

LAW ENFORCEMENT ON ILLEGAL DUMPING AND ILLEGAL TREATMENT OF MEDICAL WASTE IN JAPAN

November 2021



Between the 1990s and early 2000s, large-scale illegal dumping and improper treatment of medical waste was a common occurrence in Japan, and became a serious social issue owing to the potential human health risk and environmental damage resulting from the waste itself, which could be infectious or contained sharps or chemical and toxic substances. However, such cases have been on the decline since 2000. This case study analyses how operations which could result in improper waste management have been improved and what measures have been taken in terms of changes in legislation and other related factors, with a particular focus on enforcement.

Summary

Repeated amendments of the Waste Management and Public Cleansing Law (the Law herein) along with tougher penalties and more robust inspections have together made it more difficult for waste generators and waste management operators to commit illegal acts in waste management. The Ministry of Environment clarifies aspects of the Law and a related manual ("The manual for the management of infectious waste in accordance with the Waste Management and Public Cleansing Law"; the Manual herein) for waste generators and waste management operators to integrate into their operations by sharing the related legal information and providing technical training and financial assistance for the operators concerned. There are agencies in the waste management industry that play a significant role in connecting legislation to practice, which has contributed to better law enforcement. Further, the role of the media has been important, since it raised the public's awareness of the consequences of illegal dumping and improper treatment for the environment, and in so doing has cooperated their voluntary support in performing a monitoring and reporting role. Above all, introduction and promotion of the e-manifest system has made it easier and more efficient to control operations related to dumping and treatment, leading to less infractions being committed. The data accumulated on medical waste management using this system has helped provide better understanding of the overall situation, identify problems, and highlight areas needing improvement, which in turn will help bring about a circular economy.

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1. Introduction

1.1. Risks of medical waste

Due to its ease of disposal and portability, practices of illegal disposal of medical waste containing sharp needles and other infectious waste used to be widespread due to the lack of robust controls in place. One of the largest such cases in Japan occurred on the border between Aomori and Iwate Prefectures, a northern area, in which around 1.5 million tonnes of cinders, waste plastics and medical waste were illegally dumped. Removal of the dumped waste and soil restoration have continued up to the present day (Figure 1) since the incident came to light in 1999. Estimated 12,000 companies were involved, including about 1,000 healthcare facilities (HCFs) in Tokyo, which are alleged to have contracted out illegal operators to collect and treat their waste. (Tokyo Metropolitan Government Environment Corporation, n.d.)



Figure 1. Removal of illegally dumped waste
(Source: Iwate prefecture)



Another issue concerns the inappropriate disposal of medical waste. For example, a cash-strapped collector and transporter left medical waste in a parking lot on the outskirts of Tokyo in order to avoid treatment fees at an intermediate treatment facility (Figure 2). The waste comprised 1,330 boxes of infectious waste and 250 containers of waste liquid, dumped by an illegal dumping operator that had been outsourced by HCFs to handle their waste collection and disposal. As the HCFs had failed to carry out correct manifest procedures, they were ordered to remove the waste. (Bureau of Environment, Tokyo Metropolitan Government, 2013)

As exemplified by the above, cases of large-scale illegal dumping often took place in Japan, which became a serious social issue. The dumped wastes comprised a wide range of medical waste such as needles, syringes, scalpels, and laboratory equipment generated by HCFs, some of which could be infectious, represented risk of injury (sharps), or contained chemical or toxic substances with potential environmental or public health risk.

The number of such cases reported by the media seems to be decreasing (based on an interview with the Japan Industrial Waste Information Centre (JW Centre)), thus it can be assumed the number of cases of related accidents, illegal dumping and disposal has decreased. Figure 3 displays the historical trend in number of cases of illegal dumping and volume. While the figure does not indicate cases of illegal medical waste dumping, it is assumed that the number would decrease in proportion to overall cases.



Figure 2. Waste left in a parking lot
Source: Bureau of Environment, Tokyo Metropolitan Government

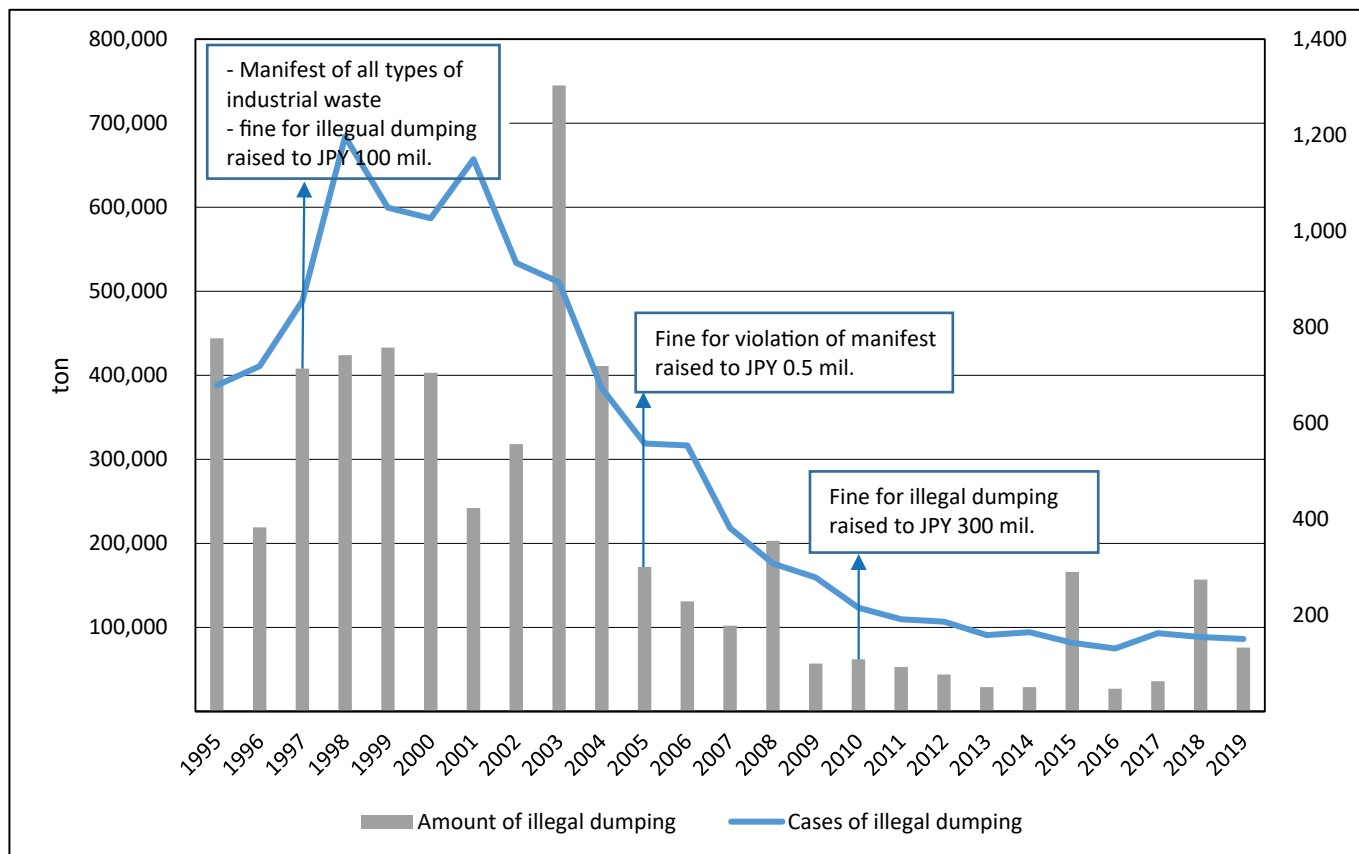


Figure 3. Number of cases of illegal waste dumping, volume and related legal amendments
(Source: MoEJ, 2021)

1.2. Objectives

In partnership with IETC, IGES Centre Collaborating with UNEP on Environmental Technologies (CCET) developed the present case study to demonstrate good practices in medical waste management in Japan, in which illegal dumping and improper treatment of medical waste have been reduced, which has in turn contributed to reduced levels of risk to human health and environmental pollution. Such outcome has been analysed in terms of aspects related to changes in legislation as well as other influencing factors, with a particular focus on enforcement approaches. In so doing, the intention is for the analysis and lessons learnt presented in this case study to help policy makers and practitioners in various countries and cities facing challenges in law enforcement to improve the systems involved in medical waste management.

1.3. Scope

Along with the rapid economic growth after World War II, more waste was being generated, which caused significant environmental pollution in Japan. The

Waste Disposal Act, which had previously focused on the disposal of garbage, sludge, and animal carcasses was completely revised, and replaced with the Waste Management and Public Cleansing Law (the Law) in 1970. The protection of human life was added on top of public health as an objective. Under the Law, waste was categorised into industrial waste and municipal waste. Industrial waste comprised of 20 types (see Table 1), of which cinder, sludge, oil, acid, alkali, plastics, rubber, metal, glass, concrete and ceramic scrap, dust and soot formed the bulk of that generated by HCFs as well as imported waste. Under the Law, waste generators and waste management operators¹ are obligated to properly treat and dispose of industrial waste. Municipal waste refers to waste other than industrial waste, and waste generators, including households and commercial sectors, are obligated to follow the rules of disposal and separation of such waste in accordance with the municipality in which the waste generator is located.

Waste materials generated in hospitals and clinics (healthcare facilities: HCFs) can fall under both

¹ Waste transporter, treatment operator and disposal operator.

