醫療器材採認標準資料表

編號	DOH-000168
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA18-A
標準名稱	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline
制定日期	December 1994
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Immunological Testing for Infectious Diseases
簡要說明	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline (NCCLS document I/LA18-A) is intended for use by laboratorians who perform immunodiagnostic testing within clinical and reference laboratories. The document addresses the generic problems of preparation and characterization of antigens and antibodies, testing using these reagents, and understanding the results. Specifications for Immunological Testing for Infectious Diseases; Approved Guideline offers recommendations on specimen collection, handling, and storage, and performance criteria for the comparison of immunological test kits, as well as specifications for reference materials.

醫療器材採認標準資料表

編號	DOH-000169
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM3-A
標準名稱	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline
制定日期	December 1995
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDs to Detect Infectious Diseases by Molecular Diagnostic Methodology
簡要說明	Molecular methods that use nucleic acid hybridization and amplification techniques for clinical diagnosis offer significant opportunities for the clinical microbiologist to obtain more rapid and accurate results. Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline (NCCLS document MM3-A) addresses topics that relate to the direct detection of nucleic acid targets, use of amplification technologies, and related methodologies. These topics include methods, applications, qualification of sequences, hybridization, quality assurance, proficiency testing, specimen handling, inhibitors and interfering substances, contamination controls, interpretation of results, limitations and evaluation of test results, test confirmation and optimization, and recommendations for manufacturers and clinical laboratories.

醫療器材採認標準資料表

編號	DOH-000170
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C12-A
標準名稱	Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard
制定日期	September 1994
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Blood pH and Gas Analyzers
簡要說明	Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard (NCCLS document C12-A) addresses problems in nomenclature, measurement of blood pH/blood gas, and quantities derived from these measurements. This document represents a concerted effort to standardize the symbolism used to represent terms related to pH and blood gas analysis.

醫療器材採認標準資料表

編號	DOH-000171
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C21-A
標準名稱	Performance Characteristics for Devices Measuring *P*O2 and *P*CO in Blood Samples 2
制定日期	March 1992
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Devices measuring PO2 and PCO2 in blood samples
簡要說明	Performance Characteristics for Devices Measuring PO_2 and PCO_2 in Blood Samples; Approved Standard (NCCLS document C21-A) lists performance characteristics and related methods for instruments designed to measure the partial pressures of oxygen and carbon dioxide in blood samples. The standard is intended to provide guidance for: identifying the performance characteristics that describe the device; specifying performance claims in a clear, concise, and uniform manner; and evaluating test methods used to determine the performance characteristics. Examples are included, but they do not imply expected performance of blood gas analyzers.

醫療器材採認標準資料表

編號	DOH-000172
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C25-A
標準名稱	Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline
制定日期	January 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Devices to determine fractional oxyhemoglobin, oxygen content and saturation, and related quantities in blood
簡要說明	This document is intended primarily for clinical laboratory directors, clinical chemists, medical technologists, cardiopulmonary technologists, respiratory care practitioners, physicians, nurses, and others involved in the measurement and reporting of oxygen content, hemoglobin oxygen saturation and related quantities, and the use of these quantities in patient care. C25-A provides recommendations on terminology and symbols to be used when reporting results and the measurement principles involved in the methods that are recommended. Preanalytical considerations, physiological and analytical measurement limitations, and recommendations for cutaneous oximetry

醫療器材採認標準資料表

編號	DOH-000173
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C27-A
標準名稱	Blood Gas Pre-Analytical Considerations: Specimen Collection, Calibration, and Controls
制定日期	April 1993
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Blood gas analyzers
簡要說明	This document is intended primarily for clinical laboratory directors, medical technologists, cardiopulmonary technologists, respiratory therapists, physicians, nurses, and others involved in analyzing arterial blood for pH and blood gases. In Section 2.0, the document addresses areas that have to be considered when collecting the specimen, including the condition of the patient (2.1), the collection procedure and the containers used (2.4), specimen samples (2.3), transportation (2.6), and the handling of the specimens in the laboratory (2.7). In Section 3.0, calibration of the blood gas analyzer is considered, including kinds of calibrants (3.2), methods of calibration (3.3), and potential sources of calibration error (3.4). In Section 4.0, the document addresses the principles of an effective quality control program and outlines, in Sections 4.1 through 4.7, the areas that must be considered. Section 4.9 presents the subcommittee's recommendations for a minimum acceptable quality control program. Section 4.4, Sources of Error in Blood Gas Analyzers, and Section 4.6, Requirements for Commercial Blood Gas Controls, contain supplementary information that might not be of interest to the general reader.

醫療器材採認標準資料表

編號	DOH-000174
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C30-A
標準名稱	Ancillary (Bedside) Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline
制定日期	September 1994
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	All Ancillary (Bedside) Blood Glucose Testing Devices
簡要說明	Ancillary (Bedside) Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline (NCCLS document C30-A) provides information for use by acute and chronic care facilities for structuring an ancillary (primarily bedside) blood glucose testing (ABGT) service intended to ensure quality test results, as well as high-quality patient care.

醫療器材採認標準資料表

編號	DOH-000175
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C42-A
標準名稱	Erythrocyte Protoporphyrin Testing; Approved Guideline
制定日期	November 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Erythrocyte protoporphyrin testing
簡要說明	Erythrocyte Protoporphyrin Testing; Approved Guideline (NCCLS document C42-A) is a comprehensive document for use by laboratorians who perform erythrocyte protoporphyrin (EP) determinations; its aim is to reduce/eliminate the lack of uniformity in current measurement practices. The biochemistry and pathology of EP are discussed, the history of EP determinations is summarized, and the applications of the test are defined. The document recommends the adoption of a specific molar absorptivity constant for the standardization of EP methods and the universal adoption of reporting units expressed as the molar ratio of protoporphyrin to heme. Detailed methods for the measurement of EP by extraction and hematofluorometry are included, and the interpretation of EP results is discussed.

醫療器材採認標準資料表

編號	DOH-000176
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H10-A2
標準名稱	Solubility Test to Confirm the Presence of Sickling Hemoglobins -Second Edition; Approved Standard
制定日期	August 1995
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Solubility test for sickle cell hemoglobin
簡要說明	Solubility Test to Confirm the Presence of Sickling Hemoglobins-Second Edition; Approved Standard (NCCLS document H10-A2) is the result of several years of use and evaluation by the clinical laboratory community. The subcommittee that wrote the document, the NCCLS Subcommittee on Hemoglobinopathies, worked to standardize the detection and confirmation of hemoglobinopathies. H10-A2 describes the solubility test used to confirm the presence of sickling hemoglobins, which are apparently detected by cellulose acetate electrophoresis. The document is intended to assist clinical laboratories in the identification of hemoglobinopathies.

醫療器材採認標準資料表

編號	DOH-000177
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H14-A2
標準名稱	Devices for Collection of Skin Puncture Blood Specimens—Second Edition
制定日期	December 1990
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Devices for Collection of Skin Puncture Blood Specimens; All Skin Puncture Collection Devices
簡要說明	This guideline describes devices for collecting, processing, and transferring diagnostic blood specimens obtained by skin puncture. It gives the laboratory user of these devices information on their capacity, applications, directions for use, coding systems, and the anticoagulants used. The devices described are not used for specimens to be collected for microbiological analysis.

醫療器材採認標準資料表

編號	DOH-000178
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H20-A
標準名稱	Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard
制定日期	March 1992
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Leucocyte differential counters
簡要說明	NCCLS document H20-A, Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard, evaluates automated and semiautomated hematology instruments for their capability to perform an acceptable leukocyte differential count. The standard focuses on leukocytes found in the peripheral blood films. The standard presents a detailed description of an acceptable manual-visual leukocyte differential count which serves as the reference for the instrumental differential counter. The types of abnormalities to be included are outlined.

醫療器材採認標準資料表

編號	DOH-000179
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H44-A
標準名稱	Methods for Reticulocyte Counting (Flow Cytometry and Supravital Dyes); Approved Guideline
制定日期	October 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Methods for reticulocyte counting
簡要說明	Methods for Reticulocyte Counting (Flow Cytometry and Supravital Dyes); Approved Guideline (NCCLS document H44-A) provides guidance for the performance of reticulocyte counting by flow cytometry. H44-A addresses methods for determining the precision and accuracy of the flow cytometer and recommendations for calibration and quality control. A description of the New methylene blue (NMB) method, a method against which the test instrument can be compared, is also included. Additional topics discussed include reference intervals and use of the Reticulocyte Maturation Index.

醫療器材採認標準資料表

編號	DOH-000180
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H47-A
標準名稱	One-Stage Prothrombin Time (PT) Test andActivated Partial Thromboplastin Time (APTT) Test; Approved Guideline
制定日期	June 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Prothrombin Time Test
簡要說明	This document is a consolidation of the following previously published documents: ・ H28-T, One-Stage Prothrombin Time Test (PT); Tentative Guideline. ・ H29-T, Activated Partial Thromboplastin Time Test; Tentative Guideline. One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (NCCLS document H47-A) is part of a series of guidelines that addresses methodology in blood coagulation. H47-A also responds to comments on the two constituent documents. It describes the principles and procedures necessary for the routine performance of the PT and APTT by conventional techniques using citrated plasma. Each of the two tests measures the time for a fibrin clot to develop in test plasma after activation. The chemical reactions are complex and, characteristically, results are affected by pretest and analytic variables. The PT and APTT are important screening tests to be used in laboratory evaluation of patients suspected to have disorders of blood coagulation, including the presence of circulating coagulation inhibitors. The PT measures the extrinsic or tissue factor pathway of the coagulation system and it is used to monitor oral anticoagulant therapy. The APTT measures the intrinsic coagulation pathway and it is used in monitoring heparin therapy. The objective of this guideline is to improve test reproducibility through standardization of technique and to ensure clinical relevance by setting test performance goals. The document also highlights the international effort for standardization of the PT through the use of the international normalized ratio (INR).

醫療器材採認標準資料表

編號	DOH-000181
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA2-A
標準名稱	Quality Assurance for the Indirect Immunofluorescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved Guideline
制定日期	December 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Devices to test for autoantibodies to nuclear antigen (ANA)
簡要說明	Quality Assurance for the Indirect Immunofluorescence Test for Autoantibodies to Nuclear Antigen (IF- ANA); Approved Guideline (NCCLS document I/LA2-A) provides guidance for laboratorians who perform immunofluorescence tests for autoantibodies to nuclear antigen to detect diseases. Topics addressed include substrate and fixative variations, fluorescence-labeled conjugates, reference intervals, test results, and criteria for classification of systemic lupus erythematosus.

醫療器材採認標準資料表

編號	DOH-000182
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA6A
標準名稱	Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline
制定日期	October 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Rubella IgG antibody testing devices
簡要說明	Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline (NCCLS document I/LA6-A) is presented in two parts in order to provide a complete review of rubella serology testing. Part I is intended for use primarily by manufacturers to enable them to meet the general product criteria outlined in Section 3, the general performance criteria and specific performance criteria (Sections 4 and 5, respectively), and to implement the validation testing procedures presented in Section 6. Part I should also be useful to clinical laboratories that participate in the validation testing of these products and be of general interest to laboratories in which rubella serological testing is carried out. Part II (formerly NCCLS document I/LA7-P) is intended to create an awareness of the pre-analytical factors related to rubella serology tests that may affect patient care. Sections 8 through 12 recommend procedures for collecting and handling specimens submitted for serological testing and describe the reporting and interpreting of test results.

醫療器材採認標準資料表

編號	DOH-000183
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA10-A
標準名稱	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline
制定日期	December 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Choriogonadotropin (hCG) Devices
簡要說明	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (NCCLS Document I/LA10-A) was developed for those involved in the processing and analysis of specimens for the determination of choriogonadotropin and its subunits, and for those interested in the clinical utility of the test results. The guideline promotes an awareness of issues related to choriogonadotropin testing with the goal of improving the outcome of the test, as well as patient care.

醫療器材採認標準資料表

編號	DOH-000184
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA17-A
標準名稱	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Open Neural Tube Defects; Approved Guideline
制定日期	April 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Alpha-fetoprotein (AFP) assay used in prenatal screening and diagnosis of open neural tube defects.
簡要說明	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Open Neural Tube Defects; Approved Guideline (NCCLS document I/LA17-A) is written for clinical laboratorians who perform AFP measurements, as well as for clinicians and manufacturers who have a direct interest in the tests. The guideline is intended to present the necessary considerations, both preanalytical and analytical, to assure the reliability of AFP testing during the second trimester of pregnancy. If properly applied, AFP determinations on maternal serum and amniotic fluid can contribute constructively to the field of prenatal diagnosis and to the welfare of pregnant women and the fetus.

