

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0667228	(X3) Date Survey Completed 06/13/2023
Name of Provider or Supplier Consolidated Nuclear Security, Llc	Street Address, City, State 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director the laboratory failed to have a written procedure for their General Laboratory System requirements. The laboratory performs approximatey 198K tests per year. Findings include: 1. Record review revealed the laboratory procedure titled " "Patient Tracer Quality Assessment", found it did not include their specific policy for patient confidentiality, specimen identification, specimen integrity, complaint investigation, communication, personnel competency and proficiency testing performance in the document. The laboratory procedure manual which contained all of their policies did not include a procedure titled "Quality Assessment" in the table of contents. 2. The "Patient Tracer Quality Assessment procedure" document provided guidance on how to complete the laboratory tracking for preanalytic, analytic and post-analytic testing areas reviewed on a monthly basis. 3. An interview of the laboratory director on June 13, 2023, at 12:00 PM confirmed that the laboratory did not have a Quality Assessment procedure for the laboratory.</p>