102.103 – REGULATORY GUIDELINE

PART 1 - GENERAL

1.01 INTRODUCTION

A. Numerous building codes, standards, federal and state legislation, and federal, state and local agency regulations have significant impact on healthcare projects. When discovered and addressed early in the design process, the impact to projects can be minimized.

B. The design and construction teams are responsible to design and construct the Work in accordance with all applicable codes and regulations.

1. All laws, codes, ordinances, rules, regulations and statutes applicable to the Project or any existing structures or facilities that will be impacted by the proposed construction, including, without limitation, the Americans with Disabilities Act ("ADA") and applicable hospital codes and regulations promulgated by the Missouri Department of Health (or the Illinois Department of Public Health, whichever is applicable), and standards established by The Joint Commission.

PART 2 - GUIDELINE

2.01 BUILDING CODES

A. The primary focus of the building codes is to ensure the life/safety conditions of the project are met. Compliance with building codes will result in an Occupancy Permit.

B. Building Codes are determined by the municipality that governs the project through a city charter or ordinance. The Authorities Having Jurisdiction to interpret the codes and approve the project include the municipality and the Fire Marshal of the applicable Fire Protection District.

1. Design team is responsible to verify with the municipality and Fire Marshal a complete list of applicable building codes that will be enforced, prior to commencing work on the project.

2. Design team is responsible to engage building code consulting services for reviews and reports as necessary or as directed.

C. Code Data Blocks shall be provided for all projects, shall begin at the onset of the project, shall be reviewed and developed during the design phases, and shall be finalized at the completion of Design Development. Code Data blocks shall include side-by-side documentation of the International Building Code and the National Fire Protection Association Life Safety Code (NFPA 101) requirements. Minimum information required shall be as follows.

1. List of applicable codes
2. Authorities Having Jurisdiction
3. Occupancy
4. Construction type
5. Automatic sprinkler
6. Building height and area
7. Fire resistance ratings
8. Occupant load
9. Egress capacity

D. Life Safety Plans shall be provided for all projects and as required by the AHJ. Preparation of Life Safety Plans shall begin at the onset of the project, shall be reviewed and developed during the design phases, and shall be finalized at the completion of Design Development. Life/Safety plans shall depict and indicate the following minimum requirements:

1. Means of Egress – Exit, horizontal exit, travel distances, common path of travel, exit remoteness
2. Suites – existing and new
3. Smoke Compartments – existing and new. Labels in accordance with facility labeling.
4. Rated walls (smoke, fire including rating in hours)
5. Fire extinguisher cabinet (including hose valve) locations
6. Standpipes
7. Project limits (Limits of Construction, Limits of Disturbance)

2.02 LICENSURE

A. A license is legal permission from a governing body to own and operate a facility or equipment, or for a provider to provide services for the intended function. Compliance with the licensure requirements will result in a license to own and operate the facility.

B. Design and construction team is responsible to deliver a project that meets all applicable licensing requirements.

1. Design and construction team shall be familiar with and make available for Owner's use the governing code(s) and/or licensing requirements.
2. Design team shall coordinate with the agency granting licensure prior to commencing work on the project and at intervals as necessary for proper project development.
3. Meeting(s) with the agency granting licensure may be required and will be determined on a project basis. When meetings are determined to be necessary, design team shall schedule, attend and facilitate the meeting, document the outcome, coordinate with other disciplines, and incorporate comments in the design and contract documents. Follow the process identified by the state for determining if and when state reviews will occur.

Refer to the partially completed state application forms in Chapter 1. Coordinate with BJC Corporate Architect and Design Project Manager for dates/times of licensure meetings.