醫療器材採認標準資料表

編號	DOH-000185
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA19-A
標準名稱	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline
制定日期	June 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA)
簡要說明	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (NCCLS document I/LA19-A) is written for developers and manufacturers of prostate-specific antigen products for in vitro diagnostic use. This guideline describes procedures for the purification, characterization, and concentration value assignment of primary standards for PSA and PSA-ACT, and a blend (90:10 molar ratio) of PSA-ACT:PSA. These standards are intended to ensure consistency in determined concentration values between assay formats, equipment, operators, and laboratories.

醫療器材採認標準資料表

編號	DOH-000186
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA20-A
標準名稱	Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline
制定日期	December 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Immunological Assays for Human Immunoglobuline E (IGE) Antibodies of Defined Allergen Specificity
簡要說明	Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (NCCLS document I/LA20-A) is written for both laboratorians (users) and manufacturers (producers) of IgE antibody assay reagents and kits. The guideline summarizes the current state of technology by describing the immunoassay configurations of currently used clinical IgE antibody assays, biological specimens that are routinely tested, and practical methods for the evaluation of component reagents. Emphasis is placed on nomenclature and methods for evaluating the specificity of allergen-containing assay reagents and human, IgE-specific, immunologic reagents. Strategies for a unified calibration scheme among IgE antibody assays are discussed with a focus on the pros and cons of the homologous and heterologous interpolation methods. Procedures are included for evaluating assay precision, analytical accuracy, sensitivity, parallelism, and interference. Guidelines for supplier validation and quality assurance, intra laboratory quality control practices, and interlaboratory proficiency testing are discussed within the context of practical procedures. Finally, performance targets are outlined with recommendations for both the manufacturer and diagnostic allergy laboratory.

醫療器材採認標準資料表

編號	DOH-000187
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H26-A
標準名稱	Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard
制定日期	December 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Cell Counters
簡要說明	Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard (NCCLS document H26-A) provides recommendations for performance goals for the internal quality control of multichannel hematology analyzers on the basis of the use of physical and chemical standards, accepted reference methods, subcommittee recommendations on what is currently achievable, and the concept of medical usefulness. Critical performance characteristics of quality control systems (i.e., the probabilities of error detection and false rejection) also are considered. A well-designed internal quality control program must achieve the level of error detection specified in this standard; yet it should not be so sensitive as to falsely reject valid results.

醫療器材採認標準資料表

編號	DOH-000188
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H15-A3
標準名稱	Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard third Edition
制定日期	December 2000
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	DEVICES THAT MEASURE HEMOGLOBIN IN BLOOD
簡要說明	NCCLS document H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard third Edition, describes the measurement of blood hemoglobin using the hemiglobincyanide (HiCN) method, including composition of, and criteria for, the reagent and the calibration of photometers. The procedures described in H15 are required for whole blood calibration procedures for automated hematology analyzers; are necessary in the evaluation of instruments and alternative methods for the determination of hemoglobin concentration; and should be applied when patient red blood cell measurements are used for calibration and control of hematology analyzers. A separate section contains specifications for, and spectral characteristics of, HiCN solutions suitable for use as standards. The document enables users to achieve accurate hemoglobin concentration values for diagnostic or reference purposes. Producers of HiCN calibration standards can use the document as a guideline; users will have the information necessary to check for the content and purity of those materials.

醫療器材採認標準資料表

編號	DOH-000189
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H42-A
標準名稱	Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline
制定日期	December 1998
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	DEVICES THAT UTILIZE FLOW CYTOMETRY METHODOLOGY AND DEVICES INTENDED FOR LYMPHOCYTE IMMUNOPHENOTYPING BY FLOW CYTOMETRY.
簡要說明	NCCLS document H42-A was developed to address issues of procedures and quality assurance for clinical applications of flow cytometry. It is designed to aid clinical laboratorians in the development of quality assurance procedures and to establish the foundation for different laboratories using different commercially available instruments to obtain comparable results. Specific topics covered include: specimen collection, transport, and preparation; sample quality control and staining procedures; instrument calibration; sample analysis; and data analysis, storage, and reporting.

醫療器材採認標準資料表

編號	DOH-000190
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA21-A
標準名稱	Clinical Evaluation of Immunoassays; Approved Guideline
制定日期	June 2002
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	ALL
簡要說明	This document addresses the need for the clinical evaluation of new immunoassays and new applications of existing assays. Existing NCCLS documents provide guidance for assessing analytical performance, methods comparison, and clinical accuracy of laboratory tests. However, none of the documents define the elements that are integral to generating clinical data. As a guide to designing, executing, and analyzing a clinical evaluation, this document will aid clinical and regulatory personnel responsible for commercializing products, developers of "in-house" assays for institutional use, and developers of assays used for monitoring pharmacologic effects of new drugs or biologics.

醫療器材採認標準資料表

編號	DOH-000191
標準分類	ABC. 體外檢驗醫療器材
標準號碼	M6-A
標準名稱	Protocols for Evaluating Dehydrated Mueller Hinton Agar; Approved Standard
制定日期	December, 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	ALL SUSCEPTIBILITY DISCS FOR STANDARD METHOD
簡要說明	This document describes three protocols for the evaluation of dehydrated Mueller Hinton agar in the disk diffusion procedure for antimicrobial susceptibility testing. The first protocol is for use by manufacturers to evaluate production lots of Mueller Hinton agar. The second and third are for selection and stability testing of primary and secondary reference lots of Mueller Hinton agar.

醫療器材採認標準資料表

編號	DOH-000192
標準分類	ABC. 體外檢驗醫療器材
標準號碼	M15-A
標準名稱	Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline
制定日期	June 2000
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDS
簡要說明	NCCLS document M15-A, Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline, presents instructions for preparation of thick and thin blood films, the appropriate use of stains, and methods to assist in the diagnosis of many parasitic diseases. Procedures for blood collection by skin puncture and venipuncture, techniques for preparing films for blood parasite examination, and steps for preparing Giemsa stain and other reagents, including a special stain for microfilariae, are provided. The optimum times for preparing blood films for five particular parasites—Plasmodium species (malaria), Babesia species, Trypanosoma cruzi (Chagas' disease), African trypanosomiasis, and filariasis—are identified and explained. A thorough list of blood film examination supplies is included. Basic guidelines and reference materials for the identification of blood parasites are given.

醫療器材採認標準資料表

編號	DOH-000193
標準分類	ABC. 體外檢驗醫療器材
標準號碼	M22-A2
標準名稱	Quality Assurance for Commercially Prepared Microbiological Culture Media second Edition; Approved Standard
制定日期	December 1996
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDS
簡要說明	This document is a revision of the approved standard published in December 1990. M22-A2 provides users and manufacturers with quality assurance procedures for commercially prepared microbiological culture media. The basic premise of this standard is that certain culture media, because they have demonstrated very low failure rates, do not require retesting by the user. In addition, procedures by which manufacturers can evaluate the performance of prepared culture media are provided.

醫療器材採認標準資料表

編號	DOH-000194
標準分類	ABC. 體外檢驗醫療器材
標準號碼	M23-A
標準名稱	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline
制定日期	June 1994
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDS
簡要說明	This document offers guidance for developing data on antimicrobial susceptibility testing of aerobic and anaerobic bacteria; data developed according to this guideline will be used in establishing interpretive and quality control criteria for NCCLS antimicrobial susceptibility testing standards. Human pharmacokinetics, in vitro drug characteristics, distributions of microorganisms, and correlation of test results with outcome statistics are addressed from the perspective of interpretation of test results. In addition, the document addresses clinical confirmation of interpretive criteria and quality control limits. For clinical confirmation, the "ideal" data set may not be obtained during development of a new drug. Users of this guideline should understand the limitations and work together toward the best educated conclusions.

醫療器材採認標準資料表

編號	DOH-000195
標準分類	ABC. 體外檢驗醫療器材
標準號碼	M28-A
標準名稱	Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline
制定日期	December 1997
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDS
簡要說明	The diagnosis of parasites from the intestinal tract depends on the recovery and identification of the etiologic agents. Therefore, the ability to collect, process, and examine fecal specimens is important in terms of clinical relevance and patient care. Parasitic infections are not normally treated without demonstration of the specific causative agent. Thus, the ability to recover and identify these organisms is an important part of the overall microbiological responsibilities of the diagnostic laboratory. Communication of instructions to the patient, specimen collection and handling techniques, diagnostic tests, and result reporting are key components in proper patient management. Major sections of this document cover these topics, as well as equipment, reagents, and specific techniques used in diagnosing intestinal parasitic infections.

醫療器材採認標準資料表

編號	DOH-000196
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM1-A
標準名稱	Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline
制定日期	April 2000
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IVDS
簡要說明	NCCLS document MM1-A Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline, provides general recommendations for all phases of the operation of a molecular genetics diagnostic laboratory. The recommendations cover nomeclature for human pedigrees and the designation of mutations; laboratory safety; and "front-end" activities, such as intake information, specimen identification and accessioning, and sample preparation. Other topics addressed are molecular analytical techniques, test validation and characterization, quality assurance, results reporting, and selection of referral laboratories. The guideline also includes definitions of selected terms commonly used in the theory and practice of molecular genetics.

醫療器材採認標準資料表

編號	DOH-000197
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C46-A
標準名稱	Blood Gas and pH Analysis and Related Measurements; Approved Guideline
制定日期	September 2001
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	CHEMISTRY, TOXICOLOGY, ALL IVDS
簡要說明	This guideline is a consolidation of six NCCLS documents and projects. The Area Committee on Clinical Chemistry and Toxicology concluded that NCCLS's constituencies (professions, government, and industry) would be better served with the production of a single document that retains the essential information from the six original documents while making it even more relevant and useful. It addresses blood gas, pH, and related measurements (e.g., fractional oxyhemoglobin, oxygen content, hemoglobinoxygen saturation, and selected electrolytes as measured in whole blood). It defines terminology and discusses performance characteristics as well as preanalytical variables and analytical considerations. It also addresses quality control issues.

醫療器材採認標準資料表

編號	DOH-000198
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H43-A
標準名稱	Clinical Applications of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline
制定日期	June 1998
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	DEVICES THAT UTILIZE IMMUNOFLUORESCENCE-BASED FLOW CYTOMETRY METHODOLOGY FOR THE IMMUNOPHENOTYPIC ANALYSIS OF LEUKEMIC AND LYMPHOMA CELLS
簡要說明	The increasing acceptance of immunophenotyping for the proper management of patients with leukemia and lymphoma necessitates the development of guidelines for the appropriate performance of these techniques in the clinical laboratory. NCCLS document H43-A-Clinical Applications of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline, addresses issues of safety, specimen collection and transportation, sample preparation, immunofluorescent staining, instrument quality control, data acquisition, and data storage for the application of flow cytometry to the immunophenotypic analysis of these disorders. This document builds on NCCLS document H42-A-Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Peripheral Blood Lymphocytes.

醫療器材採認標準資料表

編號	DOH-000199
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM2-A
標準名稱	Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline
制定日期	December 1995
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	T-Cell Receptor Gene Rearrangement Assays
簡要說明	Assays that detect monoclonal rearrangement of immunoglobulin or T-cell receptor genes are useful adjunct methods in the diagnosis of leukemia or lymphoma. Prudent clinical use requires a thorough understanding of the sensitivity and technical artifacts associated with these methods, together with the ability to prudently weigh the results. Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline (NCCLS document MM2-A) helps the laboratorian perform and interpret gene rearrangement assays. It includes indications for gene rearrangement analysis and acceptable methods for specimen collection, transport, and processing. Also included are ways to assess specimen adequacy, as well as technical methods for conducting gene rearrangement assays, including information on sensitivity, specificity, controls, and test interpretation. Quality assurance procedures are interspersed throughout the document.

醫療器材採認標準資料表

編號	DOH-000200
標準分類	ABC. 體外檢驗醫療器材
標準號碼	ISO 15197
標準名稱	In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
制定日期	2003-05-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES FOR THE MEASUREMENT OF GLUCOSE
簡要說明	ISO 15197:2003 specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users. These systems are intended for self-testing by laypersons for management of diabetes mellitus.

