Questions and Answers

FSIS DIRECTIVE 6100.4

VERIFICATON INSTRUCTIONS RELATED TO SPECIFIED RISK MATERIALS

Note: FSIS Directive 6100.4 is arranged in chapters. The following Q&As are grouped according to the chapters where they most readily apply. Additional sections not specifically addressed in the directive are included.

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- I. General verification activities (design and execution) for HACCP, SSOP, and PR programs
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Chapter 1 General Introduction

Identification of SRMs

Q1. What are Specified Risk Materials (SRMs)?

A1. Per 9 CFR 310.22(a), except when derived from beef imported from countries that demonstrate their status to meet or exceed the food safety status in the USA having prohibited SRMs for use in human food, the following materials from cattle 30 months of age and older are SRMs: the brain, skull, eyes trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia. SRMs also include the tonsils and distal ileum from cattle of all ages.

Q2. Why does FSIS prohibit the use of SRMs for human food?

A2. Scientific and epidemiological studies have linked the fatal human disease variant Creutzfeldt-Jacob Disease (vCJD) to exposure to BSE, most likely through human consumption of beef products contaminated with the BSE agent. The tissues designated as SRMs in 9 CFR 310.22(a) are those tissues that are known to contain the BSE agent in cattle infected with BSE, as well as materials that are closely associated with these potentially infective tissues. These materials may harbor the infectious agent before the animal shows any clinical signs of disease. Therefore, FSIS prohibits SRMs from use as human food to minimize potential human exposure to the BSE agent. Canada took similar actions when a single case of BSE was discovered there in May 2003.

Q3. How will FSIS ensure that SRMs are not present in human food?

A3. Per 9 CFR 310.22(e), slaughter and processing establishments are required to develop, implement, and maintain written procedures to ensure that SRMs are removed from the carcasses of cattle, segregated from edible product, and disposed of as inedible. To ensure that SRMs are not present in edible product, FSIS inspectors will verify that establishments are properly implementing their procedure for the removal, segregation, and disposition of SRMs.

The vertebral column and the skull of cattle 30 months of age and older are SRMs and, as such, must be disposed of as inedible. Vertebral columns are also prohibited for use in AMR systems per 9 CFR 318.24.

Q4. Must all SRMs be removed at the slaughter establishment?

A4. Per 9 CFR 310.22(e), all SRMs must be removed before the product can leave the slaughter establishment except for the vertebral column from cattle 30 months and older. 9 CFR 310.22(g) permits slaughter establishments to ship carcasses or parts of carcasses that contain vertebral columns from cattle 30 months of age and older to another federally

inspected facility for further processing and removal if both establishments have controls in place to ensure that the SRM portions of the vertebral column are removed and properly disposed of by the processing establishment. For cattle, 9 CFR 310.22(c) specifically states spinal cord must be removed at the slaughter establishment. All SRMs must be removed before the carcass or parts can enter commerce.

Q5. Regarding the diagram in FSIS Directive 6100.4, Page 22, Attachment 2, can you clarify what the circled area includes that should not be intended for food?

A5. All tissues identified as SRMs in 9 CFR 310.22(a) are designated as inedible and not for human food. The circled area is a stylized representation demonstrating only the bony portion of the vertebral column prior to splitting that is not eligible for human food. It does not mean that all the muscle portions adjacent to the vertebral column (not shown) under the circled area must always also be removed.

Chapter 2: Slaughter and Processing Verification Activities

General Verification Duties (Design and execution) of HACCP, SSOP and PR Programs

Q6. Can a processing establishment control SRMs through a prerequisite program?

- **A6.** Yes. Per 9 CFR 310.22(e), the removal, segregation, and disposal of SRMs may be addressed one of three ways under the HACCP system. Establishments may incorporate their procedures for the removal, segregation, and disposition of SRMs into a HACCP, SSOP, or other pre-requisite (PR) program. If the establishment determines in the hazard analysis that the hazard (of SRMs) is not reasonably likely to occur because of a SSOP or other PR program, the removal of SRMs is effected as part of the written SSOP or PR program. According to HACCP requirements in 9 CFR 417.2(a), if a plant determines in its hazard analysis that SRMs are a hazard reasonably likely to occur, control of the hazard by a CCP is required.
- Q7. Must processing establishments that use boneless beef (beef trimmings, ground beef, etc.) from other inspected facilities develop written procedures for the removal, segregation, and disposal of SRMs and reassess their HACCP programs?
- **A7.** Yes. Per 9 CFR 310.22(e) and 9 CFR 417.4(a)(3), all establishments that slaughter cattle and all establishments that process the carcasses or parts of cattle must reassess their HACCP plan and develop, implement, and maintain written procedures for the removal, segregation, and disposal of SRMs.

