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Information Collection: Packaging and Transportation of Radioactive Material

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Submitter Information

Email: ALanger@mail.conservative.org
Organization: CPAC Foundation Center for Regulatory Freedom

General Comment

Attached are comments of the CPAC Foundation Center for Regulatory Freedom,

Attachments

CRF Comments to DOE NRC RFI Transportation Paperwork FINAL 020926

CENTER FOR REGULATORY FREEDOM
PROJECT OF CPAC FOUNDATION

515 KING STREET, ALEXANDRIA VA 22314

M E M O R A N D U M

To: **Hon. Chris Wright, Secretary, US Department of Energy**
Hon. David Wright, Chairman, Nuclear Regulatory Commission
From: **Andrew Langer, Director, Center for Regulatory Freedom, CPAC Foundation**

Date: **February 9, 2026**
Re: **Comments on the Department of Energy/Nuclear Regulatory Commission Request for Information, "Information Collection: Packaging and Transportation of Radioactive Material," Docket #NRC-2025-0034, Fed. Reg. 2025-22640, Published December 12, 2025**

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter "CPAC Foundation") Center for Regulatory Freedom (hereinafter "CRF"), in response to the Department of Energy/Nuclear Regulatory Commission Request for Information, "Information Collection: Packaging and Transportation of Radioactive Material," Docket #NRC-2025-0034, Fed. Reg. 2025-22640, published December 12, 2025.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

Introduction

The Center for Regulatory Freedom (CRF) appreciates the opportunity to comment on the Nuclear Regulatory Commission's renewal of the information collection for the packaging and transportation of radioactive material. CRF strongly supports the NRC's core mission to ensure the safe handling, packaging, and transportation of radioactive materials, including those used in medical applications.

Public confidence in nuclear safety depends on rigorous oversight, clear standards, and disciplined compliance, and CRF recognizes the essential role the NRC plays in maintaining that trust.

CRF also recognizes that documentation, recordkeeping, and quality assurance requirements are not ancillary to nuclear safety, but integral to it. Accurate records, standardized procedures, and verified compliance systems help ensure that radioactive materials are transported safely, incidents are promptly identified, and corrective actions are taken when necessary. Properly designed paperwork requirements can enhance safety, accountability, and regulatory transparency.

At the same time, Congress enacted the Paperwork Reduction Act (PRA) to ensure that federal information collections serve a clear and practical purpose. The PRA requires agencies to assess whether the information they collect is necessary to perform their functions, whether it has practical utility, and whether the burden imposed on regulated entities is justified by the benefits achieved. Importantly, the PRA is not a deregulatory statute; it is a discipline statute, intended to ensure that paperwork supports effective governance rather than substituting for it.

These comments focus narrowly on a specific and growing category of regulated activity: the transportation of time-critical medical radiopharmaceuticals, particularly radioligand therapies. These therapies represent a significant advance in cancer treatment and depend on tightly coordinated production, transportation, and clinical administration. Unlike many other radioactive materials regulated under 10 CFR Part 71, these products are intended for immediate therapeutic use rather than long-term storage or industrial application.

Radioligand therapies and similar medical isotopes operate under severe real-world time constraints. From the moment of production, the clock is running: many of these therapies must be transported, prepared, and administered to patients within approximately 96 to 120 hours. Delays anywhere in the chain—from production to shipment to clinical delivery—can render a dose unusable, leading to canceled treatments and lost opportunities for patients who may have limited alternatives.

CRF's concern is that shipment-by-shipment documentation requirements, while well-intentioned and rooted in safety objectives, can introduce delays that are disproportionate in time-critical medical contexts. When the same information is repeatedly collected for routine, identical shipments, paperwork can become a source of friction that materially reduces patient access without yielding corresponding new safety insight. Under the PRA, this raises legitimate questions about practical utility and proportionality.

Accordingly, CRF submits these comments to offer constructive, PRA-consistent recommendations that preserve the NRC's safety objectives while better aligning transportation documentation practices with the operational realities of time-critical medical therapies. By focusing regulatory attention on what meaningfully changes, and by exploring more efficient approaches to routine shipments, the NRC can strengthen both nuclear safety oversight and patient access to lifesaving innovation.

