



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

April 19, 2022

Ryan Craffey, Senior Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety and Safeguards
U.S. NRC Region III

Re: LETTER TO D. CROWLEY RE: NORTH CAROLINA FY2022 IMPEP SCHEDULING AND
QUESTIONNAIRE DATE February 25, 2022

Dear Mr. Craffey:

The North Carolina Agreement State Program (hereafter "the Program") looks forward to the upcoming Integrated Materials Performance Evaluation Program (IMPEP) review in a couple weeks, from May 2 – 6, 2022. We see the review process as a learning opportunity and a chance to identify areas to make the Program even stronger in the future.

Enclosed with this letter is a response to the "2022 IMPEP Questionnaire" per your request. Additional attachments are included where necessary to fully satisfy each item. The Program is also preparing to have all items requested for the "On-Site Portion" available for the Team's arrival.

If you need additional information to any of these responses, please contact our Interim Radioactive Materials Branch Manager, Louis Brayboy, at louis.brayboy@dhhs.nc.gov or call at 1-919-814-2304.

Very respectfully,

David Crowley, Chief
Radiation Protection Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services

Enclosure:

1 – 2022 IMPEP Questionnaire Response with Attachments

NORTH CAROLINA AGREEMENT STATE PROGRAM
Integrated Materials Performance Evaluation Program Questionnaire Response
Reporting Period: March 10, 2018 – May 6, 2022

A. GENERAL

1. The below table summarizes actions taken in response to each of the open recommendations from previous IMPEP reviews:

Indicator	Recommendation	Corrective Actions
SS&D	(1) improve the thoroughness, completeness, accuracy, and consistency of SS&D reviews and ensure that the reviews address health and safety concerns and product integrity;	CA(1)a. - Acquire additional hands on training opportunities from NRC SS&D staff, aimed to provide actual SS&D review case studies. Week long of multiple reviews to practice applying procedures, NUREGS, and technical evaluation. This was to learn the approach and standards expected from NRC SS&D reviewers. (Done) CA(1)b. - Hold regular meetings throughout the course of an SS&D action. Meetings will include management, concurrence SS&D reviewer, SS&D staff in training, licensing and inspection staff. Including various perspectives on the review process will help with consistency overtime, not allowing a single reviewer to drift as easily or become complacent in review technique. (Implemented) CA(1)c. - Implement the procedures written prior to last IMPEP, they addressed a lot of these weaknesses but we did not have the time or actions to actually demonstrate a use. Review and revise these procedures as necessary after each SS&D action. (Done) CA(1)d. - Training, both initial and refresher. Large part about this first recommendation relies on well trained and capable staff. We increased the amount of actions to become qualified from 3 to 6. Also, specify that within those 6 actions there must be something relating to tritium, medical, and gauge devices. Other 3 may include inactivations or amendments of any type. Refresher training will also be required specific to SS&D. (Implemented) CA(1)e. - Petition National Materials Program to develop centers of excellence for SS&D reviewers. These individuals may assist with certain processes or technical questions when reviewers have them; additionally, may be able to act as primary or concurrent reviewers when there is insufficient staffing at a local SS&D program. (Done) CA(1)f. - Identify and establish a lead SS&D reviewer to take ownership over the program and monitor all reviewer activities. Not a supervisory position, but a functional lead with focused responsibility on the success and continuous improvement for the SS&D program. (Done)

SS&D	(2) improve the concurrence review process to ensure that concurrence reviewers fully assess SS&D evaluations;	CA(2)a. - Regularly scheduled meetings as stated in CA(1)b. will verify that the reviews were thorough, followed procedures, used correct checklists, asked appropriate questions and that everyone feels confident in moving an SS&D towards acceptance. (Implemented) CA(2)b. - Implement procedures, NUREGs, and checklists as stated in CA(1)c. (Implemented) CA(2)c. - Ensure that the proper individuals are signing the certificates as stated in procedures, only fully qualified individuals may act as primary and concurrence signatures on certificates. (Implemented)
SS&D	(3) ensure that each SS&D evaluation is properly documented, including all licensee correspondence, deficiency letters and responses, and memos to file.	CA(3)a. - Before any new SS&D action is issued, both the primary and concurrence reviewer must review the files associated with the action. Only when all documents are present on the shared (s:) drive and in WBL may they submit for final approval and activation of the SS&D. SS&D Lead reviews that all necessary documents are present in both electronic record locations. (Implemented) CA(3)b. - Implement procedures, NUREGs, and checklists as stated in CA(1)c. (Done) CA(3)c. - Ensure documentation is discussed regularly during SS&D team meetings CA(1)d. (Implemented)

B. COMMON PERFORMANCE INDICATORS

I. TECHNICAL STAFFING AND TRAINING

2. Organizational structure and personnel:

(a) The Governor's Office down to the Radiation Control Program Director (RCPD) is represented in "I.2.(a) NC Executive-Cabinet Chart.pdf" and "I.2.(a) DHHS-OChart August 2021.pdf".

