

NIH Policy Manual

26101-18-2 - Turnkey Roles and Responsibilities

Issuing Office: OD/OM/ORFDO **Phone:** [\(301\) 594-0999](tel:3015940999)

Release Date: 8/21/2019 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** This Manual Chapter provides the policy, procedures and guidelines for managing the planning, design, and construction requirements to support the procurement and installation of special purpose equipment in National Institutes of Health (NIH) owned facilities.
2. **Filing Instructions:**

Insert: Manual Issuance 26101-18-2, dated 08/21/2019.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Management Support, OMA on 301-496-4606, or enter this URL: <http://oma.od.nih.gov/DMS/Pages/Manual- Chapters.aspx>.

A. Purpose

The purpose of this Manual Chapter is to establish the policy, procedures, and guidelines to ensure an effective management structure is in place to plan, design, and support the construction requirements for the acquisition of specialized equipment at the National Institutes of Health (NIH) using Turnkey Operations.

B. Scope

This policy provides the guidelines, procedures, and the checks and balances necessary for the Office of Research Facilities Development and Operations (ORFDO) to maintain the integrity of NIH owned buildings and systems when Turnkey acquisitions are used to install specialized equipment in support of the NIH mission.

C. Background

Public Health Service Act, 42 U.S.C. § 282(b)(4)(A) authorizes the Director of NIH on behalf of the Secretary of the Department of Health and Human Services (HHS), to acquire, construct, improve, repair, operate and maintain facilities and equipment on NIH campuses.

By authority of the Director of NIH, the Office of Research Facilities Development and Operations (ORFDO) is delegated the responsibility for:

1. The day-today maintenance, management and accountability for real property for which NIH is the holding agency, except as otherwise delegated¹;
2. To exercise administrative authorities related to engineering, facilities planning and construction, and direct Federal special-purpose construction activities²; and
3. To grant rights-of-entry for construction for Federal real property within the NIH's jurisdiction³.

The planning, design, and construction activities that take place in NIH facilities to support the installation of specialized equipment warrant a cradle-to-grave management structure. Institutes, Centers and Offices (ICOs) Subject Matter Experts (SMEs) are required to address the specialized equipment operations. The ORFDO technical experts manage the building and infrastructure needs to support the special purpose equipment and associated research.

The installation and operation of major medical and scientific equipment often require changes to walls, structures, or utilities. The ORFDO's engineers and architects must be involved throughout the life of Turnkey Acquisitions to ensure the availability and reliability of buildings and the infrastructure to support these acquisitions, and to reduce potential risk to the health and safety of patients, the public, accreditation(s), and the NIH mission.

¹ [Delegation of Authority \(DoA\), Property: Real, No. 04: Maintenance, Management and Accountability of Real Property](#)

² [DoA, Property: Real, No. 06: Engineering and Facility Management Services](#)

³ [DoA, Property: Real, No. 06A: Construction Management](#)

D. Policy

To ensure efficient, effective and reliable operations of NIH buildings and the supporting infrastructure are maintained for Turnkey procurement actions, ICOs must establish a Memorandum of Understanding (MOU) with ORFDO, agreeing to:

1. Identify an ICO Contracting Officer Representative (COR) for each procurement;
2. Only the COR and CO can provide guidance to vendor and changes are made solely by the cognizant contracting officer.

3. Include the ORFDO identified Project Officer as the technical expert to address the building infrastructure requirements to work with the official contract COR;
4. Adhere to the NIH Design Requirements Manual;
5. Adhere to ORFDO's Building Permitting Process;
6. Adhere to ORFDO's Project Management Desk Guide for Design and Construction Projects; and to
7. Include the requirements of Items 1 - 6 above in the acquisition plan supporting the procurement action.

