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# Radiation Sterilization And Health Informatics In Nuclear Pharmacy Practice: A Safety And Quality Perspective With Applications In Emergency Care

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**Abstract**
Nuclear pharmacy practice operates at the intersection of sterile preparation, radiation safety, and time-sensitive clinical service delivery, where small-batch production, short radionuclide half-lives, and rapid handoffs increase vulnerability to preventable harm if sterility or documentation fails. This integrative review synthesizes contemporary evidence and authoritative guidance on (1) radiation sterilization principles relevant to healthcare materials and components, (2) radiopharmacy quality systems and quality risk management, and (3) health informatics capabilities that strengthen traceability, auditability, and workflow reliability, with emphasis on applications in emergency care environments where interruptions and surge conditions are common (Gillings et al., 2021; Gillings et al., 2022; ISO, 2025; WHO, 2018; WHO, 2021). Evidence converges on five themes: sterility assurance as a validated process outcome requiring controlled parameters and documented evidence; irradiation compatibility as conditional and material-specific, necessitating stability and performance verification; quality risk management as the governance "decision engine" for substitutions and process adaptation; informatics as an operational safety-control layer enabling end-to-end traceability, audit trails, and deviation learning loops; and emergency care as a reliability stress test that clarifies which controls must remain functional under pressure (Jacobs, 2022; Charoo et al., 2023; Gómez Perales, 2022; Hansen et al., 2020; Owens et al., 2020; Mulac et al., 2021). The synthesis supports a unified "sterility assurance + data assurance" model in which change control, traceability, and data integrity are treated as core patient-safety functions rather than administrative tasks.

**Keywords:** nuclear pharmacy; radiopharmacy; radiation sterilization; gamma irradiation; X-ray sterilization; sterility assurance; quality risk management; data integrity; health informatics; traceability; audit trail; interoperability; emergency care; patient safety.

## Introduction

Nuclear pharmacy practice operates at a uniquely high-risk intersection of sterile preparation, radiation protection, and time-sensitive clinical service delivery. Unlike many conventional medication pathways, radiopharmaceutical workflows often involve short half-lives, limited windows for quality

control and release, and tightly controlled handling requirements. These characteristics amplify the consequences of any breakdown in sterility assurance, documentation, or traceability. Current European guidance for small-scale radiopharmaceutical preparation (cGRPP) emphasizes that radiopharmacy should be managed within a structured quality framework—covering facilities, personnel competence, standard operating procedures, quality assurance, and documentation—aligned with good manufacturing practice principles but tailored to radiopharmaceutical realities (Gillings et al., 2021).

Within this quality framework, sterility assurance is not simply a technical endpoint; it is a system outcome produced by validated processes and controlled conditions. Radiation sterilization—using gamma, electron beam, or X-ray sources—represents a well-established sterilization modality in healthcare industries, supported by internationally standardized requirements for process development, validation, and routine control (International Organization for Standardization [ISO], 2025). However, applying radiation sterilization concepts to pharmaceutical contexts requires careful interpretation, because irradiation may induce chemical and physical changes in drug substances, excipients, and packaging materials. A contemporary review of pharmaceutical irradiation highlights that feasibility is product-specific, and that compatibility must be demonstrated using stability-indicating approaches rather than assumed from sterilization capability alone (Jacobs, 2022). For nuclear pharmacy, this evidence is especially relevant when considering sterile components, containers, closures, and consumables that may be radiation-sterilized upstream, as well as when planning contingency substitutions under supply constraints.

Parallel to sterility assurance, health informatics has become central to modern radiopharmacy quality operations. Digital health strategy at the global level increasingly frames information systems as a foundation for safer, more effective health services—particularly when governance, interoperability, and trustworthy data flows are prioritized (World Health Organization [WHO], 2021). In radiopharmacy practice, informatics enables operational control of the preparation-to-administration pathway: identity management, traceability from dose preparation to patient administration, standardized release documentation, audit trails, deviation reporting, and rapid retrieval of records during incident investigation. Evidence from an implemented radiopharmacy information system demonstrates how structured digital workflows can support correct traceability of radiopharmaceuticals administered to patients and strengthen workflow reliability (Gómez Perales, 2022). These informatics functions are not ancillary; they are integral to quality risk management because risk controls must be demonstrable through reliable records.

Quality risk management (QRM) provides the governance logic that binds sterility assurance and informatics into a coherent safety system. The EANM QRM guideline for radiopharmaceuticals emphasizes structured risk assessment and mitigation for small-scale “in-house” preparation, encouraging professionals to identify hazards, evaluate risk, and implement proportional controls while documenting decisions in a manner suitable for review and continuous improvement (Gillings et al., 2022). When radiopharmacy workflows are exposed to operational variability—staffing changes, workflow interruptions, urgent requests, and supply disruptions—QRM becomes especially dependent on robust data capture, version control, and auditability, all of which are strengthened by well-governed informatics systems.

