



CHAIRMAN

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

December 20, 1999

The Honorable John D. Dingell
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Dingell:

I am responding to the October 25, 1999 letter from you and Congressmen Ron Klink and Edward Markey. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

P.O. Comp

DF02

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material. In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid

material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to

adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose

analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways, assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,



Richard A. Meserve

Enclosures:

1. November 19, 1999 Letter from M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative Tom Bliley
Representative Joe Barton



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

December 20, 1999

The Honorable Edward J. Markey
Subcommittee on Telecommunications,
Trade and Consumer Protection
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Markey:

I am responding to the October 25, 1999 letter from you and Congressmen Ron Klink and John Dingell. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material. In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid

material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to

adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose

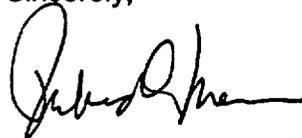
analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways, assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,



Richard A. Meserve

Enclosures:

1. November 19, 1999 Letter from
M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative W. J. Tauzin



CHAIRMAN

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

December 20, 1999

The Honorable Ron Klink
Subcommittee on Oversight and Investigations
Committee on Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Klink:

I am responding to the October 25, 1999 letter from you and Congressmen John Dingell and Edward Markey. In your letter, you raise a series of questions and issues relating to the release of solid materials containing low levels of radioactive byproduct material, the respective Federal and State jurisdiction over such activities, and a specific licensing action taken by the State of Tennessee, an Agreement State, involving Manufacturing Sciences Corporation (MSC). To assist in providing an integrated response, we have restated the issue as we understand it, addressed the immediate action request, explained how the Nuclear Regulatory Commission (NRC) conducts its licensing activities, explained the Agreement State program and regulatory role, and discussed the specific licensing action in Tennessee given this regulatory context.

Your letter focuses on the issue of control/release of solid materials that contain low levels of radioactive material and the proper execution of the current regulatory program. Let me first express my full agreement that additional work is needed on how we proceed to address the release of solid material and how our nation will collectively handle solid materials containing low levels of both natural and man-made radioactive material. The Commission is currently considering the issue of control of solid materials regulated under the Atomic Energy Act and has recently conducted workshops to seek public input. In addition, NRC is actively working with the Environmental Protection Agency, Department of State, and the International Atomic Energy Agency in their efforts to develop generally applicable radiological screening guidelines which may influence the import and export of contaminated materials or products.

On November 15, 1999, I provided an interim response in which I noted we are not aware of any effect on public health and safety that warrants immediate action to exercise NRC's authority to suspend all or part of the Tennessee Agreement. Our final response, which follows, and our enclosed response to the specific questions in your letter, will help explain that determination. Based on information reviewed in preparing this response, we have not identified any factors that would lead us to believe that Tennessee's action creates a public health and safety or compatibility concern warranting the exercise of NRC's authority to suspend Tennessee's Agreement. In addition, the Commission believes that the State has acted within its regulatory authority under its Agreement with the NRC, and that the State's action is not preempted by NRC's Federal regulatory program. We further understand that no release of nickel material from MSC has occurred and none is planned by MSC until the fall of 2000.

NRC's Regulatory Authority and Current Practice With Regard to Release of Material

The NRC has statutory responsibility for the protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act of 1954, as amended (AEA). The Commission's regulations that set standards for protection of the public against radiation appear in 10 CFR Part 20. These regulations limit the radiation exposure (or "dose") that a member of the public can receive from the operation and decommissioning of a NRC-licensed activity. The NRC has used public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid releases from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. As noted above, NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

In applying the case-by-case approach, NRC does not consider most releases of solid material to be "disposals" authorized under Part 20 or Part 61. Instead, many such releases are authorized by specific license conditions and do not fall into one of the specific disposition categories in Subpart K of Part 20. However, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (see, e.g., §20.2001(a)(3) and §20.2005).

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92. Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see, e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material. In the non-reactor nuclear materials license context, NRC usually authorizes the release of solid

material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

As noted above, the authority for a release from a materials licensee is generally a specific provision contained in the license itself. By allowing such actions through license conditions, the NRC has provided a specific approval for such actions in lieu of applying one of the generally applicable standards of Part 20. This approach is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through case-specific measures, such as orders or license conditions.

As discussed in the issues paper, NRC's existing approach to these matters, although protective of public health and safety, does not provide a consistent, overall framework to address the disposition of solid material in the possession of NRC licensees. The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach to these issues and will continue to ensure that any actions undertaken by licensees are protective of public health and safety.

NRC Authority Over the Distribution of Certain Products to Exempt Persons

Since the advent of the Agreement State program in the early 1960s, the NRC (then Atomic Energy Commission) has reserved exclusive authority over certain distributions to exempt persons of products containing radioactive material. NRC has limited its reservation of authority to the distribution of products into which radioactive material has been intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties (e.g., in the operation or use of the product itself, such as use of tritium in self-luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). NRC has not reserved authority over the release of material containing low levels of radioactive material, such as the releases long authorized by NRC under the case-by-case approach described above.

