



From Regulations to Rural Excellence

Because every patient deserves exemplary care.

Kate Hill, RN

Vice President, Client Success
The Compliance Team



Learning Objectives

Putting Regulations to Work.

Avoiding Deficiencies.

Survey

- **Surveyor arrives unannounced.**
- **Short meeting. Tour of clinic.**
- **Place for surveyor to work.**
- **Evaluating HR files, patient files, and policies**
- **Exit conference**



**Let's
Get
Started!**



Organization is Key

- **Develop a Survey Readiness Binder.**
 - Policies
 - Reports
 - Other evidence of compliance
- **Determine who will attend/how to inform.**
- **Keep the Clinic “Company Ready”.**
- **Staff should know where everything is stored.**



Reminder

This is an open book test. There should be no surprises.

Checklist

Facility Name/Clinic:	Surveyor Number(s):	
	Survey Start Date:	Survey End Date:
Total Number of Exam Rooms:	Time In:	Hours Onsite:
	Time Out:	

CORPORATE COMPLIANCE	STANDARD	YES	NO
The Clinic has a written Corporate Compliance Plan.	COM 1.0		
The Clinic is in good standing with the Medicare/Medicaid Programs.	COM 2.0		
The clinic that participates in Medicare/Medicaid programs has been free of sanctions for a period of at least 2 years.	COM 2.0.1		
The clinic prohibits employment/contracting with individuals or companies, which have been convicted of a criminal felony offense related to healthcare.	COM 2.0.2		
Clinic can provide evidence of verification of individuals through OIG exclusion database.	COM 2.0.2(a)		
Evidence of the process and documentation upon hire and re-verification at a minimum annually.	COM 2.0.2(b)		
Staff of the clinic are licensed, certified, or registered in accordance with applicable State and local laws. (§491.4(b))	COM 3.0		
The clinic has a process to verify personnel are licensed, certified, or registered with applicable State laws.	COM 3.0.1		
This information is documented and tracked in an organized format.	COM 3.0.2		
ADMINISTRATION	STANDARD	YES	NO
The clinics hours of operation are posted outside the clinic.	ADM 3.0.4		
All clinic documents and signage (both internal and external) are consistent with the CMS-855A enrollment application.	ADM 3.0.5		
The Clinic has a governing body or individual who has legal responsibility for the conduct of the clinic.	ADM 4.0		
The clinic discloses the names and addresses of the following: (§491.7(b))	ADM 4.0.1		
<ul style="list-style-type: none"> Names of the owner(s). (§491.7(b)(1)) 	ADM 4.0.1(a)		
<ul style="list-style-type: none"> Person principally responsible for directing the clinic's operation. (§491.7(b)(2)) 	ADM 4.0.1(b)		
<ul style="list-style-type: none"> Person responsible for medical direction. (§491.7(b)(3)) 	ADM 4.0.1(c)		

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Clinic Information

**Established clinics
check it on:**

QCOR CMS Data Base

<https://qcor.cms.gov/main.jsp>



**Does your name
match what is on
your 855a?**

**Are your clinic
hours posted
near or on the
door?**

Waiting Room

**How
secure
is your
clinic?**



Exam Tables

How do you clean this table?

Wet time

Health grade disinfectant



Can a torn table be disinfected?

Needs to be repaired



Manufacturer's Instruction for Use (IFU)

Equipment.

Is there documentation that mechanical and electrical equipment is regularly inspected, tested, and ...

