



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 7, 2000

Mr. L. Edward Nanney, Acting Director
Division of Radiological Health
Department of Environment & Conservation
L&C Annex, Third Floor
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Nanney:

Thank you for providing information on the Manufacturing Sciences Corporation (MSC) license. As you are aware, we have been examining the MSC licensing action in connection with questions raised in an October 25, 1999 letter to the Nuclear Regulatory Commission (NRC) from Congressmen Dingell, Klink, and Markey. As a part of this effort, we requested and you supplied license file documentation in support of issuance of the license amendment to MSC authorizing the processing and release for unrestricted use of nickel containing very low levels of residual radioactivity. The NRC staff has completed a review of the information and the results are contained in the enclosed report (Enclosure 1). We are providing the report to you to assist you in providing responses to the areas identified by the team as needing clarification or further information. We are also providing a copy of that report to Congressmen Dingell, Klink, and Markey as part of our response to their December 23, 1999 letter.

The staff's review focused on four areas:

- (1) the basis for the concentration limit criteria specified in the license,
- (2) the procedures and sampling to be performed by MSC to ensure that nickel ingots leaving their site would meet the concentration criteria in the license,
- (3) the special nuclear material possession limits, and
- (4) the overall licensing process used by Tennessee.

The staff identified no health and safety issue which would warrant action at this time by Tennessee to amend or modify the license. The staff review did identify a number of questions requiring clarification, questions on the licensing process followed by Tennessee, and need for additional detail and supporting information.

We request that you review the staff report and address the information needs so that these questions can be answered. To assist in responding, Enclosure 2 specifically identifies each information request area contained in the team's report. If you need clarification on the questions in the review report, please contact Dennis Sollenberger. A response within 2 weeks of receipt of this letter would be appreciated. The review of this licensing action will be included as part of the Technical Quality of Licensing Program indicator to be addressed during your upcoming Integrated Materials Performance Evaluation Program review.

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We appreciate your assistance in this matter. If you have any questions on our request, please call me at 301-415-3340 or Dennis Sollenberger at 301-415-2819 or DMS4@NRC.GOV.

Sincerely,

Original Signed By:
PAUL H. LOHAUS

Paul H. Lohaus, Director
Office of State Programs

Enclosures:
As stated

Distribution:
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DATE	01/06/2000*	01/06/2000*	01/06/2000*	01/06/2000* via E-mail	1/7/2000

OSP FILE CODE: SP-AG-26

L. Edward Nanney

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We appreciate your assistance in this matter. If you have any questions on our request, please call me at 301-415-3340 or Dennis Sollenberger at 301-415-2819 or DMS4@NRC.GOV.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul H. Lohaus". The signature is written in a cursive style with a large initial "P".

Paul H. Lohaus, Director
Office of State Programs

Enclosures:
As stated

Review of the Tennessee (TN) License Approval of Release of Nickel from the Manufacturing Sciences Corporation (MSC) Facility in Oak Ridge, TN.

NRC requested TN to supply the license application and supporting documentation, including analyses by TN for the license amendment authorizing the release of nickel for unrestricted use. The proposed nickel release would be permitted if the concentration of radioactivity in the nickel did not exceed proposed volumetric and surficial contamination limits. Documents supplied by TN included the following:

- Letter dated November 16, 1999 from L. E. Nanney to P. Lohaus supplied the following information:
 1. Amendment 20 to R-01078-L00 dated October 1, 1999
 2. Amendment 19 to R-01078-L00 dated July 13, 1999
 3. Amendment 18 to R-01078-L00 dated April 8, 1999
 4. Letter from MSC to TN dated September 10, 1999
 5. Amendment 57 to S-01046-L00 dated July 13, 1999
 6. Amendment 56 to S-01046-L00 dated March 26, 1999
 7. Intraoffice correspondence from JMK to JCG, MHM dated March 24, 1999 with attached calculations.
 8. Letter from MSC to TN dated February 18, 1999
 9. Letter from MSC to TN dated January 29, 1999
 10. Letter from MSC to TN dated January 18, 1999
 11. Letter from MSC to TN dated December 8, 1998 with attachments (the license amendment application.
 12. TN calculation sheet dated 11/15/99

- Letter dated November 19, 1999 from M. Hamilton to W. Travers.

