Veritas Quality Assurance Procedures

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Medical Solutions

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FOREWORD

Manufacture of the VeriShield™ product line follows a strict Quality Assurance program. Each phase of this program, from the ordering of material constituents through manufacturing and delivery, ensures that the VeriShield™ product is of the highest quality materials, produced with strict quality control measures. This program has also been implemented to guarantee that the product arrives at the job site intact and of proper shielding effectiveness, with as little chipping or damage during shipping and handling as practicable.

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PROCEDURE #1:

MATERIAL SELECTION INTRODUCTION

The material composition of VeriShield Products is a highly protected Trade Secret that is to be considered proprietary intellectual property of Veritas Medical Solutions, LLC. Anyone involved with the ordering of materials, manufacturing, testing, handling, installation or testing of the products is to be trained in their respective disciplines and duties to ensure protection of the product data, manufacturing means and methods, materials suppliers and processes etc.

Material composition for the various product lines differs for each product. A thorough understanding of which products may be used is critical to produce the highest quality radiation shielding materials on the market. It is important that all employees and suppliers understand that different materials react differently to types of radiation and the respective energy of the incident radiation beam on the material. For example, some products are more apt to give off (or produce) an unwanted neutron component when shielding high-energy photon radiation (above 10 MV). Likewise in some applications materials may be more prone to induced and long-term radiation activation such as when used in a particle beam of high-energy protons or carbon ions.

Material Specification or Selection

When a material is to be considered as a constituent of the product it must be either:

a) chosen from an approved supplier vendor whose materials are known and previously tested and inspected by Veritas or

b) compliant with a written specification generated in advance of bid solicitation where the material characteristics including "Z" number, particulate size, gradation, chemical and/or mineral type, foreign contaminates etc. are known and measured.

Supplier materials

All suppliers are to be inspected by Veritas prior to bid solicitation or invitation. A representative from the Veritas physics team is part of the selection process of materials and vendor suppliers to ensure materials offered are approved for use. Materials used in the manufacturing of the VeriShield™ products can vary in a variety of ways,

which may affect shielding attenuation capabilities and manufacturing quality. For example variation in gradation of materials can significantly affect material density or material conformity.

Material Sampling and Testing
Material samples are to be gathered in accordance with the "sampling methods" herein and tested at a qualified and approved testing lab. The type of tests conducted on material samples and the reporting are proprietary information of Veritas Medical Solutions. All material testing is complete in advance of invitation to bid or purchase from approved vendor suppliers. The results of these tests are to be filed and available for review by Veritas Q/A personnel and physics staff traceable from time of sampling to procurement and manufacturing in batch lots.

Supplier Facilities
It is important in the selection of suppliers to not only pre-qualify and quantify materials and material availability but also facility accommodations. All suppliers must have proper material handling capabilities to adequately fulfill the orders placed by Veritas. This is to include bulk handle means, weigh scales - along with a program in place for calibrating and periodic certification of scales, proper long term storage of materials such that material quality will not be adversely affected by weather, settling, or separation from handing, moisture, or oils contamination etc. An inspection of supplier facilities is conducted periodically of all approved suppliers and must be conducted prior to approval of any new suppliers. The physics and Q/A staff of Veritas must be consulted and an appropriate supplier site checklist used or drafted for the intended material needs. In addition to quality of plant facilities the supplier must conform to basic traceability guidelines of raw materials as further enumerated in Veritas Material Suppliers Guidelines.

PROCEDURE #2:
RECEIVING MATERIALS

Supplier Selection and Delivery
Upon approval and prior to product purchase, material suppliers must review and execute the Veritas Confidentiality and Non-Disclosure Agreement. Suppliers are evaluated based on material property scoring, cost evaluations, supply availability and other factors. A written purchase order is generated by Veritas' Purchasing Department that identifies the exact materials and quantities to be delivered to the receiving location(s) for manufacturing. Suppliers are expected to deliver material in truckload quantities for handling and conveyance of materials by standard wheel loaders and belt conveyors. As materials arrive at the plant or receiving yard, they are to be accompanied by a Bill of Lading and related paperwork, which further promotes traceability back to the original purchase request and specification. All Bills of Lading refer to the original purchase order date and number and include date and pick-up location of delivered material; tare weight of the product being delivered; name and address of supplier; signature and printed name of hauler; and time and date of delivery.