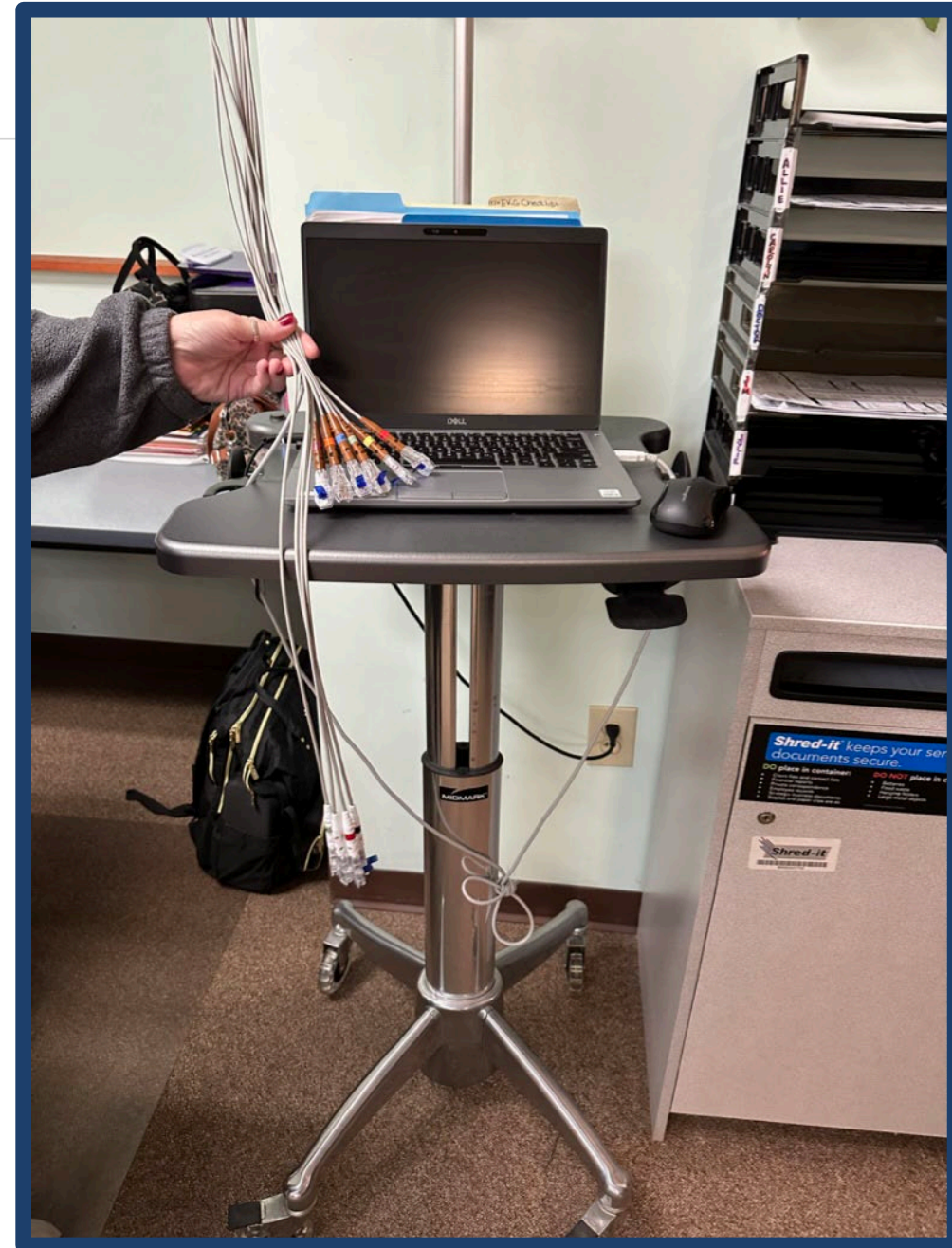
- Is all your equipment on a list?
- Maintained in accordance with manufacturer's recommendations?
- Review the manufacturer's instructions for a piece of equipment.
- Do you know what needs calibration and what needs preventative maintenance?
- Is there a process in place for tracking due dates for PM?
- Equipment not in use is labeled as such and stored away.

What Needs Calibration?

Does your **EKG/ECG** machine need to be calibrated?

Most do except for the Welch Allyn CPWS and CP150.

