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Guidelines for Certification of Compliance with Industrial Safety and Health Law GLP concerning Test Facilities, etc.

LSB Notification No. 123 dated March 17 1989
Amendment LSB Notification No. 0525001 dated May 25, 2009

No. 1 Objective

The objective of the present guidelines is to prescribe matters related to certification of compliance of test facilities, etc. (referred to be judged “in compliance” in No.3-3-(1) of these guidelines as the test facilities comply with the Industrial Safety and Health Law GLP (referred to the standard to be satisfied by the test facilities, etc. pursuant to provisions of Section 2 of Article 34-3 of the Ordinance on Industrial Safety and Health (Labour Ministerial Ordinance No.32 of 1972. Hereinafter referred to as the "Ordinance") (ML Notification No.76 of 1988)) for the investigation of toxicity in section 1 of Article 57-3 of Industrial Safety and Health Law (Law No. 57 of 1972) through the compliance monitoring of test facilities, etc. (referred to implementing examination with the Industrial Safety and Health Law GLP through examination and inspection prescribed in No.3-(2)-a of these guidelines) with the Industrial Safety and Health Law GLP in order to implement the provisions of Article 34-3 and Article 34-4 of the Ordinance.

No. 2 Applicable Test

The applicable tests for carrying out certification of compliance based on these guidelines are mutagenicity studies and carcinogenicity studies prescribed in Article 1-1 of the Industrial Safety and Health Law GLP.

No. 3 Procedures for Compliance monitoring

1. Application procedures

(1) The person who intends to receive compliance monitoring applies to Director-General of Labour Standards Bureau, Ministry of Health, Labour, and Welfare by submitting the application by Form 1 (hereinafter referred to as “application form”), together with the documents shown in (2) below, for each test facility. The person who intends to receive the certification of compliance by and before a designated date shall apply at least 6 months before the relevant date.

(2) It is necessary for the documents attached to the application form (hereinafter referred to as “document attached”) to contain the following contents.

- a. Date of establishment of the test facilities, etc., main body of establishment, site area, stories and total floor area of the building in which the facilities, etc. occupied for investigation of toxicity are located. In addition to those, articles of incorporation shall be attached the applicant is a corporate body.
- b. Plan view of the test facilities, etc. and layout of main facilities and equipment.
- c. Name, quantity, type No., etc. of the main equipment and apparatus to be used for the test items for which the certification of compliance is supposed to be received
- d. Organization (including personnel composition) of the test facilities, etc. name and responsibilities of the management and other main persons, and their curriculum vitae, research career, names of academic societies or learned societies they belong to
- e. Rules related to internal audit and implementation state of the internal audit for the last three years
- f. Implementation state of education and training of the personnel for the last three years
- g. Execution state of the study items for which certification of compliance is intended to receive for the last 10 years
- h. A copy of standard operating procedures used for the tests on the application, procedures of making, revising and scraping standard operating procedures, and a catalogue of titles of standard operating procedures
- i. Stream of tested substances, positive controls, and waste (including drainage), etc.

(3) The application form and the documents attached above are submitted in duplicate, i.e. an original and a copy.

2. Compliance Monitoring

(1) The compliance monitoring is carried out, in principle, by examination of the application form and documents attached (if additional documents are requested in (2) below, relevant documents are also included) and by inspection of test facilities, etc. related to the relevant application.

(2) If additional documents come to be in need when implementing inspection, these relevant documents shall be requested to submit.

(3) Inspections associated with certification of compliance shall be carried out pursuant to the provisions set forth in Appendix "Guidelines for Inspection on Industrial Safety and Health Law GLP (hereinafter referred to as "inspection guidelines")."

(4) Submission of Explanation Papers, etc. and Advice from Scholars and Experts

a. Submission of Explanation Papers, etc.

Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare requests the applicants to submit explanation papers or evidence or shall request measures for improvement (it can be replaced by the submission of plan for improvement if prompt improvement is not available) and reports of the result on relevant items before performing the evaluation of 3. (1) below, with noticing relevant points to be improved to the test facilities, etc. and with full consideration of giving enough time for the applicants to respond to it, with designated deadline less than 30 days, provided that items are found that are deviated from or can be deviated from the Industrial Safety and Health Law GLP (minor items that do not recognized to spoil the credibility of investigation of toxicity performed in the relevant facilities, etc.).

b. Asking Advice to Scholars and Experts

Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare shall ask advice to inspection experts or other scholars before performing evaluation of 3. (1) below, if it is recognized necessary.

