Central Administration of Operations
General Administration of Licensing Scientific Offices, Medical Product Store
Warehouse, Stability and Bioequivalence Centers
General Administration for Market Control

Regulatory Guide on licensing for Integrated Management Facilities of Pharmaceutical products and Medical Devices Waste

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1. Introduction

The Integrated Management Unit for Pharmaceutical products and Medical Devices waste, under the General Administration of Licensing Scientific Offices, Medical Product Stores, Warehouse, Stability and Bioequivalence Centers, is responsible for establishing the system and procedures governing the licensing of the integrated management facilities of pharmaceutical products and medical devices waste, whether within or outside pharmaceutical institutions and facilities.

2. Scope

The work procedures of the Integrated Management Unit for Pharmaceutical products and Medical Devices Waste under the Central Administration of Operations at the Egyptian Drug Authority headquarter shall apply to the following:
Licensing of the transportation of pharmaceutical products and medical devices waste
Licensing of the treatment of pharmaceutical products and medical devices waste
Licensing of the transportation and treatment of pharmaceutical products and medical devices waste
Updating licenses due to reasons necessitating such updates;
Renewal of license validity period.

3. Definitions

Institution: Any public or private entity duly licensed to practice activities related to pharmaceutical products and medical devices, such as pharmaceutical and medical devices factories, pharmacies, etc.

License: The document issued by the competent administration of the Authority authorizing the handling and circulation of hazardous materials and waste as stipulated by Law No. 202 of 2020 and Law No. 4 of 1994, as referred to herein.

Licensee: A pharmaceutical facility licensed to carry out the integrated management of pharmaceutical products and medical devices waste.

Integrated Waste Management: The integration of various waste-related activities, including waste minimization, reuse, collection, storage, segregation, transportation to designated sites or facilities, treatment, valorization, recycling, and the final environmentally safe disposal thereof.

Pharmaceuticals Products: Pursuant to Article (1) of Law No. 151 of 2019 promulgating the law establishing of the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management, and the Egyptian Drug Authority: “Any product or preparation containing one or more substances intended for treatment, prevention, or diagnosis in humans or animals, or claimed to have any other therapeutic effect, or designed to restore, correct, or modify physiological functions through the exercise of a pharmacological, immunological, or metabolic action in the interest of public health, in accordance with the applicable standards and references; as well as any preparations or substances that may be developed in line with scientific advancements and/or international standards and references."

Medical Device: Pursuant to Article (1) of Law No. 151 of 2019 promulgating the law establishing of the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management, and the Egyptian Drug Authority: "Any device, instrument, tool, machine, apparatus, appliance , application—including implanted or inserted items, laboratory reagents for in vitro use, software, substances, or any other similar or related items—manufactured by the producing company for human use, either individually or in combination, for one or more medical purposes.

Waste: Any damaged or discarded materials, items, or products abandoned by their holder, whether suitable for recycling or requiring disposal.

Industrial Waste: Waste resulting from industrial or craft activities, or any similar activity that does not contain hazardous components.

Hazardous Waste: Waste containing organic or inorganic components or compounds that may pose a risk to human health or the environment due to their physical, chemical, or biological properties, or by virtue of exhibiting hazardous characteristics such as infectiousness, flammability, explosiveness, or toxicity.

Hazardous waste is classified according to its degree of hazardousness as follows:

- Chemical Waste: Waste containing chemical substances, whether in solid, liquid, or gaseous forms, generated from diagnostic, therapeutic, or laboratory activities, or used in cleaning, disinfection, or sterilization procedures.
- Pharmaceutical Waste: Waste resulting from preventive or therapeutic activities, or from the production, preparation of pharmaceutical products, drugs, or expired /damaged medications.

- Biological Waste: Includes biological product waste and waste generated from biological research, encompassing syringes, expired medical drugs, human vaccines, sera, blood and plasma products and derivatives, as well as products manufactured using biotechnology or equivalent methods, and any other preparations or substances that may be developed in accordance with scientific advancements and/or pharmaceutical standards and references.
- Mixed Waste: Waste that contains more than one type of the aforementioned wastes, which have become mixed, either as a result of interrelated medical processes and activities or by accident. Such waste is considered to possess the characteristics of the most hazardous component, and it is classified, treated, and disposed of accordingly.

Non-Hazardous Waste: Waste that, by its nature, does not exhibit hazardous characteristics, whether it is municipal, industrial, agricultural, or generated from demolition and construction works, or similar sources, such as:

- Packaging materials, including cardboard boxes, paper bags, plastic bags, syringe packaging, needle covers, IV equipment, etc.
- Kitchen waste, including organic waste and packaging materials, which should be segregated at the source and subsequently handled similarly to household solid waste.

Pharmaceutical Waste: Waste generated by pharmaceutical facilities and institutions of all types licensed and supervised by the Authority.

Hazardous Materials: Materials possessing hazardous properties that harm human health or adversely affect the environment, such as infectious, toxic, explosive, flammable, or ionizing radiation-emitting substances.

Handling and Circulation of Hazardous Materials: All operations leading to collection or transportation thereof, including cross-border transport and the procedures required for export, import, storage, recycling, treatment, recovery of useful components, or reuse.

Waste Management: The management of any stage of integrated waste management, encompassing all activities related to segregation, classification, collection, storage, treatment, transportation, and disposal of waste.

Waste Storage: The temporary placement of waste within a facility or at a site with specific technical specifications, without performing any treatment operations.

Waste Handling: Any process leading to the collection, transportation, storage, treatment, or utilization of waste.

Waste Collection: The process of collecting waste within the facility and classifying it according to type and nature thereof in preparation for transportation to a temporary storage site or a waste treatment unit.

Waste Segregation: The process of classifying waste according to type and nature thereof in preparation for transportation to a temporary storage site or a waste treatment unit.

Transportation: The movement of waste outside the institution to treatment centers or units.

Transporter: The natural or legal person engaged in the transportation of waste to treatment and disposal units.

Treatment: Operations performed on waste to alter its chemical, physical, or biological properties, composition, reduce its volume, or to convert hazardous waste into safe or less hazardous waste during transportation, temporary storage, or final disposal. Treatment may be conducted within or outside the institution before the waste is transported to a landfill.

Waste Disposal: The final disposal of residues or remnants of Pharmaceutical products and Medical devices waste after treatment, in such a way that they cannot be reused or repurposed, and pose no hazardous or harmful impact on public health or the environment.