Emergency care is a setting where these requirements become more visible and less forgiving. Emergency systems are defined by time pressure, high uncertainty, and frequent handoffs; quality and safety frameworks in emergency medicine emphasize system-level reliability and governance to reduce preventable harm during acute care delivery (Hansen et al., 2020). WHO’s emergency care system perspective similarly underscores that cross-cutting functions—such as coordination, documentation, and quality improvement—are essential to maintaining safe care across the emergency pathway (WHO, 2018). In this context, nuclear pharmacy contributes to emergency readiness not only through access to radiopharmaceutical services, but also through the reliability of its sterility assurance and the integrity and availability of its data, particularly when urgent decision-making and rapid handoffs are involved.

This integrative review synthesizes recent guidance and evidence on (1) radiation sterilization concepts relevant to sterility assurance in nuclear pharmacy environments, (2) the role of health informatics in strengthening traceability, documentation, and quality risk management in radiopharmacy workflows, and (3) how the combined sterility-and-data assurance approach can support safety and quality with practical applications in emergency care contexts (Gillings et al., 2021, 2022; Gómez Perales, 2022; Hansen et al., 2020; ISO, 2025; Jacobs, 2022; WHO, 2018, 2021).

## Background and rationale

### 1) Why sterility assurance is a central challenge in nuclear pharmacy

Radiopharmaceutical preparation and dispensing sits in a narrow space between pharmaceutical manufacturing logic and bedside clinical urgency. In small-scale radiopharmacy, batches are typically limited, patient-linked, and constrained by radionuclide half-life; therefore, "quality at the end" is rarely feasible. Instead, quality must be built into the workflow through controlled environments, trained personnel, validated steps, and complete documentation. The EANM guideline on current good radiopharmacy practice (cGRPP) reinforces this point by framing radiopharmacy as a quality-critical activity that requires structured governance, defined procedures, and traceable records even in non-industrial settings (Gillings et al., 2021).

Sterility assurance in this context is not simply "using sterile items." It is a system outcome shaped by (a) material sterility and compatibility, (b) aseptic technique and environmental controls, (c) validated preparation and handling steps, and (d) documentation that can demonstrate what occurred and support corrective action if deviations arise. This system view is also consistent with broader pharmaceutical quality thinking that emphasizes prevention, validation, and documentation rather than reliance on final inspection alone (Gillings et al., 2022).

### 2) Radiation sterilization: what it offers, and why it must be framed carefully

Radiation sterilization (gamma, electron beam, X-ray) is a mature sterilization technology used widely for healthcare products, particularly when heat or moisture could damage the material. The ISO 11137 framework emphasizes that radiation sterilization is a validated process that requires defined development activities, validation, and routine control to ensure consistent sterilization performance (International Organization for Standardization [ISO], 2025). Although ISO 11137 is written primarily for medical devices, its underlying logic—dose control, process qualification, and documentation—offers a transferable quality mindset for nuclear pharmacy, particularly for upstream-sterilized components and for contingency decision-making when substitutions occur.

However, applying radiation sterilization concepts to pharmaceuticals introduces a critical caveat: ionizing radiation can change the chemical and physical properties of active ingredients, excipients, or packaging through radiolysis and related mechanisms. A contemporary review of pharmaceutical irradiation emphasizes that feasibility is product-dependent and requires stability-indicating evaluation rather than assumption (Jacobs, 2022). Earlier pharmaceutical-focused work also highlights that gamma sterilization can be practical but must be justified by formulation stability evidence and product-specific testing (Hasanain & Guenther, 2014).

Recent applied research adds a further nuance that is relevant to real-world procurement and supply resilience: X-ray irradiation is being evaluated as an alternative to gamma for sterilizing single-use polymers used in bioprocessing, with implications for equivalence claims, material performance, and risk-based substitution decisions (Grzelak et al., 2023). For nuclear pharmacy practice, this is important because many critical consumables (syringes, sterile sets, tubing, container-closure components) are manufactured using sterilization pathways that may shift with industry changes or supply constraints. If the sterilization modality changes, radiopharmacy leaders need a defensible, quality-system method to evaluate whether the component remains fit for purpose and whether any new risks are introduced (ISO, 2025; Jacobs, 2022; Grzelak et al., 2023).

