

Current Situation of the International Recognition of Toxicologists - Update of the Japanese Society of Toxicology -

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Abstract : Issuance of certification and licensing for toxicologists authorized by the Japanese Society of Toxicology (JST) became effective on July 24, 1997. The certification system consists of examination, eligibility requirements for the applicants, authorization/license by the board of trustees of JST, and the re-certification of previously authorized qualification. In the last 2~3 years, about 30~40% of candidates for the examination have succeeded. The Committee has estimated that the level of the examination would be sufficient to determine qualified toxicologists. This updated status and a detailed explanation are to be presented at the workshop. In global terms, the JST special committee agrees that "harmonization of certification/registration procedure for qualified toxicologists means to ensure/set the minimum requirement for the global authorization of qualified toxicologists". The following items in global authorization are addressed for further discussion: (1) What's the benefit? (2) Toxicological safety assessment standards, and (3) the JST position for authorization.

Key Words : Toxicologist, Certification, Licensing, Japan, Toxicology, Authorization

Since 1995, with enormous efforts, the working group of the Education Committee in the Japanese Society of Toxicology (JST), have been intensively investing the system set-up of toxicologist certification and its implementation in order to conform to the current foreign certification system, especially to that of the American Board of Toxicology (ABT). Based on this assessment, several points were addressed for further consideration including: Who should be first certified by whom? What are the criteria of certification and what is the definition of a certified toxicologist? What are the privileges and the role of a certified toxicologist? With these in mind, JST put forth the following seven issues at the working group meeting in 1996:

- (1) Necessity of certification
- (2) Definition of a toxicologist
- (3) Certification examination
- (4) Certification
- (5) Re-certification
- (6) Education (coursework in toxicology)
- (7) Relationship between certified toxicologist and

pathologist.

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List of Abbreviations : JST, Japanese Society of Toxicology;
ABT, American Board of Toxicology

I. CERTIFICATION AND LICENSING FOR TOXICOLOGISTS IN JST

1. Certification Examination by JST Committee

In order to conduct/manage the certification examination, JST forms a committee on the certification examination (hereinafter referred to as Committee). Applicants who are desirous of receiving a license as a qualified toxicologist are obliged to meet the eligibility requirements and take a closed book examination prepared by Committee. Certification examinations are to be conducted normally once a year in the form of a closed book examination. As the first step, Committee selected the grandfathers who would prepare the examination questions and contribute the education coursework. Selection criteria of grandfathers were based on the past qualification as an experienced toxicologist, publications, activity at JST and contribution or attendance of relevant coursework.

2. Eligibility Requirements for Applicants

Applicants must meet the following requirements:

1) have belonged to JST for more than 5 consecutive years at the time of application. 2) have had sufficient experience in the practice of toxicology for at least 5 years for one who has completed a 6-year university, 7 years for one who has completed a 4-year university, or any combination totaling 11 years in the field of toxicology), 3) have a total of 80 or more points in the attached criteria for the certified application to the examination and test (Table 1).

3. The Certification Examination

1. The examination is weighted as follows:

1) Adverse effects of chemicals (25%)

Metals, organic solvents, pesticides, gases, dusts, industrial chemicals, radioactive compounds, plant

poisons, animal poisons, food additives, drugs, cosmetics, biotechnology products.

2) Manifestation of toxicity/Toxicity testing (40%)

General toxicity (including clinical tests and their significance), general pharmacology, mutagenicity, carcinogenicity, reproductive and developmental toxicity, respiratory organ toxicity (including inhalation toxicity), neuro-behavioral toxicity, immunotoxicity, skin/mucosa toxicity (including gastro-intestinal toxicity), blood/hematopoiesis toxicity, cardiovascular toxicity, hepatotoxicity, nephrotoxicity, endocrine toxicity, motor apparatus toxicity (including bones/muscles/joints), sensory organ toxicity (including ophthalmic toxicity), experimental method of toxicity (including experimental animals).

3) Principle of toxicology/Applied toxicology (35%)

General principles, influential factors in toxicity, toxicokinetics, pharmacokinetics, mode of toxicological manifestation, risk assessment, environmental toxicology, epidemiology, clinical toxicology, biostatistics, regulatory toxicology.

2. Level of the examination is described below.

1) Detailed knowledge of the provisions of the regulations shall not be required, but understanding concerning regulatory intervention in the guarantee of safety, adjustment among various guidelines, and goals of the guidelines and GLP shall be tested/necessary?