Executive Summary

The Center for Regulatory Freedom (CRF) submits these comments in response to the Nuclear Regulatory Commission's request for comment on the renewal of the information collection for the packaging and transportation of radioactive material. CRF supports the NRC's safety mission and recognizes the essential role that transportation documentation plays in protecting public health and

maintaining confidence in the nuclear regulatory framework. These comments focus on ensuring that paperwork requirements, consistent with the Paperwork Reduction Act (PRA), meaningfully support safety while avoiding unnecessary delays that can undermine access to time-critical medical therapies.

- The information collection authorized under 10 CFR Part 71 encompasses a broad range of transportation-related documentation, including package approvals, shipment preparation records, incident reporting, and quality assurance verification, effectively reauthorizing the full paperwork framework governing radioactive material transport.
- Radioligand therapies and other advanced medical radiopharmaceuticals are time-critical products that must be transported, prepared, and administered within narrow clinical windows, often within 96–120 hours of production, making them uniquely sensitive to administrative delays.
- Shipment-by-shipment documentation requirements frequently require the repeated collection of static information for routine, identical shipments, producing diminishing safety returns while consuming time that is critical to patient care.
- Under the PRA, information collections must have practical utility, and paperwork that predictably delays or frustrates the delivery of lifesaving medical treatments warrants careful re-evaluation to ensure that it remains necessary and proportional.
- The NRC should consider standing or routine shipment authorizations for recurring medical isotope transport, allowing baseline approvals to cover identical packages, isotopes, routes, and licensees, while focusing shipment-level documentation on deviations or anomalies.
- Portfolio-level or time-limited certifications for routine shipments could preserve safety oversight while eliminating redundant paperwork that does not generate new safety insight.
- Expanded use of automated and standardized documentation systems could improve both safety and efficiency by reducing transcription errors, accelerating routine compliance, and allowing regulators to focus on exceptions rather than repetitive confirmations.
- Transportation paperwork burdens can have downstream affordability and access implications, disproportionately affecting smaller hospitals and regional treatment centers and limiting patient access to advanced therapies.

CRF respectfully urges the NRC and the Office of Management and Budget to use this PRA renewal as an opportunity to reassess whether existing transportation documentation practices appropriately reflect the operational realities of time-critical medical radiopharmaceuticals. Thoughtful, PRA-consistent reforms can preserve nuclear safety while improving speed, reliability, and patient access to lifesaving innovation.

I. The Scope of the Information Collection Under 10 CFR Part 71

The information collection titled “Packaging and Transportation of Radioactive Material” encompasses the full range of documentation requirements the Nuclear Regulatory Commission relies upon to oversee the safe transport of radioactive materials under 10 CFR Part 71. This includes applications and supporting materials for package design approvals, records associated with shipment preparation and compliance, required notifications and reports related to incidents or package degradation, and documentation demonstrating adherence to NRC-approved quality assurance programs. Together, these requirements form the administrative backbone of the NRC’s transportation safety regime.

Importantly, this Paperwork Reduction Act renewal does not concern a narrow or isolated set of forms. Rather, it effectively reauthorizes the entire documentation framework governing the transportation of radioactive material in the United States. By renewing this information collection, the NRC is

affirming the ongoing necessity and utility of the cumulative paperwork obligations imposed on licensees who ship radioactive materials, including those used for medical purposes.

Within this framework, not all information collected serves the same function or has the same informational value. Some documentation reflects static, recurring information—such as previously approved package designs, established quality assurance programs, or routine shipment parameters that do not change from one shipment to the next. Other information is dynamic and safety-critical, including reports of incidents, deviations from approved conditions, package degradation, or anomalies that warrant regulatory attention and corrective action.

The Paperwork Reduction Act requires agencies to examine whether the repeated collection of unchanged information continues to have practical utility. When identical information is gathered repeatedly for routine activities without yielding new safety insight, the PRA calls for a reassessment of whether that information collection remains necessary in its existing form. This inquiry is particularly relevant where paperwork requirements operate as a gating function that can delay regulated activity without enhancing safety outcomes.

Under the current framework, time-critical medical radiopharmaceutical shipments are generally treated procedurally the same as non-time-sensitive shipments or materials with long half-lives and non-clinical end uses. The documentation requirements apply uniformly, regardless of whether a shipment involves a routine, recurring medical isotope delivery intended for immediate patient care or a materially different category of radioactive material transport.