### 3) Radiopharmacy quality risk management links sterility and documentation into one system

A repeated theme in radiopharmacy governance is that "good practice" must be supported by quality risk management (QRM). The EANM QRM guideline emphasizes a structured approach to identifying hazards, assessing and controlling risk, documenting decisions, and supporting continuous improvement (Gillings et al., 2022). This matters because radiopharmacy workflows face routine variability: urgent add-on requests, staffing fluctuations, interruptions, time pressure from decay, and occasional supply disruptions.

In such conditions, QRM becomes dependent on the quality of documentation and traceability. If records are incomplete or inconsistent, it becomes difficult to reconstruct events, identify root causes, or demonstrate compliance with safe practice expectations. Pharmaceutical data-integrity literature reinforces that weak documentation systems can undermine safety even when technical processes are

otherwise robust, and it proposes mitigation strategies centered on governance, audit trails, access control, and structured quality systems (Charoo et al., 2023). This makes QRM the "bridge" that conceptually ties radiation sterilization (as a validated process principle) to informatics (as the mechanism that captures, secures, and operationalizes those controls).

**4) Why health informatics is essential in modern nuclear pharmacy practice**

Health informatics is increasingly recognized as a foundation for safe, coordinated healthcare, provided that digital systems are governed, interoperable, and aligned with clinical workflows (World Health Organization [WHO], 2021). In nuclear pharmacy, informatics is particularly consequential because radiopharmaceutical processes depend on precise identity and time management: patient identification, correct product selection, activity calculation and assay documentation, beyond-use time tracking, release authorization, and confirmation of administration.

Evidence from a radiopharmacy information system experience report illustrates how dedicated systems can support workflow organization and traceability of radiopharmaceuticals administered to patients, indicating that informatics can function as an operational safety layer rather than simply a repository (Gómez Perales, 2022). Beyond radiopharmacy-specific systems, broader patient-safety literature increasingly links poor interoperability to safety risks, including documentation gaps and delayed information exchange. A systematic review protocol focusing on interoperability and patient safety signals that this issue is sufficiently consequential to require structured evidence synthesis and safety-oriented evaluation methods (Li et al., 2021). In emergency-linked workflows—where time is compressed and handoffs are frequent—interoperability and rapid record retrieval become even more critical.

**5) Emergency care as the "stress test" for sterility assurance and informatics**

Emergency care environments reveal system weaknesses faster than routine settings. They are characterized by high uncertainty, interruptions, surges in demand, and rapid handoffs. Emergency medicine quality and safety frameworks emphasize the need for reliable systems and governance to minimize preventable harm under these conditions (Hansen et al., 2020). WHO's emergency care system perspective similarly highlights cross-cutting functions—coordination, data, quality improvement, and integrated pathways—as essential to safe performance across the emergency trajectory (WHO, 2018).

For nuclear pharmacy practice, "applications in emergency care" should be understood as readiness for time-critical operations rather than limited to a narrow list of emergency nuclear medicine indications. Readiness includes:

- confidence in the sterility and compatibility of critical components and supplies,
- rapid traceability from preparation to administration,
- auditable release documentation, and
- the ability to reconcile discrepancies quickly during incidents or surges.

Evidence from emergency department medication safety supports the relevance of digital verification and structured workflows under time pressure. A pre–post evaluation of bar-code medication administration in an emergency department reported reductions in medication administration errors and changes in nursing satisfaction, supporting the general principle that informatics-enabled verification can improve safety in high-pressure settings (Owens et al., 2020). At the same time, observational evidence suggests that barcode systems can be undermined by workflow deviations and workarounds, emphasizing that implementation design and fit are decisive for real safety gains (Mulac et al., 2021). These findings strengthen the rationale for discussing emergency applications through the lens of reliability engineering: emergency performance depends not only on the presence of technology, but on governance, usability, and integration with real workflows.

**6) The gap this review addresses**

Despite the maturity of radiation sterilization standards and the increasing adoption of informatics in clinical systems, there is a persistent gap in the literature that explicitly integrates these domains within nuclear pharmacy quality governance while also mapping implications to emergency care readiness. Existing radiopharmacy guidance provides strong foundations for good practice and QRM (Gillings et al., 2021, 2022), and sterilization literature clarifies the need for validated processes and compatibility

evidence (ISO, 2025; Jacobs, 2022; Grzelak et al., 2023). Informatics literature highlights traceability and interoperability as patient-safety mechanisms, with emergency care studies demonstrating both benefits and implementation risks of digital verification (Gómez Perales, 2022; Li et al., 2021; Owens et al., 2020; Mulac et al., 2021).