Table 1. Main types of industrial and municipal waste generated at HCFs

Waste types		Examples of medical waste
Industrial Waste (Some of the 20 categories specified by Waste Management Law)	Cinders	Incineration ash
	Sludge	Blood (limited to that which has coagulated), sludge generated by wastewater treatment at testing laboratories, etc., and other sludge
	Waste oil	Organic solvents such as alcohol, xylol, chloroform, etc., fuel oils such as paraffin and gasoline, food oil used for feeding hospitalized patients, lubricating oil for refrigeration machines and pumps, and other oils
	Waste acid	X-ray fixative, formalin, chromic sulphuric acid and other acidic effluents
	Waste alkali	X-ray developing effluent, blood test effluent, blood waste (in uncoagulated form) and other alkaline fluids
	Plastic waste	Instruments made by synthetic resin, x-ray films, vinyl tubes and other synthetic resin items
	Rubber	Natural rubber utensils, disposable gloves, etc.
	Metal	Metal machinery and equipment, injection needles, metal beds and other metal objects
	Glass, concrete and ceramic scrap	Ampoules, glassware, bottles and other glassware, plaster for plaster cast, ceramic ware and other ceramic ware
	Dust and soot	Dust and soot generated by incineration facilities, etc.
Municipal solid waste (waste other than industrial waste)		Paper waste, kitchen waste, textiles (bandages, gauze, absorbent cotton, linen), wood, leather, dead bodies of testing animals, cinders from the incineration of such municipal solid waste, etc.

Source: The Manual (2018)

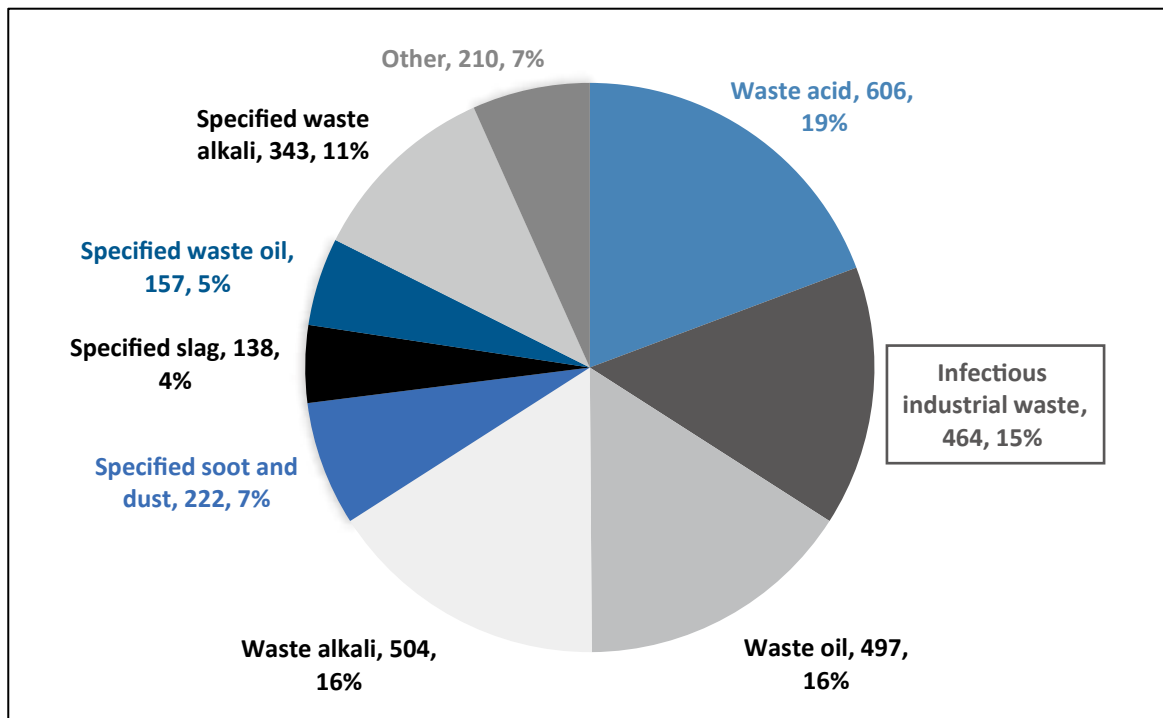


Figure 4. Industrial Waste Subject to Special Control by waste type (2019) (1,000t/year)

(Source: MoEJ, 2021)

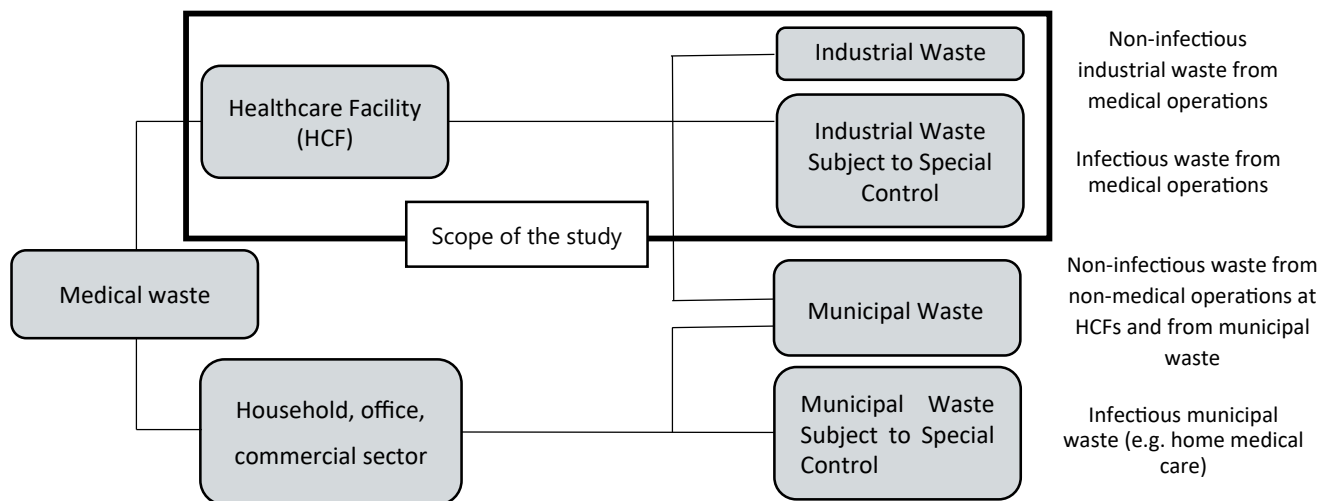


Figure 5. The scope of this study

industrial waste and municipal waste, depending on the type of waste. In general, plastic and paper items as well as other non-infectious waste generated from offices and canteens of HCFs are separated at source in the same way as ordinary municipal waste and treated as municipal waste which does not require special treatment. On the other hand, the large volumes of waste generated through medical operations of patients suffering from infectious diseases in HCFs is categorized as infectious waste, which falls under 'Industrial Waste Subject to Special Control'. This refers to industrial waste that is explosive, toxic or infectious, or has other potential risks/negative impacts on human health or the living environment. These wastes need to be treated with due care, and their treatment and disposal are strictly controlled under the Law (Article 12-2). It was reported that infectious waste from industrial waste would account for approximately

15%, i.e., one of the four largest fractions of the total generation of Industrial Waste Subject to Special Control in 2019 (see Figure 4).

A similar category, 'Municipal Waste Subject to Control', also exists, and refers to municipal waste with explosive, toxic, infectious, or other properties that may cause damage to human health or the living environment. Infectious municipal waste requires stricter controls for collection, transport, treatment and disposal than normal municipal waste (Act 6-2). Although waste management operators who handle infectious industrial waste are permitted to handle infectious municipal waste, this case study omits municipal waste and focuses only on the medical waste that falls under the category of industrial waste, as shown in Figure 5.

Box 1. Medical waste from households

Home medical care and treatment has become more common in Japan, with rising numbers of patients receiving it. Growing numbers of elderly people wish to be cared for at home, particularly as a result of Japan's aging population; of the 124 million population, those 65 and over account for about 28%, or 35 million people. As of 2019 there were 11,580 home nursing stations nationwide. (Ministry of Health, Labour and Welfare, 2021) Amounts of medical waste generated in households have therefore risen, some of which is thrown away as municipal solid waste even if infectious. Regulations on infectious municipal waste is still inadequate. Nappies, in particular, are often disposed of as household waste despite the risk of infection they represent.

Although no strict law regulating infectious waste from households currently exists, Yokohama city for example, requests citizens to place sharp objects, including hypodermic needles in a hard, transparent container when disposing of them as general municipal solid waste. The city has also published detailed guidelines on medical waste treatment for HCFs in the city. (Yokohama city, 2020)

2. Law Enforcement

2.1 Waste Management and Public Cleansing Law

In Japan, the Waste Management and Public Cleansing Law (the Law) was enacted in 1970 to control the increasing volume and range of waste generated as a result of Japan's period of rapid economic growth,

involving mass production and mass consumption. Consequently, inappropriate treatment and disposal as well as illegal dumping of waste, including toxic and dangerous medical waste, led to environmental pollution and public health risks.