Verification of Sanitation Procedures regarding SRMs

- Q8. May an establishment slaughter mixed aged groups of cattle (i.e., those containing animals less than 30 months of age and those 30 months of age or older) without segregating if they clean and sanitize equipment after they process cattle 30 months of age and older before they process cattle less than 30 months of age?
- **A8**. Yes. Under 9 CFR 310.22(f), if an establishment slaughters cattle and does not segregate the two age groups, the establishment must either: 1) use dedicated equipment to cut through SRMs or 2) clean and sanitize equipment after it comes in contact with SRMs from the cattle 30 months of age and older, and before it is used on cattle less than 30 months of age.
- Q9. When cleaning and sanitizing equipment between cattle of different age classes, what is required for equipment to be considered "cleaned and sanitized"?
- **A9**. Equipment that comes in contact with SRMs from cattle 30 months of age and older must be cleaned (i.e., washed to remove visible contamination) and then sanitized (i.e., 180°F degree water) before it can be used on carcasses or parts of carcasses from animals less than 30 months of age. Cleaning means the removal of organic debris that is adhering to the equipment prior to sanitization (this precludes the transfer of SRM to product from cattle less than 30 months of age). However, it is not expected that "clean and sanitize" would be taken to the preoperational state of cleanliness.

Q10. Does the splitting saw blade housing area need to be opened and cleaned, or is just dipping adequate?

- **A10**. The "clean and sanitize" procedure must be adequate to remove visible tissue residue and followed by sanitizing with 180°F water. If the plant can demonstrate the interior surfaces of the saw are maintained in a clean condition to be effectively sanitized by the 180°F water without opening the saw door, it may be an acceptable procedure. Equipment need not be cleaned to a pre-operational state before sanitizing.
- Q11. When establishments slaughter cattle of mixed ages (both less than 30 months as well as 30 months and older) and slaughters the older and younger animals separately, what is the required intervention for cleaning the equipment (e.g., splitting saw) between animals?
- **A11.** All plants that slaughter cattle or process cattle carcasses or parts have the responsibility of developing, implementing, and maintaining written procedures for the removal, segregation, and disposition of Specified Risk Materials (SRMs). These procedures must be incorporated into the plant's HACCP plans, SSOPs, or other prerequisite program.

Under 9 CFR 310.22(f), if an establishment segregates older (30 months and older) from younger (less than 30 months) cattle, and slaughters and processes the younger cattle first, the establishment may use routine operational sanitation procedures to prevent cross contamination of SRMs between all cattle 30 months and older. If cattle 30 months and older are slaughtered, all equipment should be cleaned and sanitized before slaughtering the younger animals to prevent cross-contamination of the edible portions of the carcasses and parts of younger cattle with SRMs from the older cattle.

- Q12. FSIS notice 7-04 directed that readily identifiable SRM contamination be removed from the carcass. However, for establishments that are splitting carcasses (down the vertebral column) from cattle 30 months of age and older, did the final rule change the requirements for dealing with vertebral bone dust?
- **A12**. The final rule does not change the agency's position on bone dust. The information in FSIS Notice 7-04 has been incorporated into FSIS Directive 6100.4 "Verification Instructions Related to Specified Risk Materials," which became effective October 1, 2007. The Agency expects readily identifiable SRM material to be removed from the carcass; knife trimming is an accepted method.
- Q13. Our state inspection program has an establishment that does not identify or segregate carcasses according to age and treats all animals as 30 months and older. Its SSOP states that it will remove all SRMs as if the carcass and parts are from beef animals over 30 months. At what point would the inspector verify sanitation procedures for this establishment once it has removed the spinal column with the band saw?
- **A13.** If the establishment does not segregate between beef carcasses less than 30 months of age and carcasses equal to or greater than 30 months of age (in other words, treats all carcasses as 30 months and older), then normal or regular sanitation requirements are expected. Normal sanitation requirements require that any grossly identifiable SRM that can end up in the meat be removed as it is considered to be inedible contamination and not for human food. Since all carcasses are being processed on the processing floor as 30 months and older, then all tissues that are considered SRMs are removed and disposed of as inedible regardless of the age of the animal.
- Q14. Assuming that the spinal cord has been properly removed by the slaughter establishment, is it permissible for the vertebral column of a carcass or sub-primal, i.e., chuck, to come in contact with edible tissue from another carcass or sub-primal?
- **A14.** Contamination of meat or meat products by SRMs is based on identification of readily or grossly identifiable (e.g. a piece of spinal cord) SRM tissue. No further action is required so long as the plant has implemented all procedures it deems necessary to prevent potential contamination of meat by readily identifiable SRMs.

