Documentation of continuing IRB approval is required each year by the renewal date assigned by the cognizant IRB. Documentation of continuing IRB approval must be submitted to the Government for review and approval as soon as it occurs. Continuing approval of the human subjects research must be obtained from the cognizant IRB and provided to the Government until the research is completed or terminated. The contractor may proceed with previously approved human subjects research, if any, under this contract while the Government is conducting continuing review and approval of the human subjects research protocol. In the event that the Government determines, during the course of its review, that the human subjects research in this contract is not in compliance with the regulations set forth at 15 CFR Part 27, or this contract, the Contracting Officer may take the appropriate enforcement action, including disallowing costs, suspending or terminating the human subjects protocol or the contract, by notifying the contractor in writing.

(f) If the conditions upon which IRB approval is based should change in any way, contractor shall immediately notify the Contracting Officer, in writing, of the specified change.

(g) Failure to comply with this contract clause will be considered material noncompliance with the contract, and the Contracting Officer may take appropriate enforcement action, including disallowing costs, suspension or termination of the contract.

(End of clause)
(2) Documentation of approval for the human subjects research protocol, advertisements, recruitment material, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [Note: this option is not available for activities that fall under 45 CFR Part 46 Subpart C].

(g) In addition, if contractor modifies a human subjects research protocol, advertisement, recruitment material, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for Agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

(h) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

1352.237–70 Security processing requirements—high or moderate risk contracts.

As prescribed in 48 CFR 1337.110–70 (b), insert the following clause:

SECURITY PROCESSING REQUIREMENTS—HIGH OR MODERATE RISK CONTRACTS (APR 2010)

(a) Investigative Requirements for High and Moderate Risk Contracts. All contractor (and subcontractor) personnel proposed to be employed under a High or Moderate Risk contract shall undergo security processing by the Department’s Office of Security before being eligible to work on the premises of any Department of Commerce owned, leased, or controlled facility in the United States or overseas, or to obtain access to a Department of Commerce IT system. All Department of Commerce security processing pertinent to this contract will be conducted at no cost to the contractor. The level of contract risk will determine the type and scope of such processing, as noted below.

(1) Investigative requirements for Non-IT Service Contracts are:

(i) High Risk—Background Investigation (BI).

(ii) Moderate Risk—Moderate Background Investigation (MBI).

(2) Investigative requirements for IT Service Contracts are:

(i) High Risk IT—Background Investigation (BI).

(ii) Moderate Risk IT—Background Investigation (BI).

(b) In addition to the investigations noted above, non-U.S. citizens must have a pre-appointment check that includes an Immigration and Customs Enforcement agency check.

(c) Additional Requirements for Foreign Nationals (Non-U.S. Citizens). To be employed under this contract within the United States, non-U.S. citizens must have:

(1) Official legal status in the United States;

(2) Continuously resided in the United States for the last two years; and

(3) Obtained advance approval from the servicing Security Officer of the contracting operating unit in consultation with the DOC Office of Security (OSY) headquarters. (OSY routinely consults with appropriate agencies regarding the use of non-U.S. citizens on contracts and can provide up-to-date information concerning this matter.)

(d) Security Processing Requirement. Processing requirements for High and Moderate Risk Contracts are as follows:

(1) The contractor must complete and submit the following forms to the Contracting Officer’s Representative (COR):

(i) Standard Form 85P (SF–85P), Questionnaire for Public Trust Positions;

(ii) FD–258, Fingerprint Chart with OPM’s designation in the ORI Block; and

(iii) Credit Release Authorization.

(2) The Sponsor will ensure that these forms have been properly completed, initiate the CD–254, Contract Security Classification Specification, and forward the documents to the cognizant Security Officer.

(3) Upon completion of security processing, the Office of Security, through the servicing Security Officer and the Sponsor, will notify the contractor in writing of an individual’s eligibility to be provided access to a Department of Commerce facility or Department of Commerce IT system.

(4) Security processing shall consist of limited personal background inquiries pertaining to verification of name, physical description, marital status, present and former residences, education, employment history, criminal record, personal references, medical fitness, fingerprint classification, and other pertinent information. For non-U.S. citizens, the Sponsor must request an Immigration and Customs Enforcement agency check. It is the option of the Office of Security to repeat the security processing on any contract employee at its discretion.