The fundamental objectives of the Law were to protect the living environment and improve public health. The Law clearly states that "No person shall dump waste" (Article 16) and that waste generators have the responsibility to properly treat and dispose of the waste

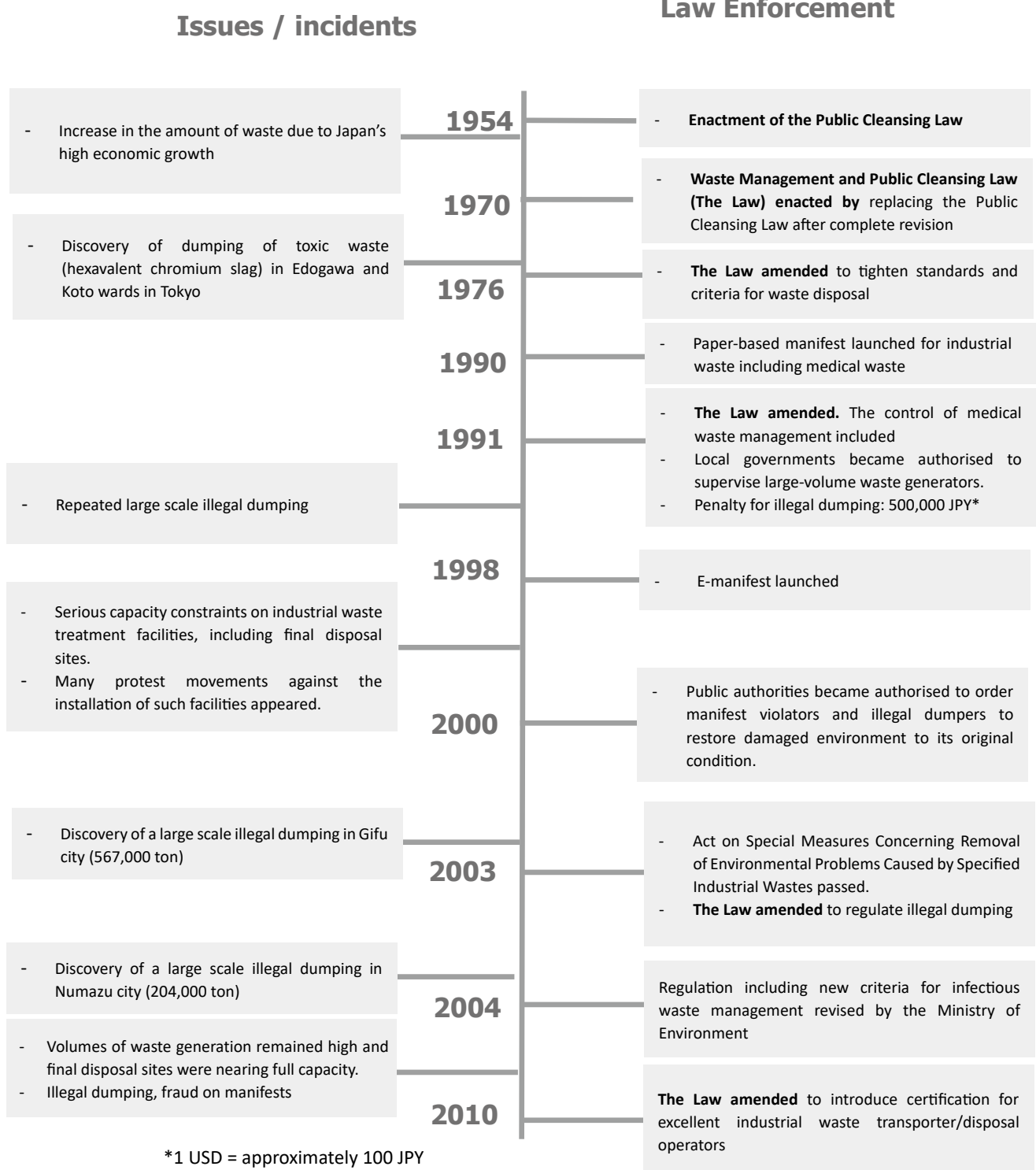


Figure 6. Amendments to the laws and waste management issues (1954-) (MoEJ)

generated in the course of their business activities. In the case of medical waste, HCFs are duty-bound to complete the necessary processes up to waste disposal. However, despite the Law being enacted in 1970, no strict legislation on medical waste management came into being until 1991.

2.2 Amendment of the Law and the Manual

As can be seen in Figure 6, the legal enforcement measures associated with industrial waste management changed in correspondence with the incidence of cases, although incidents caused by improper medical waste management were not explicitly recorded. The Law, which regulates both municipal and industrial waste management, underwent several amendments as a result of changes in social and economic conditions. It was extensively amended in 1991 in order to strictly control the management of waste in general, including medical waste, in response to major cases of illegal dumping as well as injuries resulting from improper waste handling. This led to the designation of 'Infectious Wastes' for waste materials generated in HCFs as a result of medical care or research and containing pathogens with potential to transmit infectious diseases. Infectious waste was then re-defined as 'Industrial/Municipal Waste Subject to Special Control'. After the 1991 amendment of the Law, the first regulation concerning infectious waste management for HCFs such as hospitals, clinics, laboratories and vets occurred in 1992.

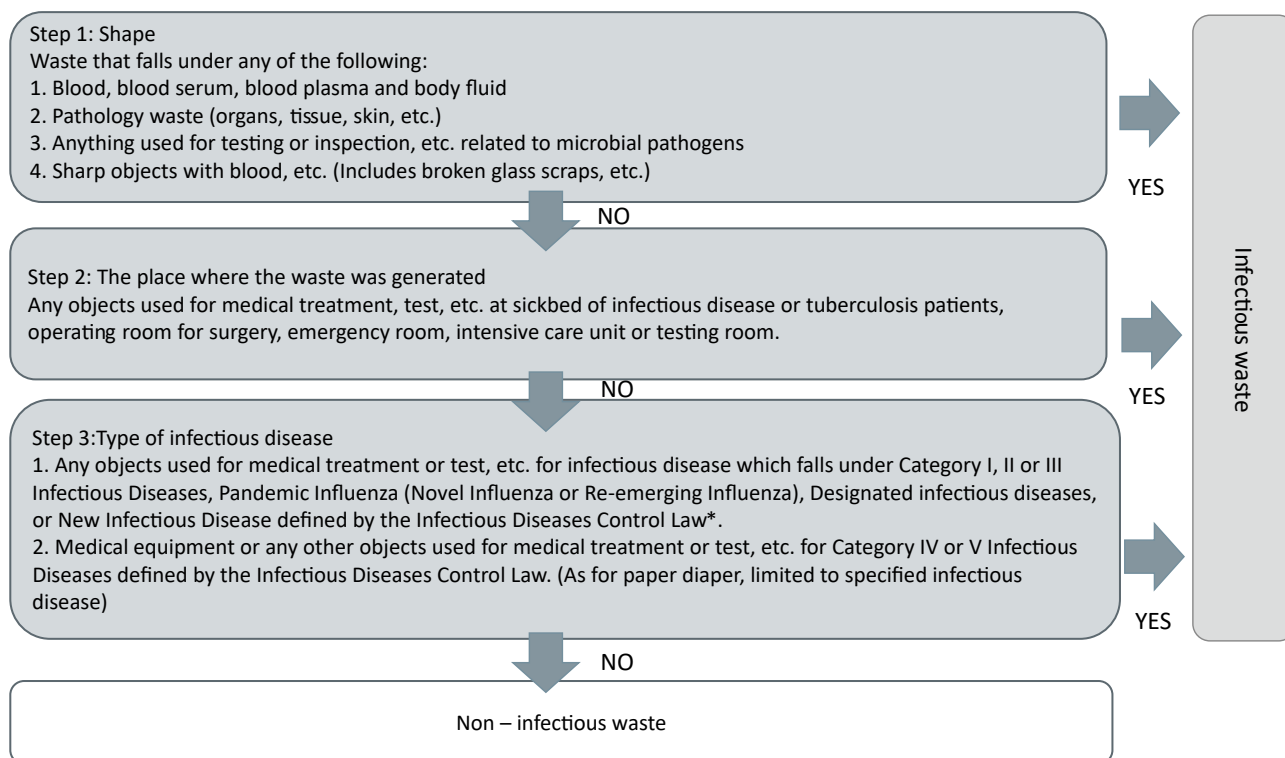
On the other hand, the 'Guideline for Medical Waste Management', issued in 1989 by the Ministry of Health on the proper treatment and disposal of medical waste, was replaced by the 'Manual for the Management of Infectious Waste' in 1992 to align with the amendment of the Law in 1991. However, the criteria defining infectious waste was not yet clear enough to enable judgement by medical professionals based solely on its features. Together with the amendment of The Law in 2003 to further secure sound waste management, including strengthening administrative supervision, the Manual was revised in 2004 to prevent the spread of pathogens and protect the environment and public health. Infectious wastes was then identified by three steps of flow (Figure 7): the shape of waste; the place of waste generation; and the type of infectious

diseases. The Manual details the appropriate treatment of infectious and other medical waste and requires HCFs nationwide to manage their waste in accordance with the Manual. Since then, the Manual was amended twice in 2012 and 2018. As with old versions of the Manual, the new regulation also excludes radioactive medical waste management as this is regulated under the Radioactive Prevention Law of 1958. Medical radioactive waste generated by HCFs needs to be handled by either HCFs or by a radioactive waste treatment operator, as designated in accordance with Article 30 of the Medical Care Act Enforcement Regulations. (Currently, Japan Radioisotope Association is a designated operator.) (Ministry of Health, Labour and Welfare, 2017 and 2019)

The amendment also stipulates the criteria for issuing an administrative order by public authority. In cases where a waste generator fails to confirm the final status of transport and treatment of their waste, such generator shall receive an administrative order from public authorities to take proper action. The Law further requires waste generators to provide sufficient payment for the transport and treatment operators to conduct appropriate operations and management. To ensure this takes place, prior to signing the contract, the treatment operator prepares a quotation based on the total cost of treatment. However, it was often observed that waste treatment or disposal operators received waste at a low price and then proceeded to illegally dump it. The Law therefore requires that consignment contracts be made between waste generators, transporters and treatment or disposal operators and that such contracts should clearly show the fees related to disposal operations.

Along with the amendment of the Law in association with industrial waste management, penalties have been tightened over the years. Notably, fines have been increased and reached as high as 300 million JPY (approximately 3 million USD) per case of illegal dumping. Table 3 lists the types of penalties imposed on waste generators, transporters and disposal operators based on types of violation. The penalties and sanctions for waste generators and waste management operators include imprisonment, fines, restoration measures order (rectification of violations), and revocation of business permission, and so on. Such penalties and sanctions were aimed at preventing

2 the National Epidemiological Surveillance of Infectious Diseases



* see Table 2 for the detail prescription of each category.

