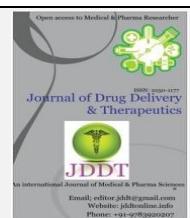


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Research Article

## Drafting of comprehensive harmonized regulatory guideline for storage and disposal of radiopharmaceuticals

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### ABSTRACT

Recent era has witnessed an inordinate rise in the demand for radiopharmaceuticals due to their multifarious biomedical and clinical application. Scientific fraternity worldwide is continuously working in developing different innovative radiopharmaceuticals of immense clinical importance both from specialized theranostics and personalized medicine point of view. However, this increased production and use of radiopharmaceuticals in various nuclear medicine procedures have been accompanied by an inevitable problem concerning their storage after use and final disposal. Keeping in view the inherently hazardous nature of radiopharmaceuticals due to the presence of radionuclide in them, it is imperative to have an adequate regulatory backup which if followed meticulously can assure their safe storage and disposal so that threat to men and environment is prevented. The present work has been aimed to draft comprehensive regulatory guidelines for the storage and disposal of radiopharmaceuticals which is in resonance with the global standards. For this, the methodology consisting of a thorough research of existing guidelines from Atomic Energy Regulatory Board (AERB) exclusively on storage and disposal of radiopharmaceuticals in India has been done with the objective to identify and select various parameters not yet explicitly covered as is their scope. The guideline has been made to suitably address all sorts of necessary documentation, allocation of responsibility, ways of waste prevention, various mechanisms to deal with radiopharmaceuticals waste in all forms of matter and suggestive recommendations.

**Keywords:** Radiopharmaceuticals, Atomic Energy Regulatory Board, Regulatory guidelines of radiopharmaceuticals

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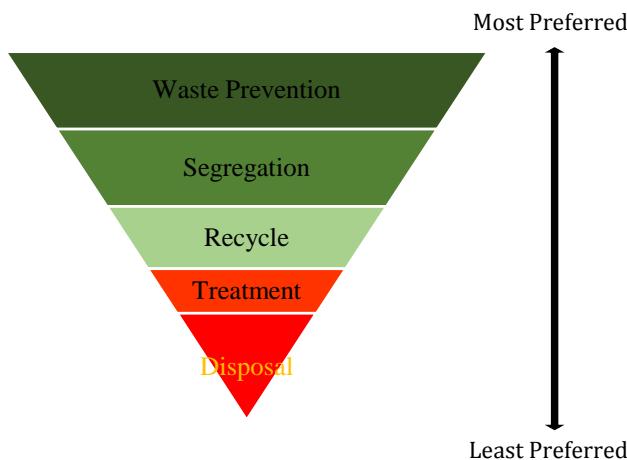
### INTRODUCTION

Storage and disposal of radiopharmaceuticals constitute an important step in the lifecycle management of radiopharmaceuticals. Technically, storage and disposal are two different terms. The term 'storage' relates to placement of radiopharmaceutical waste in an appropriate facility with the intention of retrieving it at some point of time in the future. The term 'disposal', on the other hand, refers to emplacement of radiopharmaceutical waste into a suitable waste management facility or location with no intention of retrieving in the future. The production of most of the radiopharmaceuticals and their application on patients is accompanied by radiopharmaceutical waste chiefly consisting of beta and gamma emitting radionuclides that lose half of their radioactivity in periods ranging from a few hours to some days <sup>1,2</sup>. Alpha emitting radionuclides are limited to only trace quantities. The production of radiopharmaceuticals consists of irradiating the parent

nuclide to produce daughter radionuclide in which other unwanted radionuclides may also creep in and constitute the radiopharmaceutical wastes<sup>3</sup>. It is estimated that as much as 95% of the original radioactive material during manufacturing of radiopharmaceuticals may be rejected as waste. Moreover, many radiopharmaceuticals consisting of radionuclides chiefly carbon-14, phosphorus-32, phosphorus-33, sulfur-35 and iodine-125 finds their applications in various theranostic procedures in nuclear medicine centres, leading to the production of wastes in various forms of matter<sup>4,5</sup>.

Keeping in view the hazardous nature of radiopharmaceuticals and the varied form in which the radiopharmaceutical waste can be obtained, including discrete sealed or unsealed radiation sources, it is indispensable to design relevant methods and regulatory actions for their organized and effective storage and disposal at institutional as well as national level that meets the

demand of safety both for men and environment<sup>6</sup>. The first and leading most way for effectively dealing with radiopharmaceutical waste is following the 'Waste Hierarchy' concept which aims at minimizing the waste generation at each and every step. **Figure 1** presents an overview of 'Waste Hierarchy'.