E. Responsibilities

1. **Requester:** Responsible for initiating the procurement request and obtaining the required clearances or technical coordination from the ORFDO as noted herein and as listed in Appendix 2.
2. **Head of the IC Program Office:** Responsible for:
 - a. **Developing a MOU with ORFDO agreeing to comply with ORFDO's design, building, permitting and project management guidelines;**
 - b. Signing the MOU with ORFDO; and
 - c. Obtaining the ORFDO Director's signature approving the MOU.
3. **Chief of the ICO Contracting Office:** Responsible for concurring with the IC/ORFDO MOU to comply with ORFDO's design, building, permitting and project management guidelines.
4. **ICO Contracting Officer's Representative (COR):** Responsible for performing the specific technical or administrative functions delegated in writing by the Contracting Officer and is the sole technical point of contact with vendors to address equipment functional requirements identified in Appendix 2.
5. **ORFDO Project Officer (PO):** Responsible for working with the COR to ensure the Turnkey procurement follows ORFDO's planning, design, construction and commissioning guidelines identified in Appendix 2.
6. **Office of Research Facilities Development and Operations (ORFDO):** Responsible for identifying to the ICO, the proposed ORFDO Project Officer to coordinate with the contract COR regarding the building and facilities interface requirements for Turnkey acquisitions consistent with the facility stewardship roles identified in Appendix 2, and for charging a Fee for Service based on the cost of construction.

F. Procedures

1. The ICO submits a [Request for Construction Project Service](#) to ORFDO to obtain technical support and the applicable HHS, ORFDO, and the Office of Research Services (ORS) acquisition clearances identified in Appendix 2.
2. ORFDO assigns a PO to coordinate technical requirements with the identified COR and charges a Fee for Service based on the cost of construction.
3. The Head of the Program Office signs and issues the MOU officially acknowledging ORFDO's cradle-to-grave responsibility to manage NIH buildings to ensure the

availability and reliability of those assets to support Turnkey Acquisitions. The MOU shall state that:

- a. All parties understand that ORFDO has a responsibility to be a good steward of NIH owned facilities;
 - b. ORFDO understands that ICO's within NIH may procure equipment from a commercial vendor or other agencies through an Interagency Agreement (IAA), such as Magnetic Resonance Imaging (MRI) systems, to advance scientific discoveries;
 - c. When such procurements involve design or impact real property, ORFDO must be involved consistent with the roles and responsibilities identified in Appendix 2;
 - d. The COR must consult with ORFDO's PO as the subject matter expert regarding design and construction matters;
 - e. Failure of all parties to approve the MOU in advance of the procurement will absolve ORFDO of responsibility for costs resulting from the need to modify real property assets; and
 - f. Failure to adhere to the procedures in this manual chapter, whether intentional or through negligence, will result in the ICO being responsible for any and all cost, both direct and incidental, to remediate the damage caused to NIH equipment and buildings in accordance with NIH Policy Manual 26307-31- Institutes, Centers and Offices (ICOs) Equipment and Building Damage Compensation Policy.
4. ORFDO's Director signs the MOU and returns it to the Head of the IC Program Office.
 5. The Chief of the ICO Contracting Office reviews the MOU and provides the necessary support to meet the needs of the Program Office.
 6. A template for the MOU is included as Appendix 3.

G. References

1. The Economy Act (31 U.S.C. 1535)
2. Federal Acquisition Regulations (FAR) subpart 17.5
3. [Federal Acquisition Regulations \(FAR\) 1.602-2](#)
4. [Health and Human Services Program Manual, \(Volume 1\), Section 2-3 HHS Facility Project Approval Agreements \(FPAA\)](#)
5. [NIH Delegations of Authority, Real Property, Number 4 – Maintenance, Management and Accountability of Real Property](#)
6. [NIH Delegation of Authority, Real Property, Number 06 – Engineering and Facility Management Services](#)
7. [NIH Delegation of Authority, Real Property, Number 06A – Construction Management](#)
8. [NIH Manual Chapter 1165 – Agency Agreements](#)
9. [NIH Manual Chapter 1370 - Fire Protection and Life Safety Building Permit Process](#)
10. [NIH Manual Chapter 1743 – Keeping and Destroying Records](#)

11. [NIH Manual Chapter 6307-3-Special Clearance and Other Acquisition Procedures](#)
12. [NIH Manual Chapter 26307-31 – Institutes, Centers and Offices \(ICOs\) Equipment and Building Damage Compensation Policy](#)
13. [Office of Research Facilities Division of Technical Resources \(DTR\) Permit Review \(accessible by permission\)](#)
14. [NIH Facilities Development Manual Section 3-10-Clinical Center Complex \(CCC\) Interim Life Safety Measures \(ILSMs\) and Construction Risk Assessment \(CRA\)](#)
15. [NIH Design Requirements Manual](#)