C. State of Missouri Licensing

1. Missouri Department of Health and Senior Services (MODHSS or DHSS)

a. Governing code: Missouri Code of State Regulations (CSR)
b. The primary licensing (and therefore state review) required for facilities, equipment and providers is as follows:

1) Ambulatory Surgery Centers
2) Hospitals
3) Hospice
4) Nursing Homes and other Long-Term Care Facilities
5) X-ray services (regulated uses of radiation)
6) Routine radiology
7) Dental X-ray
8) Fluoroscopy
9) Computed Tomography
10) Mammography
11) Linear Accelerators used in radiation therapy
12) Bone Density testing
13) Non-medical Industrial uses of radiation in a variety of applications (non-destructive testing, mineral analysis, electron microscopes, security, QC, etc)
14) Other facilities, equipment or providers include Child Care, Emergency Medical Services, Food Safety, Lodging, Restaurant and Food Inspections

2. Missouri Board of Pharmacy

a. Governing code: Missouri Code of State Regulations (CSR)
b. The primary licensing required for facilities, equipment and providers is as follows:

1) Compounding Pharmacy

D. State of Illinois Licensing:

1. Illinois Department of Public Health (IDPH)

a. Governing code: Illinois Administrative Code, Title 77
b. The primary licensing (and therefore state review) required for facilities, equipment and providers is as follows:

1) Ambulatory Surgery Centers
2) Health Maintenance Organizations

3) Home Health Agencies
4) Hospices
5) Hospitals
6) Laboratories (independent, hospital, and physician office)
7) Nursing Homes
8) Other facilities, equipment of providers include Certified Nurse Aides, Physical Therapists (in independent practice), Poison Control Resource Centers, Pregnancy Termination Centers, Rural Health Clinics, Sperm and Tissue Banks.

2. Illinois Board of Pharmacy

a. Governing code: Illinois Administrative Code, Title 77, USP 797 by reference
b. The primary licensing required for facilities, equipment and providers is as follows:

1) Compounding Pharmacy

2.03 OPERATIONAL REGULATIONS

A. The primary focus of operational regulations is to ensure that the project meets specific functions as intended. In some instances, the licensing of the facility or service could be influenced by adherence to the regulations.

B. Design and construction team is responsible to deliver a project that meets all operational regulations.

1. As these operational regulations are dependent on the Owner's specific intended use, the design team shall coordinate with BJC to develop a list of all operational regulations prior to commencing work on the project.

2. Meeting(s) with the agency granting licensure may be required and will be determined on a project basis. When meetings are determined to be necessary, design team shall schedule, attend and facilitate the meeting, document the outcome, and incorporate comments in the design and contract documents.

C. Federal Regulations: These may include but are not limited to the following federal regulatory agencies:

1. Center for Medicare and Medicaid (CMS) – for all locations where healthcare services are provided.

a. Types of CMS regulated services.

1) Ambulatory Surgery Centers
2) Clinical Labs
3) Critical Access Hospitals

4) Federally Qualified Health Centers
5) Home Health Agency
6) Hospice
7) Hospital
8) Rural Health Clinics
9) Skilled Nursing Facility
10) All Fee-For-Service Providers
11) Other locations and services including ambulance services. anesthesiologists, durable medical equipment, practice administration, pharmacist, physician.

b. Administration. The Joint Commission (TJC) is a non-profit organization recognized in most states (including Missouri and Illinois) to certify healthcare organizations meet the Condition of Participation required for reimbursement under the federal Medicare program. While TJC accreditation is technically a voluntary program, BJC remains committed to TJC accreditation in lieu of other forms of accreditation for its facilities and services.

2. Centers for Disease Control (CDC)
3. Federal Aviation Administration (FAA) – heliports
4. Food and Drug Administration (FDA)
5. Nuclear Regulatory Commission (NRC)

a. For locations where nuclear radiation is present including but not limited to linear accelerators, PET CT's, proton therapy, blood irradiation, etc.

D. State Regulations. These may include but are not limited to the following state level regulatory agencies:

1. Environmental Protection Agency (EPA)
2. Department of Natural Resources (DNR)
3. Department of Transportation (DOT)
4. Certificate of Need program (CON). Certificate of Need is a legal document required in most states (including Missouri and Illinois) that requires state approval before healthcare providers can acquire, expand or create certain healthcare facilities and/or services. There are differences in the conditions and categories of service for each state. BJC representatives are responsible for applying for a Certificate of Need as necessary. CON approval is required before BJC Scrubbers and Board approval. Design teams may be asked to provide information for the Certificate of Need application.

a. State of Missouri CON. Administered by the Department of Health and Senior Services, Missouri Health Facilities Review Committee, the following is a list of conditions and categories of service that require CON approval. (The list of conditions and categories of service which require a CON may not be complete or may have changed since the publication of this document. Consult with the state for applicable conditions.)