Figure 7. Three steps used to identify infectious waste (Source: The Manual 2018)

Table 2. Category of infectious diseases covered by the Law

Category I	Infectious diseases that are extremely threatening based on factors such as infectivity and seriousness of disease: Ebola haemorrhagic fever, Crimean-Congo haemorrhagic fever, smallpox, South American haemorrhagic fever, plague, Marburg disease, Lassa fever
Category II	Infectious diseases that are highly threatening based on factors such as infectivity and severity: Poliomyelitis, tuberculosis, diphtheria, severe acute respiratory syndrome (only if the pathogen is SARS coronavirus of the genus Beta-coronavirus), Middle East respiratory syndrome (only if the pathogen is MERS coronavirus of the genus Beta-coronavirus), avian influenza (H5N1), avian influenza (H7N9).
Category III	Infectious diseases that are not highly threatening based on factors such as infectivity and severity, but that may lead to an outbreak through employment in certain occupations: Cholera, shigellosis, entero-haemorrhagic Escherichia coli infection, typhoid fever, paratyphoid fever.
Category IV	Infectious diseases where human-to-human transmission is generally rare, but that require actions such as the disinfection or disposal of animals/articles, due to transmission via animals, food, drink, or other articles: Hepatitis E, West Nile fever (including West Nile encephalitis), hepatitis A, echinococcosis, yellow fever, psittacosis, Omsk haemorrhagic fever, etc.
Category V	Infectious diseases that require the prevention of occurrence and spread, through the operation of NESID ² and through the provision and feedback of the resultant necessary information to the general public and healthcare professionals: Amebic dysentery, viral hepatitis (excluding hepatitis E and A), carbapenem-resistant Enterobacteriaceae infection, etc.
Pandemic Influenza (novel influenza or re-emerging influenza)	Pandemic influenza (novel influenza): a type of influenza caused by a virus that has recently acquired the capacity for human-to-human transmission, and that is regarded to have the potential to seriously affect the lives and health of people through rapid, nationwide spread. Re-emerging influenza: a type of influenza that once spread on a global scale and has recently re-emerged after a long period of non-circulation, and that is regarded to have the potential to seriously affect the lives and health of people through rapid, nationwide spread.
Designated infectious diseases	Known infectious diseases that are not classified in category I, II, or III above, but that require actions equivalent thereto (specified by Cabinet Order, and applies for one year only).

Source: Infectious Disease Surveillance Center, National Institute of Infectious Diseases (2018)

Table 3. Main prison terms and fines defined under the Waste Management Law

(1) Imprisonment of not more than five years (individuals only), a fine of not more than 10 million yen (not more than 300 million yen for corporations), or both.
<ul style="list-style-type: none"> • Unauthorized business (or obtaining a business license by illegal means) • Unidentified export of waste (including attempted export) • Dumping waste (including attempt) • Illegal incineration (including attempt)
(2) Imprisonment of not more than five years (individuals only), a fine of not more than 10 million yen, or both.
<ul style="list-style-type: none"> • Violation of consignment standards (consignment to an unlicensed firm) • Unauthorised installation of treatment facilities (or obtaining an installation permit by illegal means) • Violation of commissioning standards
(3) Imprisonment of not more than 3 years (individuals only), a fine of not more than 3 million yen, or both.
<ul style="list-style-type: none"> • Violation of consignment standards (violation of consignment standards specified by Cabinet Order) • Violation of re-commissioning standards • Violation of an order to improve or suspend use of a treatment facility • Violation of improvement order
(4) Imprisonment of not more than two years (individuals only), a fine not exceeding two million yen, or both.
<ul style="list-style-type: none"> • Collection/transport for the purpose of unconfirmed export of waste
(5) Imprisonment of not more than six months (individuals only), a fine of not more than 500,000 yen
<ul style="list-style-type: none"> • Violation of an order to change the shape of land in a designated area
(6) Imprisonment of not more than one year, or a fine of not more than 1 million yen
<ul style="list-style-type: none"> • Violation of manifest submission, false statement
(7) Fine of up to 300,000 yen
<ul style="list-style-type: none"> • Violation of obligation to notify of abolition or change of waste treatment business or treatment facility • Violation of maintenance records of treatment facility and refusal of access • Violation of obligation to designate a person in charge of Industrial Waste and Industrial Waste subject to Special Control • Violation of reporting obligations (refusal to report, false reporting) • Refusal of on-site inspection

HCFs and waste management operators performing illegal dumping and improper operations. On the other hand, a number of other measures and incentives were also introduced, such as implementation of manifests, certification system of excellent industrial waste disposal companies, and strengthening of inspection and monitoring by the government.

2.3 Manifest

2.3.1 Purpose and process of manifest

To further prevent illegal dumping and improper treatment of industrial waste, a system involving manifests was introduced. The manifest system ensures transparency and traceability of waste handling by tracking the flow of industrial waste from generation point to disposal point in accordance with

contracts made between waste generators and waste management operators. In this system, the Law obliges waste generators to record the required information in manifests when outsourcing waste management services to licensed operators (Article 12). However, such manifests are exempted for waste generators who treat and dispose of waste by themselves, those who contract out waste management services of municipal waste, and those who contract out waste management services to local governments, and so on.

Paper-based manifest, which consists of seven carbon-copy paper forms, was introduced in 1990. Waste generators using paper-based manifests are obliged to report the information listed below to the governors concerned on an annual basis. On the contrary, e-manifest users are exempted from reporting, as the JW Centre (organisation in charge of e-manifest

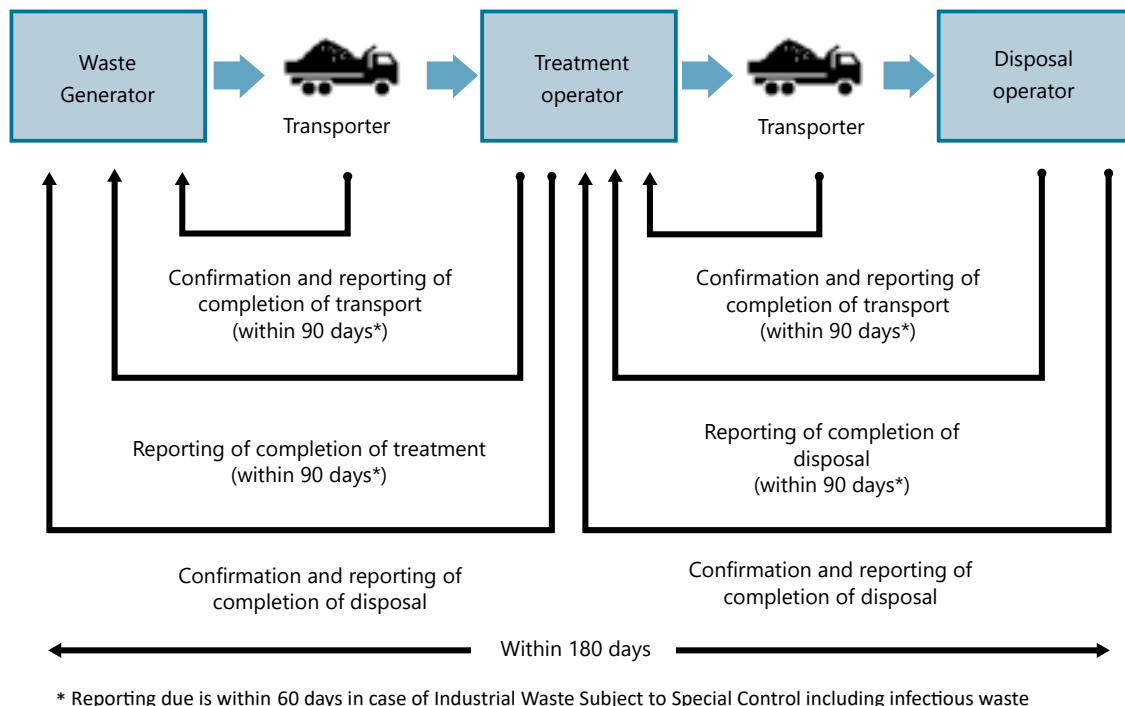


Figure 8. Flow in manifest system (source: Japan Industrial Waste Information Centre)

management) reports to the governors on behalf of the waste generators. Copies of paper-based manifest must be kept for a period of five years, which emphasises the importance of archiving the paper-based manifests by waste generators, transporters, treatment operators and disposal operators.

- Name, address, phone number of waste generator
- Type of business activity carried out at generation point
- Type and amount of manifested industrial waste, and number of manifests issued
- License number and name of transporter
- Address of transport origin
- Permission number and name of disposal operator
- Address of disposal site

If manifests are not returned within the specified period (indicated in Figure 8) or contain omissions or false statements, the waste generator is to inspect the operators involved and report to the governor of prefectural government (as per Article 12-3 of the Law). In case of Industrial Waste Subject to Special Control including infectious waste, the manifest has to be returned to the waste generator within 60 days after it is issued.

2.3.2 Development of manifest system

The regulations related to manifests have undergone

modifications in accordance with the circumstances related to waste management. However, despite repeated modifications, aimed at reducing improper or illegal waste management, it has still been possible to submit false reports. Public authorities are, under the Law, entitled to request disclosure of the necessary manifest information and statistics. Table 4 summarizes the history of developments in the use of the manifest system.

2.3.3 Paper-based manifests and e-manifests

Paper-based manifests were used every time collected waste was passed on to transporters and disposal operators, and involved returning the related forms from each operator to the waste generator or treatment operator upon the completion of each operation.

