October 16, 2015

Mr. Michael Griffin
Vice President of Permitting, Regulatory
and Environmental Compliance
Strata Energy, Inc.
PO Box 2318
Gillette, WY 82717-2318

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION (NRC) VERIFICATION OF QUALITY ASSURANCE PLAN, LICENSE CONDITION 12.10, ROSS IN-SITU RECOVERY (ISR) PROJECT, CROOK COUNTY, WY, SOURCE MATERIAL LICENSE SUA-1601, DOCKET NO. 040-09091, TAC J00735

Dear Mr. Griffin:

By letter dated March 5, 2015, Strata Energy, Inc. (Strata) submitted Revision 0 of its Quality Assurance Plan (QAP) in response to preoperational license condition (LC) 12.10 of its Materials License SUA-1601 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15076A045). LC 12.10 states:

12.10 At least 60 days prior to the preoperational inspection, the licensee will submit a completed Quality Assurance Plan (QAP) for NRC staff review and verification. The QAP will include the requirements in 10 CFR 20.1703(c)(4)(vii), and be consistent with guidance for a Quality Assurance Project Plan in Regulatory Guide 4.15 (as revised). The portion of the QAP fulfilling requirements of 10 CFR 20.1703(c)(4)(vii) may be included as a section or attachment in the applicable SOP(s).

Strata revised its QAP by letters dated July 6, 2015, August 12, 2015, and e-mail dated August 17, 2015 (ADAMS Accession Nos. ML15190A124, ML15233A422, and ML15278A256, respectively). As described in the enclosed evaluation, the NRC staff has reviewed and verified that Revision 1 of the QAP described by Strata meets the requirements in 10 CFR 20.1703(c)(4)(vii) and is consistent with Regulatory Guide 4.15 (as revised).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure" a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this action, please contact me at 301-415-0697 or by e-mail at John.Saxton@nrc.gov.

Sincerely,

/RA/

John Saxton, Hydrogeologist
Uranium Recovery Licensing Branch
Division of Decommissioning, Uranium Recovery
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 040-09091
License No.: SUA-1601

Enclosure:
NRC staff verification of LC 12.10
information

cc: D. Schellinger WDEQ

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OFC	DUWP	DUWP	DUWP	DUWP	DUWP	DUWP
NAME	DBrown	RBurrows	JSaxton	SAchten	BVonTill	JSaxton
DATE	10/6/15	10/14/15	10/15/15	10/15/15	10/15/15	10/16/15

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NRC Staff Verification of Strata Energy, Inc., Letters Dated March 5, 2015, July 6, 2015, August 12, 2015, and August 17, 2015, Regarding Preoperational License Condition 12.10 Materials License SUA-1601; Docket No. 040-09091

Background

By letter dated March 5, 2015, Strata Energy, Inc. (Strata) submitted Revision 0 of its Quality Assurance Plan dated March 3, 2015, in accordance with preoperational license condition (LC) 12.10 (Strata 2015b). LC 12.10 states:

> At least 60 days prior to the preoperational inspection, the licensee will submit a completed Quality Assurance Plan (QAP) for NRC staff review and verification. The QAP will include the requirements in 10 CFR 20.1703(c)(4)(vii), and be consistent with guidance for a Quality Assurance Project Plan in Regulatory Guide 4.15 (as revised). The portion of the QAP fulfilling requirements of 10 CFR 20.1703(c)(4)(vii) may be included as a section or attachment in the applicable SOP(s). (NRC 2014)

The regulation in 10 CFR 20.1703(c)(4)(vii) requires the licensee to implement and maintain a respiratory protection program that includes written procedures regarding storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment. As stated in acceptance criterion 5.7.3.3(6) of NUREG-1569 (NRC 2003), the respiratory protection program should be consistent with guidance in Regulatory Guide 8.15, Revision 1, "Acceptable Programs for Respiratory Protection" (NRC 1999) and Regulatory Guide 8.31, Section 2.7 (NRC 2002). The recommendations in Regulatory Guide 8.15 are supported in NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials." (NRC 2001). Strata did not include a description of its quality assurance program for respiratory protection equipment in Revision 0 of its QAP. By letter dated July 6, 2015, Strata summarized revisions to its QAP to include both a sub-section F.1.9 on Respiratory Protection Equipment and an additional Section J, "Preventive and Corrective Actions." (Strata 2015c). As noted below, with these additions, Strata's revised QAP contains all the elements required by LC 12.10.