**Figure 1:** Waste hierarchy concept for management of radiopharmaceutical waste.

Also important is to implement these regulations effectively by following a monitoring mechanism that ensures that the rules laid down are properly adhered<sup>7</sup>. The focus should be made to meticulously design a regulatory infrastructure that allows for protection of occupational workers and community as whole dealing with these hazardous agents and a way to take legal recourse for loss incurred while dealing with them. An effective radiopharmaceutical waste management regulation should also consist of a well-defined radiation protection program. Therefore, the management of such a waste of varied half-life needs an effective management at the outset which should be inherent in the regulatory setup before the commencement of any nuclear medicine facility.

## OBJECTIVES

Guidelines for disposal of radiopharmaceuticals, particularly in India, were systematically reviewed for their content and completeness so that disposal of radiopharmaceuticals does not pose any significant hazard both to the society as well as to the environment. The focus was to identify and select various parameters not yet included in the guidelines exclusively meant for the storage and disposal of radiopharmaceuticals in India. On the basis of careful scrutiny of various parameters, a draft has been made which, if followed meticulously, can bring about adequate monitoring, management and disposal of radiopharmaceuticals in India so that threat to men and environment from the radiopharmaceuticals is prevented.

## METHODOLOGY

A comprehensive and relevant research on the existing guidelines by Atomic Energy Regulatory Board (AERB) on disposal of radiopharmaceuticals in Indian scenario has been done. Atomic Energy Regulatory Board (AERB) is the premier most agency for radiopharmaceuticals and their regulations in India and is under the overarching surveillance of Department of Atomic Energy (DAE), Government of India. AERB has framed many mandatory requirements in form of various codes, rules and guides for exercising its regulatory effect on radiopharmaceuticals in India. Concerning disposal, it has issued Atomic Energy (Safe Disposal of Radioactive Waste) Rules, G.S.R. 125, 1987<sup>8</sup> and

other code named Management of Radioactive Waste, 2007<sup>9</sup>. Apart from it, it has also issued another safety code named Nuclear Medicine Facilities, 2010 which covers the whole spectrum of operations commencing from the approval of the site, its setting up and design to the ultimate decommissioning<sup>10</sup>. Some specifications concerning disposal have also been mentioned in it along with other relevant guidelines by AERB. However, none of these guidelines and codes explicitly details the requirement for disposal of radiopharmaceuticals exclusively in a detailed manner which is in line with the global standards. The work has been aimed to fill this regulatory void in the present regulatory landscape concerning radiopharmaceuticals in India and drafting of comprehensive regulatory guidelines of global standard. Radiopharmaceuticals waste are available in all form of matter and therefore regulatory guidelines should address each of them adequately<sup>11</sup>.

### **Solid radiopharmaceuticals wastes**

Solid radiopharmaceutical waste consists of used radionuclide generator, waste obtained during production of radionuclides from particle accelerator and nuclear reactors, radiopharmaceutical kit after use at the end of their expiry date/time, contaminated drinking straws used by the patients, contaminated swabs, vessels, needles, gloves and syringes used in production of radiopharmaceuticals, contaminated hospital gowning, towels, bed covers, absorbent papers, laboratory bench top coverings and removable tiles, contaminated glass wares consisting of pipettes, scalpels, measuring cylinders, syringes, needles, glass slides, plastic containers, blood lancets, conical flasks used for performing various in vitro tests, contaminated media and disposable plastic tips of radioimmunoassay test, animal carcasses, lead pots used for decay in storage contaminated with radioactive material, and spent and disused sealed sources at the end of their useful life.

### **Liquid radiopharmaceutical waste**

This type of waste chiefly consists of wastewater from decontamination of contaminated radiation patients/victims, equipment and glass wares, radioactive stock and standard solution remaining unused at the end, unused and opened radiopharmaceuticals and labelled compounds, excreta from patients receiving theranostic radiopharmaceuticals such as <sup>131</sup>I, <sup>89</sup>Sr, <sup>90</sup>Y, and <sup>32</sup>P during course of their treatment and/or diagnosis, organic and aqueous solution obtained as a result of etching and dissolution of target materials during radioisotope production, contaminated blood samples of patient undergoing haematological studies, and radionuclides such as <sup>14</sup>C and <sup>3</sup>H employed for biochemical studies on metabolic pathway.

### **Gaseous radiopharmaceutical waste**

Radiopharmaceutical waste in gaseous form arise during production and radiolabelling of various compounds, during treatment of solid and liquid waste, and as radioactive gases such as <sup>133</sup>Xe, <sup>81m</sup>Kr, and <sup>18</sup>F used for investigation of pulmonary ventilation.

