

For Internal Use Only

FOCUSED INSPECTIONS FOR (b) (7)(E) AAALAC ACCREDITED RESEARCH FACILITIES
FAQ

1. Does a focused inspection count as the annual inspection for research facilities.
 - Focused annual inspections, performed as described in question 8 below, 'count' as the required annual inspection for research facilities.
 - Focused inspections in response to a complaint or incident do not 'count' as the required annual inspection.
2. What are the criteria for determining whether to conduct a focused or routine annual inspection?
 - Conduct a routine inspection if:
 - (b) (7)(E)
 - The facility is not AAALAC accredited.
 - Conduct a focused inspection if all of the following are met:
 - (b) (7)(E)
 - There are no other circumstances that warrant a routine inspection.
3. What actually constitutes a focused annual inspection? How can we be sure that we are being consistent in completing our focused inspections?
 - A focused inspection is an unannounced inspection that does not include the entire facility, animals and required documentation (Inspection Guide 3.3.5). It is critical that all of us follow this focused inspection guidance consistently:
 - i. All regulated research facilities must be treated fairly. They have worked hard to be AAALAC accredited (b) (7)(E) They have a right to expect that each inspector will follow this guidance.
 - ii. (b) (7)(E) Animal Care must prioritize our resources to spend time at the facilities of highest risk.
 - iii. Animal Care's credibility, with our customers, with our internal and external auditors, and in terms of our performance and workload management, depends on each inspector adhering to required procedures.
 - We will assure that we are being consistent by routinely monitoring the implementation of the focused research inspections.
4. If a facility is not AAALAC accredited, is it eligible for a focused inspection?
 - No, a research facility has to be (b) (7)(E)
5. If only a portion of a facility is AAALAC accredited what do we do?
 - If the unaccredited portion is a separate site, handle each site separately according to its accreditation status.
 - If the unaccredited portion cannot be separated from the accredited portion of the facility, conduct a routine inspection.

6. Are there instances when I should convert a focused inspection into a routine inspection?

- (b) (7)(E)

7. Can I conduct a focused inspection every year?

- (b) (7)(E)

8. How do I decide what to inspect during a focused annual inspection?

- The three areas of concentration during a research inspection are animals, facilities and paperwork.
- You must rotate your focus for each visit (i.e., the focus could be on records one year and animals or facilities the next). (b) (7)(E)

(b) (7)(E)

9. Should the inspection report document the area or areas the inspection was focused on?

- No, those areas should be listed on the space provided on the protocol selection worksheet (PSW).

10. Do I follow the PSW requirements during a focused inspection?

- If paperwork is not part of the focused inspection, fill out the PSW to indicate zero protocols reviewed.
- If paperwork is part of the focused inspection, follow the guidance in the Inspection Guide for reviewing protocols and completing the PSW.

11. If we don't review protocols, will we have problems during our next research audit?

- Not if you are following the guidance for focused inspections.

12. If we are doing a focused inspection on the facility's animals, may we still review records or facilities based on need?

- Yes, you may do a focused on animals and ask for records as they are needed, without doing a routine records inspection. Remember that a PSW must be filled out for every inspection, regardless of whether the inspection is routine or focused.

13. There are some AAALAC accredited programs that are very small, without any covered species nor protocols. A routine inspection may entail review of IACUC minutes. Is it ok if they were to receive a routine inspection in these circumstances?

- If there have been no animals reported on the facility's annual report for 2 consecutive years, follow the guidance in Section 7.6.2.2 for such facilities. If there have not been 2 consecutive years of no animals being reported, and the facility qualifies for a focused inspection, follow the guidance for focused inspections.

14. Is a facility that has a very small program, meeting all criteria of focused inspection, approved for focused although the inspection may not take very much time in those circumstances in comparison to the time to drive out to the facility?

- Yes, the guidance for a focused inspection should be followed.

15. If the facility qualifies for a focused inspection but requests a routine, what do we do?

- Conduct a routine inspection, but you must send an email to your supervisor after the inspection has been completed to let him or her know that you conducted a routine inspection when only a focused was required. We will be working with the SACS to track that info on who gets a routine and why.

16. Should the revised PSW be used for all research facility inspections to include non-AAALAC or just for the AAALAC facilities?

- The PSW is to be used on both non-AAALAC and AAALAC facilities.