PROCEDURE #3:
INITIAL INSPECTION AND MATERIAL HANDLING

Receiving, Off-loading, and Inspection
The receiving party for Veritas must review the Bill of Lading for each load upon its entrance to the facility and prior to its off-loading, in order to ensure that it is an approved and pre-ordered material. The off-loading and storage of materials is to be in a predetermined location in a clean holding bin or bin of same material type in current or recent operation. (Note: type, by definition, means not only chemical or mineral classification but also conformance to the above noted bulk properties of gradation, foreign contamination, bulk density, etc.) Different materials are not to be mixed together for convenience of space or other reason unless pre-approved on a limited and for a specific one-time delivery approval.

It is important to note that the simple handling of materials can impact the end quality of the manufactured product. Handling should be kept to a minimum and materials should always be handled in bulk large quantities and moved over short distances in preference to long conveyances and multiple handling occasions. Excessive handling and conveyance can lead to separation of materials (especially of premixed to specification) by type or gradation. While methods are to be enacted to measure such properties just prior to manufacturing, such separations can produce sub-standard product, the removal of which from the process line delays operation.

PROCEDURE #4:
MATERIAL STORAGE

Storage of Materials at Veritas Plants or Approved Storage Locations
Materials are stored in accordance with all material safety data sheets and supplier recommendations. Bulk materials are to be stored in approved storage bins or protected sealed casks as appropriate for material constituents. Any liquids are to be placed into leak proof casks with proper ventilators, pumps, hydrostatic gauges, and reservoirs to ensure liquids can be delivered in the measured quantity needed in manufacturing of the VeriShield™ Products. All dry or semi-dry aggregate type materials are to be stored in bins or hoppers appropriate for the weights and types of materials being stored. While some materials may be stored outdoors in uncovered bins, all materials are only stored in leak-proof and weather-protected hoppers or holding tanks.

Storage of materials from various suppliers of same or similar type is separated from each other when feasible. This segregation procedure ensures traceability to vendor suppliers' materials at all times. While it may be impractical to separate every incoming bulk delivery of same supplier/type material, efforts are made to identify materials delivered over a single purchase order of multiple deliveries. For example, materials from the same supplier and material type delivered over the period of a week or several weeks may be combined and mixed together so long as those materials were recorded and checked for quality upon each delivery. Bulk materials are immediately inspected with each truck-load delivery. Inspection consists of document review as well as intermittent sampling and factory testing compliant with benchmark standards. Once approved, loads may be combined into a single bin or storage cask and presumed homogeneous from one batch-lot order.

PROCEDURE #5:
MATERIAL TRANSPORTATION

Bulk Transport and Conveyance for Manufacturing Operations
Materials are conveyed or transported in bulk and over as short a distance as practical to eliminate settling and separation of material constituents or aggregates types, gradations, and sizes. Materials are first transported from the holding storage bins or casks to gated measuring hoppers. These hoppers will subsequently regulate the amount of materials of each type to be transported by belt conveyors to the mixing tank. Belt conveyors are tested and inspected to ensure that there is no loss of material throughout the conveyed distance such as would occur from spillage over the sides of the belts; back-charge from clutch slippage, tears, or unsupported belt sections. Belt conveyors deliver materials to a measuring weigh hopper. The weigh scales of the hopper regulate the way in which materials are delivered into the hopper by the belt conveyors for the respective constituents. The weigh scales also regulate the material formulation being produced. When the appropriate amount of a given material is measured into the hopper, the belt conveyor is signaled to immediately stop and no additional material shall be discharged unless manually overridden by the plant operations team. Any additional discharge of materials into the hopper shall be recorded and filed with the batch lot that is being produced.

All measured materials (both by weight and volume) are recorded for each material batch and lot number. Formulations for materials produced are entered into the automated batch system program or may be manually executed by measuring and recording the incorporation of materials of each type for the product being manufactured.

PROCEDURE #6:
TRACEABILITY:
BATCH AND LOT NUMBER RECORDING

Batch and lot numbers are assigned to every batch and include a time/date stamp or alternate method of recording date and time of manufacture. The quantity of each material constituent is also recorded for each produced batch and lot. Furthermore, mixing times and other machine settings are recorded with each batch or lot. Mixture times and methods are in strict accordance with the product manufacturing protocol as under- or over-mixing may result in poor quality product. Over-mixing may result in material separation/segregation, poor moisture, or unworkable material flow. Under-mixing may result in non-homogenous material, improper saturation, separation and cracking, and other detrimental effects.