醫療器材採認標準資料表

編號	DOH-000201
標準分類	ABC. 體外檢驗醫療器材
標準號碼	DI1-A2
標準名稱	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials – Second Edition, Approved Guideline
制定日期	July 1992
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Immunoarray Systems
簡要說明	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials – Second Edition, Approved Guideline (NCCLS document DI1-A2) is written for users and manufacturers of immunodiagnostic test methodologies. DI1-A2 is a generic guideline that defines common terminology for improving the exchange of information related to immunodiagnostic technologies. Brief descriptions of basic methodologies used in the detection and /or quantification of antibodies and antigens and recommendations for immunodiagnostic kit and reagent guidelines are also included.

醫療器材採認標準資料表

編號	DOH-000202
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM5-A
標準名稱	Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline
制定日期	April 2003
制定標準組織名稱	Clinical and Laboratory Standards Institute (CLSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	NUCLEIC ACID AMPLIFICATION ASSAYS
簡要說明	The use of gene rearrangement in diagnostic hematopathology is now a standard of practice for which recommendations for assay performance and application have been developed. During the period of development, however, a shift has occurred in the way that gene rearrangement assays are accomplished. Now, many laboratories are performing assays first using polymerase chain reaction (PCR).

醫療器材採認標準資料表

編號	DOH-000203
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS C24-A2
標準名稱	Statistical Quality Control for Quantitative Measurements: Principles and Definitions: Approved Guideline - Second Edition (1999)
制定日期	February 1999
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC QUALITY CONTROL
簡要說明	Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline—Second Edition (NCCLS document C24-A2) addresses the principles of statistical quality control (QC), with particular attention to the planning of a QC strategy, the definition of an analytical run, the selection of control materials, and the application of statistical QC in a healthcare laboratory. This guideline is a revision of an earlier guideline. The original definitions are maintained for the manufacturer recommendation run length (MRRL) and the user defined run length (UDRL). Changes include a strong emphasis on defining quality up front to guide the selection of control rules and the number of control measurements, recognition that methodology should be developed to establish run lengths on a scientific basis, and a recommendation that the best response to an out-of-control situation is to identify the sources of the problem and eliminate the cause, rather than routinely repeating control measurements.

醫療器材採認標準資料表

編號	DOH-000204
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS C29-A2
標準名稱	Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard (2000)
制定日期	October 2000
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES FOR THE MEASUREMENT OF SODIUM AND POTASSIUM USING ION-SELECTIVE ELECTRODES SYSTEM
簡要說明	Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard Second Edition (NCCLS document C29-A2) offers a protocol for standardizing instruments that contain direct ion-selective electrodes to give results in concentration terms that are verifiable to the reference method (flame photometry) for specimens with normal plasma water (i.e., lipids and proteins).The document describes the preparation of serum pools to carry out the procedure. Laboratories without the resources, equipment, or personnel to prepare the pools can purchase them from the National Institute of Standards and Technology (Gaithersburg, MD). It is recommended in C29-A2 that the accuracy of each new direct potentiometric instrument be verified with these standard pools, together with the flame photometer, if it is also used to report patient results.

醫療器材採認標準資料表

編號	DOH-000205
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS C31-A2
標準名稱	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline - Second Edition (2001)
制定日期	June 2001
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES FOR THE MEASUREMENT OF IONIZED CALCIUM
簡要說明	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline—Second Edition (NCCLS document C31-A2) is a guideline for specimen collection for ionized calcium determinations. The primary audience for this publication is personnel responsible for ionized calcium determinations. This document discusses the reasons for in vivo (nonpathologic) and in vitro changes in ionized calcium concentrations, and it presents recommendations for avoiding or minimizing these effects.

醫療器材採認標準資料表

編號	DOH-000206
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS DI02-A2
標準名稱	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline
制定日期	October 1993
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Immunoglobulins A, G, M, D, and E immunological test system devices using nephelometric and immunodiffusion methods
簡要說明	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials—Second Edition; Approved Guideline (NCCLS document DI2-A2) is intended for use by all clinical laboratories that perform immunoprecipitin assays and by the manufacturers of immunoprecipitin test systems. Use of these guidelines will promote a greater understanding of the specific requirements, capabilities, and limitations of this important diagnostic tool. Interlaboratory comparability of test results will also be improved.

醫療器材採認標準資料表

編號	DOH-000207
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS H1-A5
標準名稱	Tubes and Additives for Venous Blood Specimen Collection; Approved Standard
制定日期	December 2003
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES (EVACUATED TUBES AND RELATED ADDITIVES) FOR COLLECTION OF VENOUS WHOLE BLOOD, PLASMA AND SERUM SPECIMENS FOR CHEMISTRY, HEMATOLOGY, AND IMMUNOLOGY LABORATORY PROCEDURES.
簡要說明	NCCLS document H1-A5—Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition is a performance standard for manufacturers of venous blood collection tubes and additives and users of venous blood collection tubes. H1 addresses requirements for the materials, construction, and labeling of venous blood collection tubes, and it provides methods for the evaluation of venous blood collection tube and closure assemblies. Specifications for the additives heparin, ethylenediaminetetraacetic acid (EDTA), and sodium citrate are also included.

醫療器材採認標準資料表

編號	DOH-000208
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS H4-A4
標準名稱	Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard - Fourth Edition
制定日期	September 1999
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	ANY DEVICE FOR WHICH VENOUS BLOOD MAY BE USED BUT FOR WHICH VENOUS SAMPLES CANNOT BE PRACTICALLY OR SAFELY OBTAINED BECAUSE OF PATIENT CHARACTERISTICS (INFANTS, BURN PATIENTS, ETC.); DEVICES INTENDED FOR THE POINT OF CARE OR FOR HOME USE AND FOR WHICH CAPILLARY SAMPLING IS THE ONLY PRACTICAL BLOOD COLLECTION METHOD.
簡要說明	This document is a consolidation of the following previously published documents: H4-A3 Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture ThirdEdition; Approved Standard H14-A2 Devices for Collection of Skin Puncture Blood Specimens Second Edition; Approved Guideline. H4-A4 provides a technique for the collection of diagnostic blood specimens by skin puncture, includingrecommendations for collection sites and specimen handling and identification. Specifications fordisposable devices used to collect, process, and transfer diagnostic blood specimens obtained by skinpuncture are also included.

醫療器材採認標準資料表

編號	DOH-000209
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS H7-A3
標準名稱	Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition
制定日期	October 2000
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	In vitro diagnostic devices for measuring packed cell volume, Whole blood calibration of instrument methods
簡要說明	NCCLS document H7-A3 C Procedure for Determining Packed Cell Volume by the Microhematocrit Method describes a standard method for direct measurement of packed cell volume (PCV). The standard is intended for reference use by clinical laboratory personnel and by manufacturers of instruments that determine PCV. The method can also be used (with appropriate precautions as described in the document) in the clinical laboratory for diagnostic purposes, for monitoring a patient's response to therapy, and for evaluating instruments and other methods for determining PCV; the standard should be used for whole blood calibration procedures of hematology analyzers. The document gives detailed specifications of the materials to be used in the procedure, contains information for calibrating the centrifuge and reading device, and includes information on verification of calibration. Expression of results, generally accepted reference values, and potential sources of error are given.

醫療器材採認標準資料表

編號	DOH-000210
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS H30-A2
標準名稱	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline Second Edition
制定日期	November 2001
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES FOR THE MEASUREMENT OF FIBRINOGEN IN CITRATED PLASMA.
簡要說明	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition (NCCLS document H30-A2) is a performance guideline for laboratory and/or clinical healthcare professionals responsible for the routine performance of fibrinogen assays. This guideline describes a technique, based on the method described by Clauss,that is practical, precise, and widely used in the clinical laboratory. Preanalytical and analytical factors and conditions that may alter results are discussed.

醫療器材採認標準資料表

編號	DOH-000211
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS H51-A
標準名稱	Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline
制定日期	September 2002
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	IN VITRO DIAGNOSTIC DEVICES FOR MEASURING VON WILLEBRAND FACTOR ANTIGEN IN PLASMA, IN VITRO DIAGNOSTIC DEVICES FOR MEASURING RISTOCETIN COFACTOR ACTIVITY AS A FUNCTION OF PLATELET AGGLUTINATION (AGGREGATION) IN PLASMA
簡要說明	NCCLS document H51-A—Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline is part of a series of guidelines that address methods in hemostasis testing. The assay of ristocetin cofactor is the most common single test used in the diagnosis of von Willebrand disease and its classification into different subtypes. It is a functional assay of von Willebrand factor activity that measures the ability of the antibiotic ristocetin to induce platelet agglutination in the presence of von Willebrand factor. Thus, the rate and extent of platelet agglutination is a function of the concentration and functional integrity of von Willebrand factor. Determination of von Willebrand factor antigen is another common single test used in the diagnosis of von Willebrand disease and its classification into numerous subtypes. The method described allows the quantitation of von Willebrand factor antigen (protein) by an enzyme-linked immunosorbent assay (ELISA). This guideline describes appropriate test specimens, reagents and materials, methods of platelet agglutination and ELISA, preparation of reference curves, determination of reference intervals, quality control procedures, result interpretation, and sources of error for assays of von Willebrand factor antigen and ristocetin cofactor activity. A brief description of von Willebrand disease and its various subtypes is included, as well as a list of references to more comprehensive reviews of this commonly inherited and rarely acquired bleeding disorder.

醫療器材採認標準資料表

編號	DOH-000212
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS LA01-A2
標準名稱	Assessing the Quality of Radioimmunoassay Systems - Second Edition; Approved Guideline
制定日期	December 1994
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	All Radioummunoassay Systems
簡要說明	Assessing the Quality of Radioimmunoassay Systems—Second Edition; Approved Guideline (NCCLS document LA1-A2) contains definitions, procedures, and other information needed to evaluate radioimmunoassay (RIA) systems. The guideline is intended for use by both manufacturers of RIA systems and laboratory end users. Subjects addressed include receptors, radiolabeled analytes, separation reagents, and calibrators. Recommendations for product labeling and clinical evaluations are also provided.

醫療器材採認標準資料表

編號	DOH-000213
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M2-A8
標準名稱	Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - 8th Edition
制定日期	January 2003
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	ANTIMICROBIAL SUSCEPTIBILITY DISCS
簡要說明	Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy, if its susceptibility cannot be reliably predicted from knowledge of the organism's identity. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used antimicrobial agents. A variety of laboratory methods can be used to measure the *in vitro* susceptibility of bacteria to antimicrobial agents. In many clinical microbiology laboratories, an agar disk diffusion method is used routinely for testing common, rapidly growing, and certain fastidious bacterial pathogens. This document includes a series of procedures to standardize the way disk diffusion tests are performed. The performance, applications, and limitations of the current NCCLS-recommended methods are also described.

醫療器材採認標準資料表

編號	DOH-000214
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M7-A6
標準名稱	Methods for Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard -- Sixth Edition
制定日期	January 2003
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	ANTIMICROBIAL SUSCEPTIBILITY SYSTEMS FOR AEROBIC BACTERIA
簡要說明	Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy, if its susceptibility cannot be reliably predicted from knowledge of the organism's identity. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used antimicrobial agents. A variety of laboratory methods can be used to measure the *in vitro* susceptibility of bacteria to antimicrobial agents. This document describes standard broth dilution (macrodilution and microdilution) and agar dilution techniques, and it includes a series of procedures to standardize the way the tests are performed. The performance, applications, and limitations of the current NCCLS-recommended methods are also described.

醫療器材採認標準資料表

編號	DOH-000215
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M11-A6
標準名稱	Methods for Dilution Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard - Sixth Edition
制定日期	January 2004
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	ANTIMICROBIAL SUSCEPTIBILITY SYSTEMS FOR ANAEROBIC BACTERIA
簡要說明	Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy if its susceptibility cannot reliably be predicted from existing antibiograms. Antimicrobial resistance patterns for many anaerobic bacteria have changed significantly over the last several years, resulting in a lack of predictability for many species. Susceptibility testing of anaerobes is recommended for surveillance purposes and for specific clinical situations. Two endpoint-determining susceptibility testing methods for anaerobic bacteria are described in this standard. The agar dilution method (Wadsworth) remains the reference standard, and is well suited for surveillance testing and research. It is also the standard to which other methods are compared. Broth microdilution is well suited for the clinical laboratory, but is currently limited to testing of *Bacteroides fragilis* group organisms and selected antibiotics. Quality control criteria for each procedure are also described.