## RESULTS

The existing scenario for radiopharmaceuticals guidelines in India concerning their storage and distribution has some limitations. In a move towards harmonization and fulfilling the regulatory void, a detailed regulatory guideline is presented which takes into account all form of radioactive wastes. Specifications regarding record keeping, responsibility, safety considerations, predisposal management, storage, packing, labelling, and disposal have been suitably addressed.

**1. General:** Radiopharmaceutical waste arises from the production of radiopharmaceuticals and their use for various diagnostic and therapeutic purposes. The inherent hazardous nature of radiopharmaceutical waste necessitates immediate action for abatement, storage and further safe disposal so that threat to environment and public can be minimized. This mandates best practices to be followed right from the point of waste generation to the ultimate disposal. The emphasis of this guideline is on the protection of both people and environment from any undue exposure to ionizing radiation emanating from the radiopharmaceutical waste.

**2. Scope:** This guideline is intended to cover all activities starting from generation to the acceptance of radiopharmaceutical waste, including spent and disused sealed sources, at its acceptance facility and the various procedures to be followed for the safe management, storage and disposal of radiopharmaceutical waste arising from their production and use. This guideline covers various technomanagerial procedures and practices to be followed for safe handling, management, storage and disposal of radiopharmaceuticals waste. It emphasizes various approaches to ensure the establishment of correct procedures and its compliance so that the hazardous radioactive waste is appropriately stored and discarded following the best possible option.

**3. Protection of men and environment:** The prime focus of all procedural set up and management practices in radiopharmaceutical waste management program should focus on protection of both men and environment from undue exposure from radiopharmaceutical wastes. Focus also needs to be made on the optimization of protection and safety standards so that the magnitude and extent of individual exposure, number of personnel exposed and the probability of exposure are all subjected to dose constraints having the regulatory approval for each practice concerned which should be commensurate to the applicable international standards.

**4. Roles and responsibilities:** An effective radiopharmaceutical waste management program should encompass a clear allocation of roles and responsibilities that should be commensurate with the activity concerned and having the prime focus of achieving compliance to the various established national and international standards. The responsibility of radiopharmaceutical waste disposal rests with multiple levels of organization consisting of supplier (source supplier), the waste generator, waste manager and the authorized waste management agency consisting of radiological safety officer (RSO) and the regulatory body.

The primary level of organization starts with producers of radiopharmaceutical cum 'waste generators' who are responsible for overall safe management of radiopharmaceutical waste and are involved in the collection, segregation, labelling, characterization, classification, pretreatment, treatment, conditioning, packing, documentation, storage, and the disposal of radioactive waste. The waste generators should have the responsibility of safe management and execution of waste, including notification to the regulatory body in case of any event or accident. They should also ensure that adequate radiation protection of the workers, the general public and the environment are fulfilled at all the times and in compliance with the regulatory authority requirement. It is also their responsibility to establish and implement the emergency preparedness associated with radiopharmaceutical waste management. Also, radiation

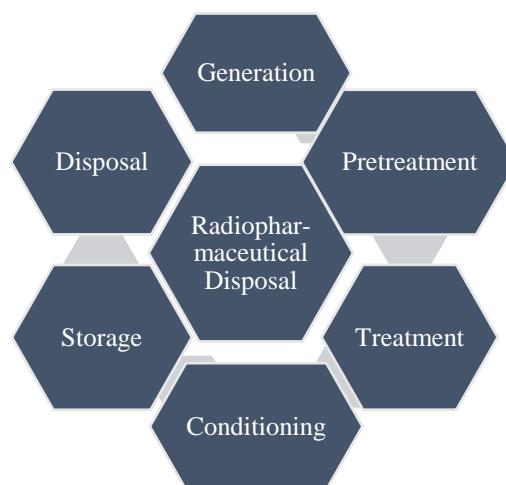
safety officer and environmental management staff should bear the prime responsibility of arranging removal of wastes which have suitably decayed into non-radioactive waste during the course of their storage prior to disposal. In situations where predisposal management of waste is required and a need to transfer waste from one operator to other arise, a clear allocation of responsibility for each of the operation concerned to all the operators should be predefined.

**5. General safety consideration:** Safety is of paramount importance while dealing with radiopharmaceutical waste. This part of guideline concerns the various safety considerations in radioactive waste management, facilities generating radioactive waste and the environmental impact assessment for an effective management of radiopharmaceutical waste. The safety consideration should include a choice of preferred option, control of waste generation and the characterization and classification of waste. Also important is to devise a safety culture, environmental monitoring mechanism and the emergency preparedness as a part of general safety consideration.

