Study on the Impact of Total β Emission Limits on Lu-177 Therapy Implementation in Medical Institutions and Optimization Pathways-20240112

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Abstract

Current national standards in China stipulate that radioactive wastewater from medical institutions must be treated by decay tanks, and discharge is permitted only when the total beta radioactivity level at the decay tank outlet is below 10 Bq/L (daily average). Lu-177 is a beta-emitting radionuclide accompanied by low-energy gamma rays, which holds broad application prospects in the treatment of neuroendocrine tumors. When medical institutions use Lu-177 for radionuclide therapy, a portion of Lu-177 enters the decay tank along with patient excreta. Wastewater containing Lu-177 must be temporarily stored in the decay tank for a certain period before the total beta radioactivity can be reduced to not exceed the discharge limit. Through theoretical derivation, this paper presents theoretical calculation formulas for the total activity of Lu-177 in the decay tank when it reaches full capacity under full-capacity hospital operation, for both inpatient and outpatient treatment modes; further provides the minimum temporary storage time for wastewater and the required decay tank capacity that medical institutions should be equipped with; introduces the provisions on total beta discharge limits in China' s wastewater discharge standards during different historical periods; and discusses the rationality of the current total beta discharge limit for wastewater and possible optimization pathways.

Full Text

The Impact of Total Beta Discharge Limits on Lu-177 Therapy Implementation in Medical Institutions and Pathways for Optimization

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Abstract

Current national standards in China stipulate that radioactive wastewater from medical institutions must be treated in decay tanks and can only be discharged when the total beta radioactivity level at the decay tank outlet falls below 10 Bq/L (daily average). Lu-177 is a beta-emitting radionuclide accompanied by low-energy gamma rays, offering broad application prospects in neuroendocrine tumor treatment. When medical institutions administer Lu-177 therapy, a portion of the radionuclide enters decay tanks through patient excreta. Lu-177-containing wastewater must be stored for a certain period before the total beta activity decays to within discharge limits. This paper derives theoretical formulas for calculating the total Lu-177 activity in a decay tank when the tank reaches capacity under full hospital operation in both inpatient and outpatient treatment modes. It further determines the minimum temporary storage time for wastewater and the required decay tank capacity that medical institutions should construct. The paper also reviews historical regulations on total beta discharge limits in China and discusses the rationality of current wastewater total beta discharge limits and potential optimization pathways.

Keywords: Lu-177; Total Beta; Discharge Limit; Decay Tank

Peptide Receptor Radionuclide Therapy (PRRT) represents a highly promising approach for treating neuroendocrine tumors [1]. The primary radionuclides used in this therapy include Lu-177 and Y-90. Lu-177 is a beta-emitting radionuclide with a half-life of 6.73 days and two main gamma-ray energy levels: 208 keV (branching ratio 11%) and 113 keV (branching ratio 6.4%). Due to these characteristics, Lu-177 is widely used in neuroendocrine tumor treatment [2]. The "Medium and Long-Term Development Plan for Medical Isotopes (2021-2035)," jointly issued by eight ministries including the National Atomic Energy Agency in 2021, repeatedly emphasized the development of Lu-177 production and manufacturing technologies [3]. Currently, the most commonly used Lu-177-labeled drugs in clinical practice are 177Lu-DOTATATE and 177Lu-DOTATOC, with recommended single administration doses of 150–200 mCi. Patients typically undergo 3–5 treatment sessions per course, with intervals of 6–12 weeks between treatments [4].

According to the "Medium and Long-Term Development Plan for Medical Isotopes (2021-2035)," China' s Lu-177 usage was 50 Ci in 2019, with domestic demand projected to grow at 30% annually. Data from the National Nuclear Technology Utilization Radiation Safety Management System shows that by the end of December 2023, 100 general hospitals had obtained radiation safety licenses for Lu-177 use, with many additional hospitals planning to apply for such licenses. As a radioactive nuclide, Lu-177 must comply with relevant radiation safety and environmental protection regulations during use. Notably, most

of the Lu-177 injected into patients is excreted through urine and other bodily wastes, significantly increasing the total beta radioactivity level in medical institution wastewater. Consequently, the total beta limit specified in environmental standards becomes a critical factor that cannot be ignored when implementing Lu-177 therapy.

