
Draft
Jamaican Standard
Specification

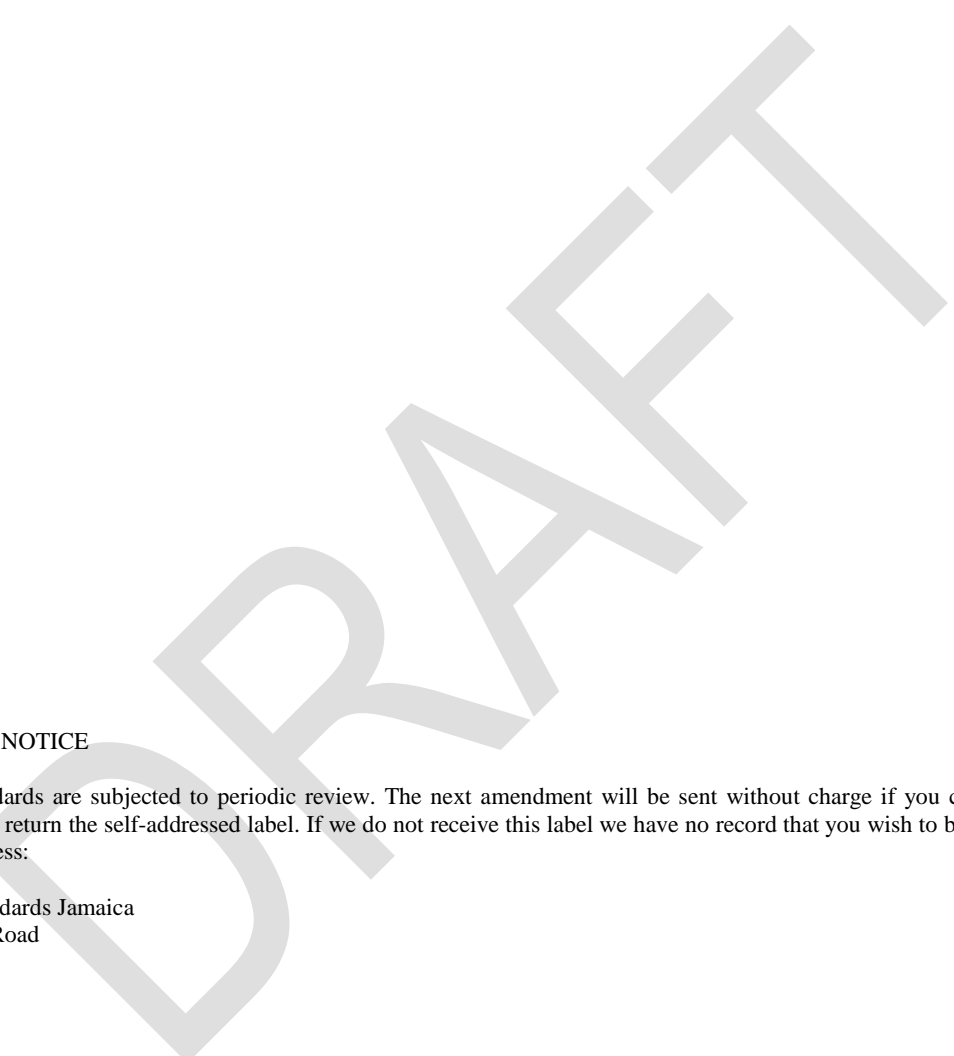
for

Diagnostic Imaging Facilities



BUREAU OF STANDARDS JAMAICA

PUBLIC COMMENTS PERIOD JULY 14 TO SEPTEMBER 12, 2020



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JS 351: 2020

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CERTIFICATION MARKS



Product Certification Marks



Plant Certification Mark



Certification of Agricultural Produce (CAP) Mark



Jamaica-Made Mark

Draft Jamaican Standard Specification

for

Diagnostic Imaging Facilities

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This standard was circulated in the draft form for comment under the reference DJS 352: 2020
Jamaican Standards establish requirements in relation to commodities, processes and practices, but do not purport to include all the necessary provisions of a contract.

