Records Management

RO Webinar

July 14, 2021

What records are required?

Section 17: Record-Keeping Requirements

- Biological select agents and toxins (BSAT) inventory records - *17(a)(1), 17(a)(3)*
- Select agent-infected animal/plant records - *17(a)(2)*
- APHIS/CDC Forms 2, 3 (eFSAP) - *17(a)(1), 17(a)(3)*
- List of approved personnel (Form 1, eFSAP) - *17(a)(4)*
- Entries into areas containing BSAT (approved & non-approved personnel) - *17(a)(5)*

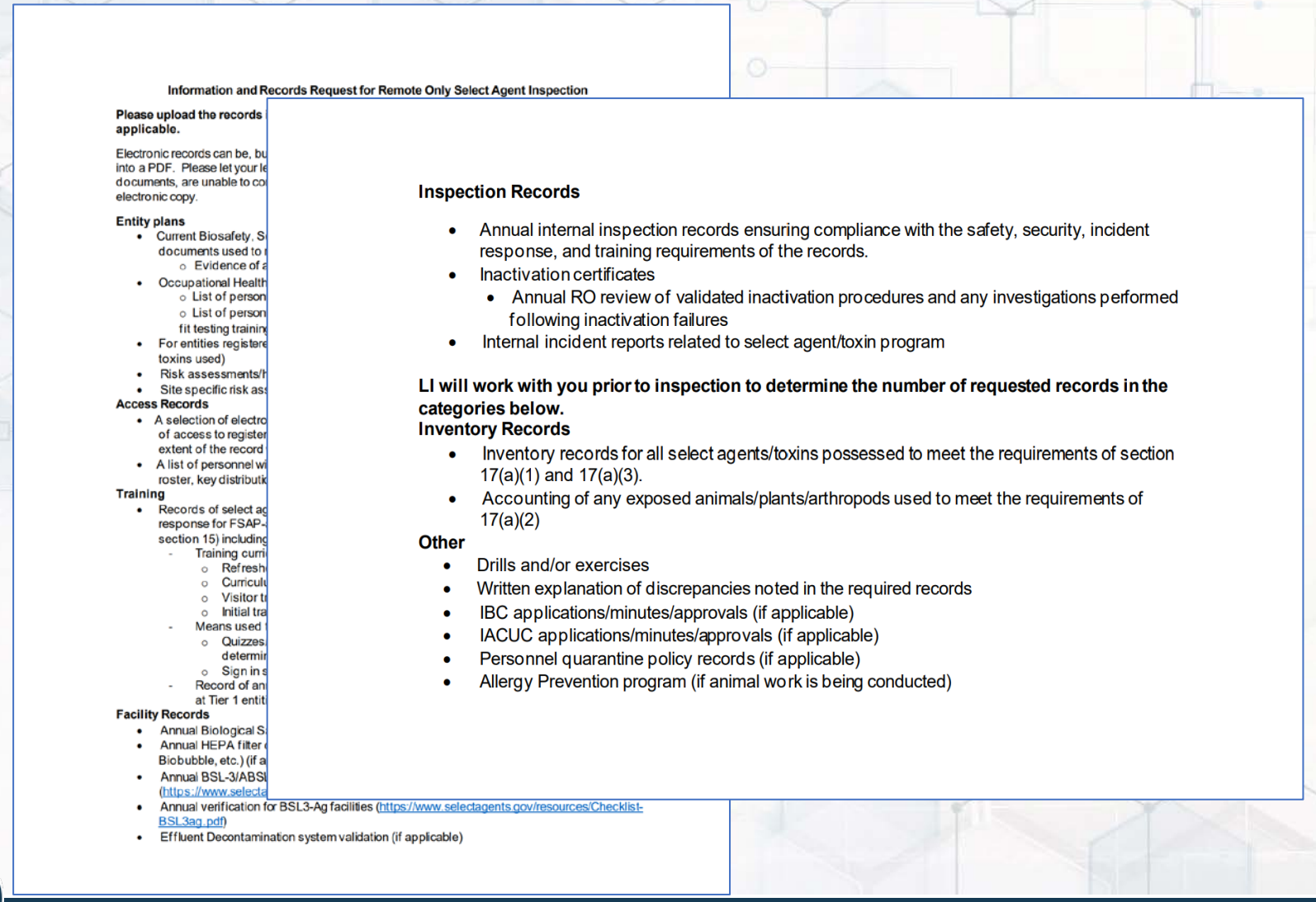
Section 17: Record-Keeping Requirements

- Accurate, current records (covering other sections) - *17(a)(6)*
  - 9 (Responsible Official [RO]), 11 (Security), 12 (Biosafety), 14 (Incident Response), 15 (Training)
- Written explanations of discrepancies - *17(a)(7)*
- BSAT inactivation records - *17(a)(8)*
  - 9 (RO), 12 (Biosafety)

Inspection Document Request List

General Document request for (A)BSL-2/3 laboratories

(example)



Information and Records Request for Remote Only Select Agent Inspection

Please upload the records applicable.

Electronic records can be, bu into a PDF. Please let your le documents, are unable to co electronic copy.

Entity plans

- Current Biosafety. S documents used to
  - Evidence of
- Occupational Health
  - List of person
  - List of person fit testing trainin
- For entities registere toxins used)
- Risk assessments/
- Site specific risk as

Access Records

- A selection of electro of access to register extent of the record
- A list of personnel wi roster, key distributi

Training

- Records of select ag response for FSAP- section 15) including
  - Training curri
    - Refresh
    - Curricul
    - Visitor t
    - Initial tra
  - Means used
    - Quizzes determi
    - Sign in s
  - Record of an at Tier 1 entit

Facility Records

- Annual Biological S
- Annual HEPA filter Biobubble, etc.) (if a
- Annual BSL-3/ABSL (https://www.selecta
- Annual verification for BSL3-Ag facilities (https://www.selectagents.gov/resources/Checklist-BSL3ag.pdf)
- Effluent Decontamination system validation (if applicable)

Inspection Records

- Annual internal inspection records ensuring compliance with the safety, security, incident response, and training requirements of the records.
- Inactivation certificates
