Release Criteria of Treated Animals with Radionuclides

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Abstract. In this study, release criteria of animals treated with radionuclides were introduced. The criteria were considered for licensed radionuclides for the purpose of veterinary medicine uses. For the practical use in institutes, the criteria were derived as external radiation level (dose rate) based on an effective dose 1 mSv to an individual. For unrestricted use of the released animals, conservative assumptions were introduced. Under the domestic regulation, animals treated with radionuclides were considered as radioactive. Therefore, the licensee, who use radionuclides for veterinary medicine purpose, should make every effort to maintain dose to other individuals as low as reasonably achievable, such as assessment of individual dose from released animals and distribution of written instructions. In applying the criteria for release of animals, patient-specific information such as actual pattern with animal keepers or owners, should be considered.

KEYWORDS: Release criteria, animals treated with radionuclides, veterinary medicine

1 INTRODUCTION

Recently, in Korea, some applicants and licensees tried to use ionizing radiation in veterinary medicine for nuclear medicine and radiotherapy purpose. According to the applications, radiation generating devices (RGs), such as linear accelerators were considered to treat tumors in companion animals. Also the licensees requested use of unsealed radioactive sources for diagnostic and therapeutic purpose, for example hyperthyroid treatment of feline, under the Nuclear Safety Acts.

In the view of radiation protection and safety, those animals treated with licensed radioactive sources should be considered as radioactive. Especially release of animals after treatment should be controlled with proper regulations. Because those animals would cause radiation exposure to public members including their owners and care takers. But there are no specific regulations or criteria for the release. In this study, derived release criteria of treated animals with unsealed radioisotopes were introduced. Recommendations and guides by National Council on Radiation Protection and Measurements (NCRP) and a nuclear regulatory (NUREG) report prepared by U.S. Nuclear Regulatory Commission (NRC) staff were referred. Based on the references and regulatory experiences, the criteria were derived as external radiation level with conservative assumptions.

2 MATERIALS AND METHODS

2.1 Recommendations and Guides

2.1.1 NCRP Report No. 148

This report gave comprehensive information for radiation protection in veterinary medicine [1]. It included recommendations for radiation safety program requirements, facility design, such as shielding for radiation generating devices and design considerations for unsealed radioactive sources, diagnostic practices such as radiography and fluoroscopy, radiation therapy, radiopharmaceuticals, quality assurance programs and even nonionizing radiation in veterinary medicine.

It introduced a typical release criterion as $\leq$ 0.5mR/h exposure rate at 1 meter. It would ensure that the owner would not exceed the limit of 1mSv annual effective dose. According to their another recommendation on exposure limit to ionizing radiation [2], the council considered the exposure by the released animal as continuous exposure (1mSv annual effective dose limit for continuous exposure and 5mSv annual effective dose limit for infrequent exposure). 1 meter was considered as typical distance between a human and the animal. It would be applied to radioiodine (I-131) and radiotechnecium (Tc-99m). For example, in case of cats treated for hyperthyroidism with 148MBq of I-131, it would take a

week to reach this exposure rate and animals scanned using Tc-99m, it would take 24 hours after injection. And the council also recommended owners to be cautioned against holding the animal for some time after release depending on the exposure rate and the half-life of the radionuclide. For 0.5mR/h, waiting for two to four half-lives was recommended.

2.1.2 NUREG-1556 Volume 7.

This technical report was intended to provide specific guidance and assist applicants and licensees in preparing applications for materials (radioisotopes) licenses by giving information for implementing the mandatory information in U.S. NRC regulations, such as title 10, Code of Federal Regulations part 20 (10 CFR 20) [3]. Among the consolidated guidance, appendix D of volume 7 gave specific information for laboratory animal and veterinary medicine uses, such as training for staff using radionuclides in animals, contamination control, waste handling and release of animals.

The report considered the treated animals with radionuclides would be released to uncontrolled population and owners and recommended licensees to develop criteria for assessing this release. As developing the criteria, type of radionuclide, concentration in excreta and dose rate on contact or some distance from the accessible side of the cage which the animals place in were introduced to be considered. The assessed dose would be within limits in regulations such as 1mSv in a year and 0.02mSv in any one hour to individual members of public [4]. It also recommended that there must be special care, such as providing instructions on the care and handling of the released animals, to keep doses to people around the animal as low as reasonably achievable (ALARA).

The report gave an example of release criteria of cats after administration of I-131 for the treatment of hyperthyroidism[1] as ≤ 10μSv/h (1.0mR/h) at 6 inches (15.24cm) or 2.5μSv/h (0.25mR/h) at 1 foot (30.48cm) with 4 complete days (96 hours) holding after administration. It added that criteria above 0.5mR/h at 1 foot are not recommended because it is unlikely to meet dose limits to public. The criteria were much conservative than those of NCRP 148, because it considered unrestricted use after releasing.

