TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL: EVALUATION OF 10 CFR 35.300 LICENSEE LOCATIONS

Introduction:

The U.S. Nuclear Regulatory Commission (NRC) staff determined the locations of NRC and some Agreement State licensees authorized to use materials under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.300, "Use of unsealed byproduct materials for which a written directive is required." For NRC specific licensees, staff also determined the number of authorized users (AUs) authorized for full use of materials under 10 CFR 35.300 (i.e., "10 CFR 35.300 full AUs") listed on these licenses. This supplemental information document contains maps showing licensee locations in 12 non-Agreement States, the District of Columbia, Puerto Rico, and 14 Agreement States[1]—and when available for NRC licensees, the number of 10 CFR 35.300 full AUs listed on the license.

Discussion:

The intent of this document is to illustrate locations of NRC and Agreement State licensees where radiopharmaceuticals could be provided by AUs. This data was gathered in response to stakeholder concerns regarding patient access to radiopharmaceuticals, including the issue of access disparities in more rural parts of the U.S.

The NRC staff did not draw any conclusions from this data regarding whether the locations of licensees and number of AUs are sufficient to satisfy patient demand for radiopharmaceuticals, and the data did not contribute to the staff's conclusions regarding potential regulatory changes to the training and experience (T&E) requirements. To conduct a thorough evaluation of patient access to radiopharmaceuticals, detailed health care market data would be required. Based on feedback received during the T&E public comment periods, this could include but would not be limited to: data on the number and type of radiopharmaceutical therapies being performed in the U.S.; how many patients forgo radiopharmaceutical therapy due to prohibitive travel distances to the nearest AU or long waiting times to receive therapy (i.e., unmet demand); insurance coverage of radiopharmaceutical therapies, physician reimbursement, and other financial incentives or disincentives; failure of physicians to refer patients for radiopharmaceutical therapy for reasons such as availability of and preference for alternative non-nuclear medicine therapies; and the larger issue of health care access in rural communities. The NRC's medical regulations focus on radiation safety for workers, the public, and patients—consideration of health care market data is outside the scope of this evaluation and the NRC's mission of regulating the safe use of radionuclides.

Mapping Efforts

Figure 1 shows the number of 10 CFR 35.300 AUs listed on NRC specific licenses in NRC-regulated States and territories. Figure 1 illustrates that Alaska, Connecticut, Hawaii, Montana, Puerto Rico, South Dakota, Vermont, and Wyoming have relatively small numbers of AUs listed on licenses in those States and territory. However, many of these States and Puerto Rico have smaller populations and so patient demand may not require more AUs. Additionally, patients in

[1] As of September 30, 2018, Wyoming became the NRC's 38th Agreement State (83 FR 48905; September 28, 2018), however, the NRC retained jurisdiction over commercial nuclear power plants, Federal agencies using certain radioactive materials in the State, and uses of radioactive material other than uranium and thorium milling activities.

smaller States like Connecticut and Vermont may be likely to cross State lines for radiopharmaceuticals (this may not be likely or even possible in larger or more remote States). Figure 1 makes a distinction between "full" and "limited" AUs. "Full" AUs are authorized to administer any radiopharmaceutical under 10 CFR 35.300, and in this dataset, staff defined "limited" AUs as those limited to oral administration of sodium iodide I-131.[2] This "full" and "limited" distinction was considered because patient access concerns refer to access to any parenteral radiopharmaceutical, and accordingly, the staff's evaluation of T&E focuses on the requirements under the alternate pathway, 10 CFR 35.390(b)(1), which, when casework in all categories of radiopharmaceuticals is included, permit an AU to administer all radiopharmaceuticals under 10 CFR 35.300.

To gain a sense of geographic distribution of 10 CFR 35.300 licensees, Figures 2 through 16 map 10 CFR 35.300 licensees in NRC-regulated States and one territory, and Figures 17 through 29 map Agreement State licensees. Thirteen Agreement States responded to a voluntary request for information regarding the location of State licensees authorized to use radiopharmaceuticals requiring a written directive and having at least one full AU listed on the license (RCPD-19-0004; ADAMS Accession No. ML19028A422 [non-public]). The final map in the enclosure, Figure 30, is a composite map of the U.S. showing all available licensee locations. States without color are Agreement States that did not submit licensee data.

The maps include color-coded population density data obtained from the 2010 U.S. Census.[3] Staff included population data to illustrate that 10 CFR 35.300 licensees are mostly located in areas of higher population density. However, as noted above, this observation did not influence the staff's evaluation of the T&E requirements.

Data Limitations

The staff obtained NRC licensee data from the NRC's Web-Based Licensing (WBL) system in November 2018. In spring 2019, the 13 Agreement States that responded to the voluntary request for information pulled their licensee data from their own databases and provided the location data in spreadsheets for the NRC staff to map. While mapping the data, the NRC staff attempted to determine that the mapped locations appeared to be accurate.

The NRC staff did not contact licensees to determine what, if any, radiopharmaceuticals were being administered at their facility. It's important to note that even if a licensee is authorized to use 10 CFR 35.300 materials and a full AU is listed on the license, for reasons outside the purview of this evaluation, a licensee may only provide one type of radiopharmaceutical therapy, such as only oral administration of I-131 for thyroid diseases, or the licensee might not be offering radiopharmaceutical therapies at all. The maps included in this document simply provide geographic locations of facilities that, from a regulatory standpoint, would be permitted to provide any available radiopharmaceutical therapy. Additionally, to obtain a complete picture of geographic distribution of 10 CFR 35.300 licensees, staff would need licensee data for all Agreement States.

[2] NRC specific licenses include this information—names of AUs and their full or limited authorizations. Broad scope licenses do not list AUs.
[3] U.S. Census Bureau, Decennial Census of Population and Housing, 2010 Census (https://www.census.gov/programs-surveys/decennial-census/decade.2010.html).

Figure 1. Number of Full and Limited Authorized Users for 10 CFR 35.300 Materials in NRC-Regulated States

