

# Points of regulation difference between domestic agencies and overseas agencies

- In terms of registration requirements and obligation of inspections and examinations, among others, the same points as for those of domestic inspection and verification agencies are imposed.
- A request to conform will be issued when registration requirements are not met and a request to improve will be issued when there is a breach of obligation for inspections and examinations.
- Registration will be revoked when requests and/or on-site inspections, etc. are rejected.

\* Similar regulations to the Electrical Appliances and Materials Safety Act and the Ship Safety Law, etc. where overseas inspection agencies are systematically allowed

	Registration Requirements, Obligation of Inspections and Examinations, etc.	Authority of Minister of Health, Labour and Welfare	Revocation, etc. of Registration
Registered Manufacturing Inspection, etc. Agencies, etc. (Domestic Agencies)	<ul style="list-style-type: none"> <li>○ Registration (Article 46 of the Act)                             <ul style="list-style-type: none"> <li>* Including cases where this is applied mutatis mutandis to Article 53-3, etc. Hereinafter the same                                     <ul style="list-style-type: none"> <li>- Registration by application</li> <li>- Causes for disqualification of registration</li> <li>- Registration requirements</li> <li>- Entries for registration</li> </ul> </li> </ul> </li> <li>○ Renewal of registration (Article 46-2 of the Act)                             <ul style="list-style-type: none"> <li>- Duration of force</li> <li>- Mutatis mutandis application</li> </ul> </li> <li>○ Obligations, etc. of inspections (Article 47 of the Act)                             <ul style="list-style-type: none"> <li>- Obligation to carry out inspections</li> <li>- Obligation to let inspectors carry out inspections</li> <li>- Inspections using a method which is fair and according to standards</li> <li>- Hazard prevention measures</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Order to comply (Article 52 of the Act)                             <ul style="list-style-type: none"> <li>→ When not compliant with registration requirements</li> </ul> </li> <li>○ Order to improve (Article 52-2 of the Act)                             <ul style="list-style-type: none"> <li>→ When obligations, etc. of inspections are breached</li> </ul> </li> <li>○ On-site inspections (Article 96 Paragraph 3 of the Act)</li> <li>○ Collection of report (Article 100 Paragraph 2 of the Act)</li> </ul>	<ul style="list-style-type: none"> <li>○ Prerequisites for revocation (Article 53 Paragraph 1 of the Act)                             <ul style="list-style-type: none"> <li>- When it comes under disqualification</li> <li>- Breach of obligation of inspections, etc.</li> <li>- When requests to view financial statements, etc. are refused.</li> <li>- Breach, etc. of obligation to register appointment of inspectors</li> <li>- Breach of order to comply and breach of order to improve</li> <li>- When registered by unlawful means</li> </ul> </li> </ul>
Overseas Registered Manufacturing Inspection, etc. Agencies, etc. (Foreign Institution)	<ul style="list-style-type: none"> <li>- Hazard prevention measures</li> <li>○ Registration of changes (Article 47-2 of the Act)</li> <li>○ Operational rules (Article 48 of the Act)                             <ul style="list-style-type: none"> <li>- Registration of operational rules</li> <li>- Entries for operational rules</li> </ul> </li> <li>○ Suspension and dissolution of operations</li> <li>○ Preservation, etc. of financial statements, etc. (Article 50 of the Act)</li> <li>○ Registration of the appointment, etc. of inspectors (Article 51 of the Act)</li> <li>○ Recording books (Article 103 Paragraph 2 of the Act)</li> </ul>	<p style="text-align: center;"><b>Mutatis mutandis is applied by reading "order" as "request"</b></p> <ul style="list-style-type: none"> <li>○ <b>Request to conform</b> (Article 52-3 of the Act)                             <ul style="list-style-type: none"> <li>→ When not compliant with registration requirements</li> </ul> </li> <li>○ <b>Request to improve</b> (Article 52-3)                             <ul style="list-style-type: none"> <li>→ Breach of obligation of inspections and examinations</li> </ul> </li> <li>○ On-site inspections</li> <li>○ Collection of report</li> </ul>	<ul style="list-style-type: none"> <li>○ Prerequisites for Revocation (Article 53 Paragraph 2 of the Act)                             <ul style="list-style-type: none"> <li>- When it comes under disqualification</li> <li>- Breach of obligation of inspections, etc.</li> <li>- When requests to view financial statements, etc. are refused</li> <li>- Breach, etc. of obligation to register appointment of inspectors</li> <li>- When registered by unlawful means</li> </ul> </li> </ul> <div style="border: 1px solid red; padding: 5px;"> <ul style="list-style-type: none"> <li>- When there was not a response to requests to conform or requests to improve.</li> <li>- When there was not a response to request to suspend inspection operations</li> <li>- When on-site inspections are refused</li> <li>- When there was no response to collection of report</li> <li>- When the needed expense was not borne for on-site inspections</li> </ul> </div>

Exactly the same requirements regardless of whether it is domestic or overseas

When not compliant with regulations, registration will be revoked aside from overseas agencies

In addition to domestic agencies, cases where requests and on-site inspections are refused are added to the prerequisites for revocation