

G.S. 150B-21.3A Report for 10A NCAC 42, LABORATORY SERVICES									
Agency - Commission for Public Health									
Comment Period - 11/11/16 - 1/10/17									
Date Submitted to APO - Filled in by RRC staff									
Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
SUBCHAPTER 42A - GENERAL POLICIES		10A NCAC 42A .0101	SCOPE	Amended Eff. September 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493 40CFR142.10(b)(4)	No	Necessary without substantive public interest
		10A NCAC 42A .0102	DEFINITIONS	Amended Eff. September 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 42A .0103	FORMS	Amended Eff. October 1, 1985	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493 40CFR142.10(b)(4)	No	Necessary without substantive public interest
		10A NCAC 42A .0104	ACQUIRING SERVICES OF CDC	Amended Eff. September 1, 1990	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 42A .0105	SUBMITTING SPECIMENS OR SAMPLES AND RECEIVING RESULTS	Amended Eff. September 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493 40CFR142.10(b)(4)	No	Necessary without substantive public interest
		10A NCAC 42A .0106	FEES	Amended Eff. January 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 42A .0107	PAP SMEAR FEES	Eff. May 1, 2004	Unnecessary	No		No	Unnecessary
SUBCHAPTER 42B - LABORATORY SECTIONS		10A NCAC 42B .0101	CANCER CYTOLOGY	Eff. October 1, 1985	Unnecessary	No		Yes	Unnecessary
		10A NCAC 42B .0102	CLINICAL CHEMISTRY/NEWBORN SCREENING	Amended Eff. September 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493	Yes	Necessary without substantive public interest
		10A NCAC 42B .0103	ENVIRONMENTAL SCIENCES	Eff. October 1, 1985	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR142.10(b)(4)	No	Necessary without substantive public interest
		10A NCAC 42B .0104	LABORATORY IMPROVEMENT	Eff. October 1, 1985	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 42B .0105	MICROBIOLOGY	Eff. October 1, 1985	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493	No	Necessary without substantive public interest
		10A NCAC 42B .0106	VIROLOGY/SEROLOGY	Amended Eff. September 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42CFR493	No	Necessary without substantive public interest

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SUBCHAPTER 42C - MILK AND WATER LABORATORY CERTIFICATION		10A NCAC 42C .0101	MILK LABORATORY CERTIFICATION	Amended Eff. September 1, 1990	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	US DHHS, Public Health Service, Food and Drug Admin., Grade A <i>Pasteurized Milk Ordinance</i>	No	Necessary without substantive public interest
		10A NCAC 42C .0102	WATER LABORATORY CERTIFICATION	Amended Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR142.10(b)(3)(i)	No	Necessary without substantive public interest
SUBCHAPTER 42D - CERTIFICATION AND IMPROVEMENT	SECTION .0100 - LABORATORY CERTIFICATION	10A NCAC 42D .0101	CERTIFICATION FOR LABORATORIES CONDUCTING HIV TESTING	Amended Eff. July 1, 1995	Unnecessary	No		No	Unnecessary
	SECTION .0200 - LABORATORY CERTIFICATION	10A NCAC 42D .0231	SCOPE	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0232	NOTICE AND PROCEDURE	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0233	CERTIFICATION, CERTIFICATION RENEWAL AND FEES	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0234	CRITERIA AND PROCEDURES: DECERT./DENIAL/DOWNGRADING	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0235	RECERTIFICATION	Amended Eff. April 1, 1993	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0236	CERTIFICATION OF OUT-OF-STATE LABS	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0237	CONTRACT LABORATORIES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0238	CHEMISTRY FACILITIES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0239	CHEMISTRY EQUIPMENT AND INSTRUMENTATION	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest

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		10A NCAC 42D .0240	CHEMISTRY LABORATORY PRACTICES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0241	CHEMISTRY METHODOLOGY	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0242	CHEMISTRY SAMPLE COLLECTION, HANDLING, AND PRESERVATION	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0243	CHEMISTRY QUALITY ASSURANCE	Amended Eff. August 1, 2004	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0244	CHEMISTRY DATA	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0245	CHEMISTRY ACTION RESPONSE	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0246	MICROBIOLOGY FACILITIES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0247	MICROBIOLOGY EQUIPMENT/SUPPLIES/ASSOCIATED QUALITY CONTROL	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0248	MICROBIOLOGY GENERAL LABORATORY PRACTICES	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0249	MICROBIOLOGY METHODOLOGY	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0250	MICROBIOLOGY SAMPLE COLLECTION, HANDLING AND PRESERVATION	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0251	MICROBIOLOGY QUALITY ASSURANCE	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest

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		10A NCAC 42D .0252	MICROBIOLOGY DATA	Amended Eff. January 1, 1996	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0253	MICROBIOLOGY ACTION RESPONSE	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0254	RADIOCHEMISTRY FACILITIES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0255	RADIOCHEMISTRY EQUIPMENT	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0256	RADIOCHEMISTRY GENERAL LABORATORY PRACTICES	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0257	RADIOCHEMISTRY METHODS	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0258	RADIOCHEMISTRY SAMPLE COLLECTION/HANDLING/PRE SERVATION	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0259	RADIOCHEMISTRY QUALITY CONTROL	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0260	RADIOCHEMISTRY DATA	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest
		10A NCAC 42D .0261	RADIOCHEMISTRY ACTION RESPONSE	Eff. December 1, 1991	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	40CFR141.28	No	Necessary without substantive public interest

Agency	Rule	Name	Type of Comment	Comment	Agency Response
Commission for Public Health	10A NCAC 42B .0102	CLINICAL CHEMISTRY/NEWBORN SCREENING	Public Coment as defined in G.S. 150B-21.3A(a)(5)	What is the fee for Newborn screening?	Comment does not pertain to the rule. Current Newborn Screening Fee (per NC General Statute 130A-125) is \$44.00 per specimen.
	10A NCAC 42B .0101	CANCER CYTOLOGY	Public Coment as defined in G.S. 150B-21.3A(a)(5)	Cervical cancer is the easiest to detect and screen for. Not providing the test would be detrimental to women's heal	Comment does not pertain to the rule. Decision to no longer offer cervical cancer testing is based on budgetary constraints and lack of demand for the tests.