4. Main topic

First: License for the Transportation of Pharmaceutical product and Medical Devices Waste

Required Documents:

1. An application from the company addressed to the Director of the Integrated Management Unit for Pharmaceutical product and Medical devices waste at the Egyptian Drug Authority, for licensing the company to transport pharmaceutical product and medical devices waste, and licensing for the vehicles used for such transportation. The application shall be Signed by the Chairman of the Board of Directors or by an authorized representative acting within the administrative powers and commercial register signature, duly authenticated by bank certified-signature, and shall include all required information, as follows:
   - The detailed address of the company's administrative headquarters (including building number, floor, and apartment).
   - The detailed address of the garage.
   - The number of vehicles and details thereof, including :(license plate number – vehicle make – chassis number – engine number – vehicle activity/purpose)

- Company contact details (e-mail, telephone, and fax).

2. A photocopy of the valid National ID Card of the company owner or the duly authorized representative for the issuance of the license.
3. A photocopy of the proof of possession (lease or ownership contract) for the company's premises. (The premises shall be a fully constructed property with a complete utilities (water and electricity), bearing a visible sign displaying the company's name and activity. All contracts shall be valid, duly notarized (by the Real Estate publicity department, or by a court judgment), the lease term shall not be less than five (5) years, (The original to be reviewed).
4. A photocopy of the proof of possession (lease or ownership contract) for the vehicles parking garage. The contracts shall be valid, duly notarized, and the lease term shall not be less than five (5) years.
5. A photocopy of the company's valid Commercial Register, (the original to be reviewed).
6. A photocopy of the company's valid Tax Card, (the original shall be presented for review).
7. Submission of documentary proof of the licensed company's ownership of the vehicle, or a duly notarized annual lease agreement therefor, authenticated by the Real Estate Publicity Department.
8. A photocopy of the valid vehicle license.
9. Civil Defense approval of the garage
10. Environmental approval of the medical pharmaceutical products and medical devices waste transportation project, issued by the Egyptian Environmental Affairs Agency (EEAA).
11. An engineering drawing of the garage, clearly indicating (the horizontal plan, vertical section, and Site location sketch of the garage), duly stamped by a registered syndicate engineer.
12. An undertaking by the company to comply with ensuring that transport vehicles are free from any pharmaceutical products and medical devices waste during overnight parking at the garage, and that the vehicles are properly disinfected and sterilized. Such undertaking shall be duly authenticated by bank certified-signature
13. Payment of the prescribed service fees in accordance with the applicable decision in this regard.

The license for the transportation of pharmaceutical products and medical devices waste shall be issued by the Central Administration for Operations for a period of one (1) year. An application for renewal shall be submitted at least three (3) months prior to the expiry date of the license

Work Procedures to be followed for Licensing the Transportation of Pharmaceutical Products and Medical Devices Waste

1- The license application shall be submitted by the company owner or authorized representative thereof at the premises of the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, at central Administration for Operations.
The application shall be accompanied by all required documents for licensing.

2- Upon fulfillment of the essential documents required for licensing, a date shall be scheduled for the initial inspection of the company premises, the vehicle(s) used for the transportation of pharmaceutical products and medical devices waste, and the vehicle garage, within thirty (30) days as of the date of receipt of the complete application file, in accordance with the inspection schedule. The applicant shall be notified of the inspection date by a registered letter with acknowledgment of receipt.

3- The initial inspection shall be conducted by the Unit's pharmacists. If the inspection reveals non-compliance with the required conditions, the company shall be notified of the observations to be addressed. In such case, the company shall be granted an initial grace period of eight (8) months as of the date of inspection to complete the required requirements.

4- Upon addressing the observations, the company shall submit a request to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, detailing the corrective actions taken by the company to address the observations, together with a request to schedule a second inspection.

5- The second inspection shall be conducted by the Unit's pharmacists to verify compliance with the required observations. If non-compliance is found, the company shall be granted a second grace period of four (4) months. The company shall be notified of the required observations and the granted period by a registered letter with acknowledgment of receipt.

6- Upon addressing the observations, the company shall submit a request to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, detailing the corrective actions taken by the company to address the observations, together with a request to schedule a final inspection.

7- The final inspection shall be conducted, and if the required conditions are not met, the license application shall be achieved. If the conditions are fulfilled, the company shall be granted a period of one (1) month to complete the remaining required documents.

8- Where the company fulfills all the required documents and conditions, it shall submit a valid contract / agreement with an entity duly licensed to treat pharmaceutical products and medical devices waste, provided that the contract term being no less than one year.

9- All documents submitted by the company, together with the inspection reports conducted, shall be presented to the Pharmaceutical

Products and Medical Devices Waste Committee, formed under the chairmanship of the director of the Central Administration for Operations, for decision thereof regarding the (granting or non-granting) of the license authorizing the company to operate in the field of transportation of pharmaceutical products and medical devices waste for a period of one (1) calendar year.

10- In the event of approval to grant the company a license to operate in the field of transportation of pharmaceutical products and medical devices waste, the company owner shall submit a list containing the details of the drivers and personnel assigned to the vehicle(s).
The geographical scope the license shall be limited to the governorate where the license is issued. Except for the Greater Cairo governorates, where the licensee may request to operate within these governorates.

11- The facility manager shall be appointed by the license holder through a letter of appointment, signed by the Chairman of the Board of Directors of the company or its authorized representative in accordance with the administrative powers and commercial registry signature, duly authenticated by bank certified-signature.

12- The Company's original license authorizing the transportation of pharmaceutical products and medical devices waste shall be handed over to the license holder or his authorized representative after payment of the prescribed service fees applicable in this regard.

Procedures for Updating the License for the Transportation of Pharmaceutical Products and Medical Devices Waste

1. In the event of adding a vehicle, the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste shall be notified, and all documents related to the vehicle shall be submitted for presentation to the Pharmaceutical Products and Medical Devices Waste Committee to provide its opinion.
2. In the event of any change to the company's details, including but not limited to (the company's registered address – modification to the layout of the garage-vehicle license plate numbers- changes in contracts with waste disposal contractors- employee data, etc.), the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste shall be notified of such change in order to take the necessary procedures in accordance with the specific amendment requested.

Work Procedures for Updating the License

1. The license holder or its authorized representative shall submit an application for updating the storage license, clearly stating the purpose of the requested update and enclosing all required supporting documents, to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste. The application shall be signed by the Chairman of the Board of Directors of the company or authorized representative thereof pursuant to administrative powers and commercial register signature, duly authenticated by bank certified-signature. The application shall include all required data.

