

Audit Report
American Radiolabeled Chemicals
November 29, 1990

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1.0 Introduction

A second audit of American Radiolabeled Chemicals (ARC) was conducted on November 29, 1990. The audit focused, as shown on the checklist provided in Appendix A, on three aspects of the ARC radiation protection program: shipping, compliance with 40CFR61, and an overall facilities inspection. Each of these aspects are discussed in Section 2.0.

An audit closeout meeting was attended by Dr. Gupta, Mr. Soldan, the radiation safety officer, Mr. Woodford, the alternate radiation safety officer, and Mr. Green, the auditor. During the audit closeout meeting ARC personnel suggested a change in the format of formal audit reports prepared by the auditor. The first audit report documented two levels of activity - Findings and Observations. Findings were items of noncompliance with the ARC license with the Nuclear Regulatory Commission (NRC). Observations were not items of noncompliance with the NRC license, but would lead, in the opinion of the auditor, to improvement in the ARC radiation protection program. ARC personnel understood that the sole purpose of the audits was to document areas of noncompliance with their NRC license. Therefore ARC personnel requested that audit reports document Findings only.

This is acceptable to the auditor, but conflicts with the written audit plan referenced in the ARC license with the NRC. Thus a proposed revision to the audit plan is provided as Appendix B.

2.0 Audit Results

A discussion of the results of the audit of the ARC radiation protection program is contained in this section. No Findings are cited.

2.1 Shipping

Six recent shipments of hazardous materials were evaluated during the audit. The evaluation was performed by comparing documentation in the ARC shipping log book and shipping papers with applicable requirements of 49CFR and the International Air Transportation Association. A description of the contents of each shipment is contained in Table 2.1. Each of these shipments were made according to regulations.

The following proficiencies regarding the ARC shipping program were observed: 1) hazardous paperwork is double checked; first by the shipping technician then by the alternate radiation safety officer; 2) exempted quantities of radioactivity are clearly posted in the shipping room for easy reference; and 3) the shipping log book was found to match copies of shipping papers with 100 percent accuracy.

Table 2.1 Shipment Description

Date	Compound	Amount of Radioactivity	Form	Destination
11/28/90	Methyl Iodide	250 mCi 3H	Liquid	USA
11/28/90	Serine Inositol Inositol Indole acetic acid Fucose	200 mCi 14C 5 mCi 3H 5 mCi 3H 50 uCi 14C 5 mCi 3H	Liquid Liquid Liquid Liquid Liquid	Switzerland
11/28/90	Octadeca- trienoic acid	50 uCi 14C	Liquid	USA
11/28/90	Ornithine	250 uCi 14C	Liquid	USA
11/28/90	Choline Chloride	1 mCi 3H	Liquid	USA
11/28/90	Methyl Iodide	5 uCi 14C	Liquid	USA

2.2 Compliance with 40CFR61

The National Emissions Standards for Hazardous Air Pollutants; Regulation of Radionuclides contained in 40CFR61 apply to NRC licensees and require that releases of radioactivity to the atmosphere do not cause an annual effective dose equivalent in excess of 10 mrem. To assure this standard is met NRC licensees must estimate radionuclide emissions in accordance with Appendix D to 40CFR61, or other procedure which EPA has granted prior approval; monitor emission rates; or monitor concentrations at critical receptors provided EPA has approved the monitoring plan.

During the audit, and at the audit closeout meeting ARC personnel indicated that they would probably not attempt to estimate radionuclide release rates by the procedures in 40CFR61, Appendix D. Their more appropriate course of action would be to use the monitoring data currently collected. This requires radionuclide concentration and flow rate measurements in release stacks.

Current ARC radionuclide concentration measurements conform to procedures in 40CFR61. No determination was made during the audit whether flow rate measurements conform to 40CFR61. This is because these measurements are to be made according to reference

method 2, Appendix A of 40CFR61 which was unavailable during the audit. ARC personnel will obtain a copy of the required reference and evaluate their current stack flow rate monitoring procedure. A future audit will revisit this issue.

2.3 Facilities Inspection

The facilities inspection involved a walk-through inspection of the laboratory restricted area and collection of swipe samples in high traffic areas of unrestricted areas. No items of noncompliance with the NRC license were observed in the laboratory restricted area. Results of the swipes revealed no contamination in excess of license limits.

Appendix A

Audit Checklist

Note that Section IV of the checklist, Dose Histories, was not used during the audit. Dose histories will be evaluated during a future audit.

I. Facilities

A) Request ARC personnel to swipe at least 10 locations in restricted and unrestricted areas.

1) Were the swipes properly taken?

2) Were the swipes properly analyzed?

3) Are permissible levels less than 1100 dpm/100cm² for tritium and 2200 dpm/100 cm² for other beta-emitters?

B) Laboratory inspection

1) Are laboratory personnel following good practice?