**6. Quality Assurance:** A robust quality assurance program overseeing the entire process of radiopharmaceutical waste disposal provides confidence regarding optimal management and execution of each and every step according to the approved protocols. It helps to maintain all the records starting from waste collection to the final disposal of radiopharmaceutical waste which can be used as a reference for the safety of the site in the future. Quality assurance department should be made responsible for providing all the necessary training, control measures and audits for radiopharmaceutical waste disposal site and the associated aspects of radiation protection and operational procedures to be followed for best management of radiopharmaceutical waste.

## 7. Waste Disposal - The Process

Radiopharmaceutical waste disposal is an elaborated multiple step process consisting of management of waste from the point of its generation, storage to its final disposal. The various important stages in the life cycle of radiopharmaceutical waste management consist of the collection, pretreatment, treatment, conditioning, decay in storage and finally the disposal. **Figure 2** below gives the pictorial view of various steps to be involved in radiopharmaceutical waste management process.



**Figure 2:** Various steps to be involved in radiopharmaceutical waste disposal.

Briefly, the radiopharmaceutical waste, after collection, should be processed by various means to change its characteristics and convert it into a form amenable to disposal. This processing should essentially form the part of 'predisposal management' after which it can be stored followed by decay and disposal. The storage should consist of placing the treated radiopharmaceutical waste until such time that it no longer comes under the purview of radioactive waste and can be disposed of as normal trash. In this method, the radiopharmaceutical waste, before disposal, should be stored in a secured place for a suitable amount of time to allow for the degradation of the radioactive nuclide of waste to its nonradioactive counterpart. Short half-life radioactive waste should be stored at the quarantined site of its generation for physical decay of activity. Radiopharmaceutical wastes of a high level of activity and long half-life radionuclides should be packed and suitably secured in the interim facility after segregation, treatment, conditioning and final disposal. The site for final disposal facility can be nationally or regionally situated depending upon the quantity and type for waste generated. Thus the waste management can be done both 'onsite' and 'offsite' at a specified waste management facility.

**7.1 Predisposal management of radiopharmaceutical waste:** Following collection, the next step in radiopharmaceutical waste management should have appropriate predisposal management. It must consist of various processing steps that can change the characteristics of the waste. Various steps in predisposal management should include pretreatment, treatment and conditioning which can convert the waste into a form amenable to further processing. The various methods employed for processing should be selected based on the type of waste.

**7.1.1 Pretreatment:** It should be the first step in radiopharmaceutical waste management and must consist of the collection, segregation and chemical adjustments. The collection and further segregation of waste should be done according to half-life, radionuclides, activity, and the physical form of waste. Segregation allows for volume reduction and cost saving of the entire waste management program. The waste should be placed in containers which are compatible both physically and chemically and provide its suitable containment.

**7.1.2 Treatment:** The treatment of radiopharmaceutical waste should consist of various steps including chemical precipitation, ion exchange, ultrafiltration, immobilization and adsorption. For biological radioactive wastes, treatment option should focus on both radiological as well as non-radiological hazard. Prior to treatment, the radiopharmaceutical waste, particularly the liquid waste, should be segregated in case they vary greatly in their chemical and radionuclide content. However, at all times, it should be ensured that the implications of secondary wastes, being generated as a result of treatment, should be given consideration in environmental impact and safety assessment. The secondary wastes should preferably be immobilized to produce a solid waste in a stable form which can be further managed.

Recent advancement in waste management practices has resulted in the advent of new technology of advanced benefit and more safety. One such technology is 'biochroma' having chromatography based adsorption as final phase and can be suitably exploited for an effective management of liquid radiopharmaceutical wastes<sup>12</sup>.

**7.1.3 Conditioning:** This should form the last stage in predisposal management of the radiopharmaceutical waste aiming to convert the processed waste into a form amenable

to handling, storage and disposal. It should include matrix immobilization of waste or placing the waste into a container provided with additional packing for fragile wastes. This stage helps in removal of any free space in the container and ensure the prevention of leaching of container contents while in storage. Most of the radiopharmaceutical waste is short-lived and as such does not require any treatment.

**8. Packing prior to storage:** Packing the radiopharmaceutical waste constitutes one of the most critical operations in its safe disposal. The primary aim of packing should be to secure waste in a proper form and prevent the release of potential contaminants. This can be achieved by double containment in which the waste such as liquid is placed in a closed bottle inside a spill container or a plastic bag inside hard plastic bucket for solid wastes or even double plastic bags sealed individually. It is prudent to pack the waste in as small as possible container relevant to waste accumulated as it prevents wastes being collected over a long period of time. The bag should be of sufficient strength to withhold the waste and should have the option to seal with cable tie as it facilitates easy opening of the bag when required. Primary packs should preferably be transparent as it helps in easy identification of waste without the need of opening it. For solid wastes, leak-proof plastic bags or sharps containers are advisable. Scintillation vials, appropriately secured in approved containers, should be used to dispose of the liquid wastes.