Evaluation

Regulatory Guide 4.15, Section C., "Regulatory Position," states, "The following presents the QA program elements that should be developed and implemented to ensure the quality of data/results for radiological effluent and environmental monitoring programs." (NRC 2007). The elements listed in Regulatory Guide 4.15 are:

1. Organizational Structure and Responsibilities of Managerial and Operational Personnel
2. Specification of Qualifications of Personnel
3. Operating Procedures and Instructions
4. Records
5. Quality Control in Environmental Sampling
6. Quality Control in the Radioanalytical Laboratory
7. Quality Control for Radioactive Effluent Monitoring Systems
8. Verification and Validation
9. Assessments and Audits

10. Preventive and Corrective Actions

The NRC staff reviewed the QAP submitted by Strata (Strata 2015b), as revised by submittals dated July 6, 2015 (Strata 2015c), August 12, 2015 (Strata 2015d), and August 17, 2015 (Strata 2015e). The revised Strata QAP contains all of the elements of a QAP identified in Regulatory Guide 4.15.

In Section A, "Purpose and Scope," Strata explained that its QAP describes the quality program elements of the Strata Environmental Monitoring Program (EMP) and Radiation Protection Program (RPP), and that detailed quality-related implementing procedures are contained in those programs. Strata stated that the purpose of its QAP is to ensure the quality of measurements used to assess potential worker and public exposure to ionizing radiation. The NRC staff's evaluation of the major elements of the QAP is provided below.

Organizational Structure and Responsibilities of Managerial and Operational Personnel

Strata addressed this QAP element in QAP Section B, "Corporate Management, Organization and Responsibilities." Strata described its commitment to design, implementation, and management of a QAP and identified the Federal and state regulatory requirements for the QAP, including 10 CFR Parts 20 and 40, Regulatory Guides 4.14 (NRC 1986), 4.15 (NRC 2007), and 8.31 (NRC 2002), and Wyoming Department of Environmental Quality Land Quality Division Noncoal Rules and Regulations Chapter 11.

In QAP Sections B.3.1 through B.3.8, Strata explained the roles and responsibilities of key staff at the Ross Project from the Chief Executive Officer down to Supervisors, Employees and Contractors. The Radiation Safety Officer (RSO) (Section B.3.3), who is also the QA/QC Administrator (Section B.3.5), is responsible for, among other things, review and approval of new equipment and changes in processes and procedures that affect radiological safety. The RSO will also collect and interpret employee exposure-related monitoring data. The RSO reports to the Vice President of Permitting, Regulatory, and Environmental Compliance, who has no production-related responsibilities and is responsible for implementing changes and/or corrective actions involving environmental protection and radiation safety. By letter dated July 23, 2015 (NRC 2015a), NRC staff requested that Strata reconcile the key positions identified in the QAP with the NRC-approved management organization described in Strata's Technical Report (Strata 2011). Several key positions in QAP Revision 0 were not consistent with the NRC-approved management organization. NRC staff also requested that Strata clarify which key position is responsible for determining which activities are associated with critical safety, health, and environmental activities. By letter dated August 12, 2015 (Strata 2015d) and e-mail dated August 17, 2015 (Strata 2015e), Strata stated that it had revised the QAP to reflect the current management organization, which it had revised through the Safety and Environmental Review Panel (SERP) process. Strata also clarified that the Vice President of Permitting, Regulatory, and Environmental Compliance and the RSO shall determine which activities are associated with critical safety, health, and environmental activities.

The NRC staff evaluated this element of Strata's QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.1 of Regulatory Guide 4.15, including: a clear statement of Strata's commitment to quality assurance (QA); a description of quality-related functions in the structure of the organization; a clear description of who is responsible for reviewing and approving quality-related procedures, monitoring data and reports; and a

description of how persons with QA functions have sufficient authority and freedom to identify and solve quality-related problems free from consideration of performance, costs and schedule.

