

§5b.12 Contractors.

(a) All contracts entered into on or after September 27, 1975 which require a contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function must contain a provision requiring the contractor to comply with the Act and this part.

(b) All unexpired contracts entered into prior to September 27, 1975 which require the contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function will be amended as soon as practicable to include a provision requiring the contractor to comply with the Act and this part. All such contracts must be so amended by July 1, 1976 unless for good cause the appeal authority identified in §5b.8 of this part authorizes the continuation of the contract without amendment beyond that date.

(c) A contractor and any employee of such contractor shall be considered employees of the Department only for the purposes of the criminal penalties of the Act, 5 U.S.C. 552a(i), and the employee standards of conduct listed in Appendix A of this part where the contract contains a provision requiring the contractor to comply with the Act and this part.

(d) This section does not apply to systems of records maintained by a contractor as a result of his management discretion, *e.g.*, the contractor's personnel records.

§5b.13 Fees.

(a) *Policy.* Where applicable, fees for copying records will be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual requests that a copy be made of the record to which he is granted access. No fee may be charged for making a search of the system of records whether the search is manual, mechanical, or electronic. Where a copy of the record must be made in order to provide access to the record (*e.g.*, computer printout where no screen reading is available), the copy will be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual or to

a physician or health professional designated by a parent or guardian under §5b.6 of this part, no fee will be charged.

(b) *Fee schedule.* The fee schedule for the Department is as follows:

(1) Copying of records susceptible to photocopying—\$.10 per page.

(2) Copying records not susceptible to photocopying (*e.g.*, punch cards or magnetic tapes)—at actual cost to be determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying does not exceed \$25.

APPENDIX A TO PART 5b—EMPLOYEE
STANDARDS OF CONDUCT

(a) *General.* All employees are required to be aware of their responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a. Regulations implementing the Act are set forth in 45 CFR 5b. Instruction on the requirements of the Act and regulation shall be provided to all new employees of the Department. In addition, supervisors shall be responsible for assuring that employees who are working with systems of records or who undertake new duties which require the use of systems of records are informed of their responsibilities. Supervisors shall also be responsible for assuring that all employees who work with such systems of records are periodically reminded of the requirements of the Act and are advised of any new provisions or interpretations of the Act.

(b) *Penalties.* (1) All employees must guard against improper disclosure of records which are governed by the Act. Because of the serious consequences of improper invasions of personal privacy, employees may be subject to disciplinary action and criminal prosecution for knowing and willful violations of the Act and regulation. In addition, employees may also be subject to disciplinary action for unknowing or unwillful violations, where the employee had notice of the provisions of the Act and regulations and failed to inform himself sufficiently or to conduct himself in accordance with the requirements to avoid violations.

(2) The Department may be subjected to civil liability for the following actions undertaken by its employees:

(a) Making a determination under the Act and §§5b.7 and 5b.8 of the regulation not to amend an individual's record in accordance with his request, or failing to make such review in conformity with those provisions;

(b) Refusing to comply with an individual's request for notification of or access to a record pertaining to him;

Pt. 5b, App. A

(c) Failing to maintain any record pertaining to any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such a record, and consequently a determination is made which is adverse to the individual; or

(d) Failing to comply with any other provision of the Act or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual.

(3) An employee may be personally subject to criminal liability as set forth below and in 5 U.S.C. 552a (i):

(a) Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by the Act or by rules or regulations established thereunder, and who, knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

(b) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements [of the Act] shall be guilty of a misdemeanor and fined not more than \$5,000.

(c) *Rules Governing Employees Not Working With Systems of Records.* Employees whose duties do not involve working with systems of records will not generally disclose to any one, without specific authorization from their supervisors, records pertaining to employees or other individuals which by reason of their official duties are available to them. Notwithstanding the above, the following records concerning Federal employees are a matter of public record and no further authorization is necessary for disclosure:

- (1) Name and title of individual.
- (2) Grade classification or equivalent and annual rate of salary.
- (3) Position description.
- (4) Location of duty station, including room number and telephone number.

In addition, employees shall disclose records which are listed in the Department's Freedom of Information Regulation as being available to the public. Requests for other records will be referred to the responsible Department official. This does not preclude employees from discussing matters which are known to them personally, and without resort to a record, to official investigators of Federal agencies for official purposes such as suitability checks, Equal Employment Opportunity investigations, adverse action proceedings, grievance proceedings, etc.

45 CFR Subtitle A (10-1-02 Edition)

(d) *Rules governing employees whose duties require use or reference to systems of records.* Employees whose official duties require that they refer to, maintain, service, or otherwise deal with systems of records (hereinafter referred to as "Systems Employees") are governed by the general provisions. In addition, extra precautions are required and systems employees are held to higher standards of conduct.

(1) Systems Employees shall:

(a) Be informed with respect to their responsibilities under the Act;

(b) Be alert to possible misuses of the system and report to their supervisors any potential or actual use of the system which they believe is not in compliance with the Act and regulation;

(c) Make a disclosure of records within the Department only to an employee who has a legitimate need to know the record in the course of his official duties;

(d) Maintain records as accurately as practicable.

