controlled substances which are the subject of the award.

(2) The following certification shall be made a part of the IFB (and contract) to be completed and signed by the bidder and returned with the bid:

The bidder certifies that he/she is registered with the Drug Enforcement Administration, Department of Justice, as a manufacturer, distributor, or dispenser of the controlled substances for which a bid is submitted and that the registration number is _____.

_____
Name of bidder (print or type)

_____
Signature of bidder

_____
Address of bidder (print or type)

_____
City, State, Zip code

(3) As a condition precedent to making an award for surplus controlled substances, the following shall be submitted to the Drug Enforcement Administration (DEA), Department of Justice, Washington, DC 20537, Attn: Regulatory Support Section (ODR):

(i) The name and address of the bidder(s) to whom an award is proposed to be made and the bidder(s) registration number(s);

(ii) The name and address of both the holding activity and the selling activity;

(iii) A description of the controlled substances, how those substances are packaged, and the quantity of substances proposed to be sold to the bidder;

(iv) The identification of the IFB by its number, and date on which such bid(s) expire(s); and

(v) A request for advice as to whether the bidder is a registered manufacturer, distributor, or dispenser of controlled substances.

(d) *Destruction of controlled substances.* Controlled substances shall not be abandoned, and destruction of controlled substances must be accomplished in accordance with the terms and conditions applicable to drugs, biologicals, and reagents under § 101–42.1102–5(d).

(1) The following shall be destroyed by the holding agency or State agency:

(i) Controlled substances determined surplus at one time and one place with an acquisition cost of less than $500;

(ii) Controlled substances in a deteriorated condition or otherwise unusable;

(iii) Controlled substances for sale in accordance with § 101–42.1102–3(c) but for which no satisfactory or acceptable bids were received.

(2) In addition to the requirements set forth herein, each executive agency and State agency shall comply with the DEA regulations, 21 CFR 1307.21, which provide procedures for disposing of controlled substances, or with equivalent procedures approved by DEA.

(3) Destruction of controlled substances shall be performed by an employee of the holding agency or State agency in the presence of two additional employees of the agency as witnesses to that destruction unless the special agent in charge (SAC) of the DEA Divisional Office directs otherwise.

§ 101–42.1102–4 Nuclear Regulatory Commission-controlled materials.

(a) *General.* The Nuclear Regulatory Commission (NRC) has exclusive control over licensing, use, transfer, and disposition of NRC-controlled materials.

(b) *Transfer of NRC-controlled materials.* NRC-controlled materials shall not be reported to GSA as excess personal property, nor shall they be made available for excess and surplus screening as nonreportable property. Transfer and disposition of such materials do not require GSA approval and shall be accomplished only under the applicable regulations of the NRC (see 10 CFR parts 30 through 35, 40, and 70).

(c) *Information and inquiries.* All inquiries for further information or specific instructions regarding the licensing, use, transfer, or disposition of NRC-controlled materials shall be directed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555.

§ 101–42.1102–5 Drugs, biologicals, and reagents other than controlled substances.

In addition to the requirements of subparts 101–42.2 through 101–42.4, drugs, biologicals, and reagents which are fit for human use shall be reported as provided in this § 101–42.1102–5. Drugs, biologicals, and reagents that

are controlled substances are subject to the provisions of § 101–42.1102–3.

(a) *Utilization requirements.* Excess drugs, biologicals, and reagents shall be reported or otherwise made available to GSA as provided in § 101–42.204 and subpart 101–43.3. Drugs, biologicals, and reagents other than controlled substances may be separately packaged or may be components of a drug kit. Drug kits shall be clearly labeled to identify components unfit for human use. The holding agency shall destroy, as provided in paragraph (d) of this section, both separately packaged items and kit components which have been determined by the holding agency to be unfit for human use. However, items determined unfit because of expired shelf life may be transferred for animal experimental use on a case-by-case basis subject to prior approval by GSA.

(b) *Donation requirements.* Surplus drugs, biologicals, and reagents other than controlled substances which are not required to be destroyed as provided in paragraph (d) and which are not transferred pursuant to paragraph (a) of this section may be donated to eligible organizations as provided in subpart 101–42.3 and part 101–44. Drugs, biologicals, and reagents which are unfit for human use will not be offered for donation. However, items determined unfit because of expired shelf life may be donated for animal experimental use on a case-by-case basis subject to prior approval by GSA.