17. When a VMO goes to the facility for the first time, and that inspection qualifies for a focused inspection, are they to do a focused inspection? Or are they to evaluate the entire program as it is his/her first introduction to the facilities and personnel?

- If the facility qualifies for a focused inspection, a focused inspection should be conducted.
- If you feel that you need specific information about portions of the facility that you are not inspecting, ask the facility or a previous inspector.

18. How do we determine if a facility is AAALAC accredited? The AAALAC website has a search engine that tells you if a facility is accredited but does not tell you the status of their accreditation. Their website states that there are four categories that are all considered 'accredited' (full, conditional, deferred and probation).

- You may ask the facility directly and/or look-up the facility status on the AAALAC website. The website address with the accredited facility list is: <https://www.aaalac.org/accreditedorgsdirectorysearch/aaalaclistall.cfm>

- (b) (7)(E)
(b) (7)(E) The website address with the accredited facility list is: <https://www.aaalac.org/accreditedorgsdirectorysearch/aaalaclistall.cfm>

19. Are the conditional, deferred and on probation accredited facilities eligible for a focused inspection?

- (b) (7)(E)

20. If we ask, is the facility required to show us their accreditation letter showing the category of accreditation?

- No, so do not ask for the accreditation letter.

21. (b) (7)(E) facility asked for an incentive and it was not granted. The incident was in the past and it was decided it would be reviewed and any NCIs would be cited on the next facility inspection. Is this facility eligible for a focused inspection on that next facility inspection?

- If the facility's (b) (7)(E) and it is AALAC accredited, you should conduct a focused inspection. If you have an area of concern, you can inspect that area as part of your focused inspection or switch from a focused inspection to a routine inspection.

22. Can we share the FAQ sheet for focused inspections outside of AC?
- No, the document is for official use, internal only.
23. How are we disseminating the information to the field?
- We are using a low key approach. There will be no stakeholder announcement. The message is to be conveyed by the inspector to their facilities.
24. Will this information be in the Inspection Guide (IG)?
- This FAQ will not be in the IG.
25. If I'm training a new inspector, and the facility qualifies for a focused inspection, should I do a routine or a focused inspection?
- You should do a focused inspection, and the new inspector can observe how the focused inspection process works.
26. I don't want all or most of my research facilities to be on the same inspection cycle. If a facility qualifies for a focused inspection, can I go ahead and do a routine inspection to avoid that?
- If the facility meets the criteria for focused inspection, you need to follow the guidance for a focused inspection.
 - Many facilities have already had a routine inspection in 2019 and we believe that workload issues will balance out using the guidance as written.

5/24/2019

FOR INTERNAL USE ONLY

FOCUSED INSPECTIONS FOR (b) (7)(E) RESEARCH FACILITIES Q&A

1. What are the criteria for determining whether to conduct a focused or routine inspection?
 - Conduct a routine inspection if:
 - (b) (7)(E)
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 - Conduct a focused inspection if all of the following are met:
 - (b) (7)(E)
 - (b) (7)(E)
 - There are no other circumstances that warrant a routine inspection.
2. If a facility is not AAALAC accredited, is it eligible for a focused inspection?
 - No, a research facility has to be (b) (7)(E)
3. If only a portion of a facility is AAALAC accredited what do we do?
 - If a research facility is both AALAC accredited and (b) (7)(E) conduct a focused inspection for the AALAC accredited areas and conduct a full inspection for the non-AALAC accredited areas. The inspection report should be labeled as “focused.”
4. Are there instances when I should convert a focused inspection into a full inspection?
 - (b) (7)(E)
5. Can I conduct a focused inspection every year?
 - (b) (7)(E)
6. How do I decide what to inspect during a focused inspection?
 - The three areas of concentration during a research inspection are animals, facilities and paperwork.
 - You must rotate your focus for each visit (i.e., the focus could be on records one year and animals or facilities the next). (b) (7)(E)
7. Should the inspection report document the area or areas the inspection was focused on?
 - No. Those areas should be listed on the space provided on the protocol selection worksheet.
8. Do I follow the protocol selection worksheet requirements during a focused inspection?
 - If paperwork is not part of the focused inspection, fill out the protocol selection worksheet to indicate zero protocols reviewed.