Specification of Qualifications of Personnel

Strata addressed this QAP element in Section C, "Personnel Qualifications and Training," of its QAP. Strata described the minimum qualifications for the RSO and Radiation Safety Technician (RST), which are based on the minimum qualifications contained in Regulatory Guide 8.31, Regulatory Position 2.5. Strata also stated that the minimum qualifications of a Radiation Safety Technician Designee will be as determined in consultation with NRC staff on LC 12.4. By separate letter dated September 8, 2015, NRC staff verified that LC 12.4 had been met (NRC 2015b). Strata also described the initial and annual refresher training requirements for employees, which includes the following topics: Industrial Safety; Radiation Safety; Hazardous Materials Transportation; Environmental Management; and Safety, Health and Environment Management. Strata also described on-the-job training; visitor and contractor training; RSO refresher training; and training documentation and records.

The NRC staff evaluated this element of Strata's QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.2 of Regulatory Guide 4.15, including: the qualifications of individuals needed to carry out radiological monitoring functions and the qualifications, training and retraining of all employees.

Operating Procedures and Instructions

Strata addressed this QAP element in QAP Section D, "Operating Procedures." Strata stated, "Strata management shall determine which activities are associated with critical safety, health, and environmental activities," which includes, at a minimum:

- Start up and shut down procedures
- Upset/emergency conditions
- Critical maintenance activities
- Normal/standby operating mode activities
- Activities with potential for employee or public radiation exposure to radioactive material
- Release of materials from the site

By letter dated July 23, 2015, NRC staff asked Strata to provide a list of radiation protection program and environmental monitoring program procedures which contain quality assurance requirements (NRC 2015a). NRC staff requested that the list include the procedure number or unique identifier, title, revision number, and date approved. Strata provided this information as Appendix 1 to its letter dated August 12, 2015 (Strata 2015d). NRC staff also asked Strata to clarify who is involved in the drafting and reviewing of procedures involving occupational and safety risks. Strata had identified two positions ("Safety Supervisor" and "Safety and Environmental Coordinator") in Section D of the QAP that were not addressed in Section B.3, "Organization Structure and Responsibilities," or the NRC-approved Technical Report. In its responses dated August 12, 2015 (Strata 2015d) and August 17, 2015 (Strata 2015e), Strata summarized a revision to the QAP in which reference to the Safety Supervisor was removed. Strata explained that the Safety and Environmental Coordinator role was added to the organization through the SERP process. Strata also clarified that the RSO, Safety and Environmental Coordinator, and Vice President of Permitting, Regulatory, and Environmental Compliance are responsible for reviewing new or revised procedures.

Strata stated that its employees will be trained on the operating procedures in accordance with their assigned duties. Strata also stated that operating procedures associated with key safety, health and environmental activities will be reviewed and updated, as needed, by the responsible supervisor and RSO.

The NRC staff evaluated this element of Strata's QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.3 of Regulatory Guide 4.15, including provisions for preparation of written procedures for data generation and support function by qualified persons.

Records

Strata addressed this QAP element in QAP Section E, "Record Keeping and Reporting Requirements." Strata described the categories of records it will generate and explained that it will maintain hard copy original records and may also store electronic records in accordance with 10 CFR Part 20, Subpart L and 10 CFR 40.61(d) and 40.61(e). Strata will also maintain duplicate records offsite. The RSO will be responsible for maintaining and securing records.

Strata explained that it will specify field and laboratory analysis documentation requirements in applicable procedures, and it committed to maintain legible, reproducible, accurate, complete and traceable records. Strata stated that the RSO will authorize changes to field procedures, which will be fully documented. Strata also listed the circumstances under which variances will be authorized (e.g., sample collection technique not according to the method specified).