醫療器材採認標準資料表

編號	DOH-000216
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M24-A
標準名稱	Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard
制定日期	April 2003
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Susceptibility testing of nontuberculous mycobacteria (NTM), Mycobacterium tuberculosis complex (MTBC) and aerobic actinomycetes
簡要說明	This document addresses the susceptibility testing of Mycobacterium tuberculosis complex (MTBC), clinically significant slowly and rapidly growing mycobacterial species, Nocardia spp., and other aerobic actinomycetes. Included in this standard are recommendations for the selection of agents for primary and secondary testing, organism group-specific methodologies, reporting recommendations, and quality control criteria for the above-listed organisms. Recommendations regarding the selection of agents for testing mycobacteria are based primarily on guidelines from U.S. agencies. For testing MTBC, M24-A recognizes the method of agar proportion as the primary methodology upon which all other methodologies are essentially based; there are also recommendations for use of commercial broth susceptibility methods with shorter incubation times, which are now in widespread use in the susceptibility testing of this significant group of microorganisms.

醫療器材採認標準資料表

編號	DOH-000217
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M26-A
標準名稱	Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline
制定日期	September 1999
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	All of the susceptibility test methods commonly performed by clinical microbiology laboratories (e.g.,disk diffusion, broth dilution, and agar dilution)
簡要說明	Established laboratory methods that can assess the bactericidal activity of an antimicrobial agent are needed, both because of the increase in the number of patients who do not have completely normal host immune defenses and because of the new classes of antimicrobial agents that have been introduced. Clinical cure depends largely upon host factors. Bactericidal tests can provide a rough prediction of bacterial eradication. It should be noted, however, that other factors (e.g., postantibiotic effect and the growth-inhibitory effects of sub-MIC concentrations of antibiotics) may also impact bacteriologic response of patients. The special susceptibility tests that assess lethal activity are not routinely applied to all microorganisms, but are applied in unusual situations; e.g., endocarditis. Uniform test procedures are thus needed to permit comparison of different datasets.

醫療器材採認標準資料表

編號	DOH-000218
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M27-A
標準名稱	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard (1997).
制定日期	June 1997
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Antifungal susceptibility testing of yeasts
簡要說明	This document describes a method for testing the susceptibility of antifungal agents to yeast that cause invasive fungal infections, including Candida species (and Candida glabrata), and Cryptococcus neoformans variety neoformans. Selection and preparation of antifungal agents, implementation and interpretation of test procedures, and the purpose and implementation of quality control procedures are discussed. A careful examination of the responsibilities of the manufacturer and the user in quality control is also presented.

醫療器材採認標準資料表

編號	DOH-000219
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS M31-A2
標準名稱	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard—Second Edition
制定日期	May 2002
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	In vitro susceptibility testing of bacteria to antimicrobial agents.
簡要說明	If the susceptibility of a bacterial pathogen to antimicrobial agents cannot be predicted based on the identity of the organism alone, in vitro antimicrobial susceptibility testing of the organism isolated from the disease processes in animals is indicated. Susceptibility testing is particularly necessary in those situations where the etiologic agent belongs to a bacterial species for which resistance to commonly used antimicrobial agents has been documented, or could arise.

醫療器材採認標準資料表

編號	DOH-000220
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS RS2-A
標準名稱	THE NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY (NRSCL) ASPARTATE AMINOTRANSFERASE (AST)
制定日期	October 1988
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Clinical reference material：ASPARTATE AMINOTRANSFERASE (AST)
簡要說明	APPROVED SUMMARY of Methods and Materials Credentialed by the Council of the NRSCL.

醫療器材採認標準資料表

編號	DOH-000221
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS RS3-A
標準名稱	THE NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY (NRSCL) CHOLESTEROL
制定日期	September 1987
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Clinical reference material：CHOLESTEROL
簡要說明	APPROVED SUMMARY of Methods and Materials Credentialed by the Council of the NRSCL.

醫療器材採認標準資料表

編號	DOH-000222
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS RS5-A2
標準名稱	THE NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY (NRSCL) TOTAL PROTEIN
制定日期	December 1993
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Clinical reference material：TOTAL PROTEIN
簡要說明	SECOND EDITION APPROVED SUMMARY OF METHODS AND MATERIALS CREDENTIALED BY THE COUNCIL OF THE NRSCL

醫療器材採認標準資料表

編號	DOH-000223
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS RS6-A
標準名稱	THE NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY (NRSCL) TOTAL BILIRUBIN
制定日期	July 1989
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Clinical reference material：TOTAL BILIRUBIN
簡要說明	APPROVED SUMMARY of Methods and Materials Credentialed by the Council of the NRSCL.

醫療器材採認標準資料表

編號	DOH-000224
標準分類	ABC. 體外檢驗醫療器材
標準號碼	NCCLS T/DM6-A
標準名稱	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997)
制定日期	September 1997
制定標準組織名稱	NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS (NCCLS)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Blood Alcohol Testing
簡要說明	T/DM6-A, Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline, is designed to aid the clinical laboratory in producing timely and accurate blood alcohol results. Its key objective is to address, as comprehensively as possible, recommendations to assure the integrity of the laboratory report on blood alcohol. The document conforms to the objective by addressing specimen collection, methods of analysis, quality assurance, and reporting and significance of results as separate sections. Statutory provisions are included as additional resource information.

醫療器材採認標準資料表

編號	DOH-000225
標準分類	3. 滅菌
標準號碼	ANSI/AAMI ST8:1994
標準名稱	Hospital steam sterilizers
制定日期	4 January 1994
制定標準組織名稱	The Association for the Advancement of Medical Instrumentation (**AAMI**)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Steam sterilizers used in health care facilities
簡要說明	This standard establishes minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent and have a volume greater than 2 cubic feet.

醫療器材採認標準資料表

編號	DOH-000226
標準分類	3. 滅菌
標準號碼	AOAC 6.2.02:2005, Official Method 991.47
標準名稱	Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Applicable to testing disinfectants miscible with H_2O to determine effectiveness of given bactericidal concentration using standard test strains under controlled conditions. Test results may not necessarily reflect a product's efficacy on a variety of inanimate surfaces or within specified environments. These microbiological methods are very sensitive and technique-oriented. Extra adherence to the method with identified critical control points, good microbiological techniques, good laboratory practices, and quality control are required for proficiency and for validity of results. It is essential that the glass carriers employed in these tests are discarded after one use. Do not reuse carriers.

醫療器材採認標準資料表

編號	DOH-000227
標準分類	3. 滅菌
標準號碼	AOAC 6.2.03:2005, Official Method 991.48
標準名稱	Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Applicable to testing disinfectants miscible with H_2O to determine effectiveness of given bactericidal concentration using standard test strains under controlled conditions. Test results may not necessarily reflect a product's efficacy on a variety of inanimate surfaces or within specified environments. These microbiological methods are very sensitive and technique-oriented. Extra adherence to the method with identified critical control points, good microbiological techniques, good laboratory practices, and quality control are required for proficiency and for validity of results. It is essential that the glass carriers employed in these tests are discarded after one use. Do not reuse carriers.

醫療器材採認標準資料表

編號	DOH-000228
標準分類	3. 滅菌
標準號碼	AOAC 6.2.05:2005, Official Method 991.49
標準名稱	Testing Disinfectants Against Pseudomonas aeruginosa, Hard Surface Carrier Test Method
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Applicable to testing disinfectants miscible with H_2O to determine effectiveness of given bactericidal concentration using standard test strains under controlled conditions. Test results may not necessarily reflect a product's efficacy on a variety of inanimate surfaces or within specified environments. These microbiological methods are very sensitive and technique-oriented. Extra adherence to the method with identified critical control points, good microbiological techniques, good laboratory practices, and quality control are required for proficiency and for validity of results. It is essential that the glass carriers employed in these tests are discarded after one use. Do not reuse carriers.

醫療器材採認標準資料表

編號	DOH-000229
標準分類	3. 滅菌
標準號碼	AOAC 6.3.02:2005, Official Method 955.17
標準名稱	Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Applicable for use with H_2O-miscible fungicides used to disinfect inanimate objects.

醫療器材採認標準資料表

編號	DOH-000230
標準分類	3. 滅菌
標準號碼	AOAC 6.3.05:2005, Official Method 966.04
標準名稱	Sporicidal Activity of Disinfectants
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Suitable for determining sporicidal activity of liquid and gaseous chemicals. Applicable to germicides for determining presence or absence of sporicidal activity against specified spore-forming bacteria in various situations and potential efficacy as sterilizing agent.

醫療器材採認標準資料表

編號	DOH-000231
標準分類	3. 滅菌
標準號碼	AOAC 6.3.06:2005, Official Method 965.12
標準名稱	Tuberculocidal Activity of Disinfectants
制定日期	2005
制定標準組織名稱	AOAC INTERNATIONAL
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Liquid chemical sterilants (high level disinfectants), general purpose disinfectants
簡要說明	Suitable for determining maximum tuberculocidal dilution of disinfectants used on inanimate surface. This method has not been validated for glutaraldehyde-based products.

醫療器材採認標準資料表

編號	DOH-000232
標準分類	3. 滅菌
標準號碼	ST50: 2004
標準名稱	Dry heat (heated air) sterilizers
制定日期	7 April, 2004
制定標準組織名稱	ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dry heat sterilizers used in health care facilities
簡要說明	This standard establishes minimum labeling and performance requirements for dry heat (heated air) sterilizers intended for use in dental and medical offices, laboratories, ambulatory-care clinics, hospitals, and other health care facilities.

醫療器材採認標準資料表

編號	DOH-000233
標準分類	3. 滅菌
標準號碼	CNS 14709
標準名稱	保健產品之滅菌－輻射滅菌確效與例行管制規定
制定日期	91 年 12 月 9 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	加馬射線、輻射的產生裝置
簡要說明	本標準適用於保健產品輻射滅菌的確效規定、程序控制與例行監測。適用於使用 鈷 60 與銫 137 核種的加馬連續型或批次型加馬射線的產生裝置，及適用於使用電子束或 X 射線等之輻射產生裝置。

醫療器材採認標準資料表

編號	DOH-000234
標準分類	3. 滅菌
標準號碼	CNS 14393-7
標準名稱	醫療器材生物性評估－第 7 部：環氧乙烷滅菌之殘留物
制定日期	94 年 3 月 25 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	以環氧乙烷滅菌處理之醫療器材
簡要說明	適用範圍：本標準規範以環氧乙烷滅菌之個別醫療器材上殘留環氧乙烷及 2-氯乙醇的可容許限制值、測定環氧乙烷及 2-氯乙醇的步驟、及判定器材符合標準可放行的方法。附錄中亦包含更多的背景數據及指引。 本標準不包括以環氧乙烷滅菌但不與人體接觸的器材，如體外用之診斷器材。

醫療器材採認標準資料表

編號	DOH-000235
標準分類	2. 生物相容性
標準號碼	CNS 14393-8
標準名稱	醫療器材生物性評估－第 8 部：生物測試用參考材料之選擇及資格認定
制定日期	94 年 3 月 25 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	生物測試用參考材料
簡要說明	本標準適用於測定材料之生物反應時所用的參考材料或已認可的參考材 料之必備條件。此規範專指生物測試用參考材料的選擇與資格認定及參考材料的特性，以便使用參考材料作為實驗對照組。

醫療器材採認標準資料表

編號	DOH-000236
標準分類	2. 生物相容性
標準號碼	CNS 14393-10
標準名稱	醫療器材生物性評估－第 10 部：刺激性及延遲型過敏性測試
制定日期	94 年 3 月 25 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	醫療器材及其組成材料
簡要說明	本標準規定醫療器材及其組成材料潛在產生刺激及延遲過敏反應之評估程序，包括： (a) 測試前之考量 (b) 詳細之試驗步驟 (c) 詮釋結果之主要參數 備考 1. 附錄 A 特別針對與上述測試方法相關之材料製備， 提供指導。 2. 附錄 B 提供特別針對以皮內方式應用於眼、口、直腸、陰莖、及陰道等部位之器材， 所可能被要求之補充測試方法。