The submittals from TN contained no proprietary information, at NRC's request. TN identified that the information describing the decontamination process is proprietary. Therefore, the process information was not submitted to NRC.

NRC established a review team to evaluate the information submitted. The review team members are:

Dennis Sollenberger, OSP
Tom O'Brien, OSP
Anthony Huffert, NMSS
Giorgio Gnugnoli, NMSS
Sami Sherbini, NMSS
Betsy Ullrich, Region I
James Kottan, Region I

The review focused on the basis for, and acceptability of, four items: (1) the concentration limits specified in the license; (2) the procedures and sampling to be performed by MSC to

ensure that nickel leaving the site would meet the concentration criteria in the license; (3) the special nuclear material (SNM) possession limits; and (4) the overall licensing process used by TN. The review team did not focus on the overall operational health physics and environmental aspects of this licensed operation because this information was not provided by TN. The review team did, however, consider the technical quality of TN's review and approval of the MSC license amendment application.

I. Basis for Concentration Limit Criteria

A. TN's basis or criteria for accepting MSC proposal.

In a letter dated November 19, 1999, TN stated that both the licensee's dose assessment and a comparison to criteria in Regulatory Guide (RG) 1.86 were used as bases for accepting the MSC proposal. Regarding the dose assessment, the review team did not identify the specific acceptance criteria (dose level) used by TN as their decision criteria to either grant or deny the license amendment proposal. Regarding the use of RG 1.86 surface contamination limits in this licensing action, the staff agrees that application of RG 1.86 *removable* surface contamination limits is acceptable. However, the comparison of RG 1.86 *fixed* surface contamination limits to the proposed volumetric release limits is beyond the scope of the intended application of RG 1.86 as a licensing basis. From information contained in the letter dated November 19, 1999, and other documents provided by TN, the review team was uncertain how the comparison was used by TN in this licensing action.

B. MSC's basis for their proposal.

The MSC proposal identified specific concentration limits for technetium-99 and uranium in nickel after being processed through MSC's decontamination process. The MSC proposal did not describe how the proposed concentration levels were selected by MSC. Also, the review team was not able to determine whether the proposed release limits were based on the nickel decontamination process performance, as portions of the process are proprietary and thus were unavailable to the review team.

MSC submitted a dose assessment for end-users of products manufactured with nickel released at the proposed concentration limits. The MSC assessment evaluated in detail the doses from use of nickel in hip replacements and flatware. The dose calculated were 0.0014 mrem and 0.00022 mrem, TEDE, respectively. The assessment did not include exposure scenarios, such as scrap and slag workers, that may result in doses higher than those expected from users of consumer products. This issue is discussed further below.

C. Review Details.

1. TN comparison of volumetric to surficial release criteria.
 - a. Attachment to TN Intraoffice memorandum dated March 24, 1999.

This attachment presents a method for comparing RG 1.86 surface contamination criteria to the proposed volumetric concentration limits by uniformly mixing surficial contamination throughout the volume of material. This method is geometry dependent and the geometry of the nickel sheets to be released from MSC was not included in the submitted documentation. The team review raised questions regarding the calculations, such as the basis for assuming a half-inch thick sheet of nickel, dilution of the nickel into stainless steel by a factor of 0.12, and contamination on only one side of the sheet. The review also identified a mathematical error (5000 dpm/100 cm², not 5000 dpm/cm²) in the calculation, which, if corrected, would result in a volumetric concentration that is less than the proposed volumetric release limit. As stated above, it was unclear to the review team how the comparison was used by TN in this licensing action.

b. Calculation sheet dated November 15, 1999.

This sheet presents a revised calculation for converting RG 1.86 surface contamination limits to the proposed volumetric concentration limit. This calculation is also geometry dependent, but assumed a thinner (half-centimeter) sheet of nickel, in contrast to the 3/24/99 calculation that assumed a thicker (half-inch) piece of nickel sheet, as well as surficial contamination on both sides of the sheet. There was no documentation supplied by TN on the maximum thickness of nickel sheet that would be produced by MSC. The review team understanding, which is based on earlier discussions with MSC staff, is that the sheets could be up to three quarters of an inch thick.

