



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 1

5 POST OFFICE SQUARE, SUITE 100  
BOSTON, MA 02109-3912

Ms. Jean Palmateer  
DePuy Orthopaedics, Inc.  
325 Paramount Drive  
Raynham, MA 02767

Re: Applicability of National Emission Standards for Hazardous Air Pollutants: Area Source  
Standards for Nine Metal Fabrication and Finishing Source Categories, 40 CFR Part 63,  
Subpart XXXXXX

Dear Ms. Palmateer:

The U.S. Environmental Protection Agency, Region 1 (EPA) has reviewed your letter dated March 23, 2011 requesting a determination as to whether the National Emission Standards for Hazardous Air Pollutants, Area Source Standards for Nine Metal Fabrication and Finishing Source Categories, 40 CFR Part 63, Subpart XXXXXX (Subpart 6X), applies to metal processing operations at DePuy Orthopaedics, Inc. of Raynham, MA (DePuy). This letter provides you with a written applicability determination.

DePuy's March 23, 2011 letter summarizes the metal processing operations at the facility and provides that the facility is an area source of hazardous air pollutants. DePuy manufactures a broad range of orthopedic solutions, including hip and knee replacement components and operating room products. DePuy operates an investment casting process in which stainless steel and cobalt-chromium alloys are cast into single use molds. The cast parts are then finished using typical metal processing operations including blasting, grinding and polishing. The alloys contain chromium and nickel. DePuy's North American Industry Classification System (NAICS) code is 339113, Surgical Appliance and Supplies Manufacturing.

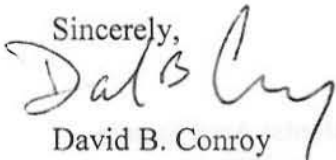
The Subpart 6X applicability provisions at 63.11514(a) specify that Subpart 6X applies to an area source that is primarily engaged in the operations in one of the nine source categories listed in paragraphs (a)(1) through (9) of this section. Descriptions of these nine source categories are shown in Table 1 of Subpart 6X. "Primarily engaged" is defined in section 63.11522 to mean the manufacturing, fabricating or forging of one or more products listed in one of the nine metal fabrication and finishing source categories where this production represents at least 50 percent of the production at a facility<sup>1</sup>. Surgical appliance and supplies manufacturing is not one of the nine source categories identified in Section 63.11514(a). Because DePuy is not primarily

<sup>1</sup> See section 63.11522 for the complete definition of primarily engaged.

engaged in manufacturing products in one of the nine source categories listed in section 63.11514(a) and Table 1 of the regulation, EPA has determined that DePuy is not subject to Subpart 6X.

This applicability determination is made in reliance on the accuracy of the information provided to EPA, and does not relieve DePuy of the responsibility for complying fully with any and all applicable federal, state and local laws, regulations and permits. If you have any questions about this letter, please contact Susan Lancey of my staff at (617) 918-1656.

Sincerely,



David B. Conroy  
Manager, Air Programs Branch

cc: Marc Wolman, MassDEP