  - Annual RO review of validated inactivation procedures and any investigations performed following inactivation failures
- Internal incident reports related to select agent/toxin program

LI will work with you prior to inspection to determine the number of requested records in the categories below.

Inventory Records

- Inventory records for all select agents/toxins possessed to meet the requirements of section 17(a)(1) and 17(a)(3).
- Accounting of any exposed animals/plants/arthropods used to meet the requirements of 17(a)(2)

Other

- Drills and/or exercises
- Written explanation of discrepancies noted in the required records
- IBC applications/minutes/approvals (if applicable)
- IACUC applications/minutes/approvals (if applicable)
- Personnel quarantine policy records (if applicable)
- Allergy Prevention program (if animal work is being conducted)

Inspection Document Request List

General Document request for (A)BSL-4 laboratories (example)

Requested Information and Records for Select Agent BSL4 Verification Inspection

Electronic and/or hard copy of the following information and required records is acceptable

General Documents

- Biosafety Plans for BSL4
- Occupational Health Plan
- Security Plan
- Incident Response Plan
- Floorplans for lab suites and HEPA deck
- List of SOPs developed
- Training Records
- Lab Access Records
- Irradiator chain of custody documents
- Irradiator kill curve data
- Validation data
  - BSL4 specimens that are removed from containment for nucleic acid, protein, fluorescence, immunofluorescence, histopathology, and immunohistopathology analysis. SOPs will need to be supplied for all methods listed.
  - Autoclave parameters utilized for carcass cycles. Validation data will need to be provided using surrogate carcasses (i.e. turkey, Cornish game hen, etc.) that would mimic tissue density of the largest animal model intended to be decontaminated. Validation data will need to be provided for all carcass cycles used (small rodents, NHPs, etc.).
  - Gross decontamination parameters used for room decontaminations.
- All laboratory incident reports
  - Summary/SOP that explains how staff are to report incidents, how they are assessed for further action including potential reporting to the CDC as a Form 3, and by whom
- Inventory records
- BSL4 drills and exercises reports
- IBC/IACUC minutes

