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Ensuring a Reliable Supply Chain: Best Practices for Sourcing FDA-Approved Radiopharmaceuticals

When a single delivery delay can shut down a PET scanner, it can cost a hospital up to \$15,000 per hour.¹ If delays drag on, the losses can reach hundreds of thousands of dollars, with disrupted workflows, frustrated patients and the potential to jeopardize patient care. Supply chain reliability isn't just a logistics issue—it's a clinical imperative. From reactor outages and short-lived isotopes to regulatory red tape, hospitals face relentless pressure to keep critical PET and SPECT tracers flowing. This article dives into the systemic weak points threatening nuclear medicine and reveals practical, battle-tested strategies for hospitals to stay ahead. Featuring real-world insights and best practices—alongside an inside look at how Jubilant Radiopharmacies is setting a new standard with multi-source reliability, dedicated medical couriers, and personalized service—this article empowers healthcare leaders to proactively strengthen imaging operations and ensure uninterrupted patient care today and into the future.

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I. The Day the Scanner Went Silent

It was a Tuesday morning like any other. Patients had arrived early at the imaging department of a major metropolitan hospital, fasting and anxious for their scheduled PET scans. But something was different that day. A call came in from the nuclear pharmacy: a shipment of a critical PET tracer had been delayed indefinitely.

By noon, physicians were scrambling to reschedule appointments, patients were being sent home disappointed—and in one case, a delayed diagnosis would later lead to a more aggressive treatment plan. The PET scanner sat idle, costing the hospital dearly. Just one hour of downtime can mean more than \$15,000 in lost revenue, not to mention wasted doses and disrupted workflows.¹ Multiply that by repeated outages—especially in high-throughput settings—and the losses can easily climb into the hundreds of thousands annually.

This scenario is not uncommon. Hospitals across the U.S. are navigating an increasingly complex web of supply chain disruptions that threaten the timely delivery of radiopharmaceuticals. From global manufacturing issues and short shelf-lives to transportation hurdles and regulatory complexities, ensuring a consistent supply of FDA-approved radiopharmaceuticals has become a mission-critical challenge.

The good news? Hospitals don't have to tackle these challenges alone. This article outlines best practices for procurement, inventory management, supplier partnerships, and regulatory navigation—along with real-world examples—to help hospitals become active drivers of a more resilient, responsive, and reliable radiopharmaceutical supply chain.



II. Cracks in the Chain: Radiopharmaceutical Supply Challenges

To build a stronger, more resilient radiopharmaceutical supply chain, it's essential to first understand the challenges that can threaten it. These challenges are not unique to one facility—they reflect broader industry-wide pressures that every institution must navigate. At the same time, each hospital or healthcare organization faces its own distinct set of circumstances. Recognizing how local realities fit into this broader landscape empowers leaders to take informed, strategic steps toward lasting improvement.

Whether it's the fragility of global ^{99m}Tc production or the minute-by-minute decay of PET tracers like ^{18}F and ^{68}Ga , hospitals face a constant race against the clock.² The COVID-19 pandemic further exposed just how brittle this supply chain can be, amplifying vulnerabilities that had long gone unaddressed. With aging infrastructure, regulatory bottlenecks, and razor-thin delivery windows, even a small hiccup can cascade into canceled scans, delayed diagnoses, and compromised care.

Below are key structural challenges that continue to threaten radiopharmaceutical supply chain reliability.



Aging infrastructure and global dependency: Most molybdenum-99 (^{99}Mo)—the parent of ^{99m}Tc —comes from a handful of international reactors, many built decades ago.³ Outages or maintenance abroad can cripple SPECT imaging at home.



Ultra-time sensitive logistics: Whether it's ^{99m}Tc 's 6-hour decay, ^{18}F 's 110-minute half-life, or ^{68}Ga 's rapid 68-minute clock, radiopharmaceuticals demand just-in-time precision.² Delays in generator elution, courier routes, or dose prep can mean instant waste.