Strata committed to retain records for a period as required by license condition or regulation. If a period is not known, it will retain records indefinitely. NRC staff notes that the applicable records requirements from 10 CFR Part 20, include, but are not limited to:

1. *10 CFR 20.2102(b): records of the radiation protection program until the Commission terminates the license.*
2. *10 CFR 20.2102(b): records of audits and other reviews of the radiation protection program for 3 years after the record is made.*
3. *10 CFR 20.2103(a): records of surveys and calibrations required by 20.1501 and 20.1906(b) for 3 years after the record is made.*
4. *10 CFR 20.2103(b): Until the Commission terminates the license: records of dose from external sources; records of individual intakes; air sampling, surveys and bioassays in support of the respiratory protection program; measurements and calculations to evaluate the release of radioactive material to the environment.*
5. *10 CFR 20.2104: records of prior occupational dose until the Commission terminates the license.*
6. *10 CFR 20.2105: records of planned special exposures until the Commission terminates the license.*
7. *10 CFR 20.2106: records of individual monitoring results until the Commission terminates the license.*
8. *10 CFR 20.2107: records of public dose until the Commission terminates the license.*
9. *10 CFR 20.2108: Records of on-site waste disposal in accordance with 20.2002, 20.2003, 20.2004, and 20.2005 until the Commission. Permanent retention of waste disposal and decommissioning records is addressed in 10 CFR 40.61(d)*

Strata committed to maintaining electronic records onsite and off-site, and performing backup of electronic media once per week.

The NRC staff evaluated this element of Strata's QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.4 of Regulatory Guide 4.15, including provisions for maintaining a records system, maintaining record quality, location, security, retrievability, and retention time.

Quality Control in Environmental Sampling

Strata addressed this QAP element in Section F, "QA/QC of Radiological, Environmental and Effluent Monitoring Data and Samples," of its QAP. Strata described quality-related activities for:

- occupational dose monitoring (Section F.1)
- effluent and environmental monitoring (Section F.2)
- sample collection and documentation (Section F.3)
- quality control samples (Section F.4)
- sample handling, storage, and shipping for effluent and environmental monitoring (Section F.5)
- spatial and temporal variation (Section F.6)
- uncertainty limits for volume and mass measurements (Section F.7)

In Section F.1, "Radiological Monitoring," Strata committed to the more frequent of either an annual instrument calibration frequency or the frequency specified by the instrument manufacturer for all radiological survey instruments and samplers. Strata stated that the RSO will be responsible for reviewing and approving vendor QA/QC programs. By letter dated July 23, 2015, NRC staff requested clarification of who in the organization is responsible for performing and reviewing annual audits (NRC 2015a). By letter dated August 12, 2015, Strata clarified the key positions responsible for preparing and reviewing annual ALARA audits, annual QA/QC audit reports, and RSO Monthly reports (Strata 2015d). By letter dated July 23, 2015, NRC staff requested a description of how Strata will properly select calibrated check sources (NRC 2015a). By letter dated August 12, 2015, Strata explained that it will select sources in accordance with ANSI N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." (Strata 2015d).

In Revision 0 of its QAP, Strata stated that quality control of radiological exposure (occupational dose) monitoring will be addressed in RPP procedures, including requirements for how to conduct surveys; collect samples, sample shipment; sample chain-of-custody; data reduction; data evaluation; and reporting.

Strata stated that the required lower limit of detection (LLD) for air sampling for occupational dose will be 10% of the DAC.

The guidance in Regulatory Position C.5 of Regulatory Guide 4.15 states that licensees should also address: the use of field duplicates that check reproducibility; sample packaging, shipping, and storage; minimum detectable concentrations of methods used, as compared to regulatory limits; and sample frequency and number of sample locations.

In Section F.2, “Quality Control of Radiological Effluent and Environmental Monitoring Measurements,” Strata described how QA/QC is implemented through approved procedures and that its QA/QC objectives are to obtain reproducible and comparable measurements consistent with the data’s intended use. Strata described radiological air monitoring, direct radiation monitoring, surface and groundwater sampling, and soil and sediment sampling. By letter dated July 23, 2015 (NRC 2015a), NRC staff asked Strata to address its proposed plan for effluent monitoring in accordance with LC 12.7, as described in its letter dated March 1, 2015 (Strata 2015a). In its response, Strata stated that a new section F.2.4 was added to QAP Revision 1 to include a description of quality control for radon in water sampling. Strata stated that the QA aspects for obtaining process solution samples for radon are contained in Standard Operating Procedure (SOP) L-8, “Radon in Water Sampling.”