1.1 Relevant Environmental Standard Provisions

Regarding Lu-177 discharge into the environment, current environmental standards contain two key provisions: discharge limits and total discharge amounts. The "Discharge Standard of Water Pollutants for Medical Institutions" (GB 18466-2005) [5] imposes strict restrictions on total beta activity at medical institution decay tank outlets, requiring levels not to exceed 10 Bq/L, with monitoring conducted according to the "Determination of Total Beta Radioactivity in Water—Evaporation Method" (EJ/T 900) [6]. Section 8.6.2 of the "Basic Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (GB 18871-2002) [7] stipulates that when low-level radioactive wastewater is discharged into sewers, the total monthly activity must not exceed 10 ALImin, and single discharges must not exceed 1 ALImin.

Based on Appendix B, Sections 1.3.4 and 1.3.5 of GB 18871, the total amount of Lu-177 that medical institutions can discharge is calculated as: monthly total discharge not exceeding 0.54 mCi $\times$ 10 = 5.4 mCi, and annual discharge not exceeding 64.8 mCi.

1.2.1 Lu-177 Excretion Ratio from the Body

Similar to I-131 nuclide therapy, most Lu-177 injected into the human body is excreted through patient urine and other bodily wastes [4][8]. Research findings on the excretion ratio and retention rate of Lu-177 in the body vary due to differences in patient pathology, drug type, and measurement timing. For instance, Levart et al. found that after administration of 177Lu-DOTATATE, the retention rate of Lu-177 in patients was approximately 36% after 18.1 hours [9]. Esser J P' s team measured that approximately 71% and 81% of the drug was excreted through urine within 24 hours for patients receiving 177Lu-DOTATATE or 177Lu-DOTATOC, respectively [10]. Kwekkeboom et al. reported that about 64% of Lu-177 was excreted through urine in the first 24 hours after 177Lu-DOTATATE administration [11]. A paper by Ma Guangyu et al. from the First Medical Center of the Chinese PLA General Hospital mentioned that the clearance rate of 177Lu-DOTATATE reached 44% within 5 hours, increased to 58% within 24 hours, and reached 65% within 48 hours [12].

1.2.2 Management Requirements for Patients After Lu-177 Treatment

Global scholars have conducted studies on whether patients receiving Lu-177 injections should be hospitalized, though no legally binding regulations have

been issued by radiation safety or environmental authorities. In 2013, the International Atomic Energy Agency' s "Practical Guidance on Peptide Receptor Radionuclide Therapy (PRRNT) for Neuroendocrine Tumours" provided a sample informed consent form suggesting patients could return home 24–48 hours after administration [13]. Research by Ma Guangyu et al. from the First Medical Center of the Chinese PLA General Hospital found that at King' s College London, 177Lu-DOTATATE treatment is offered in both outpatient and inpatient modes: outpatients are discharged the same afternoon after morning administration, while inpatients are discharged the day after afternoon administration [12]. Calais et al. reported that outpatient Lu-177 treatment does not violate regulatory requirements in Australia. In the United States, a 2019 expert consensus recommended both inpatient and outpatient modes, with the vast majority adopting the outpatient model. However, the University Hospital of Munich in Germany requires patients receiving 177Lu-DOTATATE treatment to be hospitalized for over 48 hours.

The choice between outpatient and inpatient modes significantly impacts radioactive wastewater management in medical institutions. In outpatient mode, Lu-177 excreted by patients is effectively diluted by the municipal sewage network and does not affect the total beta radioactivity level in the institution' s wastewater. In inpatient mode, Lu-177 excreted through patient urine must be stored in decay tanks, requiring medical institutions to construct sufficient tank capacity to meet storage requirements.

1.2.3 Management Requirements in China

Currently, Chinese regulations including the "Regulations on the Safety and Protection of Radioactive Isotopes and Radiation Devices," the "Administrative Measures for Safety Licensing of Radioactive Isotopes and Radiation Devices," and the "Administrative Measures for the Safety and Protection of Radioactive Isotopes and Radiation Devices" do not directly specify whether patients receiving Lu-177 therapy should be hospitalized. Neither the "Radiation Protection and Safety Requirements for Nuclear Medicine" (HJ 1188-2021) [14] nor the "Radiological Protection Requirements for Nuclear Medicine" (GBZ 120-2020) [15] explicitly establishes discharge standards for Lu-177. Given that Lu-177' s administration method, decay pattern, and dosage are extremely similar to I-131 thyroid cancer treatment, and considering China' s large population base, the fact that medical institutions treat far more patients daily than developed countries, relatively fragile environmental carrying capacity, high public sensitivity to radiation, and strict radiation safety management, patients receiving Lu-177 nuclide therapy should be hospitalized or at least remain in the hospital for an extended period on the treatment day. The following sections analyze the total Lu-177 activity in decay tanks when they reach capacity, the minimum temporary storage time for wastewater, and the required decay tank capacity under both inpatient and outpatient treatment modes.