2. The submitted application and all attached thereto documents, as well as the file maintained by the Unit, shall be received and reviewed. The license holder shall be notified of any documents required to be completed, if any.
3. The necessary inspections shall be conducted by the competent pharmacists of the Unit.
4. Upon fulfillment of all requirements and completion of all documents, all documents submitted by the company, together with the inspection reports conducted, shall be presented to the Pharmaceutical Products and Medical Devices Waste Committee for decision thereof.
5. The data of the license for the transportation of pharmaceutical products and medical devices waste shall be updated, and the license holder shall be notified to attend for receipt thereof, surrender the previous license, and pay the prescribed service fee, if any.
6. The license shall be updated for the remaining validity period.

Second: License for the Treatment of Pharmaceutical Products and Medical Devices Waste

Required Documents

1. An application submitted by the company and addressed to the Director of the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste at the General Administration for the Licensing of Scientific Offices, Drug warehouse and Storage Facilities, and Bioavailability and Bioequivalence Centers, requesting the licensing of the treatment of pharmaceutical products and medical devices waste.
   The application shall be signed by the Chairman of the Board of Directors or his authorized representative in accordance with the administrative powers and commercial registry signature, duly authenticated by bank certified-signature. The application shall be duly

completed and include all required data, as follows:

- The detailed address of the company's administrative headquarters (building number, floor, and apartment).
- Details of the treatment unit/equipment.
- Company contact details (email, telephone, and fax).

2. A photocopy of the valid national ID card of the company owner or the person authorized to obtain the license.
3. A photocopy, (with the original to be reviewed), of the proof of possession (lease or ownership contract) for the company's headquarter. The premises shall be a fully constructed property with complete utilities (water and electricity), bearing a visible sign displaying the company's name and activity. All contracts shall be be valid and duly notarized, and the lease term shall not be less than five (5) years.
4. A photocopy of the company's valid commercial register, (with the original to be reviewed).
5. A photocopy of the company's valid tax card, (with the original to be reviewed).
6. A photocopy of the maintenance contract or a photocopy of the warranty card of the treatment device.
7. A certified copy of the approval issued by the Pharmaceutical Products and Medical Devices Waste Committee for the technology used in the treatment device.
8. A copy of the incinerator emissions measurement report in accordance with Environmental Law No. 4 of 1994 and its Executive Regulations, and a copy of the analysis results of the shredding and sterilization output.
9. Environmental approval for the project of treating pharmaceutical products and medical devices waste, issued by the Egyptian Environmental Affairs Agency (EEAA).
10. An engineering drawing of the premises subject to licensing, showing the horizontal layout, vertical section, and site sketch, duly stamped by a syndicate-registered engineer.
11. The prescribed licensing service fee for the treatment of pharmaceutical products and medical devices waste shall be paid in accordance with the applicable decisions in force in this regard.

The license for the treatment of pharmaceutical products and medical devices waste shall be issued by the Central Administration for Operations for a period of one (1) year. An application for renewal shall be submitted within three (3) months prior to the expiry date of the license.

Procedures to be followed for Issuing a License for the Treatment of Pharmaceutical Products and Medical Devices Waste

1- The licensing application shall be submitted by the company owner or its authorized representative at the headquarter of the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste at the Central Administration for Operations. The application shall be accompanied by all documents required for licensing.
2- In the event that the essential licensing documents are duly completed, an initial inspection date shall be scheduled for the company's premises, the treatment device, and the temporary storage rooms for pharmaceutical products and medical devices waste, and to verify their compliance with the prescribed requirements, within thirty (30) days as the date of receipt of the complete file, in accordance with the inspection schedule. The applicant shall be notified of the inspection date by a registered letter with acknowledgment of receipt.
3- The initial inspection shall be conducted by the Unit's pharmacists. In the event that the required conditions are not me, the company shall be notified of the observations to be fulfilled, and the company shall be granted an initial grace period of eight (8) months as the date of the inspection.
4- Upon addressing the observations, the company shall submit an application to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, indicating the corrective actions taken by the company to rectify the deficiencies, and to request the scheduling of a second inspection.
5- The second inspection shall be conducted by the Unit's pharmacists to verify compliance with the required observations. If non-compliance is found, the company shall be granted a second grace period of four (4) months and shall be notified of the required observations and the granted period, by a registered letter with acknowledgment of receipt.
6- Upon rectification of the observations, the company shall submit a request to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, detailing the corrective actions taken by the company to address the observations, together with a request to schedule a final inspection.
7- The final inspection shall be conducted, and if the required conditions are not met, the licensing application shall be achieved. If the conditions are fulfilled, the company shall be granted a period of one (1) month to complete the required documents.
8- In the event that the company fulfills all the required documents and completes the necessary inspections, the matter shall be submitted to the Pharmaceutical Products and Medical Devices Waste Committee, formed by the director of the Central Administration for Operations, to take its decision regarding the granting or non-granting of the license for the treatment of pharmaceutical products and medical devices waste to the company.

9- The facility's responsible manager shall be appointed by the license holder pursuant to an appointment application signed by the Chairman of the Board of Directors of the company or his authorized representative, according to the administrative powers and commercial register signature, duly authenticated by bank certified-signature.
10- The original license of the company for the treatment of pharmaceutical products and medical devices waste shall be delivered to the license holder or his authorized representative after payment of the prescribed service fees in this regard.

Procedures for Updating the License for the Treatment of Pharmaceutical Products and Medical Devices Waste

1- In the event of adding a treatment device (incinerator or shredding and sterilization device), the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste shall be notified, and all documents referred to in items (5), (6), (7), and (8) above shall be submitted for presentation to the Pharmaceutical Products and Medical Devices for opinion Thereof.
2- In the event of any changes to the company's information, including (the company's registered address- modifications to the facility's layout-changes in contracts with the waste disposal contractor- or a change of the responsible manager), the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste shall be notified of such change in order to take the necessary procedures in accordance with the specific data to be amended.

Work Procedures for Updating the License

1- The license holder or its authorized representative shall submit an application for updating the storage license, clearly stating the purpose of the requested update and enclosing all required supporting documents, to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste. The application shall be signed by the Chairman of the Board of Directors of the company or authorized representative thereof in accordance with the administrative powers and commercial register signature, duly authenticated by bank certified-signature. The application must be complete and include all required data
2- The submitted application and all attached thereto documents, as well as the file maintained by the Unit, shall be received and reviewed. The license holder shall be notified of any documents required to be completed, if any.

3- The necessary inspections shall be conducted by the competent pharmacists of the Unit.
4- Upon fulfillment of all requirements and completion of all documents, all documents submitted by the company, together with the inspection reports conducted, shall be presented to the Pharmaceutical Products and Medical Devices Waste Committee for its decision.
5- The data of the license for the transportation of pharmaceutical products and medical devices waste shall be updated, and the license holder shall be notified to attend for receipt thereof, surrender the previous license, and pay the prescribed service fee, if any.
6- The license shall be updated for the remaining validity period.