The RCPD reports to the Deputy Division Director of Health Service Regulation (DHSR), who reports to the Division Director of DHSR. The DHSR Director reports to a Deputy Secretary for the Department of Health and Human Services (DHHS), who reports to the Department's Secretary. The Department Secretary reports to the Governor's office.

(b) The Program is represented in the attachment labeled "I.2.(b) RPS O-Chart April 2022.png".

(c) Members of the Sealed Source and Device (SS&D) Program are identified in the staffing list below with an asterisk (*).

3. Staffing list and individual full-time equivalent (FTE) contributions to various program areas, as of April 6, 2022:

Name:	Position:	Area of Effort (%):	FTE:
Vacant	Manager, Radioactive Materials Branch	Administration (100)	1
Louis Brayboy	Interim Branch Manager / Supervisor, Licensing	Administration (85) Licensing (15)	1
Chinwe Ekwuribe*	License Reviewer	Licensing (90) SS&D (10)	1
Randy Crowe	License Reviewer / General License Coordinator	Licensing (90) General Licensing (10)	1
Matthew Barrett	License Reviewer	Licensing (100)	1
Vacant	License Reviewer	Licensing (100)	1
Patrick Cox	Environmental Program Coordinator	Environmental Monitoring (100)	1
Caleb Smith*	Lead, Sealed Source and Devices	SS&D (40) Inspection (30) Licensing (30)	1
James Albright	Environmental Consultant and QA Reviewer	Administration (100)	1
Nick Driver	Administrative Assistant and Reciprocity Coordinator	Administration (100)	1
Travis Cartoski	Supervisor, Inspections and Incident Response	Administration (70) Inspection (30)	1
Ken Bugaj*	Inspector	Inspection (90) SS&D (10)	1
Tawny Morgan	Inspector	Inspection (100)	1
Allen Howe (will be vacant 4/15/2022)	Inspector	Inspection (100)	1
Vacant (hired, starting 5/2/2022)	Inspector	Inspection (100)	1

4. New hires since March 10, 2018, accurate as of April 6, 2022:

Name:	Hire Date:	Degree:	Additional Training and Relevant Health Physics Experience (Years):
Ken Bugaj*	10/21/2019	BS – Nuclear Engineering Technology	U.S. Navy Nuclear Power (7 years) Maintenance Technician – Manufacturing and Engineering (4 years)
Matt Barrett	7/6/2020	MA – Chemistry BSc – Chemistry	Health Physics Technologist UNC (2 years) Nuclear Medicine School and Experience (4 years) Laboratory Tech using radioactivity (8 years)
Allen Howe	7/20/2020	BS – Nuclear Engineering	Naval Shipyard – Nuclear Test Engineer (5 years) U.S. NRC – multiple positions from resident inspector to deputy director (31 years)

			Senior Nuclear Safety Consultant (4 years)
Tawny Morgan	5/17/2021	BS Biology	Multiple NRC Training, previous work with SC Agreement State program.
Terri Richards	5/2/2022	BS Biology/Emergency Response	NC Emergency Management, ROSS Coordinator for Radiological Emergency Program.

5. Unqualified staff members (see individual qualification journals for necessary experience and coursework), progress as of April 6, 2022:

Name:	Completed Qualifications:	Qualifications in Progress:	Timeline to Complete in Progress Qualifications:
Matthew Barrett	Some Licensing	Licensing	< 6-9 months
Tawny Morgan	Some Inspections	Inspections	< 6-9 months
Ken Bugaj	Inspections	Inspections	4 months

6. The only change was to expand the number of SS&D actions required to become a qualified SS&D reviewer. This was captured in the table to response A.1. above, specifically corrective action CA1(d). addresses this change.

7. The following staff left the Program during the review period:

Name:	Date Left Employment:
Sharn Jeffries*	4/26/2019
Dawn Burke	5/24/2019
Cliff Harris	1/27/2020
Sheila Nelson	2/8/2020
Daren Scott Houchin	4/5/2021
William Johnson	10/1/2021
Allen Howe	4/15/2022

8. There are currently three staffing vacancies with the Program, as of April 6, 2022.

Position:	Time Vacant:	Efforts to Fill:
Licensing Reviewer	8 months	Posted, interviewed, applicant selected, and now awaiting human resources to extend an offer to applicant.
Inspector	7 months	Hired, starting 5/2/2022.
Branch Manager	2 weeks	We will post soon, Louis Brayboy is presently acting as the Interim Branch Manager.
Soon to be vacant – Inspector	-1 week	Allen Howe's position will be posted in the near future.

9. The Program does not have an oversight board or committee for daily business; however, the North Carolina Radiation Protection Commission (RPC) promulgates the Program's regulations and it is made up of professionals throughout the State's radiation industry. To avoid any potential conflicts of interest, the following statement is read at the beginning of all business meetings: "In accordance with the State Government Ethics Act, it is the duty of every Commission member to avoid both conflicts of interest and potential conflicts. Does any Commission member have any known conflict of interest or potential

conflict with respect to any matters coming before the Radiation Protection Commission today? If so, please identify the conflict or potential conflict and refrain from any participation in the particular matter involved.”