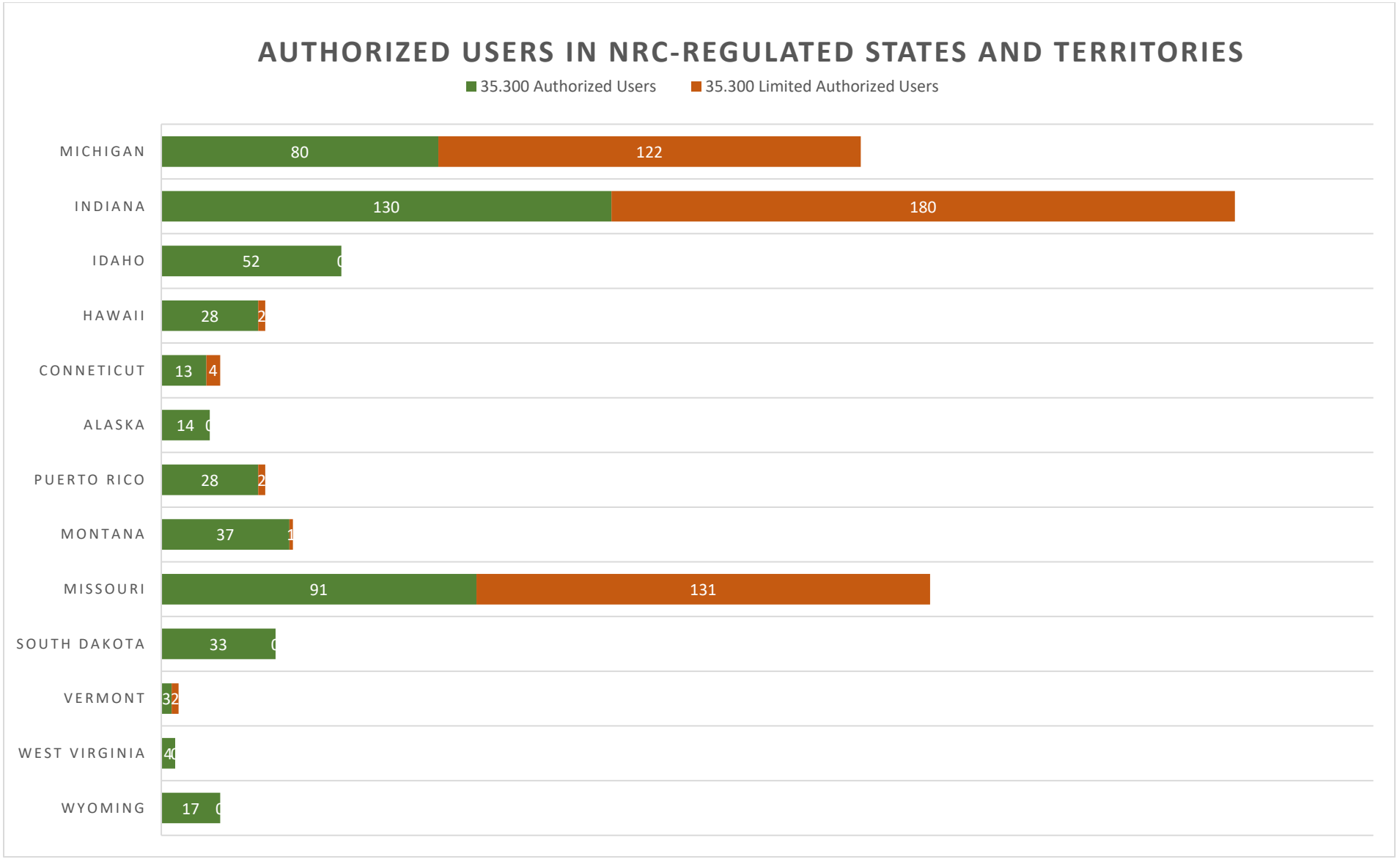


Figure 2. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Alaska

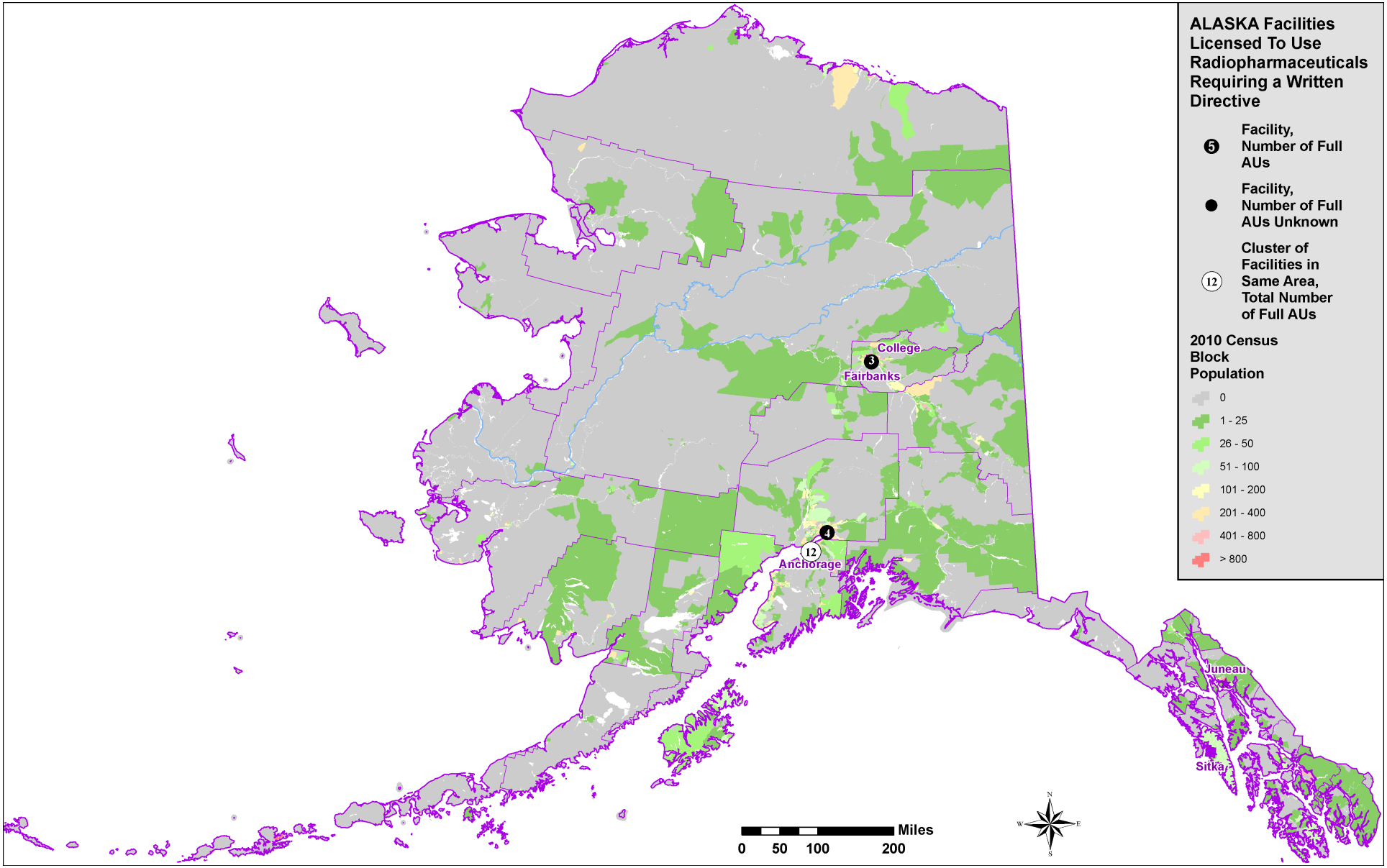


Figure 3. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Connecticut

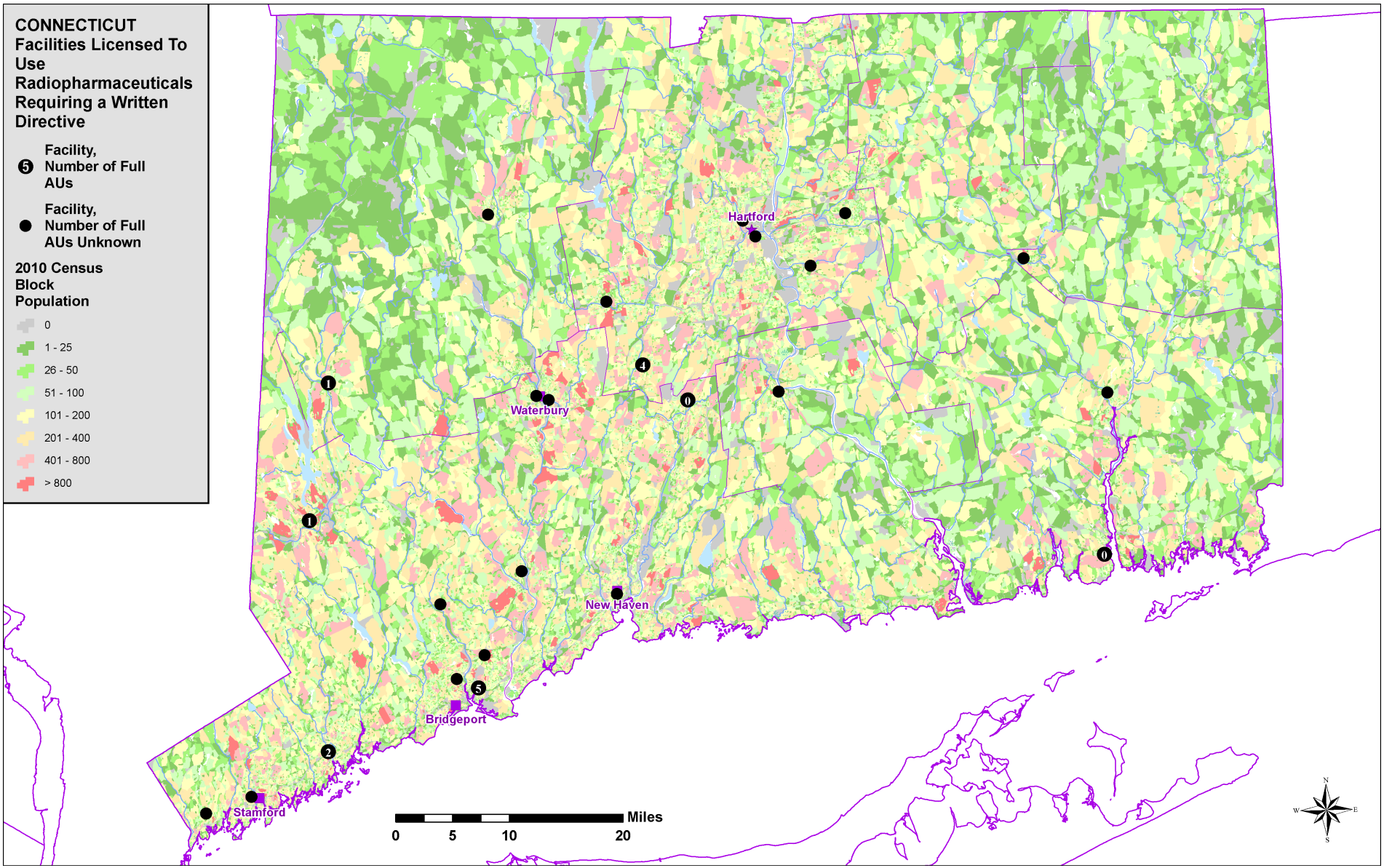


Figure 4. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Delaware

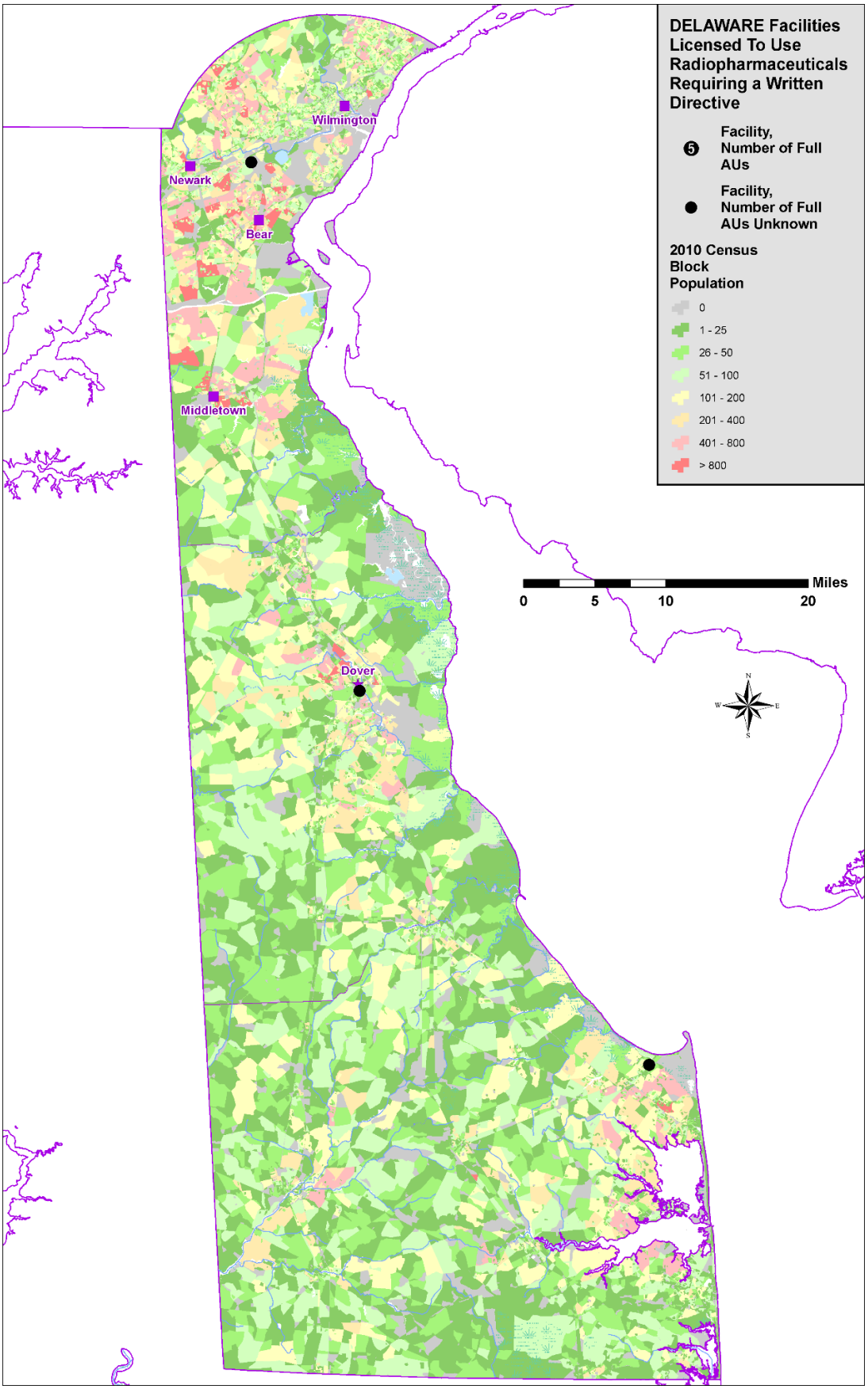


Figure 5. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in the District of Columbia