Third: Licensing Procedures for Companies Engaged in the Transportation and Treatment of Hazardous Medical Waste

Required Documents

1- An application submitted by the company and addressed to the Director of the Integrated Management Unit for Pharmaceutical products and Medical devices waste, at the General Administration for Licensing Scientific Offices, Medical Product Stores, Warehouses, Stability and Bioequivalence Centers, requesting licensing of the company to transport and treat Pharmaceutical products and Medical devices waste; and Licensing of the vehicles designated for the transportation of Pharmaceutical products and Medical devices waste. The application shall be signed by the Chairman of the Board of Directors or by an authorized representative acting within administrative powers and commercial register signature, duly authenticated by bank certified-signature; and inclusive of all required data.
2- A photocopy of the valid National Identification Card of the company owner or the duly authorized representative responsible for submitting the licensing application.
3- A photocopy (with the original to be reviewed) of the proof of possession (lease or ownership contract) of the company's headquarters (the headquarters shall be a fully constructed and fully serviced real estate unit with water and electricity connections), bearing a visible sign displaying the company’s name and activity. All contracts shall be valid, duly notarized, if a lease, the term shall not be less than five (5) years.
4- A photocopy (with the original to be reviewed) of the proof of possession (lease or ownership contract) of the vehicles’ overnight parking garage, provided that all contracts are valid, duly notarized, if a lease, the term shall not be less than five (5) years.
5- A title deed (lease or ownership contract) of the premises, in cases where licensing is sought outside a pharmaceutical facility/institution, provided that all contracts are valid, duly notarized, and that the lease term, if applicable, shall not be less than five (5) years.

6- A photocopy, (with the original to be presented for verification), of the company's valid Commercial Register extract.
7- A photocopy, (with the original presented for verification), of the company's valid Tax Card.
8- Submit of proof of the company's ownership of the vehicle or a notarized annual lease agreement for the vehicle registered with the Real Estate Registration Office.
9- A copy of the valid vehicle license.
10- Approval issued by the Civil Protection Authority for the garage.
11- Environmental approval for the project of transportation and treatment of Pharmaceutical products and Medical devices waste, issued by the Egyptian Environmental Affairs Agency (EEAA).
12- An engineering drawing of the garage, illustrating the horizontal projection - vertical projection- a site sketch of the garage), duly signed and by a registered syndicate engineer.
13- A photocopy of the maintenance contract or a copy of the warranty card for the treatment device.
14- A photocopy of the approval by the Waste Committee concerning the technology utilized in the treatment device.
15- A copy of the emissions measurement report of the incinerator, in accordance with Environmental Law No. 4 of 1994 and Executive Regulations thereof, and a copy of the analysis results of the output of shredding and sterilization processes.
16- The prescribed fees of the licensing service for the transportation and treatment of Pharmaceutical products and Medical devices waste shall be paid in accordance with the applicable decisions in force in this regard.

The license for the transportation and treatment of pharmaceutical products and medical devices waste shall be issued by the Central Administration for Operations for a period of one (1) year. An application for renewal shall be submitted at least three (3) months prior to the expiry date of the license.

Work Procedures to be followed for Issuing a License for the Transportation and Treatment of Pharmaceutical products and Medical devices waste

1- The licensing application shall be submitted by the company owner or the duly authorized representative at the headquarters of the Integrated Management Unit for Pharmaceutical products and Medical devices waste, at the Central Administration for Operations. The application shall be accompanied by all documents required for licensing.
2- Upon verification that the essential licensing documents are complete, a date shall be scheduled for the initial inspection of the following: the company premises, the hazardous medical waste transport vehicle, the vehicle garage, the treatment device, and the waste

storage room, to assess their compliance with the applicable requirements. Such inspection shall be conducted within thirty (30) days as the date of receipt of a duly completed application file, in accordance with the inspection schedule. The applicant shall be notified of the inspection date by registered letter with acknowledgment of receipt.

3- The initial inspection shall be conducted by the Unit's pharmacists. In the event that the required conditions are not fully satisfied, the company shall be notified of the observations to be addressed. In such case, the company shall be granted an initial grace period of eight (8) months as of the date of inspection to fulfill the required requirements.
4- Upon addressing the observations, the company shall submit an application to the Integrated Management Unit for Pharmaceutical products and Medical devices waste, detailing the corrective actions taken by the company to rectify the observation, and requesting the scheduling of a second inspection.
5- The second inspection shall be conducted by the Unit's pharmacists to verify compliance with the required observations. In the event that the observations have not been fully addressed, the company shall be granted a second grace period of four (4) months, and shall be notified of the outstanding observations, and the granted period by registered letter with acknowledgment of receipt.
6- Upon addressing the observations, the company shall submit an application to the Integrated Management Unit for Pharmaceutical products and Medical devices waste, detailing the corrective actions taken by the company to rectify the observation, and requesting the scheduling of a final inspection.
7- The final inspection shall be conducted, and if the required conditions are not met, the licensing application shall be archived. If the required conditions are fulfilled, the company shall be granted a period of one (1) month to complete the remaining required documents.
8- Upon the company's fulfillment of all required documents and completion of all necessary inspections, the matter shall be submitted to the Waste Committee to decide whether to (grant /deny) the company a license for the treatment of Pharmaceutical products and Medical devices waste.
9- In the event of approval to grant the company a license to operate in the field of transportation and treatment of Pharmaceutical products and Medical devices waste, the company owner shall be required to submit a list containing the details of the drivers and personnel assigned to the vehicle used for transportation.
10- The facility manager shall be appointed by the license holder through a formal appointment application signed by the Chairman of the Board of Directors of the company, or by an authorized representative acting within the administrative powers and commercial registry signatures, duly authenticated by a bank certified-signature.
11- The original company license for the transportation and treatment of Pharmaceutical products and Medical devices waste shall be handed over to the license holder or the duly authorized representative thereof, upon payment of the prescribed service fees applicable in this regard.

Procedures of Updating the License for the Transportation and Treatment of Pharmaceutical products and Medical devices waste

1. In the event of adding a vehicle or a treatment device (incinerator -or shredding and sterilization unit), an application shall be submitted to the Integrated Management Unit for Pharmaceutical products and Medical devices waste, together with all required supporting documents, for submission to the Waste Committee to obtain its opinion.
2. In the event of any change to the company's details, including but not limited to (the company's registered address-modification to the engineering drawings of the garage -vehicle license plate numbers-changes to the contracts with the waste disposal contractor- or a change of the responsible manager-modification to the facility's layout-or changes to the treatment device), the Integrated Management Unit for Pharmaceutical products and Medical devices waste shall be duly notified of such change in order to take the necessary procedures in accordance with the specific item subject to amendment.

