Outlines of Legal Measures on the Specifications of Dental Materials and Appliances in Japan

by

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In the year 1930 a provisional deliberative committee for medicines and drugs was established at the instance of Japanese Government for the purpose of promoting the level of domestic production in this branch of industry. On this committee, three gentlemen served to deal with the dental materials; Morinosuke Chiwaki, the President of Japan Dental Association, Tsurukichi Okumura, Vice-dean in Tokyo Dental College and Goro Morita, President of the Morita Dental Manufacturing Company. At that time, however, standard specifications had not been worked out for dental materials and Kenji Shofu, President of Shofu Dental Manufacturing Company, supplemented their activity in the advisory capacity.

Mr. Shofu was of the opinion that the establishment of dental material specifications would be very important to the welfare of national health and insisted on the matter being handled by the Japan Dental Association but the existing situations within the Association then rendered an execution of plan quite impossible. The need of adequately dealing with the laboratory equipment for researches in dental materials at dental colleges was equally felt and Mr. Shofu was given the sole responsibility for this investigation. Since he was directly connected with the manufacturing of dental materials, Mr. Shofu recommended a society with an independent status should be established, consequently the Japan Society for Dental Materials coming into birth two years later (1932). Being the director of this society himself, he appointed as committee members Jin Matsuo, Chief, Bureau of Sanitation, Ministry of Welfare, Yutaka Kinugawa, Director of Tokyo Sanitation Institute, Tatsuo Karigome, Tokyo Sanitation Institute, General Senju Matsuminami, Director in Charge of Medicines and Drugs in the Japanese Army, and General Kitaji Miuchi, the Japanese Army Medical Corps, among many others selected from the deans of dental colleges, professors of dentistry in medical colleges, the Japan Dental Association and Japan Society for Dental Materials. A committee tentatively formed to work for the study of dental specifications was housed in Tokyo Sanitation Institute, which is to be considered as the first attempt at the direction of material specifications in Japan. In July, 1938, a report on the specifications of dental materials was made public by the said committee, embodying the following matters.

Methods of general examinations and testings

No. 1 specifications for Ag-amalgam alloy

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No. 2 specifications for mercury for dental amalgam
No. 3 specifications for fusible alloy
No. 4 specifications for substitute alloy for the use of clasps
No. 5 specifications for zinc phosphate cement
No. 6 specifications for impression materials
No. 7 specifications for wax for the inlay casting
No. 8 specifications for non-casting alloy of substitute gold alloy
No. 9 specifications for inlay casting alloy as substitute gold alloy
No. 10 specifications for clasp casting alloy as substitute gold alloy
No. 11 specifications for alloy for artificial denture as substitute gold alloy
No. 12 specifications for investment material for the inlay casting
No. 13 specifications for non-casting gold alloy
No. 14 specifications for casting gold alloy

In this connection, it must be added that Dr. Okumura, one of the committee members, recommended reports issued by the U.S. National Bureau of Standards to be adopted as reference materials of much value by the committee and they have been used with great benefit. The author likes to take this opportunity to acknowledge here the courtesy of the American Dental Association.

The items enumerated above contain other substitute alloys than gold alloys and they are to be taken as being peculiar to Japan. The author firmly believes that researches in the area of other substitute alloys than gold have been much advanced in this country. For instance, there are published the peculiar findings on the effects of metal corrosion in the oral cavity and these on the vital body.

Further in 1943, more specifications were made for silicate cement, acrylic resin, porcelain teeth, and gold palladium alloy among others by the efforts of the Society, thus bringing up the total number of established specifications to twenty-two kinds. With the establishment of dental specifications, it came to be dissolved after a existence of more than 10 years, in June 1943. These dental specifications had value of high merit as a guide both for the dental practitioners and manufacturers of materials. This was especially true of a few years during the Pacific War when no dental materials and appliances were allowed to come from abroad. And these specifications played a principle part in the domestic manufacturing of dental materials.

After the conclusion of Second World War, the Japanese Government promulgated the Industrial Standardization Law in the year 1949 for the purposes of introducing uniformity into the specifications and enhancing the level of mining industry at the same time. Under the provisions of this Law, the specifications for medical instruments, apparatus and dental materials are required to receive sanction from the Ministry of Welfare.

