



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
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Ames, IA 50010

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-06

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

SUBJECT: Virtual Inspections for Remodeled or New Facilities for Existing Licensed Establishments

I. PURPOSE

This Notice informs regulated entities of a new process for an option to perform an inspection of remodeled or new facilities used in the preparation of veterinary biological products. Inspections confirm the facility, equipment, personnel, and processes are acceptable for the purposes intended and a virtual inspection will assist with the continuity of business for currently licensed establishments.

This is only to be implemented for existing establishments holding an unsuspended or unrevoked establishment license with the Center for Veterinary Biologics (CVB) and is not intended for prelicensing inspections of unlicensed establishments. CVB reserves the right to refuse to perform virtual inspections.

II. BACKGROUND

The current travel situation resulting from COVID-19 makes timely on-site inspections of remodeled or new facilities difficult. Due to restrictions on the market release of serials produced in unauthorized areas, the investment made in a remodeled room or area, new building construction, and/or acquisition of a new site may not be fully realized for product prepared for the marketplace prior to an on-site inspection.

Title 9, *Code of Federal Regulations*, part [101.2](#) defines inspection as an examination made by an inspector to determine fitness of facilities and procedures used in connection with the preparation, testing, and distribution of biological products. Traditionally, the inspection has been performed on-site for remodeled, newly constructed buildings or a new site.

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-06

Page 2

The term “new construction” will be used in the remainder of this Notice and includes remodeled rooms/areas in current facilities, additions to current facilities, new building construction on currently licensed premises, and new sites not currently listed on an existing establishment license.

III. ACTION

- A. Licensee Pre-inspection Activities – This information may be submitted via the NCAH Portal
1. Inform CVB- Inspection and Compliance (IC) of the proposed new construction; this may include a preliminary drawing for review and comment as noted in Veterinary Services Memorandum [800.78](#), Section V.F. This submission should include an overview of the project, including why the project is being done, what equipment is being moved or added, impact to other production areas, and the proposed timelines for milestones and completion of the project. CVB-IC will respond to the submission with additional requests related to the specific virtual inspection. The requests may include, but are not limited to:
 - a. A listing of critical equipment, new or moved, for the new construction and a statement affirming the equipment has been qualified and validated for the purposes intended. Any deviations or issues associated with the implementation of the equipment and how these issues were addressed should also be submitted.
 - b. A personnel list, including title and role, for those scheduled to perform functions in the new construction.
 - c. A list of any products (antigens and/or serials) prepared at risk in the new construction post qualification and validation of the area.
 2. Submit completed facility documents for the new construction.
 3. Submit a video of the finished new construction on a USB Flash Drive – this will serve as the initial tour of the area. The USB Flash Drive will not be returned. We recommend the video format be MP4 or MOV and keeping the file size to 35 MB or less. Depending on the size of the new construction, this may mean submission of several videos. Due to the constraints with the NCAH Portal, this submission cannot be transmitted electronically at this time.

Mail this to: Attention CVB-IC, 1920 Dayton Avenue, Ames, IA 50010.

The video should address the following points:

- a. Include the room number prior to entering each room;
- b. Include the unique equipment identification for all critical equipment in place;
- c. Equipment operation, such as a fill line, may be included;
- d. Capture all aspects of the room including floors (ie. drains, outlets), walls, and ceilings (including HEPA filters, air supply and returns, plumbing and electrical penetrations, and materials used in construction);
- e. Demonstrate personnel and material flow.

Editing may be done to provide a more concise tour, but should not omit critical information. Include a statement in the cover letter that the video depiction is true and accurate and include the date the video was recorded.

B. CVB Inspection Activities

1. CVB will review the submitted information, comparing the video to the submitted documents.
2. Additional information may be requested for review, including live video and/or pictures. The additional information may include the following:
 - a. Qualification and validation summaries for specific areas and/or equipment. The validation should encompass the range at which the equipment will be used and demonstrate consistent quality.
 - b. Training records for select employees.
 - c. Production records for particular antigens and/or serials.
3. Any violations noted or actions required will be communicated to the Liaison through a conference call, similar to an on-site closing meeting.

C. CVB Post-inspection Activities

1. A written field inspection report will be provided to the entity.
 - a. The report will detail any actions required prior to use of the new construction.
 - b. If facilities, equipment, processes, and personnel were found acceptable, permission to use the new construction will be granted in the report.

- c. Products manufactured at risk post qualification and validation may not be eligible for release if issues are found.
2. Facility documents will be processed, filed (if acceptable), and returned. Acceptable facility documents must be on file with CVB prior to consideration of release for products prepared in the new construction.
3. CVB may require notification of initial serials prepared in the new area when products are submitted for consideration for market release. These serials may be tested by CVB as a part of the consideration for market release.
4. The special inspection performed by virtual means has the same regulatory outcome as an on-site inspection. Special attention will be given to the new construction at the next in-depth inspection and if needed appropriate regulatory actions will be taken at that time.

IV. IMPLEMENTATION/ APPLICABILITY

This practice goes into effect immediately.