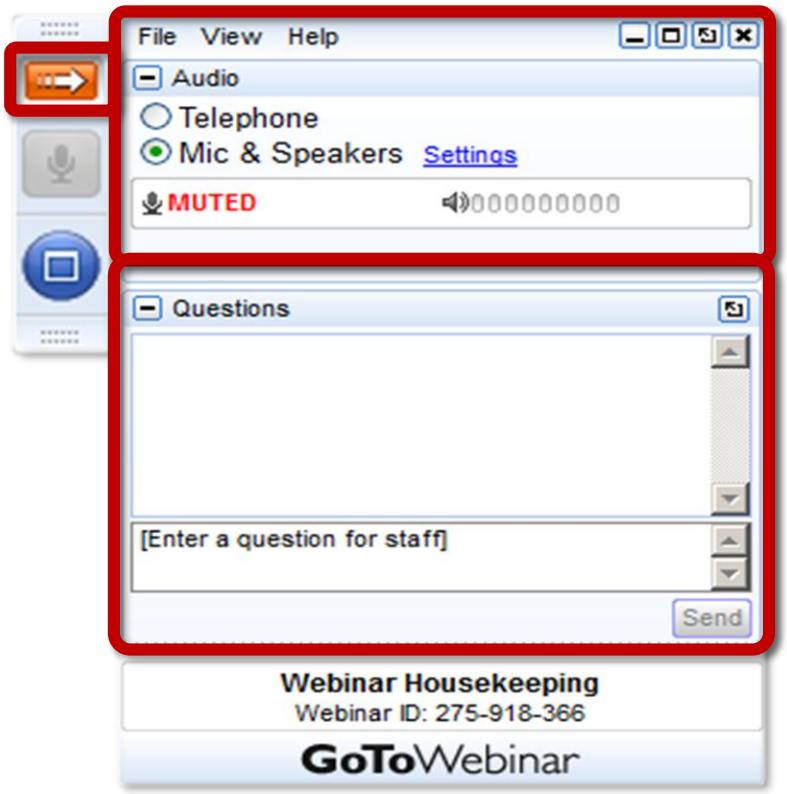
Achieving Gold Seal Accreditation for Your IVF Lab

March 7, 2019

The Joint Commission

Webinar Housekeeping



- **Join audio:**
  - Choose “Mic & Speakers” to use VoIP
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      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

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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