Appendix 1: Definitions

1. **Construction Risk Assessments:** Assessments conducted in the hospital environment as noted in Appendix 2 to identify demolition, construction, renovation, maintenance and infection control risks that have the potential or are known to compromise the safety of occupants, result in disruption of services or cause property damage.
2. **Contracting Officer (CO):** The individual with authority to execute contracts on behalf of the Government. The individual is the sole authorized agent in dealing with the contract. The Contracting Officer has authority to negotiate and execute contracts on behalf of the Government and make changes, amendments, approve payments, terminate contracts, and close out contracts upon satisfactory completion.
3. **Contracting Officer’s Representative (COR):** A federal employee designated in writing by a contracting officer to act as the contracting officer’s representative in monitoring and administering specified aspects of contractor performance *after* award of a contract or order. A COR has no authority to alter any term or condition in the contract or order.
4. **Delegation of Authority:** The specific, formal deputation, assignment, or commitment of a legal power or right to take certain actions and to make certain decisions having legal significance. Such delegations must be stated in writing by the official authorized to delegate the authority.
5. **Design-Build:** Combines design and construction in a single contract with one contractor.
6. **Department of Health and Human Services (HHS) Acquisition Regulations (HHSAR):** Establishes uniform HHS acquisition requirements, policies and procedures to conform to the Federal Acquisition Regulation (FAR) System. The HHSAR implements FAR requirements, policies and procedures, and provides additional policies and procedures that supplement the FAR. The HHSAR contains HHS policies and procedures that govern the acquisition process or otherwise control acquisition relationships between HHS’ contracting activities and contractors.
7. **Federal Acquisition Regulation (FAR):** The Federal Acquisition Regulation (FAR) System is established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies. The FAR System consists of the Federal Acquisition Regulation (FAR), which is the primary document, and agency acquisition regulations that implement or supplement the FAR.

8. **Facility Project Approval Agreement (FPAA-HHS Form 300):** A written agreement between a designated Operating Division (OPDIV) official of HHS (i.e. Project Manager, Project Director and OPDIV Board Member) and the HHS evidencing the OPDIV's commitment to execute a particular project. A FPAA is required for all facility construction projects exceeding \$1 million and improvement projects exceeding \$2 million which includes the cost of the installation of equipment or scientific instruments requiring attachment to a building or its infrastructure, and all repair projects exceeding \$5 million. The FPAA documents the project's scope and description, basis of need, funding source(s), and total cost from all sources. It identifies project schedule milestones, including completion of design, construction, activation, and operational phases.
9. **Head of Contracting Activity (HCA):** The official who has overall responsibility for managing the contracting activity. At the NIH, this individual is the Director, Office of Acquisition and Logistics Management (OALM), Office of Management (OM), Office of the Director (OD).
10. **Interim Life Safety Measures (ILSM): Conducted as noted in Appendix 2** when fire code deficiencies are identified and cannot be immediately corrected, or during renovation, construction or maintenance activities, the safety of occupants is diminished, and ILSMs need to be implemented. ILSMs are administrative actions (e.g. conducting safety training, instituting a fire watch when a fire alarm system is not in operations) that compensate for diminished life safety by providing equivalent protection for occupants.
11. **Project Officer (PO):** The government representative assigned by the Program Office, as defined in the HHS Facilities Development Manual, to advise the ICO CO and or COR in administering architect-engineering (A/E), construction and/or service contracts. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the cost of the contract or a change in performance period of the contract.
12. **Real Property:** Federal real property is defined as any real property owned, leased, or otherwise managed by the Federal Government, both within and outside the United States, and improvements on Federal lands⁴.
13. **Requester:** The individual, usually in an Institute, Center and Office (ICO), who initiates a procurement request, either online or by use of a requisition form.
14. **Special Purpose Equipment:** Equipment including Magnetic Resonance Imaging (MRI) systems, CAT Scanners, scientific instruments and other equipment that require connections to the building infrastructure to operate.
15. **Subject Matter Expert:** A person with bona fide, expert knowledge and expertise in a specific subject for a project.
16. **Turnkey:** A variation of design-build project delivery in which one entity is responsible to the owner for design and construction.