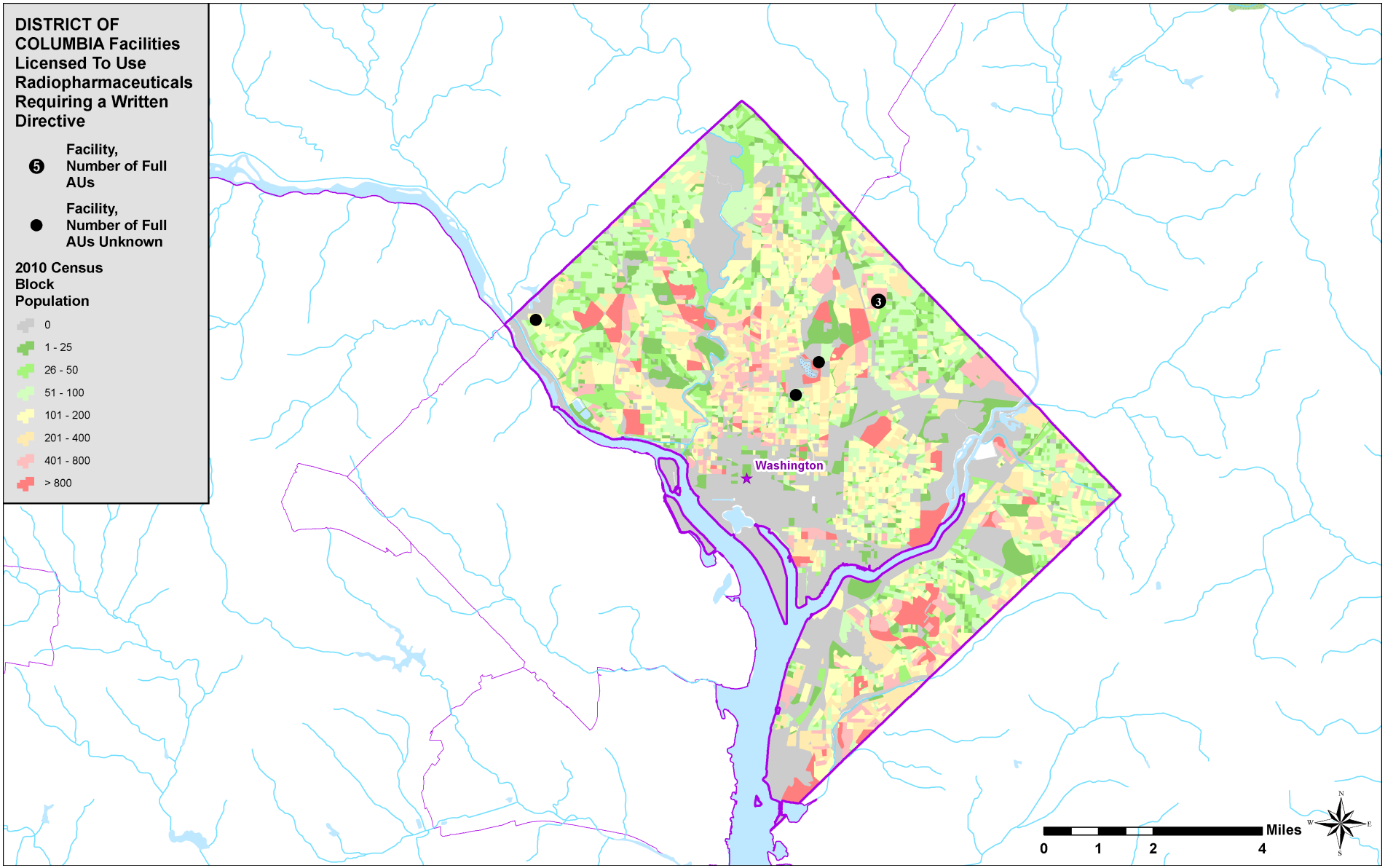


Figure 6. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Hawaii

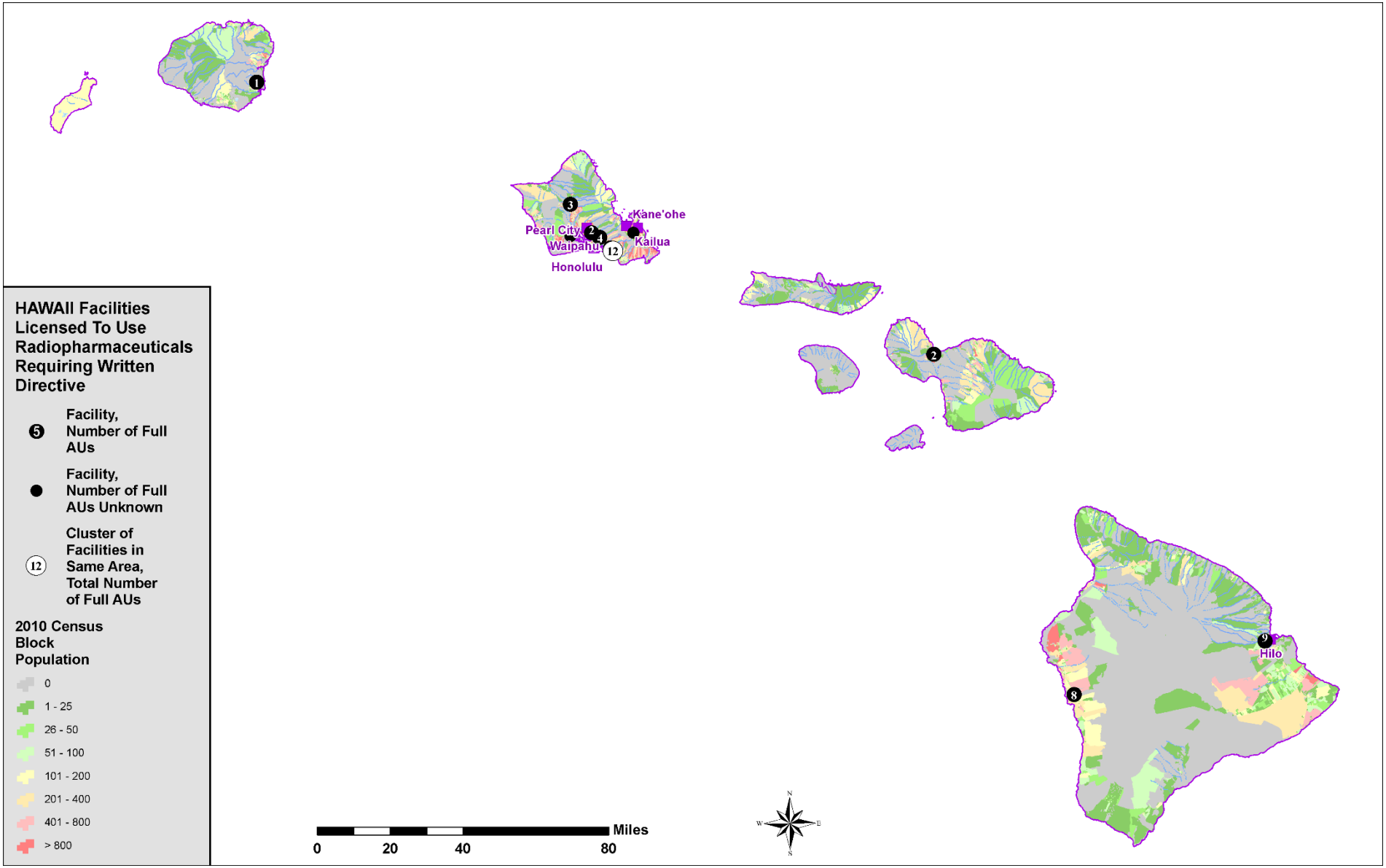


Figure 7. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Idaho

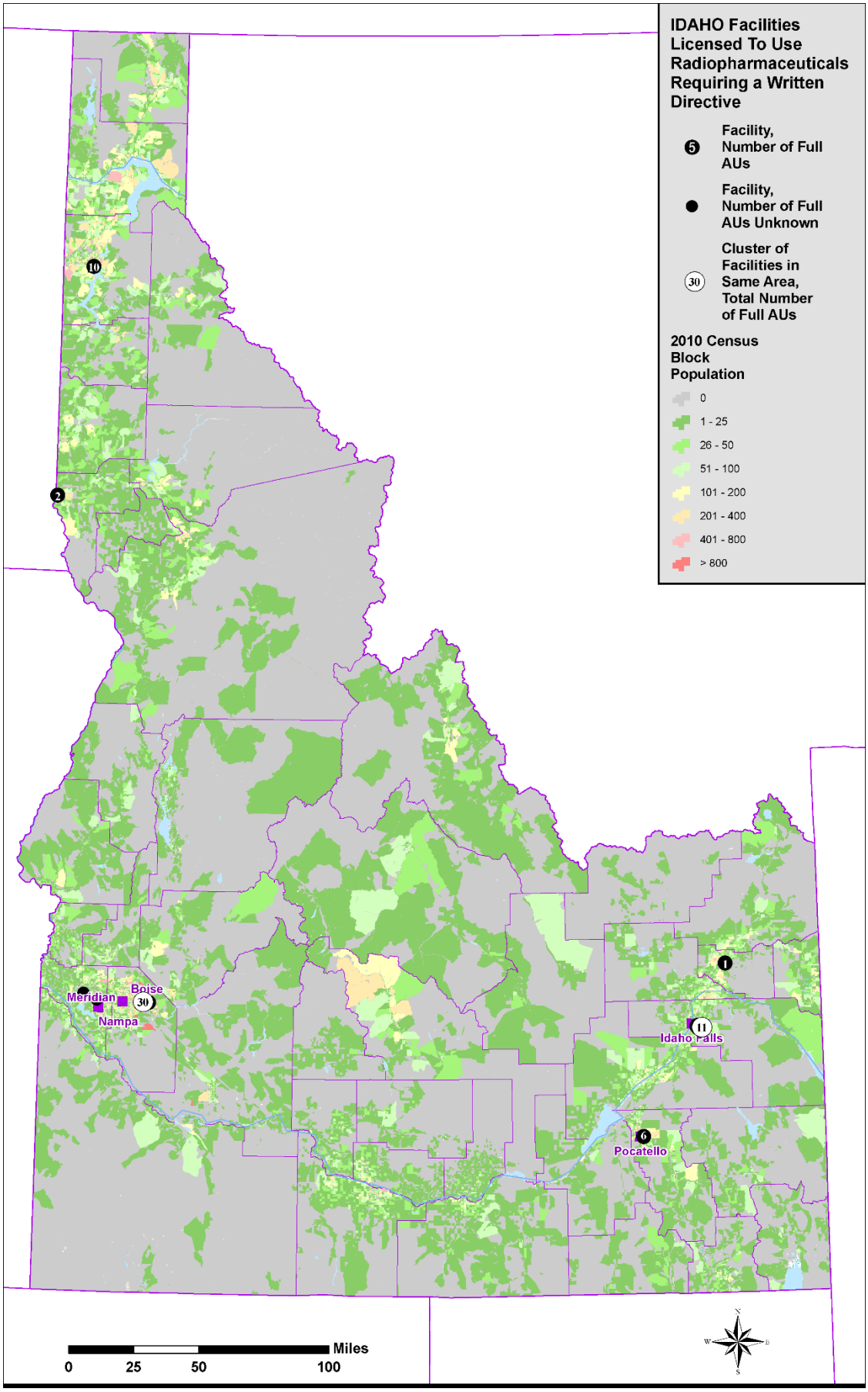


Figure 8. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Indiana

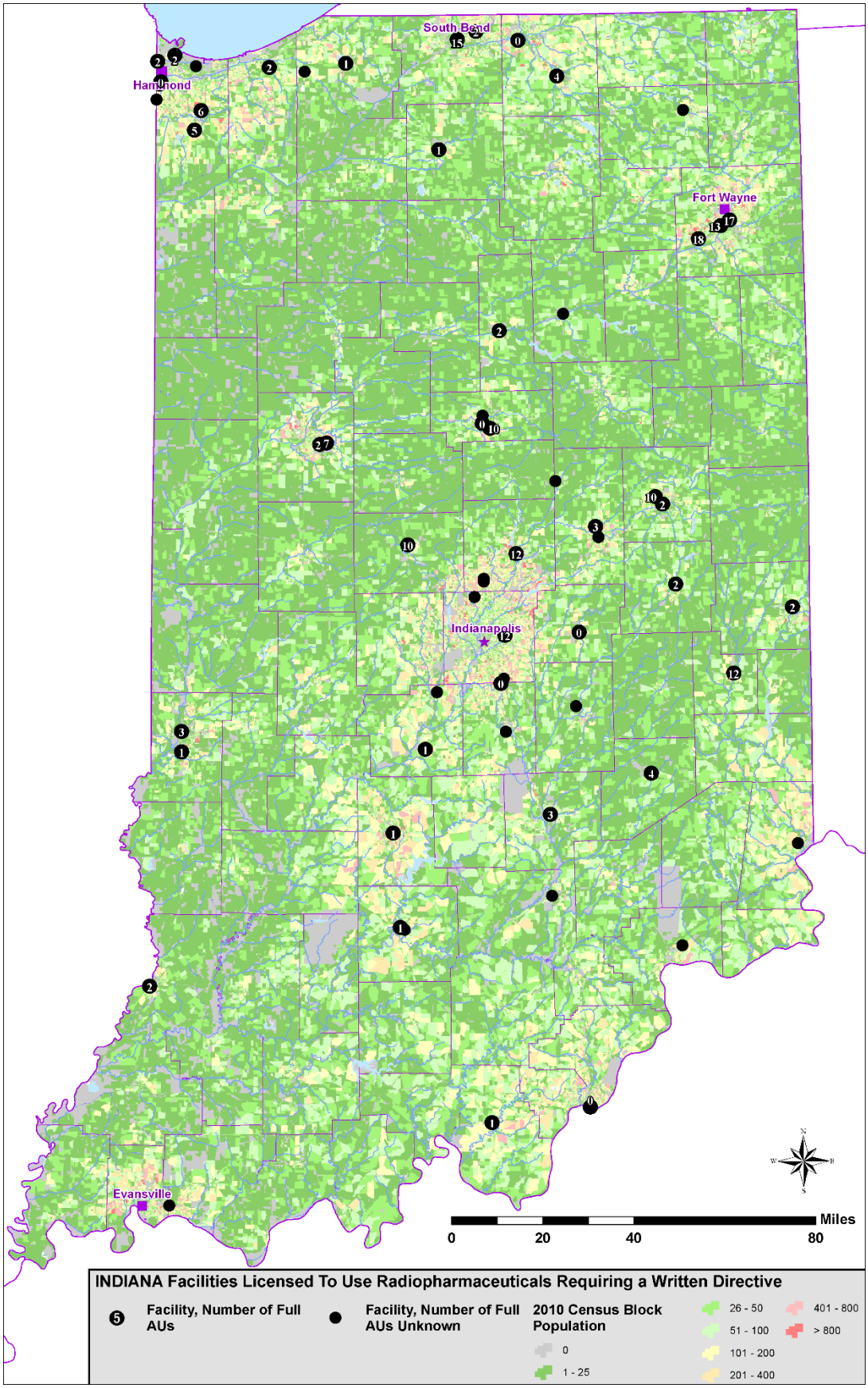


Figure 9. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Michigan

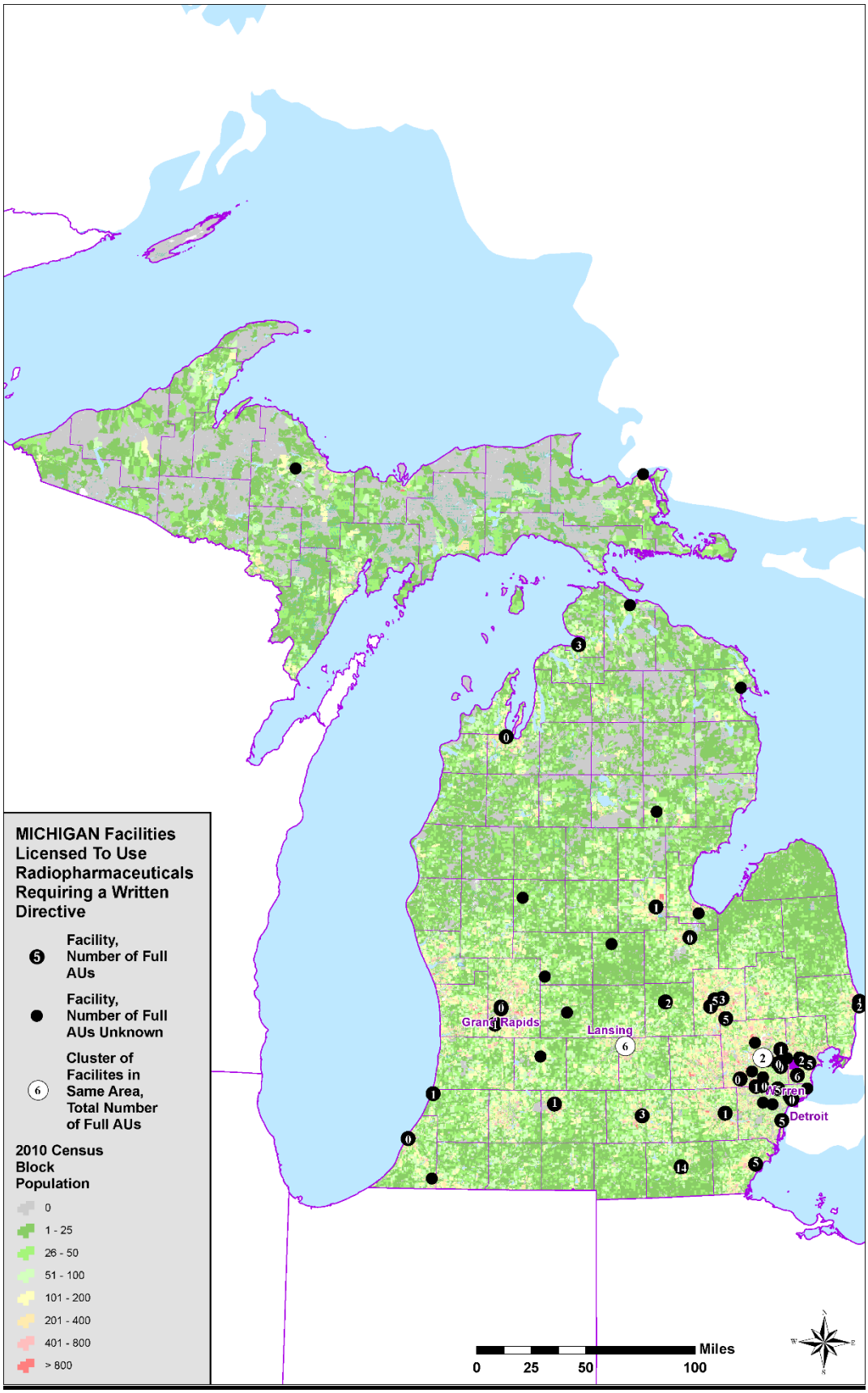


Figure 10. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Missouri