Work Procedures for Updating the License

1- The license holder or the duly authorized representative shall submit an application for updating the license, clearly stating the purpose of the update, together with the required supporting documents, to the Integrated Management Unit for Pharmaceutical products and Medical devices waste. The application shall be signed by the Chairman of the Board of Directors or by an authorized representative acting within the administrative' powers and commercial registry signature, duly authenticated by bank certified-signature
2- The submitted application and all documents attached thereto, as well as the file maintained by the Unit, shall be received and reviewed. The license holder shall be notified of any additional documents required to be completed, if applicable.
3- The necessary inspections shall be conducted by the competent pharmacists of the Unit.
4- Upon fulfillment of the health requirements and completion of all required documents, all documents submitted by the company and the inspection reports shall be presented to the Pharmaceutical products and Medical devices waste Committee to render its decision.
5- The data of the license for the transportation and treatment of Pharmaceutical products and Medical devices waste shall be updated, and the license holder shall be notified to attend for receipt of the updated license, surrender of the previous license, and payment of any applicable service fees, if any.
6- The license shall be updated for the remaining validity period.

Fourth: Procedures of Renewal the License Validity Period

Required Documents

1- An application submitted on the company's letterhead, signed by the Chairman of the Board of Directors or by an authorized representative acting within the management and signature authorities as recorded in the commercial register, and duly certified for authenticity by a bank. The application shall be addressed to the Integrated Management Unit for Pharmaceutical products and Medical devices waste for the purpose of renewing the license, provided that the application clearly states the full license details and its type.
2- A photocopy, (with the original to be reviewed), of the company's valid and up-to-date Commercial Register extract.
3- A photocopy, (with the original to be reviewed), of the company's valid and up-to-date Tax Card.
4- A photocopy of the valid National Identification Card of the license holder or the duly authorized representative.
5- The original facility license

Required Documents According to the Type of License

First: License for the Transportation of Pharmaceutical products and Medical devices waste

1- A certified copy, (with the original to be reviewed), of the proof of possession (lease or ownership contract) for the company's premises and the vehicle parking garage(s). All contracts shall be valid, duly notarized, and the lease term, if applicable, shall not be less than five (5) years.
2- Submit proof of company ownership of the vehicle or a notarized annual contract with the vehicle, or a duly notarized annual contract for the use of the vehicle(s), registered with the Real Estate Publicity Department.
3- A copy of the valid vehicle license(s).
4- Approval by the Civil Protection Authority for the garage.
5- Environmental approval for the project of transporting Pharmaceutical products and Medical devices waste, issued by the Egyptian Environmental Affairs Agency (EEAA).

Second: License for the Treatment of Pharmaceutical products and Medical devices waste

1- A photocopy of the maintenance contract or a copy of the warranty certificate of the treatment device.
2- A certified copy of the approval by the Pharmaceutical products and Medical devices waste Committee regarding the technology used in the treatment device.

3- A copy of the emissions measurement report for the incinerator, in accordance with Environmental Law No. 4 of 1994 and its Executive Regulations, and a copy of the analysis results of the output from the shredding and sterilization processes.
4- Environmental approval for the project of treating Pharmaceutical products and Medical devices waste, issued by the Egyptian Environmental Affairs Agency (EEAA).

Third: License for the Transportation and Treatment of Pharmaceutical products and Medical devices waste

1- A certified copy, (with the original presented for verification), of the proof of possession (lease or ownership contract) for the company's administrative headquarters and the vehicle parking garage(s). All contracts shall be valid, duly notarized, and the lease term, if applicable, shall not be less than five (5) years.
2- Submit proof of company ownership of the vehicle or a notarized annual contract with the vehicle, or a duly notarized annual contract for the use of the vehicle(s), registered with the Real Estate Publicity Department.
3- A photocopy of the valid vehicle license(s).
4- Approval by the Civil Protection Authority for the garage.
5- Environmental approval for the project of transporting Pharmaceutical products and Medical devices waste, issued by the Egyptian Environmental Affairs Agency (EEAA).
6- A photocopy of the maintenance contract or a copy of the warranty card for the treatment device.
7- A certified copy of the approval by the Pharmaceutical products and Medical devices waste Committee regarding the technology used in the treatment device.
8- A copy of the emissions measurement report for the incinerator, in accordance with Environmental Law No. 4 of 1994 and its Executive Regulations, and a copy of the analysis results of the output from the shredding process.
9- Receipt of payment for the license renewal service for a pharmaceutical storage, in accordance with the applicable decisions in force in this regard.

Note:

In the event that the license expires and the license holder fails to submit a renewal application prior to the expiration date, the said license shall be considered suspended, cannot be used until the renewal application is submitted and the procedures for issuing the renewed license, with its specified validity period, are complete

Work Procedures for Updating the License

1- The license holder or its authorized representative shall submit an application for updating the storage license, clearly stating the purpose of the requested update and enclosing all required supporting documents, to the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste. The application shall be signed by the Chairman of the Board of Directors of the company or authorized representative thereof in accordance with the administrative powers and commercial register signature, duly authenticated by bank certified-signature. The application must be complete and include all required data.

2- The submitted application and all attached thereto documents, as well as the file maintained by the Unit, shall be received and reviewed. The license holder shall be notified of any documents required to be completed, if any.

3- The necessary inspections shall be conducted by the competent pharmacists of the Unit, and the company shall be notified in case any corrective actions are required.

4- After all health requirements and supporting documents have been fulfilled, the matter shall be submitted to the Waste Management Committee for its decision.

5- The renewed license shall then be issued according to its type, indicating a validity period of one Gregorian year.

6- The renewed license shall be delivered to the licensee upon submission of the original expired license.

Service Fees for Licensing and Inspection of Integrated Management Facilities for Pharmaceutical Products and Medical Devices Waste – Provided by the Central Administration of Operations

Service Provided	Service fee payable (EGP)
Licensing of Integrated Management Facilities for Pharmaceutical Products and Medical Devices Waste	EGP 100.000 (One Hundred Thousand Egyptian Pounds)
Annual Inspection of Integrated Management Facilities for Pharmaceutical Products and Medical Devices Waste	EGP 10.000 (Ten Thousand Egyptian Pounds)
Registration of Companies under Licensing	EGP 20.000 (Twenty Thousand Egyptian Pounds)

Supervision and Inspection

1- Supervision of the safe disposal of pharmaceutical products and medical devices waste through supervision and inspection, as of the segregation, collection, and transportation of such waste within the pharmaceutical facility, and its temporary storage, continuing with its transport outside the pharmaceutical facilities, the facilities transporting the waste, the treatment facilities, and ending with the safe disposal of the waste.