2.1.3 Draft safety report by International Atomic Energy Agency (IAEA)

The international basic safety standard (BSS) required that veterinarian uses of radiation sources meet the standards [5]. But there is no specific guidance to support the requirement and the Agency is developing the guidance. In the chapters for nuclear medicine and radiotherapy, animal release, disposal of waste and safety and security of radioactive sources will be dealt with [6]. Also it will give instructions on the release of animals after the administration of I-131 as an appendix.

2.2 Approaches to derive release criteria of treated animals with radionuclides

In this study, dose rates were derived as release criteria using relationship between total dose after release and dose rate measured at the time of release. The relationship was expressed as equation below [7].

$$\mathrm{D} = D_r \frac{T_{eff}}{\ln 2} \sum_n E_n \left(\frac{d_0}{d_n}\right)^2 \quad (1)$$

where D is total dose; D_r is the dose rate measured at a distance from the animal, d_0; T_{eff} is the effective half-life; and E is the occupancy factor of a person at a specific distance, d_n from the animal.

For the calculation, public dose limit, 1mSv in a year described in the domestic regulation was set as total dose [8]. Physical half-lives of radionuclides were applied as T_{eff}. And the term of $\frac{T_{eff}}{\ln 2}$ was to

[1] According to the NUREG-1556 volume 7 appendix D, the most common veterinary uses of unsealed radionuclides in animals are the administration of I-131 for therapeutic treatment of cats and Tc-99m for diagnostic studies in horses

consider accumulated dose by total integration during decay of radionuclides. Similar with release of human patients after administration of nuclear medicine, time to release is dependent on both the administered activity and the biological clearance from the animal body. But the biological clearance would vary from animal to animal [1], so only physical half-life was employed for the derivation. 8.0 hours a day (E_n = 1/3) at 15 centimeters was assumed as occupancy factor with close distance from the animal.

3 DERIVED RELEASE CRITERIA

The derived release criteria were listed in table 1. Radionuclides applied for veterinary medicine purpose by domestic licensees were considered. In table 2, derived release criteria of this study were compared with those in references and of human patients.

Table 1: Derived release criteria of treated animals with radionuclides.

Radionuclides	D_r @ 30cm [μSv/hr]
Cu-64	41
I-124	5.2
I-131	2.7
In-111	7.7
Lu-177	3.3
Sn-117m	1.6
Tc-99m	86.5
Zr-89	6.6

Table 2: Comparison of release criteria

Radionuclides	Patients[(a)]			Animals		
				NCRP	NRC	This study
	Activity		Dose rate (@ 1m)	Dose rate (@ 1m)		
	[GBq]	[mCi]	[μSv/hr]	[μSv/hr]		
I-131	1.2	33	70	5.0	0.23	0.24
Tc-99m	28	760	580		N/A	7.8

(a) Release criteria of human patients were derived not exceeding effective dose of 5mSv to public members such as family members and care takers [9].

From the dose rates, residual activities in animal would be calculated to estimate holding time by releasing. In case of hyperthyroid cats treated with I-131, using gamma constant (i.e., Γ = 7.65E-05mSv·h^{-1} per MBq @ 1m [10]) and point source assumptions (for small animals, like cats, shielding effect and distribution of radionuclide in the body would be negligible), 65.4MBq (1.8mCi) of residual activity was derived from the criteria recommended by NCRP. For the typical administration activity of 148MBq, holding time was calculated as 9.48 days, (about 1.2 half-lives) from physical half-life (8.04 days).

NRC provided much smaller dose rate as release criteria but its recommended holding time was at least 4 complete days, shorter than NCRP recommendation (about 7 to 10 days). If I-131 biokinetics to cats are similar with human, thyroidal uptake and urinary excretion are maximal before 24 hours [11], holding time would be shorter than estimation from physical half-lives and aimed dose level. And this means facilities need to survey radiation level of treated animals and their excreta in regular basis after administration.

4 CONCLUSION

In this study, release criteria of treated animals with radionuclides were introduced. Recommendations and guides which deal with safety of radiation use in veterinary medicine were studied. From information in literatures with conservative assumptions, release criteria were calculated. Different from human patient release, 1 mSv was set as the total accumulated dose, but it was not severely conservative. Because exposure from artificial radioactive sources has been increased continually. And there were many variables in derivation the criteria, such as occupancy factor, distance from the animal, biological clearance and so on. In the same way, the release criteria should be developed by licensees based on dose assessment with clear rationale.

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