**Always check
Manufacturer's IFUs.**



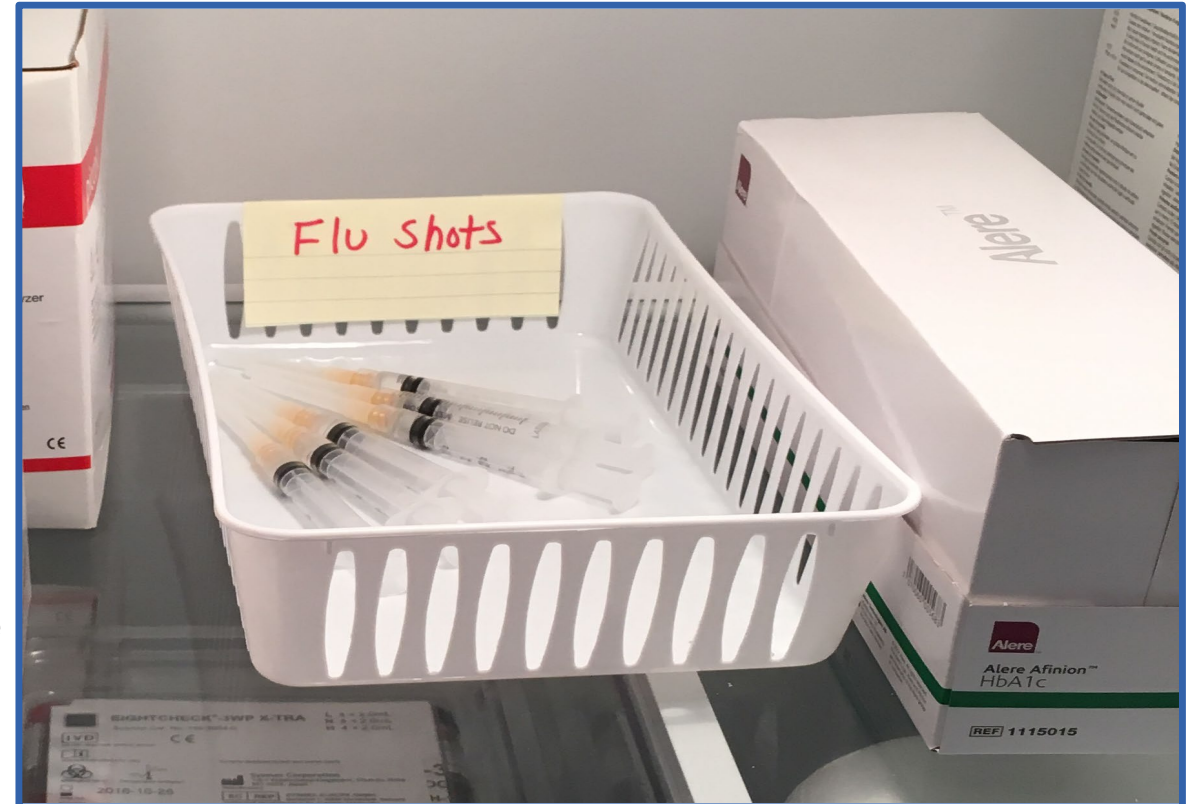
Medication Management

- Is there a robust medication policy?
- All drugs secured in the clinic?
- Drugs stored according to Manufacturer's instructions?
- All medications delivered to the clinic properly documented in the EMR?
- Are we noting the 5 rights?
 1. Right patient
 2. Right medication
 3. Right dose
 4. Right route
 5. Right time
- Everyone dealing with drugs trained on vials?
- Everyone trained on safe injection practices?
- Is there proper recording for receipt and disposition of scheduled drugs?



Pre-Filled Syringes

- **Once vaccine is inside syringe, difficult to tell which vaccine is which.** This may lead to administration errors.
- **Most syringes designed for immediate administration,** not for vaccine storage.
- **Bacterial contamination and growth can occur in syringes prefilled** with vaccines that do not contain bacteriostatic agents, such as vaccines supplied in single-dose vials.
- **No stability data available for vaccines stored in plastic syringes.** With time, vaccine components may interact with plastic syringe components, reducing vaccine potency.
- **Prefilling syringes is a violation of medication administration guidelines,** which state - an individual should only administer medications they have prepared and drawn up.



Vials

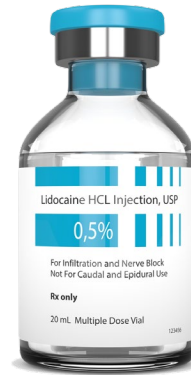
Possible...

- Staff member does not know the difference between a single-dose or multi-dose vial.
- Drug always comes as an MDV; but supplier sent a shipment where the drug was an SDV.
- Store MDVs and SDVs together making it easy to confuse.



Single-Dose Vial

Don't assume all staff know the difference between SDVs and MDVs.



Multi-Dose Vial

Ensure Single-Dose Vials (SDVs) are never used for more than one patient.

What to do:

- Train all staff to always look at the vial to verify if an SDV or MDV and to check the date.
- Train staff that SDVs do not have a preservative in the vial and why that's important.
- Separate MDVs from SDVs in the drug closet
- Label all SDVs with a sticker

Vials

Multi-Dose Vial



Never dated

Multi-Dose Vials



Dated for 28 Days

Vials

Ensure Single-Dose Vials (SDVs) are never used for more than one patient.

One and done. **Discard!**

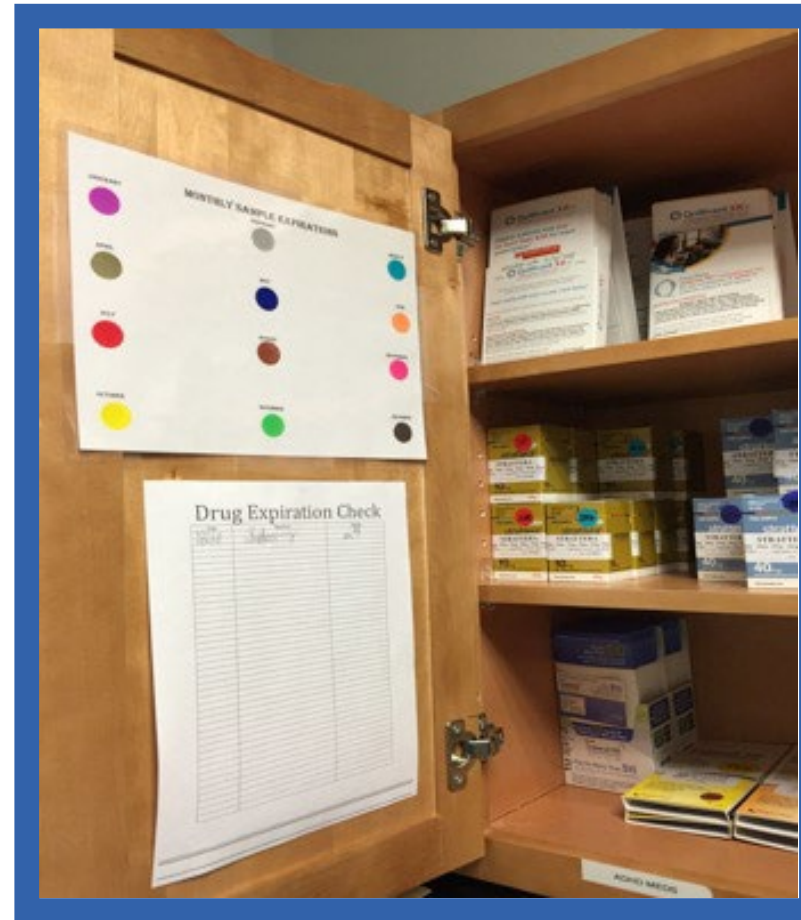


Sample Closet

Secured/Organized
in original containers



Colored dots system. **Smart!**



Reminder

**Sample meds
need a log.**

Staff Education



- **What do they know?**
- **Train them.**
- **Document that training.**

What's Posted?