**9. Labelling requirements for wastes:** Proper labelling of the radiopharmaceutical waste is another important regulatory requirement and should be commensurate to its stage. Separate labelling requirements exist for waste corresponding to different stage. Label for waste collection, also called 'in use' label, should consist of only basic information concerning the radiopharmaceutical wastes like the type of radionuclide present and the details of waste generator. These labels are required while the waste is being collected. The collection of radiopharmaceutical waste should generally be done in primary containers which can be securely sealed in a secondary container. There is no specific label requirement for primary containers as long as they are kept within secondary containers. This facilitates an easy disposal of waste present in a primary container at the time of disposal as it is ideally free of any label bearing sign of radioactivity at the time of disposal. However, the secondary container label should have all the details of waste consisting of type of radionuclide present, its physical form, and its radioactivity at the time of packing. A three level of packing is recommended here to better ensure the correctness of the label according to its stage.

- Primary packing: Clear bag sealed appropriately with a cable tie.
- Secondary packing: Having proper waste disposal label.
- Tertiary packing: Brightly coloured bag appropriately sealed with a cable tie which can be removed before disposing of the waste.

**10. Storage of radiopharmaceutical waste:** After suitable pretreatment of radiopharmaceutical waste, they should be further subjected to storage in suitable waste storage facilities until the time they have suitably decayed to its nonradioactive part. The radiopharmaceutical waste should be stored in a manner so as to allow suitable inspection, monitoring, and preservation during the storage time. The management approach to storage should be to place the radiopharmaceutical waste in a suitable waste storage facility, with adequate shielding consisting of lead or concrete block according to the complexity of the operation, as a part of their 'decay in storage' program. This approach

to radiopharmaceutical waste management is equally suitable to all physical states of waste and can be easily applied to waste having half-lives of less than 100 days as per International Atomic Energy Agency recommendations. The primary objective of storage should be isolation and containment of waste for a period of time during which it decays to its non-radioactive part and can be treated as normal waste. During storage, it is important to have full traceability of waste packages by suitable record keeping. Also important is to do periodic monitoring of such site for establishing safety during the course of their storage. A dose

limit of 1mSv per year at the boundary of the radiological facility as suggested by the International Commission on Radiological Protection should be referred for confirming safety aspect during storage of radioactive wastes.

Majority of radiopharmaceutical waste consists of radionuclides having a half-life ranging from a few hours to months and can be effectively managed using this approach alone. **Table 1** below presents a list of most commonly used medical radioisotopes for various purposes that can be managed using 'decay in storage' approach.

**Table 1:** Presenting the most commonly used medical radioisotopes which can be disposed of following 'delay and decay' approach.

Sr. No.	Isotope	Half-life	Application	Type of Waste
1	<sup>18</sup> F	1.83 h	PET imaging	Solid, liquid
2	<sup>24</sup> Na	15.0 h	Clinical measurement	Liquid
3	<sup>32</sup> P	14.3 d	Therapy	Solid, liquid
4	<sup>59</sup> Fe	44.5 d	Clinical measurements	Liquid
5	<sup>58</sup> Co	70.8 d	Clinical measurements	Solid, liquid
6	<sup>67</sup> Ga	3.26 h	Clinical measurement	Liquid
7	<sup>89</sup> Sr	50.5 d	Therapy	Liquid
8	<sup>99m</sup> Tc	6.02 h	Clinical measurement	Solid, liquid
9	<sup>125</sup> I	60.1 d	Clinical measurement, labelling	Solid, liquid
10	<sup>131</sup> I	8.04 d	Clinical measurement, therapy	Solid, liquid

After securely placing radioactive wastes in suitably shielded lead-lined containers, they should then be allowed to go for 'decay in storage' in which a minimum storage of 10 half-lives should be achieved. This period is generally recommended as it is adequate to reduce the initial activity of waste to less than one-thousandth of the initial activity. The waste should be sufficiently held in storage until the radiation exposure rate cannot be distinguished from the background radiation levels. On successful completion of decay period, the dose rate emanating from these wastes should be recorded before moving to the next step of final disposal. On all occasions, it should be ensured that the clearance level has been achieved. The radioactive waste must be monitored at the surface of the container with an appropriate radiation detection instrument set at its most sensitive scale and with no interposed shielding between the detector and the waste, in a low background radiation environment. Once the radioactive waste has decayed sufficiently and a confirmation is made for the absence of radioactivity, they should be disposed of as chemical, biological or industrial waste as regular trash. Segregation of waste should also be done at the end of the decay storage period based on remaining activity.