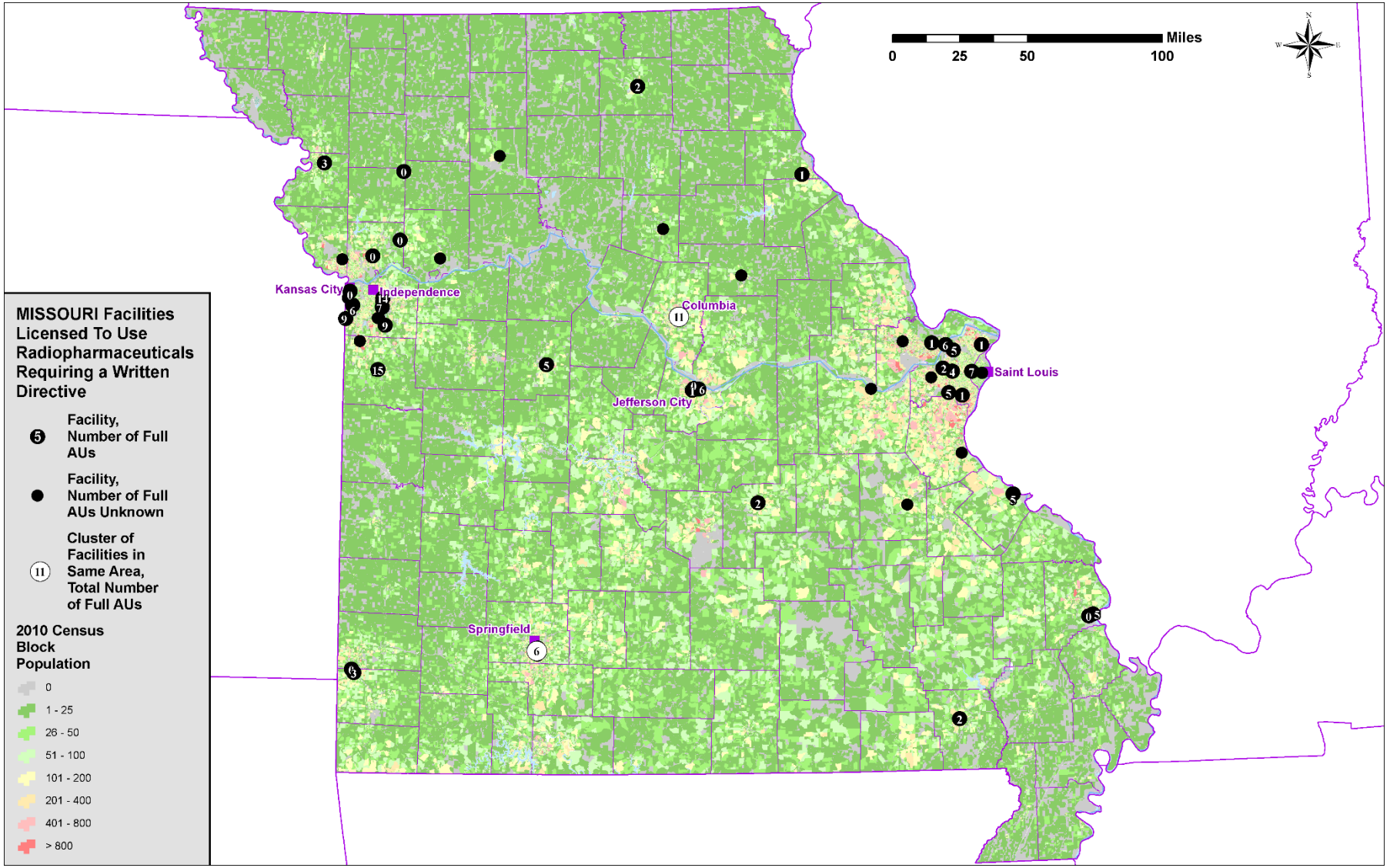


Figure 11. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Montana

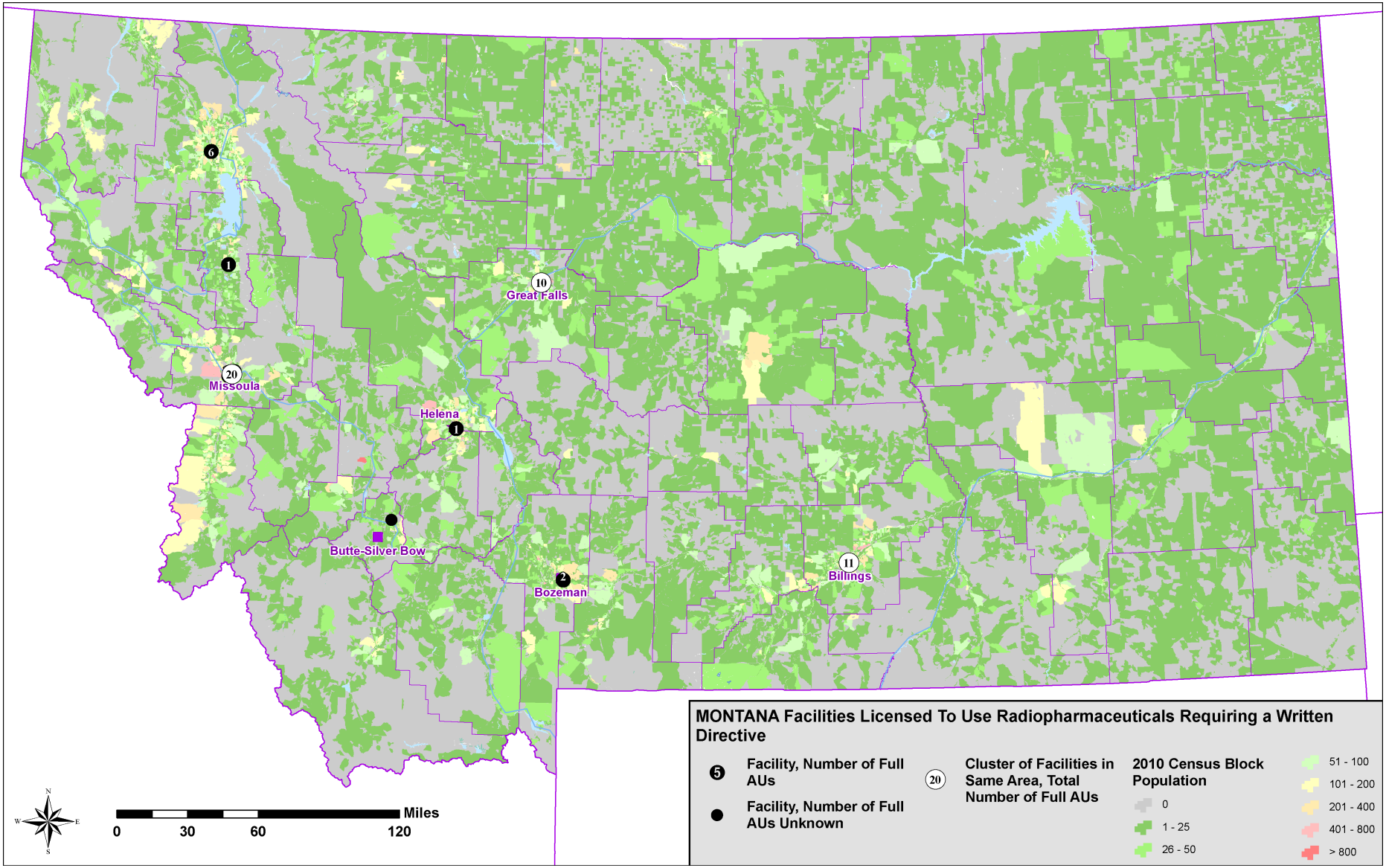


Figure 12. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Puerto Rico

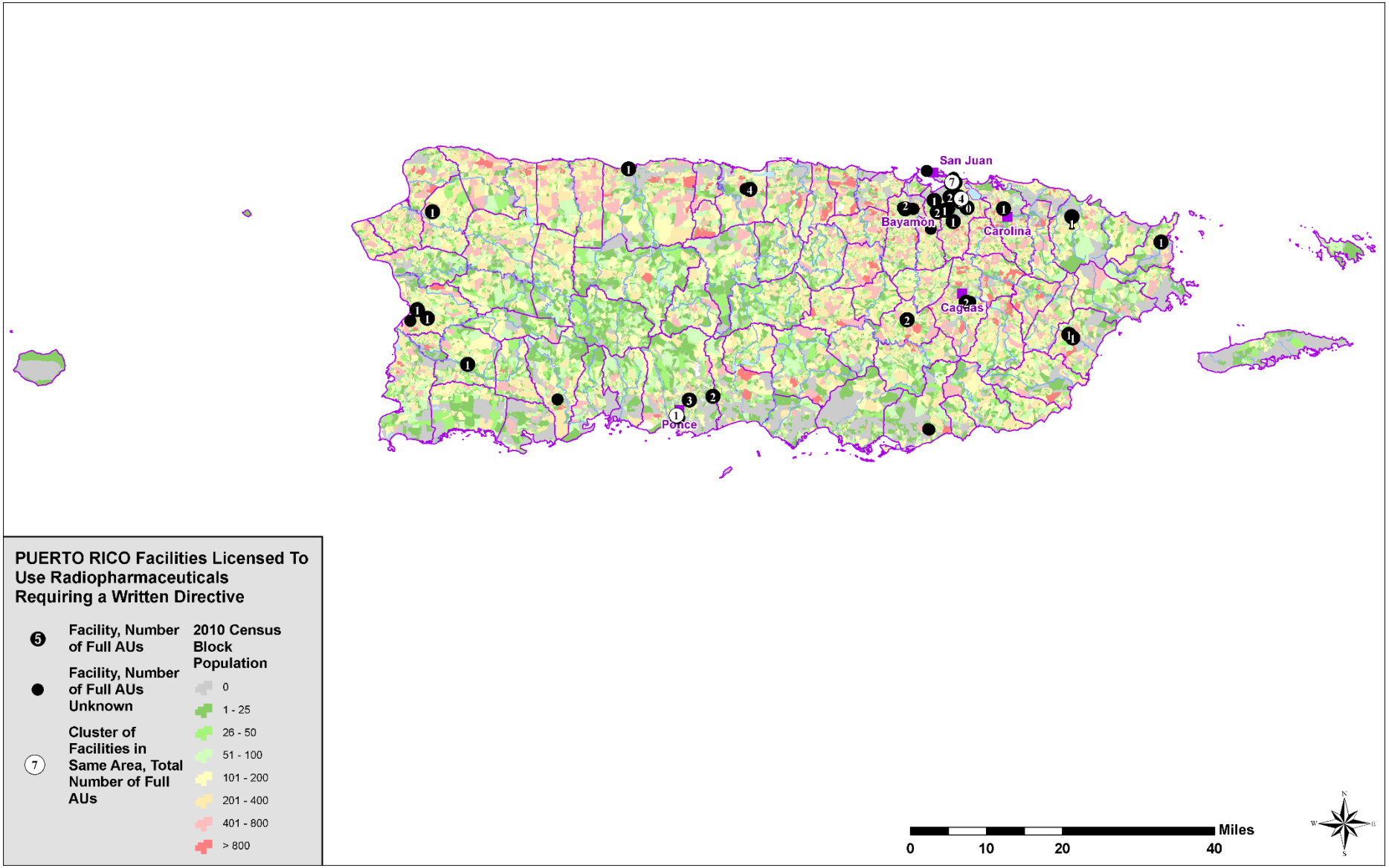


Figure 13. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in South Dakota

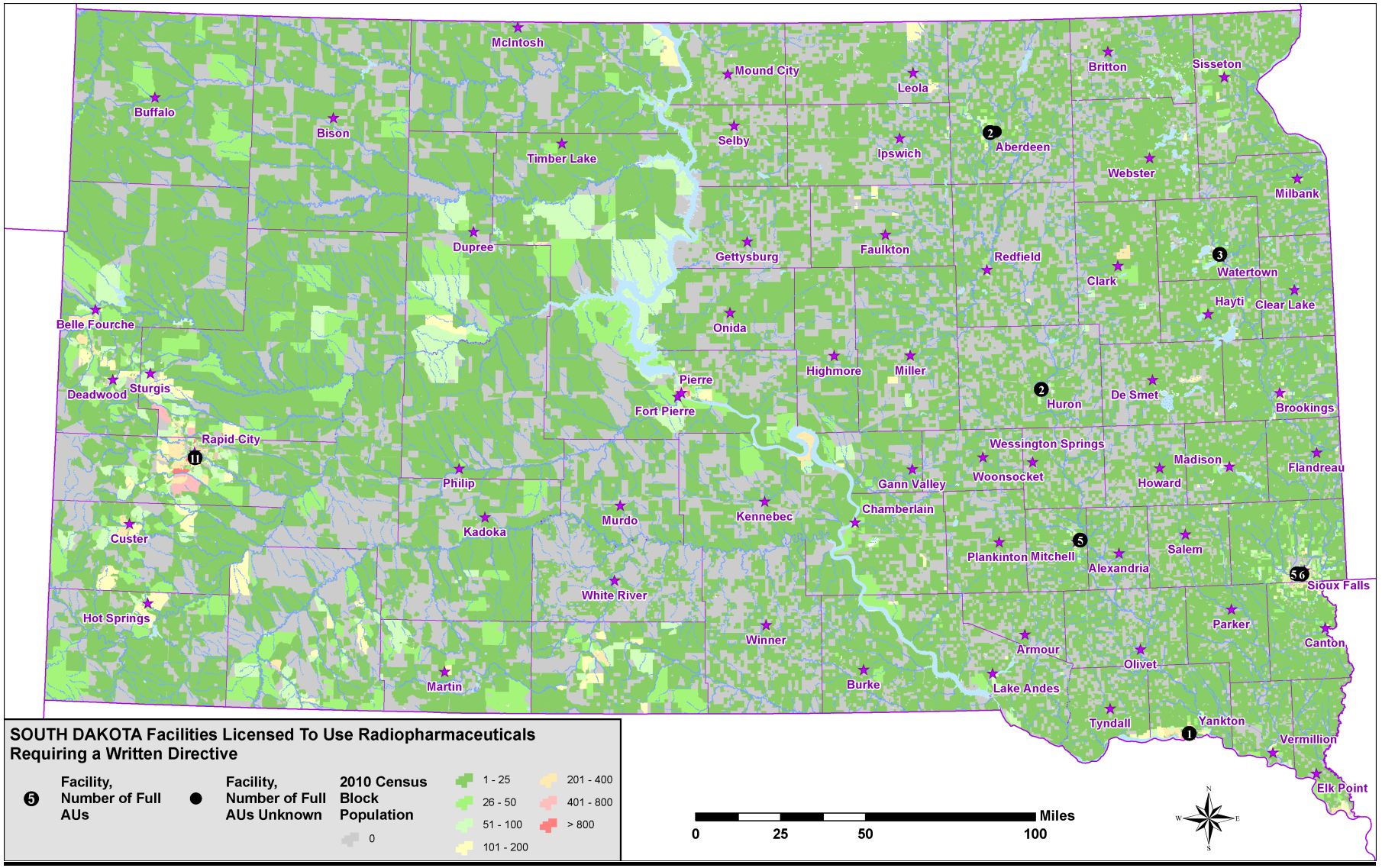


Figure 14. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Vermont

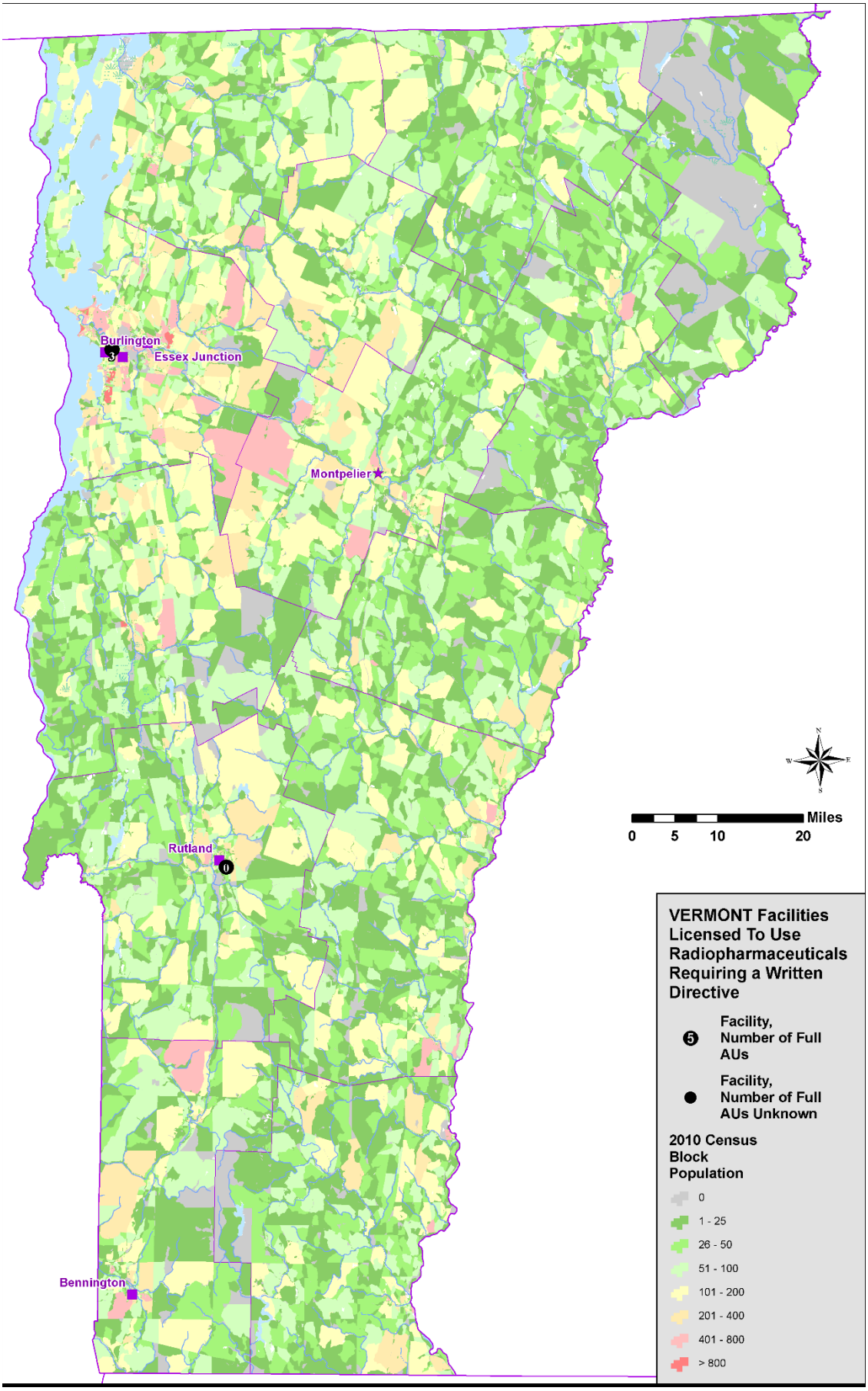


Figure 15. Location of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in West Virginia