In a letter from MSC dated 1/29/99, there was a similar comparison made between RG 1.86 and the proposed volumetric release limits. There was no documentation of the TN evaluation of the information contained in this 1/29/99 MSC letter, which shows that a 1/4-inch thick sheet of steel with 12% nickel would exceed the RG 1.86 surficial limit. The review team could not identify whether TN resolved the differences between TN's calculations and MSC's calculations.

2. Dose Assessment.

The team reviewed the available documents for consistency with NRC regulations, dose assessment practice, and case-by-case approaches NRC has used in the past. Although a number of inconsistencies are noted, the review team does not believe there is any significant public health and safety concern, based on the small doses calculated in the MSC assessment of users of consumer products (0.0014 mrem/y, TEDE) and the NRC staff's independent dose assessment which included the scenarios, scrap and slag worker (about 1 mrem/yr, TEDE). Consumer products would give doses lower than the worker scenarios. The following comments were identified by the review team.

- a. TN referred to the MSC submittals, including the risk assessment, as their basis for issuing the license amendment. However, in the information provided by TN, there was no documentation of any specific analysis of comments or questions on the assessment by TN staff.
- b. The assessment did not include exposure scenarios such as the slag worker and scrap metal handler. Other studies have demonstrated that these exposure

scenarios are limiting, not consumer products, as analyzed in MSC's assessment. In conducting this review, the review team discussed the removal of material from the K-25 complex and decontamination of the material at MSC with Department of Energy (DOE) staff and reviewed, in part, several DOE documents prepared in support of DOE decommissioning of Oak Ridge and other DOE facilities. These documents, as well as International Atomic Energy Agency (IAEA) documents on recycle of metal, discussed that the metal and slag worker scenarios will dominate the dose impacts. If additional scenarios were considered by MSC and supplied to TN or independently were analyzed by TN, these documents should be part of the information supporting the amendment.

- c. The MSC assessment selected two potential consumer products (hip joint prostheses and flatware) to focus their detailed calculations. The 12% nickel content in the prosthesis may be non-conservative because such devices are also manufactured with nickel alloys that are on the order of 35% nickel. Other medical devices, such as stents, are made with nickel alloys that contain approximately 55% nickel. Consideration of higher nickel content devices would vary the resultant doses by up to a factor of 4 which would not affect the significance of these pathways.
- d. The MSC comparison of their dose assessment results to the 25 mrem/yr limit in 10 CFR 20.1402 (pages 24 and 25 of the MSC assessment) is inappropriate because that regulation concerns the release of lands and structures - not materials and equipment - from regulatory control.
- e. An International Commission on Radiological Protection (ICRP) -60 tissue dose weighting factor of 0.01 for bone surfaces and skin is applied in the dose calculations, which differs from the standard approach in 10 CFR 20 (bone surface, 0.03; skin, 0.06). The basis for using 0.01 instead of 0.03 and 0.06 needs to be stated. The documents provided by TN did not address this aspect of the dose assessment. The review team could not determine whether TN approved the use of the ICRP-60 tissue weighting factors. The use of the ICRP-60 tissue-weighting factors would lower the TEDE doses by factors of 3 and 6 below that calculated using Part 20 tissue-weighting factors. Adjusting the doses for this factor difference would not change the conclusion of the assessment since the doses would still remain small fractions of a mrem.
- f. The nickel to be released comes from DOE material contaminated with enriched uranium with the majority of the uranium varying from about 1% to 3% enrichment with a small amount up to about 6% enrichment based on discussions with DOE. The review team could not identify from the information available whether MSC considered differing enrichment levels in their assessment.

However, the review team determined from the uranium isotopic mix used in the assessment that it appears an enrichment of about 2% was used for the dose assessment. Based on information from DOE, this value would be representative of the average enrichment for the nickel material being removed

from the K-25 complex under the contract with MSC. The MSC license limits the maximum enrichment that MSC can possess to 3%.

