

- i.1. Alloys with more than 25% nickel and 20% chromium by weight;
- i.2. Ceramics;
- i.3. Ferrosilicon;
- i.4. Fluoropolymers;
- i.5. Glass (including vitrified or enameled coatings or glass lining);
- i.6. Graphite or carbon-graphite;
- i.7. Nickel or alloys with more than 40% nickel by weight;
- i.8. Tantalum or tantalum alloys;
- i.9. Titanium or titanium alloys, or
- i.10. Zirconium or zirconium alloys.
- j. Incinerators designed to destroy chemical warfare agents, chemical weapons precursors controlled by 1C350, or chemical munitions having specially designed waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1000° C in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:
 - j.1. Alloys with more than 25% nickel and 20% chromium by weight;
 - j.2. Ceramics; or
 - j.3. Nickel or alloys with more than 40% nickel by weight.

Technical Note: Carbon-graphite is a composition consisting primarily of graphite and amorphous carbon, in which the graphite is 8 percent or more by weight of the composition.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B352 is amended by revising the List of Items Controlled to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

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List of Items Controlled

Unit: Equipment in number

Related Controls: N/A

Related Definitions: For purposes of this entry, isolators include flexible isolators, dry boxes, anaerobic chambers and glove boxes.

Items:

a. Complete containment facilities at P3 or P4 containment level.

Technical Note: P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, 1983).

b. Fermenters capable of cultivation of pathogenic microorganisms, viruses, or for toxin production, without the propagation of aerosols, having a capacity equal to or greater than 20 liters.

Technical Note: Fermenters include bioreactors, chemostats, and continuous-flow systems.

- c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:
 - c.1. One or more sealing joints within the steam containment area;
 - c.2. A flow rate greater than 100 liters per hour;
 - c.3. Components of polished stainless steel or titanium; and
 - c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note: Centrifugal separators include decanters.

- d. Cross (tangential) flow filtration equipment and accessories, as follows:
 - d.1. Cross (tangential) flow filtration equipment capable of separation of pathogenic microorganisms, viruses, toxins or cell cultures, without the propagation of aerosols, having all of the following characteristics:
 - d.1.a. A total filtration area equal to or greater than 1 square meter (1 m²); and
 - d.1.b. Capable of being sterilized or disinfected in-situ.

N.B.: 2B352.d.1 does not control reverse osmosis equipment, as specified by the manufacturer.

- d.2. Cross (tangential) flow filtration components (e.g., modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m²) for each component and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: In this ECCN, “sterilized” denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. “Disinfected” denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. “Disinfection” and “sterilization” are distinct from “sanitization”, the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

- e. Steam sterilizable freeze-drying equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours, but less than 1,000 kgs of ice in 24 hours.
- f. Protective and containment equipment, as follows:
 - f.1. Protective full or half suits, or hoods dependant upon a tethered external air supply and operating under positive pressure;

Technical Note: This entry does not control suits designed to be worn with self-contained breathing apparatus.

- f.2. Class III biological safety cabinets or isolators with similar performance standards, e.g., flexible isolators, dry boxes, anaerobic chambers, glove boxes or laminar flow hoods (closed with vertical flow).
- g. Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 m³ or greater.

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2E001 is amended by revising the License Requirements section to read as follows:

2E001 “Technology according to the General Technology Note for the “development” of equipment or “software” controlled by 2A (except 2A991, 2A993, or 2A994), 2B (except 2B991, 2B993, 2B996, 2B997 or 2B998), or 2D (except 2D991, 2D992, or 2D994).

License Requirements

Reason for Control: NS, MT, NP, CB, AT

Control(s)	Country chart
NS applies to “technology” for items controlled by 2A001, 2B001 to 2B009, 2D001 or 2D002.	NS Column 1
MT applies to “technology” for items controlled by 2B004, 2B009, 2B018, 2B104, 2B105, 2B109, 2B116, 2B117, 2D001 or 2D101 for MT reasons.	MT Column 1
NP applies to “technology” for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B232, 2D001, 2D002, 2D101, 2D201 or 2D202 for NP reasons.	NP Column 1
NP applies to “technology” for items controlled by 2A290 to 2A293, 2B290, or 2D290 for NP reasons.	NP Column 2
CB applies to “technology” for equipment controlled by 2B350 to 2B352 and for valves controlled by 2A226 or 2A292 having the characteristics of those controlled by 2B350.g.	CB Column 3