

FACILITY DOCUMENT FORM
BLUEPRINT/BLEUPRINT LEGEND – PRELIMINARY REVIEW (BCA)
[9 CFR 108.4 and 108.5(b)]

Firm _____ Est. No. _____

Site Address _____

Building/Floor _____

ML _____ Date Received _____

Submission Type: New Address New Building Remodeled Facility Pre-licensing Revision

Information to Review (add comment if necessary)

BLUEPRINT

- | | | |
|--|--|---------------|
| 1. Scale Indicated? [108.4(a)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 2. Rooms Identified? [108.4(e)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 3. Stationary Equipment Identified? [108.4(f)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 4. Compass Point? [108.4(h)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 5. Building Number Included? [108.4(i)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 6. Date of Preparation Included? [108.4(j)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 7. Signature of Liaison/Alternate? [108.4(k)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 8. Summary of Changes? [108.6(a)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 9. Two Copies? [108.7] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |

BLUEPRINT LEGEND (add comment if necessary)

- | | | |
|---|--|---------------|
| 1. Legend Identified by Building/Floor? [108.5] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 2. Pages numbered? [108.5] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 3. Rooms Identified? [108.5(b)(1)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 4. Summary of Changes? [108.6(a)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 5. Two Copies? [108.7] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |

BLUEPRINT LEGEND ADDENDUM LISTING

- Decontamination Procedures
- Other Precautions against Cross Contamination
- Fraction List(s)

- 1. _____
- 2. _____
- 3. _____

- Exemptions to 109, Sterilization of Equipment

Other (list)

- 1. _____
- 2. _____

BLUEPRINT LEGEND ADDENDUM (add comment if necessary)

- | | | |
|---|--|---------------|
| 1. Legend Identified by Building/Floor? [108.5] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 2. Pages numbered? [108.5] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 3. Summary of Changes? [108.6(a)] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |
| 4. Two Copies? [108.7] | <input type="checkbox"/> YES <input type="checkbox"/> NO | Comment _____ |

ADDITIONAL COMMENTS

BCA ACTION:

Submit to the Biologics Specialist _____

Return to Firm _____