The attention of those using this standard specification is called to the necessity of complying with any relevant legislation.

Amendments

No.	Date of Issue	Remarks	Entered by and date

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Foreword

This standard sets out the requirements for diagnostic imaging facilities operating in Jamaica. This diagnostic imaging standard has been developed to address the level of risk according to the type of services provided to clients. The provision of diagnostic imaging services can be harmful to patients if best practices are not utilized. This Diagnostic Imaging Standard provide a framework that protects the public from harm, ensures the highest level of patient safety and quality of care, and protects the diagnostic imaging healthcare team before, during and after delivering diagnostic imaging services. Standards are critical in outlining core ethical principles of the practice of medical diagnostic services, set out what patients can expect of the imaging team, ensure what is to be done to meet patient expectations, and provide guidance as to how the standards are to be met. This standard aims to ensure that all stakeholders are on the same page by setting standards of conduct and performance that provide guidance to the practice of diagnostic imaging in a particular setting. Diagnostic Imaging standards are also internal quality assurance parameters that provide diagnostic imaging centers with a benchmark for their certification of the treatment of patients, and meeting the diagnostic imaging standards are akin to meeting accreditation standards. By having standards for their recruitment, appointment, and treatment, patients will know that once offices have been certified, they can expect the same standards of patient safety and quality diagnostic imaging services. This standard has been prepared by the Bureau of Standards Technical Standard Committee.

Committee representation

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1 Scope

The standard describes the requirements (general and specific) for all facilities providing medical diagnostic imaging services. The standard includes but is not limited to:

- The overall management of the operations of the facility
- The management of patient records and identification systems
- Standard operating procedures for clinical and non-clinical practices
- Patient & staff safety
- Sanitation and infection management
- Hazardous substance management and disposal
- Equipment procurement, installation, and maintenance/upkeep
- Maintenance of resources and environment
- Facilities layout
- Human resources

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 2.1 Nuclear Safety and Radiation Protection Act, 2015
- 2.2 Nuclear Safety and Radiation Protection Regulations, 2015

3 Terms and Definitions

For the purposes of this document, the terms and definitions given and the following apply.

3.1 Patients. Persons receiving diagnostic imaging services.

3.2 Diagnostic imaging provider. Physicians, dentists and technologists providing diagnostic imaging services within the organization.

3.3 Indicator. A single, standardized measure, expressed in quantitative terms, that captures a key dimension of individual or population health, or health service performance. An indicator may measure an aspect of a process or a health or service outcome.

3.4 Referring medical professionals. Any registered physician in Jamaica or allied health professionals under supervision of a registered physician.

3.5 Team. Depending on services provided, the team may include clinical and senior administrative leaders, diagnostic imaging providers (e.g physicians, dentists and technologists), , biomedical engineers, medical physicists, and senior administrative staff.

3.6 Emergency request. Emergency care refers to a medical situation where the condition is likely to deteriorate or result in death if not addressed immediately.

3.7 Urgency request. Urgency care refers to a medical situation where the condition is unlikely to deteriorate or result in death if not addressed immediately but is indicated to be done in a timely manner. For example, a suspicion of cancer may lead to an urgent request for diagnostic imaging services.

4. Requirements for Patient Care and Medical Referral

4.1 The team shall plan and design its diagnostic imaging services to meet the needs of current and future patients and referring medical professionals.

4.1.1 The organization shall have a current license to deliver diagnostic imaging services.

4.1.2 The organization's license shall clearly state which diagnostic imaging services it provides and can be viewed by all patients, families, visitors, and staff and service providers.

4.1.3 The organization's policies and procedures for delivering diagnostic imaging services shall comply with applicable laws and regulations.

4.1.4 The team shall collect and review information at least annually about service volumes, wait times, patient's perspective on services, and trends in use across different groups, such as age cohorts or condition-specific populations as required.

4.1.5 The team shall collect information as required for quality control.

4.1.6 The team shall meet at least annually to review information collected from patients and health professionals to identify strengths and weaknesses, with the objective of making changes in accordance with improvement of the quality of the services delivered.