II. STATUS OF MATERIALS INSPECTION PROGRAM

10. The Program inspects all license categories at least as often as what is called for in the NRC’s IMC 2800; none are inspected less frequently. Program inspection procedures contain a table of categories and inspection periods, but the differences are listed here:

- Mobile Medical: 2 (NC) vs. 3 (NRC)
- Veterinary: 3 vs. 5
- Irradiator Self Shielded: 4 vs. 5
- Irradiator ≥ 10 K Ci: 2 vs. 5
- Irradiator < 10 K Ci: 4 vs. 5
- Portable Nuclear Gauges: 3 vs. 5
- Fixed Nuclear Gauges: 4 vs. 5
- XRF: 4 vs. 0

Note that the Program chose to do these inspection types more frequently based on our perceived risk with those activities or due to the number of incidents that are reported in those areas.

11. The following table provides for the number of priority 1, 2, 3 routine inspections and initial inspections of any priority type. These are counted from March 10 of one year to March 9 of the following year, except in the final year those will be from March 10, 2021 to March 29, 2022.

Year Period:	Pri(1) Routine:	Pri(2) Routine:	Pri(3) Routine:	Pri(All) Initial:
March ‘18-‘19	28	38	100	9
March ‘19-‘20	24	36	91	14
March ‘20-‘21	14	16	25	10
March ‘21-‘22†	12	46	108	1

†Numbers from 3/10/2021-3/29/2022.

12. See attached spreadsheet named “Inspection Data 3-29-2022.xls” for minimum information requested regarding overdue priority 1, 2, 3 routine inspections and initial inspections conducted over the review period. A summary count of the overdue inspections performed for each year and type is listed below. These are counted from March 10 of one year to March 9 of the following year, except in the final year those will be from March 10, 2021 to March 29, 2022.

Year Period:	Pri(1) Routine:	Pri(2) Routine:	Pri(3) Routine:	Pri(All) Initial:
March ‘18-‘19	0	0	0	0
March ‘19-‘20	2	0	0	0
March ‘20-‘21	1	1	0	0
March ‘21-‘22†	0	2	1	0

†Numbers from 3/10/2021-3/29/2022.

13. As of March 29, 2022, none are overdue per the IMC 2800. See attached spreadsheet named “Inspection Data 3-29-2022.xls” for more information.

14. The number of reciprocity candidates for inspections each calendar year and the number performed are as follows:

Year Period:	Candidate Count:	Candidates Inspected:	Total Reciprocity Licenses Notifying:	Total Reciprocity Licenses Inspected:
CY '18	22	17	57	17
CY '19	14	7	52	7
CY '20	18	1	53	1
CY '21	N/A; risk-based analysis utilized.	2	74	2
CY '22†	N/A; risk-based analysis utilized.	2	72	2

†Numbers from 1/1/2022-3/29/2022.

III. TECHNICAL QUALITY OF INSPECTIONS

15. The Program revised Inspection Procedures in March of 2022 to reflect the new risk-based approach to conducting reciprocity inspections. Other changes were minor and general in nature (formatting, grammatical, etc.). Beginning in 2021, the inspection criteria for selecting reciprocity activities to inspect changed to the new risk-based criteria.

This risk-based approach to selecting reciprocity inspections was captured in the Reciprocity & Inspection Procedures. A draft of this procedure was implemented for the 2021 reciprocity year, but it was formally adopted in early 2022.

16. The following table represents all supervisory accompaniments made during the review period:

Inspector	Supervisor	Category	Date
Sharn Jeffries	Travis Cartoski	Priority 3, Medical	9/25/2018
Sheila Nelson	Travis Cartoski	Priority 3, Accelerator Therapy	9/27/2018
Scott Houchin	Travis Cartoski	Priority 5, Pharmacy Accelerator	9/11/2018
Cliff Harris	Travis Cartoski	Priority 3, Medical I-131 < 33 mCi	8/27/2018
Caleb Smith	Travis Cartoski	Priority 2, Blood Irradiators	9/6/2018
Travis Cartoski	David Crowley	Priority 1, Industrial Radiography	10/9/2018
Sheila Nelson	Travis Cartoski	Priority 1, IR/PT37	7/22/2019
Scott Houchin	Travis Cartoski	Priority 3, Academic Broad	11/20/2019
Caleb Smith	Travis Cartoski	Priority 2, Blood Irradiator/PT37	10/29/2019
Ken Bugaj	Travis Cartoski	Priority 3, Medical, Diagnostic	3/4/2020

Ken Bugaj	Travis Cartoski	Priority 1, IR/PT37	2/11/2021
Allen Howe	Travis Cartoski	Priority 3, Medical Diagnostic	9/9/2021
Tawny Morgan	Travis Cartoski	Priority 1, IR/PT37	7/27/2021
Caleb Smith	Travis Cartoski	Priority 5, Lab	6/4/2021
Scott Houchin	Travis Cartoski	Priority 2, Medical 1000 Uses	2/11/2021
Travis Cartoski	David Crowley	Priority 4, Research Lab	12/17/2021

The Program performed limited accompaniments in 2019 and 2020 due to staff leaving the program before conducting the accompaniments for that individual, but also due to COVID-19.