This integrative review is therefore justified as a synthesis that (a) connects sterility assurance principles to radiopharmacy quality systems, (b) positions informatics as a functional safety control, and (c) translates the combined framework into emergency care–relevant implications that are actionable for practice leaders and policy makers.

**Methods (continuing in English)**

**Study design**

An integrative review design was selected to enable synthesis of heterogeneous evidence (standards, practice guidelines, implementation reports, and empirical studies) relevant to radiation sterilization, nuclear pharmacy quality systems, health informatics, and emergency care applications. This approach is appropriate for complex, cross-disciplinary topics where limiting evidence to a single study design would omit key operational and governance insights (Whittemore & Knafl, 2005; Torraco, 2016).

**Review objective and questions**

**Objective:** To synthesize contemporary evidence on how radiation sterilization principles and health informatics capabilities can jointly strengthen safety, quality, and emergency-care readiness in nuclear pharmacy practice.

**Guiding questions:**

1. What validated principles and standards governing radiation sterilization are most relevant to nuclear pharmacy materials and workflows?
2. How do radiopharmacy quality systems and quality risk management frameworks define requirements for sterility assurance and documentation?
3. Which informatics functions (traceability, audit trails, interoperability, workflow enforcement) are most consistently linked to safer radiopharmacy operations?
4. How can these findings be translated into emergency-care–relevant applications and readiness recommendations?

**Data sources and search strategy**

The search strategy prioritized recent evidence (2019–2025), while allowing inclusion of essential methodology references for integrative review conduct. Searches were planned across biomedical, pharmacy, and informatics sources, including: PubMed/MEDLINE, Scopus, Web of Science, Embase, and relevant publisher platforms for radiopharmacy and sterilization standards literature (e.g., SpringerLink). Standards and authoritative guidance were retrieved from issuing organizations and professional bodies (e.g., ISO standards documents; WHO strategy/framework publications; EANM radiopharmacy guidelines).

**Example keyword blocks (combined with AND/OR):**

- “radiation sterilization” OR “gamma sterilization” OR “electron beam sterilization” OR “X-ray sterilization” AND “pharmaceutical” OR “drug stability” OR “polymer”
- “nuclear pharmacy” OR “radiopharmacy” AND “quality risk management” OR “cGRPP” OR “good radiopharmacy practice”
- “health informatics” OR “digital health” OR “information system” OR “traceability” OR “audit trail” OR “interoperability”
- “emergency care” OR “emergency department” OR “emergency medical services” OR “surge” OR “handoff” AND “safety” OR “quality”

**Eligibility criteria**

**Inclusion criteria:**
- Peer-reviewed studies (quantitative, qualitative, mixed methods), implementation reports, and high-quality narrative/systematic reviews addressing any of the intersections among radiation sterilization, radiopharmacy quality/sterility assurance, health informatics, or emergency-care applications.
- Authoritative standards and guidance (e.g., ISO sterilization standards; WHO digital health strategy and emergency care frameworks; EANM radiopharmacy practice and QRM guidelines).

**Exclusion criteria:**
- Non-methodological opinion pieces without transparent sourcing.
- Studies unrelated to healthcare sterility/quality or not applicable to medication/radiopharmaceutical workflows.
- Reports lacking sufficient detail to support thematic extraction.

**Screening and selection process**
Records were screened in two stages: (1) title/abstract screening for relevance to the review questions; (2) full-text assessment against eligibility criteria. Reasons for exclusion at full-text stage were documented to ensure transparency. Reporting followed PRISMA 2020 principles where applicable for documenting selection flow and synthesis decisions (Page et al., 2021).

**Data extraction**
A standardized extraction framework was used to capture:
- Study type, setting, and population/workflow context
- Sterilization modality and sterility assurance concepts (dose/validation themes; material compatibility)
- Radiopharmacy QA/QRM elements (controls, documentation requirements, deviation handling)
- Informatics functions (traceability, auditability, interoperability, workflow enforcement)
- Emergency-care relevance (time-critical workflow, surge, handoffs, reliability considerations)
- Key findings and implementation lessons

**Quality appraisal**
Given the heterogeneity of evidence, appraisal was matched to evidence type. Empirical studies were assessed for methodological transparency and risk of bias appropriate to design; implementation reports were appraised for clarity of context, intervention description, and plausibility of outcome claims. Standards and guidance documents were assessed based on issuing authority, currency, scope, and clarity of operational requirements (Torraco, 2016).

**Data synthesis**
A thematic synthesis was performed. Extracted findings were coded and organized into higher-order themes that reflect: (1) sterilization science and validation logic, (2) radiopharmacy quality systems and QRM governance, (3) informatics as an operational safety-control layer, and (4) emergency-care readiness and reliability under time pressure. Themes were then integrated into practice-oriented implications and recommendations.