This section establishes the foundation for considering whether a more differentiated approach is warranted. By examining use case, risk profile, and time sensitivity, the NRC and the Office of Management and Budget can better assess whether aspects of the existing information collection could be tailored to preserve safety while improving proportionality and practical utility for time-critical medical shipments.

II. Time-Critical Radiopharmaceutical Therapies Present Distinct PRA Considerations

Radioligand therapies and other advanced medical radiopharmaceuticals are first and foremost lifesaving medical products. They are designed to deliver targeted therapeutic benefit to patients with serious and often life-threatening conditions, including advanced cancers. While these products are appropriately subject to NRC oversight due to their radioactive properties, they are fundamentally different in purpose and use from many other radioactive materials regulated under 10 CFR Part 71. Their regulatory treatment should reflect their role in direct patient care rather than treating them solely as hazardous commodities in transit.

A defining characteristic of these therapies is their short physical half-lives and limited clinical viability windows. From the moment of production, radioactive decay begins to reduce therapeutic effectiveness. As a result, radioligand therapies must be transported, prepared, and administered within narrow timeframes—often within approximately 96 to 120 hours. These constraints require highly coordinated logistics and leave little margin for delay at any stage of the process.

Within this context, even modest paperwork delays can have outsized consequences. Delays measured in hours rather than days can determine whether a dose reaches a patient in time or becomes unusable

due to decay. When transportation documentation functions as a bottleneck, the effect is not merely administrative inconvenience but the loss of a therapy that cannot be recovered or re-used.

Under the Paperwork Reduction Act, agencies are required to consider whether information collections have practical utility and whether they support, rather than frustrate, the purpose of the regulated activity. When paperwork requirements predictably impede the timely delivery of a medical therapy without producing commensurate safety insight, the PRA calls for careful re-evaluation of whether those requirements are appropriately designed.

The consequences of such delays extend beyond individual shipments. Transportation documentation bottlenecks can lead to canceled treatments, reduced throughput at medical facilities, and scheduling uncertainty for patients and providers. Over time, these effects can constrain the availability of advanced therapies, limit the willingness of facilities to offer them, and reduce the overall efficiency of radiopharmaceutical delivery networks.

Critically, these impacts are not captured in traditional PRA burden estimates that focus solely on staff hours spent completing forms or maintaining records. Measures such as aggregate reporting hours do not account for lost doses, missed treatment windows, or reduced patient access. As a result, the true cost of transportation paperwork in time-critical medical contexts may be significantly understated.

CRF emphasizes that this is not a critique of regulatory oversight or safety requirements, but a question of regulatory design. The challenge is to ensure that information collections are structured in a way that advances safety while recognizing the operational realities of time-critical medical use cases. Thoughtful, PRA-consistent design can protect public health and nuclear safety while ensuring that lifesaving therapies reach patients when they are needed most.

III. Shipment-by-Shipment Documentation Produces Diminishing Safety Returns

Many medical radiopharmaceutical shipments involve the repeated transportation of identical isotopes in identical, previously approved packages between the same licensed entities. These routine shipments often follow established routes, use the same handling procedures, and occur with high frequency as part of ongoing clinical operations. Despite this consistency, current documentation practices frequently require licensees to generate and review substantially the same paperwork for each individual shipment.

Re-certifying unchanged information on a shipment-by-shipment basis provides diminishing marginal safety insight. When package designs, quality assurance programs, handling procedures, and shipment parameters remain constant, repeated documentation does not meaningfully increase safety or reduce risk. Instead, it primarily confirms information that regulators and licensees already know and have previously validated through approved processes.

By contrast, effective safety systems are designed to focus regulatory attention on what changes. Oversight is most valuable when it identifies deviations from approved conditions, detects anomalies, and responds to unexpected events. Systems that emphasize exception-based review—rather than routine repetition—are better suited to identifying genuine safety concerns and preventing incidents.

CRF emphasizes that robust incident, degradation, and anomaly reporting must remain non-negotiable. Documentation that captures package defects, transportation incidents, or deviations from approved

procedures is essential to maintaining safety and public confidence. Nothing in these comments should be read to suggest weakening or eliminating such reporting requirements, which serve a critical safety function.