1.3 Inpatient Mode with Two-Day Hospitalization Cycle

Assuming a two-day hospitalization cycle, with average single-patient dosage A (in mCi) and N patients, the ratio of Lu-177 activity excreted on the first day to administered dosage is P1, and on the second day is P2. The decay constant of Lu-177 is λ. The decay tank reaches capacity after T days of operation.

Further assuming the decay tank reaches capacity at T = 2n, where n is a positive integer representing the number of hospitalization cycles experienced during the tank filling process, and under continuous operation without intervals with beds continuously occupied, the contribution D1 of patient excretion on day 1 to the total Lu-177 activity in the tank at capacity is:

The contribution D2 of patient excretion on day 2 to the Lu-177 activity in the decay tank is

As described in Section 1.2.1, different literature sources provide slightly varying excretion ratios for Lu-177. Following the conservative principles and treatment methods adopted in ICRP Report 94 for radiation safety and protection assessment [8], we assume that 70% of the administered Lu-177 is excreted from the patient on the first day, i.e., P1 = 0.7. Further assuming that all Lu-177 injected into the body is eventually excreted, the proportion P2 of Lu-177 excreted on the second day can be determined as:

When the decay tank reaches capacity, the total Lu-177 activity D in the tank is 39.3( )07.1

Typically, T $\geq$ 30 days, and 1 - exp(-λT) can be approximated as 1. Therefore, the total Lu-177 activity in the tank can be simplified to 4.46NA.

When the filling time T = 2n + 1, the total Lu-177 activity in the decay tank can be considered as the sum of the following two components:

2. Lu-177 activity excreted by patients on the administration day.

When T = 2n + 1, the total Lu-177 activity in the tank is

Thus, when T = 2n, the k value is 4.46; when T = 2n + 1, the k value is 4.72.

Based on the discussion in Section 1.1, medical institution radioactive wastewater discharge faces dual constraints of total activity and activity concentration, but is primarily limited by activity concentration. According to the 10 Bq/L total beta standard, discharging 2.0 $\times$ 10^4 m^3 of wastewater would be required to reach the monthly total discharge limit specified in GB 18871 Section 8.6.2, while wastewater generated by nuclear medicine departments is far less than 2.0 $\times$ 10^4 m^3 per month. Taking an example with 5 beds, single-patient dosage of 200 mCi, and a decay tank reaching capacity after 60 days of operation, the total Lu-177 activity at capacity is 5 Ci. Assuming a decay tank capacity of 60 m^3, the Lu-177 activity concentration reaches 3.1 $\times$ 10^6 Bq/L. If discharged

directly at this point, the theoretically measured total beta activity concentration at the decay tank outlet would also be 3.1×10^6 Bq/L, far exceeding the environmental limit of 10 Bq/L specified in GB 18466. The wastewater would need to be stored for 123 days before discharge, with the total discharged Lu-177 amount being 0.016 mCi, far below the monthly total discharge limit.

Table 1 presents the total Lu-177 activity in the decay tank at capacity and the required temporary storage time for the total beta level at the decay tank outlet to decay to 10 Bq/L under different numbers of beds and decay tank volumes, assuming a single-patient single-dose administration of 200 mCi.

For newly constructed nuclear medicine departments, decay tank capacity V must be planned during environmental impact assessment to meet environmental discharge requirements. When the decay tank reaches capacity, the Lu-177 activity concentration in the tank is kNA / . To satisfy the requirement that total beta at the decay tank outlet does not exceed 10 Bq/L, the minimum temporary storage time should satisfy

Let M be the number of decay tanks and W1 be the daily wastewater volume discharged into a decay tank. The capacity V of a single decay tank should satisfy

When equation holds as an equality, the solved V represents the required minimum decay tank capacity. At this point,

Assuming daily wastewater volume W1 discharged into decay tanks is proportional to the number of beds, W1 = W0 × N (number of patients), where W0 represents daily water consumption per bed. Equation can be rewritten as

Substituting equation into equation yields

Let X = V/N and substitute into equation to obtain

The final system of equations becomes a function of X. Based on survey results of decay tank wastewater from nuclear medicine departments, assuming daily water consumption per bed W0 = 0.11 m^3 (refer to Table 2), number of decay tanks M = 3, and single-patient dosage of 200 mCi, substituting into equation yields X = V/N = 6.98 m^3 per patient, meaning the decay tank capacity required per patient is 6.98 m^3. Assuming filling time T = 2n, the corresponding minimum temporary storage time is calculated as 126.9 days.