醫療器材採認標準資料表

編號	DOH-000237
標準分類	2. 生物相容性
標準號碼	CNS 14393-12
標準名稱	醫療器材生物性評估－第 12 部：樣品製備及參考材料
制定日期	94 年 3 月 25 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	生物測試用器材與材料
簡要說明	適用範圍： 本標準用以規範醫療器材依照 CNS 14393 系列進行生物測試時，應遵循之醫療器材樣品製備程序及參考材料選擇之規定與指引。 本標準闡述之範圍包括： — 測試材料的選擇； — 器材代表部位的選擇； — 試樣的製備； — 實驗對照組； — 參考材料的選擇及其規定； — 萃出物的製備。

醫療器材採認標準資料表

編號	DOH-000238
標準分類	2. 生物相容性
標準號碼	CNS 14393-6
標準名稱	醫療器材生物性評估—第六部分：植入後的局部效應測試
制定日期	93 年 4 月 20 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	各類別醫療用植入物
簡要說明	本標準規定測試方法來評估植入物在活體組織內，在巨觀和微觀層次上所造成的局部效應。 將試樣植入適合作材料生物安全性評估的位置和組織。此植入物不受機械性或功能性負載。局部反應之評估為比較試樣與在臨床上使用的材料所引起的組織反應。 本方法用來測試植入後所造成的局部反應，以評估亞慢性(短期，12 週以下)或慢性 (長期，12 週以上)植入效應。

醫療器材採認標準資料表

編號	DOH-000239
標準分類	2. 生物相容性
標準號碼	CNS 14393-11
標準名稱	醫療器材生物評估－第 11 部：全身毒性測試
制定日期	94 年 3 月 25 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	醫療器材組成之原料
簡要說明	本標準適用於醫療器材的組成成分釋放到人體中可能造成的全身毒性的評估方法。此標準亦包含熱原性測試。 備考：本標準主要針對實際產品以及其溶出物。本標準之測試是採用合適的萃取溶媒以得到最大量的溶出材料萃取液，來進行生物試驗。

醫療器材採認標準資料表

編號	DOH-000240
標準分類	F. 牙科裝置
標準號碼	ISO 1562
標準名稱	Dental casting gold alloys
制定日期	December 1, 1993
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Gold based alloys and precious metal alloys for clinical use
簡要說明	This International Standard gives the classification of, and specifies requirements and test methods for gold-based dental casting alloys with a content of at least 75 % (m/m) of gold and platinum group metals. lt applies to casting alloys suitable for the fabrication of dental restorations and appliances. lt does not apply to alloys intended for use as the substructure of a metallo-ceramic restoration, which is covered by ISO 9693; nor does it apply to dental casting alloys with noble metal content of 25 % up to but not including 75 %, which are covered by ISO 8891.

醫療器材採認標準資料表

編號	DOH-000241
標準分類	F. 牙科裝置
標準號碼	ISO 1563
標準名稱	Dental alginate impression material
制定日期	September 1, 1990
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental alginate impression materials
簡要說明	This International Standard applies to dental alginate impression materials used in dentistry to take impressions of teeth and tissues of the oral cavity. lt specifies requirements for dental materials containing an alginate as essential gel-forming ingredient, which, after mixing with water in accordance with the manufacturer's instructions, is capable of reacting to form a material suitable for taking impressions.

醫療器材採認標準資料表

編號	DOH-000242
標準分類	F. 牙科裝置
標準號碼	ISO 1564
標準名稱	Dental aqueous impression materials based on agar
制定日期	November 1, 1995
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental impression materials
簡要說明	This International Standard specifies requirements for essential physical properties and other characteristics of impression materials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements. lt also specifies requirements with respect to the manufacturer's instructions, and the essentials for packaging, labeling and marking.

醫療器材採認標準資料表

編號	DOH-000244
標準分類	F. 牙科裝置
標準號碼	ISO 6871-1
標準名稱	Dental base metal casting alloys - Part 1: Cobalt-based alloys
制定日期	September 15, 1994
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Cobalt-based dental casting alloys
簡要說明	This part of ISO 6871 specifies requirements and test methods for cobalt-based dental casting alloys suitable for use in fabrication of removable dental appliances. It does not apply to alloys intended for use in fabrication of metal-ceramic dental restorations.

醫療器材採認標準資料表

編號	DOH-000245
標準分類	F. 牙科裝置
標準號碼	ISO 6871-2
標準名稱	Dental base metal casting alloys
制定日期	September 15, 1994
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental base metal casting alloys
簡要說明	This part of IS0 6871 specifies requirements and test methods for nickel-based dental casting alloys suitable for use in fabrication of removable dental appliances. It does not apply to alloys intended for use in fabrication of metal-ceramic dental restorations.

醫療器材採認標準資料表

編號	DOH-000246
標準分類	F. 牙科裝置
標準號碼	ISO 6872
標準名稱	Dental ceramic AMENDMENT 1
制定日期	June 15, 1998
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Porcelain teeth, porcelain powder for clinical use
簡要說明	This International Standard specifies the requirements and the corresponding test methods for dental ceramic materials for all fixed ceramic restorations.

醫療器材採認標準資料表

編號	DOH-000247
標準分類	F. 牙科裝置
標準號碼	ISO 6874
標準名稱	Dental resin-based pit and fissure sealants
制定日期	June 15, 1988
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental resin based pit and fissure sealant
簡要說明	This International Standard specifies requirements and test methods for resin-based materials suitable for sealing pits and fissures in teeth. This International Standard covers both chemically cured and external-energy-cured materials.

醫療器材採認標準資料表

編號	DOH-000248
標準分類	F. 牙科裝置
標準號碼	ISO 6876
標準名稱	Dental root canal sealing materials
制定日期	August 15, 2001
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Root canal filling resin
簡要說明	This International Standard specifies requirements and test methods for root canal sealing materials which set with and without the assistance of moisture and are used for permanent obturation of the root canal, with or without the aid of obturating points. It is applicable only to sealers intended for orthograde use, i.e. a root filling placed from the coronal aspect of a tooth.

醫療器材採認標準資料表

編號	DOH-000249
標準分類	F. 牙科裝置
標準號碼	ISO 6877
標準名稱	Dental root-canal obturating points
制定日期	June 1, 1995
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Root canal filling resin, gutta percha, endodontic silver points
簡要說明	This International Standard specifies the dimensions and compositional requirements for prefabricated metallic or polymeric-based points or cones suitable for use in the obturation of the dental root-canal, but not for support of a coronal restoration. It also specifies numerical systems and a colour coding system for designating the sizes.

醫療器材採認標準資料表

編號	DOH-000250
標準分類	F. 牙科裝置
標準號碼	ISO 10477:1998
標準名稱	Dentistry – Polymer-based crown and bridge materials
制定日期	March 2001
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Tooth shade resin material, temporary crown and bridge material
簡要說明	ISO 10477classifies polymer-based dental crown and bridge materials and specifies their requirements. It also specifies the test methods to be used to determine compliance with these requirements. ISO 10477 is applicable to polymer-based dental crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns that may or may not be attached to a metal substructure. It also applies to polymer-based dental crown and bridge materials for which the manufacturer claims adhesion to the metal substructure without macromechanical retention such as beads or wires. ISO 10477 is not applicable to polymer-based materials that are used to make crowns, veneers or repairs in the operatory, nor does it cover the application of those materials to stress-bearing areas of posterior teeth.

醫療器材採認標準資料表

編號	DOH-000251
標準分類	F. 牙科裝置
標準號碼	ISO 11498:2000
標準名稱	Dental handpieces -- Dental low-voltage electrical motors
制定日期	February 15, 1997
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Low voltage electric motors used with handpieces
簡要說明	Gives requirements and test methods for dental low-voltage electrical motors used in connection with dental handpieces. It also contains specifications on manufacturer's instructions, packaging and marking. Refers to IEC 601-1, the basic standard on safety of medical electrical equipment

醫療器材採認標準資料表

編號	DOH-000252
標準分類	F. 牙科裝置
標準號碼	ISO 13294
標準名稱	Dental handpieces - Dental air-motors
制定日期	May 1, 1997
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Air powered handpieces, dental operative units
簡要說明	This International Standard specifies requirements and test methods for dental air-motors, operated by dental units, and used for straight and geared angle handpieces for application on patients. It also contains specifications on manufacturer's instructions, marking and packaging. This International Standard refers to IEC 601 -1 :1988, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 601-1 :1988. This International Standard takes priority over IEC 601-1:1988 as specified in the individual clauses of this International Standard. Only the specifications laid down in this International Standard are applicable.

醫療器材採認標準資料表

編號	DOH-000253
標準分類	F. 牙科裝置
標準號碼	ISO 8891
標準名稱	Dental casting alloys with noble metal content of at least 25% but less than 75%
制定日期	December 15, 1998
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Base metal alloys, gold-based alloys and precious metal alloys for clinical use.
簡要說明	This International Standard gives the classification of, and specifies requirements and test methods for, dental casting alloys with a noble metal content of at least 25 % (mass fraction) up to but not including 75 % (mass fraction). It applies to casting alloys suitable for the fabrication of dental restorations and appliances.

醫療器材採認標準資料表

編號	DOH-000254
標準分類	F. 牙科裝置
標準號碼	ISO 9693
標準名稱	Metal-ceramic dental restorative systems
制定日期	December 15, 1999
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Base metal alloys, gold based alloys and precious metal alloys for clinical use, porcelain teeth, porcelain powder for clinical use, endosseous implant for prosthetic attachment
簡要說明	This International Standard specifies requirements and test methods for dental metallic materials processed by casting or machining, and for ceramics suitable for use in the fabrication of metal-ceramic dental restorations, together with requirements and test methods for the composite structure. The requirements of this International Standard apply to the metallic materials and ceramics when used in combination, and compliance may not be claimed for either metallic materials or for ceramics alone.

醫療器材採認標準資料表

編號	DOH-000255
標準分類	F. 牙科裝置
標準號碼	ISO 9917-2
標準名稱	Dental water-based cements — Part 2: Light-activated cements
制定日期	Jul 1, 1998
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental water based cements, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.
簡要說明	This part of ISO 9917 specifies requirements for dental cements, including hand-mixed, encapsulated cements used for mechanical mixing and one-component materials, which are intended for base, lining and restoration purposes and for which the materials are water-based and set by multiple reactions which include an acid-base reaction and polymerization.

醫療器材採認標準資料表

編號	DOH-000256
標準分類	F. 牙科裝置
標準號碼	ISO 13716
標準名稱	Dentistry — Reversible-irreversible hydrocolloid impression material systems
制定日期	May 1, 1999
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Impression Material
簡要說明	This international Standard specifies requirements and test methods for tensile bond strength and linear dimensional change of reversible-irreversible hydrocolloid impression materials used in dentistry, as well as requirements for their labelling and manufacturer's instructions. This International Standard is applicable to those alginate and syringeable agar dental impression materials which have been formulated such that they will bond to each other, when used in combination, to provide elastic impressions of oral tissues.

醫療器材採認標準資料表

編號	DOH-000257
標準分類	F. 牙科裝置
標準號碼	ISO 9917-1
標準名稱	Dental materials - Water-based cements - Part 1: Powder / liquid acid-base cements
制定日期	May 13, 2002
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental water based cements, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.
簡要說明	This International Standard specifies requirements and test methods for powderkquid acid-base dental cements intended for permanent cementation, lining and restoration. This International Standard is applicable to both hand-mixed and capsulated cements for mechanical mixing. This International Standard specifies limits for each of the properties according to whether the cement is intended for use as a luting agent, a restorative material, a base or a liner.

醫療器材採認標準資料表

編號	DOH-000258
標準分類	F. 牙科裝置
標準號碼	ISO 10139-1
標準名稱	Dentistry - Resilient lining materials for removable dentures – Part 1: Short-term materials
制定日期	December 1, 1991
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	OTC denture reliner
簡要說明	This part of IS0 10139 specifies requirements for the physical properties, test methods, packaging, marking and manufacturer's instructions for denture lining materials suitable for short-term use.

醫療器材採認標準資料表

編號	DOH-000259
標準分類	F. 牙科裝置
標準號碼	ISO 10139-2
標準名稱	Dentistry — Soft lining materials for removable dentures —Part 2: Materials for long-term use
制定日期	October 15, 1999
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	OTC Denture Reliner
簡要說明	This part of ISO 10139 specifies requirements for softness and elasticity of soft denture lining materials suitable for long-term use.