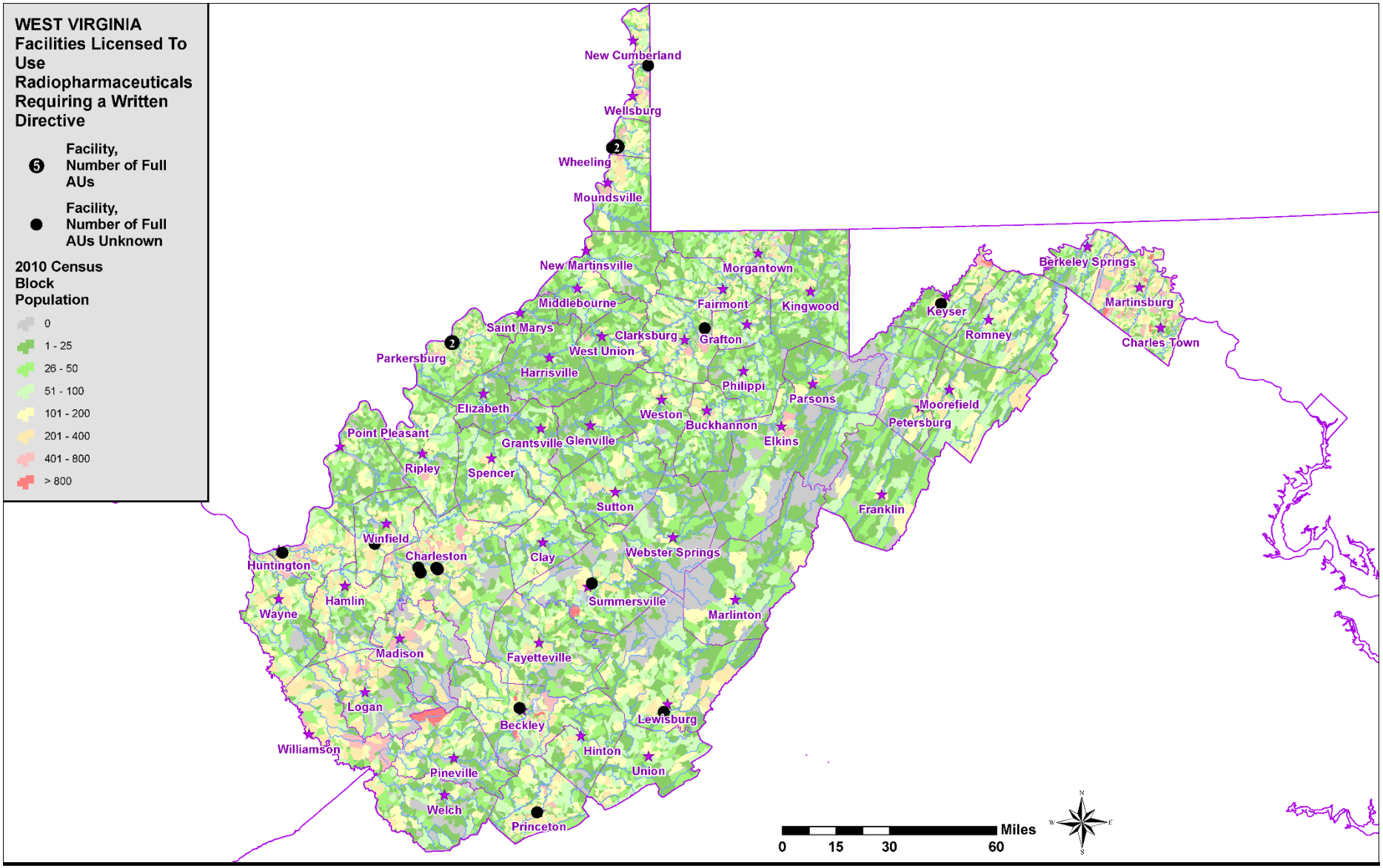


Figure 16. Locations of NRC Licensees Authorized to Use 10 CFR 35.300 Materials in Wyoming

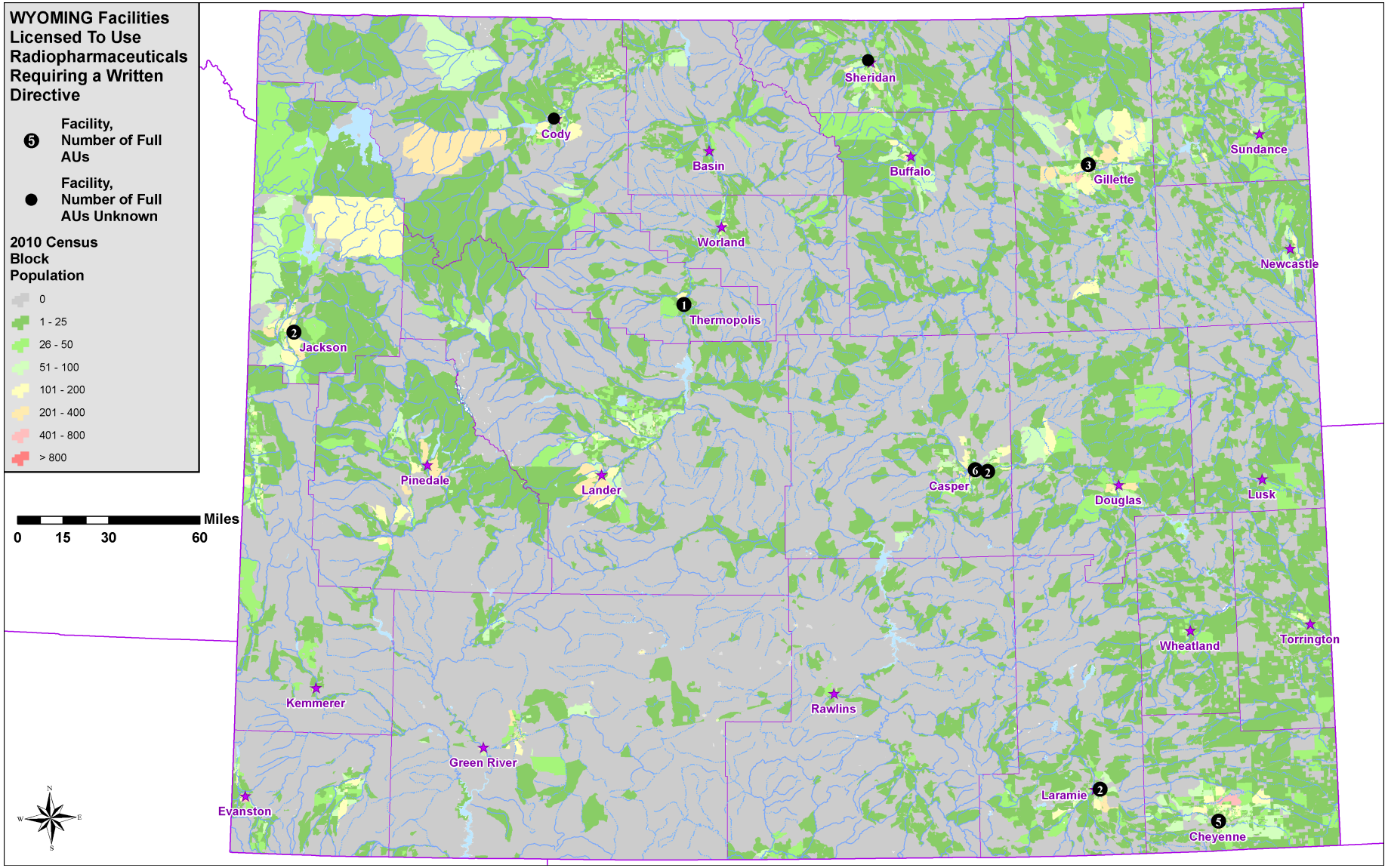


Figure 17. Locations of California Licensees Authorized to Use 10 CFR 35.300 Materials

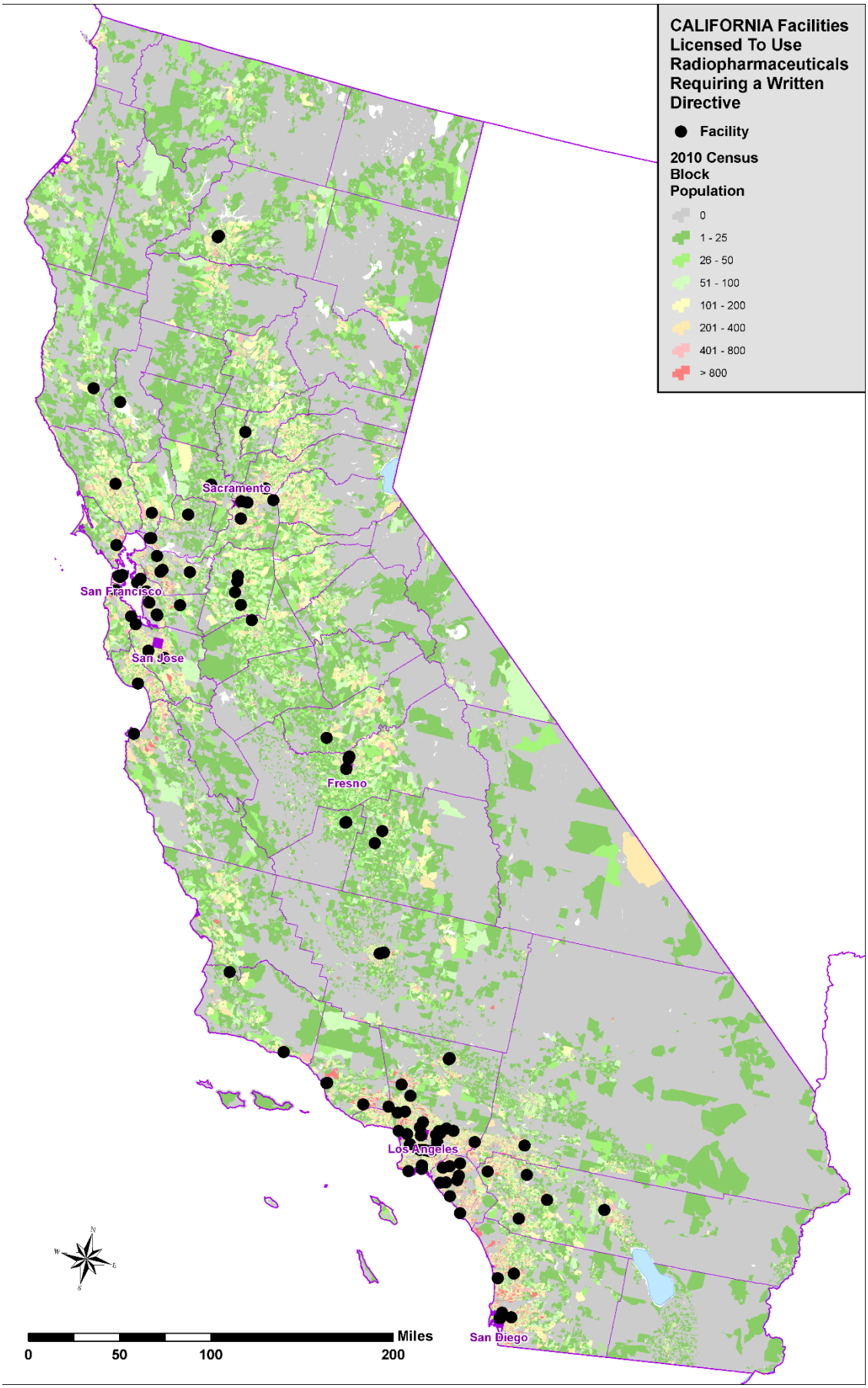


Figure 18. Locations of Colorado Licensees Authorized to Use 10 CFR 35.300 Materials

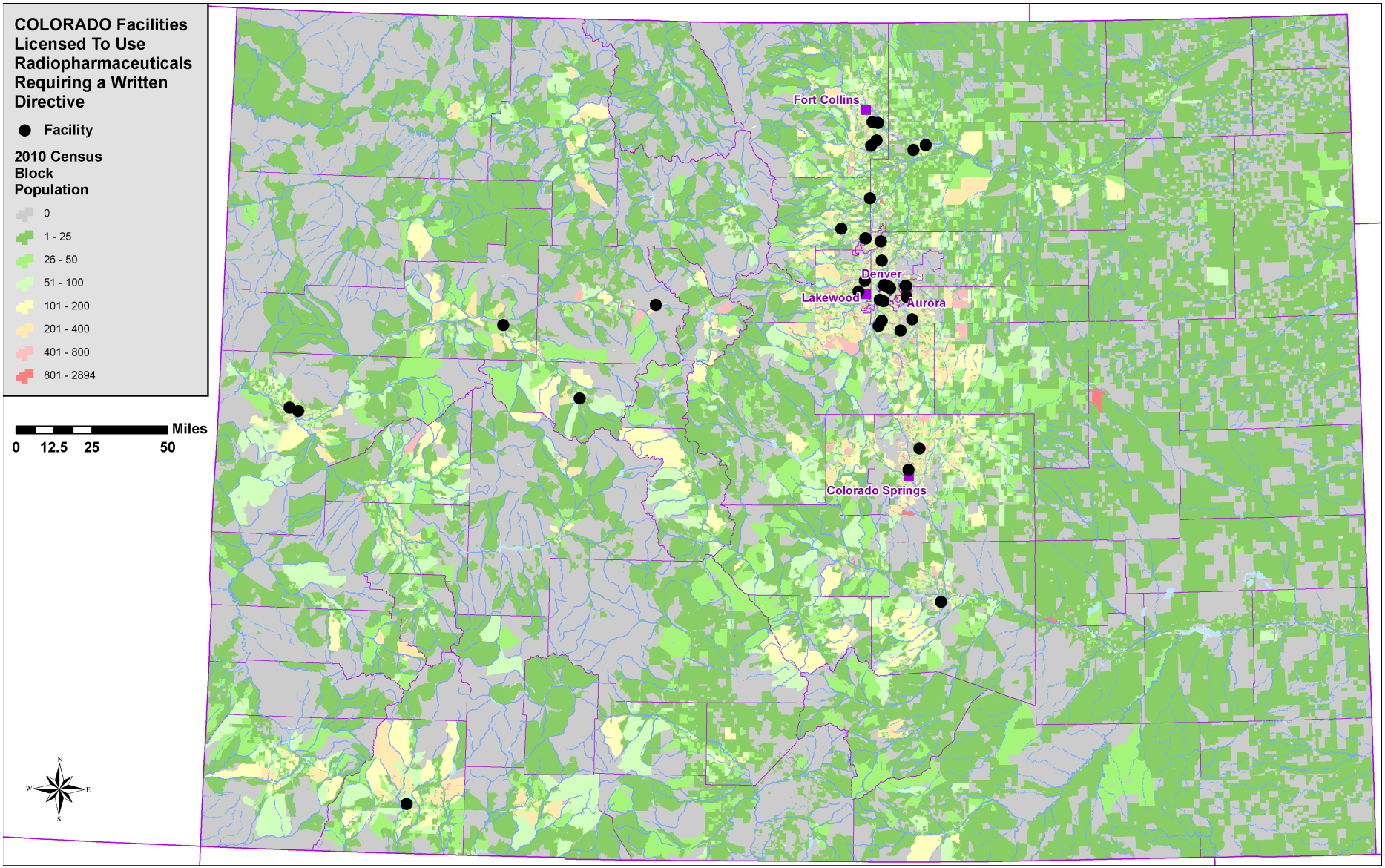


Figure 19. Locations of Florida Licensees Authorized to Use 10 CFR 35.300 Materials

