

## Stipulation on GLP inspectors

March 31, 1994

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Labor Standards Bureau, Ministry of Health, Labour and Welfare

### 1 Commission

- (1) Director-General of Labour Standards Bureau, Ministry of Health, Labour and Welfare, appoints GLP inspectors from among the person who has the following requirements and entrusts GLP inspection to him/her.
  - A. a person who has majored in and graduated from a courses related to the regular course of science of a university, a technical college under the School Education Act, and those who are considered to have same or more competence than that, and who falls under any of the following each requirement.
    - a. a person who has experiences having engaged as work related targeted test related inspection (hereinafter referred to as a test for inspection targeted) and research related test for inspection targeted for five years or longer. (for seven years or longer in case of a person other than those who graduated after graduating from the regular course of the science of a university (excluding junior colleges) under the School Education Act, and those who are considered to have same or more competence than that.)
    - b. a person who has joined GLP inspection and evaluation (including those equivalent to those related to laws and regulations other than the laws and regulations of occupational safety and health, and those equivalent to those in foreign countries) within five years, with relevant knowledge and experience
    - c. a person who has attended OECD-GLP training course within three years, and those who are considered to have same or more competence than a or b.
  - B. It must be a person who might not hinder in fair execution of the inspection
- (2) The tenure of Industrial Safety and Health Law GLP inspectors is within three years. The reappointment is not prohibited.

## 2 Tasks

In response to the request of the Director-General of Labor Standards Bureau, Ministry of Health, Labour and Welfare, the non-governmental inspector shall carry out the following matters.

- (1) Participating in the inspection and conduct compliance monitoring.
- (2) Expression of opinions on the results of inspections for which the inspector is not participating.
- (3) Expression of opinions on the system under Industrial Safety and Health Law GLP

## 3 Rewards, etc.

- (1) In cases where the inspector makes the matters listed in 2 from (1) to (3), they will be paid rewards and travel expenses
- (2) Payment of rewards and travel expenses according to (1) is assumed to be performed based on expenditure standards at the Labour Standards Bureau for rewards, for travel expenses for travel expenses of national public officials (Act No. 114, 1952) and Handling Rules for Handling Travel by the Ministry of Health, Labor and Welfare (the Ministry of Health, Labour and Welfare Division No. 13, 2001).

## 4 Procedure of commission

The commission or dismissal of the non-governmental inspectors shall be in accordance with the following provisions.

- (1) In case of the commission
  - A. when trying to commission an inspector, make the following documents.
    - a. inauguration consent form of the said person (Form 1) 1 sheet
    - b. for persons with other occupations, as necessary, appointment letter of assumption from the department head (Form 2) 1 sheet
    - c. curriculum vitae (Form 3) 1 sheet
    - d. written appointment of commission (Form 4) 1 sheet
  - B. when the Director-General of Labour Standards Bureau, Ministry of Health, Labour and Welfare has commissioned, shall deliver an identification card of the inspector under ISHL-GLP (Form 5) (hereinafter referred to as "identification card for the inspector").
- (2) In case of the re-commission

It shall be dealt pursuant to the commission, but it is acceptable for the resume to be unnecessary.
- (3) In case of the dismissal

When trying to dismiss the inspector, make a sheet of written appointment of dismissal (Form 6). If the inspector died, the bereaved family shall

inform the death notification (Form 7) soon.

(4) Return of the identification card for the inspector

The Director-General of Labour Standards Bureau, Ministry of Health, Labour and Welfare, when the expiration date of identification card for the inspector expires, when the inspector is dismissed or when the inspector died, let inspector and the bereaved family return it without delay.

5 The duty of confidentiality

Industrial Safety and Health Law GLP inspectors must not reveal secret which they come to know through inspection.