- State and Federal Posters required in places visible to the staff.
- Provider based clinics must have postings in the clinic; even if clinic is in the hospital building.
- Rights and Responsibilities
- Privacy Notice

Order 2024 today!

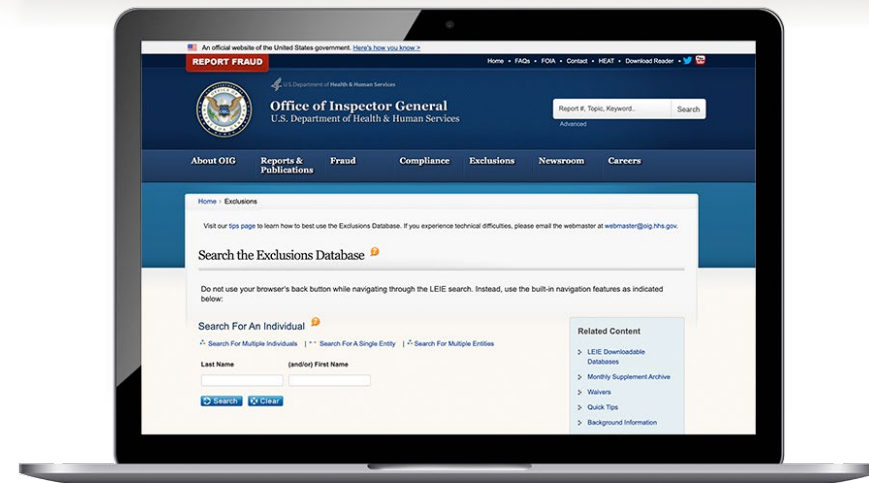


What's Secured?



Are HR Files Complete?

- Application
- I-9
- W-4
- OIG Exclusion
- Signed Job Description
- Standards of Conduct
- Performance evaluations, according to your clinic schedule
- Annual Training
- Competency
- Background checks as appropriate
- TB screening on hire
- Hep B for those who work with patients



Medical Direction

The Medical Director must be an MD or DO.

He/she must be licensed in the state where the clinic resides.

The Medical Director is a reportable event.

- Reported on a CMS 29 to the state or to your accreditor.

There is no waiver for Medical Director.

- CMS provides a reasonable time to come back into compliance.
- Can you show your efforts to find a new Medical Director?
- Can you show what efforts you have made for a temporary Medical Director?



Infection Prevention

Is the clinic appropriately monitoring house keeping?

How does the clinic prevent the spread of infection:

- Hand hygiene for staff.
- Are single use devices only used once?
- How are the clinic surfaces cleaned?
- Does the person know the wet/kill time?
- How is medical waste disposed?
- Are we certain instruments are sterile?
- Is the staff trained on point-of-care devices?



Sterilizing Instruments: Mfr's IFUs

**What is
your
process?**



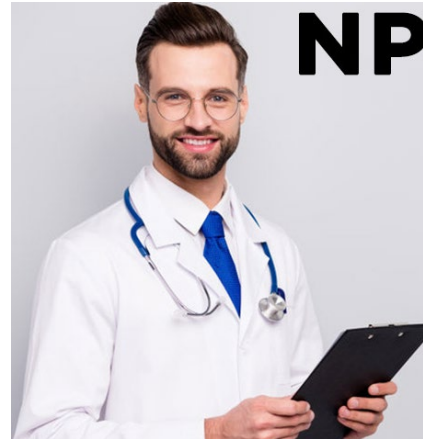
Reminder

**Compare your
process to
manufacturer's
IFUs.**

Staffing

NP/ PA Waivers

- An existing RHC may request a waiver from the state after 90 days for one year on the loss of an NP or PA.
- During that 90 days, the RHC must demonstrate it has been unable, despite reasonable efforts, to hire an NP or PA in the 90-day period.
- Waivers are requested from the State Survey Agency. They are the only ones that can grant them.



Helpful Tip

Chart review required even if your NPs have autonomy.

Staffing

50%

- An NP, PA or Certified nurse midwife is available to furnish patient care at least 50% of the operating hours.
- All time spent in the clinic counts toward the 50%.
- Time spent in a patient's home, swing bed or SNF rounds, counts toward the 50%.



How do you document this time?

Staffing

Medical Record Review

If your State is silent, then you must determine how many and how often this occurs.

- What is your policy on record review by a physician?
- What is your documentation to show the record review has been done?
- How do you document the NP/PA collaborated with the physician?



Surveyed Measured

51%

51% of a clinic's health services are primarily engaged in providing outpatient health services.

Appendix G

“The services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system. These services include taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs and family planning.”

Services: Primarily Engaged

- **RHC services include the services of Physicians, NPs, PAs, CNM, Clinical Psychologists, Clinical Social Workers. Now includes Marriage and Family Therapists and Mental Health Counselors.** The services of these practitioners are those commonly furnished in a physician's office or at the entry point into the health care delivery system.
- **RHCS are not prohibited from furnishing other services** but cannot be primarily engaged in specialty services.
 - Does your website reflect the types of services you offer?
 - Does it include specialty services?
- **Review the hours that specialty services are offered** to determine the number of hours that is the majority of time.