- If paperwork is part of the focused inspection, follow the guidance in the Inspection Guide for reviewing protocols and completing the protocol selection worksheet.
9. If we don't review protocols, will we have problems during our next research audit?
 - Not if you are following the guidance for focused inspections.
 10. In the past, a focused inspection has not counted as the annual inspection for research facilities. Has this changed?
 - Focused inspections 'count' as the required annual inspection for research facilities.
 11. What actually constitutes a focused inspection? How can we be sure that we are being consistent in completing our focused inspections?
 - A focused inspection is an unannounced inspection that does not include the entire facility, animals and required documentation. (Inspection Guide 3.3.5) It is critical that all of us follow this focused inspection guidance consistently:
 - i. All regulated research facilities must be treated fairly. They have worked hard to be AAALAC accredited and (b) (7)(E). They have a right to expect that each inspector will follow this guidance.
 - ii. (b) (7)(E)
 - (b) (7)(E) spend time at the facilities of highest risk.
 - iii. Animal Care's credibility, with our customers, with our internal and external auditors, and in terms of our performance and workload management, depends on each inspector adhering to required procedures.
 - We will assure that we are being consistent by carefully monitoring the implementation of the focused research inspections.
 12. There are some AAALAC accredited programs that are very small, without any covered species nor protocols. A full inspection may entail review of IACUC minutes. Is it ok if they were to receive a full inspection in these circumstances?
 - The guidance should be followed....a focused inspection on IACUC minutes, or semi-annual inspections, or empty animal rooms, etc should be conducted.
 13. Is a facility that has a very small program, meeting all criteria of focused inspection, approved for focused although the inspection may not take very much time in those circumstances in comparison to the time to drive out to the facility?
 - The guidance should be followed....a focused inspection should be conducted.
 14. Should the revised PSW be used for all research facility inspections to include non-AAALAC or just for the AAALAC facilities?
 - The PSW is to be used on both non-AAALAC and AAALAC facilities.
 15. When a VMO goes to a facility for the 1st time which qualifies for a focused inspection, are they to do a focused inspection or are they to evaluate the entire program as it is there first introduction to the facility and personnel?
 - If the facility qualifies for a focused inspection, a focused inspection should be conducted. It doesn't matter if it's the VMO's 1st, 2nd, or 12th visit.
 16. How do we know the accreditation status of a facility? The AAALAC website has a search engine that tells you if a facility is accredited but does not tell you the status of their accreditation. Their website states that there are four categories that are all considered 'accredited' (full, conditional, deferred and probation). See attachment (copied from AAALAC website) for definitions.
 - (b) (7)(E)

(b) (7)(E) The website address with the accredited facility list

is: <https://www.aaalac.org/accreditedorgsdirectorysearch/aaalaclistall.cfm>

17. Are the conditional, deferred and on probation accredited facilities eligible for a focused inspection?

- (b) (7)(E)

18. If we ask, is the facility required to show us their accreditation letter showing the category of accreditation?

- No.

19. (b) (7)(E) facility asked for an incentive and it was not granted. The incident was in the past and it was decided it would be reviewed and any NCIs would be cited on the next facility inspection. Is this facility eligible for a focused inspection on that next facility inspection?

- If the facility's (b) (7)(E) and it is AALAC accredited, it is eligible for focused inspections. As stated in the Q&A, if an area of concern is identified, you should also inspect that area, or switch from a focused inspection to a full routine inspection.

3/20/19

Research Facility Protocol Selection Worksheet^{*}

Legal Name:

Customer Number:

Certificate Number:

Site Number:

Inspection Date:

Inspection Type: Routine ☐ Focused ☐ (list areas inspected) _____

Inspector:

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	
2. Column E protocols (select all)	
3. Protocols with IACUC-approved exemptions/exceptions (select all)	
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	
Total Protocols Selected and Reviewed	

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Version 2/11/19

Research Facility Protocol Selection Worksheet ^{*}

Inspection Date:

Facility Name:

Registration and Site Number:

Reasons Protocols Were Selected for Review:	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	
2. Column E protocols (select all)	
3. Protocols with IACUC-approved exemptions/exceptions (select all)	
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance)	
Total Protocols Selected and Reviewed	

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Inspector:

Research Facility Protocol Selection Worksheet ^{*}

Legal Name : _____

Customer Number: _____

Certificate Number: _____

Inspection Date: _____

Site Number: _____

Inspector: _____

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	
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3. Protocols with IACUC-approved exemptions/exceptions (select all)	
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