



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
NASHVILLE, TENNESSEE 37243-0435

DON SUNDQUIST
GOVERNOR

MILTON H. HAMILTON, JR.
COMMISSIONER

November 19, 1999

William D. Travers
Executive Director for Operations
Nuclear Regulatory Commission
Washington DC 20555-0001

Dear Mr. Travers:

In response to your request of November 16, 1999, I am enclosing information addressing the four points you raised concerning Manufacturing Sciences Corporation (MSC). This will supplement the copy of the March 1999 amendment to the MSC license and the supporting documentation provided to Mr. Paul Lohaus of the NRC's Office of State Programs under a cover letter dated November 16, 1999.

I am completely committed to ensuring the health and safety of our citizens, and will continue to closely monitor this project. If you require any other materials, please contact me or the Division of Radiological Health.

Sincerely,

Milton H. Hamilton, Jr.

MHH:LEN:jhg

EXECUTIVE SUMMARY

MANUFACTURING SCIENCES CORPORATION AUTHORIZATION TO DECONTAMINATE NICKEL FOR UNRESTRICTED RELEASE

Description of Activities Authorized by the March 1999 Amendment

The March 1999 amendment authorized, in general terms, the receipt, decontamination, sampling and survey (to determine compliance with approved unrestricted release criteria), and release of 6000 tons of decontaminated nickel. This authorization was issued following years of research and process development activities performed by Manufacturing Sciences Corporation (MSC), to develop and validate the effectiveness of its decontamination process, under license authorization issued in 1990.

In accordance with a November 15, 1999, verbal request by NRC staff, copies of the March 1999 amendment to the MSC license (originally issued on August 8, 1985) and non-proprietary referenced supporting documentation have been provided to the NRC, under a cover letter dated November 16, 1999.

Basis on Which Authorized

The basis for the March 1999 amendment was:

- Operational information submitted during the research and development phases of the project as authorized in earlier amendments which demonstrated the feasibility of the process.
- Criteria for unrestricted release based on various analyses performed by the licensee and the Division, including "Risk Analysis: Nickel Contaminated with ⁹⁹Tc and Uranium," submitted in support of the amendment request, and comparison to the criteria of NRC Regulatory Guide 1.86.
- The sampling plan submitted in support of the amendment request, which provided for each finished nickel ingot to be sampled and analyzed for quality control purposes during ingot production and for quality assurance purposes after production.
- The presence of an adequate radiological worker and environmental protection program as determined through the routine inspection program conducted by the Division.

Process Description

A complete description of the electro-refining process used by MSC to decontaminate nickel is contained in the following documentation, which is proprietary information as provided under Tennessee "State Regulations for Protection Against Radiation," supporting an earlier amendment request:

- "Functional Specification Full Scale Electro-refining Experiment Modification 1, April 2, 1998"

The following is a general description of the activities authorized ancillary to the processing of nickel:

- Nickel barriers from the gaseous diffusion process are removed from the decommissioned facilities at the former K-25 site.
- Contaminated nickel components are transported to MSC in sealed security containers.
- MSC personnel with appropriate security clearances transfer the nickel into the induction furnaces where it is melted.
- A fluxing agent is added to the melt to promote movement of contaminants into the slag.
- The nickel is poured into a mold to form a nickel anode.
- The nickel anode is processed electro-chemically to remove contaminants to meet established criteria.
- Each nickel ingot is sampled and analyzed for compliance with established criteria for quality control and quality assurance purposes.
- Nickel not meeting the criteria may either be reprocessed or disposed in accordance with the Division's regulations.

Description of Status of Operations Under the License

- One production-scale cell is currently being operated for experience and optimization of the process.
- Construction of the production facility has not yet begun. Current plans call for construction activities to commence early in the year 2000 and to require about four (4) months to complete. Facility design engineering is approximately sixty (60) percent complete.
- No nickel has been released for unrestricted use to date.
- First shipment of processed nickel is expected approximately November 2000.

**REQUESTS AND QUESTIONS
FOR THE NUCLEAR REGULATORY COMMISSION**

QUESTION 1. Please provide a copy of the complete agreement between the Nuclear Regulatory Commission (NRC) and the State of Tennessee issued pursuant to Section 274 (b) of the Atomic Energy Act, including any amendments issued subsequent to the original 1965 amendment.

ANSWER.

This information was submitted in our interim response letter dated November 15, 1999.

QUESTION 2. Please provide a copy of the complete license issued by the State of Tennessee to Manufacturing Sciences Corporation (MSC), including any amendments issued subsequent to the original 1965 amendment.

