General Guidelines on Designating a Building or Area Separate and Apart

Background: Only buildings or areas on licensed premises that are physically and/or functionally distinct from the production facility can be considered separate and apart.

If a research facility is considered to be separate and apart from the production building or area by the Center for Veterinary Biologics (CVB), CVB does not need to authorize the preparation of experimental biological products as listed in title 9, *Code of Federal Regulations* (9 CFR), part 103.1.

CVB is extending this practice to Quality Control buildings or areas that are separate and apart from the production building or area. Entities will not need CVB authorization to move experimental products, CVB pre-confirmed master seeds or master cells into the separate and apart Quality Control building or area. The entity will be responsible for updating and submitting the list of fractions on an annual basis or as requested by CVB for these Quality Control areas.

This guideline may also be used to determine if non-biological process areas are also deemed separate and apart from the biological production areas, such as pharmaceutical manufacturing in the same building.

Determination if a research or testing building or area is entirely separate and apart is made by CVB-Inspection and Compliance. The decision may necessitate an inspection of the facility in order to adequately make the determination.

The determination if an area is entirely separate and apart must include certain building structures.

1. The walls must go from the floor deck to the roof deck (not just the ceiling) to provide separation.
2. Penetrations through a shared wall must be adequately sealed; unsealed penetrations allow air movement, especially in a pressurized system.
3. If the penetration in a shared wall is for an emergency exit only, the exit must be well marked and sealed to prevent air movement.

The determination if a building or area is entirely separate and apart is not limited to only the analysis to the building structure. An overall risk assessment of the possible contamination of licensed product is required.

Possible areas to evaluate:

1. Personnel movement
2. Personnel intermingling
3. Shared HVAC
4. Shared plumbing – backflow prevention
5. Shared electrical – vermin and airflow contamination
6. Intake and exhaust locations – failure risk to licensed products
7. Equipment and materials movement

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8. Training
9. Standard processes and controls
10. Types and nature of organisms to be brought into area
11. Shared materials, chemicals, ingredients, etc.

Each evaluation is dependent on the situation. Other areas to evaluate may be necessary.

Once a building or area has been determined to be separate and apart, this designation should be added to the facility documents in the plot plan legend with reference to the documentation citing CVB's approval (mail log number) that it is separate and apart.