Note: Be aware that additional requirements may apply if the plant is participating in an AMS Export Verification (EV) program. Also, other monitoring, verification, record keeping, or corrective actions may apply depending on how the plant addresses SRMs under the HACCP umbrella (HACCP, SSOP, or PR programs).

Q15. Is it permissible to bone a chuck on a table given that the vertebral column will come into contact with food contact surfaces, i.e., conveyor belts and cutting boards?

A15. Yes, the vertebral column may touch food contact surfaces provided the plant has implemented procedures to prevent cross contamination of meat with readily identifiable SRMs. For example, the plant may include in their written SRM control procedures (HACCP, SSOP, or PR program) employees will monitor the spinal cord has been completely removed from each vertebral column of each carcass quarter prior to dropping on the table for breaking.

Q16. Is a knife used to cut through SRM material considered contaminated?

A16. A knife used to cut through SRMs is a potential source of contamination. FSIS expects the plant to implement whatever procedures it deems necessary to prevent the contamination of meat with SRMs. Any knives used to split SRMs, specifically vertebral columns from cattle 30 months and older, must be cleaned and sanitized before being used on carcasses or products of cattle less than 30 months of age unless the establishment uses dedicated equipment to cut through SRMs. See 9 CFR 310.22(f).

Q17. How would FSIS personnel verify that water being re-cycled in a carcass wash cabinet or steam pasteurization cabinet is free of SRM?

A17: In operations that utilize re-cycled water in carcass wash cabinets and steam pasteurization cabinets, FSIS personnel would periodically verify that carcasses are washed free of visible bone remnants before the carcass enters the wash cabinet or steam pasteurization cabinet. In addition, FSIS personnel would ensure that the water being recycled is being filtered in accordance with the standard for reuse of water in 9 CFR 416.2(g)(3) to remove any build-up of biological material.

Post-mortem On-Line Verification Activities

Q18. Can an establishment collect spinal cord for sale for edible product for human consumption from cattle younger than 30 months of age?

A18. Spinal cord material from cattle younger than 30 months of age is not a specified risk material as listed in 9 CFR 310.22. There is no regulation that prohibits an establishment from harvesting spinal cord from cattle younger than 30 months of age for human consumption, provided it is wholesome, unadulterated, and properly labeled. However, 9 CFR 318.6(b)(4) limits the manner in which spinal cord may be used for human food. 9 CFR 318.6(b)(4) provides:

(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material. Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.

<u>Verification of SRM Removal, Segregation, and Disposition; General</u> Recordkeeping

Q19. How much of the back bone or vertebral column from cattle 30 months and older needs to be removed?

A19. Per 9 CFR 310.22(a) and (c), before beef product can enter commerce outside a federal establishment, the entire vertebral column (back bone) has to be removed except for the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum. The cuts are just beyond both sides of the back bone. This cut will not be through the vertebrae themselves but will go through the transverse processes and ribs. See the two diagrams in Attachment 2 of FSIS Directive 6,100.4 that illustrate transverse processes and ribs in relation to the vertebrae.

Q20. If the establishment is removing the meat from around the vertebral column with electric ("wizard") knives, is this a potential problem when used around the transverse processes of the thoracic and transverse vertebrae?