There was born a committee which works in close conjunction with the said Law and this committee is known under the official designation of Deliberative Committee of Japan Industrial Standardization Law, being composed of three levels or steps of activity. Under this Committee there is organized a plenary session which is divided into twenty-four divisions or panels, including one for medical instruments and apparatus. Each of these twenty-four divisions in turn has a special committee under its jurisdiction.

This special committee forms a sub-group to deal with one specific product and one that deals with the specifications for dental materials and apparatus is composed of dentists as users, manufacturers and researchers in this field, and when they have
carefully considered the given proposed specifications from the specialized point of view, they will refer their recommendation to the division of medical instruments and apparatus. The corresponding division is made up of delegates from physicians, dentists, manufacturers of medical and dental apparatus and materials, government officials concerned and researchers in the respective fields. They go over the recommendation sent in by the sub-group to see whether or not it is justified from the overall standpoint of medical administration and their findings are then submitted to the Minister of Welfare. Based on their findings, the Minister of Welfare in the name of Japanese Government announces the official sanction of Japanese Industrial Standards (commonly referred to as JIS) for a particular product.

With reference to the dental apparatus and materials for which the JIS specifications have been granted, there are at present twenty-one kinds of dental materials and twenty-seven items of dental apparatus.

**JIS DENTAL INSTRUMENTS**

1. Hypodermic Needle
2. Hypodermic Glass Syringe
3. Electric Motor for Dental Use
4. Resistance for Dental Engine, and Controller
5. Engine Belt Arm
6. Pulley
7. Engine Wrist and Slip-Joint
8. Engine Belt
9. Engine Stand
10. Bracket Arm
11. Dental Bur
12. Hand Reamer
13. Mandrel
14. Barbed Broach
15. Plain Broach
16. Engine-Reamer
17. Piesso's Reamer
18. Cotton Plier
19. Explorer
20. Dental Chisel
21. Spoon Excavator
22. Plastic Instrument
23. Dental Scaler
24. Dental Elevator
25. Dental Handpiece
26. Cuspidore
27. Dental Mirror and its Handle

**JIS DENTAL MATERIALS**

1. Ni-Cr Alloy Wire for Dental Use
2. Ni-Cr Alloy Plate for Dental Use
3. Stainless Steel Wire for Dental Use
4. Cr-Co Alloy Wire for Dental Use
5. Au-Ag-Pd Alloy (not for casting) for Dental Use
6. Au-Ag-Pd Alloy for Dental Casting
7. Solder Alloy for Au-Ag-Pd Alloy
8. Silver Alloy for Dental Casting
9. Silver Amalgam Alloy
10. Acrylic Resin for Denture Base
11. Paraffin Wax
12. Inlay Wax
13. Impression Compound
14. Alginate Impression Material
15. Resin Teeth
16. Temporary Stopping Material
17. Investment for Dental Use
18. Zinc Phosphate Cement
19. Silicate Cement
20. Plaster of Paris for Dental Use
21. Stone Plaster for Dental Use

Under the Law referred to, those products which have succeeded in obtaining the legal sanction from the Minister of Welfare are stamped with the official mark of JIS on them and thus the JIS mark serves for the convenient selection on the part of users. The Industrial Standardization Law also provides that when the manufacturing companies pass a rigid governmental inspection for their organization, operation, production equipment, production process and quality control, the Minister of Welfare will grant them to operate their business under the designation of JIS specifications mark.

The chart which accompanies this lecture gives the details of the dental apparatus and materials for which JIS specifications have been recognized. Specifications for porcelain teeth are presently under discussion by the Committee. As a civilian organization, we have what is called the Japan Society for Dental Materials and Appliances, and it is comprised of three constituent parts of researchers, clinicians and manufacturers of dental materials and apparatus. This Society also deliberates an original proposal for dental specifications and answers to the Ministry of Welfare. In the preparation of new proposals for dental specifications, we derive a large measure of benefit from the Specifications for Dental Materials which are issued by the U. S. National Bureau of Standards, Washington, D.C., and warm appreciation is hereby expressed for all those connected with this worthy organization.

As a next item I will take up the subject of a plan of "test specimen standardization" for dental amalgam specifications.

And also, I am going to make a report on a new type of dental cement developed by Professor Higashi, who is associated with Tokyo Medical and Dental University.