(e) Consult with a supervisor prior to taking any action where they are in doubt whether such action is in conformance with the Act and regulation.

(2) Systems Employees shall not:

(a) Disclose in any form records from a system of records except (1) with the consent or at the request of the subject individual; or (2) where its disclosure is permitted under §5b.9 of the regulation.

(b) Permit unauthorized individuals to be present in controlled areas. Any unauthorized individuals observed in controlled areas shall be reported to a supervisor or to the guard force.

(c) Knowingly or willfully take action which might subject the Department to civil liability.

(d) Make any arrangements for the design development, or operation of any system of records without making reasonable effort to provide that the system can be maintained in accordance with the Act and regulation.

(e) *Contracting officers.* In addition to any applicable provisions set forth above, those employees whose official duties involve entering into contracts on behalf of the Department shall also be governed by the following provisions:

(1) *Contracts for design, or development of systems and equipment.* No contract for the design or development of a system of records, or for equipment to store, service or maintain a system of records shall be entered into unless the contracting officer has made reasonable effort to ensure that the product to be purchased is capable of being used without violation of the Act or regulation. Special attention shall be given to provision of physical safeguards.

(2) *Contracts for the operation of systems of records.* A review by the Contracting Officer, in conjunction with other officials whom he

feels appropriate, of all proposed contracts providing for the operation of systems of records shall be made prior to execution of the contracts to determine whether operation of the system of records is for the purpose of accomplishing a Department function. If a determination is made that the operation of the system is to accomplish a Department function, the contracting officer shall be responsible for including in the contract appropriate provisions to apply the provisions of the Act and regulation to the system, including prohibitions against improper release by the contractor, his employees, agents, or subcontractors.

(3) *Other service contracts.* Contracting officers entering into general service contracts shall be responsible for determining the appropriateness of including provisions in the contract to prevent potential misuse (inadvertent or otherwise) by employees, agents, or subcontractors of the contractor.

(f) *Rules Governing Responsible Department Officials.* In addition to the requirements for Systems Employees, responsible Department officials shall:

(1) Respond to all requests for notification of or access, disclosure, or amendment of records in a timely fashion in accordance with the Act and regulation;

(2) Make any amendment of records accurately and in a timely fashion;

(3) Inform all persons whom the accounting records show have received copies of the record prior to the amendments of the correction; and

(4) Associate any statement of disagreement with the disputed record, and

(a) Transmit a copy of the statement to all persons whom the accounting records show have received a copy of the disputed record, and

(b) Transmit that statement with any future disclosure.

APPENDIX B TO PART 5b—ROUTINE USES APPLICABLE TO MORE THAN ONE SYSTEM OF RECORDS MAINTAINED BY HHS

(1) In the event that a system of records maintained by this agency or carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(2) Referrals may be made of assignments of research investigators and project mon-

itors to specific research projects to the Smithsonian Institution to contribute to the Smithsonian Science Information Exchange, Inc.

(3) In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

(4) A record from this system of records may be disclosed as a "routine use" to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

(5) In the event that a system of records maintained by this agency to carry out its function indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether state or local charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(6) Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

(7) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

(8) Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt

Pt. 7

from mandatory disclosure, disclosure may be made from this system of records.

(9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

(10)-(99) [Reserved]

(100) To the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

(101) To individuals and organizations, deemed qualified by the Secretary to carry out specific research solely for the purpose of carrying out such research.

(102) To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

(103) Disclosures in the course of employee discipline or competence determination proceedings.

APPENDIX C TO PART 5b—DELEGATIONS OF AUTHORITY [RESERVED]

PART 6 [RESERVED]

PART 7—EMPLOYEE INVENTIONS

Sec.

- 7.0 Who are employees.
- 7.1 Duty of employee to report inventions.
- 7.3 Determination as to domestic rights.
- 7.4 Option to acquire foreign rights.
- 7.7 Notice to employee of determination.
- 7.8 Employee's right of appeal.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR 1953 Supp. E.O. 10096, 15 FR 391; 3 CFR, 1950 Supp. and E.O. 10930, 26 FR 2583; 3 CFR 1961 Supp.

§ 7.0 Who are employees.

As used in this part, the term *Government employee* means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Commissioner of Patents that to include him or them would be impracticable or inequitable, given the reasons therefor. A person shall not be considered to be

45 CFR Subtitle A (10-1-02 Edition)

a part-time employee or part-time consultant for this purpose unless the terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

[27 FR 7986, Aug. 10, 1962]

§ 7.1 Duty of employee to report inventions.

Every Department employee is required to report to the Assistant Secretary (Health and Scientific Affairs) in accordance with the procedures established therefor, every invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information, or of time or services of other Government employees on official duty.

[31 FR 12842, Oct. 1, 1966]

§ 7.3 Determination as to domestic rights.

The determination of the ownership of the domestic right, title, and interest in and to an invention which is or may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the Assistant Secretary (Health and Scientific Affairs), in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Commissioner of Patents as follows:

- (a) The Government as represented by the Assistant Secretary (Health and Scientific Affairs) shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are