A20. Based on the diagram in Attachment 2 of FSIS Directive 6100.4, the use of a wizard knife above the transverse processes (non-SRM) appears to be of little risk. The use of a wizard knife *below* the transverse process of the lumbar vertebrae may be of greater risk. The regulations require each plant to develop effective procedures for the removal, segregation, and disposal of SRMs. It is up to the plant to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. These procedures must be incorporated into the plant's HACCP plans, SSOPs, or other pre-requisite program.

Q21. Can I cut steaks from the loins of cattle 30 months of age or older first and then remove the SRMs associated with the vertebral column?

A21. No. Plants are expected to develop procedures in the HACCP plan, SSOP or other pre-requisite program that ensure the effective removal of all SRMs and ensure that SRMs do not contaminate edible product. FSIS has determined that the removal of SRMs from cut steaks increases the potential for contamination of edible tissue with SRMs and presents an unacceptable and unnecessary risk to consumers.

Q22. Are very small plants that address SRM removal, segregation and disposition in a prerequisite program (or SSOPs) required to keep daily records

documenting monitoring, verification, recordkeeping and corrective actions, including reassessment?

A22. Yes. In the case of SRMs, 9 CFR 310.22 has specific recordkeeping requirements that apply regardless of whether the establishment addresses its procedures for the removal of SRMs in its HACCP plant, SSOP, or other prerequisite program. Records are only required for the days when the plant is in operation and producing product that has SRM tissues. If the establishment chooses to address SRMs in a prerequisite program, then that prerequisite program must meet the all the requirements of 9 CFR 310.22 that specify daily recordkeeping.

Verification Activities for Tonsil Removal, Segregation and Disposal

- Q23. How do FSIS inspectors verify that 5 mm of tissue is removed from tongues to ensure removal of lingual tonsils?
- **A23**. Inspection program personnel should verify that the establishment has appropriately addressed the use of a skinning machine through verifiable equipment settings and procedures so that a minimum of 5mm, or more, of tissue is removed, and that visible tonsillar tissue (i.e., the SRM) does not remain on the blade or any part of the skinning machine in a manner that may cross-contaminate edible product with SRM material.
- Q24. In addition to boneless beef, the plant saves head meat and tongues. The rest of the head is condemned. The plant identifies various SRMs except for tonsils. Does the plant need to address removal of tonsils in its hazard analysis?
- **A24.** Yes. Tonsils are a SRM in cattle of all ages. The establishment must consider all SRMs in their hazard analysis. SRM hazards should be addressed in the HACCP, SSOP, or PR program. Since tonsils are SRMs, the establishment must remove the tonsils from the edible tongue tissue and address tonsil removal in their written procedures as described in 9 CFR 310.22(e).

Verification Activities for the Prohibition of Air-Injection Stunning

- Q25. The regulations prohibit the use of stunning devices that inject air into the cranial cavity of cattle. Does this include stunning devices which merely use air to power the bolt (as with the more common explosive charge bolt stunners) and may incidentally inject air?
- **A25**. No. The regulations do not specifically prohibit pneumatic stunning devices. 9 CFR 310.13(a)(2)(iv)(C) prohibits the use pneumatic stunning devices that inject compressed air into bovine skulls during stunning. This regulation would apply to malfunctioning captive bolt stunners that use compressed air. 9 CFR 313.15(b) specifically prohibits the use on cattle of captive bolt stunning devices that deliberately inject air into the cranial cavity at the end of the penetration cycle.

Verification of Disposal and Rendering of SRMs

Q26. What are the record keeping requirements for disposal of SRMs to inedible rendering? Specifically, do we need a separate vertebral column weight with the rendering company providing a record stating that a given weight of SRMs were received and subjected to inedible rendering, or can the establishment maintain a weight ticket for the weight of all bones received and subjected to inedible rendering?

A26. Plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. Plant records must demonstrate that the plant is following its procedures to remove and dispose of SRMs per 9 CFR 310.22(c) and 310.22(e)(4). Plant records may show separate specific weights of SRMs, but they are not required to do so. The records of plants that receive product with SRMs must show that the SRMs in the specific product have been removed and disposed of per 9 CFR 310.22(g)(4).

(4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in paragraph (a)(1) of this section and disposed of them in accordance with Sec. 314.1 or Sec. 314.3 of this subchapter.