**Results (Thematic Synthesis)**
Because this is an integrative review, the “results” are presented as a thematic synthesis that combines standards, professional guidelines, implementation experience, and empirical safety studies. Across the included evidence types, five interlinked themes emerged: validated sterility assurance, material/packaging compatibility under ionizing radiation, radiopharmacy quality governance and quality risk management, informatics-enabled traceability and data integrity, and emergency-care readiness as a reliability stress test (Gillings et al., 2021; Gillings et al., 2022; ISO, 2025; Jacobs, 2022; Charoo et al., 2023; Gómez Perales, 2022; Hansen et al., 2020; WHO, 2018; WHO, 2021).

**Thematic map of the evidence base**

| Theme | What the evidence consistently supports | Representative evidence types and examples |
|---|---|---|
| Sterility assurance as a validated process | Sterility is achieved through process validation, routine control, monitoring, and documentation, not by assumption | Radiation sterilization standard requirements (ISO, 2025); radiopharmacy practice governance (Gillings et al., 2021) |
| Compatibility and stability under irradiation | Radiation can alter materials and pharmaceutical constituents; feasibility is product/material specific and must be demonstrated | Pharmaceutical irradiation review (Jacobs, 2022); polymer equivalency studies (Grzelak et al., 2023; Roxby et al., 2024) |
| Quality risk management (QRM) binds sterility and documentation | Risk controls must be explicit, proportional, and traceable; deviations must feed learning cycles | EANM QRM guideline (Gillings et al., 2022) |
| Informatics is a safety-control layer | Systems can enforce traceability, audit trails, workflow checkpoints, and deviation capture | Radiopharmacy information system experience (Gómez Perales, 2022); interoperability-safety linkage (Li et al., 2021); data integrity synthesis (Charoo et al., 2023) |
| Emergency care exposes weak points | Time pressure, handoffs, and interruptions increase error risk; digital verification can help but depends on fit and governance | Emergency quality framework (Hansen et al., 2020); ED barcode implementation outcomes (Owens et al., 2020); BCMA deviation/workaround patterns (Mulac et al., 2021); WHO emergency system functions (WHO, 2018) |

**Theme: Sterility assurance is a process outcome, not a label**

The most consistent "result" across standards and professional guidance is that sterility assurance is fundamentally a validated process outcome that depends on controlled parameters and routine verification. Radiation sterilization standards emphasize development and validation steps, followed by routine control and monitoring to sustain consistent sterilization performance (ISO, 2025). Even though ISO 11137-1 primarily targets medical devices, the transferable concept for nuclear pharmacy is the discipline of verification: sterility must be defensible through documented controls rather than inferred from intent or vendor claims (ISO, 2025).

Radiopharmacy guidance converges on the same logic from the operational side. cGRPP frames small-scale radiopharmaceutical preparation as an activity that must be organized and governed using structured quality expectations: defined procedures, competent staff, environmental control, and complete documentation that supports traceability and review (Gillings et al., 2021). In synthesis, sterility assurance and radiopharmacy quality governance align around one core message: if sterility cannot be demonstrated through evidence and records, it is not robust enough for high-risk workflows.

**Theme: Irradiation compatibility must be demonstrated, especially for materials and packaging**

Across the irradiation literature, the central pattern is conditional feasibility. Jacobs (2022) consolidates evidence showing that irradiating pharmaceuticals and pharmaceutical materials can lead to radiolysis and other chemical/physical changes; therefore, irradiation compatibility is product-dependent and must be verified with stability-indicating evaluation rather than assumed.

Two complementary strands strengthen this theme for applied practice:

- **Single-use polymer equivalency under modality changes.** Studies comparing X-ray and gamma irradiation in bioprocessing polymers highlight that shifts in sterilization modality can raise questions about equivalency and performance, and that material characterization is needed to support safe substitution decisions (Grzelak et al., 2023).

- **Dose and dose-rate effects in common healthcare polymers.** Work examining polymer modifications under gamma and X-ray sterilization stresses that dose and dose-rate matter, and that polymer families (e.g., polyethylenes and polypropylene) can respond differently, reinforcing the need for risk-informed procurement and change control (Roxby et al., 2024).

For nuclear pharmacy practice, the synthesis implication is practical: even when radiopharmaceutical products are not terminally radiation-sterilized on-site, radiation-sterilized components and consumables are common in the pathway. When suppliers change sterilization modality or when emergency substitutions occur, the radiopharmacy quality system needs a structured method to confirm continued fitness for use (Jacobs, 2022; Grzelak et al., 2023; Roxby et al., 2024).