More recently, owing to the increased speed, convenience and simplicity of sharing data digitally, made possible through developments in the Internet and digital platforms, e-manifests have become available. The e-manifest mechanism allows three parties (waste generator, waste transporter, and waste disposal operator) to use and share the manifest information online, and offers various advantages over paper-based manifests, including timely monitoring and reporting, avoidance of statement omissions, saving of administrative costs, easy comprehension

Table 4. History of manifest system

Year	Action/measure
1990	Paper-based manifests launched as guidance or trial by the government.
1993	Obligation of manifest use for all Industrial Waste Subject to Special Control
1998	Obligation of manifest use for all types of industrial waste. e-manifests launched.
2001	Obligation of reporting on completion of final disposal through manifests.
2005	Change in penalty for violation of manifest: “Fine of less than 500 thousand yen” → “Fine of less than 500 thousand yen or imprisonment of less than 6 months”
2011	Obligation of storage of paper-based manifests extended to 5 years.
2018	Change in penalty for submitting false information in manifest: “Fine of less than 500 thousand yen or imprisonment of less than 6 months” → “Fine of less than 1 million yen or imprisonment of less than 1 year”
2020	Obligation of e-manifests for large waste generators (more than 50 tons/year) of Specified Industrial Wastes (excluding PCB waste)

(Modified from: Japan Industrial Waste Information Centre³)

Table 5. Comparison of paper-based and e-manifests

	Paper-based manifest	e-manifest
Waste generator / treatment operator		
Registration	A manifest is issued at the point the waste is handed over to the waste transporter or disposal operator	Manifest information is registered within 3 working days after waste is handed over to waste transporter or disposal operator
Confirmation of completion of transport, treatment, or disposal	Report is verified by comparing two manifest forms showing before/after each operation	Confirmed by notification (e-mail) from the JW Centre
Storage	Manifest forms to be stored for 5 years	JW Centre responsible for storage of manifest data for 5 years
Report to governor	Obligation to report falls on waste generator and treatment operator	JW Centre reports on behalf of waste generator and treatment operator
Waste transporter		
Report of completion of transport	Enter the required information and report to the waste generator within 10 days after completion of transport	Enter the required information within 3 days after the completion of transport.
Storage	Manifest sheets to be stored for 5 years	JW Centre responsible for storage of manifest data for 5 years
Disposal operator		
Report of completion of disposal	Enter the required information and report to the waste generator within 10 days after the completion of disposal.	Enter the required information within 3 working days after the completion of disposal.
Storage	Manifest sheets to be stored for 5 years	JW Centre responsible for storage of manifest data for 5 years

³ <https://www.jwnet.or.jp/jwnet/about/system/purpose/index.html> [in Japanese]

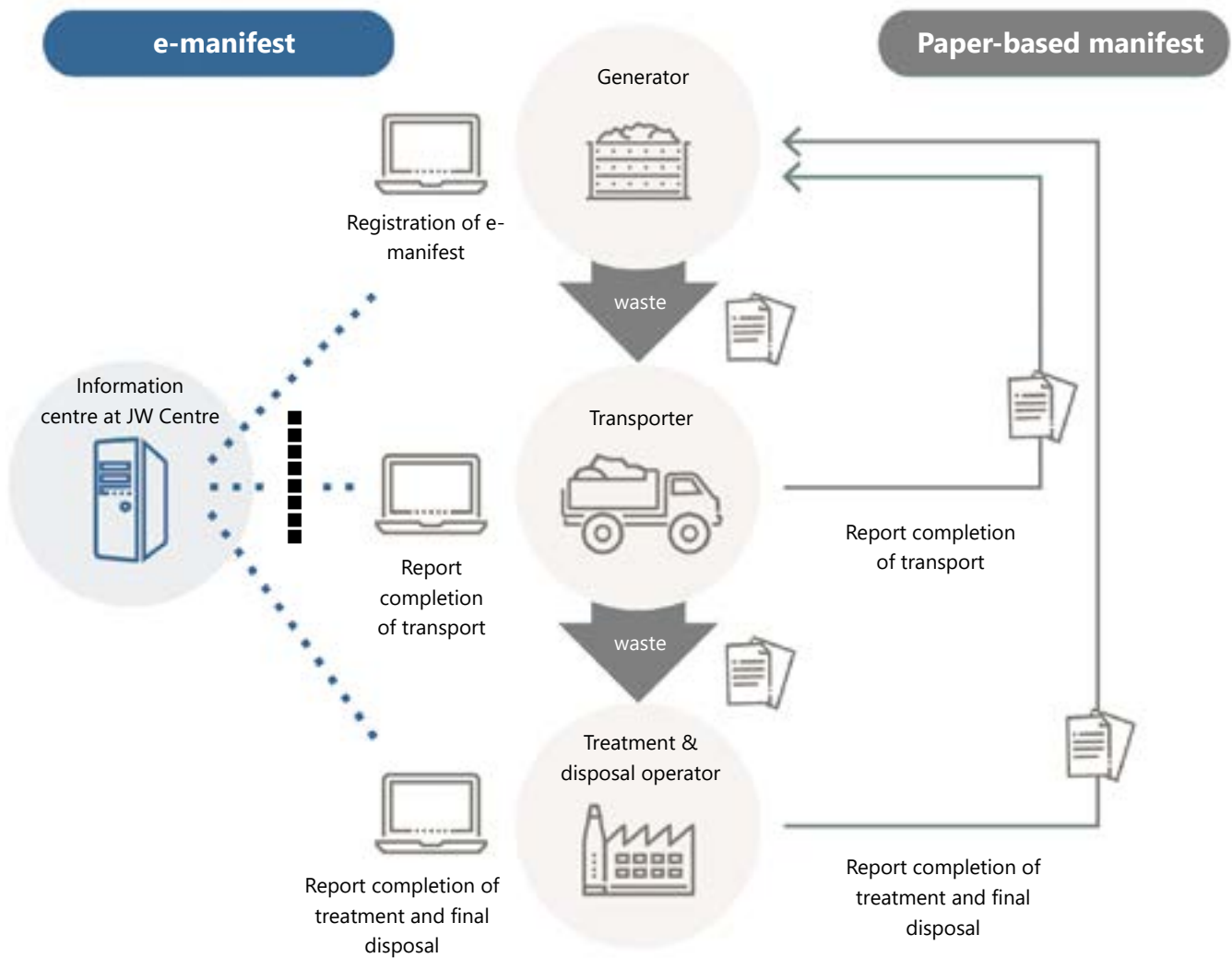


Figure 9. Flow of manifest at each stage of waste management (Source: JW Centre)

compared to the handwritten format, and saving of space required for storing documents over many years. Table 5 and Figure 9 compare the operations of each actor for the two types of manifests.

Due to promotion efforts undertaken by JW Centre, registrations in the e-manifest system have risen since its launch in 1998 (see Figure 10). In 2021, e-manifest registration accounts for about 65% of total manifests registered. The JW Centre currently receives about 120,000 e-manifest registrations daily. To achieve a target of 70% for e-manifest registrations by FY 2022, a roadmap was developed.

Among the total waste generators making use of e-manifests, the medical and welfare sector accounts for 50%. As shown in Figure 11, amounts of infectious waste and plastic waste generated from the medical and welfare sector rose in 2021 from 2020, which can be attributed to the COVID-19 pandemic. Declarations of state of emergency were issued four times in Japan

as of October 2021, starting in April–May 2020 followed by January–March 2021, April–June 2021, and July–September 2021 when case numbers rose significantly.

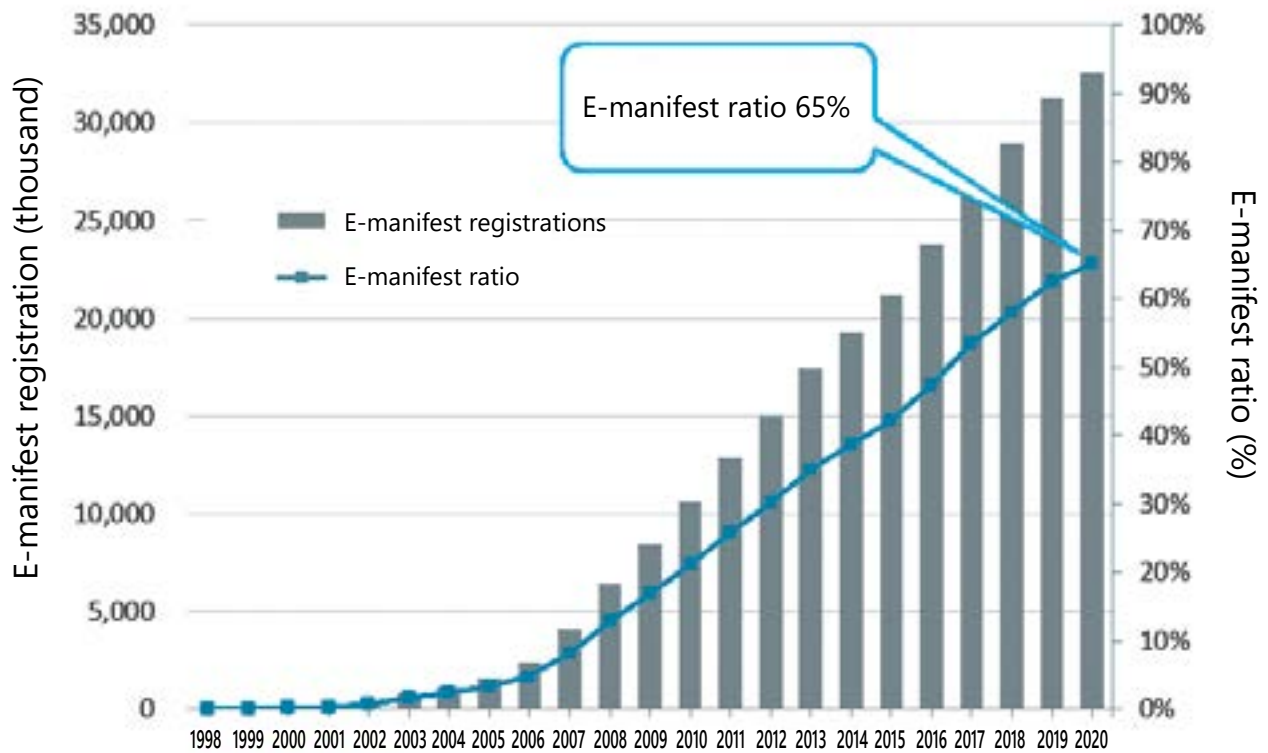


Figure 10. Historical change in E-manifest registration and ratio (Source: JW Centre)