4.1.7 For independent diagnostic imaging centres, partners shall also include hospitals if referrals are necessary.

4.1.8 The inter-relationship of structures and functions within the institution shall be clearly defined in order to ensure proper levels of accountability.

4.2 The team provides timely access to diagnostic imaging services.

4.2.1 The team should track wait times and average response times for elective, urgency and emergency requests for diagnostic imaging services.

4.2.2 The team shall identify, and remove where possible, physical and other barriers that prevent patients or referring medical professionals from accessing diagnostic imaging services in a safe and timely manner.

4.2.3 The team should regularly collaborate with referring medical professionals about how to improve access to diagnostic imaging services and address delays in reporting diagnostic imaging results and patient outcomes.

4.2.4 The team leaders should advocate to senior management on the team's behalf for the resources needed to deliver quality diagnostic imaging services.

5 Requirements for Recruiting and Employing Staff

5.1 The diagnostic imaging providers shall be trained, qualified and competent.

5.1.1 The team shall have clearly defined job descriptions that define qualifications, roles and responsibilities.

5.1.2 The team shall recruit and selects team members based on their qualifications, experience, and fit within the team.

5.1.3 The team shall have a management structure in place with clear reporting relationships and lines of accountability.

5.1.4 The team shall have an administrative leader responsible for the administration and management of diagnostic imaging services including supervising and directing diagnostic imaging providers.

5.1.5 The team shall have a medical director responsible for supervising and directing physicians.

5.1.6 The team's medical director and physicians shall be a registered physicians and or imaging specialists credentialed by the appropriate professional college or association.

5.1.7 The team's diagnostic imaging providers delivering specialized modalities shall have specific credentials or training and are approved by their respective college or association to practice each specialized modality.

5.1.8 Team members who administer sedation or monitor patients under sedation shall maintain an up-to-date certificate of proficiency in basic cardiopulmonary resuscitation (CPR).

5.1.9 The team shall support diagnostic imaging providers to participate in professional development activities on a regular basis.

5.1.10 The team shall evaluate and document each team member's performance in an objective, interactive, and constructive way.

5.1.11 Each team member shall have an up-to-date, comprehensive personnel file or employment record.

6. Requirements for the Environment for which Diagnostic Imaging Services is offered

6.1 The team shall work in a safe, clean, and private physical environment.

6.1.2 The physical environment shall have clear signage in place to direct patients to the imaging service.

6.1.3 The team shall have a separate service area that includes space for patients to wait and space for conducting diagnostic imaging procedures.

6.1.4 For nuclear medicine, the team shall designate separate waiting areas to segregate patients who have been injected with radioactive substances.

6.1.5 The patient service area shall include a space for screening patient which ensures confidentiality prior to their diagnostic imaging examination.

6.1.6 The patient service area shall be equipped with a private and secure space for patient

to change.

6.1.7 The patient service area shall include patient restrooms.

6.1.8 The patient service area shall include a space with appropriate equipment and staff for patients to recover following the examination.

6.1.9 The patient service area shall be accessible to patients using mobility equipment such as trolleys, wheelchairs, walkers and crutches.

6.1.10 The team shall be knowledgeable on how to identify, correct and/or report any environmental issues related to temperature regulation, humidity, ventilation and other indoor occupational hazards.

6.1.11 The team shall post safety warnings at the entrances and exits of the imaging room and restrict access when necessary.

6.1.12 The facility should have a back-up power generating system that is regularly tested and meets required operational standards.

6.2 The team shall implement policies and procedures for the safe storage, handling, and the appropriate disposal of material and supplies.

6.2.1 The team shall be oriented and updated on applicable regulations regarding hazardous material.

6.2.2 The team shall label and store chemicals and solutions in compliance with applicable regulations.

6.2.3 The team shall comply with the regulations for the storing, handling, use and disposing of radioactive and other hazardous material.

6.2.4 The team shall clean up and dispose of contaminated materials from spills, blood, and bodily fluids and other substances in compliance with the respective regulations.

6.2.5 The team shall discard glassware, sharps, and needles in puncture-resistant containers prior to disposal in conformance with environmental standards.