2- Ensuring that pharmaceutical facilities and waste transportation and safe disposal facilities properly carry out all stages of the safe disposal of pharmaceutical products and medical devices waste.

3- Monitoring and inspection of the licenses of pharmaceutical facilities and waste transportation and safe disposal facilities by the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, validity, the approval of the treatment unit, and the licensing of waste transport vehicles thereof.

4- Monitoring and inspection of compliance with the requirements of the Egyptian Drug Authority for the licensing of pharmaceutical facilities, waste transportation and safe disposal facilities, transport vehicles, and treatment equipment by the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, and verifying the extent of compliance with and fulfillment of such requirements.

5- Monitoring and inspection of the conduct of activities of pharmaceutical facilities and waste transportation and safe disposal facilities under the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste, and verifying the implementation of the provisions of the applicable laws, regulations, and circulars issued to regulate their operations.

6- Taking all possible legal and administrative measures to prevent and limit the risks that may result from violations of laws and regulations or improper handling of waste, in order to prevent their escalation.

7- Taking all possible procedures deemed necessary to follow up on the institutions and facilities of the integrated management of pharmaceutical products and medical devices waste.

8- Providing advice and guidance to waste management officials.

9- Examining the records of the institutions and facilities of the integrated management of pharmaceutical products and medical devices waste related to the registration of waste data, quantities, methods of segregation,

collection, and storage in temporary storages, as well as other waste-related records.

10- Examining the records of the institutions and facilities of the integrated management of pharmaceutical products and medical devices waste related to the transportation, delivery and receipt of waste, routes, transport vehicles, garages, and other records pertaining to waste transportation.

11- Examining the records of the institutions and facilities of the integrated management of pharmaceutical products and medical devices waste related to waste treatment, the treatment unit, the treatment process, fumes and emissions, treatment outputs, capacity, packaging, and storage in temporary storages, as well as other records pertaining to waste treatment.

12- Inspecting the processes of segregation, collection, transportation, and temporary storage of waste within pharmaceutical facilitys, and verifying compliance with the application of the governing laws and regulations.

13- Inspecting the processes of receipt, delivery, and transportation of waste outside pharmaceutical facilities, and verifying compliance with the application of the governing laws and regulations in this regard.

14- Inspecting waste treatment processes, treatment equipment and their meters, safety measures, fumes and emissions and their analyses, civil protection means and requirements, and verifying compliance with the application of the governing laws and regulations in this regard.

15- Conducting investigations and preparing technical reports in cases of accidents.

16- Examining the schedule for the temporary storage of waste, transportation, and safe disposal thereof, ensuring that waste does not remain in transport vehicles or is stored therein overnight, and that it is delivered to the treatment facility on the same day of its receipt from the pharmaceutical facility.

17- Verifying that waste transport vehicles operating outside pharmaceutical facilities deliver the waste to the designated treatment facility and do not dispose of it or deliver it to any other location.

18- Verifying that the treatment facility contracts with a landfill and transports the ash to the contracted landfill for burial.

19- Inspecting the personal protective equipment of workers and employees at the institutions and facilities of the integrated management of pharmaceutical products and medical devices waste, including protective clothing, safety footwear, masks, and other items necessary to ensure their safety.

20- Inspecting the suitability of containers and bags used for the collection and packaging of waste, and verifying their compliance with the applicable standard specifications and the specific requirements for each product individually, as well as the placement of the relevant international markings on each.

21- Verifying that the workforce is properly trained and that training programs are in place to qualify them to handle hazardous waste.

22- Verifying the conduct of periodic medical examinations for workers to assess their health status, as well as the provision of periodic vaccinations whenever required.

23- Verifying that applicants for the disposal of pharmaceutical products and medical devices waste notify the Destruction Unit of the Egyptian Drug Authority, and that a pharmaceutical inspection officer affiliated with the Destruction Unit at the Central Administration for Operations of the Egyptian Drug Authority is present throughout all stages of the safe disposal process of pharmaceutical waste.

24- Inspecting and monitoring emission and fume levels, as established by analyses conducted annually. In the event of suspicion regarding the inefficiency of the equipment or chimney, based on the apparent characteristics of the fumes and emissions, re-analysis shall be conducted at the expense of the facility owner at one of the inter-laboratory monitoring laboratories affiliated with the Ministry of Health.

25- Inspecting and monitoring the sterility levels of the shredding output, as established by analyses conducted on a monthly basis.

26- Inspecting and monitoring heavy metal levels at the treatment unit, as established by analyses conducted annually.

27- Detecting violations, preparing technical reports thereon, and taking the necessary legal measures in accordance with the provisions of applicable laws and regulations, as well as administrative measures, including suspension of activity and license revocation.

28- Detecting transport and treatment facilities that handle pharmaceutical products and medical devices waste without obtaining a license

from the Egyptian Drug Authority, taking the necessary legal measures against them, and considering them unlicensed entities conducting the activity.

29- Coordinating joint campaigns with the competent security authorities when necessary.

30- Drafting an official report of the incidents and violations stipulated under Law No. 202 of 2020, registering it at the competent police station, and submitting it to the Public Prosecution to take the necessary legal action.

(Attached: a photocopy of the penalties under the Waste Management Regulation Law)

Measures to be taken against the Company in Case of Violations

First: Suspension of the License Pending Regularization of situation:

In the event that any of the following violations is detected:

1- Expiry of the contracts related to the company's (premises, vehicle, or garage, or the vehicle license), without renewal.
2- Changing the overnight parking location of the vehicle without notifying the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste at the Central Administration for Operations.
3- Absence of operational records within the system of safe disposal of pharmaceutical products and medical devices waste, (in accordance with the company's activity).
4- Discrepancy in weights between the quantities delivered and received by (the vehicle, facilities, and treatment devices).
5- Violation of the health and safety requirements applicable to the vehicle, the vehicle parking garage, or the waste storage room.
6- Non-compliance of the results of emission sample analyses and shredding and sterilization results. In such case, the company's license shall be suspended until the violation is remedied and new tests are conducted proving compliance with the permissible limits.

Note: In all cases, a report shall be drawn up for the incidents stipulated under Law No. 202 of 2020 at the competent police station, and shall be referred to the Public Prosecution to take the necessary legal action.

