Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0880678	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oncology & Radiation Associates Pa	3659 S Miami Ave Ste 2001, Miami, FL	

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
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on review of Casper report 96 Clinical Laboratory Improvement Amendments (CLIA) Application and Survey Summary, review of proficiency testing (PT) records, and interview with testing person (TP) A, the laboratory failed to enroll in a PT program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for hematology specialty during 2017 and the first event of 2018. Findings include: Review of Casper report 96 pulled on 11/16/18 revealed blanks for the 3 events of 2017 and for the first event of 2018. Review of American Association of Bioanalysts (AAB) PT records revealed that there were no records for 2017. Review of the AAB invoice showed that the last payment was on 11/25/15 for enrollment in 2016. Review of American Proficiency Institute (API) records for 2018 revealed no results for the 1st event. Review of the API invoice showed a date of 06/22/18. During an interview on 11/20/18 at 11:30 a.m. TP A confirmed that the facility failed to enroll in PT for 2017 and the first event of 2018.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review, interview with the laboratory director (LD), and lack of documentation, the quality assurance program (QAP) failed to detect that the laboratory was not enrolled in PT for 2017 and the first testing event of 2018. Findings include: Review of the QAP on 11/20/18 revealed that there was a requirement to review and document each aspect of the plan 3-4 times a year. There was no documentation to indicate that the laboratory realized that they were not enrolled in PT during 2017 at the time of the inspection on 11/20/18. During an interview on 11/20/18 at 4:40 p.m., the LD confirmed that there was no documentation of PT review during 2017.
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 record review and interview with laboratory director, the Laboratory Director (LD) failed to provide overall management and direction to ensure the laboratory enrolled in proficiency testing during 2017 and 1st event 2018 (refer to D6015); failed to ensure that the quality assurance program monitored 3-4 times a year review of each aspect of the plan and document what has been reviewed (refer to D6021).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of Casper report 96 (CLIA Application and Survey Summary). Review of proficiency testing (PT) facility records and interview with laboratory director, the laboratory director (LD) failed to ensure that the facility enrolled in a PT program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for hematology specialty during year 2017. Findings include: Review of Casper report 96 pulled on 11/16/2018 revealed a blank for the 3 events of year 2017 and for the first event 2018. Review of American Association of Bioanalysts (AAB) PT records revealed no results for 2017. Review of AAB invoice, showed the last payment on 11/25/2015 corresponding to the

	enrollment for 2016. Review of American Proficiency Institute (API) PT records for year 2018 revealed no results for the 1st event. Review of API invoice showed a date of 6/22/2018. During an Interview on 11/20/2018 at 4.30 pm, the LD confirmed that she failed to ensure that the facility enrolled in a PT program for year 2017 and 1st event of 2018. Refer to D2001
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory director (LD), the LD failed to ensure that the laboratory's quality assurance (QA) program monitored the proficiency testing (PT) enrollment. Findings include: Review of the "Quality Assurance Program " policy, states that the LD overseas the implementation of their QA. Review of the "Quality Assurance Plan" states that quality assurance monitoring will be conducted 3-4 times per year review and document what has being reviewed. There was no documentation to indicate that the laboratory director realized that the facility was not enrolled in PT during 2017 and that the facility missed the deadline to enroll for the 2018 PT program at the time of the inspection on 11/20/18. During an interview on 11/20/18 at 4:40 p.m., the LD confirmed that there was no documentation of PT review during 2017 on their QA monitoring. Refer to D5293