Q27. Can SRMs be rendered or must they be sent to an approved landfill?

A27. SRMs from any bovine that passes AM inspection may be sent to inedible rendering or disposed of in an approved landfill after denaturing as per 9 CFR 314.1 or 314.3. SRMs are not restricted from being rendered unless the animal was condemned by FSIS on AM and samples were collected on-site and are being tested for BSE.

When any condemned carcass is being tested on-site for the presence of BSE, FSIS inspection personnel should request that the any part of the carcass or SRMs not go into inedible rendering until a negative BSE result is obtained. Any carcasses or parts from condemned animals that are being tested for BSE may be disposed of in a lined landfill or incinerated in accordance with state or local sanitary codes when a test result has not yet been received. The establishment must maintain accurate records documenting the location of carcass or parts disposal.

Chapter 3: Transportation of Carcasses and Parts that Contain SRMs

- A. Verification at Slaughter Establishments
- B. Verification at Receiving Establishments

Verification at Slaughter (Shipping) Establishments

Q28. Is the shipping establishment required to provide documentation with every shipment?

A28. The shipping establishment must include in its hazard analysis decisions on food safety hazards that can occur before, during, and after entry into the establishment. The shipping establishment can ship bone-in product with SRMs (e.g., vertebral columns) as long as it verifies their removal by the receiving establishment. In addition, the shipping establishment must provide documentation to account for all product on every shipment of product containing SRMs (e.g., vertebral columns from cattle 30 months and older) to the receiving establishment.

Q29. If the shipping establishment is shipping only boneless product or is removing all SRMs, is there a need to certify every shipment?

A29. No. If the establishment is shipping only boneless product or bone-in products from cattle under 30 months, it should provide adequate documentation to the receiving establishment that verifies its SRM control programs are on-going and still in effect. The plant need not necessarily provide such documentation for each shipment. See Question 27 and 37.

Q30. Are there any specific requirements for the use of company seals, as described in prior notices dealing with SRMs or FSIS Directive 6100.4? For example, can they simply use a padlock to seal the trailer in transport with specified risk materials (SRMs) on board?

A30. The plant is responsible for developing its own controls. Such controls should be effective and may include the use of company seals or padlocks. The use of a padlock alone does not provide adequate control unless it can be demonstrated that the identity of the product is maintained, or the shipment cannot be opened during transit before reaching the receiving official establishment. Inspection personnel are to ensure that the method of control is equivalent to use of tamper-evident seals and does not allow diversion for other purposes. Any unloading of the controlled products without the knowledge of the establishment, and without providing clear evidence (allowing FSIS verification) that control has been maintained, would not be considered adequate.

Q31. FSIS Directive 6100.4 clarifies that beef carcasses from cattle 30 months of age and older can be shipped with vertebral columns still in. Can these carcasses be shipped with <u>spinal cord</u> still present within the vertebral column? These carcasses are shipped split, but there are often mis-splits where the spinal cord is still present.

A31. No. 9 CFR 310.22(c) states the following:

the spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.

- Q32. EST A slaughters cattle and provides carcasses containing the vertebral column to EST B, located in the next town. EST B transports the carcasses from EST A to EST B in a transport vehicle owned and controlled by EST B. The carcasses are further processed at EST B. The Public Health Veterinarian is satisfied that both EST A and EST B have documentation to demonstrate that all carcasses leaving EST A arrive at EST B, and that EST B removes and disposes of all SRM. Based on this, is the establishment required to use company seals?
- **A32.** The regulations specify plants must be able to demonstrate "control" of SRMs. The use of company seals is only one of several means to control SRMs. If the establishment has developed an alternative means to maintain control of the adulterated products, the use of company seals is not specifically required. Inspection personnel are to ensure that the method of control is equivalent to use of tamper-evident seals, does not allow diversion for other purposes or unloading of the controlled products without the knowledge of the establishment, and provides clear evidence (allowing FSIS verification) that control has been maintained.
- Q33: How specific must the records be to verify that the receiving establishment removed and properly disposed of the SRMs? Does the shipping establishment need to receive specific records for each carcass, part, load, etc, or would a blanket letter from the receiving establishment expressing their intent to remove the SRMs be appropriate?
- **A33.** Yes. Blanket letters are not an acceptable means to verify removal and disposal of SRMs in bone-in or other products with SRMs by the receiving plant since they typically do not contain specific identifying information. The shipping establishment must have records that demonstrate that the receiving establishment removed and properly disposed of the SRMs from specific products through lot numbers, dates, or other specific product identifying information.
- Q34. Previously, we used a blanket letter from the receiving plant to document that all SRMs were removed. If a blanket letter that accompanies each shipment of beef products with SRM is no longer acceptable, what information must be included?
- **A34.** By blanket letter, we presume you mean a letter of guarantee without specific information identifying the product or shipment. Per 9 CFR 310.22(e)(4), plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. Establishments that transport carcasses or parts from cattle 30 months of age and older for further processing will have to obtain these records from the receiving establishment in order to verify that the receiving establishment removed and properly disposed of the SRMs. Records that document the removal of SRMs at the receiving plant need to identify the specific product. Examples of records that might identify specific product containing SRMs requiring removal may include some or all of the following:
 - 1. date shipped, load number