**Theme: Quality risk management provides the governance "glue"**

The EANM QRM guideline consistently positions risk management as the operational logic needed to keep small-scale radiopharmacy safe under variability. The guideline emphasizes structured risk assessment, proportional controls, documentation of decisions, and continuous improvement mechanisms (Gillings et al., 2022). Within the synthesized evidence, QRM functions as the "glue" that links sterilization realities (compatibility uncertainty, supplier changes, process sensitivity) to day-to-day radiopharmacy decisions (what controls are required, what can be adapted, what must be escalated).

A recurrent synthesis finding is that QRM effectiveness depends on record quality. Without reliable traceability, audits, and deviation records, it becomes difficult to demonstrate that risk controls were followed or to learn from failures. This dependency connects QRM directly to informatics and data integrity requirements (Gillings et al., 2022; Charoo et al., 2023).

**Theme: Informatics is not "supportive" — it is a safety mechanism**

Across radiopharmacy-specific informatics experience and broader digital health governance, informatics emerges as a control layer that can reduce reliance on memory, prevent omission of critical checks, and preserve auditability.

A radiopharmacy information system experience report shows how a dedicated radiopharmacy system can support workflow organization and maintain correct traceability of radiopharmaceuticals administered to patients, which is foundational for incident investigation and quality improvement (Gómez Perales, 2022). WHO's digital health strategy reinforces the systems view that trustworthy data flows, governance, and interoperability are prerequisites for digital tools to meaningfully strengthen health services (WHO, 2021).

Two cross-cutting evidence signals deepen this theme:

- **Interoperability and patient safety concern.** A protocol targeting EHR interoperability and patient safety highlights that interoperability is treated as a safety-critical domain warranting structured synthesis and evaluation (Li et al., 2021).
- **Pharmaceutical data integrity risk patterns.** A synthesis of data integrity observations in pharmaceutical contexts emphasizes that poor quality culture, governance, and technology controls can lead to unreliable records and downstream safety risk, underscoring the need for audit trails, access control, and validated systems (Charoo et al., 2023).

Taken together, the integrative finding is that nuclear pharmacy informatics should be framed as part of sterility-and-quality assurance, because traceability and audit trails are the means by which sterility assurance, release decisions, and deviation handling become demonstrable and reproducible (Gómez Perales, 2022; Gillings et al., 2022; Charoo et al., 2023).

**Theme: Emergency care is the reliability "stress test" that clarifies what must not fail**

Emergency care contexts magnify operational risk: time pressure, interruptions, and handoffs make errors more likely if systems are fragile. WHO's emergency care framework identifies essential functions across the emergency pathway and highlights cross-cutting system capacities that must work reliably (WHO, 2018). Emergency medicine quality frameworks similarly emphasize system-level reliability and governance to reduce preventable harm (Hansen et al., 2020).

Empirical ED medication-safety evidence supports the idea that informatics-enabled verification can reduce error rates under pressure. A study evaluating barcode medication administration in an emergency department found reductions in medication administration errors and improved nursing satisfaction after implementation, suggesting that structured digital verification can be beneficial in

emergency settings (Owens et al., 2020). However, evidence on policy deviations and workarounds in barcode medication administration shows that benefits can be undermined when workflow fit is poor or when staff adapt around system friction, highlighting implementation design as a decisive factor (Mulac et al., 2021).

Synthesizing these findings into emergency-care relevance for nuclear pharmacy yields a clear result: emergency readiness is strengthened when radiopharmacy systems provide rapid, unambiguous traceability, time governance, and auditable release documentation that remains functional under interruptions and surge conditions (WHO, 2018; Hansen et al., 2020; Gómez Perales, 2022; Mulac et al., 2021).

**Integrated result: A combined "Sterility Assurance + Data Assurance" control model**

Across themes, the evidence supports an integrated operational model in which sterility assurance and informatics are treated as a single safety loop:

- **Input assurance:** verified sterile supplies, known sterilization modality where relevant, controlled master data, and validated systems (ISO, 2025; Jacobs, 2022; Charoo et al., 2023).
- **Process assurance:** standardized radiopharmacy procedures, QRM-defined controls, and informatics-enforced checkpoints (Gillings et al., 2021; Gillings et al., 2022; Gómez Perales, 2022).
- **Output assurance:** release documentation, traceability to administration, and rapid incident reconstruction capability (Gómez Perales, 2022; Li et al., 2021).
- **Learning loop:** deviation capture, root-cause analysis, CAPA, and governance-driven improvement (Gillings et al., 2022; Charoo et al., 2023).

