

VAMHCS RESEARCH & DEVELOPMENT SERVICE
SRS Process Module

PM-SRS-030

Effective Date: July 2016

Handling of Audit Reports or Other Compliance Reports

Applicable Regulatory Context:

[VHA HB 1058.01 §8.c]:

Within 5 business days of becoming aware of any incident reportable under applicable Federal standards, including but not limited to VHA Handbooks on research safety, NIH OBA guidelines, Occupational Safety and Health Administration (OSHA) requirements, CDC requirements, Department of Transportation (DOT) requirements, and Nuclear Regulatory Commission (NRC) requirements, members of the VA research community are required to ensure that the incident has been reported in writing to the SRS.

[VHA HB 1058.01 §8.d]:

The SRS must review at its next convened meeting any report involving an incident or event described at subparagraph 9a through 9c. ***NOTE:** If the significance of a reported event is not clear, the SRS Chair, or designee, must consult the ORO Associate Director for Research Safety and Animal Welfare.*

(1) Incidents that present a significant risk to the safety of research personnel or the environment may require immediate attention and result in the need to convene an emergency session of the SRS prior to the next scheduled meeting.

(2) Should the SRS determine that a reportable incident or event as described at subparagraph 9a through 9c occurred, the SRS Chair must report the determination directly (without intermediaries) to the facility Director within 5 business days after the SRS's determination.

1. The following are "Standing Line items" on the SRS agenda:

- a. Drills
- b. Facility Inspection Reports
- c. Audits (vulnerability assessments, ORC audit reports,¹ other audits)
- d. Compliance Reports (ORC report, oversight visits/reports).

¹ VAMHCS Office of Research Compliance (ORC) Research Safety and Animal Welfare (RSAW) audit

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2. SRS discusses the reports and any findings of concern.
3. If the SRS determines that incidents or findings
 - a. represent a significant risk to the safety or security of research personnel or the environment, or
 - b. represent a deficiency that substantively compromises the effectiveness of a facility's research safety programs, or
 - c. are reportable under other circumstances,then the SRS Chair must report the determination directly (without intermediaries) to the facility Director within 5 business days after the SRS's determination with simultaneous copies to the ACOS for Research, the R&D Committee, and any other relevant research review committee.²
4. If the significance of a reported event is not clear, the SRS Chair, or designee, may consult ORO RSAW for guidance.
5. The SRS reports to the Director within 5 business days after:
 - a. A determination that a reportable event has occurred or
 - b. A determination that incidents specified in VHA HB 1059.09 §9 were not reportable. See RDS Process Module 043 for details.
6. If in the opinion of the SRS Chair, there are immediate concerns, the SRS Chair may convene an ad hoc meeting of the SRS.
7. Discussion of incidents/reports and votes on determinations are documented in SRS meeting minutes.
8. ORC audit reports:
 - a. Final audit reports state the audit findings and include the PI's and the R&D Service's responses to the audit (if provided).
 - b. ORC sends final audit reports to the PI, SRS (Chair and administrative coordinator), RDC coordinator, HARPO, and RCO.
 - c. Reports are made available to SRS members for review prior to scheduled SRS meetings. Reports are made available to SRS members via encrypted email, hand-delivered, or are available in the Research Service office.
 - d. RDC coordinator files the electronic copies of the final audit reports in a designated folder of the RDC share drive so that they are available for RDC members for review.
 - e. For audit reports that indicate potential serious or continuing noncompliance or other serious concerns, the ORC auditor contacts the SRS Chair for discussion prior to the meeting.

² See R&D SOP 01.08.2 for details

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9. ORC monthly report to SRS:

- a. The ORC auditor presents a monthly report to the SRS that includes a table of audit findings for each study audited in the past month, major findings (if any), and updates on open items from previous audits. Additional information is included as appropriate for SRS oversight responsibilities.
- b. Follow item 3 above.

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