Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0499286	06/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Frio Regional Hospital	200 South Ih 35, Pearsall, TX	

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
D0000	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity The laboratory abated the immediate jeopardy findings with a letter dated June 2, 2021 stating the facility would follow all manufacturer's instructions for specimen collection and stability. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to retain the records for the verification studies performed on the Siemens Dimension EXL 200 chemistry analyzer. The findings were: 1. A review of the laboratory's records revealed the laboratory performed verification studies on the Siemens Dimension EXL 200 chemistry analyzer in May 2019. The analytes tested on

	the Dimension EXL 200 where: Alcohol CKMB Total CK Troponin Albumin Alkaline Phosphatase Alanine Transaminase Amylase Aspartate Aminotransferase Total Bilirubin Calcium Creatinine Glucose Lipase Magnesium Phosphate Total Protein Blood Urea Nitrogen Sodium Potassium Chloride CO2 Acetominophen Salicylate 2. The laboratory was asked to provide documentation of verification studies and their evaluation on June 1 and June 2, 2021. The laboratory could only provide the instrument printouts. No evaluation or documentation of approval were provided. 3. An interview with the general supervisor on 06/02/2021 at 1500 hours in his office revealed he was unable to locate the studies. He stated he had contacted the manufacturer who assisted with the installation and was requesting copies. This confirmed the findings.
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's procedures, and staff interview, it was revealed the laboratory failed to have documentation on performing competency assessments on the general supervisor. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/21/2021) revealed the laboratory identified 1 general supervisor. 2. A review of the laboratory's procedures revealed the laboratory failed to have documentation a procedure for assessing the competency of general supervisor or its frequency. 3. The laboratory was asked to provide documentation of general supervisor competency assessments. No documentation was provided. 4. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/02/2021 at 1420 hours in the conference room confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test records, surveyor observation, and staff interview, it was revealed the laboratory failed to meet preanalytic system requirements. The findings were: 1. The laboratory failed to ensure lactic acid samples were tested within 5 minutes of collection on the EPOC Blood Analysis System and the GEM 3500 analyzer (refer to D5311 A). 2. The laboratory failed to ensure blood gas samples were tested within 30 minutes of collection on the EPOC Blood Analysis System (refer to D5311 B). 3. The laboratory failed to ensure blood gas samples were tested within 15 minutes of collection of the GEM 3500

	analyzer (refer to D5311 C). 4. The laboratory failed to ensure only FDA-approved sample collection containers were used for lactic acid samples tested on the GEM 3500 analyzer (refer to D5311 D).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test records, surveyor observation, and staff interview, it was revealed the laboratory failed to: A. Ensure lactic acid samples were tested within 5 minutes of collection on the EPOC Blood Analysis System and the GEM 3500 analyzer. B. Ensure blood gas samples were tested within 30 minutes of collection on the EPOC Blood Analysis System. C. Ensure blood gas samples were tested within 15 minutes of collection of the GEM 3500 analyzer. D. Ensure only FDA-approved sample collection containers were used for lactic acid samples tested on the GEM 3500 analyzer. E. Ensure only patients over the age of 50 were tested utilizing the Siemens Dimension TPSA reagent kit. The findings were: A) Lactic Acid tested within 5 minutes 1. A review of the manufacturer's instructions for the EPOC Blood Analysis System (51008148 Rev. 08) under the section titled "Sample Collection Details" revealed that for lactic acids samples collected in lithium heparin evacuated tubes the test had to be performed within 5 minutes to avoid the effects of glycolysis. 2. A review of the manufacturer's instructions for the GEM 3500 analyzer (P/N 26000250, Rev 1 March 2015) under the section titled "Sample Storage" revealed: "Whole blood samples for blood gas /electrolyte/glucose/lactate and hematocrit analysis should be analyzed as soon as possible (within 15 minutes of collection for blood gas, electrolytes, and Hct; 5 minutes if glucose/lactate testing is included.) 3. A sampling of patient lactate specimens tested on the EPOC Blood Analysis System from December 2020, April 2021 and May 2021 identified 5 of 10 patients where the time from collection to testing exceeded 5 minutes. They were: a) Order 35027 collected: 04/02/2021 07:18 hours tested: 04/02/2021 07:28 hours elapsed time: 10 minutes b) Order 35029 collected: 04/02/2021 13:25 hours tested: 04/02/2021 13:34 hours elapsed time: 9 minutes c) Order 43409 collected: 05/08/2021 14:00 hours tested: 05/08/2021 14:20 hours elapsed time: 20 minutes d) Order 43364 collected: 05/08/2021 10:05 hours tested: 05/08/2021 10:22 hours elapsed time: 17 minutes e) Order 4414 collected: 12 /04/2020 08:45 hours tested: 12/04/2020 08:59 hours elapsed time: 14 minutes 4. A sampling of patient lactate specimens tested on the GEM 3500 analyzer from May 29, 2021 to June 2, 2021 identified 8 of 16 patients where the time of collecting to testing exceeded 5 minutes. They were: a) Order 49792 collected: 06/01/2021 17:12 hours tested: 06/01/2021 17:20 hours elapsed time: 8 minutes b) Order 49773 collected: 06 /01/2021 16:27 hours tested: 06/01/2021 16:33 hours elapsed time: 16 minutes c) Order 49644 collected: 06/01/2021 09:40 hours tested: 06/01/2021 09:50 hours elapsed time: 10 minutes d) Order 49635 collected: 06/01/2021 09:12 hours tested: 06 /01/2021 09:19 hours elapsed time: 7 minutes e) Order 49167 collected: 05/30/2021 15:00 hours tested: 05/30/2021 15:17 hours elapsed time: 17 minutes f) Order 49132