The radiopharmaceutical waste should be stored/disposed of depending upon its state as elaborated below:

**10.1 Solid wastes:** For storage of solid wastes, the following procedure should be adopted.

- Various syringes, scintillation vials, scalpels blades and hypodermic needles constituting the sharp items generated as radioactive wastes should be securely deposited in lead-lined sharp bins and labelled with caution about radioactivity. Outside of all these containers should be swiped and tested for radioactivity using a well counter. The radioactive sharp material container should be placed in a hot secured area for sufficient decay after putting it into a secondary container which further helps in preventing breakage of these susceptible items. An option for placing an

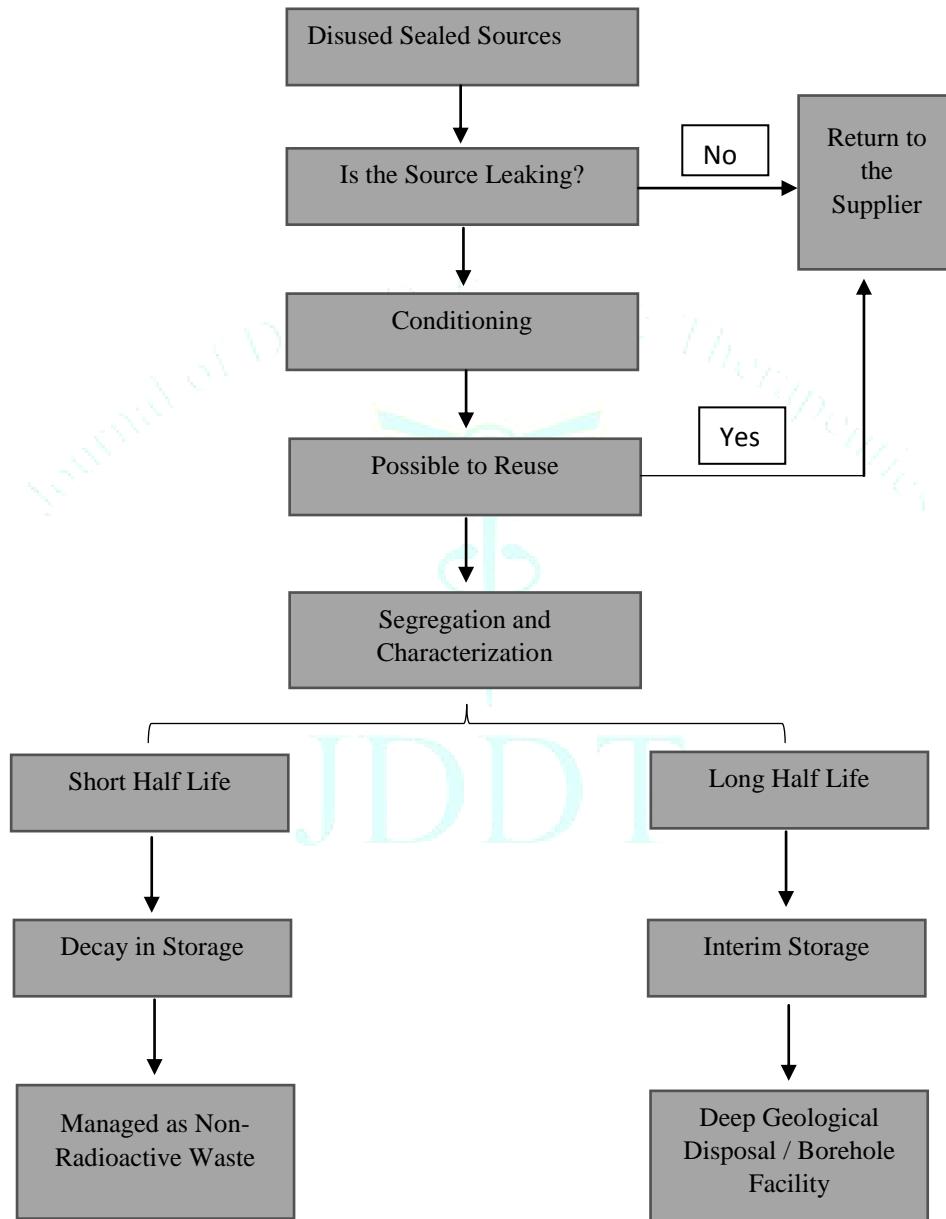
absorbent pad in the secondary container should also be used for preventing any leakage.