17. The Program utilizes the NIST traceable services of AKM Calibrations and Ludlum Measurements, Inc. to calibrate our instrumentation. All Instrumentation is calibrated annually on a cyclical basis to ensure maximum operational capabilities for the Program. All instrumentation is currently calibrated and there have been no lapses in calibration. The Program itself has no laboratory capabilities. If the need for laboratory analysis arises, items are sent to the State Laboratory of Public Health.

The Program maintains the following instrumentation calibrated for routine use:

- (12) – Ludlum 26-1 Friskers with Dose Equivalent Filters.
- (12) – Ludlum 9-3 Ion Chambers.
- (12) – Thermo Scientific RadEye SPRDs.
- (15) – Arrow-Tech Pocket Dosimeter 0-200mR.
- (3) – Ludlum 9-4 Ion Chambers.
- (3) – Ludlum 3001 Multi-Detector Digital Survey Meter with detectors.
 - (3) - 44-116 (Beta Scintillation Detector)
 - (3) - 43-90 (Alpha Scintillation Detector)
 - (3) - 44-10 (Low-Level Wide-Energy Gamma Detector)

IV. TECHNICAL QUALITY OF LICENSING ACTIONS

18. The Program regulates 526 radioactive material specifically licensed facilities as of April 6, 2022.

19. The following actions (terminations, decommissioning, bankruptcy, or renewals) occurred throughout the review period for major, unusual, or complex licensees:

License Number:	License Name:	Category of License:	Action Type:
032-1781-1	Triangle Veterinary Emergency Center, PLLC	Veterinary	(Amendment #0)New License-Use of Synovetin(Sn177m)
026-1514-1	Northgate Animal Hospital, P.A. d/b/a Riverbark	Veterinary	Amendment(#4) Add use of Synovetin(Sn177m)

060-0014-3	Charlotte–Mecklenburg Hospital Authority	Broad Scope Medical	Amendment(#163) Add use of Copper 67(Cu-67) for therapeutic use
060-0014-3	Charlotte–Mecklenburg Hospital Authority	Broad Scope Medical	Amendment(#160) Add use of I-131 for MIBG treatment
060-0014-3	Charlotte–Mecklenburg Hospital Authority	Broad Scope Medical	Amendment(#159) Add use of Lu-177 for cancer treatment
034-0158-1	Wake Forest University Health Sciences and	Broad Scope Medical	Amendment(#143) Add use of Lu-177 for the treatment of neuroendocrine tumors in adults
078-0372-1	Southeastern Health	Medical	Amendment(#67) Add use of Lu-177 for the treatment of neuroendocrine tumors in adults
065-0794-11	Cardinal Health 414, LLC	Nuclear Pharmacy	Amendment(#19) Ge-68 / Ga-68 generator
065-0794-11	Cardinal Health 414, LLC	Nuclear Pharmacy	Amendment(#13) Add Lu-177
060-1203-2	Shertech Pharmacy Charlotte, LLC	Nuclear Pharmacy	Amendment(#23) Ge-68 / Ga-68 generator and Lu-177

20. The Program granted exemptions for a limited time to allow deferment of all activities related to radioactive materials audits including inspections, inventory, instrument calibrations, and fingerprinting renewals (if applicable) for labs that were closed temporarily due to COVID-19 and unable to perform functions related to regulated requirements. This was for two broad scope licensees. The first exemption was granted March 2020, and the last exemptions was issued December 2020. The last exemption expired on February 1, 2021. The duration of each exemption was 60 days

21. The Program has made no changes to our written licensing program during this review period.

22. As of April 6, 2022, there are no license renewals pending for more than one year.

V. TECHNICAL QUALITY OF INCIDENTS AND ALLEGATIONS

23. None as of April 6, 2022.

24. No changes occurred during this period.

C. NON-COMMON PERFORMANCE INDICATORS

I. COMPATIBILITY REQUIREMENTS

25. North Carolina General Statute (NCGS) 104E is the legislative basis for the Program's authority to regulate possession and use of radioactive material.

26. The Program has a "sunset" law, NCGS 150B, known as the Administrative Procedures Act. That Act imposes a periodic review of all State rules and sets them to expire every ten (10) years unless they are re-adopted. Due to the complexity of re-adopting all of the radiation protection rules, the Program has until February 28, 2027 to complete the re-adoption process.