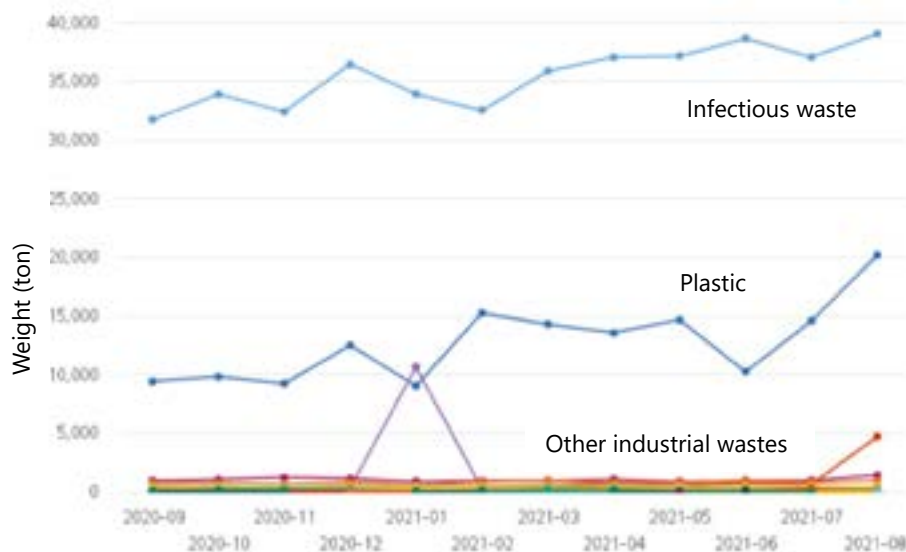


Figure 11. Trends in waste generation by type in medical and welfare sector in 2020 (source: JW Centre)

3. Roles and Responsibilities

This chapter explains the roles and responsibilities of actors such as public authorities, waste generators, transporters, treatment operators, and disposal operators involved in medical waste management.

3.1 Public authorities

3.1.1 Issuance of business licenses

According to Article 14-4 of the Law, waste management businesses cannot be operated without obtaining a license from public authorities. Prefectural governments⁴ and government-designated cities⁵ are the bodies assessing the facilities and business

⁴ Japan is comprised of 47 local government areas called prefectures, each of which operates autonomously and is empowered to enact ordinances and regulations.

⁵ According to the Law, the authorisation is given to prefectural government, 20 cities with a population of 500,000 or more, and 62 cities (as of April 2021) with a population of 200,000 or more to provide administrative services.

operations of waste transport, treatment and processing to ensure they meet all legal requirements. For waste treatment or processing, two licenses need to be obtained from the prefectural government where operations take place, which need to be renewed periodically: one for the establishment of facilities and plants, including the incineration plant, and the other for the operation of the facilities and plants.

Specifically, the prefectural governments and the government-designated cities check and evaluate the following points before issuing licences for waste management operators.

1. Operator has sufficient knowledge and skills to carry out the operation properly (i.e., Whether the operator has attended JW Centre’s training course on collection and transport)
2. Operator has sound financial standing to carry out operations
3. Operator has a sound business plan
4. Operator does not fall under any legal disqualification criteria (bankrupt, gangster, etc. i.e., those who are not expected to conduct proper business operations).
5. Operator has necessary facilities for waste management operations

3.1.2 Control of violations

In accordance with the Law, the public authorities must supervise waste generators, transporters, and treatment operators through reporting, on-site inspection, and monitoring.

1) Request for Reporting

According to Article 18 of the Law, prefectural governments and government-designated cities may request waste generators and waste management operators to submit the necessary reports on their waste management status, including storage, collection, transport, disposal, and also the structure or maintenance of waste treatment facilities.

2) Monitoring

According to Article 19 of the Law, prefectural governments and the government-designated cities can authorize officials to enter the offices, workplaces, vehicles, vessels, or other places, or the land or buildings of waste generators, waste management operators, and other organizations or persons who are involved in the management of the industrial waste in question. They can inspect books and documents and other objects concerning the storage, collection, transport, disposal of wastes or suspected wastes, and the structure or maintenance of treatment and disposal facilities.

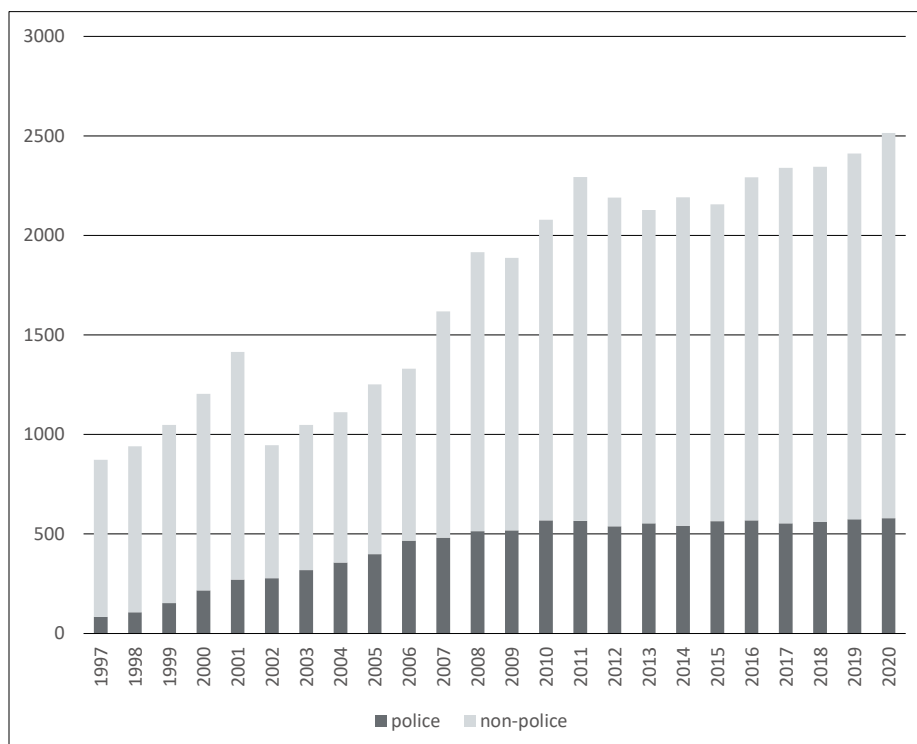


Figure 12. Number of inspectors involved in investigating illegal dumping (Source: MoEJ)

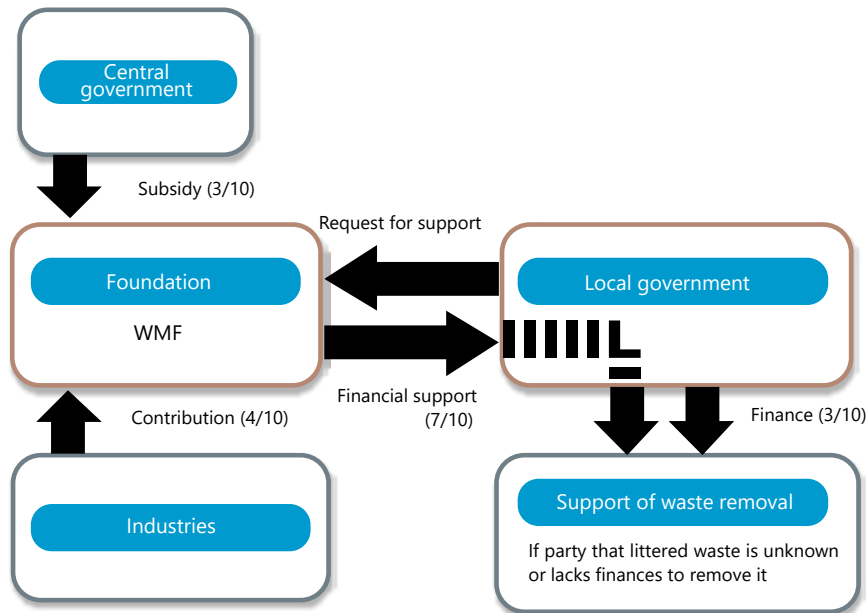


Figure 13. Operational scheme of the WMF

In addition, illegal dumping hotlines that citizens can call have been put in place. To ensure a 24/7 monitoring system, many prefectures outsource their holiday and night-time monitoring services to private security companies (MoEJ). The number of inspectors has been increasing to strengthen control measures, as shown in Figure 12.

3) Administrative orders

Prefectural governments and local governments are entitled to issue administrative orders to waste generators and hold them be liable for the costs of restoring environments to their original state if damage has occurred after medical waste has been illegally dumped or treated at such locations.

3.2 Designated Agency

3.2.1 Japan Industrial Waste Management Foundation (WMF)

WMF was established in 1992 and designated as an industrial waste proper treatment promotion centre in 1998 by Minister of Health, Labour and Welfare under Article 13-12 of the Law, which specifies the provision of support for recovery of environments damaged by illegal dumping. WMF conducts research in industrial waste treatment and provides practical information to waste generators and treatment operators as well as technical advice on hazardous PCB waste treatment. WMF is also involved in illegal dumping prevention and provision of support for the removal of illegally

dumped waste.