2) Are good housekeeping practices observed?

3) Are labels properly affixed to all containers of radioactive material as specified in the ARC RPP?

II. Shipping

A) Select at least 10 recent shipments from shipping log book. Have ARC personnel demonstrate why these shipments were properly made by referring to the appropriate regulations.

1) List the shipments audited and the means of packaging, labeling, and marking.

2) Were the shipping papers properly completed?

3) Were the shipments properly made?

III. 40CFR61

A. Are ARC personnel aware of the requirements of 40CFR61 that apply to NRC licensees?

1) Does ARC exceed annual possession quantities?

2) If so, do releases exceed environmental airborne concentrations?

3) If exemption cannot be claimed based on the above, are environmental air measurement techniques acceptable?

4) Are stack flow rate measurements properly made?

IV. Dose Histories

A. Determination of prior dose

1) Are records of prior dose available for all radiation workers?

2) Are records of exposure maintained for all radiation workers

Appendix 2

Proposed Audit Plan Revision

1.0 Purpose

Ten independent audits of the radiation protection program at American Radiolabeled Chemicals (ARC) will be conducted in the next two years. The purpose of the audits will be to provide a professional, unbiased, and in depth assessment of the ARC radiation protection program. The purpose of this plan is to describe the format of the audits.

2.0 Scope

This plan describes how audits of the ARC radiation protection program will be conducted. Terminology, conduct of audits, means of keeping track of audit findings, means of handling disputes, and content of written reports are provided in Section 3.0. Qualifications of the auditor are listed in Section 4.0.

3.0 Plan

3.1 Terminology

The purpose of the audits is to determine whether applicable NRC, DOT, and other Federal, State, and local regulations are met as stated in the ARC "Radiation Protection Program" manual. Items of that do not conform with the ARC "Radiation Protection Program" manual or applicable regulations will be termed "Findings". Findings require a written response from ARC personnel. The written response will provide a schedule for correcting the problem which caused the Finding.

3.2 Conduct

The first audit will be scheduled at the convenience of ARC and the auditor. All other audits will be scheduled three weeks in advance.

Each audit will be conducted according to a checklist developed by the auditor. This checklist will state the major topics to be audited. The auditor may, however, delve into any aspect of the ARC radiation protection program during any audit.

Each audit will consist of a site inspection. Site inspections will begin with an opening meeting. At this meeting the checklist, outstanding Findings from prior audits, and other pertinent topics will be discussed.

Site visits will consist of interviews with ARC radiation protection staff and other ARC employees. Routine operations and records will be reviewed.

Each site visit will end with a close out meeting. All Findings will be discussed with ARC personnel.

3.3 Finding Tracking System

An up-to-date list of all Findings will be maintained on the auditor's Finding Tracking System. Each Finding will be given a

unique number. The Findings that have been resolved will be shown as "closed". Findings not resolved will be shown as "open". The Finding Tracking System will be appended to each of the auditor's reports.

3.4 Disputes

Arc personnel may disagree with any Finding of the auditor. In such cases, the ARC written response to the disputed Finding shall provide a technical basis which shows why ARC believes the Finding to be in error. If the auditor agrees with the ARC technical basis the auditor will provide a written retraction of the Finding. If the auditor disagrees with the ARC technical basis, the auditor will issue a written statement of disagreement. All correspondence will be forwarded to the NRC.

3.5 Reports

The auditor will prepare a written report after each audit. The report will be submitted within two weeks after the audit. The report will contain: 1) the audit checklist; 2) a description of all subjects covered during the audit; 3) a list of the status of Findings of previous audits; 4) a description of Findings of the current audit; and 5) a technical justification for each Finding.

ARC will respond in writing to each Finding within two weeks after receipt of the auditor's report. The response will contain: 1) the means of resolving the Findings; 2) a schedule for Finding resolution; and 3) if necessary, a dispute over the correctness of any Findings.

If ARC disputes any Findings the auditor will within one week after receipt of the ARC audit response either issue a written Finding Retraction Statement or a written statement explaining why the Finding should remain open.

All correspondence in this section will be sent to the NRC.

4.0 Auditor's Credentials

The auditor has eight years of experience in applied radiation protection. Pertinent experience and qualifications as detailed on the attached resume include:

- * Oversight of a radiation safety program for hundreds of subcontract workers.
- * Experience in performing audits.
- * Experience in air sampling, contamination control, and radiation surveys.
- * Experience in laboratory operations.
- * Experience in shipping radioactive and hazardous materials.

- * Experience in internal and external dose assessments.
- * Certification by the American Board of Health Physics.
- * A masters degree in radiological health.