Second: Consideration for License Revocation

In the event that any of the following violations is detected:

1- If the company's vehicle or any employee of the company leaks or sells pharmaceutical products and medical devices waste, this shall be considered a violation, and shall be referred

to the competent Public Prosecution. The company's license shall be suspended pending the prosecution's decision.

2- The company violates the inter-governorate approval by operating its vehicle outside the governorate authorized for its activities.
3- Open burning of pharmaceutical products and medical devices waste.
4- Use of technology not approved by the Pharmaceutical Products and Medical Devices Waste Committee.
5- Changing the company's premises, the vehicle parking garage, or vehicle registration numbers without notifying the competent administration of the Egyptian Drug Authority.
6- Failure of the company to ensure that transport vehicles are free of any pharmaceutical products and medical devices waste during overnight parking.

The company's violations shall be submitted to the Pharmaceutical Products and Medical Devices Waste Committee for consideration of license revocation.

Note: In all cases, a report shall be drawn up for the incidents stipulated under Law No. 202 of 2020 at the competent police station, and shall be referred to the Public Prosecution to take the necessary legal action.

Implementation Mechanism:

First Phase

Announcement of the Guide for the Requirements and Procedures regulating the Integrated Management of Pharmaceutical products and Medical devices waste at the Egyptian Drug Authority, and Regularization of Companies Previously Approved by the Ministry of Environment but not complying with the Technical Requirements of the Egyptian Drug Authority. This phase shall last for two calendar years, with the first three months dedicated to registering the active companies in the market. During this period, the existing companies holding approval from the Ministry of Environment shall be identified, and compliance with the technical requirements of the Egyptian Drug Authority will not be required at this stage. A service fee for registration shall be paid at the end of the first three months, amounting to EGP 20,000 for each active company. Registration shall end either upon issuance of the license or upon completion of the first phase at the latest. During the registration period, companies may apply for licensing once they meet the requirements. No companies or manufacturers in the pharmaceutical market are allowed to deal with any unregistered waste disposal companies not listed with the Egyptian Drug Authority.

Second Phase:

This is the licensing phase, which follows the fulfillment of the technical requirements by the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste at the Egyptian Drug Authority. During this phase, licenses shall be issued to companies that have regularized situation thereof. This phase shall last for one (1) calendar year following the first phase. Upon the completion of this phase, no companies or pharmaceutical factories in the market shall be permitted to deal with any waste disposal companies that are not licensed by the Egyptian Drug Authority.

5. References:

1. Law No. 151 of 2019 establishing the Egyptian Drug Authority and Executive Regulations thereof, Decree No. 777 of 2020.
2. Law No. 202 of 2020 issuing the Waste Management Regulation Law and Executive Regulations thereof, Decree No. 722 of 2022.
3. Chairman of the Egyptian Drug Authority Decision No. 324 of 2024 regarding the licensing of Integrated Management Facilities for Pharmaceutical Products and Medical Devices Waste.
4. Chairman of the Egyptian Drug Authority Decision No. 325 of 2024 regarding the service fees for licensing and inspection of Integrated Management Facilities for Pharmaceutical Products and Medical Devices Waste.

Procedures for Obtaining Approval from the Pharmaceutical Products and Medical Devices Waste Committee for the Technology Used in the Treatment Device (Incinerator – Shredding and Sterilization Device):

An application shall be submitted addressed to Dr. / Director of the Integrated Management Unit for Pharmaceutical Products and Medical Devices Waste requesting approval of the technology used in the treatment device (incinerators – shredding and sterilization devices).
The application shall be accompanied by the following documents:

1. One (1) original catalog of the treatment device (incinerator – shredding and sterilization device), including a detailed description of the technology used, operation, and maintenance.
2. A photocopy of the commercial register of the supplying company.
3. A photocopy of the tax card of the supplying company.
4. Documentation of prior use or track record of the device.
5. Evidence that the device has been operated in the country of origin for the same activity.
6. Device safety certificate.
7. Certified and authenticated certificates from international organizations verifying the use of the device technology, not issued by the manufacturing company or private offices (e.g., CE certificates).

All documents submitted by the company shall be presented to the Pharmaceutical Products and Medical Devices Waste Committee for its decision regarding the granting or refusal of approval for the technology used in the treatment device (incinerators – shredding and sterilization devices).

Health Requirements for Garages of Vehicles Transporting Pharmaceutical Products and Medical Devices Waste

All of the following requirements shall be met for garages used by vehicles transporting pharmaceutical products and medical devices waste, whether located inside or outside a residential block:

1. The garage shall have a separate entrance from the building entrance (if located inside a residential block).
2. The garage shall be independent from the building's main garage (if located inside a residential block).
3. The garage shall be exclusively designated for vehicles transporting pharmaceutical products and medical devices waste.
4. There shall be no food-related activity (whether manufacturing, selling, or preparation) adjacent to the garage, and the garage location shall be at least fifty (50) meters away from any food-related activity.

5. **Flooring:** The floor shall be made of ceramic and impermeable to liquids, or of a solid material suitable for repeated cleaning and disinfection, with a slope from the exterior toward the interior in the direction of the drainage outlet.
6. **Walls:** The walls shall be made of ceramic and impermeable to liquids, or of a solid material suitable for repeated cleaning and disinfection.
7. **Space:** The garage area shall be proportional to the number of vehicles it accommodates.
8. The garage shall have a water source equipped with a hose for cleaning the vehicles.
9. The garage shall be equipped with a sanitary drainage system and a unit to treat the water resulting from cleaning before discharging it into the public sewer.
10. The garage shall provide a restroom for workers, shower facilities, and a sufficient number of washbasins proportional to the number of workers, in accordance with the general requirements for industrial facilities and worker comfort issued by the Minister of Housing. The restroom doors shall be made of non-wooden materials and shall be easy to clean and disinfect.
11. The garage shall be equipped with a cabinet for storing tools, supplies, cleaning agents, and disinfectants necessary for the cleaning and disinfection process.
12. A separate cabinet for first aid supplies shall be available, containing items such as cotton, gauze, plasters, wound disinfectants, and similar materials.
13. The garage shall be provided with civil protection equipment.
14. A logbook of vehicle routes shall be maintained to enable proper tracking of the vehicles.
15. The company shall ensure that transport vehicles are free of any waste during overnight parking in the garage, and that the vehicles are appropriately disinfected and sanitized.