The NRC staff evaluated this element of Strata’s QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.5 of Regulatory Guide 4.15, including provisions for the accuracy of mass and volume flows; measurement and calculation of uncertainties; identification of collection efficiencies; use of duplicate samples to check reproducibility; and sample frequency and number of sample locations.

Quality Control in the Radioanalytical Laboratory

Strata addressed this QAP element in Section G, “Laboratory Management and Quality Control,” of its QAP. In eight sub-sections Strata described quality control elements for: Analytical Laboratory Quality Objectives; Onsite Laboratory; Laboratory Documentation; Reference Standards and Calibration; Calibration of Instruments and Equipment; Verification and Validation of Contract Laboratory QA/QC Programs; Quality Control Samples; and Laboratory Documentation.

With regard to Analytical Laboratory Quality Objectives, Strata described performance indicators derived from QC sample results, as defined in SOPs, which will be a tool for tracking and trending performance and to identify precursors to nonconforming conditions. The performance indicators will measure precision, bias, method sensitivity, accuracy, representativeness and comparability.

Strata described the development of a laboratory QA/QC manual in sub-section G.2, “Onsite Laboratory.” The laboratory will undergo annual QA/QC reviews and participate in inter-laboratory comparisons.

In sub-section G.3, “Laboratory Documentation,” Strata described the content of laboratory reports, including descriptions of the analytical method used, chain of custody forms, sample receiving documentation, detection limits, dilution factors, and analytical uncertainty.

Under sub-section G.4, “Reference Standards and Calibration,” Strata stated that the laboratory QA/QC manual will specify standards and methods for operating, calibrating, and maintaining laboratory equipment. Strata also stated that calibration sources will be traceable to a national standards body (e.g., National Institutes of Standards and Technology) and prepared in a manner comparable to samples (“test sources”) with respect to source geometry, positioning relative to the detector, source composition, and distribution of the source material within a sample.

In sub-section G.5, “Calibration of Instruments and Equipment,” Strata stated that the methods and frequency of vendor laboratory instrument calibrations will be documented in both the applicable Strata program document and procedures and the vendors’ written procedures. Strata also stated that Strata will review such procedures prior to execution of a contract and such procedures will follow manufacturer’s recommendations and be performed by trained personnel.

In sub-section G.6, “Verification and Validation of Contract Laboratory QA/QC Programs,” Strata described its plan to ensure vendor laboratories provide valid results, which includes provisions for: vendor laboratory audits by Strata; participation by vendor laboratories in performance evaluation or intercomparison programs; and tracking and trending of vendor laboratory performance indicators by Strata.

In sub-section G.7, “Quality Control Samples,” Strata addressed the types and frequencies of quality control samples that it will use, including blanks, matrix spikes, laboratory control samples, blind samples, and laboratory duplicates. These will comprise at least 25% of samples analyzed by the laboratories.

Sub-section G.8, “Laboratory Documentation,” repeats the same information provided in sub-Section G.3.

The NRC staff evaluated this element of Strata’s QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.6 of Regulatory Guide 4.15, including provisions for the calibration and quality control of instruments, measuring devices, and test equipment; internal quality control samples and analysis; and use of performance evaluation program elements, including a interlaboratory comparison program.

Quality Control for Radioactive Effluent Monitoring Systems

Strata addressed this QAP element in Section H, “Quality Control for Maintenance and Calibration of Radiological, Environmental and Effluent Monitoring Instrumentation and Equipment,” of its QAP. In four sub-sections Strata described quality control elements for: Instruments and System Calibration and Maintenance Requirements; Calibration Requirements of Sampling Equipment and Containers; Frequencies and Procedures; and Cross Contamination.

In sub-section H.1, “Instruments and System Calibration and Maintenance Requirements,” Strata calibration procedures for flow monitors and radiological survey instruments. Strata will calibrate flow monitors annually. Radiological survey instruments will be calibrated by the manufacturer or qualified calibration laboratory no less than once per year. Strata also described test procedures for instruments returning to the site after being calibrated. Instrument checks using a check source will be performed once per day.

In sub-section H.2., “Calibration Requirements of Sampling Equipment and Containers,” Strata committed to maintaining calibration procedures of sampling equipment required to make precise measurements, such as thermometers, balances and pH and conductivity meters. In sub-section H.3, “Frequencies and Procedures,” Strata explained that the frequency of calibrations and inspections will be specified in the EMP or RPP for each instrument that is critical to the QAP.

