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Unsung regulatory approval vital to deal closing in acquiring businesses using radioactive materials

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Advancements in medical technology make healthcare and radiopharmaceutical companies attractive investment prospects. And we are seeing this interest in real time. However, acquiring businesses that use radioactive materials requires certain regulatory approvals, which can impact deal timelines and approach to diligence. Below, our team provides a summary of the relevant requirements and shares strategies to navigate these technical complexities to remain compliant and ensure a successful deal closing.

Within the first few months of 2024, a number of multi-billion dollar deals involving the acquisition of radiopharmaceutical and healthcare companies have signed and closed – likely garnering attention and piquing the interest of other investors. As we have seen already in the dynamic landscape of 2024 mergers and acquisitions (M&A), and we expect to continue to see going forward, particularly in the life sciences space, transactions involving medical companies are making up a meaningful number of publicly announced deals.

One reason this industry is booming is because radio- and biopharma are going "nuclear." Nuclear medicine is a medical specialty that uses radioactive tracers (radiopharmaceuticals) to assess bodily functions and to diagnose and treat disease. Tens of millions of procedures are performed each year using radiopharmaceuticals, and demand for radioisotopes is increasing at about 5% annually. As one example, the most common isotope, technetium-99m (Tc-99m) accounts for about 40 million procedures a year—with about half of those in North America. Other well-known isotopes include iodine-131 used to treat thyroid cancer; rubidium-82 and fluoride-18 used in PET imaging; thallium-201 used in myocardial perfusion imaging; actinium-225 used in a range of cancer treatments, among others. Radioactive material can also be used in medical devices and to sterilize equipment.

Companies that use radioactive materials tend to hold radioactive materials licenses (RMLs) issued by the U.S. Nuclear Regulatory Commission (NRC) or a state with delegated authority from the NRC (a so called, "Agreement State"), and these licenses can play an outsized role in your M&A deal. Importantly, they generally require prior approval from the nuclear regulator for a direct or indirect license transfer—such as any upstream change in ownership, no matter how far up the corporate chain—before a transaction can close. For larger companies, with multiple business units and operations across a number of states, this can potentially impact dozens and even potentially hundreds of licenses. The license can also require financial assurance instruments for decommissioning that may need to be replaced as part of a deal. In addition to RMLs, a company may also hold an NRC export license, which triggers the same kind of approval.

Being aware of a company's RMLs is not just important to understanding the business, but critical when acquiring a company in this space because of the unique considerations these types of licenses can play when doing a deal. In particular, with speed to closing and closing certainty being critical considerations for both buyers and sellers when evaluating potential acquisitions, understanding the likely approval timelines and the various factors that impact the timeline and likelihood of receiving approval for the license transaction is an important element. Buyers will also want to consider these items as part of their overall valuation of the transaction, including as they calculate integration, and transaction structure.

Below we walk through the relevant requirement, and strategies for navigating this technical analysis during deal diligence and for maximizing compliance.

RMLs generally require prior license transfer approval from the nuclear regulator before closing an acquisition

While not often at the forefront of buyer's and seller's minds during a potential transaction, for most deals—especially in the life sciences space, the parties should ascertain whether the target or any of its subsidiaries or contract development and manufacturing organizations hold RMLs. RMLs are generally issued pursuant to the authority set forth in Section 184 of the Atomic Energy Act (AEA) (42 U.S.C. § 2234). The RML is issued either by the NRC or by an Agreement State, but the underlying authority still comes from the AEA. Section 184 of the AEA states that licenses cannot be "transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of this Act, and shall give its consent in writing."

The NRC has incorporated this AEA requirement into its regulations. See, e.g., 10 C.F.R. § 30.34 (providing "[n]o license. . .shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."). Most Agreement States include similar license transfer requirements as the NRC regulations. Under these requirements, ownership changes, including upstream ownership changes and changes of control, trigger the nuclear regulatory license transfer approval requirement—and these approvals can take several months to obtain. Notably, even less than full ownership changes can trigger the need for a license transfer, such as the sale of a controlling interest in the organization.

Violations of the requirements would not only be a regulatory violation, but also a statutory violation as well as the basis for the regulation is set forth in the AEA.

While not the focus of this article, it is also important to note that the above transfer analysis is not limited to 100% acquisitions. In any circumstance where there is a change in ownership or control of a RML holder, the relevant parties need to consider whether any approval may be triggered. For example, if there is an internal personnel reorganization or if there is a change to the RML's board as a result of an investment. This is important for our investor and sponsor-backed clients to keep in mind when considering investment and other strategic transactions.