Policies

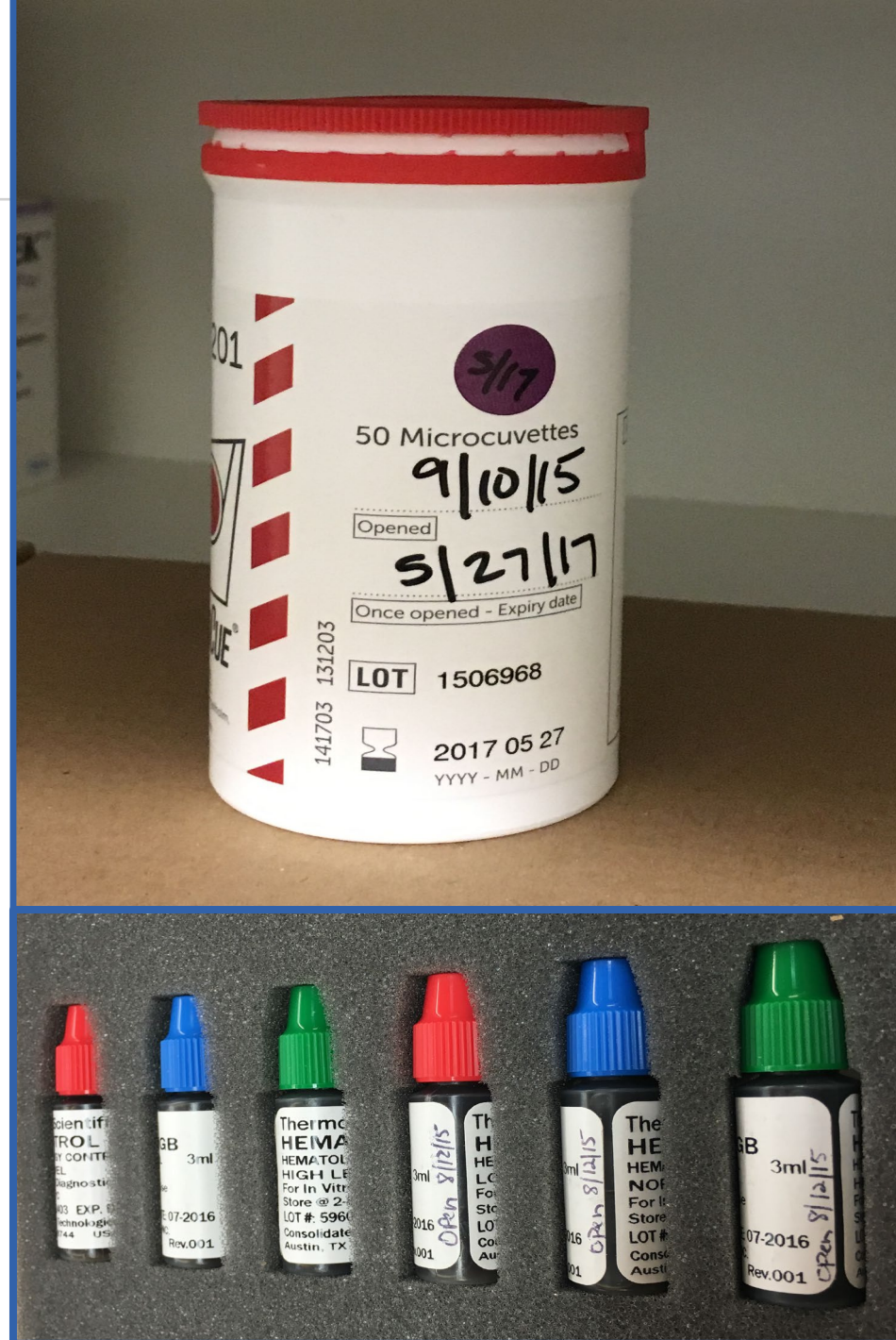
- **Keep policies organized.**
- **Review a few policies each staff meeting.**
- **Keep your policies simple. Don't lock yourself into a tight corner.**

Know what requires a policy.

- Patientcare Policies
- Biennial Review of Policies by Advisory Group
- Storage, Handling, & Dispensing of Drugs & Biologicals
- Emergency Preparedness
- Health Records
- HIPAA
- Scope of Services Provided and Referred
- Lines of Authority
- Equipment Management
- Infection Prevention
- Hiring, Training and Orienting
- Quality Improvement

The Lab: Point-of-Care Tests

- Labs are for immediate diagnosis!
- Clinic must have ability to do all six required tests.
 1. Chemical examinations of urine by stick or tablet method or both (including urine ketones)
 2. Hemoglobin or hematocrit
 3. Blood glucose
 4. Examination of stool specimens for occult blood
 5. Pregnancy tests
 6. Primary culturing for transmittal to a certified laboratory
- Most common two missing are Hemoglobin or Hematocrit and Examination of stool specimens for occult blood.
- All reagents, strips, controls, etc., must be within date.
- CLIA Certificate is current and posted.



Emergency Services

RHC ensures staff is available, at all times the clinic operates, to appropriately handle medical emergencies as a first response to common, life-threatening injuries and acute illnesses.

Must supply a complete list of drugs and biologicals it stocks.