ANSWER.

This information was submitted in our interim response letter dated November 15, 1999.

QUESTION 3. In 1962, when the NRC first promulgated its regulations setting out agreement states' authority to regulate some aspects of byproduct material use and disposal, the Commission reserved for itself - and denied to the states - the authority to license, or exempt from licensing, the transfer of possession or control over any "equipment, device, commodity or other product containing source, byproduct or special nuclear material that could be "distribut[ed] to the general public." (10 CFR 150.15.) The reason was clearly stated:

The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices and the ultimate uncontrolled release of these materials into the environment, involve questions of national policy which have not yet been resolved. It is for this reason that the Commission is retaining control over such products. (21 Fed. Reg. 1351, Feb. 14, 1962.)

Does the NRC still retain control over such products and the "ultimate" uncontrolled release of those materials? If the answer is in the negative, please explain and provide supporting documentation.

ANSWER.

NRC still maintains control over the distribution of products containing byproduct material and the ultimate uncontrolled release of those materials. However, as explained in greater detail below, the Commission has consistently applied this retention of control to products involving

the intentional introduction of radioactive material into the products to utilize the material's radioactive, physical, or chemical properties, not to materials containing very low levels of residual radioactive material.

Pursuant to 10 CFR 150.15(a)(6), NRC has reserved authority over the distribution of items containing byproduct material to persons exempt from licensing requirements. This specific reservation of authority is consistent with NRC's discretionary authority under §274 c. of the Atomic Energy Act (AEA):

... to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

Since the passage of this provision, the Commission's implementation of §150.15(a)(6) is based on the understanding that the reservation of authority to NRC applies to products involving the intentional introduction of radioactive material to take advantage of the properties of the material. The legislative and regulatory history behind these provisions, as well as decades of regulatory practice, show that it has never been the Commission's intent to reserve authority over releases of material other than those involving these types of products.

The legislative history of §274 c. itself demonstrates that the general intent of the provision was to give the Commission clear authority to retain jurisdiction, should it so choose, for those situations where manufacturers have intentionally incorporated radioactive material into

products. In the section-by-section analysis of the Senate Report for the 1958 amendment to the AEA, the Joint Committee quoted extensively from the Atomic Energy Commission's own analysis of the bill in providing the basis for enacting the last paragraph in §274 c. The language clearly shows that its intent was to address products that include the intentional introduction of radioactive material to take advantage of the radioactive, physical, or chemical properties of the material. The language in the report reads as follows (**emphasis added**):

Under the provision, the Commission will be in a position to assure that articles containing byproduct, source, or special nuclear material will not be distributed unless they meet the Commission's minimum safety requirements, including appropriate manufacturing and processing specifications and labeling requirements.

Manufacturers of such devices as gages (sic), luminous markers, radiograph and teletherapy devices, electronic tubes, and so forth sell their products throughout the United States and in many foreign countries. It is important to assure that controls with respect to such products should be uniform and should be uniformly applied.

There is an additional reason why it is important for the Commission to continue the exercise of control over the distribution of articles containing source, by product, or special nuclear material. **As the supply of such radioactive materials, particularly byproduct materials, increases, there may be increasing proposals by manufacturers and processors to incorporate such materials in articles (such as consumer products) that receive widespread distribution.** Although it is not a

present problem, the extent to which the widespread distribution of radioactive materials should be permitted in this country may in the foreseeable future present questions of public policy which can be resolved, and the hazards controlled, only at the Federal level.

S. Rep. No. 86-870, at 10-11(1959). In promulgating regulations to implement §274 c., the Atomic Energy Commission provided examples of the types of devices it had determined would remain under its authority for the purposes of distribution. For example, in the same notice quoted in the question, the Commission indicated that "(c)ontrol over consumer type devices, such as luminous watches would be retained by the Commission." (27 FR 1351, February 14, 1962). In addition, the draft version of the rule published for public comment in 1961 specifically listed the products that would be reserved to AEC authority (26 FR 9174, 9176, September 29, 1961). The products, listed in §150.8(e)(1)-(10) of the proposed rule, included sealed sources, thickness/density gauges, luminous paint, tracers, ceramic table ware, glassware, tungsten or magnesium thorium alloy products, aircraft counterweights, gas mantles, vacuum tubes, and welding rods. The proposed rule also contained a catch-all provision that did not specify the use of material. Nevertheless, without exception, all of the products specifically listed in the proposed rule involve the intentional introduction of radioactive material into a device or product that utilized the property of the material for a specific functional purpose. While this list of materials was not included in the final rule and the Commission at that time limited its authority to transfers of products designed for distribution to the general public, the Commission gave no indication that this change from the draft to the final version reflected an intention to expand its reservation of authority beyond products involving the intentional introduction of radioactive material.