Facilities Documents

- BSL4 Daily checklists
- HEPA certs on all housings, BSCs, necropsy/backdraft tables, animal caging
- Spore test data on EDS
- Spore test data on autoclaves
- Autoclave validation data for animal carcass run cycle times (see above)
- EDS cook cycle data
- Pressure decay tests
- Maintenance / Decontamination records for Pall filters
- Breathing air quality data
- Daily (shift) inspection / maintenance records
- Preventative maintenance schedule and records
- BAS critical alarm definitions
- BAS alarm notification scheme
- BAS facility power re-start sequence
- BAS calibration records
- Generator load testing, backup power reliability testing, etc. -- schedules and associated containment data
- Fan failure tests and associated containment data
- Autoclave vent filter change records

Providing Records for the Inspection Process

Useful Tip - How to Provide Records

- eFSAP Inspection Module
- PDF or Word
- Like with Like
- Call it what it is
- SharePoint
- External sites (e.g. Box)


What specific documentation is needed?
USDA
CDC

BSAT Inventory Records, 17(a)(1), 17(a)(3)

- No specific requirement on how to maintain

- Hardcopy vs. electronic
- Facility derived vs. Laboratory Information Management System (LIMS)
- Inside laboratory vs. outside laboratory

- Long-term storage records
- Usage records
- Destruction records

Select Agent-Infected Plant and Animal Records, 17(a)(2)

- Animal census logs
- Cage cards
- Animal carcass logs
- Animal sample records (e.g., fluids, tissues)
- Final disposition records

Useful Tip – What is My Record?

- Does the inventory record capture all requirements? *17(a)(1), 17(a)(3)*
  - Quantity acquired, where stored, purpose of use?
- Once infected, can you track animals from "infection-to-final disposition"? *17(a)(2)*
  - Accurate/current accounting, species, location, appropriate disposition?
  - Are samples being used immediately or going into long term storage (LTS)?
- Does the complete record consist of multiple documents?
  - LTS logs, usage logs, user comments, autoclave logs, laboratory notebooks

Useful Tip – Where is the Record?

- Records can be accessed and reviewed
  - Outside the laboratory
  - Prior to inspector entry
  - Electronically

- Full record vs. representative examples
  - Photocopies or scans
  - Presentation of electronic system
  - Screenshots

Useful Tip – Can You Follow the Record?

- Who really maintains the record?
- Is the complete record in one or multiple locations?
  - Cage cards in laboratory, animal census/carcass logs with animal care staff, other records with Principal Investigator (PI)
- Are records easy to follow?
  - Is the system straightforward?
  - Are there multiple systems in use at your facility?

Approved Personnel, 17(a)(4)

- eFSAP, Section 4
- Access permissions
  - Used to access training
  - Occupational health enrollment (Tier-1, SARS)
  - Implementation of security measures (BSAT access/laboratory entry records)

Useful Tip – Do the Records "Match"?

- Section 4 Approval vs. Access

- Does approval really mean access?
  - Federal Select Agent Program (FSAP) access approval but still under mentorship
  - SRA-approved but does not need to access BSAT (e.g., administrative, IT)

- Different access levels?
  - Registered suite but access controlled at room level
  - Tier 1 versus non-Tier 1

- Different name from Section 4?
  - Marital status or nicknames

Entries Into Areas Containing BSAT, 17(a)(5)

- Does the registered area contain BSAT at the time of entry?
- What system is used to capture entries (electronic vs. hard-copy)
  - How often are the records gathered (monthly, quarterly, before an inspection)?
  - Are these records easy to access, can you query by date, etc.?