- g. The MSC assessment stated that "any measurement attempts of the outer surface with a survey meter will be indistinguishable from background." The technical basis for this statement was not provided.

II. Sampling and Analysis Plan

- A. This document provides a phased sampling plan describing in general terms the methods that could be used to demonstrate compliance with the proposed volumetric and surficial release criteria. Although the plan describes several monitoring techniques, it did not specify which technique would be used to demonstrate compliance with the concentration limit. The plan should contain more detailed information about the radiation detection equipment, including its performance capability relative to the proposed release criteria, that will be used for measuring the radioactivity content of the nickel sheet. The procedure does not provide information on efficiency, count times, detection limits, the use of tracers, spikes, QC samples, etc. The sampling plan does not specify the minimum nickel sample to be collected (20 gram minimum for nickel analysis). The review team concluded that the phased sampling may be appropriate, but additional information is needed to determine the adequacy of the sampling plan.
- B. The relationship between this plan and the other MSC "Work Instructions" for conducting surveys is not clear from the information provided. The available information does not describe how each method of radioactivity monitoring (swipes, hand-held surveys using portable instruments, automated monitoring using a conveyor system, and destructive sampling and analysis of the final ingot) will work together in a comprehensive survey program for ensuring that the nickel ingots will be released within the proposed criteria.

From the information available, the review team had difficulty in determining whether the survey program is adequate. The sampling plan does not specify when the Phases in the sampling plan will be implemented. The review team determined that the Phase II sampling, which has a reduced number of samples collected, appears to be the sampling to be used during production. If this is correct, the results from Phase I, with a more intense sampling rate, could be used to ensure that the Phase II sampling is adequate. There were no Phase I data provided to support the adequacy of the Phase II sampling plan. The review team had additional detailed questions on how the various monitoring methods relate to the release criteria, and how background and minimum detectable activities (MDAs) for the sampling program would be determined.

- C. It was not clear to the review team whether the sampling the plating bath was going to be part of the overall survey program for ensuring compliance with the proposed release criteria. The review team did not see documentation that demonstrated this sampling represented the nickel contaminate levels. The review team felt that a more comprehensive survey program should be used while MSC gains experience with this new process. The review team did not identify procedures for the *analysis* of samples

taken from slag or the plating bath, or the acceptance criteria for the results of the analyses.

III. Possession Limit for SNM

There is no mention of a monitoring program for ensuring compliance with the SNM limits in the license (350 g of uranium-235, 200 g of plutonium, and 200 g of uranium-233) which are the maximum amounts an Agreement State can regulate. The review team had no documentation provided by TN to address this issue.

Through discussions with DOE staff familiar with the decommissioning program that generates the nickel scrap being sent to MSC, the review team has learned that the nickel is cleaned through a chemical bath prior to being sent to MSC. This action significantly reduces the radionuclide contamination on the nickel. The nickel is assayed and manifested prior to shipment to MSC. DOE staff indicated that MSC has an SNM tracking system in place including inventory controls. The review team believes this information needs to be confirmed.

IV. Licensing Process

The review team evaluated the licensing practice TN used in support of the approval of the MSC amendment request. The review team noted that there are two similar licenses issued to MSC for the nickel decontamination process. The distinction between the two licenses issued to MSC is not evident from the documents provided. Clarification on the relationship between these licenses would be useful to the review team.

- A. The November 19, 1999 letter stated that TN has conducted inspections, and has experience with the MSC process through their R&D program at this facility. TN did not provide specific documentation of this information, as requested by NRC, which is part of the support for their licensing decision. The review team could not determine what aspects of the MSC operations were evaluated through the inspections and other meetings with MSC. The lack of TN documentation of interaction with the licensee makes it difficult to evaluate the TN licensing process in this case.
- B. Letters from MSC dated January 29, 1999 and February 18, 1999, indicate a meeting occurred on January 20, 1999 at MSC. A MSC letter dated January 18, 1999 also refers to a meeting on December 8, 1998. It is unclear whether these meetings were used to support the licensing decision since no documentation of the meetings was included in the information provided to the NRC.
- C. The review team could not determine what information DOE would supply on the radiological analysis and radiation levels of the incoming nickel material that would be shipped to MSC from DOE. It could not be determined if other isotopes other than Tc-99 and U-234/235/238 would be allowed to be on the material or how much variation in the radioactivity content of the incoming nickel would be allowed. The review team could not identify if there are any restrictions (other than total SNM) on incoming material, in terms of radiation/radioactivity levels or expected concentrations.