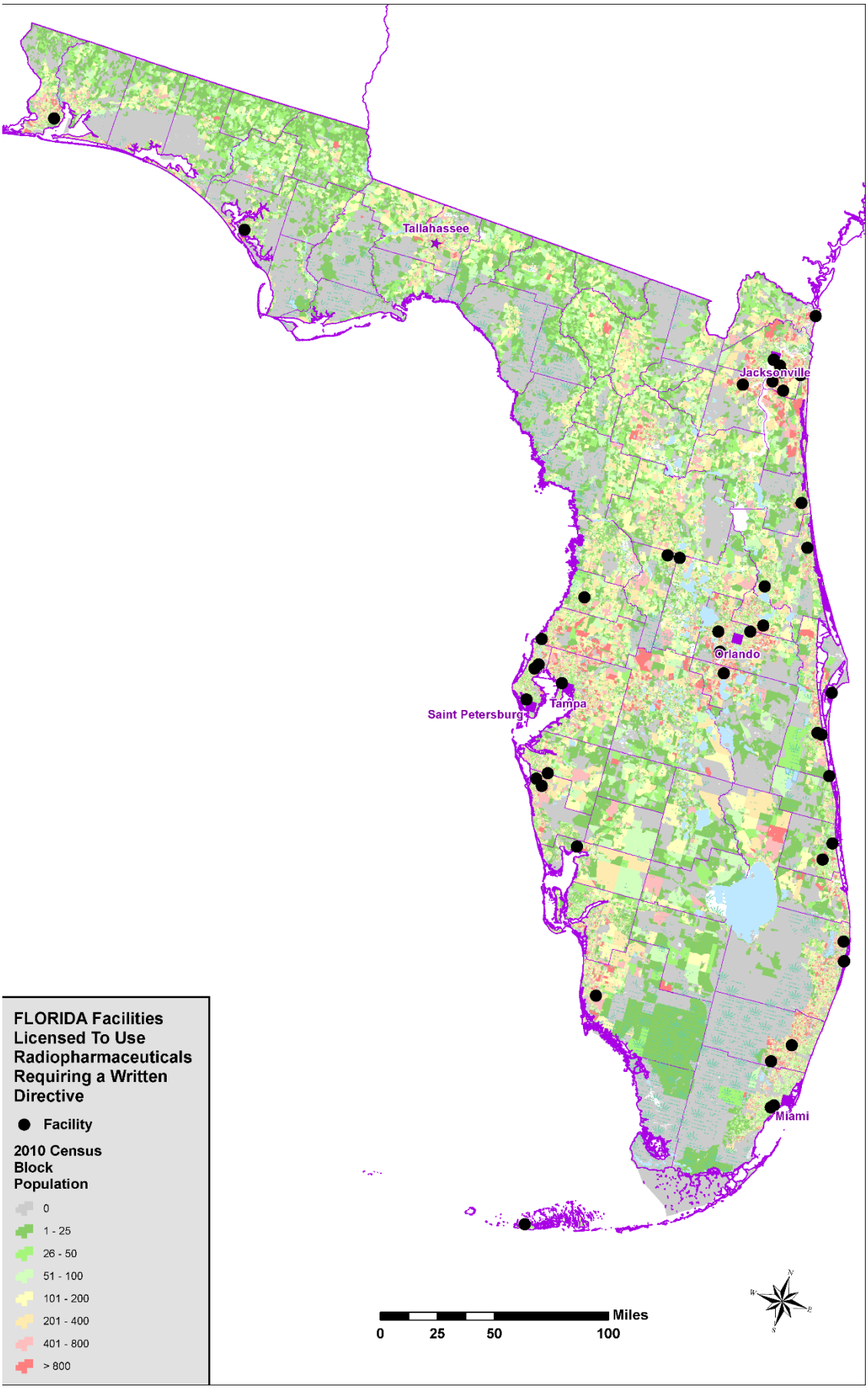


Figure 20. Locations of Illinois Licensees Authorized to Use 10 CFR 35.300 Materials

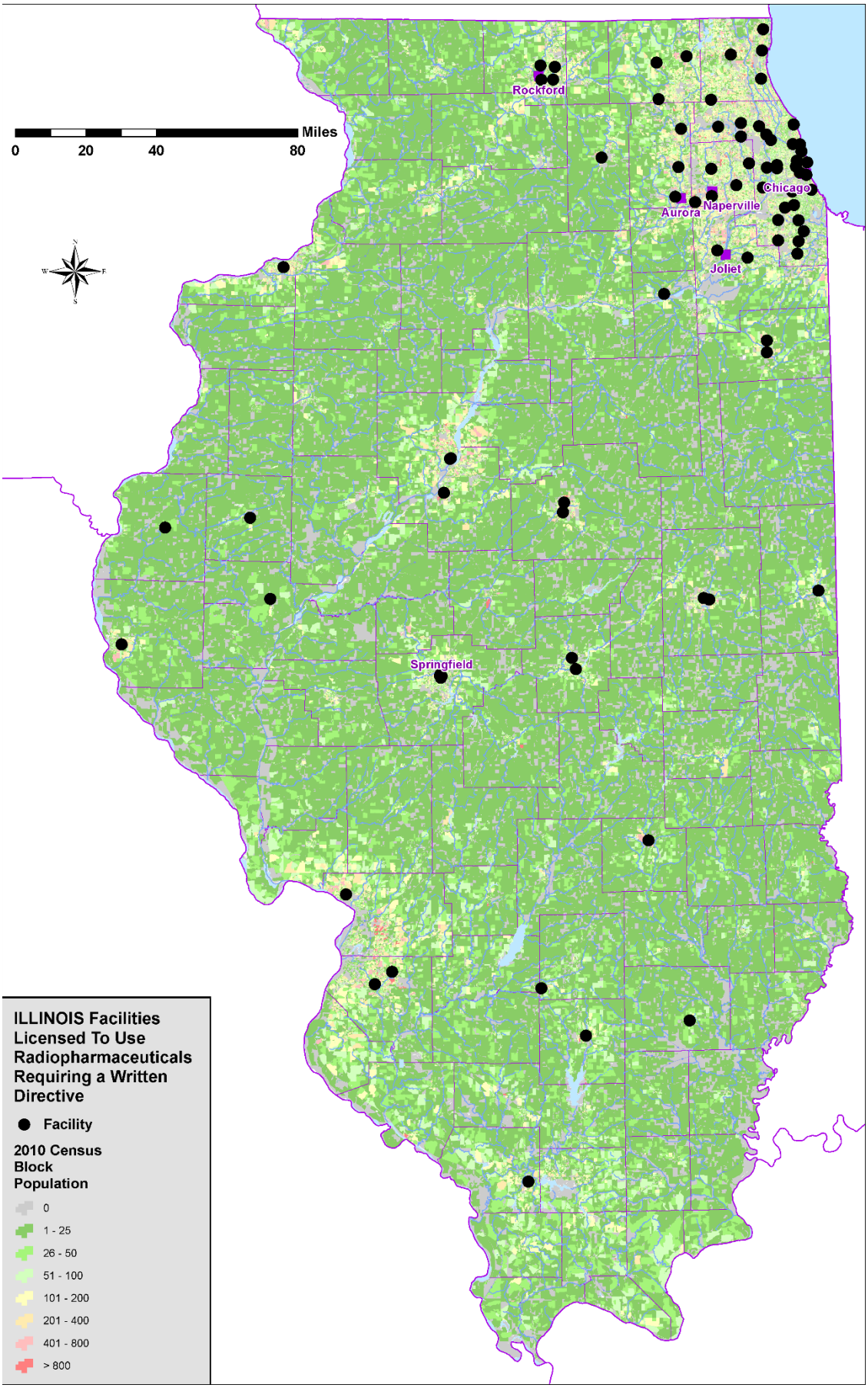


Figure 21. Locations of Iowa Licensees Authorized to Use 10 CFR 35.300 Materials

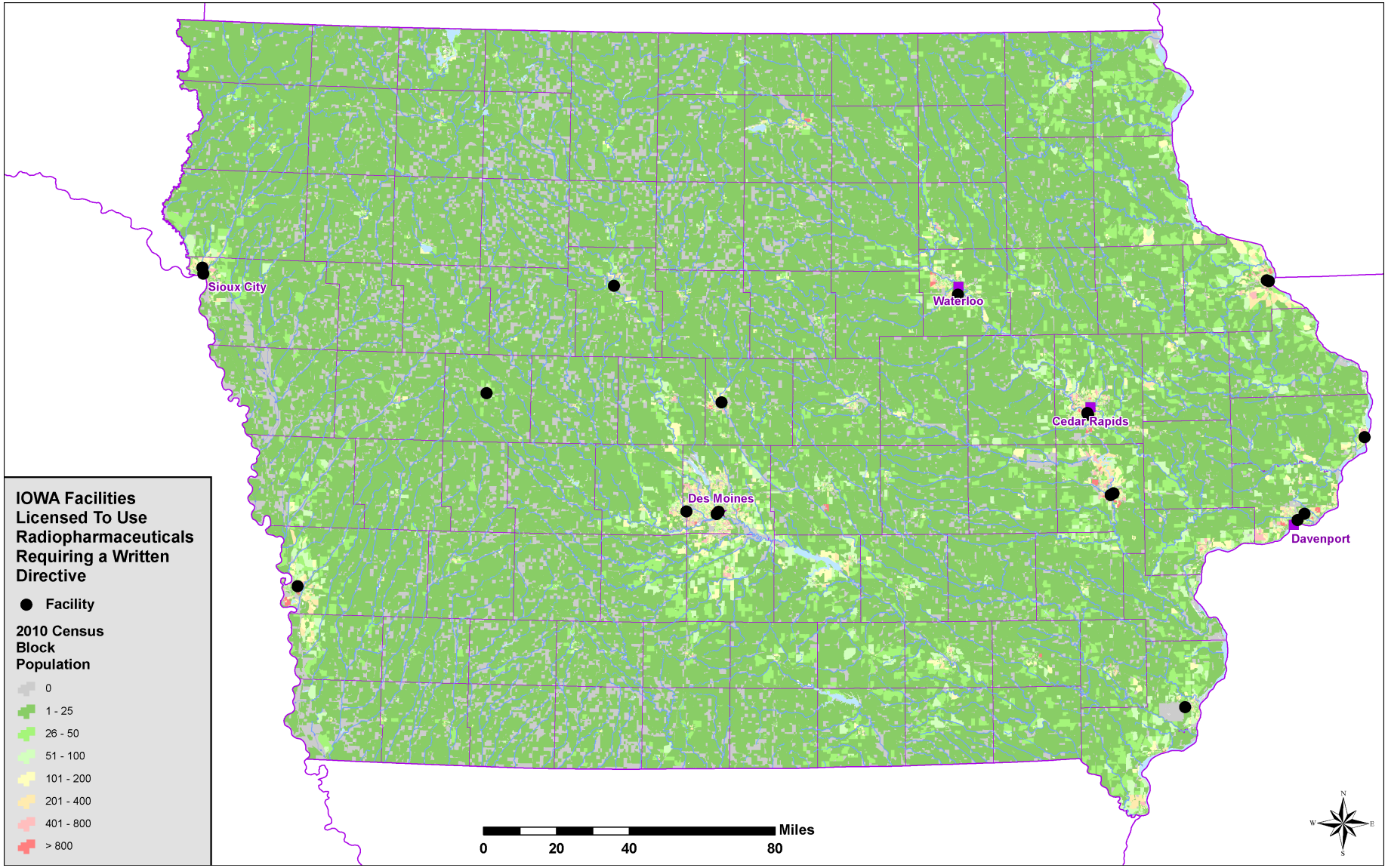


Figure 22. Locations of Kansas Licensees Authorized to Use 10 CFR 35.300 Materials