- 2. date arrived,
- 3. purchase order (PO) number,
- 4. product description; number of carcasses/parts, lot number
- 5. date/shift when processed or SRMs removed
- 6. product description indicating removal and disposal of SRMs meets requirements in 9 CFR 310.22 and 9 CFR 314.

Q35. Is the mark of inspection applied to carcasses from cattle 30 months and older with vertebral columns intact at the shipping facility or only after removal of SRMs?

A35. In the preamble discussion of the final SRM rule in Federal Register, Vol. 72, No. 134, July 13, 2007, FSIS announced, "If establishments have implemented appropriate controls, FSIS inspection personnel at the shipping establishment will apply the mark of inspection to carcasses or parts that contain SRM vertebral bones as an accommodation to facilitate their transport to a processing facility where the SRMs can be removed and properly disposed of."

Verification at Receiving Plants

Q36. Is it permissible to break the company seal and off-load other products (other than parts which contain vertebral columns) prior to arriving at the final destination with the parts which contain SRMs?

A36. Plants need not utilize company seals provided they can implement other controls to maintain identity of product and ensure the effective removal of all SRMs from the specific product before that enters commerce.

Q37. Must a receiving establishment have certification from the shipping establishment if it is receiving bone-in products?

A37. Each establishment that receives bone-in product must consider what steps, if any, are necessary to ensure that the supplier has properly identified SRMs, if present, for removal or that the product does not contain SRMs because it is from an animal that was younger than 30 months at the time of slaughter. Without adequate supplier documentation demonstrating the on-going identification, segregation, and removal of all SRMs, the products with vertebral column will be deemed from cattle 30 months and older per 9 CFR 310.22(h) and require removal. A prudent establishment may incorporate additional procedures or programs that include purchase specifications or supplier certification.

Daily records are required. 9 CFR 310.22(e)(4) states:

(4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

Q38. Must a receiving establishment have certification from the shipping establishment if it is receiving only boneless beef products?

- **A38.** Plants that only receive only boneless-beef must reassess their hazard analysis for SRMs in their process. Written procedures are not required if the plant determines and can support that SRMs are not a hazard likely to occur in its process. The use of general documentation (e.g., "blanket" letters of guarantee) identifying shipment of only beef products from cattle less than 30 months of age is acceptable here. The written hazard analysis and supporting documentation from the shipping establishment attesting to origin of beef from cattle less than 30 months of age or the complete removal of SRMs in the boneless beef products shipped satisfy the requirements in 9 CFR 310.22(e) and 9 CFR 310.22(h). See Questions 27 and 30.
- Q39. Assuming that the receiving processing establishment must account for all bone-in beef with (SRM) vertebral column received as identified on the purchase order (PO), and knowing the receiving establishment may take over two days to bone all the product on the purchase order, must the record verifying that the receiving establishment handled the SRMs correctly be generated after the entire PO is fabricated?
- **A39.** Not necessarily. Plants are required to maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs. A plant may be able to subdivide lots and produce a record for a partial lot provided the plant can ultimately account for all product listed on a single purchase order (PO).
- Q40. FSIS permits establishments to transport carcasses that contain vertebral columns from cattle 30 months of age and older (SRMs) to another official establishment. Can an establishment that is inspected under a participating state meat program be the recipient of such carcasses?
- **A40.** No. Beef products containing SRMs can not move from a ederal establishment to a state-inspected establishment. Such products moving from an establishment under Federal inspection to a plant under a non-Federal inspection system are considered to be in commerce. Beef products containing specified risk material (e.g., vertebral column) are not permitted to move unrestricted in commerce.