1) Building new or the addition of long-term care hospital beds to an existing hospital or a freestanding building
2) Building new or the addition of intermediate care facility beds to an existing hospital or a freestanding building
3) Building new or the addition of skilled nursing facility beds to an existing hospital or a freestanding building
4) Purchase of major medical equipment costing in excess of $1,000,000, regardless of location (hospital, freestanding facility, etc.)
5) Replacement of major medical equipment costing in excess of $1,000,000, regardless of location (hospital, freestanding facility, etc.)
6) Building or renovation that results in a new hospital license
7) Acute Hospital Beds
8) Cardiac Catheterization
9) Computed Tomography (CT) Scanners
10) Gamma Knives
11) Intermediate Care Facilities/Mental Retardation (ICF/MR)
12) Long Term Acute Care (LTAC)
13) Lithotripsy
14) Nursing Home Beds/Long Term Care Beds
15) Mobile Hi Technology (CT / MRI / PET, etc)
16) Magnetic Resonance Imaging (MRI) Scanners
17) Positron Emission Tomography (PET) Scanners
18) Radiation Therapy
19) Rehabilitation
20) Assisted Living & Residential Care Facilities

b. State of Illinois CON. Administered by the Illinois Department of Public Health, Health Facilities and Services Review Board (Review Board), the following is a list of conditions and categories of service that require CON approval. (The list of conditions and categories of service which require a CON may not be complete or may have changed since the publication of this document. Consult with the state for applicable conditions.)

1) Any construction project in a hospital building exceeding $11,885,000 for construction cost or for new or replaced equipment
2) Any construction project in a long term care facility exceeding $6,717,000 for construction cost or for new or replaced equipment
3) Any construction project in any other building type exceeding $3,100,000 for construction cost or for new or replaced equipment
4) An increase in bed capacity over and above 10% or 10 beds every two years
5) Any "substantial change" in functional operation of the facility
6) Any proposed establishment or discontinuation of a facility or service
7) Acute Hospital Beds
8) Ambulatory Surgical Centers (ASC)
9) Cardiac Catheterization

10) Intermediate Care Facilities/Mental Retardation (ICF/MR)
11) Long Term Acute Care (LTAC)
12) Nursing Home Beds/Long Term Care Beds
13) Neo-Natal Intensive Care
14) Obstetrics Services
15) Open Heart Surgery
16) Organ Transplants
17) Psychiatric Services
18) Rehabilitation
19) Renal Failure/Dialysis
20) Sub-acute Services
21) Swing Beds

E. Independent Regulations. Other agencies and organizations have regulations that may influence the design.

1. College of American Pathologists (CAP) - Laboratories
2. Clinical Laboratory Improvement Amendments (CLIA) - Laboratories
3. Commission on Accreditation of Rehabilitation Facilities (CARF) – Therapy
4. Various clinical certifications/accreditations that distinguish level of care
5. Factory Mutual Insurance Company (FM Global) – BJC's insurance provider

PART 3 - DOCUMENTATION

3.01 GENERAL

A. Include completed code and life/safety information in the Design Development Set.

PART 4 - SUPPORTING INFORMATION - Not used.

END OF DOCUMENT

BJC HealthCare

RESPONSIBILITY MATRIX

The following matrix identifies those individuals, roles or departments responsible for maintaining the accuracy of the information and those responsible for providing input. Refer to Preface for detailed explanation.

	BJC HealthCare													Hospital/Entity				
	PD&C																	
	Corporate Architect	Corporate Engineer	Director of Planning	Director of Design	Director of Construction	Other:	Clinical Asset Management (CAM)	Risk Management	Real Estate	Ergonomics	Infection Prevention (IP)	Info Systems, Data, Telecom (IS)	Other:	Standards Review Committee	Facilities Engineering	Housekeeping	Security	Other:
Primary Authorship	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Secondary Authorship	☐	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

DOCUMENT REVISION HISTORY

The following able indicates the date the document originated and any subsequent revisions.

Document 102.103 – Regulatory Guideline		
Issue	Description of Issue	Prepared by
2016 v1	Original Issue	G. Zipfel
2018 v1	Reorganized and updated, moved to 102.103	G. Zipfel