Table 3 presents the required decay tank capacity for different numbers of patients.

1.4 Outpatient Mode

Assuming a medical institution adopts outpatient mode for Lu-177 therapy, with patients receiving injection at 9 AM and leaving at 5 PM (8-hour stay), excreta including urine during the stay enters the decay tank for temporary storage. Conservatively assuming that 60% of the administered Lu-177 is excreted

through urine during the hospital stay, the total Lu-177 activity D in the decay tank at capacity under full hospital operation is

In outpatient treatment mode, more patients receive treatment within a given period, resulting in higher total Lu-177 activity in the decay tank at capacity. The k value in equation becomes 6.13, yielding X = V/N = 7.14 m^3 per patient and a minimum temporary storage time T = 129.8 days.

Table 3 presents the minimum decay tank capacity required for different numbers of patients in outpatient treatment mode.

1. The calculations in Sections 1.3 and 1.4 are based on the following assumptions: Lu-177 therapy wards operate at full capacity, all Lu-177 injected into patients is excreted within two days, and daily water consumption per patient (per bed) is 0.11 m^3. These assumptions are relatively conservative. In practice, due to costs, drug supply, patient numbers, physician availability, and other factors, hospitals are unlikely to operate continuously at full capacity. Effective management measures can significantly reduce daily water consumption per patient, and Lu-177 excreted through patient urine will not reach the levels assumed in this paper. Therefore, the total Lu-177 activity and activity concentration in the tank calculated in Sections 1.3 and 1.4 represent theoretical upper limits, and the resulting decay tank capacity and minimum temporary storage time are sufficient to meet environmental discharge requirements.

2. The theoretical calculation formula for total Lu-177 activity when the decay tank reaches capacity shows that total Lu-177 activity is proportional to the number of patients and average administered dosage. After 30 days of full-capacity operation, the total Lu-177 activity in the tank stabilizes. As wastewater volume in the tank increases and Lu-177 undergoes radioactive decay, its activity concentration gradually decreases. When the decay tank reaches capacity, Lu-177 activity concentration typically ranges from 10^6 to 10^7 Bq/L. Larger decay tank capacity results in lower Lu-177 activity concentration.

3. For hospitals planning to implement Lu-177 therapy using existing wards and supporting environmental protection facilities, the minimum temporary storage time for Lu-177-containing wastewater can be calculated based on the content of Section 1.3. For newly constructed hospitals, the required minimum decay tank capacity and corresponding minimum temporary storage time can be determined based on the planned number of beds using the analytical methods in Sections 1.3 or 1.4. These analytical processes and results can also serve as references for ecological and environmental departments when reviewing environmental impact assessment documents and approving radiation safety licenses.

4. Under non-full-capacity operation, the total Lu-177 activity in decay tanks will be significantly lower than the calculated results provided in Sections 1.3 or 1.4. In such cases, the method provided in reference [16] can be

used to calculate the total activity and activity concentration of Lu-177 in decay tanks. Wastewater can be discharged in compliance when the total beta activity concentration falls below 10 Bq/L.

5. When a nuclear medicine department operates both Lu-177 nuclide wards and I-131 treatment wards, W1 should represent the total daily wastewater volume discharged into decay tanks from all wards. The discharged wastewater must not only satisfy the total beta limit but also comply with relevant provisions in the "Reply Letter on Consultation Regarding Relevant Clauses of Nuclear Medicine Standards" [17].

6. The expression forms of equations and show that the decay tank capacity required per patient (V/N) is approximately proportional to the daily water consumption per patient (W0). For medical institutions with limited land availability, the required decay tank capacity per patient can be reduced by controlling daily water consumption per patient, thereby decreasing land requirements and construction costs.

3.2.1 Comparison with Drinking Water Requirements

The World Health Organization' s "Guidelines for Drinking-water Quality" [22] establishes 1 Bq/L for total beta radioactivity as a screening level for drinking water. The screening level means: (1) initial screening for total alpha and/or total beta activity to determine if activity concentrations (Bq/L) are below a certain threshold requiring no further action; (2) if total alpha and/or total beta activity concentrations exceed the screening level, investigation of each radionuclide' s activity concentration should be conducted and compared with specified guidance levels.

