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| Statement of Deficiencies                                                                                                  | (X1) Provider/Supplier/CLIA Identification Number<br><br>10D0880678     | (X3) Date Survey Completed<br><br>09/23/2026 |
| Name of Provider or Supplier<br><br>Oncology & Radiation Associates Pa                                                     | Street Address, City, State<br><br>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. |                                                                         |                                              |

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| (X4) ID Prefix Tag | Summary Statement of Deficiencies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| D0000              | An announced CLIA recertification survey was conducted at ONCOLOGY & RADIATION ASSOCIATES, PA on September 23, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited was as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| D3037              | <p>RETENTION REQUIREMENTS<br/>CFR(s): 493.1105(a)(4)</p> <p>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the Laboratory failed to retain Proficiency Testing (PT) records for the DxH520 instrument printouts in the Specialty of Hematology for five out of six PT events reviewed from November of 2024 through September 23, 2026. Findings included: 1- Review of American Proficiency Institute (API) PT records for 2024 Hematology/Coagulation - 3rd Event, 2025 Hematology/Coagulation - 1st Event, 2025 Hematology/Coagulation - 2nd Event, 2025 Hematology/Coagulation - 3rd Event, 2026 Hematology/Coagulation - 1st Event, and 2026 Hematology/Coagulation - 2nd Event, revealed that the laboratory did not keep printouts from the DxH520 analyzer for the first five events listed (2024-3rd, 2025-1st, 2nd, 3rd, and 2026-1st). The laboratory recovered the prints for 2026 Hematology/Coagulation - 2nd Event from the analyzer during the survey. 2- Review of the QUALITY ASSURANCE PROGRAM policy signed by the LD January 2026 stated under PROFICIENCY TESTING "PT results are reviewed and retained for a period of at least two years." 3- Review of API PROFICIENCY SAMPLE TESTING INSTRUCTIONS AND WORKSHEETS stated in step 7. "When testing is finished, keep your documentation (e.g., photocopied worksheets, instrument printouts, online</p> |

printouts) for your own records." 4- During interview on 09/23/2026 at 12:20 PM, Testing Personnel confirmed that the laboratory discarded the instrument print after electronic submission to API.