27. Outstanding items from the regulation table are summarized below:

RATS ID:	Date Due for Adoption:	Submitted by NC:	NRC Comments:	Notes to Maintain or Address:
2001-1	2/16/2004	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 31 – 10/1/25 Part 32 – 5/1/25
2002-2	4/05/2005	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 20 – 10/1/25 Part 32 – 5/1/25 Part 35 – 10/1/24
2007-1	10/29/2010	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 32 – 5/1/25 Part 35 – 10/1/24
2007-2	12/17/2010	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 31 – 10/1/25 Part 32 – 5/1/25 Part 150 – 10/1/25
2007-3	11/30/2010	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 20 – 10/1/25 Part 30 – 10/1/25 Part 31 – 10/1/25 Part 32 – 5/1/25 Part 33 – 5/1/25 Part 35 – 10/1/24 Part 61 – 10/1/23 Part 150 – 10/1/25
2008-1	2/15/2011	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 19 – 10/1/25 Part 20 – 10/1/25

RATS ID:	Date Due for Adoption:	Submitted by NC:	NRC Comments:	Notes to Maintain or Address:
2011-1	12/17/2015	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 20 – 10/1/25 Part 30 – 10/1/25 Part 40 – 5/1/25 Part 70 – 5/1/25
2011-2	11/14/2014	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 36 – 5/1/24 Part 39 – 10/1/22 Part 40 – 5/1/25 Part 70 – 5/1/25 Part 150 – 10/1/25
2012-4	10/23/2015	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 31 – 10/1/25 Part 32 – 5/1/25 Part 40 – 5/1/25 Part 70 – 5/1/25
2013-1	3/19/2016	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 20 – 10/1/25 Part 30 – 10/1/25 Part 32 – 5/1/25 Part 33 – 5/1/25 Part 34 – 10/1/23 Part 35 – 10/1/24 Part 36 – 5/1/24 Part 37 – 10/1/23 Part 39 – 10/1/22 Part 71 – 5/1/25
2013-2	8/27/2016	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 40 – 5/1/25 Part 70 – 5/1/25
2015-1	1/26/2018	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Date is: Part 70 – 5/1/25
2015-2	1/28/2018	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 37 – 10/1/23

RATS ID:	Date Due for Adoption:	Submitted by NC:	NRC Comments:	Notes to Maintain or Address:
				Part 150 – 10/1/25
2015-3	8/15/2020	Final Regulations	Comments on Regulations	In Periodic Rule Review. Planned Eff. Date is: Part 71 – 5/1/25
2018-1	01/14/2022			In Periodic Rule Review. Planned Eff. Dates are: Part 30 – 10/1/25 Part 32 – 5/1/25 Part 35 – 10/1/24
2018-2	12/21/2021			In Periodic Rule Review. Planned Eff. Dates are: Part 37 – 10/1/23 Part 40 – 5/1/25 Part 70 – 5/1/25 Part 71 – 5/1/25
2018-3	07/30/2022			In Periodic Rule Review. Planned Eff. Dates are: Part 34 – 10/1/23 Part 37 – 10/1/23 Part 71 – 5/1/25
2019-1	12/18/2022			In Periodic Rule Review. Planned Eff. Date is: Part 37 – 10/1/23
2019-2	12/30/2022			In Periodic Rule Review. Planned Eff. Dates are: Part 37 – 10/1/23 Part 40 – 5/1/25 Part 71 – 5/1/25 Part 150 – 10/1/25
2020-1	06/16/2023			In Periodic Rule Review. Planned Eff. Dates are: Part 34 – 10/1/23 Part 36 – 5/1/24 Part 39 – 10/1/22
2020-2	08/17/2023			In Periodic Rule Review. Planned Eff. Date is: Part 35 – 10/1/24
2020-3	11/16/2023			In Periodic Rule Review. Planned Eff. Dates are: Part 19 – 10/1/25 Part 20 – 10/1/25 Part 30 – 10/1/25 Part 34 – 10/1/23 Part 35 – 10/1/24

RATS ID:	Date Due for Adoption:	Submitted by NC:	NRC Comments:	Notes to Maintain or Address:
				Part 40 – 5/1/25 Part 70 – 5/1/25 Part 71 – 5/1/25
2021-1	09/08/2024			In Periodic Rule Review. Planned Eff. Dates are: Part 20 – 10/1/25 Part 32 – 5/1/25 Part 35 – 10/1/24 Part 37 – 10/1/23 Part 40 – 5/1/25 Part 70 – 5/1/25
2021-2	12/30/2024			In Periodic Rule Review. Planned Eff. Dates are: Part 37 – 10/1/23 Part 40 – 5/1/25 Part 71 – 5/1/25

The rule review process required by NCGS 150B began mid-2018 and ended in July 2019 when the Office of Administrative Hearings notified the Department and the Radiation Protection Commission (RPC) that the report required by NCGS 150B was approved by the Rules Review Commission. During the rule review process, all rulemaking ceased so as not to complicate matters. As noted in Item 26, NCGS 105B requires that all state rules be readopted.

NCGS 105B also required a change in how the RPC writes rules. Prior to the rule review process, the RPC copied the text from 10 CFR, made whatever changes it deemed necessary, and placed that text into rules that then went through the rule adoption process. Repeating the text of a federal regulation is no longer permitted, so a complete re-write of the NC rules is required for re-adoption. The Program and the RPC settled on incorporating 10 CFR by reference (to satisfy NCGS 150B) by Part. For example, Rule 10A NCAC 15 .1301, which is in the public comment period at the time of this IMPEP, incorporates 10 CFR Part 39. Other rules are in development, each incorporating different Parts of 10 CFR.