7. Requirements for Selecting, Operating and Maintaining Diagnostic Imaging Equipment

7.1 The team shall follow policies and procedures for selecting and operating diagnostic imaging equipment.

7.1.1 Diagnostic imaging providers shall participate in the organization's process for selecting and prioritizing diagnostic imaging equipment and devices.

7.1.2 The team shall follow national, regional and/or international regulations to register, install, and calibrate diagnostic imaging equipment.

7.1.3 Diagnostic imaging providers shall have an up-to-date manual for operating diagnostic imaging equipment that includes manufacturer's instructions and applicable safety regulations.

7.1.4 Diagnostic imaging providers shall be trained on the diagnostic imaging equipment used by the team prior to use.

7.1.5 Diagnostic imaging providers shall have a Policy and Procedure Manual that includes detailed procedures for positioning the patients for diagnostic imaging examinations that is signed by the medical director, senior administrative leader or designate.

7.1.6 The team shall orient new diagnostic imaging providers to the Policy and Procedure Manual.

7.1.7 The team shall annually review and update the Policy and Procedure Manual as necessary.

7.1.8 The team shall inform the diagnostic imaging providers of updates to the Policy and Procedure Manual.

7.1.9 The team shall retain previous versions of the Policy and Procedure Manual according to the organization's policy on record retention.

7.2 The team shall follow policies and procedures for maintaining all diagnostic equipment.

7.2.1 The team shall have an annual program for preventive maintenance of equipment consistent with manufacturers' recommendations.

7.2.2 The team shall have an equipment log in which to record maintenance and downtime, and to identify and address problems.

7.2.3 The team shall retain preventive maintenance records, for at least two years, after the equipment has been decommissioned.

7.2.4 Diagnostic imaging provider shall maintain a current equipment inventory.

7.3 The team shall follow a schedule for cleaning and reprocessing all diagnostic devices and equipment.

7.3.1 The individual responsible for the overall coordination of reprocessing and sterilization activities within the organization shall review and approve policies and procedures for cleaning and reprocessing.

7.3.2 If the team does not have access to the resources needed to safely clean and reprocess diagnostic devices or equipment at the point of use, the team shall send them to an approved medical device reprocessing department or an approved external provider.

7.3.3 If cleaning and reprocessing are contracted to approve external providers, the organization shall establish and maintain a contract with each provider and monitors the quality of services provided.

7.3.4 The team shall follow the organization's policies and procedures and manufacturers' instructions to contain and transport contaminated devices and equipment to an approved medical device reprocessing department or approved external provider.

7.3.5 The team shall ensure the staff involved in cleaning and reprocessing diagnostic devices and equipment are qualified, competent and certified.

7.3.6 All diagnostic imaging reprocessing areas shall be physically separate from patient service areas.

7.3.7 All diagnostic imaging reprocessing areas shall be equipped with separate clean and decontamination work areas as well as separate storage, dedicated plumbing and drains, and proper air ventilation and humidity levels and waste management systems.

7.3.8 The team shall follow the organization's policies and procedures and manufacturer's instructions to select appropriate cleaning, disinfecting, and reprocessing methods.

7.3.9 The team shall follow the organization's policies and procedures and manufacturer's instructions for cleaning and reprocessing diagnostic devices and equipment.

7.3.10 The team shall store clean diagnostic devices and equipment according to manufacturer's instructions and separate from soiled equipment and waste.

7.3.11 The team shall have a process to track and trace all reprocessed diagnostic devices and equipment so they can be identified in the event of a breakdown or failure in the reprocessing system.

7.3.12 The individual responsible for the overall coordination of reprocessing and sterilization activities within the organization shall oversee the team's compliance with the organization's policies and procedures on cleaning and reprocessing.

8. Requirements for Providing Safe and Appropriate Diagnostic Imaging Services

8.1 The team shall manage and respond to requests for diagnostic imaging services.

8.1.1 The team shall have a process for providing referring medical professionals with resources for selecting appropriate diagnostic imaging examinations.