NAME: STEVEN GREEN

TITLE: Radiation Protection
Manager

EDUCATION: M.E., 1983, Engineering/Radiological
Health, College of Engineering,
University of Florida

B.S., 1982, Environmental Engineering,
College of Engineering, University of
Florida

CERTIFICATIONS: Certified in the Comprehensive Practice of
Health Physics by the American Board of Health
Physics, October 1989

AFFILIATION: National and Local Health Physics Societies;
Councilman for the Greater St. Louis Chapter
of the Health Physics Society

Mr. Green has eight years of experience in the remediation of sites contaminated with radioactive and mixed radioactive/hazardous wastes. This experience spans all phases of site remediation from site characterization through NEPA/CERCLA environmental compliance documentation to final site cleanup. This experience includes DOE's Weldon Spring Site Remedial Action Project and DOE's Uranium Mill Tailings Remedial Action (UMTRA) Project. Mr. Green has a thorough understanding of CERCLA/SARA, RCRA, and NEPA.

Mr. Green is currently Radiation Protection Manager at DOE's Weldon Spring Site Remedial Action Project. He manages a staff of 12 health physics personnel. In this capacity, he is responsible for all radiological aspects of site characterization, radiological laboratory activities, health and safety for workers, remedial cleanup activities, and technical input into RI/FS and NEPA environmental compliance documents.

Mr. Green designed and directed the radiological characterization of soil, air, and building structures. This involved preparation of RI sampling plans; procurement of subcontract drilling and sampling services; soil sample collection; sample analysis by NaI and HpGe gamma spectroscopy; radon gas and radon daughter working level measurements; radioactive air particulate measurements; and field radiation surveys for beta, alpha, and gamma radiation. Mr. Green directs the operation of a radiological laboratory where gamma and alpha spectrometry are performed and radiation detectors are maintained for field operation. He also wrote the computer software for an NaI gamma spectrometer spectrum stripping routine.

STEVEN GREEN (2/3)

Mr. Green manages a comprehensive worker health and safety monitoring program for subcontract employees performing excavation of contaminated soil and dismantlement of structures. This involves preparation of worker safety and health plans, selection of chemical and radiological personal protective equipment, internal and external dosimetry, air monitoring, exposure rate monitoring, contamination surveys, and health and safety oversight of subcontract workers.

He is responsible for ensuring that remedial activities comply with EPA, DOE, and Missouri State Regulations. This involves ensuring that land areas and building structural components meet established free release criteria prior to unrestricted public use and that radioactive, chemical, or mixed wastes are properly packaged, shipped, stored, and disposed. Currently, RI/FS reports are being prepared for the wastes at the Weldon Spring Site and Weldon Spring Quarry. Mr. Green is responsible for technical accuracy of radiological sections of these CERCLA documents.

In previous employment on DOE's UMTRA Project, Mr. Green was promoted from Staff Health Physicist to Deputy Manager of Radiological Services. In this capacity, he was responsible for the technical accuracy and overall quality for all documents produced by a staff of nine health physics professionals. These documents includes EISs, EAs, Site Characterization Reports, Remedial Action Plans, and Remedial Action Audit Reports.

As Staff Health Physicist on UMTRA, Mr. Green designed and directed site characterizations at two tailings sites, prepared one EIS, three EAs, four Site Characterization Reports, three Remedial Action Plans, and several Remedial Action Audit Reports. This lead to his expertise in health risk assessments, selection and use of personal protective equipment, statistical data analysis, source term and waste volume estimation, and radon barrier cover design for waste embankments.

Mr. Green has performed health risk assessments via use of the NRC MILDOS computer code, the NRC IMPACTS computer code, and the DOE RESRAD computer code. He wrote software for a computer-assisted design package for waste disposal embankments, and developed a computer program for calculating internal dose from inhalation of radionuclides. He can operate mainframe and PC computers and is well versed with standard PC software packages.

STEVEN GREEN (3/3)

Prior to his involvement in site remediation projects, Mr. Green served as Staff Engineer for the Safety and Environmental Protection Division of Brookhaven National Laboratory. His responsibilities included preparation and instruction of radiation safety training for all occupationally exposed laboratory personnel and administration of a 10-week physics training program for 20 graduate students. He also conducted reliability testing of the radiological monitoring equipment at the Brookhaven High Flux Beam Reactor, and assisted in a QA check of personnel radiation dosimeters.

EMPLOYMENT HISTORY

JACOBS ENGINEERING GROUP INC. Radiation Protection Manager	1987 TO DATE
ROY F. WESTON, INC. Deputy Manager Radiological Services Staff Health Physicist	1984 - 1987
BROOKHAVEN NATIONAL LABORATORY Staff Engineer	1984 - 1984

Appendix C
Finding Tracking System

FINDING TRACKING SYSTEM

AUDIT NUMBER	DATE	FINDING NUMBER	BRIEF FINDING DESCRIPTION	STATUS
1	10/09/90	01-001	CONFLICT BETWEEN LICENSE AND RADIATION PROTECTION PROGRAM PLAN	CLOSED
2	11/29/90	NO FINDINGS THIS AUDIT		