GB 18466 uses 10 Bq/L solely as a discharge limit, which is inconsistent with the WHO "Guidelines for Drinking-water Quality" that establishes total beta radioactivity as a "screening level." According to the WHO calculation method, the radionuclide guidance level for Lu-177 in drinking water is:

mSv/Bq

where 5.3E-7 mSv/Bq is the dose conversion coefficient for Lu-177. Following the WHO data processing approach, rounding the logarithmic mean to the nearest integer establishes the radionuclide guidance level for Lu-177 in drinking water at 100 Bq/L. The medical institution total beta discharge limit (daily average) is only 10 Bq/L, creating a logical inconsistency where water with Lu-177 activity concentration of 100 Bq/L is considered drinkable but cannot be discharged as wastewater.

3.2.2 Comparison with I-131

Both I-131 and Lu-177 are moderately toxic nuclides with similar therapeutic doses, but Lu-177 has shorter half-life and lower beta/gamma energies than

I-131. Overall, I-131 poses slightly higher radiation hazards than Lu-177. However, I-131 excreted by patients does not affect the total beta level at the decay tank outlet because I-131 is a volatile nuclide that almost completely escapes during sampling and monitoring according to EJ/T 900. In contrast, Lu-177 is virtually non-volatile, and urine from patients receiving Lu-177 therapy significantly increases the total beta level at the decay tank outlet. The total beta discharge limit and monitoring method specified in GB 18466 do not affect I-131 nuclide therapy implementation but impose strict restrictions on Lu-177 nuclide therapy, which is also logically unreasonable.

3.2.3 Comparison with Foreign Standards

The French Nuclear Safety Authority (ASN) stipulates that the total radioactivity level in wastewater discharged by medical institutions into municipal pipelines must be below 10 Bq/L [23], but the sampling point is not at the decay tank outlet but at the general discharge point before entering municipal pipelines. ASN specifically allows a tenfold relaxation of the discharge limit for I-131 to 100 Bq/L. Considering that wastewater from nuclide therapy wards typically accounts for only one percent to one thousandth of total hospital wastewater, France' s discharge standards are approximately 2–3 orders of magnitude more lenient than China' s.

3.3.1 Pathway 1: Reference to Model of Reply Letter No. 20

Regarding wastewater containing I-131 in tank-type decay systems, in September 2023, the Department of Radiation Source Safety Regulation of the Ministry of Ecology and Environment issued the "Reply Letter on Consultation Regarding Relevant Clauses of Nuclear Medicine Standards," clarifying that wastewater containing I-131 can be discharged if any one of the following requirements is met: total discharge amount, temporary storage time, or discharge limit. Future policy design could reference this model from Reply Letter No. 20. ICRP Publication 94 and Spanish research results show that after 10 half-lives of temporary storage, the impact of I-131 on public health is minimal [8][24]. Considering that Lu-177 poses lower radiation hazards than I-131, establishing Lu-177 discharge requirements using the Reply Letter No. 20 model would not impact the public or environment.

3.3.2 Pathway 2: Establishing Total Beta Radioactivity as a Screening Level

When determining discharge standards for radionuclides in medical institution wastewater, the model from the WHO "Guidelines for Drinking-water Quality" could be referenced. Total beta radioactivity level of 10 Bq/L could be established as a screening level rather than a discharge limit for medical institution wastewater discharge. The radionuclide guidance level for Lu-177 in drinking water (100 Bq/L) could be multiplied by a reasonable factor (e.g., 10) to establish the Lu-177 discharge limit. Under this approach, the Lu-177 discharge

limit would be 1000 Bq/L, which is more reasonable both theoretically and practically.

In this study, we derived the total Lu-177 activity in decay tanks at capacity under full-load conditions and proposed methods for determining the minimum temporary storage time for Lu-177-containing wastewater and decay tank capacity to comply with total beta discharge limits. These results provide important reference value for daily operations of medical institutions, construction of nuclear medicine departments, and supervision and inspection by ecological and environmental departments.

For medical institutions, active compliance with currently effective laws, regulations, and national mandatory standards is essential. Particularly when conducting Lu-177 therapy, attention must be paid to the potential impact of Lu-177 excreted through urine on total beta discharge limits. Medical institutions need to establish reasonable wastewater temporary storage times based on decay tank capacity and number of treated patients to prevent exceeding total beta discharge limits.

This paper also conducted in-depth analysis of the rationality of total beta discharge limits. The study reviewed regulations on total beta discharge limits from different historical periods, analyzed them from scientific and international standard comparison perspectives, and proposed potential optimization pathways. Discharge limits for radionuclides are typically socially equitable values derived from balancing various interests. When formulating more reasonable total beta discharge limits, regulators, industry stakeholders, and the public should comprehensively consider radiation safety and protection, environmental impact, and the needs of nuclear medicine therapy.

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Note: Figure translations are in progress. See original paper for figures.