Under Article 19-9 of the Law, WMF⁶ provides financial support to local governments requesting removal of illegally dumped waste, but only if the actors involved cannot be identified or are unable to fulfil their responsibility due to lack of finances. WMF covers 70% of the total cost required for waste removal, of which 30% comes from central government and 40% from voluntary contributions from industry or associations such as the construction sector, Keidanren (Japan Business Federation), waste management sector, and Japan Medical Association (Figure 13).

3.2.2 Japan Industrial Waste Information Centre (JW Centre)

JW Centre is a unique organization in Japan. It was established in 1988 and designated in 1998 by Minister of Health, Labour and Welfare under Article 13-2 of the Law to manage the manifest information as an information processing centre. Since 2001, it has been designated by Minister of Environment.

Although the Centre is mainly involved with managing the information collected through the e-manifest system, it also provides seminars on proper waste treatment and application procedures for business licenses for industrial waste generators and treatment operators. Targeting HCFs, the JW Centre provides seminars in partnership with Japan Medical Association

⁶ The fund is managed by Japan Industrial Waste Management Foundation (WMF) (<https://www.sanpainet.or.jp/>) [in Japanese]

as well as evaluates and certifies containers for medical waste based on the criteria set by itself, with the aim of promoting the use of appropriate infectious waste containers.

3.3 Medical waste generator / HCFs




The main obligations for waste generators, as stated in the Law, in principle include efforts to reduce waste, compliance with requirements for outsourcing of waste treatment to licensed operators in cases where waste generators are unable to dispose of their waste on their own property under proper control, and confirmation of the completion of final disposal.

3.3.1 Management system

According to Article 12-2, managers of HCFs must designate a person in charge of infectious waste categorized as Industrial Wastes Subject to Special Control and establish internal systems to ensure proper waste management. Further, in accordance with the Manual, they need to determine which waste items fall under the category of infectious waste, determine origins and amounts of waste generation by type, and make efforts to formulate a treatment plan that stipulates the following aspects to ensure proper treatment:

- 1) Information on waste generation
- 2) Separation methods
- 3) Collection and transport methods in the facility
- 4) Methods of sterilisation (required only if treatment conducted within facility)
- 5) Packing method
- 6) Storage method

Table 6. Biohazard marking

Marking	Waste items	Type of container to be used
	Yellow biohazard mark: Sharp items (e.g., needles, scalpels)	Metal or plastic containers that are robust and penetration-resistant to prevent accidents
	Orange biohazard mark: solid products (e.g., gauze with blood)	Strong, double-layered plastic bag or a strong container
	Red biohazard mark: liquids or muddy substances (e.g., blood, body fluids, surgical effluents)	Airtight containers to prevent leakage of waste liquids

(Source: The Manual)

- 7) A copy of the license and outsourcing contract of the collection, transport, and disposal operator (only in the case of outsourcing)
- 8) System for contacting persons in charge in emergencies

3.3.2 Storage of infectious waste at HCFs

Infectious waste should be stored for the shortest time possible before transport, and storage areas should be separated from those for non-infectious wastes. Storage areas for infectious waste must be clearly indicated through markings to enable easy identification for the persons concerned (Article 12-2), and handling instructions should also be provided at such areas.

3.3.3 Packaging and labelling

If infectious waste is outsourced for treatment and disposal, it should be packed in appropriate containers that are durable, sealable, and easily stored. According to the Manual, infectious waste should be separated and packaged based on the three categories of waste: 1) sharp objects (yellow), 2) solid objects (orange) and 3) liquid or muddy objects (red) (see Table 6). The Manual recommends that the biohazard mark be placed on containers for easy identification.

If such biohazard colour-code system is not used, waste should be labelled with "liquid or muddy", "solid" or "sharp objects". In addition, the Manual recommends that packaging containers of non-infectious waste be marked with a label stating that the waste is non-infectious for clarification.

3.3.4 On-site inspection of waste treatment and disposal

The Law stipulates that the treatment of industrial waste is the responsibility of the waste generator (Article 11), which is the HCF in the case of infectious waste management. If waste generators need to outsource the transport, treatment, and disposal of their waste, they are obligated to use government-licensed operators (Article 12) as well as monitor the conditions of generation, transport, treatment and disposal of their waste to ensure all process are properly carried out (Article 12-7). HCFs are also recommended to inspect the treatment and final disposal facilities on-site periodically.

3.4 Transporters

According to the Manual, transport operators must obtain a license for operation from prefectural governors or mayors of government-designated cities. They are mandated to use manifests and submit annual reports to public authorities, and false reports result in license revocation. They are also required to make appropriate contracts with HCFs as the waste generator. Operators may request information from HCFs concerning sorting methods and condition or types of containers used, in order to prevent accidents and injuries during transportation.

3.4.1 Collection of medical waste

Transporters are to receive medical waste in the presence of the person in charge of waste management at the HCF and convey it to the waste treatment operator in the presence of the responsible person at the treatment or disposal facility. In both receiving and handing over medical waste, transporters need to carefully check manifests regarding the types, quantities, properties and handling methods of the collected waste, and note the condition of containers and any waste leakage. They also need to check for any discrepancies in the information given on waste data sheets through dialogue with the HCFs. If the given information differs or is unclear, transporters should not receive the waste. The names of the waste generators, quantities, locations of the waste delivered, the names of the operating staff, the transport vehicle number, and others specified by each operator must be recorded in the manifest, which should be stored

for five years.

In order to prevent accidents and ensure the proper disposal of waste, the following points should be monitored during collection and transport:

- Infectious waste should be collected or transported separately from other waste to prevent the risk of spread of infection. (Enforcement Order, Article 4-2 and 6-5)
- Once infectious waste is mixed with non-infectious waste, all such waste should be treated as infectious waste.
- Infectious waste should be secured on the transport vehicle with a belt to prevent it from collapsing.

3.4.2. Transport vehicles

Vehicles used for transport of medical waste should be designed to prevent any risk to human health and the environment. Particular attention should be paid to the following points:

- Vehicles should bear stickers to show they are transporting industrial waste and carry documents detailing the types and volumes of waste transported and the destination.
- Cargo compartments should be enclosed by walls and a roof made of solid materials such as metal or reinforced plastic.
- The space between the cargo compartment and driver's seat should be closed off.
- If collecting and transporting medical waste likely to decompose, the vehicle should be equipped with cooling facilities.
- The entire structure should be easy to clean.
- Vehicles should be designed to prevent leakage due to damage to the packaging container during transport.
- Vehicles must be inspected (tyres, light, fuel tank, etc.) before operations and periodically according to legal requirements.
- Vehicles transporting infectious waste must be kept clean through frequent washing and disinfection, preferably with a chlorine-free disinfectant (e.g., Oxydol) to prevent corrosion.

3.5 Treatment and Disposal Operators

According to the Manual, infectious waste should be sterilized using specific treatments. Once sterilized and

free of infectivity, such waste can be treated as non-infectious waste and landfilled as final disposal. A part of sterilised medical waste is recycled, for example, as roadbed material (Kyoei steel, n.d.).

In order to handle infectious waste, operators must meet the requirements, including compliance to waste treatment facility standards and waste treatment operation standards and obtain a business operation license. Operators bear the responsibility of securing employee health. Drivers and treatment facility plant staffs are generally provided with thick gloves to prevent needle injuries, and vaccinated against hepatitis B or other infectious diseases. Apart from complying with the Law, treatment operators also need to comply with the following laws and regulations, some of which apply to waste treatment facilities such as incineration plants:

1. Waste Management and Public Cleaning Law (Waste Management Law)
 - 1.1 Enforcement Order of the Waste Management and Public Cleansing Law
 - 1.2 Enforcement Ordinance of the Waste Management and Public Cleansing Law
2. Basic Environment Act
3. Air Pollution Control Law
4. Water Pollution Prevention Act
5. Noise Regulation Act
6. Vibration Regulation Act
7. Offensive Odour Control Law
8. Poisonous and Deleterious Substances Control Act
9. Local ordinance
10. Other related laws

3.5.1 Treatment methods

Four methods are mainly used in Japan for treating infectious waste: incineration, melting, high-pressure steam sterilisation and microwave sterilisation. Although incineration generates higher GHG emissions than the other methods, it is the most reliable and effective treatment method in terms of reduction of waste volume and eliminating infectivity. Of the total 382 thousand tons of infectious waste generated, 87% or 334 thousand tons was incinerated in Japan in 2017 (see Figure 13).

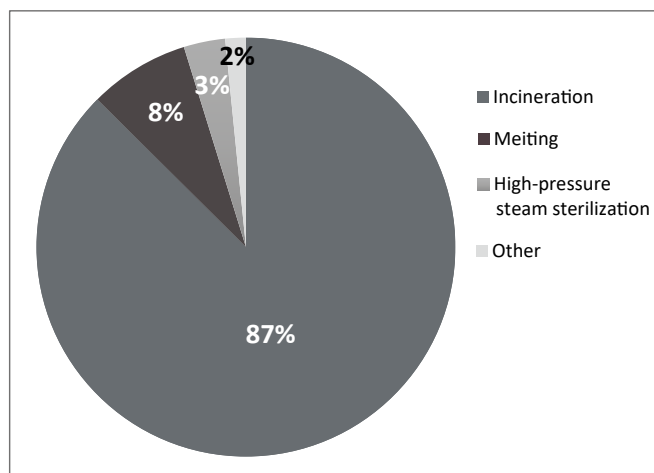


Figure 14. Ratio of treatment method of infectious waste (2017) (Source: MoEJ 2018)

1) Incineration

Most forms of incineration kill all pathogens and reduce waste volumes. As of 2019, Japan had more than 1,000 incinerators, around 380 of which are waste-to-energy (WtE) plants⁷. WtE incineration is a process involving direct controlled burning of waste in the presence of oxygen at temperatures of 850°C and above. Today, the use of the latest environmental technologies and facilities, such as those for dioxins and other various pollutants, makes it possible to meet the strict environmental standards in place in Japan. Modern incineration plants can reduce the emission of dioxins beyond the standard's requirements by appropriate incineration and flue gas treatment. WtE incineration also offers the added benefit of using waste as a resource to produce energy. This form of incineration also decreases carbon emissions by offsetting the need for energy from fossil fuel sources and reduces methane generated from landfills if used as an alternative to landfilling (IPCC, 2007). However, the introduction of MSW incineration has its own barriers (Karim and Corazzini, 2019; GAIA, 2019), such as (1) high costs for construction and operation, (2) insufficient income from waste disposal and energy sales to cover all costs, (3) minimum feedstock requirements for operations, which could potentially divert waste away from 3R treatment, and (4) risks to human health due to possible pollution.