28. Rulemaking begins with the Program recommending that the Radiation Protection Commission (RPC) commence rulemaking. The RPC then directs the Radioactive Materials Control Advisory Committee to do the actual rule making work and to write the rules to be adopted. Depending upon the complexity of the task, this can take one to three years to bring a set of rules to the RPC to be adopted.

Part of the work involved requires getting Department approval of the rule and getting the Office of State Budget to approve a Fiscal Impact Statement (FIS). After the Department has approved of the rules and the FIS is approved, the RPC will vote to approve the rules for adoption.

After the rules are approved for adoption by the RPC they are published for public comment and a public hearing is held. Any public comments are addressed, and rule revisions are made as necessary. If substantive changes are made it requires a second public comment period and public hearing.

Once all public comments are resolved, the RPC will vote to adopt the rules. A Rules Review Commission (RRC) from the Office of Administrative Hearings (OAH) will then vote to adopt the rules by the State. Rules become effective on the first day of the month following adoption by the RRC.

II. SEALED SOURCE AND DEVICE EVALUATION PROGRAM

29. The following SS&D registrations were evaluated during this review period:

SS&D Registry Number	Manufacturer, Distributor, or Custom User	Product type or use	Date Issued	Type of action
NC-1311-S-102-S	CivaTech Oncology, Inc.	(AA) Manual Brachytherapy	10/20/2020	Amendment
NC-0646-D-127-S -> NC-0646-D-833-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	10/27/2020	Inactivation
NC-0646-D-134-S -> NC-0646-D-834-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	10/28/2020	Inactivation
NC-1218-D-104-S to CA-1218-D-104-S	Rapiscan Systems, Inc.	(D) Gamma Gauge	6/12/2020	Transfer
NC-0585-S-102-S	SRB Technologies, Inc.	(W) Self Luminous Light Source	4/14/2021	Correction
NC-0585-D-103-G	SRB Technologies, Inc.	(W) Self Luminous Light Source	6/9/2021	Amendment
NC-0646-D-141-G	Troxler Electronic Laboratories, Inc.	(D) Gamma Gauge (or H?)	3/15/2022	Amendment
NC-0581-D-101-G -> NC-8339-D-801-G	Strandberg Engineering Laboratories	(E) Density Beta Gauge	10/7/2021	Inactivation
NC-1252-D-101-G -> NC-1280-D-801-G	Chemring Sensors and Electronic, Inc.	(N) Ion Generators, Chromatography	1/10/2022	Inactivation
NC-0127-D-101-G -> NC-8043-D-801-S	Houget Duesberg Bosson, S.A. Belgium	(D) Gamme Gauge	11/12/2021	Inactivation
NC-0646-D-129-S -> NC-0646-D-835-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	1/11/2022	Inactivation
NC-0646-D-137-S -> NC-0646-D-8XX-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	In progress.	Inactivation
NC-0646-D-124-S -> NC-0646-D-821-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	In progress.	Inactivation
0646 (105/125/816) -> 816-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	In progress.	Inactivation
NC-0646-D-136-S -> NC-0646-D-8XX-S	Troxler Electronic Laboratories, Inc.	(G) Portable Moisture Density Gauge	In progress.	Inactivation

30. Information on previous questions as they relate to SS&D is as follows:

i. Technical Staffing and Training

- (2) Same as 2. except that members involved with the SS&D Program are denoted with an *.
- (3) Same as 3. except that members involved with the SS&D Program are denoted with an *.
- (4) Same as 4. except that members involved with the SS&D Program are denoted with an *.
- (5) The Program currently has three qualified SS&D reviewers.

- (6) Same as 6. in that the revised training manual also incorporates SS&D qualifications.
- (7) Same as 7. except that members involved with the SS&D Program are denoted with an *.
- (8) There are currently no vacancies relating to the SS&D Program.
- (9) Same as 9.

iv. Technical Quality of Licensing Actions

- (18) As of March 31, 2022, the Program has 18 active SS&D registrations between 5 manufacturing or distributing licensees.
- (19) There was 1 major, unusual or overly complex SS&D registrations that stood out for this IMPEP review period. NC-1311-S-102-S Civatech, requested an amendment to use a currently approved brachytherapy source, for external application.
- (20) No variances in certificate review and approval took place during the review period and no exemptions from regulations were granted, with regard to SS&D.
- (21) The Program relies on NUREG-1556, Volume 3 to ensure SS&D documents are complete and address all the necessary technical details prior to issuing a new or amended certificate. The Program implemented SS&D practices to address the last IMPEP findings and better account for SS&D records. These are stored primarily on the shared drives, but they are also backed up within WBL. The Program recently updated the written procedures to reflect the changes in file storage and accountability, the creation of a SS&D technical lead position, as well as intrastate review cooperation.
- (22) 4 SS&D's are currently in queue for inactivation. No amendments or new SS&D's are in process.

v. Technical Quality of Incident and Allegation Activities

- (23) The Program is not aware of any reportable incidents regarding SS&D items that were not reported.
- (24) Same as 24. All incidents and allegations are performed according to the incidents and allegations procedures.