In sub-section H.4, “Cross Contamination,” Strata described procedures for preventing cross-contamination of samples, including rinsing and cleaning containers, and the use of blanks to verify that cross-contamination has not occurred. Methods will be described in individual SOPs.

The NRC staff evaluated this element of Strata’s QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.7 of Regulatory Guide 4.15, including applicable provisions for flow monitoring instrumentation and general quality control considerations.

Verification and Validation

Strata addressed this QAP element in Section I, “Verification and Validation,” of its QAP. In nine sub-sections Strata described quality control elements for: Validation and Verification for Accuracy and Completeness; Anomalous Data; Screening of the Data; Technical Review; Corrective Action; Verification and Validation of Field Data; Field Variance and Nonconformance; Verification and Validation of Laboratory Data; and Quality Control Samples.

In sub-section I.1 of QAP Revision 0, “Validation and Verification for Accuracy and Completeness,” Strata stated that the RSO is principally responsible for the validation and verification of activities whose failure could have an impact on the environment, health, or safety. Strata also stated that the RSO or designee is responsible to review and initial logbooks, QC reports, and logs at least monthly for completeness and accuracy. By letter dated July 23, 2015, NRC staff requested clarification of the role of the designee to perform these QA functions. By letter dated August 12, 2015, Strata stated that the phrase “or designee” had been removed from Section I.1 in Revision 1 of the QAP.

In sub-section I.2 of the QAP Revision 0, “Anomalous Data,” Strata stated that anomalous data is identified in the validation process. In sub-section I.3, “Screening of the Data,” Strata stated that sampling data will be compared to historical ranges to determine if results fall outside historical ranges. In sub-section I.3, “Technical Review,” Strata described the process of screening data to determine if corrective action is needed. Corrective actions are described in sub-section I.5, “Corrective Action,” in which Strata stated that corrective actions will include a request for the laboratory to review its documentation, sample reanalysis, re-sampling and comparison of sample results. The RSO will determine whether anomalous data is considered usable.

In sub-sections I.6, “Verification and Validation of Field Data,” and I.8, “Verification and Validation of Laboratory Data,” Strata stated that data will be reviewed for completeness, errors, compliance with procedures, and accuracy by qualified personnel. Strata described procedures for identifying if corrective action is warranted and for correcting invalid data.

In sub-section I.7, “Field Variance and Nonconformance,” Strata described the process for approving changes from field protocols identified in the EMP and RPP and documenting such changes.

In sub-section I.9, “Quality Control Samples,” Strata described which quality assurance / quality control samples (blanks, duplicates, spikes, etc.) are evaluated in the validation process.

The NRC staff evaluated this element of Strata’s QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.8 of Regulatory Guide 4.15, including applicable

provisions for determining acceptable criteria and tests and applying data qualifiers for data validation.

Assessments and Audits

Strata addressed this QAP element in Section K, "Assessments, Audits, and Surveillances," of Revision 1 to its QAP. Note: As noted above, in Strata's QAP Revision 0, Strata did not include a section on Preventive and Corrective Actions, which is addressed in Regulatory Guide 4.15, Regulatory Position C.10. By letter dated July 6, 2015, Strata revised its QAP to include a new Section J, "Preventive and Corrective Actions," and moved Section J, "Assessments, Audits, and Surveillances," of its QAP Revision 0 to a new Section K in QAP Revision 1 (Strata 2015c). In four sub-sections Strata described quality control elements for: Organizational Assignments; Audits and Inspections; QA/QC Audit; and Documentation and Record Retention Requirements.

Strata stated that the QAP will be audited periodically by individuals qualified in radiation protection and monitoring techniques. These individuals will not have direct responsibilities in the areas being audited. Strata stated that an example of an appropriate auditor is a subject matter expert from another company department or facility, or an outside consultant.

In sub-section J.1, "Organizational Assignments," Strata refers to Section B of the QAP for the responsibilities of key individuals to perform QA functions, and Section C of the QAP for the minimum qualifications and experience levels of key individuals to perform QA functions.