- What does your emergency service policy say?
- Does it match your process?
- How did the RHC decide what is in that box?
- Is the box checked regularly for outdates?



Reminder

Is the list of emergency drugs in the emergency services policy?

Patient Records

Consents For a minor patient, is there a relationship to patient on the consent.

Medications Is the EMR capturing the medication, lot number, route of administration, dose, and date?

Abnormal Labs Have abnormal labs been reported to patients?

- The notes should reflect the patient has been notified of the lab results and the plan moving forward.
- What instructions are given to the patient?

Summary Is there a documented summary of the visit with instructions for the patient?

Risk

No medications or hazardous material in this lower exam table drawer.

ThinPrep: a preservative with the following warnings:

- **Inhaled:** May cause depression of the Central Nervous System resulting in weakness, nausea, drowsiness, and possibly blindness.
- **Skin Contact:** May cause irritation and or dermatitis.
- **Ingestion:** May cause intoxication, CMS depression, nausea and dizziness. May damage liver, kidneys, and nervous system.



Policies Match Procedures

Clinics can be cited if a policy does not match their process/procedure.

Example #1

Some clinics call for an annual consent even though it's not a requirement.

So, if the surveyor reviews files and there is no new consent, but the policy says annual, they will receive a deficiency.

Example #2

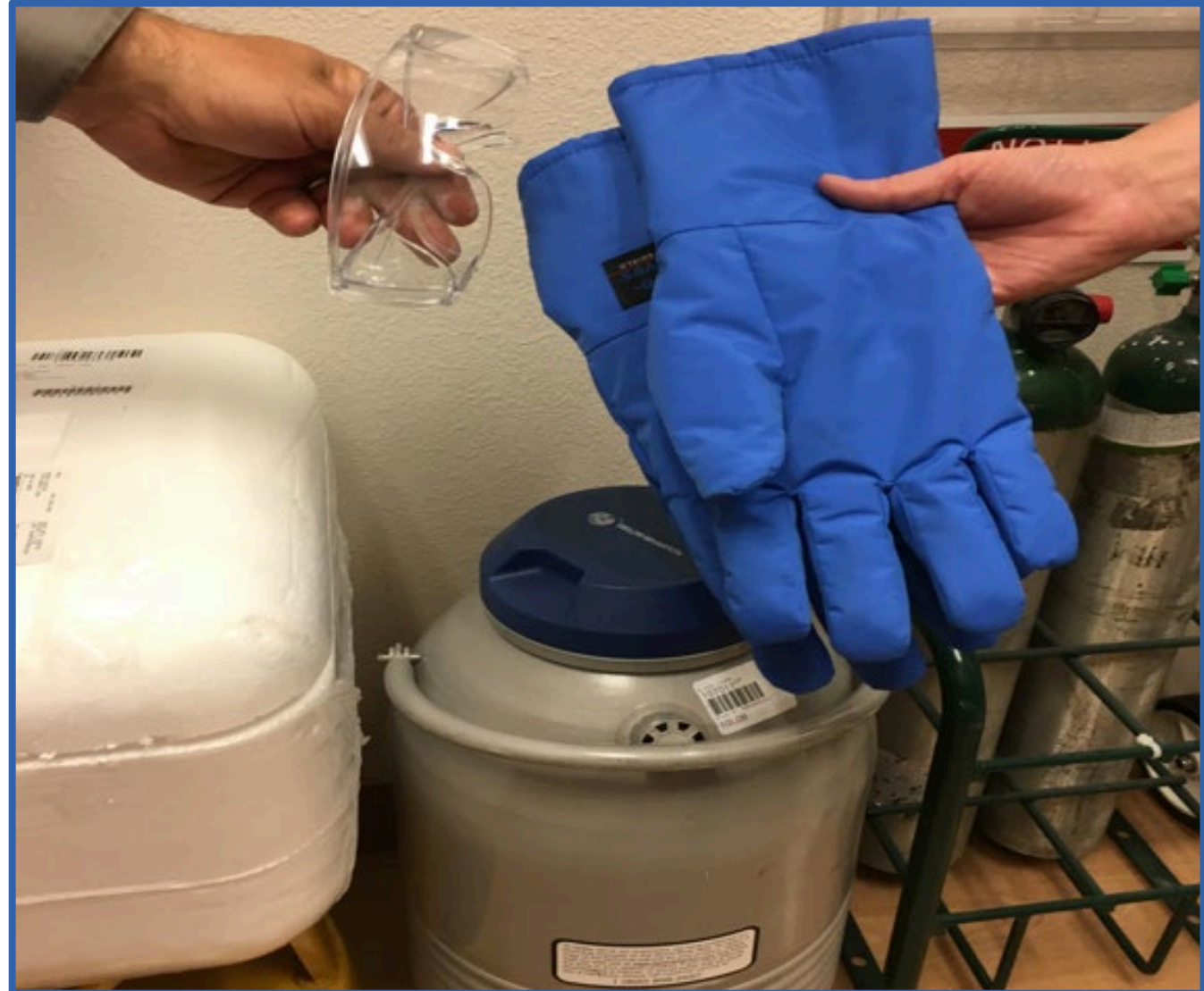
Several policies recently still say Annual Evaluation, while the reg says Biennial.