8.1.2 For diagnostic imaging services, the team shall receive a written or electronic request that identifies the patient and appropriate medical professionals, date of request, urgency/emergency, relevant clinical information, type of procedure, and special instructions.

8.1.3 If an urgent or emergent request for diagnostic imaging services is made by telephone, a qualified team member shall collect and record information and ensures a written or electronic request is received prior to interpreting the results of the diagnostic imaging examination.

8.1.4 If information on a diagnostic imaging services request is incomplete, the team shall collect additional information prior to conducting the procedure.

8.1.5 The team shall maintain a written or electronic record of requests for diagnostic imaging services received from referring medical professionals.

8.1.6 The written or electronic record shall show the daily requests for examinations and includes each patient's name, examination type, clinical history, presumptive diagnosis and the image file number.

8.1.7 The team shall respond to statim orders in a timely manner.

8.2 The team shall prepare patients and their families for diagnostic imaging examinations.

8.2.1 The team shall respect the patient's diversity including gender, culture, language,

religion, and disability when providing diagnostic imaging services.

8.2.2 The team shall provide patients and their families with information about diagnostic imaging examinations.

8.2.3 The team shall review information about the diagnostic imaging examination with patients and their families and obtains informed consent before conducting the procedure.

8.2.4 The team shall understand their roles and responsibilities when patients are unable to make informed decisions and involves a substitute decision maker/ power of attorney when appropriate.

8.2.5 The team shall screen patients for allergies and medical conditions prior to the administration of contrast media.

8.2.6 For procedures involving radiation to the abdomen or pelvis on women, the team shall ask for a complete medical history for female patients of childbearing age (whether they are or may be pregnant) and documents the response.

8.2.7 The team shall screen patients for implants, devices, and materials inside the body.

8.3 The team shall conduct appropriate diagnostic imaging examinations.

8.3.1 The team, in consultation with the referring medical professional, shall choose the least invasive diagnostic imaging technique necessary to achieve the desired results.

8.3.2 The team shall shield patients and diagnostic imaging providers during diagnostic imaging examinations in line with applicable regulations.

8.3.3 The team shall follow policies and procedures for people who assist during diagnostic imaging examinations.

8.3.4 The team shall implement a patient verification protocol for all services and procedures.

8.3.5 The team shall confirm the patient's identity, type of procedure required, and site of the procedure immediately before the interventional procedure.

8.3.6 The team shall follow the organization's policies and procedures for administering medications such as contrast media, sedatives and radiopharmaceuticals.

8.3.7 The team shall monitor patients receiving medications such as contrast media, sedatives and radiopharmaceuticals during and after the examination for adverse reactions or complications.

8.3.8 When sedatives or anaesthesia is administered, the patient shall be monitored by qualified team members during and after the examination.

8.3.9 The team shall follow the organization's policy and procedure for treating, documenting, and reporting adverse reactions.

8.3.10 When medications such as contrast media, sedatives and radiopharmaceuticals are administered to the patients, the team ensures that there is immediate access to staff trained to deal with medical emergencies (e.g. CPR training), emergency cart, and oxygen equipment. Resuscitation equipment shall be immediately available for management of adverse reactions.

8.3.11 The team shall implement standard views of each anatomic area to optimize imaging and minimize exposure to radiation.

8.3.12 The team shall use diagnostic reference levels to optimize radiation protection of adult and paediatric patients.

8.3.13 The team shall follow appropriate policies and procedures for each diagnostic imaging technique.

8.3.14 For interventional procedures, the team shall label, handle, transport, track and trace, and store samples safely and appropriately.

8.3.15 The team shall reviews diagnostic images for positioning and diagnostic quality before the patient is released.

8.3.16 The team shall follow policies and procedures for determining whether a patient is fit for release.

8.3.17 The team shall provide patients with post-procedure instructions.

8.4 The team shall interpret diagnostic imaging information

8.4.1 The team shall interpret elective, urgent and emergent diagnostic imaging results in a timely manner.

8.4.2 The team shall evaluate whether it is meeting the timeframes set for interpreting diagnostic imaging results and makes improvements as needed.

8.4.3 The team shall inform the referring medical professionals immediately following unusual, unexpected, or undetermined findings.