3. Judgment

(1) Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare synthetically evaluates the level of compliance of the relevant test facilities, etc. with the Industrial Safety and Health Law GLP taking into consideration of the results of the compliance monitoring (if explanation documents or evidence was requested to be submitted or measures for improvement or the report of the result was requested to be submitted on 2 (4) a above; or if hearing was implemented on 2(4)b above; those results are also included), and shall judge which of the following

classifications the test facilities, etc. belong. However, if judgment is not appropriate because measures for improvement based on the improvement plan are not completed in the test facilities, etc., judgment can be suspended and necessary action shall be taken on 2(4) above with notifying it to the applicant.

- a. In compliance (refer to being complied with the Industrial Safety and Health Law GLP)
 - b. Not in compliance (refers to all or part of the facilities, etc. being not complied with the Industrial Safety and Health Law GLP, and the credibility of the investigation of toxicity performed in the facilities, etc. is judged to be spoiled.)
- (2) Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare judges “Not in compliance” in (1) above in the following cases;
- a. When refusing inspection, interfering it, or not responding or making false replies to the inquiries on inspection
 - b. When refusing, not submitting by designated dates, not reporting, submitting false explanation papers, or reporting falsely, despite that explanation papers or evidence are requested to submit or measures for improvement and reports of the result are requested to submit on 2 (4) a.
 - c. When suspended period lasts for about 6 months in case judgment was suspended on the proviso (1) above. This case does not apply when inevitable reasons exist which applicants cannot be blamed.

4. Notification

Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare, in principle, notifies to the applicant for certification of compliance by Form 2 with respect to the results when judgment prescribed in 3 above is performed no more than 6 months from the date of application. The date of certification of compliance of the test facilities, etc. (refers to the date of receiving certification of compliance) shall be the date of performing inspection (the last date of the inspection when inspection had been performed for more than 2 days), in case the test facilities, etc. are judged to be complied with the Industrial Safety and Health Law GLP and received certification of compliance.

No.4 Effect of Certification of Compliance

- (1) Effect of certification of compliance arises from the date of certification of compliance and it would lose effect when 3 years has passed since the relevant date of certification of compliance.

- (2) In case new certification of compliance is received before three years have passed since the date of certification of compliance, the previously received certification of compliance would lose effect on the previous date of certification of compliance regarding the new certification of compliance.

No. 5 Notification on Change

The person who received the certification of compliance with the Industrial Safety and Health Law GLP (hereinafter referred to as “complied institution”) notifies any change in the following items to Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare without delay by Form 3.

- (1) Name and the address of the complied institution; in the case of a corporation, the name the representative
- (2) Name and address of test facilities, etc. receiving certification of compliance
- (3) Among the organization, personnel, facilities, equipment, apparatus, administration, management, etc. of the test facilities, etc., those items which may influence the credibility of test items for which certification of compliance has been received, if changed

No. 6 Notification of Discontinuation

Complied institutions notify to Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare without delay by Form 4 of discontinuation of a part or whole of the services related to the test items for which the certification of compliance has been received.

No. 7 Cancellation of Certification of Compliance

Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare cancels the certification of compliance when the complied institution would apply to any of the following cases. In case of cancellation, explanation papers are requested to submit in advance on 2-No.3-(4)-a.

- (1) When test facilities, etc. of complied institutions are deviated from the Industrial Safety and Health Law GLP and the credibility of the investigation of toxicity performed in the facilities, etc. is judged to be spoiled.
- (2) When not reporting or reporting falsely despite requesting reports, or when refusing despite requesting consent on on-site inspection, or interfering inspection despite accepting it, based on No.8 below.
- (3) When the test facilities, etc. received certification of compliance in unfair ways

No.8 Reporting and On-Site Inspection

Director-General of Labour Standards Bureau of Ministry of Health, Labour, and Welfare requests the complied facilities to report necessary items and have the officials enter the test facilities, etc. under the consent of complied facilities and make necessary inspection, in case it is recognized necessary for the proper implementation of investigation of toxicity. In this case, the on-site inspection shall be performed on the inspection guidelines.

No. 9 Reporting to the OECD Secretariat, etc.

Reporting to the OECD secretariat and other necessary measures are made when certification of compliance is cancelled or when test facilities, etc. of complied institutions are found to be deviated from the Industrial Safety and Health Law GLP and the credibility of the investigation of toxicity performed in the facilities, etc. has come out to be spoiled on No.7 above.

No. 10 Miscellaneous

Clerical works related to certification of compliance with the Industrial Safety and Health Law GLP pursuant to these guidelines shall be carried out at Chemical Hazards Control Division, Industrial Safety and Health Department, Labour Standards Bureau, Ministry of Health, Labour, and Welfare.