Appendix 2: Table of Responsibilities

AREA OF RESPONSIBILITY	ICO CO	ICO COR ⁵	ORFDO PO ⁶ (FACILITIES SUBJECT MATTER EXPERT)
PERFORM/ENSURES PERFORMANCE OF ALL CONTRACT ACTIONS IN COMPLIANCE WITH THE APPLICABLE FEDERAL ACQUISITION REGULATIONS	X		
ACQUISITION PLANNING PHASE			
Develop Scope of Work(See NIH Policy Manual 6307-3, Appendix 1)		X	X
Utilities Availability Request		X	
Coordinate Utilities Request		X	X
Provide ILSMs & CRAs (See NIH Facilities Development Manual Section 3-10)			X
Obtain HHS Approvals			X
DESIGN PHASE			
Design Development(See the NIH Design Requirements Manual)		X	X
Coordinate Design Review (See ORFDO’s Permitting Review Process) (“Permission Only”)		X	X
Verify Design is Approved by ORF and ORS	X	X	X
Verify ILSM & CRA included for acquisitions in the Clinical Center Complex (See NIH Facilities Development			

Manual Section 3-10)		X	X
CONSTRUCTION PHASE			
Crane Use/Rigging/Site Selection requirements identified			X
Coordinate Crane Use/Rigging/Site Requirements			X
Issue Construction Work Permit			X
Issue Above Ceiling Work Permit			X
Request Utility Outage		X	
Coordinate Utility Outage Request			X
Request Road Closure		X	
Coordinate Road Closure			X
Post ILSM and CRA Requirements			X
Post Davis Bacon Wage Act, etc.	X		X
Submit Safety Plan		X	
Coordinate Safety Plan Approval			X
Quality Control		X	
Quality Assurance			X
Invoice Review (Equipment Installation)		X	
Invoice Approval (Equipment Installation)	X		
Invoice Review (Facility Work)		X	X
Invoice Approval (Facility Work)	X		X
Technical Guidance Support (Facility Work)			X
Technical Guidance		X	
Ensure Facility Pressure Relationship are Maintained		X	X

Ensure ILSM and CRA Requirements are followed		X	
Monitor ILSM and CRA compliance		X	X
Obtain Daily Reports		X	X
Coordinate Change Orders with the Contracting Officer		X	X
Contract Files for Government Records	X	X	X
COMMISSIONING PHASE			
Equipment		X	
Building Support Systems		X	X
Observe Commissioning of Systems			X
Obtain Building Commissioning Reports and Distribute			X
Final Inspection (Equipment)		X	
Final Inspection Building Supporting Systems)		X	X
OPERATION PHASE			
Equipment Service/Maintenance Documentation		X	
Building Utilities Service/Maintenance Documentation		X	X

[5](#) ICO COR has primary technical responsibilities for the project as delegated by the ICO CO in accordance with FAR 1.602-2.

[6](#) ORFDO PO is a Subject Matter Expert (SME) for coordination of facility design and construction matters and has no contractual authority.

Appendix 3: Memorandum of Understanding Template

MEMORANDUM OF UNDERSTANDING COMPLIANCE WITH NIH POLICY MANUAL 26101-18-2 TURNKEY ROLES AND RESPONSIBILITIES	
<p>The _____, _____ (insert the name of the Institute and Center (IC) and the program or responsible office) agrees to administer all Turnkey Acquisitions consistent with the organizational roles and responsibilities identified in Section E. Responsibilities and Section F. Procedures of NIH Policy Manual 26101-18-2.</p>	
<p>To ensure compliance with this NIH Policy Manual _____ (insert the IC's name), requests the Office of Research Facilities Development and Operations (ORFDO) to assign a Project Officer (PO) to be designated in the _____ (insert the type of special purpose equipment being purchased) equipment contract, as the NIH technical expert to address the facility requirements to support the installation of this equipment in Building _____, Room _____ on the NIH _____ campus.</p>	
<p>This agreement has been acknowledged by _____ (insert the name of the IC Contracting Officer) and is the responsibility of _____ (insert the name of the IC program or responsible office) to implement in coordination with the ORFDO Division responsible for project management.</p>	
<p>Failure to adhere to the procedures in this manual chapter, whether intentional or through negligence, will result in the ICO being responsible for any and all cost, both direct and incidental, to remediate the damage caused to NIH equipment and buildings in accordance with NIH Policy Manual 26307-31-Institutes and Centers (IC) Equipment and Building Compensation Policy.</p>	
<p>_____ IC Program Office Managers Signature and Title</p>	<p>_____ Date</p>
<p>The ORFDO designates _____ (insert the Project Officers name) as the PO to support this Turnkey procurement and will be the subject matter expert regarding design and construction matters as identified in Section F. Procedures of this NIH Policy Manual.</p>	
<p>_____ ORFDO Division Directors Signature and Title</p>	<p>_____ Date</p>
<p>_____ ORFDO Director</p>	<p>_____ Date</p>