8.4.4 The team shall document the communication of results to referring medical professionals.

8.5 The team shall report diagnostic results immediately following interpretation of the images to the appropriate medical professionals.

8.5.1 The report shall identify the patient, the diagnostic imaging provider, the name of the referring medical professional, and includes relevant information about the procedure.

8.5.2 The report shall describe the procedure using anatomical and precise diagnostic terminology.

8.5.3 The report shall be reviewed for accuracy, authorized by written or electronic signature, and includes the name of the radiologist who dictated the report.

8.5.4 The master envelope or electronic copy shall be retrievable. The team shall store diagnostic images and reports together in a clearly labelled master envelope, electronically, or a combination of both.

8.5.5 The patient shall retain the right to request and receive a copy of report of the procedure from the physician and/ or the diagnostic service provider.

9. Requirements for Record Keeping

9.1 The team shall maintain accurate and specific medical records and diagnostic images.

9.1.1 The medical record shall include a written or electronic requisition form for the diagnostic imaging service conducted.

9.1.2 The requisition form shall identify the patient, diagnostic imaging provider, the name of the referring medical professional, and information about the procedure.

9.1.3 The team's diagnostic imaging provider shall record their initials, name or code (written or electronic) to signify their involvement with the diagnostic imaging procedure.

9.1.4 The diagnostic image shall include the patient's first and last name, a second patient identifier, the organization's name, and the time and date of the examination.

9.1.5 The team shall store securely a copy of the diagnostic image as the permanent record.

9.1.6 The permanent record shall be retrieve for updates if required.

9.1.7 The team shall use computer or paper file systems to transmit and store medical records and diagnostic images.

9.1.8 Diagnostic images and reports shall be retrieved using patient identification information.

9.1.9 The team shall follow the minimum requirements for retention of medical records consistent with policies and procedures.

9.1.10 The team shall develop a privacy policy relating to all team activities, including those involving teleradiology.

9.1.11 The team shall implement a procedure for seeking the consent of patients to the proposed use of their personal information.

10. Requirements for Monitoring the Safety and Quality of Diagnostic Imaging Services

10.1 The team shall promote safety in the diagnostic imaging service environment.

10.1.1 The team shall have a safety program led by a safety officer, a safety committee, or both.

10.1.2 The team shall have a safety manual adapted for diagnostic imaging services.

10.1.3 The team shall have policies and procedures to deal with medical emergency and urgency situations.

10.1.4 The team shall prepare for medical emergencies by participating in simulation exercises.

10.1.5 The team shall have in place a process to receive, document and follow-up on medical alerts and safety notifications issued by relevant regulatory bodies.

10.1.6 The team shall inform patients and families in writing and verbally about the team's role in promoting safety.

10.1.7 The team shall implement and evaluate a fall prevention strategy to minimize patient injury from falls.

10.1.8 The team shall follow the organization's verification processes for high-risk activities.

10.1.9 The team shall record all unintended events, near misses, and adverse events in its files and the patient record, as applicable.

10.1.10 The team shall monitor rates of unintended events, near misses, and adverse events.

10.1.11 The team shall follow the organizations and relevant authorities' policies and procedure to disclose adverse events to patients and families.

10.2 The team shall have a quality control program for its diagnostic imaging services.

10.2.1 The team shall maintain a schedule of quality control procedures.

10.2.2 The team shall record results of quality control procedures, problems identified, and corrective actions taken.

10.2.3 The team shall conduct and report on repeat/reject analysis monthly, as part of its quality control program.

10.2.4 The team shall document all repeat/reject analysis including corrective/preventative action(s) taken.

10.2.5 The team shall retain repeat/reject records for the period set by the organization's policy.

10.3 The team shall collect and use indicator data to guide its quality improvement initiatives.

10.3.1 The team shall collect information and feedback from patients, families, staff, service providers, organization leaders, and other organizations about the quality of its services to guide its quality improvement initiatives.

10.3.2 The team shall use the information and feedback it has gathered to identify opportunities for quality improvement initiatives.