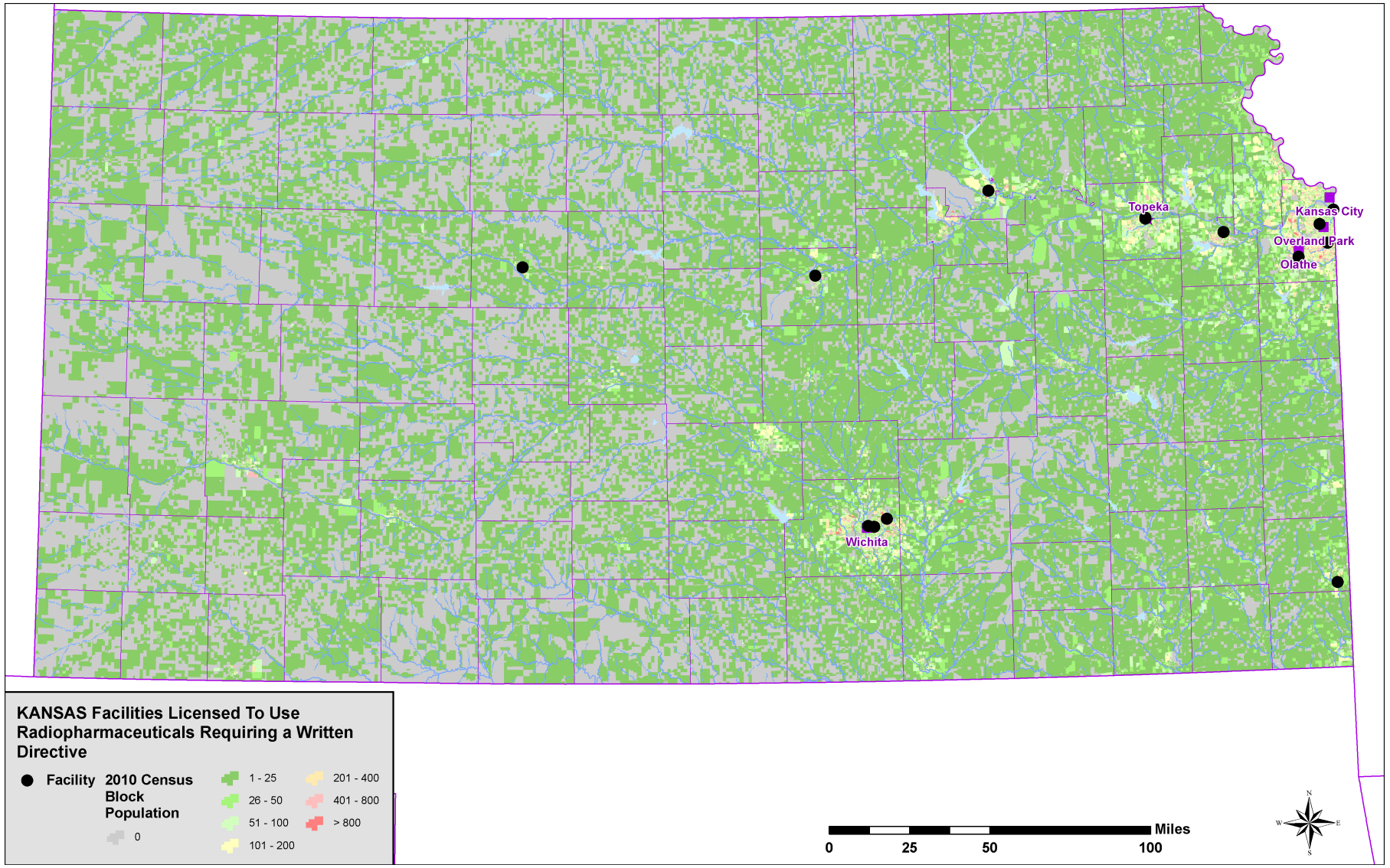


Figure 23. Locations of Maryland Licensees Authorized to Use 10 CFR 35.300 Materials

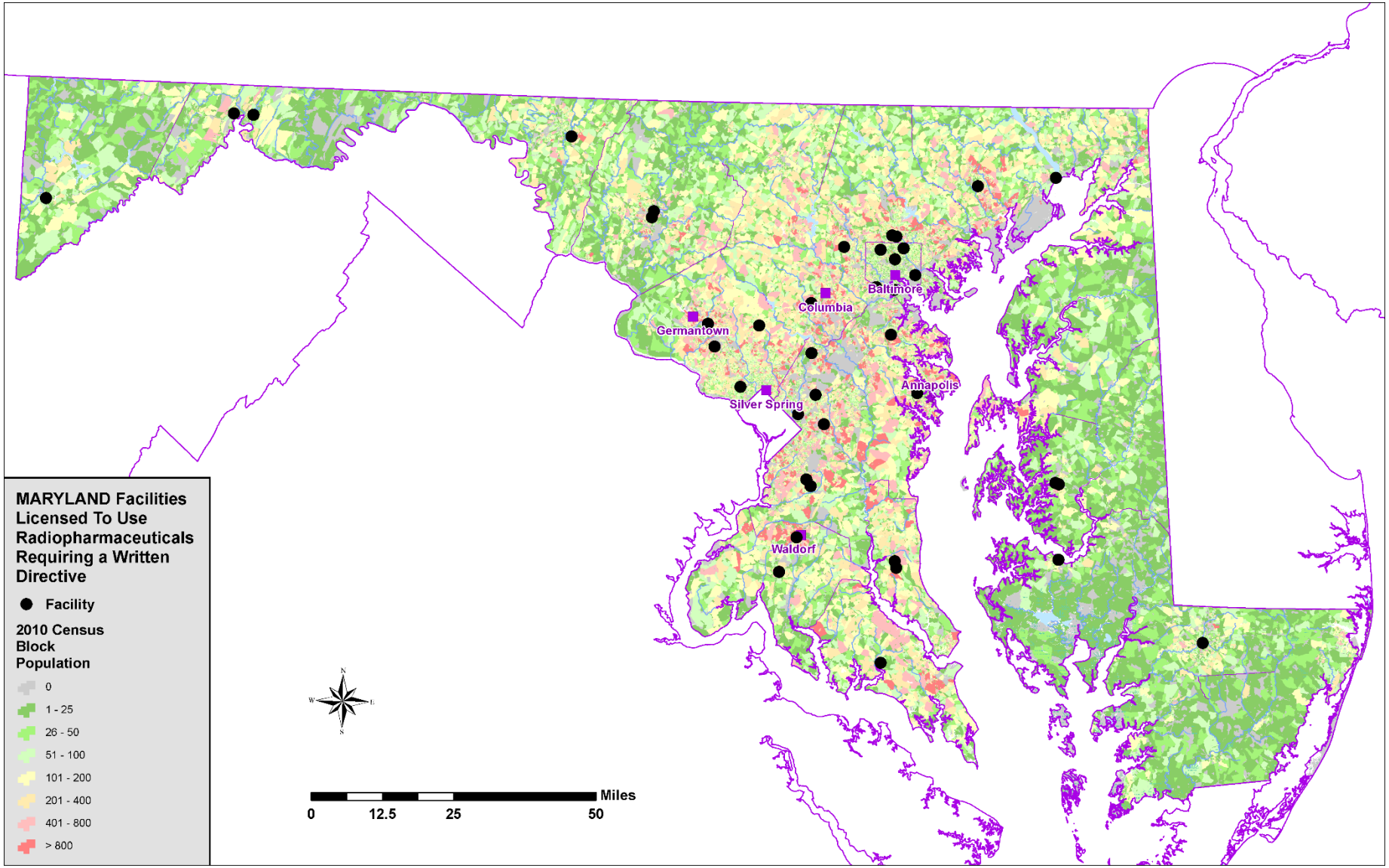


Figure 24. Locations of Massachusetts Licensees Authorized to Use 10 CFR 35.300 Materials

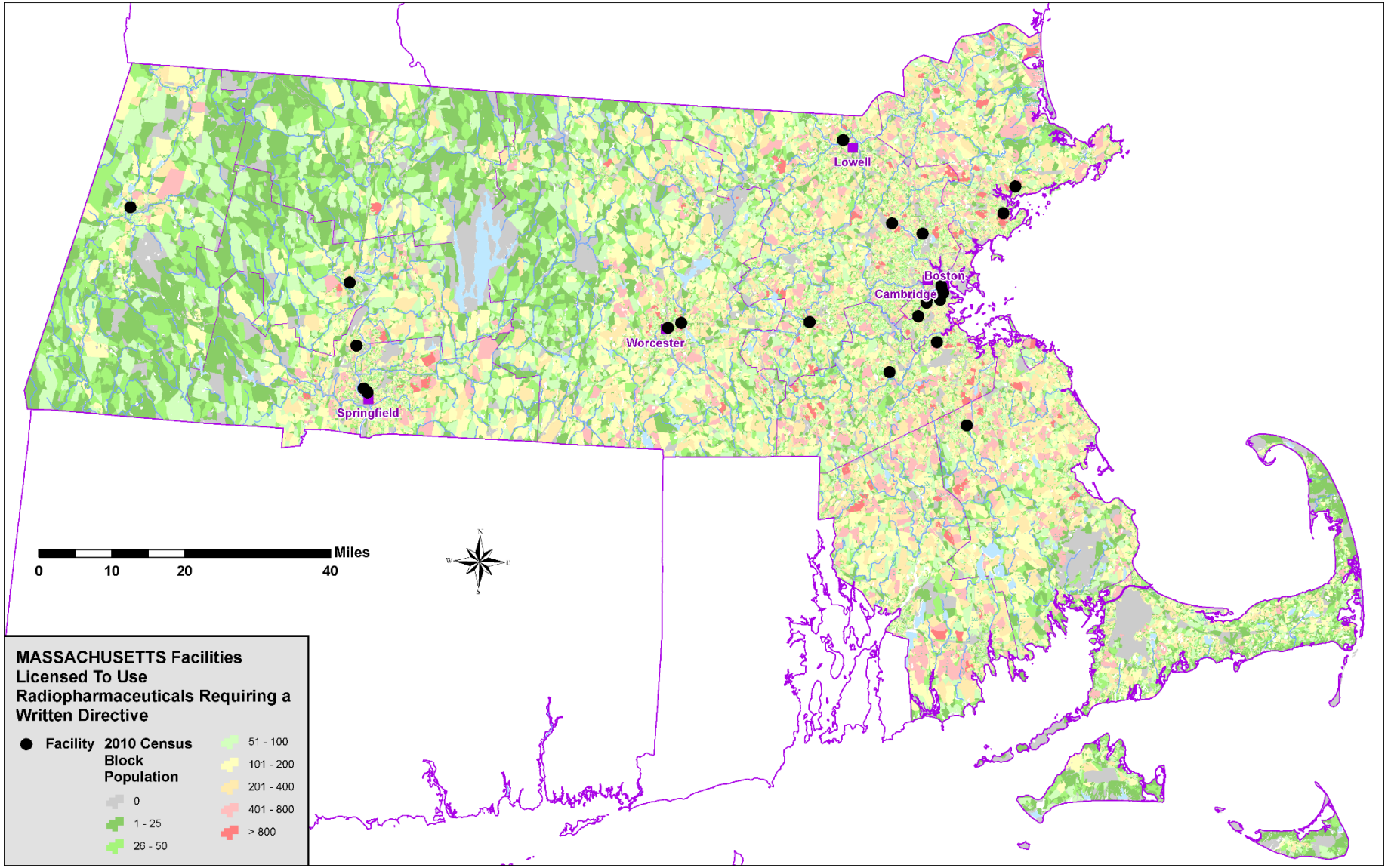


Figure 25. Locations of Nebraska Licensees Authorized to Use 10 CFR 35.300 Materials