Regulatory ripple effects: If a kit-based tracer like ^{99m}Tc -PYP disappears from the market (as it did in 2023), hospitals scramble for substitutes—often with zero notice.⁴ Similarly in 2018, as clinical demand for ^{68}Ga -DOTATATE and PSMA tracers surged, strict FDA usage limits and a lack of approved ^{68}Ga generators led to nationwide shortages, forcing scan delays.⁵



Single points of failure: Managing multiple vendors to avoid supply disruptions is complex and resource-intensive—but relying on a single partner with a diversified, multi-source supply network offers built-in resilience without the operational burden.⁵



Uneven access across hospital types: Academic centers may have on-site production capacity, but community hospitals often operate with minimal buffer—making them especially vulnerable during disruptions.

III. How to Optimize Your Procurement Strategies

In the high-stakes environment of nuclear medicine, ensuring a consistent and timely supply of FDA-approved radiopharmaceuticals is both a necessity and an opportunity. Forward-thinking hospitals are embracing this moment as a chance to strengthen their operations, support patient care, and lead their organizations into a more resilient future.

By adopting proactive, data-informed procurement models, healthcare providers can stay ahead of demand, mitigate supply chain risks, and improve coordination across teams. These strategies not only protect continuity of care—they empower hospitals to become agile, reliable partners in a fast-evolving healthcare landscape.

What follows are practical, solution-focused approaches that any hospital can adapt to build a smarter, more resilient radiopharmaceutical supply chain—one that supports patients, clinicians, and operational leaders alike.



1. Strategic forecasting and demand planning

Hospitals should implement robust, data-driven forecasting tools that account for historical usage patterns, procedural volumes, seasonal fluctuations, and upcoming clinical needs. Collaborating with nuclear medicine and scheduling teams enables procurement departments to anticipate tracer requirements and avoid last-minute scrambles.

2. Streamlined ordering and delivery processes

Standardized ordering protocols and automated procurement systems help reduce errors and administrative lag. Hospitals should align closely with radiopharmacies and logistics providers to match delivery schedules with clinical workflow—particularly important for short-lived isotopes like ^{99m}Tc and ^{18}F .



3. Inventory management and redundancy planning

Effective inventory management balances availability with waste reduction. Key strategies include:

- Real-time inventory tracking and dose forecasting
- Just-in-time delivery to reduce expiration losses
- Dual- or multi-sourcing critical isotopes to ensure continuity during disruptions



4. Risk mitigation through multi-source suppliers

Traditional procurement strategies often focus on managing multiple vendors to reduce risk—but this can create complexity and inefficiency. Hospitals are especially vulnerable when key tracers depend on single-source suppliers. Partnering with a single, strategically integrated supplier that leverages a diversified network of FDA-approved sources offers a smarter path to resilience—delivering flexibility, continuity, and simplified procurement without sacrificing supply security.

5. Leveraging technology for supply chain visibility

Integrated digital platforms that connect hospitals with their radiopharmaceutical suppliers can provide real-time visibility into product availability, shipment tracking, and regulatory status. These systems enable faster, more informed decision-making, particularly during times of supply uncertainty.



By combining strategic planning, operational alignment, and technological visibility, hospitals can strengthen their procurement systems and take control of their radiopharmaceutical supply—supporting uninterrupted, high-quality nuclear imaging services regardless of external pressures.

IV. The Role of Supplier Partnerships to Ensure Continuity of Care

A resilient radiopharmaceutical supply chain is only as strong as the partnerships that support it. While internal planning and operational efficiency are essential, hospitals can amplify their impact by forming strategic relationships with suppliers—especially in a field where timing, regulatory compliance, and innovation are critical to patient outcomes.