醫療器材採認標準資料表

編號	DOH-000260
標準分類	F. 牙科裝置
標準號碼	ISO 7494-1
標準名稱	Dentistry — Dental units — Part 1: General requirements and test methods
制定日期	November 1, 2004
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental Air and Water Supply Units
簡要說明	This part of ISO 7494 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered. It also specifies requirements for manufacturer's instructions, marking and packaging. This part of ISO 7494 is one of a series of International Standards based on IEC 60601-1; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in IEC 60601-1:1988, 1.3, the requirements of this part of ISO 7494 take precedence over those of IEC 60601-1.

醫療器材採認標準資料表

編號	DOH-000261
標準分類	5.材料
標準號碼	ISO 14708-1: 2000
標準名稱	Implants for surgery — Active implantable medical devices —Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
制定日期	November 15, 2000
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Implants for surgery
簡要說明	This part of ISO 14708 specifies requirements that are generally applicable to active implantable medical devices. The tests that are specified in this part of ISO 14708 are type tests intended to be carried out on samples of a device to show compliance, and are not intended to be used for the routine testing of manufactured products. This part of ISO 14708 is applicable not only to active implantable medical devices that are electrically powered, but also to those powered by other energy sources (for example gas pressure or springs). This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see 3.3).

醫療器材採認標準資料表

編號	DOH-000262
標準分類	D. 麻醉學用裝置
標準號碼	F 1850–00
標準名稱	Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components
制定日期	March 2000
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Anesthesiology devices, such as gas-machine, mixer, breathing gases, anesthesia inhalation, Alarm Protection, etc.
簡要說明	This specification covers minimum safety requirements for an ANESTHESIA WORKSTATION.

醫療器材採認標準資料表

編號	DOH-000263
標準分類	F. 放射科學用裝置
標準號碼	BS EN 60601-2-7: 1998
標準名稱	Medical electrical equipment - Part 2-7: Particular requirements for safety - Specification for high voltage generators of diagnostic X-ray generators
制定日期	April 1998
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Diagnostic X-ray High Voltage Generator
簡要說明	This Particular Standard applies to HIGH-VOLTAGE GENERATORS of medical diagnostic X-RAY GENERATORS and to their subassemblies including the following: - HIGH-VOLTAGE GENERATORS that are integrated with an X-RAY TUBE ASSEMBLY; - HIGH-VOLTAGE GENERATORS Of radiotherapy treatment simulators. Where appropriate, requirements for X-RAY GENERATORS are given but only where these concern the functioning of the associated HIGH-VOLTAGE GENERATOR. This standard excludes - CAPACITOR DISCHARGE HIGH-VOLTAGE GENERATORS (these are covered by IEC 60601 -2-1 5) - HIGH-VQLTAGE GENERATORS for mammography, - HIGH-VOLTAGE GENERATORS for RECONSTRUCTIVE TOMOGRAPHY.

醫療器材採認標準資料表

編號	DOH-000264
標準分類	F. 放射科學用裝置
標準號碼	BS EN 60601-2-9:1997
標準名稱	Medical electrical equipment — Part 2: Particular requirements for safety — Section 2.9 Specification for patient contact dosemeters used in radiotherapy with electrically connected radiation detectors
制定日期	June 15, 1997
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Radiation Therapy Systems
簡要說明	This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY DOSEMETERS intended for use in physical contact with a PATIENT.

醫療器材採認標準資料表

編號	DOH-000265
標準分類	D. 麻醉學用裝置
標準號碼	F 920 – 93
標準名稱	Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans
制定日期	May 1993.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Manually-Powered Ventilatory Resuscitators Intended for Emergency Use Both Outside and Inside Hospitals.
簡要說明	This specification covers ventilatory resuscitators, that is, small portable ventilators intended to be used in emergencies both outside and inside hospitals. These devices are intended for use by medical personnel and for emergency use by personnel with varying degrees of training. They are intended to be used at the site of an emergency and during patient transport. Resuscitators intended for use on all age groups are included within the scope of this specification.

醫療器材採認標準資料表

編號	DOH-000266
標準分類	D. 麻醉學用裝置
標準號碼	F 1100 – 90
標準名稱	Standard Specification for Ventilators Intended for Use in Critical Care[1]
制定日期	June 1990
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Ventilators and ventilation circuits intended for use with adult, child, or infant patients in critical care excluding body ventilators (chest cuirass); ventilators utilizing the Sanders technique or "jet" ventilation (venturi effect type), high frequency ventilators (greater than 2.5 Hz), anesthesia ventilators, transport ventilators, and home care ventilators.
簡要說明	This specification establishes minimum performance and safety requirements for all ventilators and ventilator circuits intended for use with adult, child, or infant patients in critical care within the hospital and introduced for sale after the acceptance date of this specification, except as noted below. Definitions, performance requirements, test methods, and rationale are included. Several definitions have been included in Section 3.1 and Appendix X1 that are not used in the text of this specification. This material has been included for the sake of completeness, and for any possible educational benefit that may be served.

醫療器材採認標準資料表

編號	DOH-000267
標準分類	F. 放射科學用裝置
標準號碼	ISO 2919
標準名稱	Radiation protection — Sealed radioactive sources —General requirements and classification
制定日期	1999-02-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Sealed Radioactive Sources
簡要說明	This International Standard establishes a system of classification of sealed radioactive sources based on test performance and specifies general requirements, performance tests, production tests, marking and certification. It provides a set of tests by which the manufacturer of sealed radioactive sources can evaluate the safety of his products in use and by which the user of such sources can select types which are suitable for the required application, especially where protection against the release of radioactive material, with consequent exposure to ionizing radiation, is concerned. This International Standard may also be of guidance to regulating authorities. The tests fall into several groups, including, for example, exposure to abnormally high and low temperatures, and a variety of mechanical tests. Each test can be applied in several degrees of severity. The criterion of pass or fail depends on leakage of the contents of the sealed radioactive source.

醫療器材採認標準資料表

編號	DOH-000268
標準分類	F. 放射科學用裝置
標準號碼	BS EN 60731: 1997
標準名稱	Medical electrical equipment — Dosimeters with ionization chambers as used in radiotherapy
制定日期	December 15, 1997
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Radiation Therapy Devices
簡要說明	This International Standard is applicable to the performance of DOSIMETERS with IONIZATION CHAMBERS as used in radiotherapy.

醫療器材採認標準資料表

編號	DOH-000269
標準分類	D. 麻醉學用裝置
標準號碼	F 1101–90
標準名稱	Standard Specification for Ventilators Intended for Use During Anesthesia[1]
制定日期	December 2003.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Anesthesia Gas Machines
簡要說明	This specification applies to all ventilators specifically introduced for sale following acceptance of this specification and intended for use during the administration of anesthesia. Definitions, performance requirements, test methods, and a rationale for all mandatory requirements are included.

醫療器材採認標準資料表

編號	DOH-000270
標準分類	F. 放射科學用裝置
標準號碼	G 175–03
標準名稱	Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications
制定日期	May 2003
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Oxygen Regulators, Oxygen Conserving devices that incorporate an integral regulator
簡要說明	This standard describes a test method for evaluating the ignition sensitivity and fault tolerance of oxygen regulators used for medical and emergency applications.

醫療器材採認標準資料表

編號	DOH-000271
標準分類	F. 放射科學用裝置
標準號碼	F 1456–01
標準名稱	Standard Specification for Minimum Performance and Safety Requirements for Capnometers
制定日期	December 2001
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Capnometers intended for use in the measurement of carbon dioxide concentration or partial pressure in ventilatory gases of adults, children, and neonates. Capnometers solely intended for use as cutaneous monitors and capnometers intended for use in laboratory research applications, and capnometers intended for use with flammable anesthetic mixtures are outside the scope of this specification.
簡要說明	This specification establishes minimum safety and performance requirements for capnometers based on parameters that are achievable within the limits of existing technology.

醫療器材採認標準資料表

編號	DOH-000272
標準分類	F. 放射科學用裝置
標準號碼	EN 60601-2-45
標準名稱	Medical electrical equipment Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
制定日期	July 2001
制定標準組織名稱	British Standards Institution
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Mammographic X-ray Equipment
簡要說明	This Particular Standard contains requirements for the safety of X-RAY EQUIPMENT designed for mammography and MAMMOGRAPHIC STEREOTACTIC DEVICES. The Safety requirements for the X-RAY GENERATOR and its sub-assemblies form an integral part of this standard.

醫療器材採認標準資料表

編號	DOH-000273
標準分類	F. 放射科學用裝置
標準號碼	BS EN 60601-2-22: 1996
標準名稱	Medical electrical equipment —Part 2: Particular requirements for safety— Section 2.122 Specification for diagnostic and therapeutic laser equipment
制定日期	January 1996
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Applies to laser equipment for medical applications, classified as a class 3B or a class 4 laser product according to the classification in IEC 60825-1.
簡要說明	The object of this Particular Standard is to specify particular requirements for the safety of LASER EQUIPMENT for medical applications classified as a CLASS 3B or CLASS 4 LASER PRODUCT.

醫療器材採認標準資料表

編號	DOH-000274
標準分類	F. 放射科學用裝置
標準號碼	ISO 11810-1
標準名稱	Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers —Part 1: Primary ignition and penetration
制定日期	2005-02-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Surgical drapes claiming laser resistance.
簡要說明	This part of ISO 11810 is intended for use in testing a surgical drape or other patient protective cover that claims to be laser-resistant. In addition, areas within this product may vary in material composition or design. Depending on the claims being made by the manufacturer or end-user requirements, all areas for which laser resistance is claimed may need to be tested.

醫療器材採認標準資料表

編號	DOH-000275
標準分類	F. 放射科學用裝置
標準號碼	IEC 61674
標準名稱	Amendment 1 Medical electrical equipment -Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging
制定日期	2002-06
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	DOSIMETERS USED IN X-RAY DIAGNOSTIC IMAGING
簡要說明	This International Standard is applicable to the performance of DOSIMETERS with IONIZATION CHAMBERS and/or SEMI-CONDUCTOR DETECTORS as used in X-ray diagnostic imaging.

醫療器材採認標準資料表

編號	DOH-000276
標準分類	F. 放射科學用裝置
標準號碼	ISO 11146-1
標準名稱	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams
制定日期	2005-01-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	This standard, which specifies methods for measuring beam widths (diameters), divergence angles and beam propagation factors for laser beams, is applicable to devices for which these parameters must be known for the safe operation of the device.
簡要說明	This part of ISO 11146 describes the measurement methods for stigmatic and simple astigmatic beams while Part 2 deals with the measurement procedures for general astigmatic beams. For beams of unknown type the methods of Part 2 shall be applied. Beam characterization based on the method of second order moments as described in both parts is only valid within the paraxial approximation.

醫療器材採認標準資料表

編號	DOH-000277
標準分類	F. 放射科學用裝置
標準號碼	ISO 11254-1
標準名稱	Laser and laser-related equipment —Determination of laser-induced damage threshold of optical surfaces —Part 1: 1-on-1 test
制定日期	2000-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	This standard, which specifies a test method for determining the single-shot laser-radiation induced damage threshold of optical surfaces, is applicable to devices for which this parameter must be known to ensure the continued safe operation of the device.
簡要說明	This part of ISO 11254 describes a standard procedure for determining the laser-induced damage threshold (LIDT) of optical surfaces, both coated and uncoated. The procedure has been promulgated in order to provide a method for obtaining consistent measurement results, which may be rapidly and accurately compared among different testing laboratories. In order to simplify the comparison of laser-damage measurement facilities, laser groups are defined in this part of ISO 11254.

醫療器材採認標準資料表

編號	DOH-000278
標準分類	F. 放射科學用裝置
標準號碼	ISO 11254-2
標準名稱	Lasers and laser-related equipment — Determination of laser-induced damage threshold of optical surfaces — Part 2: S-on-1 test
制定日期	2001-09-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	This standard, which specifies a test method for determining the laser-radiation induced damage threshold of optical surfaces subjected to a succession of similar laser pulses, is applicable to devices for which this parameter must be known to ensure the continued safe operation of the device.
簡要說明	In this part of ISO 11254, two evaluation methods are described for the reduction of raw data of a damage test. The characteristic damage curve method is based on a large number of S-on-1 test sites on the optical surface of the specimen. The characteristic damage curve comprises a set of three graphs indicating energy density values with damage probability values of 10 %, 50 % and 90 % for a selected number of pulses. The characteristic damage curve represents the results of a complete and extended laser-induced damage test, and it is recommended for basic investigations in newly developed or critical laser optics.

