

Radiation Safety Committee	Annual Compliance and Program Audit
Standard Operating Procedure	

Background	<p>The Radiation Safety Committee (RSC) has been delegated responsibility for the administration of radiation safety functions within the United States Department of Agriculture (USDA). The Radiation Safety Officer is delegated the day-to-day responsibility for the management and operation of the radiation safety program</p> <p>The USDA has two licenses (Broad Scope and Irradiator) issued by the US Nuclear Regulatory Commission (NRC), which regulate the procurement, use, and disposal of radioactive materials within the Department. In addition, USDA policy regulates the use of radiation emitting equipment through conformance with the guidance provided by Federal Agencies (e.g., NRC) and National Safety Associations (such as the International and National Councils on Radiation Protection and Measurements; ICRP and NCRP, respectively).</p> <p>The NRC conducts inspections of radioisotope use at USDA field locations, reviews the results of those inspections during its annual audit of the Radiation Safety Staff (RSS) activities, and it reviews the USDA management commitment to radiation safety.</p> <p>The RSC audit program is designed to ensure compliance with NRC requirements (10 CFR 20.1101(c)) that licensees review their radiation safety programs annually.</p>
Audit Criteria	<p>As a function of its management oversight, the USDA RSC will perform annual audits of the RSS. These audits will assess the following areas of operation:</p> <ul style="list-style-type: none"> ! Program management; ! RSS compliance with NRC rules and regulations; ! RSS compliance with the NRC licenses and license conditions; ! RSS interaction with the RSC; ! Effectiveness of communication with USDA field sites; and ! Implementation of radiation safety requirements at USDA field sites.
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<p>Program Management</p>	<p>The program management review will assess the RSS in the routine performance of their duties. Areas to be reviewed will include:</p> <ul style="list-style-type: none"> ! Review of workload and program activity. <ul style="list-style-type: none"> ▪ Adequacy of staffing level in FTE's (professional, technical, administrative) ▪ Number of USDA locations having active users ▪ Number of active users ▪ Number of applications processed (new, renewals, amendments, and terminations) ! Review of training needs of the RSS (professional, technical, administrative) <ul style="list-style-type: none"> ▪ Participation in professional meetings, societies, etc. ▪ Availability of professional tools such as journals, professional newsletters, etc. ▪ Recency of participation in professional training programs ! Availability of regulatory guidance documents <ul style="list-style-type: none"> ▪ Current copies of Code of Federal Regulations, Titles 10, 21, 40, and 49 available ▪ US NRC regulatory guides and bulletins available ▪ NCRP, ICRP reports available as needed ! Review of RSS guidance documents <ul style="list-style-type: none"> ▪ Program forms are adequate and available to field locations ▪ Program guidance, use conditions, special procedures are adequate and available to field locations ▪ Licenses, NRC regulations, inspection correspondence available to field locations ! Review of office procedures <ul style="list-style-type: none"> ▪ Document tracking system adequate ▪ Filing system adequate ! Review of facility inspection scheduling <ul style="list-style-type: none"> ▪ System implemented to track inspections performed and their results ▪ System implemented to track facilities due for inspection ▪ Inspection schedule meets compliance requirements ! Review of RSS program database development <ul style="list-style-type: none"> ▪ Project management system in place to track system development ▪ Milestones for timely implementation are being met
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<p>Compliance with License Conditions</p>	<p>The following activities will be reviewed to assure compliance with US NRC license 19-00915-03 (Broad Scope):</p> <ul style="list-style-type: none"> ! Sealed source leak testing program (Condition 8) <ul style="list-style-type: none"> ▪ Number and type of sources to be tested ▪ Method developed to assure testing on a six-month schedule ▪ Rate of field compliance ! Sealed source inventory (Condition 21) <ul style="list-style-type: none"> ▪ Inventory conducted on a six-month schedule ▪ Records maintained two years ! Quarterly laboratory surveys <ul style="list-style-type: none"> ▪ Method developed to assure field response ▪ Rate of field compliance ! Incineration of radioactive waste (Condition 27) <ul style="list-style-type: none"> ▪ Quarterly records submitted for each incinerator ▪ Ash analysis performed when required ▪ Compliance determination performed ▪ Inventory of locations actively incinerating waste materials ! Human studies (Conditions 14, 15) <ul style="list-style-type: none"> ▪ Protocols available for review ▪ Summary lists isotopes to be used, names of physician/users, FDA RDRC review, length of study ! Permit approval process <ul style="list-style-type: none"> ▪ Status of applications being processed ▪ Safety criteria used by reviewers ! Burial Sites (Condition 9) <ul style="list-style-type: none"> ▪ Listing of all sites available ▪ Monitoring records available ! Radioisotope inventory (Conditions 12, 13) <ul style="list-style-type: none"> ▪ Inventory summary compiled for each location ▪ Summary below 10 CFR 30.72 limits ▪ Responsible User's inventory within RSC approved limits
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Compliance with License Conditions (Con't)	<p>The following activities will be reviewed to assure compliance with US NRC license 19-00915-06 (Irradiators):</p> <ul style="list-style-type: none"> ! Irradiators <ul style="list-style-type: none"> ▪ Number of irradiators in service ▪ Current US NRC/DOT certificates on file
Dosimetry Program Review	<ul style="list-style-type: none"> ! Film badge program <ul style="list-style-type: none"> ▪ Number of badges distributed monthly ▪ Average dose received by USDA employees ▪ Maximum dose received ▪ Incident log reviewed ! Bioassay program Standard operating procedure in place for bioassay program
Survey and Laboratory Instruments	<ul style="list-style-type: none"> ! Survey instruments <ul style="list-style-type: none"> ▪ All instruments operational ▪ Calibration current for each instrument ▪ Calibration certificate available for review ! Laboratory instruments <ul style="list-style-type: none"> ▪ Survey instruments are operational ▪ Calibration and quality assurance records available
Field Compliance Review	<p>To further assess the regulatory compliance within the Department, selected field sites will be visited to assess their implementation of radiation safety guidance.</p> <p>Site visits will usually be scheduled as a follow-up to an inspection conducted by RSS. The site visit is not intended to duplicate the inspection. Rather it will assess the facility's ability to correct deficiencies noted, and will assess the facility's implementation and understanding of USDA radiation safety guidance.</p>
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Field Compliance Review, (Con't)	<p>The following activities will be reviewed:</p> <ul style="list-style-type: none"> ! Implementation of the Location Radiation Protection Officer (LRPO) program by the facility <ul style="list-style-type: none"> ▪ LRPO performance standards are implemented ▪ LRPO conducts periodic audits of permit holders ! Knowledge of the LRPO and the Responsible Users of license documents and RSS policy <ul style="list-style-type: none"> ▪ Current copies of USDA license, NRC regulations, USDA Radiation Safety Handbook and license correspondence available ▪ Knowledge of the Responsible Users regarding radiation safety practices, USDA license and approval conditions for radioisotope use ! Records management for the LRPO and the Responsible Users <ul style="list-style-type: none"> ▪ Copies of RSC approval documents, laboratory surveys, inventory available for review ▪ Documentation of employee training available for review ▪ LRPO maintains necessary files and records ! Radioactive waste management practices <ul style="list-style-type: none"> ▪ Disposal records available for review ▪ Disposal location orderly ! Site radiation safety training program <ul style="list-style-type: none"> ▪ Training program meets current standards ▪ Current employees have been trained ! Interaction between RSS and facility management <ul style="list-style-type: none"> ▪ Permit actions are timely, inventory records are promptly corrected, health physicists are responsive to permit holder needs
Evaluation Worksheet	A Field Radiation Safety Program Evaluation Worksheet is attached to this document.