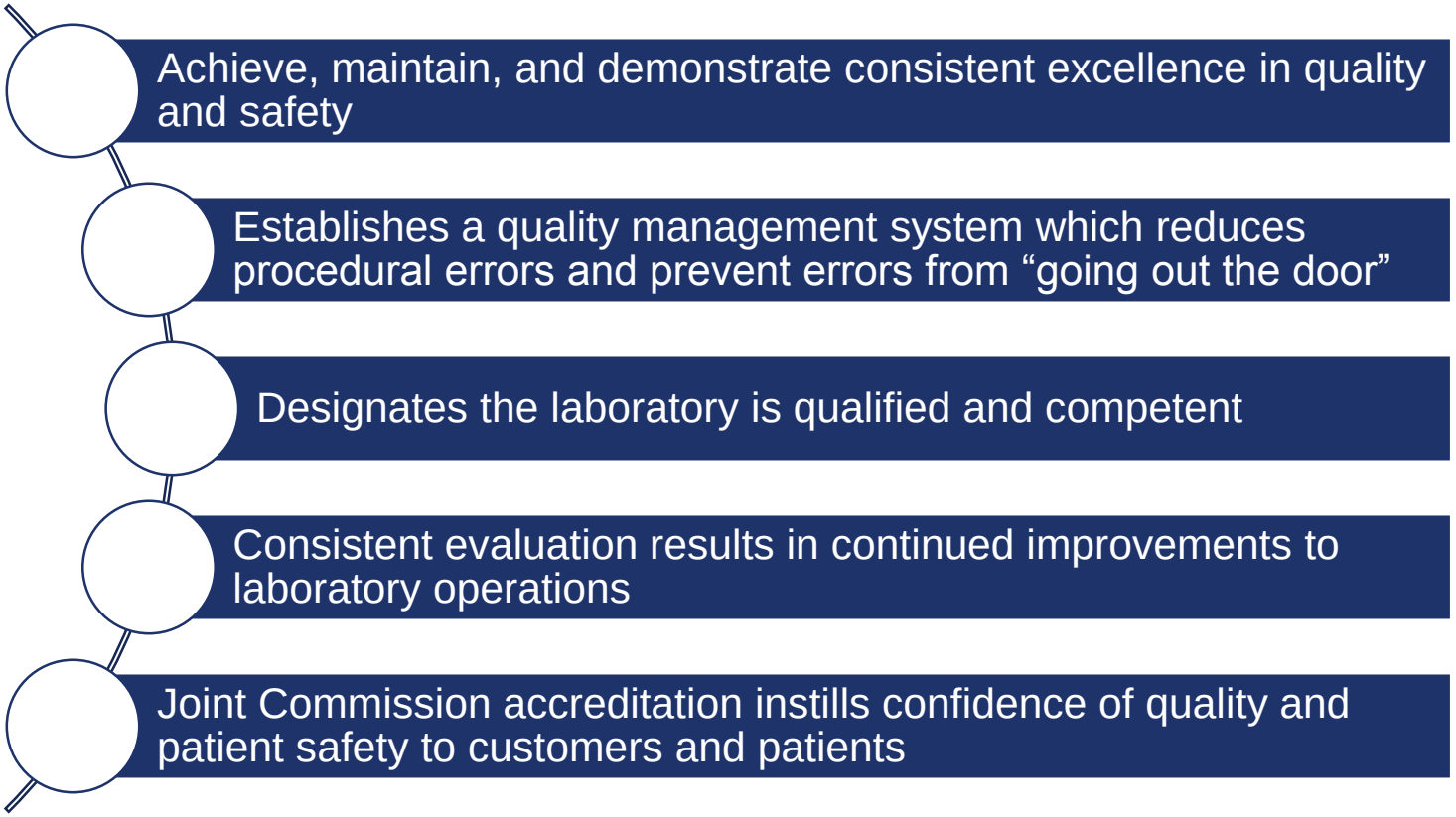
- Established in 1951
- Private, Not-for-profit
- Evaluating hospital laboratory services since 1979
- Evaluating freestanding laboratories since 1995
- Accredits more than 1,500 labs representing almost 2,000 CLIA numbers
- Accredit 43 IVF laboratories
- The Centers for Medicare & Medicaid Services (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

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Exclusive Resources Available For Your IVF Lab

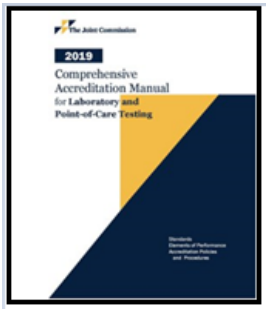
View the Standards

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)