It is clear, as pointed out in the letter and questions submitted to the Commission, that certain passages in the Federal Register notice for the final rule published in 1962, as well as language in the Commission's rules, could lead to some confusion when read out of context. However, after almost 40 years of regulatory practice in this area, the NRC, and its predecessor the AEC, have consistently applied the reservation of authority to products that involve the intentional introduction of byproduct material.

The Commission recognizes that §274 c. could be read to provide the NRC with the discretion to exercise exclusive regulatory control over a broad range of commodities containing radioactive material that may have broad national distribution and use. Moreover, material proposed for free release containing very low levels of radioactive material could be found to fall into the broad category of items over which the NRC might arguably decide to retain control. To date, however, the NRC has not made such a determination to exert exclusive authority in this area and the Commission has no plans to alter its implementation of the statutory and regulatory framework in this area. Accordingly, the Commission will continue to reserve authority pursuant to Section 150.15(a)(6) only over the distribution of products involving the intentional introduction of radioactive material.

Regulation of the distribution of products containing radioactive material to persons exempt from licensing differs in concept and practice from the release of materials for unrestricted use that contain very low levels of radioactive material. For byproduct material, NRC approves exempt distribution for a specific form, quantity or concentration of radioactive material that is contained in a product that makes use of the radioactive, physical, or chemical properties of the radioactive material. For example, one exempt distribution product that incorporates small

amounts of radioactivity is a smoke detector to detect the presence of smoke. The form, quantity, or concentration of the radioactive materials used in these products are integral to the functioning of the device. The approval of exempt distribution of such products involves regulatory decisions balancing the benefits of the intended use with the risk arising from the small amount of radioactive material introduced to the product. NRC reserves authority over the distribution of these products because of the need to undertake the balancing. No similar analysis applies to the unrestricted release of low levels of radioactive materials.

The Commission does not plan to take away the Agreement States' authority to regulate the release of slightly contaminated material for unrestricted use. Over the years, Agreement States and NRC have routinely authorized the release of low levels of slightly contaminated liquids, gases, and solids pursuant to Parts 20, 30, and 40 and Agreement State equivalent requirements, as well as through specific license conditions and guidance in cases where no generally applicable provision applies. Such releases are at levels which assure adequate protection of the public health and safety. It has never been the Commission's intent, or practice, to place itself into the position of regulating such activities conducted by Agreement State licensees. Any change of policy in this area would require pervasive involvement by NRC in specific Agreement State licensing activities. This would run afoul of one of the purposes of §274 of the AEA, which is to promote an orderly pattern of regulation between the Commission and the States in a manner which will avoid dual or concurrent regulation. Absent new information suggesting that an exclusive Federal presence is needed in this area, NRC will continue its current approach to the regulation of these activities. Of course, if the NRC were to choose to undertake a rulemaking governing the release of solid material -- a matter on which NRC is currently seeking stakeholder advice -- the Agreement States' exercise of regulatory

authority might be constrained as a result of compatibility requirements.

The NRC does seek to assure that Agreement State programs are adequate to protect the public health and safety. The NRC, with Agreement State participants, also conducts periodic Integrated Materials Performance Evaluation Program (IMPEP) reviews of Agreement States and NRC regional office programs for continued adequacy to protect public health and safety and compatibility of Agreement State programs with NRC's program. IMPEP uses a common process that is applicable to both Agreement State and NRC regional materials programs. The review areas include five common performance indicators (Status of Materials Inspection, Technical Quality of Inspection, Technical Staffing and Training, Technical Quality of Licensing, and Response to Incidents and Allegations) and six non-common review areas, as applicable, (Legislation and Program Elements Required for Compatibility, Sealed Source and Device Evaluation, Low-Level Radioactive Waste Disposal, Uranium Recovery, Regional Fuel Cycle Inspection, and Site Decommissioning Management Plan). IMPEP reviews are conducted at a frequency of between 2 to 4 years depending on the status of the Agreement State program. Periodic (approximately every 18 months) management meetings are conducted between the IMPEP reviews to determine if the status of the program may have changed. The IMPEP program is described in more detail in Management Directive 5.6 (attached).

Attachment: Management Directive 5.6