10.3.3 The team shall identify objectives for its quality improvement initiatives and specifies the timeframe in which they will be achieved.

10.3.4 The team shall identify the indicator(s) that will be used to monitor progress for each quality improvement objective.

10.3.5 The team shall use a utilization management system or review process to monitor diagnostic imaging services.

10.3.6 The team shall use result of the utilization management system review to educate referring medical professionals and diagnostic imaging providers on the appropriate use of diagnostic imaging services.

10.3.7 The team shall collect, analyze, and interpret data on the appropriateness of examinations, the accuracy of the interpretations, and the incidence and prevalence of complications and adverse events.

10.3.8 The team shall review its diagnostic reference levels at least annually as part of its quality improvement program.

10.3.9 The team shall design and test quality improvement activities to meet its objectives.

10.3.10 The team shall collect new or use existing data to establish a baseline for each indicator.

10.3.11 The team shall follow a process to regularly collect indicator data to track and trace its progress.

10.3.12 The team shall regularly analyses and evaluates its indicator data to determine the effectiveness of its quality improvement activities.

10.3.13 The team shall implement effective quality improvement activities based on the scope and content of the team's services.

10.3.14 The team shall share information about its quality improvement activities, results, and learning with patients, families, staff, service providers, organization leaders, and other organizations, as appropriate.

10.3.15 The team shall regularly review and evaluate its quality improvement initiatives for planning and development purposes.

11. Requirements for Maintaining Computer and Automated Software

11.1 The team shall maintain a computer-based data management system

11.2 The team shall ensure that when a computer-based data management system is used for acquisition, processing, recording, reporting, storage retrieval, transmission or dissemination of information; such equipment, and its operating system, are appropriate for the purpose of its use.

11.3 The team shall ensure that data management system is appropriately serviced, and that system is updated as required.

11.4 The team shall provide appropriate environmental, scalable broadband infrastructure and operating conditions to ensure the optimal functioning of the system.

11.5 The team shall ensure that additional security provisions are in place to enable the judicious sharing of health information.

11.6 The team shall ensure that adequate fail-over systems are in place to maintain records in the event of system failure.

Standards Council

The Standards Council is the controlling body of the Bureau of Standards Jamaica and is responsible for the policy and general administration of the Bureau.

The Council is appointed by the Minister in the manner provided for in the Standards Act, 1969. Using its powers in the Standards Act, the Council appoints committees for specified purposes.

The Standards Act, 1969 sets out the duties of the Council and the steps to be followed for the formulation of a standard.

Preparation of standards documents

The following is an outline of the procedure which must be followed in the preparation of documents:

1. The preparation of standards documents is undertaken upon the Standard Council's authorization. This may arise out of representation from national organizations or existing Bureau of Standards' Committees of Bureau staff. If the project is approved it is referred to the appropriate sectional committee or if none exists a new committee is formed, or the project is allotted to the Bureau's staff.
2. If necessary, when the final draft of a standard is ready, the Council authorizes an approach to the Minister in order to obtain the formal concurrence of any other Minister who may be responsible for any area which the standard may affect.
3. The draft document is made available to the general public for comments. All interested parties, by means of a notice in the Press, are invited to comment. In addition, copies are forwarded to those known, interested in the subject.
4. The Committee considers all the comments received and recommends a final document to the Standards Council
5. The Standards Council recommends the document to the Minister for publication.
6. The Minister approves the recommendation of the Standards Council.
7. The declaration of the standard is gazetted and copies placed on sale.
8. On the recommendation of the Standards Council the Minister may declare a standard compulsory.
9. Amendments to and revisions of standards normally require the same procedure as is applied to the preparation of the Original standard.

Overseas standards documents

The Bureau of Standards Jamaica maintains a reference library which includes the standards of many overseas standards organisations. These standards can be inspected upon request.

The Bureau can supply on demand copies of standards produced by some national standards bodies and is the agency for the sale of standards produced by the International Organization for Standardization (ISO) members.

Application to use the reference library and to purchase Jamaican and other standards documents should be addressed to:

Bureau of Standards Jamaica
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P.O. Box 113,
Kingston 10
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