- Radioactive wastes consisting of absorbent paper and gloves should be separately placed in another container which is also appropriately shielded and labelled.
- Solid wastes consisting of carcasses of experimental animals and blood-contaminated wastes should be hermetically sealed using polyethylene drums instead of plastic bags. It is generally recommended to first deactivate the waste using autoclaving or chemical disinfection and then storing it in the freezer. Putrescible waste consisting of carcasses of experimental animals should be stored in a deep freezer for preventing any biological decay during its transition to non-radioactive waste. Frost free deep freezer is generally recommended for preventing off-gas phenomenon which could otherwise cause trapping of radioactive material into the frost buildup.
- Lead pots should be suitably decontaminated prior to reuse or recycling as nonradioactive wastes.
- For radionuclide generator, the best practice is to go for 'decay in storage' option followed by dismantling the elution column from its shield. However, it should be ensured that the activity and dose rate should be low before removal of the elution column followed by its dismantling. No special requirements exist for disposal of radionuclide generator except for appropriate surveys to confirm total decay and removal of labels from the devices. When the generator activity has decayed to background levels, the radionuclide generator can be disposed of in non-radioactive trash.

Sealed radioactive sources have different half-lives and activity and are used for varied purposes in nuclear medicine and radiotherapy departments. Depending on the activity and half-lives of radionuclide content, these sealed sources at end of their useful life should be disposed of suitably as disused sealed sources. They may emit intense radiations and exceeds the recommended specific activity to be accepted as normal trash. Therefore different approaches

should be used for disused sealed sources. It may consist of disposal following decay in storage, near-surface disposal facilities or even deep geological disposal depending upon the level of isolation required. Also returning to the supplier can be a practical option in some cases. For sealed sources having a short half-life (about 100 days) and of reasonably high activity, the 'decay in storage' is the preferred option. However, for sources having a very high level of activity and a long physical half-life, the 'decay in storage' method is not recommended as they can constitute high localized concentration inside the facility requiring long-term storage problems and the associated risk in cases of human intrusion leading to widespread complications. Therefore, at the end of their useful half life, these high activity long half- live

sources should be disposed of as disused sealed radioactive source in borehole facilities. It should consist of placing the waste containing radionuclide in a specially engineered facility having a narrow diameter bored which can be operated directly from the surface. The most important aspect for management of disused sealed sources should be the maintenance of continuity of control irrespective they are in use or not. This is because they may contain radionuclide in a dispersible form which can create widespread havoc should their primary containment is breached. **Figure 3** presents an overview of different approaches to be followed for waste management of disused sealed sources.



**Figure 3:** Different approaches to be followed for the management of disused sealed sources.

**10.2 Liquid wastes:** Radiopharmaceutical waste obtained as liquid should be disposed of as follows:

- As in all cases, the initial step towards disposal of liquid waste should be segregation of short half-life radiopharmaceutical waste from long half-life. Short half-life radiopharmaceuticals include those containing

Tc<sup>99m</sup> and F<sup>18</sup> while long half-life includes radiopharmaceuticals containing Lutetium 177.

- For radiopharmaceuticals containing intermediate half-life radionuclides like I<sup>131</sup>, I<sup>123</sup>, and Ga<sup>67</sup>, following the decay in storage approach is advisable.
- Patients undergoing diagnostic scans are administered radiopharmaceuticals of short half-life in a very limited

amount. Therefore excreta from such patients can be discharged into the sewerage system directly provided they are centrally connected to the sewerage management system.

- Radioactive organic and aqueous wastes should be stored and disposed of separately even if they have the same radionuclide in them.
- Contaminated solution arising from rinsing activity of various apparatus of radioimmunoassay kits is diluted to a large extent and can be discharged directly through the hospital sewerage system to municipal waste. For disposal through sewerage, the most important point to confirm is the solubility of material to be disposed of in water.
- For managing excreta of inpatients on radiopharmaceutical therapy and diagnosis in hospital nuclear medicine department, best option should be to design the outlet of toilets being used by these inpatients and route it to delay tanks via leak proof pipes. These delay tanks may be of the size of the swimming pool with adequate shielding. Biochroma technique can be suitably employed in this case.
- Radioactive liquid waste can also be allowed to suitably undergo decay into a nonradioactive form using delay tanks made of concrete with suitable shielding. The activity at the end of the decay period from these tanks should be recorded by adequate sampling and after confirmation of permissible limits should be discharged to the community sewerage system.

**10.3 Gaseous Waste:** Radioactive gaseous waste should be treated at the point of its origin itself. The setup should consist of a condenser, pre-filter followed by HEPA filters. The function of condenser should be to condense the radioactive gaseous waste which is then filtered through the prefilter. The final exhaust of gas consists of passing the prefiltered gas through HEPA filter fitted at the exhaust end of chimney installed at an appropriate height.