2) Besides regulatory toxicology, data tested shall conform to the following textbooks:

i) Casarett and Doull's Toxicology: The Basic Science of Poisons (C.D. Klaassen, Ed.), 5th ed., McGraw-Hill, New York (1996)

ii) Goodman & Gilman's "The Pharmacological Basis of Therapeutics" (J.G. Hardman et al, Eds.) 9th ed., McGraw-Hill, New York (1996)

Table 1. Eligibility requirements for admission to the certification examination

Classification	Item	Point for one participation	Point for one publication
Toxicological articles	The Journal of other publication	Toxicological Sciences	10 (5)* 5 (2)
Presentation at academic society	JST-sponsored meeting	5	10 (5)
Lecture meeting under auspices JST	JST Satellite symposium	3	5 (2)
	Before 1997	10	
	After 1998	40	

(*)*: co-author or co-presenter

Total points: ≥80.

Table 2. Credit for re-certification (over five years)

Activities	Credits for each/time (paper)	Maximum
Preparation of questions for certification examination	20	75
Academic society activities		
-Participation/presentation at JST mtg.	5	25
- at authorized by JSE	3	
Lecture meeting by JST	3	25
Scientific paper on toxicology (JST journal)	5	25

3) Specified knowledge or past thought shall not be tested; however, current knowledge and basic principles shall be.

4) The contents and severity of the test shall be similar to that of the ABT-sponsored examination. The passing mark shall be 70 points or higher.

4. Authorization/licensing

Examination of submitted reports as well as the certification test are to be conducted by the Committee. Final authorization is to be approved by the Board of Trustees of JST.

5. Re-certification of authorized qualification

Every 5 years after the license is granted, certified toxicologists must be re-certified in order to keep their qualification. Credit points during the previous 5-year period must be over 80 (Table 2).

The applicant will be given a re-certification examination consisting of 100 questions. These questions are selected from certification examinations of the previous 5 years by the certification subcommittee. Applicants with 80 or more correct answers will be deemed to have passed the examination.

II. EXPERIENCES IN THE PAST SEVERAL YEARS (1ST AND 2ND EXAMINATIONS)

Standard procedure of the closed book examination is to provide 200 questions for 6 hrs (100 questions for 3 hrs a.m. and 100 questions for 3 hrs p.m.). As passing standard, 70 points or more % of correct answer should be required.

The first examination was held on October 11, 1998, and 49 out of 119 applicants were successful (success ratio: 41%).

The 2nd examination was held on October 17, 1999, and 22 out of 78 applicants were successful (success ratio: 28%).

III. GLOBAL AUTHORIZATION OF QUALIFIED TOXICOLOGISTS FROM JST STANDPOINT

The JST special committee for global harmonization recognizes the following as the global authorization of a qualified toxicologist.

Goal/Objective:

An acceptable goal/objective would be "harmonization of certification and registration procedures for qualified toxicologists ensures the minimum requirement for the authorization of qualified toxicologists."

Benefits:

Although having a slightly different background of approach than other societies in various countries, JST has to be aware and confirm that the benefit of certification be to the toxicologist, employers, and the society, clearly demonstrated in the societies of the other countries, particularly in ABT.

Toxicological safety assessment standard:

We toxicologists who are going to make a safety evaluation in many fields (academia, government, industrial, etc.) should maintain high-grade/wide-range science due to the diverse science of toxicology, as we might face critical risk assessment for safety evaluation. Since these assessments are becoming more and more global, we should take the next step toward internationally integrated harmonization of the certification of toxicologists in the future. In this context, we should have a mutual recognition of a certified toxicologist under an appropriate minimum requirement for the authorization of qualified toxicologists worldwide.

JST position/status for authorization:

The gist of the authorization for JST lies in eligibility requirements (sufficient experience, reports, etc.), an education-based system in society, and an examination (test). We believe that the level of the JST examination is comparable to those of other societies'. In the last two examinations there has been an approximate 30% success rate. After careful review of the process, contents and results of these examinations, Committee has estimated that the level of the

examination would be sufficient to measure/judge qualified toxicologists.

REFERENCES

Kurokawa, Y.: Progress Report on the Accrediting Toxicol-

ogists in Japan, ASIATOX News Letter, Sept., 1998.
Sato, T.: Information documents "a frame work for harmonization of toxicology accreditation boards and registries" for the Ad Hoc meeting at SOP 2000.
Craigmill, A. Newsletter, American Board Toxicolgy, Inc. Issue No. 28, January 2000.