Accurate/Current Records, 17(a)(6)

- Section 9(a)(6)
  - Annual internal inspections (refer to March 2019 policy statement)
  - Is this one or multiple documents? Who has these documents? Are FSAP checklists used? Are results and corrective actions documented? How?
- Section 9(a)(9)
  - Annual review of validated inactivation methods

Accurate/Current Records, 17(a)(6)

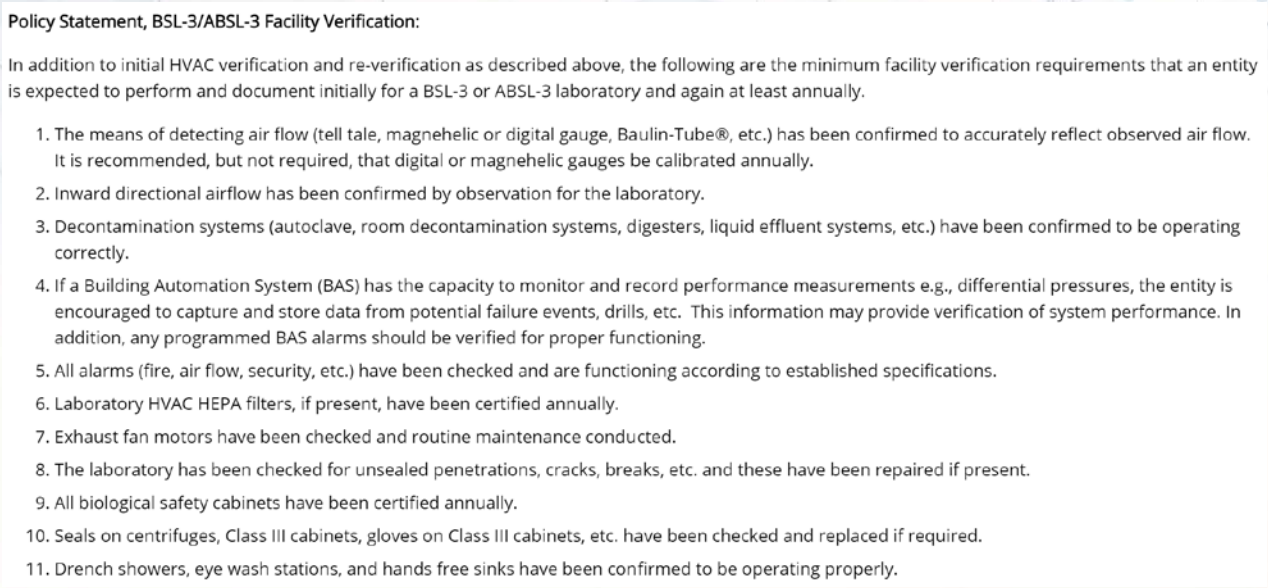
- Section 11, 12 and 14
  - Security, Biosafety, and Incident Response Plan(s)/Standard Operating Procedures (SOPs)
- Annual plan review
  - How is this documented? Revision history, SOP review?
- Drills and exercises
  - Does the after action report(AAR) capture all requirements? Are plan updates needed? How is this documented? Is the documentation clear and kept together?

Accurate/Current Records, 17(c)

- Section 12(b)
  - "The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards)."
  - FSAP policy
    - BSL-3/ABSL-3 Verification
    - BSAT inactivation (e.g., *B. anthracis*)
  - Guidelines and nationally-recognized standards
    - National Institutes of Health (NIH) Guidelines
    - Biosafety in Microbiological and Biomedical Laboratories (BMBL)

Accurate/Current Records, 17(c)

- Section 12 (Biosafety) records



Policy Statement, BSL-3/ABSL-3 Facility Verification:

In addition to initial HVAC verification and re-verification as described above, the following are the minimum facility verification requirements that an entity is expected to perform and document initially for a BSL-3 or ABSL-3 laboratory and again at least annually.