Deepening partnerships with radiopharmacies

Moving beyond transactional interactions, hospitals can foster collaborative, long-term relationships with radiopharmacies. This means:

- ▶ Engaging in regular communication to align on demand forecasts, production schedules, and delivery windows
- ▶ Participating in joint planning sessions to prepare for regulatory shifts or potential disruptions
- ▶ Establishing shared performance metrics to monitor reliability, responsiveness, and quality over time

These deeper partnerships also facilitate earlier access to newly FDA-approved radiopharmaceuticals and promote shared accountability in meeting regulatory and clinical standards.

Structuring long-term, flexible agreements

Strategic contracts with suppliers create predictability and stability in an otherwise dynamic market. Effective agreements may include:

- ▶ Volume-based pricing to stabilize costs and encourage supply consistency
- ▶ Service-level agreements (SLAs) that outline delivery timelines, product quality benchmarks, and contingency protocols
- ▶ Clauses that allow flexibility for shifts in demand or new tracer adoption

Well-structured contracts can also provide priority access to high-demand or limited-supply radiopharmaceuticals, ensuring continuity of care even during national shortages.

Driving innovation and sharing risk

Hospitals and suppliers share common pain points—such as last-mile delivery for short-lived isotopes or maintaining traceability in inventory. Collaborative innovation, such as co-developing logistics solutions or adopting digital inventory platforms, can help solve these challenges. In some cases, risk-sharing arrangements—where both parties invest in infrastructure or delivery systems—can create a more resilient and responsive supply chain.

By treating suppliers not just as vendors but as strategic partners, hospitals can build a more dependable, adaptive, and forward-looking radiopharmaceutical ecosystem—one that sustains patient care even under pressure.



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V. Navigating Regulatory Requirements for PET and SPECT Tracers

Staying compliant with FDA regulations is non-negotiable—errors can mean shutdowns, recalls, or delayed diagnostics. Hospitals should appoint dedicated compliance officers or regulatory liaisons to monitor guidance updates, Risk Evaluation and Mitigation Strategies (REMS) programs, and pharmacovigilance requirements.⁷ Partnering with suppliers who are proven in compliance helps reduce import holdups and risk of recalls. Rigorous documentation and validation are essential, especially when handling investigational tracers or running clinical trials.

Real-world examples of regulatory impact:

▶ cGMP violations halt production

In 2021, Brigham and Women's Hospital received an FDA warning after inspectors found water leaks in the aseptic production area for PET tracers—violations of current Good Manufacturing Practices (cGMP)—necessitating immediate corrective action before resuming tracer preparation.⁸

▶ PET drug application deadlines

Under FDA's 2009 PET drug rule (21 CFR Part 212), all PET tracer producers were required to file NDAs or ANDAs by December 2011 and fully comply by mid-2012.⁹ This created a compliance cliff—hospitals that hadn't filed risked losing access to essential tracers.

▶ REMS can ramp up compliance burden

Some newer radiopharmaceuticals are subject to FDA REMS—meaning hospitals must have systems in place to track, report, and ensure safe use. Failure to plan for these requirements has delayed product launches by months, or even up to a year.¹⁰



VI. Ensuring Reliability Through Strategic Partnership: The Jubilant Radiopharmacies Advantage

In an industry where timing, precision, and consistency are everything, choosing the right radiopharmaceutical partner can make the difference between a seamless care experience and a critical supply disruption. As the second largest radiopharmacy network in the United States, Jubilant Radiopharmacies plays a pivotal role in strengthening the national supply chain for PET and SPECT imaging.

With more than 1,800 healthcare providers served and over 3 million doses delivered annually, Jubilant Radiopharmacies combines the scale and infrastructure of a global leader with the responsiveness and trust of a neighborhood pharmacy. Backed by over 30 years of nuclear medicine expertise, deep integration with GPOs and IDNs, and a commitment to digital innovation, Jubilant Radiopharmacies delivers more than products—it delivers confidence, consistency, and partnership.