Indeed, excessive routine documentation can have the unintended effect of diluting oversight. When regulators and licensees devote significant time and attention to repetitive paperwork, fewer resources may be available to scrutinize meaningful safety signals. In this sense, unnecessary repetition can obscure, rather than enhance, the NRC's ability to focus on the information that matters most.

The Paperwork Reduction Act requires that information collections be necessary to the proper performance of agency functions and have practical utility. Where shipment-by-shipment documentation repeatedly collects unchanged information without yielding new safety insight, the PRA calls for reconsideration of whether that approach remains justified. Ensuring that paperwork requirements are targeted, proportionate, and information-rich is essential to both effective oversight and efficient delivery of time-critical medical therapies.

IV. Standing or Routine Shipment Authorizations as a PRA-Consistent Reform

CRF encourages the NRC and the Office of Management and Budget to consider the use of standing, routine, or baseline shipment authorizations for recurring medical isotope transport. Such authorizations would recognize that many radiopharmaceutical shipments occur under stable, well-understood conditions and do not require shipment-by-shipment revalidation of information that has already been reviewed and approved.

Under this approach, a standing authorization could cover identical package designs, the same isotopes, recurring transportation routes, and the same licensed shipper and recipient. These authorizations could be issued for a defined period of time, subject to renewal, and conditioned on continued compliance with approved quality assurance programs and applicable safety requirements. This would allow the NRC to maintain oversight while acknowledging the routine nature of certain medical shipments.

Shipment-level documentation would then focus on what changes, rather than what remains the same. Licensees would be required to document and report deviations from approved conditions, anomalies in packaging or handling, unexpected events during transport, or changes in shipment parameters. By concentrating documentation on exceptions, the NRC would receive information that is more likely to be safety-relevant and actionable.

This approach preserves safety while eliminating redundant paperwork. Standing authorizations would not relax packaging standards, radiation limits, or incident reporting obligations. Instead, they would streamline the administrative process for routine shipments by avoiding repeated collection of static information that does not enhance safety outcomes. Safety oversight would remain intact and, in many respects, could be strengthened by focusing regulatory attention on deviations rather than repetition.

There are clear parallels to portfolio-level or programmatic approvals used in other safety-critical regulatory contexts, where regulators approve baseline systems or processes and then monitor compliance through audits, inspections, and exception reporting. These models recognize that continuous re-approval of unchanged conditions is neither efficient nor necessary to ensure safety.

Standing or routine shipment authorizations align closely with the principles of the Paperwork Reduction Act. By reducing the repeated collection of static information, this approach improves practical utility and ensures that paperwork requirements are proportional to the regulatory value they deliver. It reflects the PRA's directive to minimize burden while maintaining effective oversight.

Finally, this reform is especially appropriate for time-critical medical use cases. For radioligand therapies with narrow clinical administration windows, hours matter. Standing authorizations would help ensure that paperwork does not become an unintended barrier to patient access, while preserving the NRC's ability to oversee safety, detect problems, and respond promptly when issues arise.

V. Automation and Standardization Can Improve Both Safety and Speed

CRF encourages the NRC to expand the use of automated, interoperable documentation systems for recurring shipments of radioactive medical materials. For routine radiopharmaceutical transport, digital systems that integrate package approvals, quality assurance certifications, and shipment parameters can significantly reduce administrative friction while strengthening oversight consistency.

Pre-populated records are a particularly important reform. When shipment details—such as approved package designs, licensed entities, and standard routes—are automatically populated from previously approved data, the risk of transcription errors is reduced and compliance delays are minimized. This approach improves accuracy while accelerating preparation for time-sensitive shipments.

Automation also enables real-time validation against approved parameters. Digital systems can automatically confirm that activity levels, package types, and shipment conditions fall within authorized limits before a shipment proceeds. This enhances oversight quality by providing immediate checks and clear audit trails, rather than relying on manual review of repetitive documentation.

By shifting routine confirmations into automated systems, regulators are better positioned to focus on exceptions. Automated processes can flag deviations, anomalies, or unusual conditions for human review, allowing NRC staff to concentrate attention where it is most needed. This exception-based model aligns regulatory effort with actual risk.

CRF emphasizes that technology should be deployed with clinical timelines in mind, not merely for administrative convenience. For radioligand therapies and other time-critical medical products, speed is a component of access and effectiveness. Automation should be evaluated not only on efficiency gains, but on its ability to ensure that lifesaving therapies reach patients within narrow treatment windows.