## Discussion

### 1) Interpreting the synthesis: sterility assurance and "data assurance" are inseparable in nuclear pharmacy

The central message from this integrative review is that sterility assurance and information integrity operate as a single safety system in nuclear pharmacy workflows. Standards for radiation sterilization emphasize that "sterile" is a claim supported by validated processes, routine control, and documented evidence, rather than a label attached to a product in isolation (ISO, 2025). Radiopharmacy good practice guidance similarly frames small-scale preparation as a quality-governed activity where robust documentation and traceability are not optional—they are the mechanism by which safe practice can be demonstrated and sustained (Gillings et al., 2021). When these two logics are combined, the practical implication is clear: even strong aseptic technique can be undermined if the supporting data trail is incomplete, inconsistent, or not recoverable during an incident investigation or audit (Gillings et al., 2022; Charoo et al., 2023).

### 2) What "radiation sterilization" means for nuclear pharmacy practice in real-world settings

Most nuclear pharmacies are not using radiation sterilization as a terminal sterilization method for radiopharmaceutical preparations; instead, radiation sterilization is more commonly encountered through upstream-sterilized components and single-use consumables (ISO, 2025). The discussion, therefore, should focus less on "should we sterilize radiopharmaceuticals by irradiation?" and more on "how do we manage irradiation-related variability in materials and supply chains safely within radiopharmacy quality systems?"

Two evidence strands help clarify this:

- **Pharmaceutical and material sensitivity to irradiation.** Irradiation can trigger radiolysis and material changes, so compatibility must be demonstrated using stability-indicating evaluation, not assumed (Jacobs, 2022). A detailed review of gamma sterilization across pharmaceutical components further underscores the product-specific nature of irradiation suitability, reinforcing the need for evidence-based justification and controlled decision-making (Hasanain & Guenther, 2014).
- **Equivalency and modality shifts (gamma vs X-ray).** Emerging industry shifts toward X-ray sterilization—often discussed as an alternative to gamma—create realistic scenarios where vendors change sterilization modality while maintaining "sterile" claims. Polymer-focused studies show that dose and dose-rate effects can alter polymer properties and that equivalence claims require

careful characterization rather than blanket assumptions (Roxby et al., 2024). Similarly, broader evaluation of X-ray versus gamma effects on single-use polymer systems indicates that X-ray impact may be comparable to or less than gamma for many materials, but still requires data to support equivalence in regulated contexts (Grzelak et al., 2023).

From a nuclear pharmacy governance perspective, these findings argue for treating sterilization modality changes as formal change-control events within QRM, even when the change occurs upstream in the supply chain rather than within the radiopharmacy (Gillings et al., 2022).

**3) Quality risk management is the "decision engine" for safe adaptation**

Radiopharmacy QRM guidance emphasizes structured risk assessment, proportional controls, documentation of decisions, and continuous improvement (Gillings et al., 2022). When applied to irradiation-related issues, QRM becomes the decision engine for:

- evaluating whether a new sterile component remains fit for purpose after supplier changes,
- defining what evidence is sufficient for acceptance (e.g., supplier documentation + internal verification steps),
- determining operational controls (e.g., tightened incoming inspection, restricted use, enhanced traceability), and
- documenting deviation handling and CAPA pathways for rapid learning (Gillings et al., 2022).

This is also where data integrity becomes decisive. If risk controls cannot be evidenced through reliable records—who prepared, what component lot was used, what release checks occurred—the organization's ability to demonstrate safe practice and to learn from problems is weakened (Charoo et al., 2023). In other words, QRM requires records that are trustworthy and retrievable under pressure, which naturally leads to informatics.

**4) Informatics functions as an operational safety-control layer (not a documentation add-on)**

Evidence from a radiopharmacy information system experience report demonstrates that informatics can directly support workflow organization and traceability of radiopharmaceuticals administered to patients (Gómez Perales, 2022). WHO's global digital health strategy frames digital systems as enabling safer and more effective services when governance and integration are prioritized (WHO, 2021). Together with data integrity evidence from pharmaceutical contexts, this supports a practical conclusion: in nuclear pharmacy, informatics is best conceptualized as a control layer that can (a) enforce key checkpoints, (b) preserve audit trails, and (c) reduce dependence on memory and informal workarounds (Charoo et al., 2023; Gómez Perales, 2022; WHO, 2021).

A safety-relevant informatics layer for nuclear pharmacy typically includes:

- traceability (dose ↔ batch ↔ materials ↔ preparer ↔ patient),
- time governance (calculation timestamps, beyond-use windows, release timing),
- audit trails (who changed what, when, why),
- deviation capture (structured incident logging), and
- interoperability where feasible to reduce transcription and handoff risks (Li et al., 2021).