III. LOW-LEVEL RADIOACTIVE WASTE DISPOSAL PROGRAM (NOT APPLICABLE)

IV. URANIUM RECOVERY PROGRAM (NOT APPLICABLE)

Attachments:

- I.2.(a) NC Executive-Cabinet Chart.pdf
- I.2.(a) DHHS-OChart August 2021.pdf
- I.2.(b) RPS O-Chart April 2022.png
- II. Inspection Data 3-29-2022.xls

2018

<u>Inspector</u>	<u>Supervisor</u>	<u>License</u>	<u>Category</u>	<u>Date</u>
Sharn Jeffries	Travis Cartoski	1167-2, Rex Hospital	Priority 3, Medical	9/25/2018
Sheila Nelson	Travis Cartoski	1457-A1, Accelerator	Priority 3, Accelerator Therapy	9/27/2018
ScottHouchin	Travis Cartoski	1229-A2, PET NET Solutions	Priority 5, Pharmacy Accelerator	9/11/2018
Cliff Harris	Travis Cartoski	0932-1, Burlington MedicalCenter	Priority 3, Medical I-131 < 33 mCi	8/27/2018
Caleb Smith	Travis Cartoski	0274-4, Duke Medical Center	Priority 2, Blood Irradiators	9/6/2018
Travis Cartoski	David Crowley	1466-1, Acuren Inspection	Priority 1, Industrial Radiography	10/9/2018

2019

<u>Inspector</u>	<u>Supervisor</u>	<u>License</u>	<u>Category</u>	<u>Date</u>
Sheila Nelson	Travis Cartoski	0979-1, Roberts Company	Priority 1, IR/PT37	7/22/2019
ScottHouchin	Travis Cartoski	0090-3, NC State	Priority 3, Academic Broad	11/20/2019
Caleb Smith	Travis Cartoski	0014-3, Charlotte Mecklenburg	Priority 2, Blood Irradiator/PT37	10/29/2019

2020

<u>Inspector</u>	<u>Supervisor</u>	<u>License</u>	<u>Category</u>	<u>Date</u>
Ken Bugaj	Travis Cartoski	0585-4, Moore Regional Medical Hospital, Hoke	Priority 3, Medical, Diagnostic	3/4/2020