(1) When surplus drugs, biologicals, and reagents are considered for donation, a letter of clearance shall be obtained by the State agency or designated donee from the Food and Drug Administration (FDA) indicating that the items requested may be safely donated. The letter of clearance must accompany the SF 123. Items which do not fall within the purview of FDA, or which FDA indicates are unsuitable, will not be considered by GSA for donation.

(2) For purposes of obtaining the letter of clearance from FDA, the State agency or designated donee shall be responsible for obtaining samples from the holding agency, providing these samples to FDA, and ensuring the security of the samples while in transit. Before laboratory examinations are undertaken by FDA, an estimate of the expected cost of the quality assurance examination shall be furnished by FDA to the State agency or donee. Payment of any costs for laboratory examinations for quality assurance of samples shall be arranged by the State agency or donee.

(3) Surplus drugs, biologicals, and reagents requested for donation by State agencies shall not be transported by the State agency or stored in its warehouse prior to distribution to donees. Arrangements will be made by the State agency for the donee to make direct pickup at the holding agency after approval by GSA and after notification by the holding agency that the property is ready for pickup.

(4) Standard Forms 123 from a State agency requesting surplus drugs, biologicals, and reagents for donation shall not be processed or approved by GSA until it has been determined by the GSA donation representative that the specific donee is legally licensed to administer, dispense, store, or distribute such property.

(5) The SF 123 shall also contain a statement that:

(i) The property is being requested for donation to a specific donee whose complete name and address, including the name and telephone number of the donee's authorized representative, appear on the front of the SF 123 in block 12, and that a copy of the donee's license, registration, or other legal authorization to administer, dispense, store, or distribute such property is attached and made a part of the SF 123;

(ii) The items will be distributed only to institutions licensed and authorized to administer and dispense such items or to organizations authorized to store such items; and

(iii) In addition to the normal certifications required to be executed by authorized representatives of donee institutions or organizations when property is acquired by donation, the State agency shall obtain a certification from the donee indicating that:

(A) The items transferred to the donee institution or organization will be safeguarded, dispensed, and administered under competent supervision;

(B) Adequate facilities are available to effect full accountability and proper

storage of the items under the Federal, State, and local statutes governing their acquisition, storage, and accountability;

(C) The administration or use of the items requested shall be in compliance with the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301–394).

(c) *Sales requirements.* Surplus drugs, biologicals, and reagents other than controlled substances which are not required to be destroyed as provided in paragraph (d) and which are not transferred pursuant to paragraph (a) or (b) of this section may be offered for sale by sealed bid under the provisions of subparts 101–45.3 and 101–42.4. The following safeguards and instructions shall be observed to ensure stability, potency, and suitability of the product and its labeling for use in civilian channels:

(1) Before reporting the surplus drugs, biologicals, and reagents to the selling agency pursuant to the provisions of §§ 101–45.303 and 101–42.402, holding agencies shall request that an examination be made by the Field Scientific Coordination Staff, ACFA-CF–30, located in the appropriate FDA district office, of surplus unexpired drugs and reagents, having an acquisition cost of $500 or more per manufacturer's lot/batch number.

(i) When requesting such an examination, FDA requires the submission of a list and one sample of each of the drugs to be examined.

(ii) Additional samples may be requested if necessary for laboratory examination. Reimbursement for examination of the surplus drugs or reagents may be required by FDA. Before laboratory examinations are undertaken, FDA will give the inquiring agency an estimate of the expected costs. If, under subpart 101–45.9, the cost of the quality assurance is not justified by the value of the material involved, the lot or lots may be destroyed.

(iii) The reporting document prescribed in § 101–45.303(b) shall have attached to it a copy of the letter received by the reporting agency from FDA stating that the articles offered have been reviewed and may appropriately be distributed or sold, subject when necessary to specified limitations.

(2) Surplus drugs, biologicals, and reagents normally shall not be physically transferred to the selling agency but should remain at the holding agency for precautionary and safety measures.

(3) Surplus drugs, biologicals, and reagents shall be sold only to those entities which are legally qualified to engage in the sale, manufacture, or distribution of such items.