Technical Specifications for Vehicles Transporting Pharmaceutical Products and Medical Devices Waste:

All of the following requirements must be met:

1- The vehicle's cargo compartment shall have a capacity suitable for the volume and quantity of pharmaceutical products and medical devices waste to be transported, allowing sufficient space for workers responsible for handling the waste to move easily inside. Open vehicles are strictly prohibited.
2- The interior surfaces of the cargo compartment (roof, sides, and floor) shall be covered with galvanized sheet metal or stainless steel that is corrosion-resistant. The internal corners shall be smooth, free of sharp edges, and shall not cause tearing of waste bags, to facilitate cleaning and disinfection after each transport and unloading of waste.
3- The waste compartment shall be separate from the driver's compartment and equipped with a system to secure the container within the trailer, designed to prevent shocks, leakage, or spillage of the waste, even in the event of accidents.

4- Two channels shall be provided to collect spilled liquids along the sides of the cargo floor, or the floor shall be sloped from back to front toward a transverse drainage channel leading to an under-vehicle tank equipped with a tap.
5- The vehicle shall be dedicated exclusively to waste transport; use for any other purpose is prohibited. The sides and rear of the vehicle must display, in a non-removable material, the company's name and address, emergency telephone number, the phrase "Pharmaceutical Products and Medical Devices Waste," and the biohazard symbol.
6- A metal ladder shall be installed at the rear of the vehicle to facilitate access to and exit from the cargo compartment.
7- A barrier and sealing gasket shall be installed around the cargo doors to prevent leakage of contaminated liquids and entry or exit of insects.
8- A lighting source shall be provided inside the cargo compartment.
9- A weighing scale shall be installed inside the vehicle.
10- A temperature gauge shall be installed to monitor internal temperatures.
11- A first aid kit, in good condition and ready for use, shall be available in the vehicle.
12- The vehicle shall be equipped with pharmaceutical products and medical devices waste bags and personal protective equipment for workers, including gloves, face and nose masks, and hand disinfectants.
13- The vehicle shall have a suitable communication device, personal protective equipment, and tools and materials necessary for cleaning and disinfection in case of spills or leaks, as well as equipment and materials for handling waste in the event of accidental exposure or spillage.
14- The company shall take all necessary precautions to prevent waste from falling, protruding, leaking, or spilling. In the event that such incidents occur, the company must follow the specific instructions and procedures for handling these or similar incidents.
15- The vehicle shall maintain route logs for visits to establishments for the collection of pharmaceutical products and medical devices waste, as well as route logs for delivery to treatment facilities where the waste will be handed over.
16- Records of delivery and receipt of pharmaceutical products and medical devices waste shall be maintained for the establishments visited, as well as for the treatment facilities receiving the hazardous medical waste.
17- A GPS tracking device shall be installed in the vehicle.
18- Waste shall be transported in specially designed, sealed containers made of solid, non-porous material that prevents leakage, fitted with tightly closing lids, coated with materials resistant to corrosion or reaction with the contents, and with a capacity appropriate for the quantity of waste being transported.

Health Requirements for Temporary Storage Rooms for Pharmaceutical Products

and Medical Devices Waste

All of the following requirements must be met:

1- A sign reading “Pharmaceutical Products and Medical Devices Waste Room” along with the biohazard symbol shall be displayed on the outside of the storage room door.
2- A temporary storage room shall be provided for pharmaceutical products and medical devices waste awaiting treatment, in addition to a separate room for storing treatment outputs until final disposal.
3- The room size shall be sufficient to accommodate the waste generated by the facility for at least two (2) days.
4- The door shall be tightly sealed on all sides and made of a material suitable for repeated cleaning and disinfection. Wooden doors are not permitted.
5- The entrance width shall be sufficient to facilitate entry for workers handling waste and equipment for waste transport, and the room should be located as close as possible to building exits with easy access for transport carts.
6- The room shall be located away from areas used for food storage, preparation, or kitchens.
7- Walls and floors shall be made of solid, impermeable materials such as tiles or ceramic to facilitate cleaning and disinfection.
8- The room shall be equipped with a water source and a sink for handwashing.
9- The room shall have a drainage system and a barrier inside to prevent water from exiting the room.
10- The room shall be provided with adequate lighting.
11- The room shall be well-ventilated or equipped with a cooler and secured against insect entry by installing fine mesh screens on ventilation openings; the use of fans or exhaust blowers is not permitted.
12- A barrier shall be installed at the room entrance to prevent entry of insects, reptiles, and rodents, and to prevent liquids from escaping during cleaning and disinfection.
13- Cleaning and disinfection supplies, personal protective equipment, and hazardous medical waste collection bags shall be stored near the temporary storage room.

Requirements for the Location of Treatment Units

All of the following requirements must be met:

1- The site shall be located against the prevailing wind direction, in a dedicated area so as not to cause any harm or risk, and the access road to the site shall be paved for easy reach.
2- The site shall be close to the temporary storage room for pharmaceutical products and medical devices waste.

3- The site shall be equipped with three-phase electricity, a water source, communication services, and any other necessary facilities to serve employees.
4- The site shall have a sanitary drainage system and a unit for treating wastewater before discharge into the public sewer.
5- The site shall be provided with civil protection measures.
6- The unit shall be protected from sunlight and other climatic factors, and unauthorized persons, animals, birds, or insects shall be prevented from entering.
7- The site shall be free of underground wastewater tanks.
8- The treatment unit shall be equipped with means to control air emissions resulting from treatment operations.
9- Operation, maintenance, and waste treatment in the unit shall be carried out by trained personnel.
10- The unit shall follow the manufacturer's instructions for the treatment devices regarding installation, operation, and maintenance.
11- A control panel shall be provided on the treatment unit to display operating conditions, including temperature readings, airflow rates, and other necessary measurements, with calibration and maintenance procedures in place to ensure that recorded values match actual values.
12- The chimney shall be located at least twenty-five (25) meters away from the nearest building (in accordance with Minister of Housing Decree No. 380 of 1975 regarding industrial facilities, Article 24, Clause 1) and shall extend at least three (3) meters above the highest point of the nearest building (pursuant to Prime Ministerial Decree No. 1095 of 2011 amending certain provisions of the Executive Regulations of the Environmental Law, issued by Cabinet Resolution No. 1995/338, published in the Official Gazette on 28/08/2011).
13- The site shall not contain crops intended for human or animal consumption, and it is preferable for the site to be surrounded by a fence of non-fruit-bearing trees.

Personnel: The Company shall appoint and maintain a technical manager with an appropriate scientific qualification and a training program in the integrated management of pharmaceutical products and medical devices waste and its safe disposal, in accordance with the company's activities.

7. History table

Version No.	Issue date	Summary of Changes
1	7/2024	New Issuance