In sub-section J.2, "Audits and Inspections," and J.3, "QA/QC Audit," Strata describes the types of audits and inspections it will perform, including the function of the annual ALARA audit, QA/QC Audit, routine operational inspections, and safety and environmental review panel.

By letter dated July 23, 2015, NRC staff requested clarification of a statement in Section J.3.1, "Routine Operational Inspections," of QAP Revision 0 that daily and weekly inspections and the monthly report are done by the RSO or designee (NRC 2015a). A designee may perform daily inspections in accordance with LC 9.7, but may not perform weekly inspections or prepare monthly reports. By letter dated August 12, 2015, Strata revised Sections K in QAP Revision 1 to remove reference to the designee from descriptions of the weekly inspections and monthly report (Strata 2015d).

In sub-section J.4, "Documentation and Record Retention Requirements," Strata stated that all assessments, audits and surveillances will be documented and retained in accordance with commitments in Section E of the QAP.

The NRC staff evaluated this element of Strata's QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.9 of Regulatory Guide 4.15, including applicable provisions for independent audits, the scope and frequency of assessments, audits and surveillances, and the qualifications of individuals performing these functions.

Preventive and Corrective Actions

Strata addressed this QAP element in Section J, "Preventive and Corrective Actions," of Revision 1 to its QAP. Note: As noted above, in Strata's QAP Revision 0, Strata did not include a section on Preventive and Corrective Actions, which is addressed in Regulatory Guide 4.15, Regulatory Position C.10. By letter dated July 6, 2015, Strata revised its QAP to include a new

Section J, “Preventive and Corrective Actions,” and moved Section J, “Assessments, Audits, and Surveillances,” of its QAP Revision 0 to a new Section K in QAP Revision 1.

In two sub-sections Strata described quality control elements for Deficiencies and Non-conformance and Corrective Actions.

By letter dated July 23, 2015, NRC staff stated that references throughout Section J to “appropriate personnel,” “appropriate management,” and “management or appropriate personnel,” are vague and undefined (NRC 2015a). By letter dated August 12, 2015, Strata corrected Section J to state that in every case, the Vice President of Permitting, Regulatory, and Environmental Compliance and the RSO are responsible for reviewing assessments, audits, inspections, and surveillance; receiving reports of deficiencies and non-conformances; and taking corrective action to correct problems identified under the QAP (Strata 2015d).

The NRC staff evaluated this element of Strata’s QAP and finds that Strata has addressed the guidance contained in Regulatory Position C.10 of Regulatory Guide 4.15, including applicable provisions for identifying areas for improvement, defining performance or programmatic deficiencies, and initiating appropriate corrective or preventive actions.

Conclusion

NRC staff has reviewed and verified that Strata’s QAP Revision 1 addresses the requirements in 10 CFR 20.1703(c)(4)(vii), and is consistent with guidance for a Quality Assurance Project Plan in Regulatory Guide 4.15 (as revised).

References

NRC (U.S. Nuclear Regulatory Commission). 1980. Regulatory Guide 4.14, Revision 1, “Radiological Effluent and Environmental Monitoring at Uranium Mills.” ADAMS Accession No. ML003739941.

NRC (U.S. Nuclear Regulatory Commission). 1999. Regulatory Guide 8.15, Revision 1, Acceptable Programs for Respiratory Protection. ADAMS Accession No. ML003739528.

NRC (U.S. Nuclear Regulatory Commission). 2001. NUREG-0041, “Manual of Respiratory Protection Against Airborne Radioactive Material. ADAMS Accession No. ML010310331.

NRC (U.S. Nuclear Regulatory Commission). 2002. Regulatory Guide 8.31, Revision 1, Information Relevant to Ensuring that Occupational Radiation Exposures at Uranium Recovery Facilities will be As Low As is Reasonably Achievable. ADAMS Accession No. ML021260630.

NRC (U.S. Nuclear Regulatory Commission). 2003. NUREG-1569, “Standard Review Plan for In Situ Leach Uranium Extraction License Applications.” ADAMS Accession No. ML032250177.

NRC (U.S. Nuclear Regulatory Commission). 2007. Regulatory Guide 4.15, Revision 2, Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination) – Effluent Streams and the Environment. ADAMS Accession No. ML071790506.

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