(4) Sales of surplus drugs, biologicals, and reagents other than controlled substances shall be processed as follows:

(i) The invitation for bids (IFB) shall:

(A) Consist only of surplus drugs, biologicals, and reagents;

(B) Contain the expiration date of material being offered for sale;

(C) Describe the composition of the material being offered for sale;

(D) Require the normal bid deposit prescribed in § 101–45.304–10; and

(E) Contain the following special condition of sale:

> The bidder shall complete, sign, and return with his/her bid the certification as contained in this invitation. No award will be made or sale consummated until after this agency has determined that the bidder is legally licensed to engage in the manufacture, sale, or distribution of drugs.

(ii) The following certification shall be made a part of the invitation for bids (and contract), to be completed and signed by the bidder, and returned with the bid with a copy of his/her license. Failure to sign the certification may result in the bid being rejected as nonresponsive.

> The bidder certifies that he/she is legally licensed to engage in the manufacture, sale, or distribution of drugs, and proof of his/her license to deal in such materials is furnished with this bid.

Name of bidder (print or type)

Signature of bidder

Address of bidder (print or type)

City, State, ZIP code

(d) *Destruction of surplus drugs, biologicals, and reagents.* (1) Surplus drugs, biologicals, and reagents shall

not be abandoned under any circumstances. The following shall be destroyed by the holding agency under the provisions of this paragraph (d):

(i) Surplus drugs, biologicals, and reagents determined by the holding agency to be unsafe because of deterioration or overage condition, in open or broken containers, recommended for destruction by FDA, unfit for human consumption, or otherwise unusable; and

(ii) Surplus drugs, biologicals, and reagents which have been offered for sale under the provisions of paragraph (c) of this section but for which no satisfactory or acceptable bid or bids have been received.

(2) When surplus drugs, biologicals, and reagents are required to be destroyed by the holding agency or State agency, they shall be destroyed in such a manner as to ensure total destruction of the substance to preclude the use of any portion thereof. When major amounts are to be destroyed, the action shall be coordinated with local air and water pollution control authorities.

(3) Destruction of surplus drugs, biologicals, and reagents shall be performed by an employee of the holding agency or State agency in the presence of two additional employees of the agency as witnesses to that destruction.

(i) Disposal of Resource Conservation and Recovery Act (RCRA) regulated, noncontrolled, condemned hazardous substances in Federal supply class (FSC) 6505 shall be destroyed without the witnessing by two employees of the agency. The controls which the Environmental Protection Agency places upon the disposal of RCRA regulated noncontrolled drugs, 40 CFR part 260 *et seq.*, are sufficiently stringent to ensure that these drugs will be destroyed without agency witnessing.

(ii) It is the holding agency's responsibility to take all necessary measures to ensure that contractor performance is in accordance with the provisions of this §101–42.1102–5.

(4) When surplus drugs, biologicals, and reagents have been destroyed, the fact, manner, and date of the destruction and type and quantity destroyed shall be so certified by the agency employee charged with the responsibility for that destruction. The two agency employees who witnessed the destruction shall sign the following statement, except as noted in paragraph (d)(3) of this section, which shall appear on the certification below the signature of the certifying employee:

I have witnessed the destruction of the (drugs, biologicals, and reagents) described in the foregoing certification in the manner and on the date stated herein:

Witness	Date
Witness	Date

(5) Items mentioned parenthetically in the statement contained in paragraph (d)(5) of this section which are not applicable at the time of destruction shall be deleted from the statement. The signed certification and statement of destruction shall be made a matter of record and shall be retained in the case files of the holding agency or State agency.

§101–42.1102–6 Noncertified and certified electronic products.

(a) *Utilization requirements.*(1) Excess electronic items for which radiation safety performance standards are prescribed by FDA under 21 CFR Part 1000 shall be reported or otherwise made available for transfer to Federal agencies under subparts 101–43.3 and 101–42.2. Excess reports shall identify noncertified electronic products and shall contain a statement that the items may not be in compliance with applicable radiation safety performance standards prescribed by FDA under 21 CFR Part 1000. Certified electronic products may be reported and transferred under the procedures in part 101–43.

(2) Transfers of noncertified electronic products among Federal agencies shall be accomplished as set forth in §§101–42.207, 101–43.309, and paragraph (a) of this section. The transfer order must contain a certification that the transferee is aware of the potential danger in using the item without a radiation test to determine the acceptability for use and/or modification to bring it into compliance with the radiation safety performance standard prescribed for the item under 21 CFR Part 1000 and agrees to accept the item from