Protective Equipment

Personal protective equipment for staff who handle liquid nitrogen.

Heavy duty gloves and goggles for safety.



Work Safety

- **Proper PPE**
- **SDS Sheets**



OSHA
Occupational Safety
and Health Administration

Job Safety and Health IT'S THE LAW!

All workers have the right to:

- A safe workplace.
- Raise a safety or health concern with your employer or OSHA, or report a work-related injury or illness, without being retaliated against.
- Receive information and training on job hazards, including all hazardous substances in your workplace.
- Request a confidential OSHA inspection of your workplace if you believe there are unsafe or unhealthy conditions. You have the right to have a representative contact OSHA on your behalf.
- Participate (or have your representative participate) in an OSHA inspection and speak in private to the inspector.
- File a complaint with OSHA within 30 days (by phone, online or by mail) if you have been retaliated against for using your rights.
- See any OSHA citations issued to your employer.
- Request copies of your medical records, tests that measure hazards in the workplace, and the workplace injury and illness log.

This poster is available free from OSHA.

Contact OSHA. We can help.

Employers must:

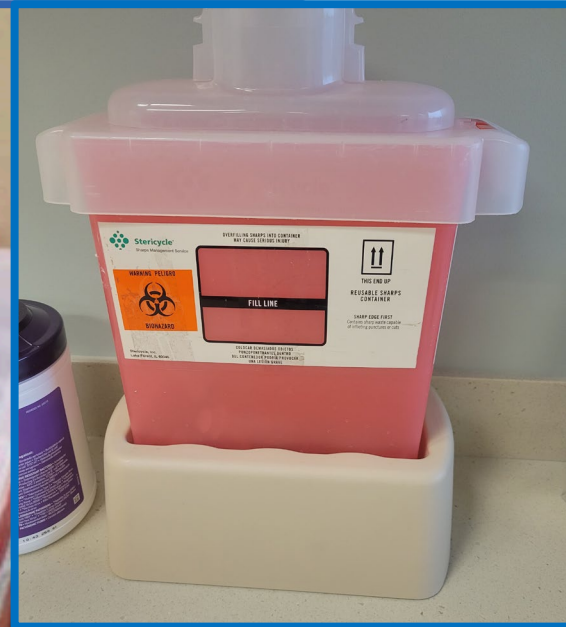
- Provide employees a workplace free from recognized hazards. It is illegal to retaliate against an employee for using any of their rights under the law, including raising a health and safety concern with you or with OSHA, or reporting a work-related injury or illness.
- Comply with all applicable OSHA standards.
- Notify OSHA within 8 hours of a workplace fatality or within 24 hours of any work-related inpatient hospitalization, amputation, or loss of an eye.
- Provide required training to all workers in a language and vocabulary they can understand.
- Prominently display this poster in the workplace.
- Post OSHA citations at or near the place of the alleged violations.

On-Site Consultation services are available to small and medium-sized employers, without citation or penalty, through OSHA-supported consultation programs in every state.



Biohazard Sharps Containers

- Sharps containers cannot be easily accessible.
- Several states require specific times for emptying sharps containers.
- Must be marked with a Bio-Hazard sticker.



Biennial Evaluation

Lack of a Biennial review of the clinic.

- Must be done every two years.
- There is no waiver for this.
- Look at date of the last one; make sure it's not more than two years old.
- This is a failed survey if not completed.
- Policy review sheet: Who signed?
 - Must be an MD, NP/PA and an outside person.
 - Is the date within two years?
- Must review evaluation

Emergency Preparedness (EP)



Power Grid Failure
Refrigerated Medications
PHI/EMR



Natural Disasters
Clinic Closure
Disruption of Services



Emerging Infectious Disease
Protocols
Risks

Emergency Preparedness (EP)

Hazard Vulnerability Analysis (HVA) must include Emerging Infectious Disease (EID)

- **Your exercise must be one of your listed items on your HVA**, unless it's an event.
- **Training and testing program is reflecting risks and hazards** identified within the facility's program (refer to facility's risk assessment to determine) .
 - This means you can't use something as an exercise unless it's on your hazard list.
- **Communication plan is complete**, including name and contact information for all staff and local, regional, state, tribal, and federal emergency staff.
- **Volunteers must be addressed** in the EP Policy.
- **Address how refrigerated medications are handled** in a power outage.



Helpful Tip

Training: Have a log to document the staff trained, with signatures, and dated every 2 years.