Best practices and recommendations for ensuring RMLs do not impact deal closing

- **Check for RMLs.** As quickly as possible in a deal, a buyer or seller should evaluate the companies involved in a transaction—including all subsidiary companies below the target—to determine whether any of them hold any RMLs. As a general rule of thumb, if the RML holder will end up under new ownership, no matter how far up the corporate chain, a license transfer is likely required.
- **Make sure you find all the RMLs, and who has issued them.** M&A deals can be complex, and many companies or assets can transfer during an acquisition. Diligence should include locating all RMLs implicated in a transaction and which nuclear regulatory agency has issued them. License transfer applications may include multiple licenses for multiple companies, but each regulator will need a separate submission—including different NRC offices (e.g., NRC Regions I-IV, Office of International Programs, etc.).
- **Compliance due diligence.** In additional to traditional diligence, the parties should be particularly mindful of any open inspection items or non-compliance (e.g., expired licenses). Regulators may require violations to be remedied prior to approving a license transfer, which can slow down approvals.
- **Checking for financial assurance instruments.** RMLs may also require that a licensee maintain financial assurance instruments for decommissioning, such as a letter of credit or surety bond, in an amount specified by the regulator. The size of these instruments can range from the hundreds of thousands of dollars to the millions of dollars. Parties should be aware of whether the RMLs require these types of instruments, and whether a deal requires new instruments be set in place. This can be triggered by an asset sale involving the license, collateral maintained by a non-transfer partner company, or—in the event of a parent company guarantee—a new parent company will be in place post-closing.

- **Transaction documents.** Ensure the acquisition agreement adequately addresses radioactive materials matters, including licensing considerations such as expiration/renewals and enforcement actions. It is typical for receipt of any nuclear regulatory approvals to be a condition precedent to closing. We also often see parties agree to provisions regarding the coordination of the filing and the efforts the parties must take in order to obtain approval as well as provisions addressing what happens to the transaction if approval is not obtained within a certain time period.
- **Understanding timing restraints and public disclosure.** While each nuclear regulator is different, the NRC and several states typically take a minimum of 90 days to review and approve a license transfer application—sometimes longer depending on the circumstances. It is important to note that the applicable regulations do not provide for a deadline for the review, which is different than the other regulatory approvals buyers may be more familiar with, like certain antitrust approvals. The NRC also requires that license transfer be posted for public comment on the NRC website for a minimum of 30 days, so the license transfer application will be public. Parties should take this into consideration, particularly if the transaction has not been publicly announced, and may need to coordinate on communication plans with other stakeholders.
    - While the parties are able to request expedited treatment of an approval request, expedited review is not guaranteed. Given the uncertainty in the approval timeline it is important to understand the various factors the nuclear regulators will review (or not) as part of the approval process, such as whether the buyer already holds RMLs or other NRC licenses, or whether there are pending enforcement actions or compliance issues associated with the license. The deal timeline and structure will need to take into account the flexibility of timing and determine whether NRC approval will be a gating item to closing (or if there are other regulatory approvals or third part consents on longer or similar timelines).
- **High quality submission.** The nuclear regulatory reviews are not administrative in nature, and applications are expected to provide specific information for the regulator to review. They are generally joint submissions executed by both the selling and acquiring parties to the transaction. Failing to provide the required information, or changing the application material mid-review, can slow down approvals.

While this article focuses on acquisitions in the healthcare and life sciences sector, these strategies and best practices are applicable to M&A across a variety of industries involving radioactive materials, such as manufacturing and industrial sectors and university research.

The Hogan Lovells nuclear and M&A teams have significant experience supporting clients that are seeking to acquire, invest in, or engage in other strategic transactions with targets that hold RMLs. Our nuclear team has prepared and obtained hundreds of license transfer approvals across the range of NRC offices and Agreement States, and we have seen the wide range of issues that can emerge in this space, which enables us to leverage our extensive experience to advise our clients in a practical way that takes into account broader transaction implications and going forward operational considerations.

Ultimately, nuclear regulatory approvals are an important part of an M&A transaction, not the least of which is because of their potential impact on the overall deal timeline. And, as noted above, for acquirers seeking to expand into this space ensuring that a viable and compliant (and appropriately licensed) manufacturing facility is available post-closing is critical to overall deal value. Using experienced nuclear regulatory counsel to work with the deal team to support diligence, draft key transaction documents, and prepare and shepherd the license transfer is key to mitigating deal risk and supporting a successful transaction.

For more information on this topic, including how we can support you on future transactions, please contact our M&A team Gabi Witt (Partner) or Jess Bisignano (Partner), or our Nuclear Regulatory team Amy Roma (Partner) or Stephanie Fishman (Senior Associate).

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