collected: 05/30/2021 14:05 hours tested: 05/03/2021 14:17 hours elapsed time: 12 minutes g) Order 48782 collected: 05/29/2021 06:30 hours tested: 05/29/2021 06:59 hours elapsed time: 29 minutes h) Order 48919 collected: 05/29/2021 18:42 hours tested: 05/29/2021 18:48 hours elapsed time: 6 minutes 5. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/02/2021 at 1230 hours in the laboratory confirmed the findings. B) Blood Gas on EPOC within 30 minutes 1. A review of the manufacturer's instructions for Blood Gas samples analyzed on the EPOC Blood Analysis System (51008148 Rev: 08) under the section titled "Test and Sample Collection Methods" revealed blood gas samples collected in syringes needed to be tested in less than 30 minutes. 2. A sampling of patient blood gas specimens tested on the EPOC Blood Analysis System from April 2, 2021 to April 9, 2021 identified 2 of 10 patients where the time of collection to time of testing exceeded 30 minutes. They were: a) Order 35766 collected: 04/05/2021 02:37 hours tested: 04/05 /2021 03:36 hours elapsed time: 59 minutes b) Order 35725 collected: 04/04/2021 2344 hours tested: 04/05/2021 00:25 hours elapsed time: 41 minutes 3. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/02/2021 at 1230 hours in the laboratory confirmed the findings. C) Blood Gas on GEM 3500 within 15 minutes 1. A review of the manufacturer's instructions for the GEM 3500 analyzer (P/N 26000250, Rev 1 March 2015) under the section titled "Sample Storage" revealed: "Whole blood samples for blood gas/electrolyte/glucose/lactate and hematocrit analysis should be analyzed as soon as possible (within 15 minutes of collection for blood gas, electrolytes, and Hct; 5 minutes if glucose/lactate testing is included.) 2. A sampling of patient blood gas specimens tested on the GEM 3500 analyzer from May 2021 identified 2 of 10 patients where the time of collection to time of testing exceeded 15 minutes. They were: a) Order 48827 collected: 05/29 /2021 12:20 hours tested: 05/29/2021 13:28 hours elapsed time: 68 minutes b) Order 43005 collected: 05/06/2021 21:08 hours tested: 05/06/2021 21:39 hours elapsed time: 31 minutes 3. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/02/2021 at 1230 hours in the laboratory confirmed the findings. D) Specimen container of GEM 3500 analyzer 1. A review of the manufacturer's instructions for the GEM 3500 analyzer (P/N 26000250, Rev 1 March 2015) revealed the collection containers approved for samples tested on the analyzer were syringes (plastic or glass) and capillary tubes. 2. Surveyor observation on 06/02/2021 at 08:48 hours in the laboratory revealed a sample being tested on the GEM 3500 which was collected in a lithium heparin vaccuette vacutainer tube. It was: a) order 49905 3. An interview with the general supervisor on 06/02/2021 at 09:00 hours in his office revealed the facility collected all samples tested on the GEM 3500 in lithium heparin tubes. 4. An email from the applications specialist from Acute Care Diagnostics dated 06/02/2021 at 10:03 am revealed: "We don't recommend vacutainers for blood gas." 5. Surveyor observation of specimens stored in the refrigerator for the last week revealed all samples for blood gas analysis were collected in lithium heparin vaccuette vacutainer tubes. 6. The laboratory reported performing 158 tests on the GEM 3500 since it was put into use on May 1, 2021. 7. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/02/2021 at 1230 hours in the laboratory confirmed the findings. E) Patients under age 50 for PSA testing 1. A review of the manufacturer's instructions for the Siemens Dimension TPSA (total prostate specific antigen) reagent cartridge (issue date 2019-07-29) under the section titled "Intended Use" revealed: "The TPSA method for the Dimension clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma: as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older..." 2. A review of patient test records from 2019, 2020, and 2021 (as of the day of the survey) identified 34 patients

