

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
 - billing practices
 - 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
 - [managing vaccine inventory](#)
 - proper [storage and handling](#)
 - temperature excursion events
 - transporting vaccine
 - preparing and administering vaccines ([clinics](#) and [pharmacies](#)) (Depots excluded.)
 - adverse events and VAERS reporting
 - 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.