- D. The license condition specifying the concentration and surface limits can be interpreted to authorize MSC to release nickel with removable surface contamination at the limit plus volumetric contamination at the limit. How this condition is interpreted can affect assumptions that should be made in the dose assessment. Clarification on this condition is needed.

V. **SUMMARY**

- A. The review team cannot draw a definitive conclusion on the acceptability of the technical quality of the MSC licensing action. There is insufficient information contained in both the license file material provided by TN and in their November 19, 1999 response to the four questions. (Also see C. below).
- B. There is sufficient information, however, to demonstrate, and the team has identified, no health and safety issue which would warrant action by TN to amend or modify the license amendment.
- C. The review team concludes that while the MSC dose assessment is non-conservative, and does not include some scenarios, the results of an independent analysis indicate that the doses from these scenarios would still result in low doses, i.e. doses in the range of 1 mrem.
- D. The review team identified a number of areas where additional information or clarification is needed.

For example:

- Information on the basis used by MSC to select the concentration limit criteria contained in their application;
 - Information on the acceptance criteria applied by TN in concluding the concentration limit criteria proposed by MSC were acceptable; and
 - Information on the methods that will be used by MSC to demonstrate compliance with the concentration release criteria.
 - Information on the relationship between the two MSC licenses.
- E. The review team concludes that review of the complete TN license file on MSC, including an opportunity to discuss review team questions and issues with TN staff, appears essential and would assist the team in conducting a complete review of the technical quality of this licensing action.

VI. Options to Resolve Outstanding Issues

The review team considered the following options to obtain additional information on the MSC licensing action from TN.

- A. Telephone conference calls to discuss information needs and verbal responses from TN.**

The review team prefers a meeting with TN because a telephone conference call may limit the interactions between the review team and TN on this licensing action. Recent telephone conference calls between the members of the review team and TN did not allow the review team to directly confirm information or view the proprietary information.

- B. Written information request with written response.**

The areas requiring additional information would be documented and provided to TN for written response. Some additional more detailed information requests or telephone conversations may be needed to clarify some of the issues. If the requested information, upon review, is unable to resolve the issues, the NRC staff will consider further action as described in the Options below. Also, this option may not enable receipt and review of the proprietary information on the decontamination process.

- C. A site visit to the TN licensing office including a site visit to the MSC facility.**

This would allow for interaction with MSC staff and TN staff to evaluate the extent of TN's interaction with MSC. This would also provide the greatest access to the information (including proprietary information) that was available to TN in considering the MSC amendment request. This information could also be considered as input to the next Integrated Materials Performance Evaluation Program (IMPEP) review of the TN program, which is currently scheduled for August 2000.

- D. The IMPEP review for TN could be moved up on the schedule from August 2000 to Spring 2000.**

This option would allow this action to be evaluated along with other licensing actions under the IMPEP process within a timeframe that would bring a conclusion prior to MSC's current schedule for release of nickel from their site (Fall 2000).

- E. The IMPEP review for TN could remain as scheduled for August 2000 with a special review of the MSC license file incorporated into that review.**

The review team considered this option as a fall back option if the other more timely options are not workable.

VII. Review Team Recommendation

The review team believes that either combined Options B and D or E, or Option C could resolve the outstanding issues identified in this report. Both would allow NRC staff to review the proprietary information and to have direct discussions with TN. As a minimum next step, the review team recommends Option B be implemented. If the issues cannot be resolved through this additional communication, the NRC staff will select the appropriate additional Option based on the outstanding issues to be resolved.