醫療器材採認標準資料表

編號	DOH-000279
標準分類	F. 放射科學用裝置
標準號碼	ISO 11551
標準名稱	Optics and optical instruments — Lasers and laser-related equipment — Test method for absorptance of optical laser components
制定日期	2003-12-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment
簡要說明	This standard, which specifies procedures and techniques for obtaining comparable values for the absorptance of optical laser components, is applicable to devices for which this parameter must be known to ensure the continued safe operation of the device.

醫療器材採認標準資料表

編號	DOH-000280
標準分類	F. 放射科學用裝置
標準號碼	BS EN ISO 11554:2003
標準名稱	Optics and optical instruments - Lasers and laser-related equipment - Test methods for laser beam power, energy and temporal characteristics
制定日期	April 2003
制定標準組織名稱	British Standards Institution
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment
簡要說明	This International Standard specifies test methods for determining the power and energy of continuous-wave and pulsed laser beams, as well as their temporal characteristics of pulse shape, pulse duration and pulse repetition rate. Test and evaluation methods are also given for the power stability of cw-lasers, energy stability of pulsed lasers and pulse duration stability. The test methods given in this International Standard are to be used for the testing and characterization of lasers.

醫療器材採認標準資料表

編號	DOH-000281
標準分類	F. 放射科學用裝置
標準號碼	ISO 11670
標準名稱	Lasers and laser-related equipment —Test methods for laser beam parameters — Beam positional stability
制定日期	2003-04-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment
簡要說明	This International Standard specifies methods for determining laser beam positional as well as angular stability. The test methods given in this International Standard are intended to be used for the testing and characterization of lasers.

醫療器材採認標準資料表

編號	DOH-000282
標準分類	F. 放射科學用裝置
標準號碼	ISO 12005
標準名稱	Lasers and laser-related equipment —Test methods for laser beam parameters — Polarization
制定日期	2003-04-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment
簡要說明	This standard, which specifies a test method for determining the polarization status and, whenever possible, the degree of polarization of the laser beam of a continuous-wave laser, is applicable to devices for which this parameter must be known to ensure the safe operation of the device. This standard may also be applied to repetitively pulsed lasers, if the electric field vector orientation does not change from pulse to pulse.

醫療器材採認標準資料表

編號	DOH-000283
標準分類	F. 放射科學用裝置
標準號碼	ISO 13696
標準名稱	Optics and optical instruments — Test methods for radiation scattered by optical components
制定日期	2004-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	This standard, which specifies procedures for the determination of the total scattering by coated and uncoated optical surfaces, is applicable to devices for which this parameter must be known to ensure the safe operation of the device.
簡要說明	This International Standard describes a testing procedure for the corresponding quantity, the total scattering (TS) value, which is defined by the measured values of backward scattering and forward scattering. The measurement principle described in this International Standard is based on an Ulbricht sphere as the integrating element for scattered radiation. An alternative apparatus with a Coblentz hemisphere, which is also frequently employed for collecting scattered light, is described in annex A. Currently, advanced studies on the comparability and the limitations of both light collecting elements are being performed (e.g. round robin tests, EUREKA-project EUROLASER: CHOCLAB).

醫療器材採認標準資料表

編號	DOH-000284
標準分類	F. 放射科學用裝置
標準號碼	14509-3
標準名稱	醫電設備電性安全-第一部分:一般安全規定-附屬標準 3:診斷用 X 射線設備輻射防護之一般規定
制定日期	90 年 1 月 30 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	診斷用 X 射線設備
簡要說明	本附屬標準適用於醫療診斷用X射線設備與此設備的次組合。

醫療器材採認標準資料表

編號	DOH-000285
標準分類	1.通用
標準號碼	ISO 14155-1
標準名稱	Clinical investigation of medical devices for human subjects —Part 1: General requirements
制定日期	2003-02-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	All kinds of medical devices
簡要說明	This part of ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfil the technical aspects of the various national, regional and international regulatory requirements. As the legal regulatory requirements presently differ throughout the world, regulatory specifics have been excluded from the scope of this part of ISO 14155. They are part of national or regional legislative texts and can be referenced in the national or regional forewords, as appropriate.

醫療器材採認標準資料表

編號	DOH-000286
標準分類	General
標準號碼	ISO 14155-2
標準名稱	Clinical investigation of medical devices for human subjects —Part 2: Clinical investigation plans
制定日期	2003-05-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	All kinds of medical devices
簡要說明	This standard is the second part of EN ISO 14155 "Clinical investigation of medical devices for human subjects", and should be read in conjunction with that standard. The standard is intended to assist manufacturers, sponsors, monitors and clinical investigators in the design and conduct of clinical investigations. It is also intended to assist regulatory bodies and ethics committees in their roles of reviewing Clinical Investigation Plans (CIP). The CIP is a framework within which appropriate experience, insight, judgement, qualification and education need to be applied. The scientific rigour of a CIP can be verified and possibly improved by an independent review of the CIP.

醫療器材採認標準資料表

編號	DOH-000287
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 595/1
標準名稱	Reusable all-glass or metal-and-glass syringes for medical use - Part 1: Dimensions
制定日期	1988-05-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	All glass, reusable luer taper syringes
簡要說明	This part of ISO 595 specifies dimensions for reusable all-glass or metal-and-glass syringes for medical use, having a graduated capacity from 1 to 100 ml. It also specifies requirements for the graduated capacity of syringes. ISO 595/2 specifies the design, the Performance requirements and the corresponding test methods for reusable syringes.

醫療器材採認標準資料表

編號	DOH-000288
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 595-2
標準名稱	Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, Performance requirements and tests
制定日期	1987-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	All reusable luer taper glass syringes
簡要說明	This International Standard on reusable syringes for medical use comprises two Parts: ISO 595-1 covers the dimensions and details of the scale and ISO 595-2 (this part of ISO 595) covers design, Performance and test methods. This part of ISO 595 specifies the design, performance and the corresponding test methods for reusable syringes having a graduated capacity from 1 to 100 ml, for general medical use. This part of ISO 595 is applicable to syringes of all-glass and metal-and-glass construction.

醫療器材採認標準資料表

編號	DOH-000289
標準分類	J. 一般醫院及個人使用裝置
標準號碼	IS0 7864
標準名稱	Sterile hypodermic needles for single use
制定日期	1993-05-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	All Hypodermic Needles
簡要說明	This International Standard covers sterile hypodermic needles intended for single use primarily in humans. This International Standard does not give requirements or test methods or freedom from biological hazard because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological tests relevant to hypodermic needles is given in **IS0 10993-1,** and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the needles are sterilized. However, national regulations may exist in some countries, and these will override the guidance in IS0 **10993-1.**

醫療器材採認標準資料表

編號	DOH-000290
標準分類	J. 一般醫院及個人使用裝置
標準號碼	BS EN 60601-2-19
標準名稱	Medical electrical equipment — Part 2: Particular requirements for safety — Specification for baby incubators
制定日期	December 1996
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Include all infant incubators except transport incubators
簡要說明	This Particular Standard concerns the safety of baby incubators. It amends and supplements IEC 601-1 (second edition 1988): Medical electrical equipment — Part 1: General requirements for safety.

醫療器材採認標準資料表

編號	DOH-000291
標準分類	J. 一般醫院及個人使用裝置
標準號碼	BS EN 60601-2-2:2001
標準名稱	Medical electrical equipment -Part 2-2: Particular requirements for the safety of high frequency surgical equipment
制定日期	November 2000
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Electrosurgical Devices
簡要說明	This Particular Standard specifies requirements for the safety of HIGH FREQUENCY SURGICAL EQUIPMENT used in medical practice, as defined in 2.1.101 and hereinafter referred to as HF SURGICAL EQUIPMENT.

醫療器材採認標準資料表

編號	DOH-000292
標準分類	J. 一般醫院及個人使用裝置
標準號碼	D 5151 – 99
標準名稱	Standard Test Method for Detection of Holes in Medical Gloves
制定日期	June 1999.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Surgical and Examination Gloves
簡要說明	This test method covers the detection of holes in medical gloves. This test method is limited to the detection of holes that allow water leakage under the conditions of the test. The smallest hole size that will allow water leakage in a medical glove has not been determined and is beyond the scope of this test method. The safe and proper use of medical gloves is beyond the scope of this test method. The values stated in SI units are to be regarded as standard.

醫療器材採認標準資料表

編號	DOH-000293
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 9626
標準名稱	Stainless steel needle tubing for the manufacture of medical devices - AMENDMENT 1
制定日期	2001-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Hypodermic Single Lumen Needles
簡要說明	The purposes of this amendment are to: a) add specifications for normal- and thin-walled tubing of metric sizes 0,2 mm, 0,23 mm and 0,25 mm to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use; b) add minimum inside diameters for thin-walled tubing of metric sizes 0,3 mm to 0,36 mm, as these data are now available; c) revise the maximum outside diameter of 0,6 mm metric size tubing to reflect current manufacturing practice; d) delete the maximum inside diameter of all types of tubing, as this value is not needed to discriminate between normal-, thin- and extra-thin-walled tubing; e) revise the means of specifying the steels to be used, as a result of the withdrawal of IS0 683-13. For clarity in this amendment, the revised values in the new Tables 2, 3 and 4 are given in boldface type.

醫療器材採認標準資料表

編號	DOH-000294
標準分類	J. 一般醫院及個人使用裝置
標準號碼	E 1112 – 00
標準名稱	Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
制定日期	August 2000
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Clinical Electronic thermometers including contact tympanic thermometers but exclude Infra red thermometers
簡要說明	This specification covers electronic instruments intended for intermittent monitoring of patient temperatures. This specification does not cover infrared thermometers. Specification E 1965 covers specifications for IR thermometers. The values stated in SI units are to be regarded as the standard.

醫療器材採認標準資料表

編號	DOH-000295
標準分類	J. 一般醫院及個人使用裝置
標準號碼	D 6124 – 01
標準名稱	Standard Test Method for Residual Powder on Medical Gloves
制定日期	September 2001.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Surgical & Examination Gloves
簡要說明	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves. This standard consists of two test methodologies. Procedure I is a method for the quantification of residual powder on gloves described as non-powdered, powder-free, powderless, no powder, or other words to that effect. Procedure II is a test method for the quantitation of powder (and other filter-retained mass) on powdered gloves.

醫療器材採認標準資料表

編號	DOH-000296
標準分類	J. 一般醫院及個人使用裝置
標準號碼	D 3578 – 01ae2
標準名稱	Standard Specification for Rubber Examination Gloves
制定日期	January 2002.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Rubber Examination Gloves
簡要說明	This specification describes certain requirements for natural rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures. It also covers natural rubber gloves used in handling contaminated medical material. This specification provides for natural rubber gloves that fit either hand, paired gloves, and gloves by size. It also provides for packaged sterile natural rubber gloves and packaged or bulk nonsterile natural rubber gloves.

醫療器材採認標準資料表

編號	DOH-000297
標準分類	J. 一般醫院及個人使用裝置
標準號碼	D 3577 – 01a$^{\varepsilon 2}$
標準名稱	Standard Specification for Rubber Surgical Gloves
制定日期	January 2002.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Rubber Surgical Gloves
簡要說明	This specification describes certain requirements for packaged sterile rubber surgical gloves used in conducting surgical procedures.