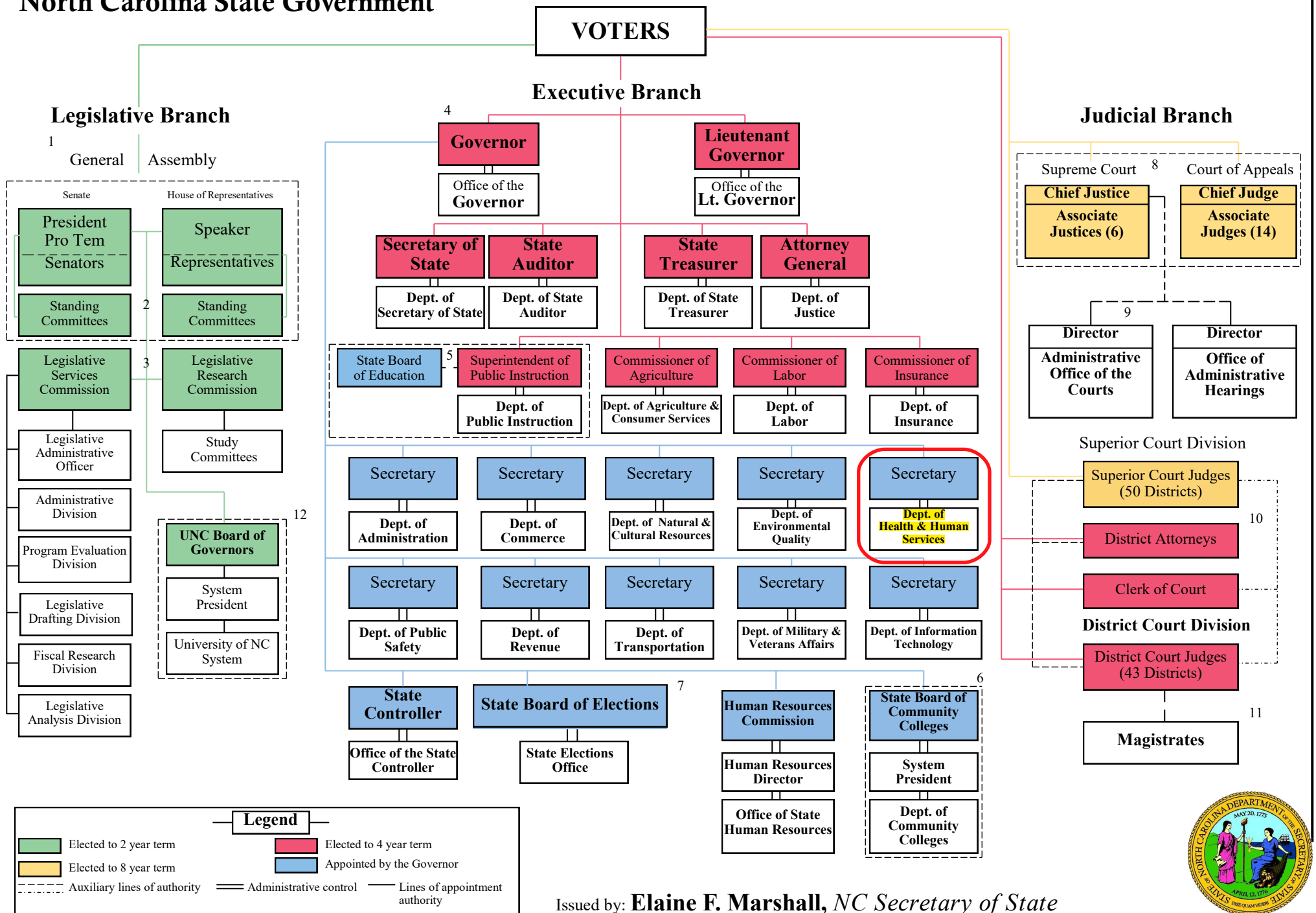
2021

<u>Inspector</u>	<u>Supervisor</u>	<u>License</u>	<u>Category</u>	<u>Date</u>
Ken Bugaj	Travis Cartoski	0922-1, S&ME	Priority 1, IR/PT37	2/11/2021
Allen Howe	Travis Cartoski	1167-10, Rex Healthcare	Priority 3, Medical Diagnostic	9/9/2021
Tawny Morgan	Travis Cartoski	1441-1, Baker Testing	Priority 1, IR/PT37	7/27/2021
Caleb Smith	Travis Cartoski	692-1, Spectrofuge, Corp. of NC	Priority 5, Lab Priority 2, Medical 1000	6/4/2021
Scott Houchin	Travis Cartoski	1542-1, DRI Partners, LLC	Uses	2/11/2021
Travis Cartoski	David Crowley	0760-1, BASF	Priority 4, Research Lab	12/17/2021

2022

None to date

Organizational Chart of North Carolina State Government



Issued by: **Elaine F. Marshall, NC Secretary of State**



Notes of Explanation

Organizational Chart of North Carolina State Government

1 The North Carolina General Assembly is divided into two chambers - the Senate with 50 members and the House of Representatives with 120. The Lieutenant Governor is presiding officer of the Senate.

2 Legislators are appointed to one or more committees within their respective chambers by the presiding officers of their chambers.

3 The President Pro Tempore of the Senate and the Speaker of the House serve on the Legislative Services and Legislative Research Commission. They also appoint five members each from their respective chambers to serve on the Legislative Research Commission and four each to serve on the Legislative Services Commission. The Legislative Services Officer is appointed by the Legislative Services Commission and provides administrative support to the legislators.

4 The Governor and the other nine elected officials of the Executive Branch form the Council of State. The heads of other executive departments, “secretaries,” are appointed by the Governor and serve at the pleasure of the Governor.

5 The State Board of Education has 13 members, with 11 of those members being appointed by the Governor, subject to confirmation by the General Assembly in joint session. The Lieutenant Governor and State Treasurer are *ex officio* members. The Superintendent of Public Instruction is the head of the Department of Public Instruction and is elected by the citizens of North Carolina.

6 The State Board of Community Colleges is not part of the Governor's Cabinet, but ten members of the State Board are appointed by the Governor, and the NC House and Senate each appoint four members. The Lieutenant Governor and State Treasurer are *ex officio* members. The State President of the Community College System is elected by the State Board and serves as the head of the department.

7 The State Board of Elections is an autonomous agency in charge of the administration of elections, and campaign finance.

8 The Chief Justice of the Supreme Court designates one of the Judges of the Court of Appeals as Chief Judge. The Chief Justice also designates one of the District Court Judges in each district as Chief District Court Judge.

9 The Administrative Office of the Courts provides administrative and research assistance to all levels of the Judicial System. The Director of the Administrative Office of the Courts is appointed by the Chief Justice of the Supreme Court.

10 District Attorneys serve as prosecuting officers at both the Superior and District Court levels. The Clerks of Court in each county also serve both courts.

11 Magistrates, one or more in each county, are appointed for two-year terms by the Senior Resident Superior Court Judge in each district and serve under the Supervision of the Chief District Court Judge in their respective districts.

12 While not a part of the Legislative Branch, for purposes of this chart the UNC System Board of Governors is listed under the legislative section because it consists of 32 members elected by the General Assembly. The Board of Governors also includes special members, including the president of the UNC Association of Student Governments, former board chairs and former state governors.

5,000 copies of this public document were printed at a cost of \$528 or \$0.105 per copy.