COVID-19 Vaccine Quality Assurance Site Visit
Self-Assessment Checklist

Prepare for the Visit
These are the areas included in your COVID-19 vaccine provider agreement and in the COVID-19 Vaccine Management Guide that could be reviewed during a formal site visit. Please use this tool as a mechanism to assess your site’s existing practices and make adaptations as needed.

Information to Know
☐ Ensure all the information requested in the provider agreement is correct and that your organization is abiding by all the agreement requirements on page 2. You can check your information at the OIP Vaccine Provider Enrollment Dashboard.
☐ If you redistribute your vaccine, know the names of all the sites that you send vaccine to.
☐ Staff are up to date with required training and training documentation is available.
☐ Be able to show the three-year record retention process for all COVID-19 related documents.
☐ Review that the COVID-19 Vaccine Management Guide is being followed, including
  o billing practices
  o reporting immunization core data elements to ALERT IIS
    ▪ facility name, address (including county) and sending organization
    ▪ recipient name, address, date of birth, sex, race, ethnicity
    ▪ administration date, administering site (on the body), route of administration, eligibility code (“S” or “O”), administering provider suffix
    ▪ manufacturer/product, lot number, unit of sale (box not vial), expiration date
  o managing vaccine inventory
  o proper storage and handling
  o temperature excursion events
  o transporting vaccine
  o preparing and administering vaccines (clinics and pharmacies) (Depots excluded.)
  o adverse events and VAERS reporting
  o ancillary supply kits

Documents to Have Accessible
☐ Staff training records related to vaccines.
☐ Paperwork that is given to vaccine recipients at the time of vaccination like the EUA fact sheets for each vaccine, vaccination record cards and v-safe information sheets.
☐ Vaccine Management Plan (can use COVID-19 Vaccine Management Guide)
☐ Temperature logs and data for all units that have been used to store COVID-19 vaccine for the month leading up to and including the date of the site visit (having data downloaded and easy to access will streamline the visit).
☐ Standard operating procedure documents related to vaccine.

Identify Staff Needed
☐ Vaccine coordinator that will be available for the entire visit.
☐ Staff member familiar with billing practices.
☐ Someone with access to circuit breakers.
☐ Staff member who administers vaccine. (Depots excluded.)
☐ Anyone else you want present to help cover pharmacy responsibilities during the visit.
Day of the Visit

**COVID-19 Vaccine:** Must have COVID-19 in stock on the day of the visit.

**Time Required:** The site visit may take **up to 2 hours** to complete onsite.

**Required Staff**
For the whole visit: The vaccine coordinator or someone else familiar with the details of your vaccine program including vaccine storage and handling, preparation and administration, and training.

For a small portion of the visit:
- Someone familiar with billing practices.
- Someone who can access circuit breaker boxes that serve vaccine storage units.
- Someone who administers the vaccine to observe vaccination process (preparation and administration). (Depots excluded.)

For any portion of the visit: other provider staff that you choose to have present for the visit.

**Tasks to be Completed**
- A series of questions about COVID-19 vaccine preparation and administration, recordkeeping, billing of COVID-19 visits, vaccine reporting, vaccine distribution, etc.
- Inspection of each vaccine storage unit.
- Inspection of vaccine preparation and administration area.
- Observation of a staff member who administers vaccine to observe vaccination process (preparation and administration) if vaccinations are taking place. (Depots excluded.)

**Access to Equipment**
- The digital data loggers (operating in the units, don’t remove them) and temperature logs.
- All units used to store COVID-19 vaccine.
- The circuit breaker box(es) that serve the refrigerator and freezer units.
- Equipment for emergency or routine transport of vaccine.