These automation and standardization reforms directly respond to PRA Question #4, which asks how the burden of information collection can be minimized, including through the use of information technology. By leveraging automation to reduce redundant paperwork while enhancing data quality and oversight, the NRC can fulfill its PRA obligations and support both nuclear safety and patient access.

VI. Affordability, Access, and Equity Implications of Transportation Paperwork

Administrative delays associated with transportation paperwork disproportionately affect smaller hospitals, community cancer centers, and regional treatment facilities. Unlike large, vertically integrated medical systems, these providers often have fewer administrative resources and less flexibility to absorb delays or last-minute disruptions. When transportation documentation slows or complicates routine radiopharmaceutical shipments, smaller providers are more likely to cancel or forego treatments, even when clinical demand exists.

Over time, paperwork burden can function as a barrier to entry for advanced radiopharmaceutical therapies. Facilities that cannot reliably navigate time-sensitive transportation requirements may decide not to offer these treatments at all, concentrating access in a limited number of large urban or academic centers. This dynamic can exacerbate geographic disparities in care and limit treatment options for patients in rural or underserved communities.

Transportation inefficiencies also contribute to higher per-dose costs and reduced treatment availability. When doses expire due to administrative delay, the cost of production and transport is effectively spread across fewer successful treatments. These inefficiencies can increase the price of therapy, reduce scheduling flexibility, and constrain the number of patients who can be treated within a given period.

Affordability and access are legitimate considerations under the Paperwork Reduction Act's requirement to assess cumulative burden. While individual paperwork tasks may appear modest in isolation, their combined effect on delivery timelines, treatment capacity, and cost can be substantial. Evaluating burden solely in terms of paperwork hours risks overlooking these real-world impacts on patients and providers.

CRF emphasizes that regulatory efficiency supports, rather than undermines, public health goals. Well-designed information collections can enhance safety while facilitating timely access to care. By ensuring that transportation paperwork is proportional, targeted, and aligned with clinical realities, the NRC can help advance both nuclear safety and equitable access to lifesaving medical innovation.

Conclusion

CRF reiterates its strong support for the Nuclear Regulatory Commission's mission to ensure the safe packaging and transportation of radioactive materials. Transportation oversight, documentation, and quality assurance are indispensable components of nuclear safety, and CRF recognizes the NRC's responsibility to maintain rigorous standards that protect public health and preserve confidence in the regulatory system.

At the same time, paperwork is a tool to advance regulatory objectives, not a substitute for regulatory clarity or proportionality. When information collections become repetitive or disconnected from real-world outcomes, they risk functioning as administrative stand-ins for judgment rather than as sources of meaningful safety insight. The Paperwork Reduction Act exists to guard against that outcome by requiring agencies to continually assess necessity, utility, and burden.

Time-critical medical therapies present a particularly compelling case for such assessment. Radioligand therapies and other advanced radiopharmaceuticals operate within narrow clinical

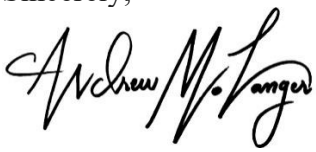
windows that leave little tolerance for delay. Regulatory processes governing their transportation must reflect this operational reality if safety oversight is to support, rather than inadvertently hinder, patient care.

CRF therefore urges the NRC and the Office of Management and Budget to use this PRA renewal as an opportunity to reassess whether shipment-level repetition of unchanged information continues to deliver meaningful regulatory utility. Where repeated documentation does not generate new safety insight, it warrants reconsideration under the PRA's proportionality and practical utility standards.

Exploring standing or routine shipment authorizations, tiered documentation frameworks, and expanded use of automation for recurring medical shipments offers a constructive path forward. These approaches can preserve safety, sharpen oversight, and reduce unnecessary delays for time-sensitive therapies without weakening regulatory controls.

CRF appreciates the opportunity to comment and reaffirms its commitment to lawful, safe, affordable, and patient-centered regulatory policy. CRF stands ready to engage further with the NRC and OMB to help ensure that transportation oversight keeps pace with medical innovation while maintaining the highest standards of nuclear safety.

Sincerely,



Andrew M. Langer
Director
CPAC Foundation Center for Regulatory Freedom