Jubilant Radiopharmacies stands apart through several key differentiators. Unlike some suppliers that depend on a single source of molybdenum-99 (Mo-99), Jubilant Radiopharmacies has invested in a multi-source strategy that enhances reliability and safeguards continuity—even during global shortages or disruptions. In addition, Jubilant Radiopharmacies is one of the only radiopharmaceutical providers that employs dedicated, in-house medical couriers for all deliveries. This specialized, end-to-end service ensures vertical and horizontal continuity and reinforces our promise to deliver the “Right dose. Right time. Reliably.”

The following examples illustrate how Jubilant Radiopharmacies’ proactive strategies, infrastructure investments, and collaborative approach help ensure continuous, compliant, and cost-effective radiopharmaceutical supply across the country.

**Right dose.
Right time.
Reliably.**



How Jubilant Radiopharmacies ensures supply chain reliability

01

Strategic generator deployment for 68Ga

Jubilant Radiopharmacies partnered with Eckert & Ziegler to equip all 45 of its pharmacy locations with GalliaPharm® 68Ga generators. This network-wide deployment was designed to meet rising demand for tracers like 68Ga-DOTATATE and 68Ga-PSMA and ensure local availability despite the isotope's short half-life. This investment allows for on-demand elution at the point of care, reducing reliance on distant suppliers and mitigating delays caused by delivery windows or generator shortages.

02

Early-morning production and distribution of 18F-FDG

To meet the logistical demands of PET imaging, Jubilant Radiopharmacies operates multiple cyclotron facilities that produce 18F-FDG between 12:00 AM and 7:00 AM, ensuring doses are ready for early-morning delivery to hospitals. This fine-tuned scheduling accounts for the ~110-minute half-life of 18F and ensures doses arrive in time for scheduled scans, helping avoid dose decay and scan cancellations.

03

Redundant supply channels

Jubilant Radiopharmacies has embraced a multi-source strategy for critical isotopes, including 99Mo/99mTc generators, 68Ga products, and cold kits. This redundancy enables the network to maintain service during regional or global shortages, such as those caused by reactor outages or supplier discontinuations. It allows hospitals to receive uninterrupted supply even when other vendors face allocation limits.

04

Regulatory expertise and compliance infrastructure

Jubilant Radiopharmacies leverages decades of experience in nuclear pharmacy operations to navigate FDA and USP regulations efficiently. These established systems help hospitals stay compliant with current Good Manufacturing Practices (cGMP) and PET drug regulations, providing assurance around documentation, sterility, and quality control. This makes them a strong partner for hospitals lacking in-house regulatory capacity.

05

Collaborative planning and responsiveness

During disruptions like the 2024 Tc-99m shortage, Jubilant Radiopharmacies has worked closely with hospitals to adjust delivery schedules, prioritize urgent cases, and implement contingency protocols. Jubilant's proactive communication and shared planning with clients helped minimize the operational impact of shortages or delays.

VII. The Power to Deliver: Building a Resilient Future

The silent scanner is no longer just a symbol of what can go wrong—it’s a reminder of what healthcare leaders can influence through the right partnerships and proactive planning. Ensuring a reliable supply of FDA-approved radiopharmaceuticals goes beyond logistics; it’s about delivering peace of mind, continuity of care, and better patient outcomes.

Hospitals today are not passive players in this process. By choosing a radiopharmacy partner who prioritizes innovation, consistency, and collaboration, providers take an active role in shaping a more resilient future for nuclear medicine. The ability to influence procurement strategy, streamline inventory, and navigate regulatory complexity is within reach—and that influence becomes a powerful form of advocacy for patients and care teams alike.

In a field where every moment counts, consistency in radiopharmaceutical delivery is not just a benchmark—it’s a moral imperative. That’s why more and more healthcare organizations across the country are partnering with Jubilant Radiopharmacies. With a national footprint, decades of expertise, and a relentless commitment to reliability, Jubilant Radiopharmacies empowers hospitals to meet every patient with confidence. When answers matter most, we make sure the dose is there—on time, every time.

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