	under the age of 50 whose samples were tested utilizing the Dimension TPSA test. Examples are: a) medical number: 274580 tested: 04/12/2019 age: 27 years b) medical number: 273912 tested: 04/01/2019 age: 36 years c) medical number: 292489 tested: 02/12/2020 age: 40 years d) medical number: 307826 tested: 11/19/2020 age: 41 years e) medical number: 311691 tested: 02/02/2021 age: 41 years f) medical number: 314719 tested: 04/07/2021 age: 41 3. An interview with general supervisor on 06/01 /2021 at 1530 hours in his office revealed the facility was not aware of the age limit for patients tested using this reagent. This confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and staff interview it was revealed the laboratory failed to follow its own laboratory procedure for performing Prothrombin Time testing. The findings were: 1. A review of the laboratory's procedure "ACL Elite" (page18) signed and placed into effect by the laboratory director on 5/1/17 revealed: "Prothrombin Time Testing shall always be done in duplicate, making sure results fall within 0.5 seconds of each other." 2. In an interview on 06/02/2021 at 0930 hours in the laboratory Testing Person stated that Prothrombin Time testing is performed only once on each sample. 3. In an interview on 06/02/2021 at 0945 hours in the laboratory General Supervisor stated that Prothrombin Time testing is performed only once on each sample. This confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's verification studies on the GEM3500 analyzer, and staff interview, it was revealed the laboratory failed to have documentation of verifying 5 of 6 patient normal values currently in use. The findings were: 1. A review of the laboratory's procedures for the GEM3500 analyzer revealed the laboratory defined patient normal values for 6 different samples types tested for blood gas analysis. They were: a) Arterial Blood Gas b) Venous Blood Gas c) Capillary Blood Gas d) Cord Blood Gas - no source e) Cord Blood Gas - arterial f) Cord Blood Gas - venous 2. A review of the laboratory's verification studies performed on the GEM3500 (placed into use on May 1, 2021) revealed the laboratory

	had documentation of verifying patient normal values for arterial blood gas specimens only. 3. The ranges which the laboratory did not verify were: a) Venous Blood gas pH 7.35-7.45 pCO2 39-52 pO2 30-50 HCO3 23-27 tCO2 21-32 BE -3 to 3 O2 Sat 50-80 b) Capillary Blood Gas pH 7.35-7.45 pCO2 35-45 pO2 49-75 HCO3 23-27 tCO2 21-32 BE -3 to 3 O2 Sat 94-100 c) Cord Blood Gas (no source) pH 7.14-7.44 pCO2 30-78 pO2 3-43 HCO3 20-29 BE -3 to 3 O2 Sat none d) Cord Blood Gas (arterial) pH 7.10-7.38 pCO2 39.1-73.5 pO2 4.1-31.7 HCO3 16-27 BE -3 to 3 O2 Sat 5-59 e) Cord Blood Gas (venous) pH 7.20-7.44 pCO2 30.4-57.2 pO2 14.1-43.4 HCO3 17-25 BE -3 to 3 O2 Sat 14-75 4. The laboratory was asked to provide documentation of verifying the identified patient normal values. No documentation was provided. 5. An interview with the general supervisor on 06/02/2021 at 1330 hours in his office confirmed the laboratory had only verified the arterial blood gas patient normal ranges. He stated all ranges were currently in use. This confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions on the Siemens Dimension EXL 200 analyzer, review of the laboratory's daily function checks on the Siemens Dimension EXL 200 analyzer July 2020 to May 2021, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the documented cuvette temperature was outside the manufacturer's acceptable range. The findings were: 1. Based on review of the manufacturer's instructions for the Siemens Dimension EXL 200 analyzer revealed the temperature of the cuvettes was to be checked daily and fall within a range of 36.8 - 37.2C. 2. A review of the laboratory's daily function checks on the Siemens Dimension EXL 200 analyzer revealed the following days where the documented temperature was outside the manufacturer's acceptable range and no corrective action was documented as being performed: a) July 2020 July 31 36.6C b) August 2020 August 15 36.7C August 16 36.7C August 17 36.7C August 29 36.7C c) September 2020 September 2 36.7C September 3 36.7C September 12 36.6C September 13 36.6C September 16 36.7C September 19 36.7C September 27 36.7C September 28 36.7C September 30 36.7C d) October 2020 October 1 36.7C October 2 36.7C October 7 36.7C October 8 36.7C October 10 36.7C October 11 36.7C October 12 36.7C October 13 36.7C October 14 36.7C October 15 36.7C October 16 36.7C October 17 36.7C October 18 36.7C October 22 36.7C October 23 36.7C October 26 36.7C October 29 36.7C e) November 2020 November 10 36.7C November 14 36.7C f) February 2021 February 24 37.3C February 25 37.3C February 26 37.3C February 27 37.4C February 28 37.5 C g) March 2021 March 1 37.3C March 2 37.3C March 3 37.3C March 4 37.3C March 6 37.4C March 7 37.4C h) April 2021 April 29 36.7C i) May 2021 May 3 36.7 C May 4 36.6C May 5 36.6C May 7 36.7C May 8 36.7C May 9 36.7C May 11 36.7C

