



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 30, 2024

Andy Hall
Radiation Safety Officer
NDC Technologies, Inc.
8001 Technology Blvd.
Dayton, OH 45424

Dear Mr. Hall:

This letter is regarding your application dated February 29, 2024 and your letter dated June 7, 2024, requesting the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 04-23264-01.

The U.S. NRC's guidance document for your proposed type of license is NUREG-1556, Volume 18, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." This guidance is available on the U.S. NRC website at: <https://www.nrc.gov/docs/ML1724/ML17242A055.pdf>

Upon review of your request, I identified the following areas requiring additional or clarifying information:

1. Section 8.5.1, "Sealed Sources," of the guidance, states that applicants must provide the manufacturer's name, model number, radionuclide, quantity, and nominal activity for each requested sealed source and manufacturer and model number for each device that they will possess, use, and service in accordance with [Title 10 of the Code of Federal Regulations \(10 CFR\) §30.32\(g\)](#). Service provider licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

While your response included a detailed listing of the requested sealed sources and devices, upon review I identified that the requested maximum activity per source exceeded that authorized in the associated Sealed Source & Device Certificate of Registration. Similarly, the maximum activity per source was omitted for some gauging devices, including the NDC Technologies, Inc., Model 105, 107, 301 and TG-2.

Further, the list omitted some authorized source models. While some of the omitted source models appear to be older source models that are no longer in active distribution, they should be included in your request if you will be performing service or repairs, leak test sample collection or other licensed activities with devices loaded with these older source models.

2. Section 8.10.1, "Operating and Emergency Procedures," indicates that licensees must develop, implement and maintain Operating and Emergency (O&E) Procedures. The purpose of the O&E Procedures is to provide personnel with specific guidance for all operations they will perform.

As previously requested, please revise and resubmit your application including applicable O&E Procedures. Note that service providers who perform specific operations involving sealed sources, such as inspection and maintenance of devices, removal, and replacement of sealed sources (source exchange), and operations that involve access to the sealed source(s) and safety systems, should include appropriate procedures and instructions for these operations in the applicant's operating and emergency procedures.

3. Section 8.10.5, "Leak Tests," of the guidance, identifies that the testing of sources containing 100 microcuries of beta/gamma or 10 microcuries of alpha radioactive material is required to determine whether there is any radioactive leakage from sealed sources.

As indicated in the Response from Applicant section of the guidance, provide one of the following statements:

- "Leak tests sample collection and analysis will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's instruction. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services," or
- "Leak testing and analysis will be done by the applicant." Provide the information in Appendix G of this NUREG supporting a request to perform leak testing and sample analysis and either (1) state that the applicant will follow the model procedures in Appendix G of NUREG-1556, Volume 18, Revision 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," or (2) submit alternative procedures.

4. Section 8.10.6, "Occupational Dose," of the guidance, states that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure as necessary.

The "Response from Applicant," section of the guidance specifies that that one of the following should be provided:

- A statement that "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502,"; or
- A statement that "We will monitor individuals in accordance with the criteria in Section 8.10.6, 'Radiation Safety Program-Occupational Dose' in NUREG-1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Your response letter dated June 7, 2024, included the statement indicating that you will monitor individuals in accordance with the criteria in Section 8.10.6, "Radiation Safety Program – Occupational Dose," in NUREG-1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Clarify if your statement rescinds your previous statement in your application dated February 29, 2024 indicating that, "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502," or if you'd like the option to either monitor individuals or maintain documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.

5. Section 8.10.9, "Maintenance," of the guidance, describes that service providers who perform maintenance as a commercial service to other licenses should include applicable maintenance commitments and procedures in the license application.
- Routine maintenance of the device includes, but is not limited to, cleaning; lubrication; and changing batteries, relays, or fuses.
 - Nonroutine maintenance is the repair, removal, replacement, or alteration involving activities during which personnel could receive radiation doses exceeding NRC limits. These activities could include maintenance on electrical and mechanical systems that directly control source or shielding movement, the device's shielding or sealed source (e.g., removal), safety interlocks, any component that may affect safe operation of the device, or any other nonroutine maintenance that must be performed by the device manufacturer (or distributor) or a person specifically licensed by the NRC or an Agreement State.

Your response did not include applicable non-routine maintenance commitments and procedures.

The "Response from Applicant," section of the guidance specifies that for performance of nonroutine maintenance, submit the following:

- Before service begins, obtain NRC approval if OEM replacement parts cannot be used for sealed source shielding, the source driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the source; and
- A statement that "We will have the device manufacturer (or distributor) or other person authorized by NRC or an Agreement State perform nonroutine maintenance."; or
- Provide alternative procedures for the NRC's review addressing the information listed in Appendix K of NUREG-1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Further, if you will perform removal, replacement and disposal of sealed sources at temporary job sites, please describe the available safety equipment (e.g., portable glove boxes and leak testing equipment) and detailed procedures for performing these procedures. Note that there have been multiple incidents in which manufacturers' representatives have inadvertently drilled into or cut open sealed sources when removing sealed sources from devices. Therefore, your procedures should include step-by-step instructions, emphasizing the means for immediately identifying and containing a

leaking or apparently ruptured sealed source and thereby limiting the spread of radioactive contamination in the event of an accident.

6. Section 8.13, "Item 13: Certification," specifies that a representative of the legal entity filing the application must sign and date the [NRC Form 313, "Application for Materials License."](#) The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant (i.e., a certifying official).

Your response included a copy of NRC Form 313, signed by Chris Vernon, General Manager. Though, the response did not indicate that all previously submitted statements and representations were recognized to be legally binding. Therefore, please have the management representative confirm that your statements and representations provided in your application dated February 29, 2024, are recognized as legally binding except where rescinded by applicable revisions included in the response dated June 7, 2024.

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your request, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information requested, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-20431
License No.: 04-23264-01
Control No.: 639856