**11. Near-surface disposal of solid waste:** For solid radiopharmaceutical waste which has sufficiently undergone disintegrations into its non-radioactive form, the subsequent steps should consist of suitably disposing these nonradioactive wastes to landfills or 'near surface disposal of solid waste'. Near-surface disposal consists of emplacement of solid radioactive waste having short-lived radionuclides in a disposal facility that is located few meters underground in form of earthen trenches or engineered structures.

The basic concept of 'containment and isolation' is followed for near-surface disposal method. Containment should be achieved by using engineered barriers like the waste package, facility structure and even the geological layers within the facility. The site to be selected for such disposal purpose should be sufficient to accommodate the waste and be suitably located keeping in mind all the socio-economic

and environment management factors. The design and layout of the site should be pre-approved from the regulatory authority. Provision for monitoring and surveillance during operation and post-closure phases should also be made available in waste disposal facility for verification of its containment capability.

The most important thing to be kept in mind for the site at which the final disposal of radiopharmaceuticals waste is to be done is that safety requirements should be commensurate with the longevity of the hazard (i.e. the amount and concentration of radionuclides) along with environmental conditions at the disposal site. Also important to keep in mind is the geology, seismic vulnerability, and the topographical location of the facility. Areas amenable to earthquake, flood and erosion should be avoided. The site should have a multi-barrier approach to assist radiopharmaceutical waste isolation from the biosphere for a suitable amount of time depending on the type of waste. The final closure of near-surface disposal facility should be done after approval from the regulatory authority on successful submission of closure and safety assessment plan. Suitable markers for identification of these disposal sites should be done for its easy identification for future. Precautions should be taken for preventing any human intrusion, land use or the removal of waste from the site.

**12. Documentation:** It is indispensable for all radiopharmaceutical waste management program to have written records of each and every step in the overall waste management life cycle. Also, records should be available for the design, layout, closure and post-closure of waste management facility. Documentation should consist of necessary details regarding the inventory of stock, including its location, and its physical and chemical characteristics. Records should be maintained/retained in multiple copies for waste disposal facility till the activity level, as measured using suitable counters, reaches a safety level. It is important to maintain the records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal. Most critical aspect deals with the waste storage step in which many radiopharmaceutical wastes are collected and stored at the same time in a waste store. Therefore full details of each and every waste package should be maintained in a radioactive waste register before its acceptance into the waste store. It should consist of details like radionuclide present, date of its generation, date of acceptance, its current activity, its physical state, and precautions if any. The waste should also be provided with a unique identification number in a suitable format like XX-YY-ZZ where XX denotes serial number of the packet, YY denotes the date on which the packet was received and ZZ denotes the year. A typical format for radiopharmaceutical waste register is presented in **table 2** below:

**Table 2:** Contents and format of the radioactive waste register.

Date Waste Generated	Waste Register Number (XX-YY-ZZ)	Radio-nuclide Present	Waste Generator	Current Activity/ Measurement Date	Type (Solid/ Liquid)/ Weight/Volume	Precaution	Date Waste Cleared

Records should also be maintained for all material from which the regulatory control has been withdrawn following suitable decay including details of all spent and/or disused sources being returned to their suppliers.

## DISCUSSION

Existing national laws and policies should be revised to devise a coherent, comprehensive and consistent set of standards that are of international level for holistically dealing with existing regulatory concerns regarding radiopharmaceutical storage and disposal. The focus needs to be drawn for assessing the available option for waste management and the search for better alternatives. A detailed study of various nuclear medicine procedures being performed annually in India along with the associated waste generated needs to be done for assessing and investigating the present capacity of various hospitals in dealing with radiopharmaceutical waste. This will provide the lead for construction of waste repositories at the regional and/or national level.

The facility for disposal of spent sealed sources of long half-lives using deep geological method should be flexible enough to address the ongoing technological advances at the outset. Periodic audits, including unplanned inspection, should be done by national authorities in an independent manner to ensure full compliance to the approved procedures which will help in building public trust and transparency. Most importantly, a study on each of the radiopharmaceutical being used in healthcare and nuclear medicine should be done to reach at an agreed set of activities and activity concentration to be used for different age group and the acceptance level for disposal to landfill, sewer or atmosphere. This will help in promoting a uniform approach to radiopharmaceutical waste disposal.

## CONCLUSION

As new radiopharmaceuticals are making their way to the market, the issue concerning their storage and disposal needs considerable attention. There is an indispensable need of adequate regulatory guidelines so that radiopharmaceuticals are stored and disposed of in the most judicious manner, taking into consideration both men and the environment. Any new radiopharmaceutical being launched into the market should have a full life cycle regulatory plan consisting of ways to minimize waste during

its production and use along with its final disposal as a part of its cradle-to-grave approach.

## CONFLICT OF INTEREST

The authors report no conflicts of interest.

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