1. The means of detecting air flow (tell tale, magnehelic or digital gauge, Baulin-Tube®, etc.) has been confirmed to accurately reflect observed air flow. It is recommended, but not required, that digital or magnehelic gauges be calibrated annually.
2. Inward directional airflow has been confirmed by observation for the laboratory.
3. Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly.
4. If a Building Automation System (BAS) has the capacity to monitor and record performance measurements e.g., differential pressures, the entity is encouraged to capture and store data from potential failure events, drills, etc. This information may provide verification of system performance. In addition, any programmed BAS alarms should be verified for proper functioning.
5. All alarms (fire, air flow, security, etc.) have been checked and are functioning according to established specifications.
6. Laboratory HVAC HEPA filters, if present, have been certified annually.
7. Exhaust fan motors have been checked and routine maintenance conducted.
8. The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present.
9. All biological safety cabinets have been certified annually.
10. Seals on centrifuges, Class III cabinets, gloves on Class III cabinets, etc. have been checked and replaced if required.
11. Drench showers, eye wash stations, and hands free sinks have been confirmed to be operating properly.

- Facilities
  - Biosafety cabinet (BSC) certifications
  - HEPA certifications
  - Annual BSL-3/ABSL-3 facility verification
    - Based on 12(b) and described in BMBL, BSL-3, D15; ABSL-3, D14
  - BSL-4 facilities/equipment (e.g., EDS, vent filters, APR door filters)

Useful Tip – Facilities Records

- Know your equipment
  - What equipment is in use? How many exhaust HEPAs do you really have?
  - Summarize into a usable list if possible
- Is your floorplan helpful?
- How are the records managed?
  - Are certification records organized by serial number, equipment number, etc.?

Useful Tip – Facilities Records

Keep facility verification documents together

- Cover page with attached documentation for each element

- Who has these records. How are they being managed?
  - Do facilities personnel have these records? RO?

- Maintain equipment certification master list(s)
  - Spreadsheet with BSCs, Animal Containment Units, BioBubbles, exhaust HEPAs.
  - Easy to review

Accurate/Current Records, 17(a)(6)

- Section 15 (Training) records
  - Approved personnel
    - Initial and annual refresher training
      - No specific requirement on how to implement
      - Based on the individual's needs and risk posed by the BSAT
        - Biocontainment, biosafety, security, and incident response; Insider threat for Tier 1
      - Prior to entering areas containing BSAT or within 12 months post-FSAP access approval
      - Understanding/acknowledgement
  - Non-approved personnel (visitors)
    - No specific requirement on how to implement
    - Based on the risk posed by the BSAT
    - Are visitor training records part of entry record?

Useful Tip – Training Records

- Training records pile up so stay on top of this
- Know what the requirements are for each person
  - Don’t provide records for training not required
- Provide to FSAP
  - Training curricula
  - How training was documented and assessed
  - If electronic system, have a spreadsheet with names, dates, training received

BSAT Inactivation Records, 17(a)(8)

- BSAT inactivation/removal records
  - Description of validated inactivation procedure or removal method; including validation data
  - Viability testing protocol
  - Name of person performing inactivation/removal
  - Date and location of inactivation/removal
  - Certificate of inactivation signed by PI

Useful Tip – Inactivation Records

- Keep procedure and viability testing protocol with certificates, if possible
- Know where this information is kept (e.g., biosafety plan, SOP, thumb drive)
- Organize certificates by PI, if possible
  - Especially if multiple PIs use a shared inactivation method
- Only provide BSAT inactivation records

Final Thoughts

Successful Records Management

- Benefits of good records management
  - FSAP inspectors can easily review the record
  - Helps ensure you are meeting all record-keeping requirements
  - Saves prep time leading up to and/or during an inspection
  - Results in a smoother, less-stressful inspection

www.selectagents.gov

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