	May 12 36.6C May 13 36.6C May 14 36.6C May 15 36.6C May 16 36.6C May 17 36.6C May 18 36.6C May 20 36.6C May 21 36.7C May 22 36.7C May 24 36.7C May 25 36.6C May 26 36.7C May 27 36.6C May 28 36.7C May 31 36.6C 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. An interview with technical supervisor number 2 (as listed on Form CMS 209) on 06/01/2021 at 1500 hours in the conference room confirmed corrective actions were not documented and that the instrument was in use each of the identified days.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide direction and oversight for the laboratory. The findings were: 1. The laboratory director failed to ensure manufacturer's instructions were followed for preanalytic systems (refer to D6007). 2. The laboratory director failed to ensure verification studies were complete (refer to D6013).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of patient test records and staff interview, it was revealed the laboratory director failed to ensure manufacturer's instruction were followed for preanalytic systems. The findings were: 1. The laboratory director failed to ensure lactic acid samples were tested within 5 minutes of collection on the EPOC Blood Analysis System and the GEM 3500 analyzer (refer to D5311 A). 2. The laboratory director failed to ensure blood gas samples were tested within 30 minutes of collection on the EPOC Blood Analysis System (refer to D5311 B). 3. The laboratory director failed to ensure blood gas samples were tested within 15 minutes of collection of the GEM 3500 analyzer (refer to D5311 C). 4. The laboratory director failed to ensure only FDA-approved sample collection containers were used for lactic acid samples tested on the GEM 3500 analyzer (refer to D5311 D). 5. The laboratory director failed to ensure only patients over the age of 50 were tested utilizing the Siemens Dimension TPSA reagent kit (refer to D5311 E).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete (refer to D5421).
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to perform competency assessments on 8 of 8 testing personnel prior to them performing patient testing when new instrumentation was placed into service. The findings were; 1. Based on review of the laboratory's instrumentation is was revealed the laboratory place a Sysmex XN-550 (serial number 19777) into service in September 2020. 2. A review of the laboratory's personnel records revealed testing personnel (as listed on Form CMS 209) were trained and had competency assessment performed on the following days: a) Testing personnel 1 trained: 09/17/2020 competency: 02/19/2021 b) Testing personnel 2 trained: 09/16/2021 competency: 03/05/2021 c) Testing personnel 3 trained: 09/18/2021 competency: 03/05/2021 d) Testing personnel 4 trained: 09/17/2021 competency: 03/04/2021 e) Testing personnel 5 trained: 09/18 /2020 competency: 03/05/2021 f) Testing personnel 6 trained: 09/17/2020 competency: 03/05/2021 g) Testing personnel 7 trained: 09/26/2020 competency: 02 /28/2021 h) Testing personnel 8 trained: 12/02/2020 competency: 02/21/2021 3. The laboratory was asked to provide documentation of performing competency assessments on testing personnel prior to them performing testing on patient samples. No documentation was provided. 4. An interview with technical consultant number 1 (as listed on Form CMS 209) on 06/01/2021 at 1030 hours in the conference room revealed she was unaware this was a requirement. This confirmed the findings.