**QUESTIONS RESULTING FROM THE
REVIEW OF THE TENNESSEE (TN) LICENSE APPROVAL OF RELEASE OF NICKEL
FROM THE MANUFACTURING SCIENCES CORPORATION (MSC) FACILITY
IN OAK RIDGE, TN**

- I.A. Regarding the dose assessment, the review team did not identify the specific acceptance criteria (dose level) used by TN as their decision criteria to either grant or deny the license amendment proposal. (Please provide the documentation of the acceptance criteria (dose level) used by TN.)**

From information contained in the letter dated November 19, 1999, and other documents provided by TN, the review team was uncertain how the comparison was used by TN in this licensing action. (Please provide an explanation of any comparison made by TN based on RG 1.86 guidance and how the guidance was applied by TN in the licensing action.)

- I.B. The MSC proposal did not describe how the proposed concentration levels were selected by MSC. Also, the review team was not able to determine whether the proposed release limits were based on the nickel decontamination process performance, as portions of the process are proprietary and thus were unavailable to the review team. (Please provide the basis for the concentration limits proposed by MSC.)**

The assessment did not include exposure scenarios, such as scrap and slag workers, that may result in doses higher than those expected from users of consumer products. (Please explain why these scenarios were not included in the assessment.)

- I.C.1.a The team review raised questions regarding the calculations, such as the basis for assuming a half-inch thick sheet of nickel, dilution of the nickel into stainless steel by a factor of 0.12, and contamination on only one side of the sheet. The review also identified a mathematical error (5000 dpm/100 cm², not 5000 dpm/cm²) in the calculation, which, if corrected, would result in a volumetric concentration that is less than the proposed volumetric release limit. As stated above, it was unclear to the review team how the comparison was used by TN in this licensing action. (Please explain the basis for selecting the thicknesses of the nickel product and other adjustment factors that were used in the surface to volume criteria conversion calculation.)**

- I.C.1.b. There was no documentation supplied by TN on the maximum thickness of nickel sheet that would be produced by MSC. The review team understanding, which is based on earlier discussions with MSC staff, is that the sheets could be up to three quarters of an inch thick. (Please address this area in the explanation requested in I.C.1.a. above.)**

The review team could not identify whether TN resolved the differences between TN's calculations and MSC's calculations. (Please explain how TN resolved the differences between the MSC and TN calculations.)

I.C.2.a. However, in the information provided by TN, there was no documentation of any specific analysis of comments or questions on the assessment by TN staff. (Please describe or provide documentation, such as deficiency letters or staff analysis, for the TN review of the MSC amendment request.)

I.C.2.b. If additional scenarios were considered by MSC and supplied to TN or independently were analyzed by TN, these documents should be part of the information supporting the amendment. (Please indicate whether additional scenarios were analyzed and, if so, provide these documents.)

I.C.2.c. Consideration of higher nickel content devices would vary the resultant doses by up to a factor of 4 which would not affect the significance of these pathways. (Please provide an explanation for the selection of the consumer products and why these other products were not considered.)

I.C.2.d. The MSC comparison of their dose assessment results to the 25 mrem/yr limit in 10 CFR 20.1402 (pages 24 and 25 of the MSC assessment) is inappropriate because that regulation concerns the release of lands and structures - not materials and equipment - from regulatory control. (Please explain why TN did not address the inappropriate use of the 25 mrem/yr limit.)

I.C.2.e. The basis for using 0.01 instead of 0.03 and 0.06 needs to be stated. The documents provided by TN did not address this aspect of the dose assessment. The review team could not determine whether TN approved the use of the ICRP-60 tissue-weighting factors. (Please provide the documentation of TN approval for the use of the ICRP-60 tissue weighting factors.)

I.C.2.f. The review team could not identify from the information available whether MSC considered differing enrichment levels in their assessment. (Please provide the documentation for the enrichment used in the MSC dose assessment.)

I.C.2.g. The MSC assessment stated that "any measurement attempts of the outer surface with a survey meter will be indistinguishable from background." The technical basis for this statement was not provided. (Please provide the basis for this statement.)