**5) Emergency care applications: benefit is plausible, but fragile without fit and governance**

Emergency care settings amplify risk through interruptions, time pressure, and frequent handoffs. WHO's emergency care system framework stresses that emergency system functions span scene-to-transport-to-emergency unit care, and readiness requires cross-cutting capabilities that remain reliable during surge (WHO, 2018). Emergency medicine quality frameworks similarly emphasize system-level reliability and governance to reduce preventable harm (Hansen et al., 2020).

Evidence from medication safety in emergency departments provides an instructive parallel: implementing barcode medication administration in an ED was associated with reduced medication administration errors and improved nursing satisfaction (Owens et al., 2020). However, observational work also shows that barcode systems can be undermined by policy deviations and workarounds when workflow fit is poor or system friction is high (Mulac et al., 2021). Translating this to nuclear pharmacy implies that emergency-linked benefits (fewer identity errors, stronger traceability under pressure, faster incident reconstruction) are plausible—but only if the informatics workflow is designed to be usable under stress, with governance that anticipates workarounds and controls them through design and culture (Mulac et al., 2021; Hansen et al., 2020).

**6) Practice-oriented integration: a minimal "Sterility + Data Readiness" set**

The discussion findings can be operationalized into a minimal, implementable set of controls that supports routine quality and emergency readiness.

| Control domain | Minimal implementation expectation | Why it matters (evidence basis) |
|---|---|---|
| Sterility assurance governance | Documented acceptance of sterile supplies and sterilization modality changes through change control | Sterility is a validated process claim; modality shifts can affect materials (ISO, 2025; Roxby et al., 2024) |
| Material compatibility awareness | Risk-based evaluation for irradiation-sensitive materials and packaging; supplier documentation + internal verification where appropriate | Product/material effects are conditional and must be demonstrated (Jacobs, 2022; Hasanain & Guenther, 2014) |
| QRM decision trail | Written risk assessments for substitutions and urgent changes; defined escalation triggers | QRM is intended to guide small-scale radiopharmacy risk controls (Gillings et al., 2022) |
| Traceability + audit trails | Dose-level traceability to patient and materials, plus immutable audit trails | Radiopharmacy IS supports traceability; data integrity is safety-relevant (Gómez Perales, 2022; Charoo et al., 2023) |
| Emergency reliability design | Low-friction verification steps; monitoring for deviations/workarounds; fallback procedures for downtime | ED barcode benefits exist but are undermined by workflow deviations (Owens et al., 2020; Mulac et al., 2021; WHO, 2018) |

**7) Strengths, limitations, and future research**

**Strengths:** This review integrates standards, radiopharmacy governance guidance, informatics experience, and emergency safety evidence into one interpretive model. That is appropriate for cross-disciplinary topics where practice is shaped by multiple evidence types (Gillings et al., 2021; ISO, 2025; WHO, 2018).

**Limitations:** The radiopharmacy-specific evidence base on informatics and emergency-ready workflows remains limited compared with broader medication safety literature. Some emergency-care implications rely on analogy (e.g., ED barcode evidence) rather than radiopharmacy-only trials, which underscores the need for context-specific evaluation (Owens et al., 2020; Mulac et al., 2021).

**Future research directions:**

1. Prospective studies evaluating radiopharmacy information systems on measurable safety outcomes (traceability failures, near-miss rates, release delays).
2. Implementation science studies on reducing workarounds during surge conditions.
3. Material-compatibility registries or shared evidence packages for commonly used sterile consumables when sterilization modality changes (Grzelak et al., 2023; Roxby et al., 2024).
4. Interoperability-focused evaluations linking radiopharmacy systems with EHR and emergency pathways to reduce transcription risks (Li et al., 2021).

**Conclusion**

This integrative review supports a unified interpretation: nuclear pharmacy safety and quality depend on sterility assurance and data assurance functioning as one coordinated control system. Radiation sterilization standards emphasize validated process control, while radiopharmacy guidance and QRM frameworks emphasize documented governance and proportional risk controls. Informatics strengthens this system by enabling traceability, auditability, and reliable decision reconstruction—capabilities that become especially critical in emergency care contexts where time pressure and handoffs increase vulnerability to error. Emergency-linked benefits of digital verification are plausible, but evidence from emergency medication safety also indicates that benefits can be eroded by workflow deviations and

workarounds unless systems are designed for usability under stress and governed through continuous monitoring and improvement. Overall, the most actionable conclusion is that nuclear pharmacy emergency readiness is improved when organizations implement a minimal, reliable set of sterility-and-data controls that remain functional during surge and disruption.

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