Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0667228	09/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Consolidated Nuclear Security, Llc	Jack Case Center 301 Bear Creek Road, Oak Ridge, TN	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, review of Laboratory Personnel Report (CLIA) Form CMS 209 and an interview with the laboratory director (LD), the laboratory failed to establish a competency assessment procedure that included the assessment of the regulatory responsibilities for one of one clinical consultant (CC). Findings Included: 1. Form CMS 209, signed by the laboratory director on September 10, 2025, listed one CC that was not the LD. 2. A review of the laboratory procedure on September 11, 2025, at 9:34 a.m. revealed that the competency assessment procedure did not include how to assess the one CC for competency. 3. By interview, the LD confirmed the above findings on September 11, 2025, at 10:45 am.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on laboratory director interviews and comparison of test results policies and

	procedures record review on September 11, 2025 at 11:00 am, the laboratory, which performs the same tests using different instruments, failed to have written policies and procedures that details the laboratory protocol for its twice a year evaluation and definition of the relationship between test results using the different instruments. Findings included: a. It was the practice of the laboratory to used two ACE Alera Clinical Chemistry System instruments to test patient routine chemistry specimens. Each instrument was used to perform the same routine chemistry tests and were interchangeable for testing patient specimens. b. Although the laboratory maintained documentation to indicate that the laboratory had, twice a year, evaluated and defined the relationship between test results using the different ACE Alera Clinical Chemistry System instruments, the laboratory director confirmed on September 11, 2025 at 11: 00 am that the laboratory maintained no written policies and procedures detailing the protocol used to evaluate the two instruments and define the criteria used to determine the acceptable relationship between the two instruments. c. According to laboratory records, the laboratory performed and reported approximately 71,800 patient routine chemistry test results annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the laboratory director (LD), the laboratory director failed to follow their patient trace quality assessment procedure and perform two patient tracers for 5 out of 24 months (September 2023 to September 2025). Findings Included: 1. The Patient Trace Quality Assessment procedure states, "At least TWO assessments per month will be performed using the attached form." 3. Review of the Patient Tracers binder on September 11, 2025, at 10: 00 a.m. revealed that two patient tracers were not performed for the following months: - September 2023 - December 2023 - January 2024 - May 2024 - June 2024 3. By interview, the LD confirmed the above findings on September 11, 2025, at 10:45 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on a review of testing personnel (TP) competency assessment records, review of Laboratory Personnel Report (CLIA) Form CMS 209 and an interview with the laboratory director (LD), the technical consultant failed to evaluate the assessment of external proficiency testing samples for two of two testing personnel performing patient testing from 2023 to 2025. Findings Included: 1. Form CMS 209, signed by the laboratory director on September 10, 2025, listed one TC which is the LD. 2. A review of the TP competency assessment records on September 11, 2025, at 9:34 a.m. revealed that the two TP competency assessment documents from 2023, 2024, and 2025 did not include the assessment of external proficiency testing samples for the

	chemistry panel, PSA testing, CBC testing, and urinalysis testing. 3. By interview, the LD confirmed that the TP competency assessment documents did not include the evaluation of external proficiency testing on September 11, 2025, at 10:45 am. Key: PSA = Prostate Specific Antigen. CBC = Complete Blood Count.