II.A. Although the plan describes several monitoring techniques, it did not specify which technique would be used to demonstrate compliance with the concentration limit. (Please identify the technique that will be used to demonstrate compliance with the concentration limit.)

The procedure does not provide information on efficiency, count times, detection limits, the use of tracers, spikes, QC samples, etc. The sampling plan does not specify the minimum nickel sample to be collected (20 gram minimum for nickel analysis). (Please provide this detailed information.)

II.B. The relationship between this plan and the other MSC "Work Instructions" for conducting surveys is not clear from the information provided. The available information does not describe how each method of radioactivity monitoring (swipes, hand-held surveys using portable instruments, automated monitoring using a conveyor system,

and destructive sampling and analysis of the final ingot) will work together in a comprehensive survey program for ensuring that the nickel ingots will be released within the proposed criteria. (Please provide an explanation of the relationship between the sampling plan and the work instructions. This should include a specification of the actions necessary to demonstrate compliance with the release limits.)

The sampling plan does not specify when the Phases in the sampling plan will be implemented. (Please provide the description of the sampling Phases as they relate to the decontamination process and release of the nickel.)

There were no Phase I data provided to support the adequacy of the Phase II sampling plan. The review team had additional detailed questions on how the various monitoring methods relate to the release criteria, and how background and minimum detectable activities (MDAs) for the sampling program would be determined. (Please provide the available data and explanation for the areas listed above.)

II.C. It was not clear to the review team whether the sampling the plating bath was going to be part of the overall survey program for ensuring compliance with the proposed release criteria. The review team did not see documentation that demonstrated this sampling represented the nickel contaminate levels. The review team felt that a more comprehensive survey program should be used while MSC gains experience with this new process. The review team did not identify procedures for the analysis of samples taken from slag or the plating bath, or the acceptance criteria for the results of the analyses. (Please provide an explanation and documentation for the use of the plating bath and slag sampling.)

III. There is no mention of a monitoring program for ensuring compliance with the SNM limits in the license (350 g of uranium-235, 200 g of plutonium, and 200 g of uranium-233) which are the maximum amounts an Agreement State can regulate. The review team had no documentation provided by TN to address this issue. (Please provide documentation for the program for tracking SNM at the MSC site to ensure possession limits remain below those which an Agreement State may license.)

DOE staff indicated that MSC has an SNM tracking system in place including inventory controls. The review team believes this information needs to be confirmed. (Please provide a description of the MSC tracking system and actions TN conducts to verify that MSC is within its SNM limit.)

IV. The distinction between the two licenses issued to MSC is not evident from the documents provided. Clarification on the relationship between these licenses would be useful to the review team. (Please provide an explanation of the relationship between the two licenses.)

IV.A. The review team could not determine what aspects of the MSC operations were evaluated through the inspections and other meetings with MSC. The lack of TN documentation of interaction with the licensee makes it difficult to evaluate the TN licensing process in this case. (Please provide any documentation of the meetings or other communication between TN and MSC, e.g., meeting minutes, letter exchanges, or telephone notes.)

- IV.B.** It is unclear whether these meetings were used to support the licensing decision since no documentation of the meetings was included in the information provided to the NRC. (Please explain the purpose of these meetings and provide any documentation on the meetings as requested in Item IV.A. above.)
- IV.C.** The review team could not determine what information DOE would supply on the radiological analysis and radiation levels of the incoming nickel material that would be shipped to MSC from DOE. It could not be determined if other isotopes other than Tc-99 and U-234/235/238 would be allowed to be on the material or how much variation in the radioactivity content of the incoming nickel would be allowed. The review team could not identify if there are any restrictions (other than total SNM) on incoming material, in terms of radiation/radioactivity levels or expected concentrations. (Please provide an explanation of the controls on the nickel to be accepted at the MSC site addressing the above points.)
- IV.D.** The license condition specifying the concentration and surface limits can be interpreted to authorize MSC to release nickel with removable surface contamination at the limit plus volumetric contamination at the limit. How this condition is interpreted can affect assumptions that should be made in the dose assessment. Clarification on this condition is needed. (Please provide clarification on how this condition should be interpreted.)