Agreement State Authority

Under the AEA, the NRC has preemptive authority to license and regulate the ownership, possession, use and transfer of AEA materials - source, byproduct, and special nuclear material - and to set such standards as are necessary to protect public health in the ownership, possession, use and transfer of such materials. As a general matter, the States have authority to regulate in areas that have not been preempted by the Federal government. In the field of nuclear regulation, such State authority includes the regulation of naturally occurring and accelerator produced radioactive materials that are not subject to regulation under provisions of the AEA. Where source, byproduct, and special nuclear materials covered by the AEA are involved, Federal law generally preempts the States from regulating such material for the purposes of radiological safety. However, Section 274 of the AEA specifically authorizes the Commission to enter into agreements with States which provide for the discontinuance of NRC's authority over certain radioactive materials and the assumption of that authority by the State. In essence, these agreements lift the bar of Federal preemption and pass the NRC's authority and responsibility to regulate the materials and activities covered by the agreement to the State. The agreements do not reflect a delegation of authority. Instead, they signify the discontinuance of authority by the Commission. Once such an agreement is signed, the Commission continues to have an oversight responsibility to ensure that an Agreement State has a program for the regulation of AEA material that is adequate to protect public health and safety and compatible with that of the Commission.

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 46524) provides that, in reviewing the adequacy of an Agreement State's program, the level of protection provided by NRC's own regulatory program defines the level of protection to be achieved in Agreement State programs. For the purposes of compatibility, the Policy Statement details those aspects of NRC's regulatory program that an Agreement State's program must contain in order to ensure that the State's regulatory efforts do not create conflicts, duplication or gaps in the overall radiation protection program across the nation.

For some NRC requirements, such as basic radiation protection standards, or those that have significant transboundary implications, the Agreement State must adopt requirements that are essentially identical to those of the NRC in order to be compatible with NRC. For other NRC requirements, such as most licensing requirements, the Agreement State has the flexibility to

adopt its own requirement, as long as the State's requirement meets the essential objectives of NRC's requirement. States may also establish more restrictive requirements provided they have an adequate supporting health and safety basis and the requirements do not preclude a practice that is in the national interest.

In cases where NRC has established a specific requirement and made a determination of the degree of Agreement State compatibility, States are expected to adopt and implement the requirement in accordance with the compatibility level assignment. In those cases where NRC has not established a specific requirement, an Agreement State has flexibility and latitude to establish its own requirement, so long as the State provides adequate protection of public health and safety and its overall program is compatible with NRC's. The Adequacy and Compatibility Policy Statement specifically provides that an Agreement State has the flexibility to adopt program elements (e.g., regulations or other legally binding requirements) that are within the State's jurisdiction but are not addressed by NRC (62 FR at 46525). In reviewing all aspects of an Agreement State's program, NRC seeks to ensure the overall program for regulating AEA material is compatible and that the State's actions do not significantly affect NRC or other Agreement State programs.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric solid radioactive material. The responses indicate that, although the States vary in their approaches, the State practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses suggest that there is a need for clarification, particularly with respect to the need for some States to differentiate between the Part 20 decommissioning rule for release of land, buildings, and structures at the time of license termination, and the release of materials for unrestricted use.

The criteria utilized by States, applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86, and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach, particularly since some released materials will cross State boundaries.

Tennessee's Licensing Decision

In the particular case at hand, it is our understanding that Tennessee has approved a license amendment which will allow MSC to process and decontaminate nickel to remove radioactive contamination (please see enclosed November 19, 1999 letter from M. Hamilton to W. Travers). The amendment also allows MSC to release resulting material containing very low levels of radioactivity for unrestricted use. The level of residual radioactive material is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of public health and safety.

The NRC does not normally conduct an independent review of a specific Agreement State licensing action. However, given your concerns in this instance, NRC staff reviewed the information from Tennessee on the licensing action and independently calculated potential dose consequences from release of nickel at the levels specified in the MSC license. Our dose

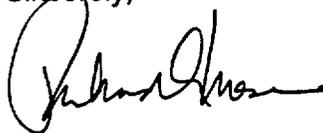
analysis is conservative and shows the doses to be comparable to those calculated by MSC and reviewed by the State of Tennessee, although our analysis considered different pathways, assumptions, and exposure groups. Our review of the Tennessee licensing action did identify some areas needing clarification or additional specific information. The staff is pursuing resolution of these matters, which include better understanding of the process Tennessee used in granting the license, the sampling and analyses that will be performed to demonstrate the release criteria are met, and the materials control by MSC to keep the total quantity of special nuclear material in its possession at any one time to quantities that can be licensed by Tennessee.

Based on the staff's review, we have not identified any issues that would lead us to believe that the action taken by Tennessee raises a significant compatibility concern. Both NRC and other Agreement States routinely approve the release of solid materials with low levels of radioactivity in accordance with current guidance or specific license provisions. Thus, Tennessee's licensing action does not differ significantly from current NRC regulatory practice in this area.

Furthermore, the Commission does not believe that the MSC license authorizing release of very low-level, slightly radioactively contaminated solid material is an activity that falls under NRC's exclusive authority to regulate the distribution of products to exempt individuals (see 10 CFR §150.15(a)(6)). The Commission has consistently applied this reservation of authority to the distribution of products (e.g., smoke detectors) involving the intentional introduction of radioactive material. Unlike the products covered by NRC's reservation of authority, there is no radioactive material intentionally introduced to take advantage of the material's radioactive, physical, or chemical properties in the context of the MSC license. And the very low level of residual radioactive contamination in the nickel that may be released by MSC is so small that it is no longer necessary to subject the nickel to regulatory control for purposes of protection of public health and safety.

We have enclosed specific answers to each of the 45 questions that were attached to your letter.

Sincerely,



Richard A. Meserve

Enclosures:

1. November 19, 1999 Letter from
M. Hamilton to W. Travers
2. Responses to Specific Questions

cc: Representative Fred Upton