Approved:

<hr style="border: none; border-top: 1px solid black; margin-bottom: 5px;"/> Chair, Radiation Safety Committee	<hr style="border: none; border-top: 1px solid black; margin-bottom: 5px;"/> Date
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Radiation Safety Committee	Field Radiation Safety Program Evaluation Worksheet
Standard Operating Procedure	

Evaluation Date: _____

Facility: _____

Location: _____

Program Management

- | | | |
|---|-------|-------|
| 1. Location Radiation Protection Officer has been identified? | G Yes | G No |
| 2. LRPO performance standards have been implemented? | G Yes | G No |
| 3. Facility director is briefed on radiation safety by LRPO? | G Yes | G No |
| 4. LRPO has received radiation safety training? | G Yes | G No |
| 5. Date of last LRPO training | | _____ |

LRPO Program Management

- | | | |
|---|-------|------|
| 5. LRPO has dedicated files for radiation safety program information? | G Yes | G No |
| 6. LRPO has file copies of permits and correspondence for Responsible Users? | G Yes | G No |
| 7. LRPO has NRC required documents posted? | G Yes | G No |
| 8. LRPO has copies of the USDA license and correspondence? | G Yes | G No |
| 9. LRPO maintains copies of radioisotope inventory and waste disposal records for the facility? | G Yes | G No |
| 10. LRPO is knowledgeable about the radioisotope use at the facility? | G Yes | G No |
| 11. LRPO is knowledgeable about the radiation emitting devices in the facility? | G Yes | G No |

Facility Training

- | | | |
|---|-------|------|
| 12. Facility has routine training for Responsible Users? | G Yes | G No |
| 13. Facility has routine training for Associate Users and Laboratory Staff? | G Yes | G No |
| 14. Facility has routine training for Ancillary Staff? | G Yes | G No |
| 15. Records are maintained of training? | G Yes | G No |

Interactions with Radiation Safety Staff

- 16. Does facility management know the Director, RSS by name? G Yes G No
- 17. Do the Permit Holders know the name of the RSS health physicist assigned to their facility? G Yes G No
- 18. Is the RSS staff responsive to facility problems? G Yes G No
- 19. Is the RSS staff timely in permit reviews? G Yes G No
- 20. Other facility concerns: _____

Name of Person Performing Evaluation: _____