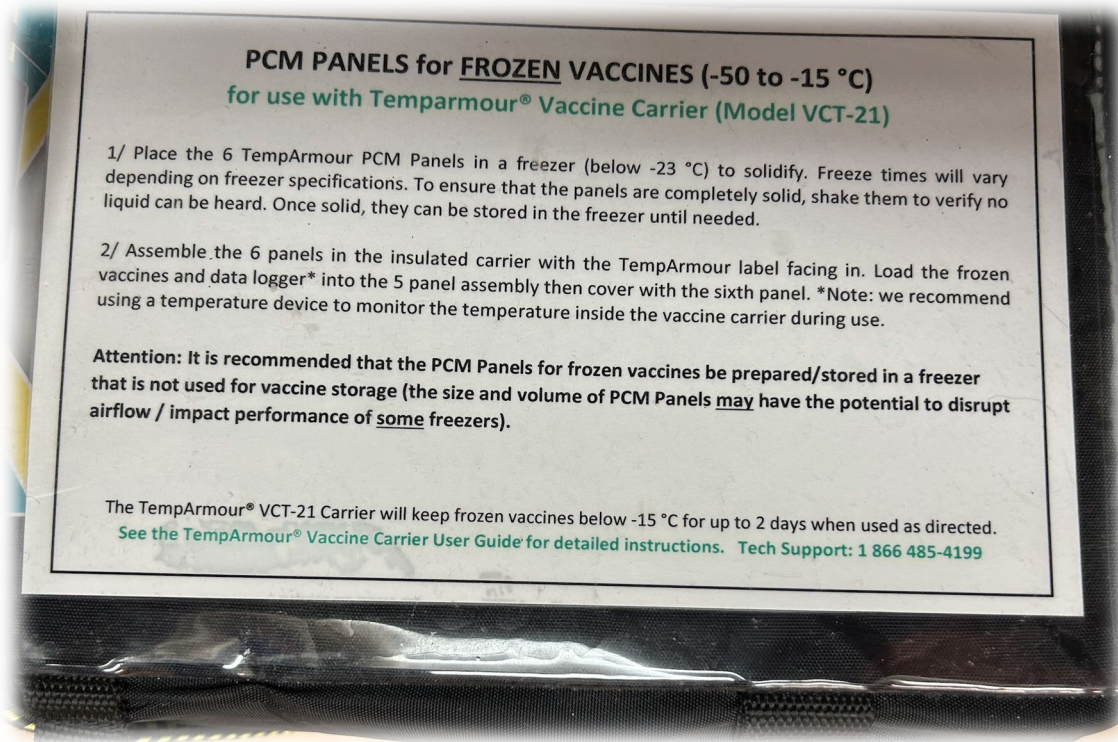
Emergency Preparedness

- **Must participate in a full-scale exercise that is community-based** or when not accessible, an individual, facility-based exercise.
- **If one year is full-scale exercise, then other can be tabletop.** Every other year full-scale or at least a clinic-based exercise.
- **Analyze the clinic's response** to exercise or activation of plan.
- **Exercise or tabletop** must be one of your hazard assessments.
- **Should not test same thing year after year.** Intent is to identify gaps in the facility's EP program, as it relates to responding to various emergencies, and ensure staff are knowledgeable on the facility's program.



Emergency Preparedness

Keeps vaccines frozen for two days!



Analysis for Event, Table-Top, or Exercise

Purpose of this report.

- Analyze event results.
- Identify strengths to be maintained and built upon.
- Identify potential areas for further improvement.
- Support development of corrective actions that will guide future emergency preparedness initiatives and advance overall emergency preparedness within your clinic.
 - Report reviewed with staff
 - Assignments given
 - Attendance log at AAR meeting

Common Deficiencies

Top 10 Deficiencies

1. Vials, single-dose dated.
2. Expired supplies in the clinic, i.e., iodoform, gloves, blood glucose supplies, etc.
3. Drugs not secured.
4. NP/PA or outside person not signing off on policies.
5. No analysis of an emergency event or exercise.
6. Not having all contact information in EP binder.
7. No documentation of chart review.
8. Not abiding by the wet time of your disinfectant.
9. Signage not matching the name you told CMS when you were called.
10. Incomplete patient records, both labs and consent.

Staff Interviews

- Can staff articulate procedures they are responsible for?
- **If asked:** *“What do you have to do to get fired here?”* Do they know the answer?
- **If asked:** *“What do you do if you have to evacuate the clinic?”* Do they know the protocol or have easy access to the emergency preparedness information for evacuation procedures?
- Staff should be prepared to answer questions related to their job responsibilities, clinic policies, and emergency protocols.



Reminder

**Train your staff
on corporate
compliance
and standards
of conduct.**

Deficiencies

Regulation at 42 CFR 488.26(b) says:

- The decision as to whether there is compliance depends on manner and degree.

Standard or Condition level:

- How serious is the deficiency in terms of its potential or actual harm to patients.
- The extent of noncompliance e.g., How many or how widespread?
- One incidence of noncompliance that poses a serious threat to patient health and safety is **CONDITION**.
- Or many instances of a standard level deficiency could lead to a **CONDITION** level citation e.g., 15 of 20 charts have no consent.

Plan of Correction (PoC)

Must contain the following:

- **The process or lack of process** that led to the deficiency.
- **Action that will be taken** to correct each deficiency.
- **Description of how the actions will correct** and or improve the issue.
- **Monitoring procedures** to ensure the plan is effective to keep the RHC in compliance.
- **Title of person responsible** (no names) for implementing the PoC.
- **Signature** of an administrator.



What to Expect on Survey Day

- RHC surveys are unannounced. **Be prepared!**
- Managers, **share your knowledge** with staff.
- **Most surveys take between 6 - 8 hours per clinic**, depending on the size and number of providers/staff.
- Remember, **having easy access to policies, personnel records, and medical records** as they are requested, will allow the survey to proceed without delay.
- Once complete, the **surveyor will conduct an exit interview** to discuss the findings.

Questions



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