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

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/

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IVF Accreditation Process

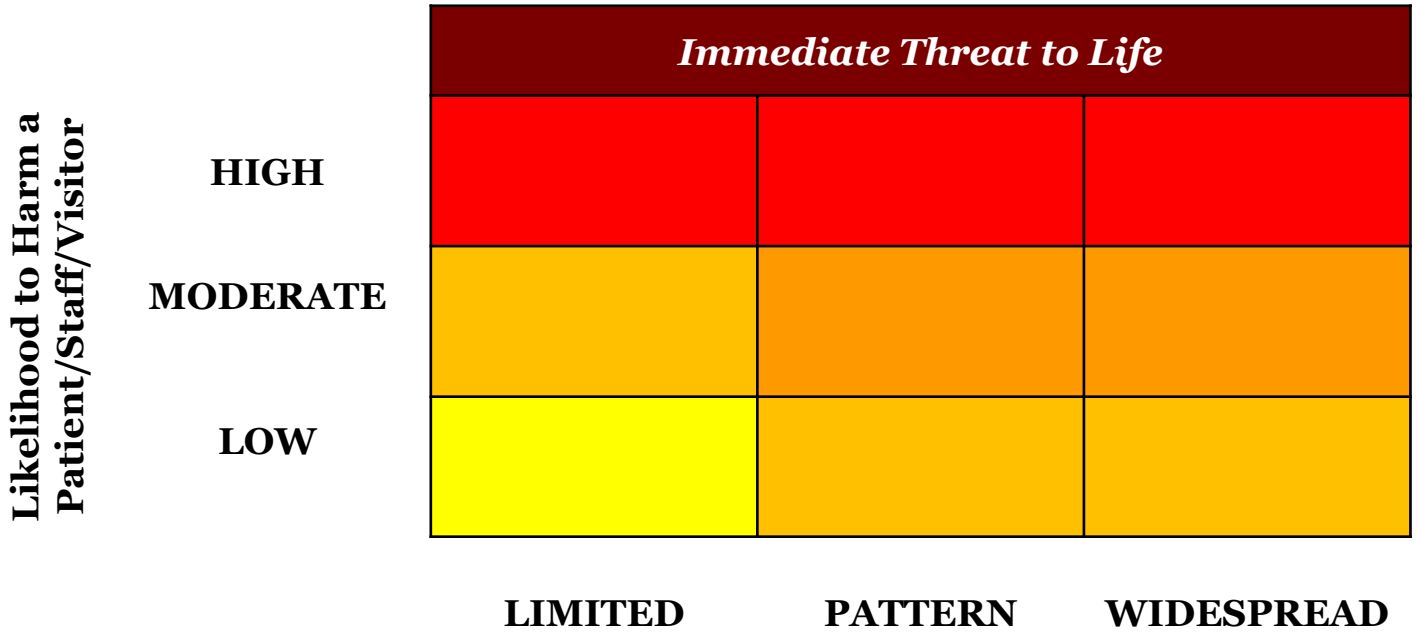
IVF Laboratory Survey

- 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



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:

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

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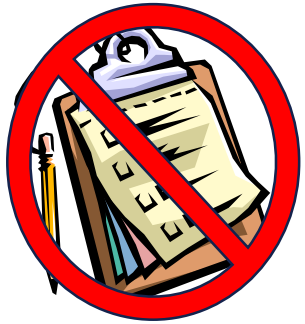
Highlights of Survey Activity Guide

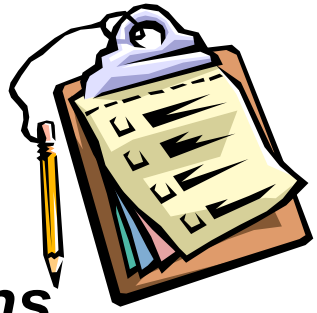
Unique Issues with Laboratories

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
- 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 otherwis

Standard Requirement Number	EP Number	Blood Donor Center	Chemistry		Clinical Cyto-gen-etics		Diagnostic Immunology	Embryology	Histocompatibility	Hematology			Immu-nohem-atology		Microbiology				Molecular Biology	Pathology				Radiobioassay	Provider-Performed Microscopy (PPM)	Tissue Storage	Waived Testing
			Toxicology/Endocrinology/ Routine Chemistry	Urinalysis	Clinical Cytogenetics	Immunogenetics				Andrology	Flowcytometry	Hematology/Coagulation	Blood Transfusion	All Other Immunohematology	Bacteriology/Mycobacteriology/ Mycology	Culture Set-up Only	Parasitology	Virology		Autopsy Services	Cytology (gynecological and nongynecological)	Electron Microscopy	Histopathology, Oral Pathology, Dermatopathology				
APR.01.01.01	1	X	X	X	X	X	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	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	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	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	X	X	X	X	X			
	3	X	X	X	X	X	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	X	X	X	X	X			
	6	X	X	X	X	X	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	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

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Real World Considerations in IVF Lab Accreditation

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It’s time for you to let us know your questions

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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

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.