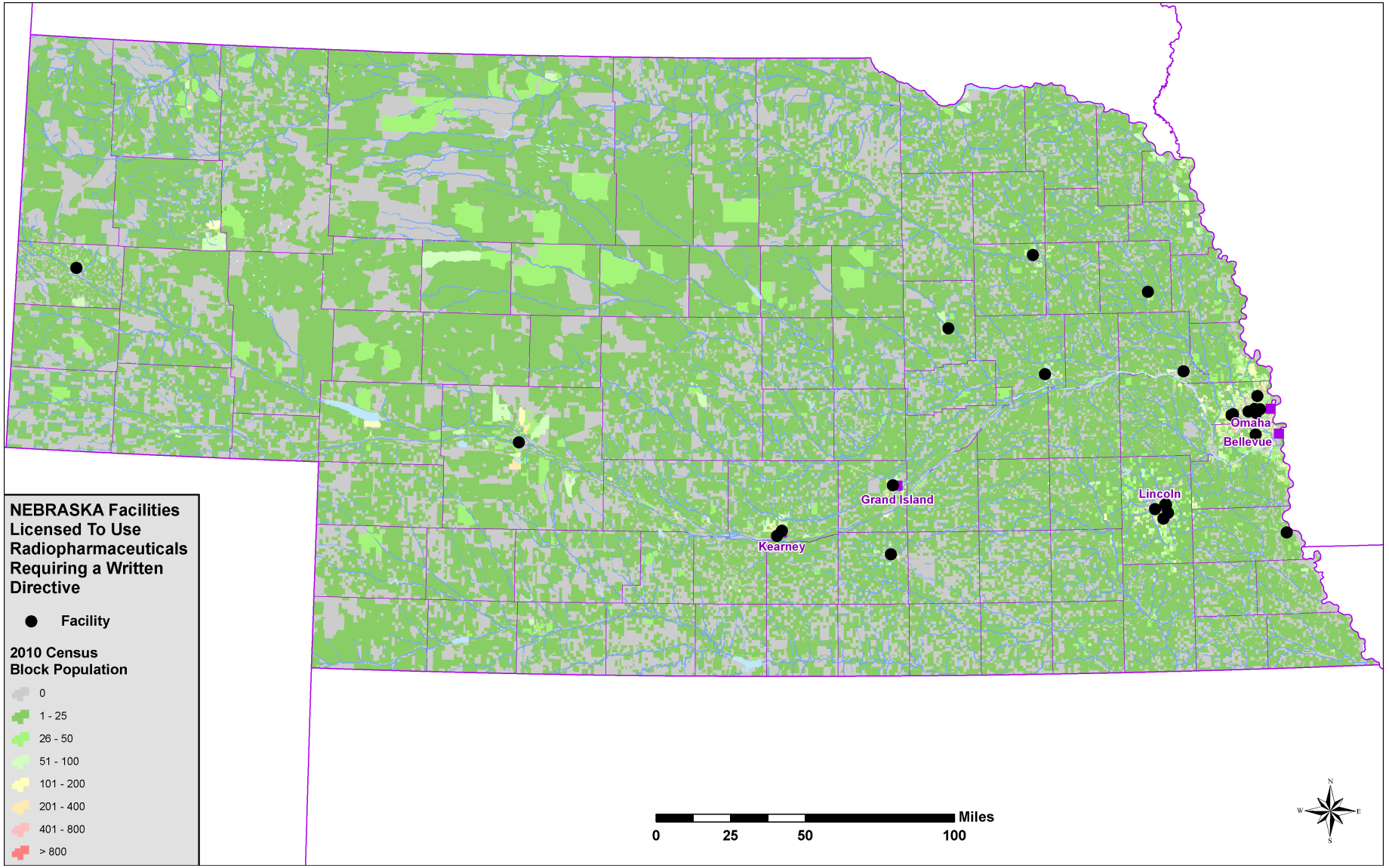


Figure 26. Locations of Ohio Licensees Authorized to Use 10 CFR 35.300 Materials

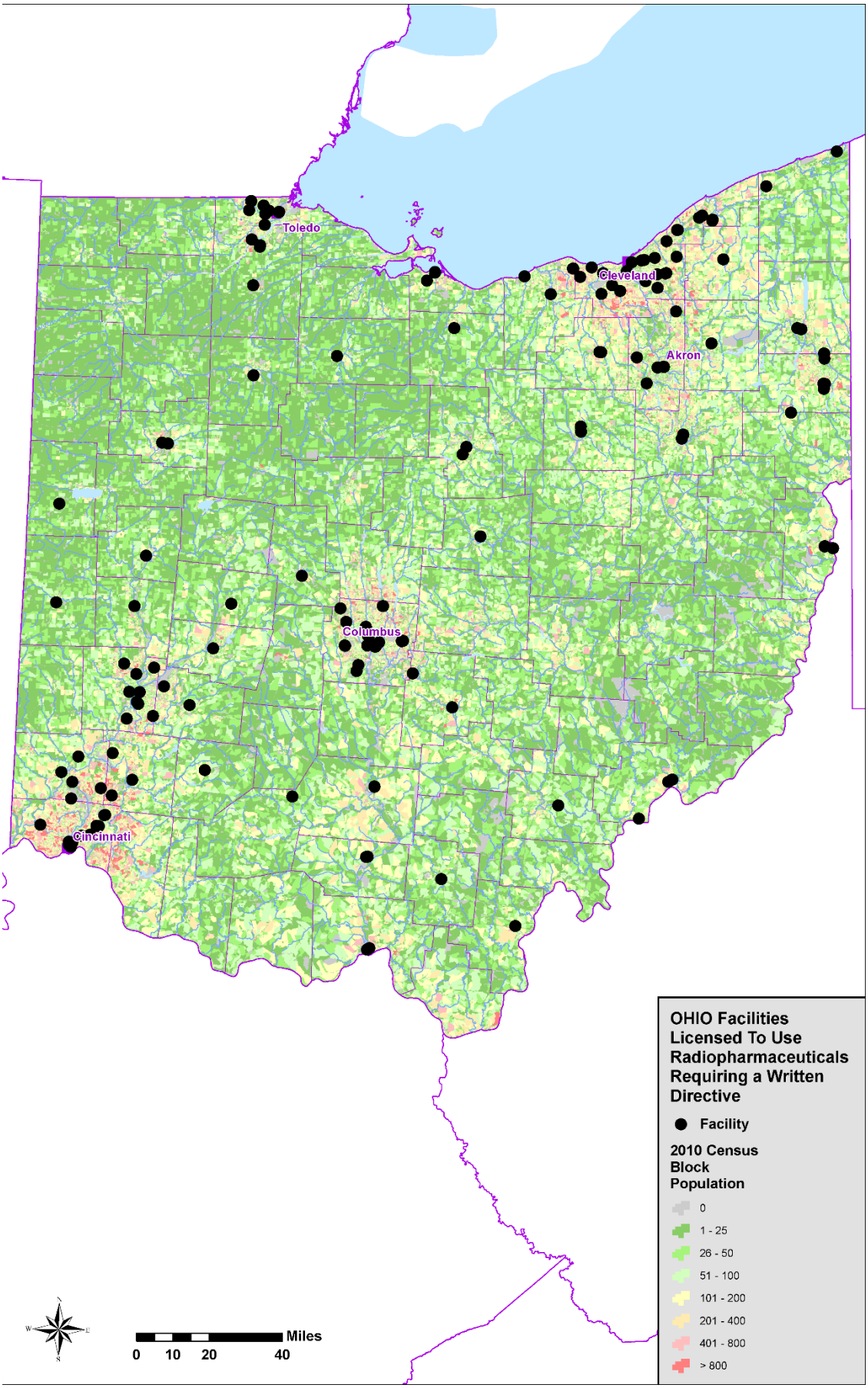


Figure 27. Locations of Pennsylvania Licensees Authorized to Use 10 CFR 35.300 Materials

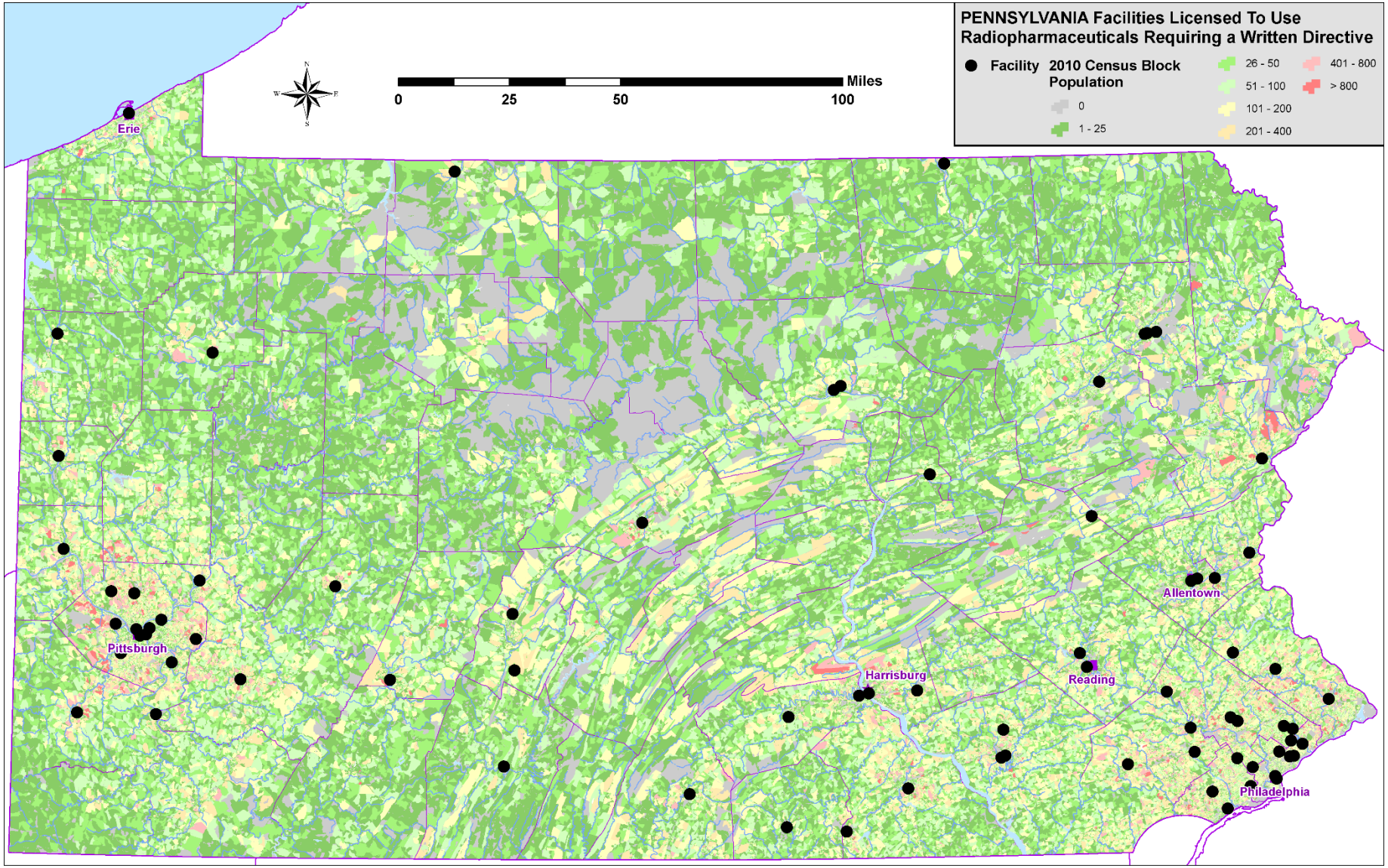
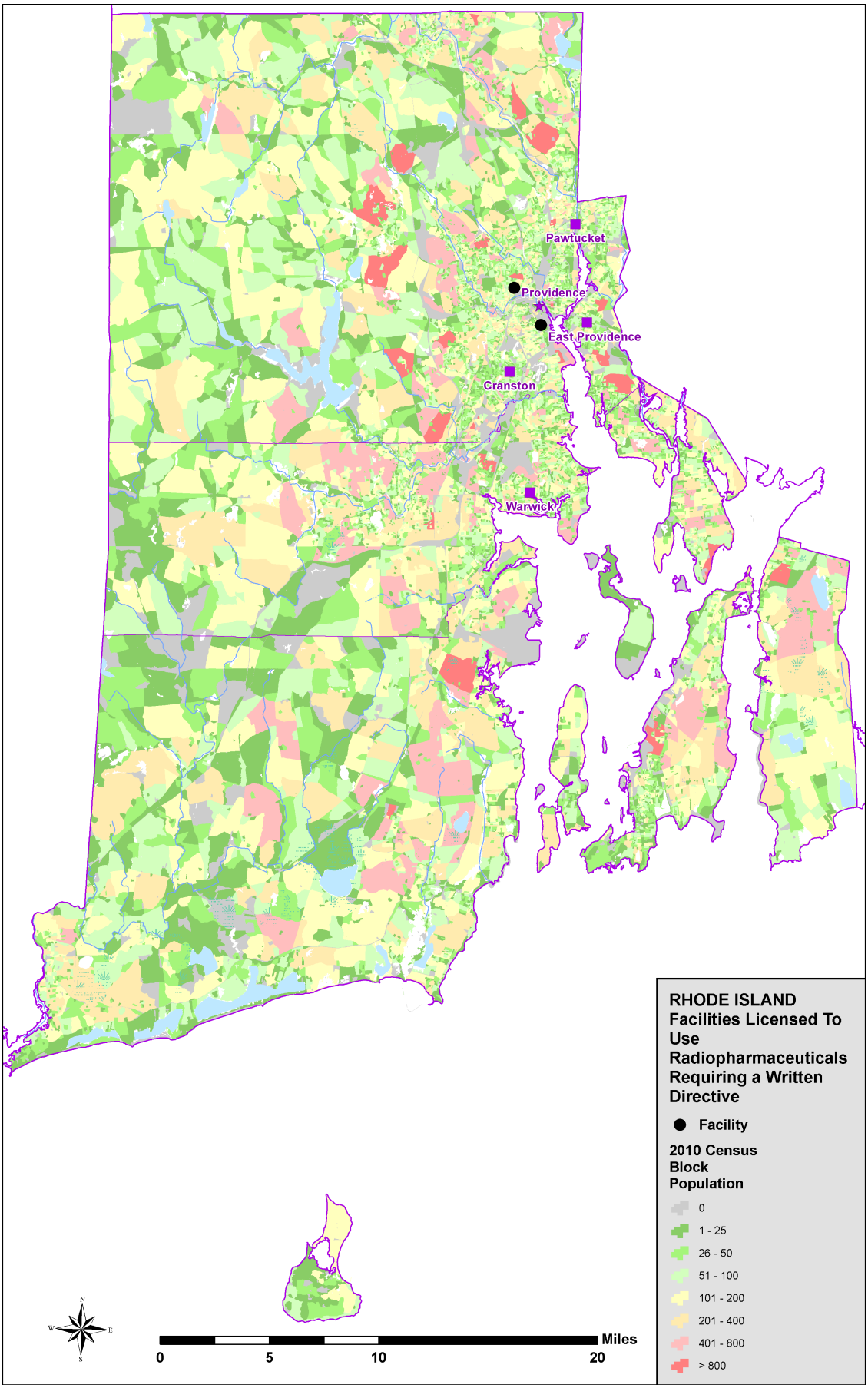


Figure 28. Locations of Rhode Island Licensees Authorized to Use 10 CFR 35.300 Materials



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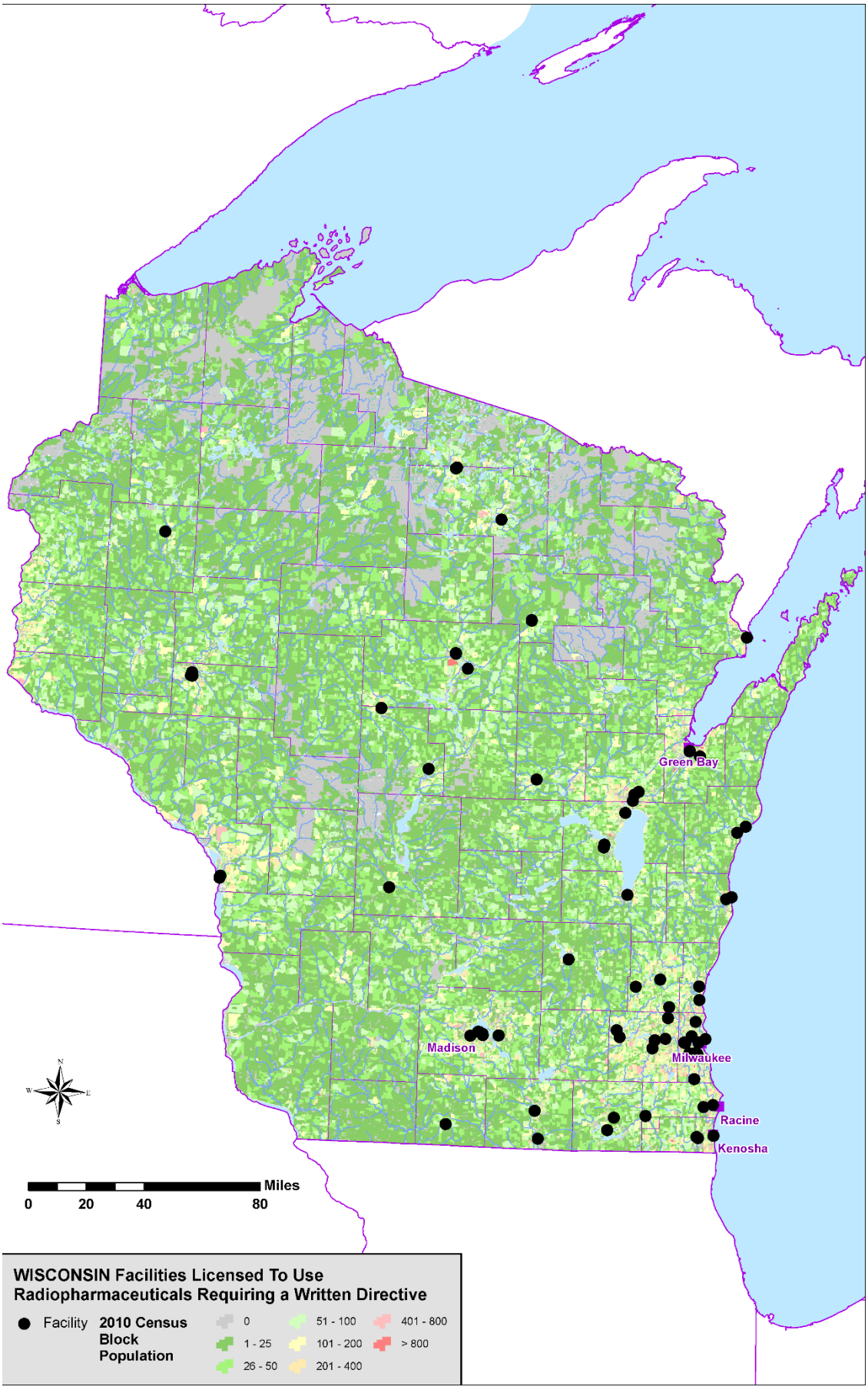

Figure 30. Locations of NRC and Agreement State Licensees Authorized to Use 10 CFR 35.300 Materials