<u>Addendum</u>

Handling of SRMs in Custom Plants

Q41. Do the SRM regulations apply to custom slaughter?

A41. Yes. By authority of the FMIA, the Secretary has designated SRMs as inedible and are not eligible for human food. This rule applies to custom as well as inspected animals and products.

Q42. Can cattle be farm slaughtered and processed in custom facilities?

- **A42.** Only cattle that are healthy, wholesome, and ambulatory (<u>not</u> non-ambulatory disabled) can be farm slaughtered and processed at a custom processing facility.
- Q43. If a federally inspected establishment has a non-ambulatory disabled cow that it mistakenly or inappropriately intends to slaughter as "custom exempt," should the on-site FSIS inspector segregate it and call a PHV so it can be condemned?
- **A43.** If the federally inspected establishment is preparing to custom slaughter a non-ambulatory disabled cow (cattle) at a federally inspected establishment, then the animal should be controlled by the inspector using a suitable retain tag with a FSIS padlock (if necessary) until the PHV can condemn it. If the animal has not been presented for inspection and could possibly be removed from the premises without FSIS permission, and there is reason to believe it will be taken elsewhere for slaughter, FSIS inspection program personnel should promptly identify the animal as "US Inspected and Condemned," retain it in a pen using a US Retained Tag and a FSIS padlock, if necessary, and notify the PHV, FLS, and District Office (DO).

If the establishment is non-federally inspected custom-exempt only operation, the reviewing officer should contact the OPEER via the DO for assistance.

Q44. Are custom operations eligible to process cattle 30 months of age and older?

A44. Yes, custom operations are allowed to slaughter and process cattle 30 months of age or older, provided they remove and handle the SRMs appropriately as required by 9 CFR 310.22. The SRMs listed in 9 CFR 310.22(a) will be considered to be from cattle 30 months of age or older unless the custom operator can demonstrate that they are from cattle under 30 months of age as stated in 9 CFR 310.22(h).

Q45. Can a plant keep custom SRM records in the same records used for SRMs under inspection?

- **A45.** Yes. Custom establishments may keep custom records with records for activities that are under federal inspection provided that they are clearly identified as custom records.
- Q46. Are custom exempt operators required to have written procedures for the removal, segregation and disposition of SRMs and associated records and to keep records as described in 9 CFR 310.22(e)(4)?

A46. No. FSIS does not require custom operator to keep records documenting *written procedures* describing the removal, segregation, and disposal of SRMs for federally inspected establishments per 9 CFR 310.22(e)(4), unless the custom operation is subject to all of 9 CFR 416 and uses SSOPs to document removal, segregation, and disposal in inspected beef.

Q47. What are the minimum recordkeeping requirements regarding SRMs for custom operations?

A47. 9 CFR 303.1(b)(3) describes recordkeeping requirements for custom operators. To facilitate identification of SRMs, FSIS Directive 5930.1, based on 9 CFR Part 320, states that custom operations must keep records that document the following: 1) cattle slaughtered or processed are less than 30 months of age; 2) cattle are ambulatory at time of slaughter per 9 CFR 310.22(h). Custom operations that fail to document the age of cattle slaughtered or processed and the ambulatory status of animals at slaughter are expected to handle the carcass as 30 months and older and remove all SRMs.

Be aware custom operations conducted in official establishments are subject to all of 9 CFR Part 16 including SSOPs per 9 CFR 303.1(a)(2)(i). If the official establishment includes its written procedure to remove, segregate, and dispose of SRMs in its SSOP, it must meet all the requirements of 9 CFR 416, including SSOP recordkeeping for its custom operations.

Q48. Can T-bones, brains, etc. be saved from older animals (30 months and older) in custom exempt facilities?

A48. No. SRMs from custom slaughtered or processed animals are considered adulterated and ineligible for use as human food. All SRMs must be removed before delivering the product to the owner.