醫療器材採認標準資料表

編號	DOH-000298
標準分類	J. 一般醫院及個人使用裝置
標準號碼	CNS 14775
標準名稱	醫用面罩材料細菌過濾效率試驗法— 使用金黃色葡萄球菌生物氣霧
制定日期	92 年 10 月 9 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	醫用面罩，如外科手術面罩、氧氣面罩、麻醉氣體面罩...等
簡要說明	本標準規定量測醫用面罩材料細菌過濾效率的試驗法，由過濾前之細菌量和過濾後之細菌殘存量之比值評估醫用面罩材料的細菌過濾效率。 備考 1. 本測試法可檢測醫用面罩材料的過濾效率至 99.9%。 2. 本測試法並不適用生物氣霧曝露的所有形式或狀態。測試者應檢視穿戴者的曝露模式並且評估出最合適測試者的測試方式。 3. 本測試法主要用來評估使用在醫用面罩其組合材料功能，而不探討面罩的設計、合適性和臉部的密合度性質，所以量測出相對高的細菌過濾效率之特殊醫用面罩材料，並不能確定穿戴者能免受生物氣霧傳染。 4. 本標準未規範所有與使用相關的安全規定，使用者須在使用前建立適當的安全和衛生程序，並判斷一般使用時之限制。

醫療器材採認標準資料表

編號	DOH-000299
標準分類	J. 一般醫院及個人使用裝置
標準號碼	D 3772 – 01
標準名稱	Standard Specification for Natural Rubber Finger Cots
制定日期	January 2002.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Rubber Finger Cots
簡要說明	This specification covers the requirements for finger cots made from natural rubber latex. The purpose of this specification is to obtain consistent performance among products produced in various locations or at various times in the same location. This specification does not cover the safe and proper use of finger cots or products of special construction for special use.

醫療器材採認標準資料表

編號	DOH-000300
標準分類	I. 一般整形及外科手術裝置
標準號碼	F 882 – 84
標準名稱	Standard Performance and Safety Specification for Cryosurgical Medical Instruments
制定日期	February 1985
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Cryosurgical Devices
簡要說明	This specification covers standards a manufacturer shall meet in the designing, manufacturing, testing, labeling, and documenting of cryosurgical medical instruments, but it is not to be construed as production methods, quality control techniques, or manufacturer's lot release criteria, or clinical recommendations.

醫療器材採認標準資料表

編號	DOH-000301
標準分類	J. 一般醫院及個人使用裝置
標準號碼	F 754 – 00
標準名稱	Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes
制定日期	August 2000
制定標準組織名稱	ASTM International
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Sutures, Facial Implants, Surgical Mesh
簡要說明	This specification describes the performance of polytetrafluoroethylene (PTFE) fabricated in sheet, tube, and rod shapes which may be used for surgical implants. PTFE is a member of the generic class of perfluorocarbon (containing only the elements fluorine and carbon) polymers.

醫療器材採認標準資料表

編號	DOH-000302
標準分類	I. 一般整形及外科手術裝置
標準號碼	F 1441 – 03
標準名稱	Standard Specification for Soft-Tissue Expander Devices
制定日期	May 2003.
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Tissue Expanders
簡要說明	This specification covers the requirements for single use saline inflatable, smooth and textured tissue expansion devices to be used intraoperatively or implanted for typically less than 6 months and then removed.

醫療器材採認標準資料表

編號	DOH-000303
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 11608-1
標準名稱	Pen-injectors for medical use —Part 1: Pen-injectors — Requirements and test methods
制定日期	2000-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Pen injectors, Auto-injectors
簡要說明	This part of ISO 11608 covers pen-injectors primarily intended for human use. It provides performance requirements regarding essential aspects, so that variations of design are not unnecessarily restricted. The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-2 and ISO 11608-3. It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and to be avoided for other medicinal products, and that future design may change the current concepts. Therefore, ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

醫療器材採認標準資料表

編號	DOH-000304
標準分類	J. 一般醫院及個人使用裝置
標準號碼	BS EN ISO 11608-2:2001
標準名稱	Pen-injectors for medical use – Part 2: Needles– Requirements and test methods
制定日期	December 2000
制定標準組織名稱	British Standards Institution
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Pen injectors, Auto-injectors
簡要說明	This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with pen-injectors. The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-1 and ISO 11608-3. It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and should be avoided for other medicinal products, and that future design may change the current concepts. Therefore, ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

醫療器材採認標準資料表

編號	DOH-000305
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 11608-3
標準名稱	Pen-injectors for medical use —Part 3: Finished cartridges — Requirements and test methods
制定日期	2000-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Pen injectors, Auto-injectors
簡要說明	This part of ISO 11608 covers finished cartridges filled with medicinal products primarily intended for human use. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted. The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-1 and ISO 11608-2. It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and to be avoided for other medicinal products, and that future designs may change the current concepts. Therefore ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

醫療器材採認標準資料表

編號	DOH-000306
標準分類	J. 一般醫院及個人使用裝置
標準號碼	F 2172-02
標準名稱	Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers
制定日期	2002
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Blood and fluid warming devices such as in-line blood warmers, in-line intravenous fluid warmers, in-line irrigation fluid warmers.
簡要說明	This Standard Specification amends and supplements IEC 601-1 (second edition, 1988): Medical electrical equipment - Part 1: General requirements for safety. as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3). This Standard Specification is necessary because of the special attention which has to be given to FLUID WARMERS, which are frequently used for PATIENTS in operating theaters, intensive care units, and other situations.

醫療器材採認標準資料表

編號	DOH-000307
標準分類	J. 一般醫院及個人使用裝置
標準號碼	F 2196-02
標準名稱	Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices
制定日期	2002
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	**Forced air device** Patient temperature management device that uses air as the heat transfer medium to warm a patient and is comprised of a controller and a blanket. **Circulating liquid device** Patient temperature management device that uses circulating liquid as the heat transfer medium to warm a patient and is comprised of a controller and a blanket.
簡要說明	This Particular Standard is necessary because attention needs to be given to features of Patient temperature management device for forced air device and circulating liquid device which are used to warm Patients in operating rooms, intensive care units and other areas of health care facilities, often when the Patient may be unable to react if excessive temperatures were to be produced.

醫療器材採認標準資料表

編號	DOH-000308
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 1135-4
標準名稱	Transfusion equipment for medical use —Part 4: Transfusion sets for single use
制定日期	1998-03-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	All blood transfusion sets & accessories
簡要說明	This part of ISO 1135 specifies requirements for single-use transfusion sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment. This part of ISO 1135 also specifies requirements for air-inlet devices for use with rigid containers for blood and blood components. Secondary aims of this part of ISO 1135 are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets and to present designations for transfusion set components. In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 1135.

醫療器材採認標準資料表

編號	DOH-000309
標準分類	J. 一般醫院及個人使用裝置
標準號碼	14509
標準名稱	醫電設備電性安全－第1部：一般安全規定
制定日期	94/04/19
制定標準組織名稱	經濟部標準檢驗局
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	醫電設備系統是由一個以上的醫電設備項目，或醫電設備與其他非醫電設備藉由內部之連接，以達成特殊功能之組合，其內部連接可由下列方法達成： -耦合，或 -可攜帶式多孔插座
簡要說明	本標準適用於醫電設備之安全性，雖然本標準主要與安全有關，它亦包含某些先關操作可性度安全上的規定。因設備訂的生理功能而導致的安全性危害，不在本標準考慮之列，除非主要條文有規範，本標準的附錄不具強制性。

醫療器材採認標準資料表

編號	DOH-000310
標準分類	J. 一般醫院及個人使用裝置
標準號碼	14509-1
標準名稱	醫電設備電性安全-第一部分:一般安全規定-附屬標準 1:醫電系統之安全規定
制定日期	90 年 1 月 30 日
制定標準組織名稱	經濟部標準檢驗局
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	醫電設備系統是由一個以上的醫電設備項目，或醫電設備與其他非醫電設備藉由內部之連接，以達成特殊功能之組合，其內部連接可由下列方法達成： -耦合，或 -可攜帶式多孔插座
簡要說明	本標準適用於第 2.3 節所定義之醫電設備系統之安全性。內容說明醫電設備系統對患者，操作者於環境保護所必須提供之安全規定。 備考:裝備或修改醫電設備系統者，會採取必要之措施以確保符合本標準。

醫療器材採認標準資料表

編號	DOH-000311
標準分類	J. 一般醫院及個人使用裝置
標準號碼	14509-2
標準名稱	醫電設備電性安全-第一部分:一般安全規定-附屬標準 2:電磁相容性之規定與測試
制定日期	90/01/30
制定標準組織名稱	經濟部標準檢驗局
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	醫電設備系統是由一個以上的醫電設備項目，或醫電設備與其他非醫電設備藉由內部之連接，以達成特殊功能之組合，其內部連接可由下列方法達成： -耦合，或 -可攜帶式多孔插座
簡要說明	本標準只適用於醫電設備，醫電系統，醫電應用之資訊之資訊技術設備或所有構成醫電系統之組成設備。

醫療器材採認標準資料表

編號	DOH-000312
標準分類	J. 一般醫院及個人使用裝置
標準號碼	14509-4
標準名稱	醫電設備電性安全-第一部分:一般安全規定-附屬標準 4:可程式化醫電系統
制定日期	T5014-4
制定標準組織名稱	經濟部標準檢驗局
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	所有可程式化電子次系統的醫電設備及系統
簡要說明	本附屬標準適用於包含所有可程式化電子次系統的醫電設備及系統(以下簡稱為可程式化醫電系統)的安全性。 備考：本附屬標準並不適用於某些包含有電腦軟體且作為醫療用途的系統，例如某些醫療資訊系統，其區別的基準在於這個系統是否符合 CNS 14509 第 2.2.15 節所定義的醫療設備，或者符合 CNS14509 第 20.203 節所定義的醫電系統。

醫療器材採認標準資料表

編號	DOH-000313
標準分類	E. 心臟血管用裝置
標準號碼	IEC 60601-2-31
標準名稱	Amendment 1 Medical electrical equipment - Part 2-31 : Particular requirements for the safety of external cardiac pacemakers with internal power source
制定日期	1998-01
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	External Cardiac Pacemakers with Internal Power Source including patient cables, but not pacing LEADS or other equipment for cardiac stimulation which either: 1) forms an integral part of equipment with other functions; or 2) applies the stimulus across the thorax externally or in the esophagus; or 3) provides antitachycardia therapy beyond high rate burst pacing; or 4) provides pacing system analysis functions
簡要說明	This Particular Standard concerns the safety of PACEMAKERS. The requirements of this Particular Standard take priority over those of the General Standard, entitled Medical electrical equipment - Part 7 : General requirements for safety.

醫療器材採認標準資料表

編號	DOH-000314
標準分類	E. 心臟血管用裝置
標準號碼	ISO 11318
標準名稱	Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements
制定日期	2002-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Implantable Cardioverter Defibrillators
簡要說明	The purpose of this International Standard is to specify a standard connector assembly, DF-1, to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer. Defibrillator connector systems not conforming to this International Standard may be safe and reliable, and may have clinical advantages.

醫療器材採認標準資料表

編號	DOH-000315
標準分類	E. 心臟血管用裝置
標準號碼	IEC 60601-2-25
標準名稱	Amendment 1 Medical electrical equipment -Part 2-25: Particular requirements for the safety of electrocardiographs
制定日期	1999-05
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.
簡要說明	This Particular International Standard amends and supplements IEC 601 -1 (second edition, 1988): Medical electrical equipment - Part 7 : General requirements for safety, hereinafter referred to as the General Standard (see 1.3). The requirements are followed by specifications for the relevant tests. Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a “General guidance and rationale” section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

醫療器材採認標準資料表

編號	DOH-000316
標準分類	E. 心臟血管用裝置
標準號碼	IEC 60601-2-47
標準名稱	Medical electrical equipment . Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
制定日期	2001-07
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.
簡要說明	This Particular Standard concerns the safety of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. It amends and supplements IEC 60601-1 (second edition 1988): Medical electrical equipment . Part 1: General requirements for safety, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

醫療器材採認標準資料表

編號	DOH-000317
標準分類	E. 心臟血管用裝置
標準號碼	IEC 60601-2-4
標準名稱	Medical electrical equipment –Part 2-4: Particular requirements for the safety of cardiac defibrillators
制定日期	2002-08
制定標準組織名稱	International Electrotechnical Commission
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Cardiac defibrillator Medical electrical equipment intended to defibrillate the heart by an electrical pulse via electrodes applied either to the patient's skin (external electrodes) or to the exposed heart (internal electrodes). May be referred to as defibrillator or equipment note Such equipment may also include other monitoring or therapeutic functions.
簡要說明	This Particular Standard concerns the safety of Cardiac defibrillators. It amends and supplements IEC 60601-1 (second edition, 1988): Medical electrical equipment – Part 1: General requirements for safety, including its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard. A first edition of this Particular Standard, based on the first edition (1977) of IEC 60601-1 was published in 1983. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above through minor changes to the technical content.