2) Melting treatment

There are two types of melting treatment: 1) melting of incineration residue left after incineration treatment,

⁷ <https://www.mordorintelligence.com/industry-reports/japan-waste-to-energy-market-industry>

and 2) melting of waste directly or gasifying by pyrolysis. Temperatures used are usually over 1,200°C, which is higher than in incineration, and the waste is recovered as molten slag.

3) High pressure steam sterilisation

Thermal energy and high-pressure steam sterilises not only the surface but also the centre of waste.

4) Microwave sterilisation

This is a sterilisation method using high frequency waves. It causes water and other molecules in the waste to vibrate at high rates, which generates heat and sterilises the waste evenly from the surface to the interior.

3.5.2 Monitoring

The name of the waste generator, the quantity of received waste, the name of the transporter and driver, the transport vehicle number, the date of receipt, the date of incineration or other treatment, the name of the operating staff, and others should be recorded in the manifest, which should be stored for five years.



Figure 15. Example of incineration facility
(Source: Okinawa Medical Waste Cooperative Associations, Nihoneisei Co., Ltd.)



Figure 16. Example of melting facility
(source: Fukuoka Sangyou Co., Ltd.)



Figure 17. Example of high-pressure steam sterilisation facility (source: PRECI Co., Ltd.)



Figure 18. Example of microwave sterilisation facility
(Source: YAMADA KOGYO Co., Ltd.)

Box 2. Challenges for waste management operators

In Japan, although incineration is the most common method for treating medical waste, constructing actual plants requires large capital investments. Further, in establishing or scaling-up such businesses, various assessments have to be conducted and licences obtained from public authorities for constructing and operating facilities. Moreover, consensus from local residents should be secured beforehand because such operations usually cause controversy at the local level, and residents normally do not support waste treatment or disposal facilities that are to be installed nearby due to concerns over possible environmental pollution and public health effects. Clearing all the above processes usually requires about five years at minimum.

4. Factors supporting law enforcement

4.1 Awareness Raising Activities

In Japan, the Japan Medical Association provides training and education on proper medical waste management for members of HCFs, in line with the Law and the Manual on the Disposal of Infectious Wastes. The presence of such institute, which provides ongoing training as well as knowledge and information sharing with member HCFs all over Japan is considered unique as few industries have such systems, according to JW Centre.

The use of 'naming and shaming' for cases of illegal dumping or treatment also takes place in Japan, in which the media often discloses the names of waste generators and waste disposal operators. Over time, the increased media exposure allied with rising cases naturally raised levels of awareness of the issues associated with medical waste handling, which has led to improvements in medical waste management at HCFs. HFCs also have a vested interest in maintaining their level of credibility.

4.2 Containers for infectious waste

To facilitate compliance with regulations as stipulated in the Manual and the Law and to prevent accidents, waste containers for infectious waste have been redesigned, and their proper use by HFCs is recommended as certified medical waste containers. Usage guidelines are as follows:

- (1) Use highly safe and robust containers to prevent accidents and disasters due to infection.
- (2) Use containers with labels indicating types of waste.
- (3) Use disposal containers that do not emit toxic gases during incineration.
- (4) Use appropriately sized containers for use in HCFs, etc.
- (5) Confirm the emergency measures including contact details in advance.
- (6) Ensure containers only contain appropriate amounts of waste within their capacity (i.e. maximum 80% of the container).
- (7) Keep infectious waste inside containers and packages and do not transfer such to other

containers.

Regarding the handling of containers, according to the Occupational Health and Safety Law, staff should not carry more than 1/3 to 1/2 of their body weight as this could lead to back injury.

Regarding handling by transporters, the following should be noted by the transport operators:

- (1) Waste containers should not be accepted if damaged and contents are leaking.
- (2) Containers should be checked especially for the following points:
 - Container lids are properly closed.
 - Containers are not damaged.
 - Contents are not leaking (no seepage of contents into the cardboard box).
 - Proper containers are used.
 - Containers are properly marked in a standard manner.

4.3 Certification for excellent industrial waste management operators

The certification system of excellent industrial waste management practices was initiated by the Ministry of Environment based on a revision to the Law in 2010. Prefectures and government-designated cities examine the performance of waste management operators and certify industrial waste transporters, waste treatment and disposal operators as 'Excellent' if they meet the stringent criteria shown in Table 7. The certified companies are listed on prefecture or city websites.

Once operators are certified, they are entitled to receive several benefits such as extended business licenses (from 5 to 7 years), omission of several documents for license applications, and low interest rates for loans. Certificates are valid for seven years.

5. Discussion

The repeated amendments of the Law along with enforcement of e-manifest registration and efforts in training and education for raising awareness have resulted in a significant reduction in cases and volumes of illegal waste dumping in Japan in recent years. Although no official statistics on improper disposal of medical waste exist, it is assumed that the number of

Table 7. Criteria for certification of excellence

1) Legal compliance	An operator conducts industrial waste disposal business for more than five years and has received no administrative orders from public authorities.
2) Business transparency	An operator continuously publishes online the business information including the details of their license, the amount of waste treated, and the maintenance of the facilities.
3) Commitment to eco-friendly activities	An operator conducts its activities in accordance with ISO 14001, Eco Action 21, etc., and in an environmentally friendly manner.
4) Use of electronic manifest system	An operator uses e-manifests.
5) Sound financial management	An operator has sound financial standing, with certain capital adequacy ratio, ordinary income, etc. and no delinquent corporate taxes, etc.

(Source: MoEJ 2020)

cases would have dropped proportionally compared to 10 years previously. This section deepens the discussion on how the level of risk associated with illegal dumping has been reduced and how it can be further reduced, from an industrial waste management perspective.

● *Tightened penalties against illegal dumping*

As explained in Chapter 1 and 2, there were many incidents of illegal dumping of industrial waste including medical waste, until the early 2000s. Whenever large-scale incidents occurred, the Waste Management Law was amended to tighten controls on illegal dumping by strengthening inspection and the requirement for licenses, increasing fines and extending the periods of imprisonment. In particular, fines have been increased to the level of 300 million JPY per case of illegal dumping. Heavy fines deter waste generators and waste management operators from committing illegal activities.

● *Strengthened monitoring*

To prevent the environmental pollution caused by illegal dumping and inappropriate disposal, the Ministry of the Environment and prefectural governments have strengthened monitoring systems to control illegal dumping through means that also include outsourcing inspection to private security agents, who monitor waste handling on holidays and at night. A number of surveillance cameras have been installed along roads and at potential illegal dumping sites in mountainous areas, which have helped lead to arrests of perpetrators (MoEJ, 2020). Another approach employed in other countries is the use of barcodes or RFID⁸ tags on waste containers so as to

track and monitor the waste.

● *Use of manifest*

The manifest system was introduced as a tool to ensure transparency in the waste management flow as well as to strengthen control over waste management. It is also expected to contribute to enhanced circular economy by analysing the accumulated data related to industrial waste management. In particular, the e-manifest system not only enables different actors to share information on waste management with transparency in a timely manner among waste generators and waste operators, but also allows prefectural and local governments to inspect the performance of waste generators and waste operators easily and rapidly. Although false statements can be made in manifests, the manifest system has prevented and deterred illegal dumping and illegal treatment since its launch in 1990.

According to JW Centre, while the ratio of e-manifest users is high at 65%, certain factors prevent this figure rising due to barriers to the system being adopted by waste generators and waste management operators, as follows:

- In order to use the e-manifest, all three parties, i.e., waste generators, transporters, and treatment operators, or treatment operators, transporters, and disposal operators have to join the manifest system. This is the prerequisite to utilising e-manifest among the parties.
- User fees. While there are different fee plans, which vary depending on the number of manifests registered per year, such fees could present a financial burden for small business entities, including medical clinics.

⁸ Radio Frequency Identification: a wireless system comprised of two components: tags and readers. The reader is a device that has one or more antennas that emit radio waves and receive signals back

from the RFID tag. (<https://www.fda.gov/radiation-emitting-products/electromagnetic-compatibility-emc/radio-frequency-identification-rfid>)

- For those who are not familiar with online data entry using a computer, paper-based manifests are still more convenient.

- *Designated Agencies*

Operations carried by both WMF and JW Centre, which are agencies designated by the national government, help reduce cases of illegal dumping by providing technical assistance and training on proper waste management, as well as the e-manifest for waste generators and waste management operators. They act as a kind of conduit between business entities and the government through information collection and sharing, which enables business entities to operate more in line with the Law and the Manual.

- *Public awareness raising through the media*

The media contributes to raising awareness among the general public by treating waste management as a serious issue and broadcasting serious incidents. Such coverage immediately impacts on the image and reputation of the related business operators, and in so doing, the media plays an important role as ethical watchdog.

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