PROCEDURE #7:
MATERIAL AMALGAMATION

Moisture and Admixture Content
Moisture and other chemical admixtures appropriate to the product manufacturing specifications shall be strictly monitored to assure best quality product. Prior to adding moisture and admixture, the bulk materials designated for the lot production must undergo prior testing for inherent moisture. An analysis of retained moisture in the bulk aggregate products is conducted to determine the amount of additional moisture and admixture content appropriate for the batch and lot mixes. Inspection of the aggregates for moisture shall be conducted daily at the start of production. Additional inspection is conducted as necessary to ensure proper moisture content. This is especially important of materials that are stored outdoors and subject to climate changes that may affect moisture content, such as rain and relative humidity.

PROCEDURE #8:
VISUAL INSPECTION OF PREFORMED-POST-MIXED MATERIALS

A trained, competent plant operator, familiar with the desired material properties, shall conduct a visual inspection of each batch mix. Before it is delivered into the mold box, the inspector selects a small quantity of mixed material at random. This inspection must include a review of material consistency, workability, texture, moisture and homogeneity. This visual inspection is the final step in assuring proper material quality prior to entering the mold manufacturing process. At the discretion of the inspector, material may be rejected or modified in order to improve any of the aforementioned criteria. Any changes to the batched materials is clearly recorded and filed with the initial batch data.

PROCEDURE #9:
BLOCK FORMATION AND INSPECTION

Material is transported from mixer to manufacturing equipment where the product is formed into a 4-sided interlocking block product. Two representative sample blocks are chosen at random from every batch and are checked visually for quality of interlocking edges; quality of face dimensions of the units to ensure that they are flat and within the specified tolerances in terms of thickness; finally, they are weighed to check for compliance with weight and density specifications.

Each batch is color-coded and segregated, making them easily-discernible and further promoting traceability. The formed product is transported to the curing area, where each individual batch is separately stored for a period of time as prescribed for the specific product.
Approximately every 20 cubic feet of material is subject to another round of inspection.

PROCEDURE #10:
PALLETIZING AND FINAL INSPECTION

After the curing period, the blocks are conveyed to the area for palletizing and packaging. At this point, another representative sample of block are chosen from each batch at random and checked as a cured unit for the aforementioned criteria, including dimensional and weight tolerances, as well as physical appearance and characteristics.

Each and every block is visually inspected before being palletized. Any block that does not meet the quality standard criteria is removed from the line. The remaining block are then palletized and wrapped. Each product is wrapped in color-coded materials by product type. While there are several ways to visually identify types of block, they are not always easily differentiated to the untrained eye. Color-coded packaging allows for easy identification on the receiving end.

PROCEDURE #11:
LABELING AND CONTAINERIZATION

The complete, color-coded wrapped pallets are immediately branded with a label that includes a serial number unique to that pallet. This data is linked to the central computer system so that each pallet can be traced to its original batch and lot. This tracking system provides detailed manufacturing information for that pallet, including the day, temperature, characteristics of the day, and how much product was made. The pallet may also be affixed a label specific to the client. Generally, each batch is labeled for a specific client during this palletizing process. If a batch is manufactured for inventory and then sold at a later date, the inventory will be pulled for a specific client and shipped to the respective jobsite.

PROCEDURE #12:
SHIPPING AND DELIVERY

Upon being packaged for containerization for shipping, the pallet and serial numbers are recorded. The container is then sealed to prevent tampering. The product is tracked with a commercial invoice and commercial Bill of Lading. The shipment is directly transported from the container port to the job site, at which point it is off-loaded into pre-designated areas, usually determined by material/type of product.

PROCEDURE #13:
CREW SELECTION AND SITE SUPERVISION

Whenever possible, trained crews are contracted to install the VeriShield™ product. When a trained crew is not available, Veritas will provide training. A Veritas representative will also perform periodic site inspections to ensure proper installation in accordance with shielding characteristics as defined by the installation drawings. Such installation drawings are clearly marked and differentiate where different product types are to be used. These drawings are then utilized to install specific products.

PROCEDURE #14:
INSTALLATION TOLERANCES

The tolerance for plumbness when building a VeriShield wall is a maximum of 1/2" over 5 coursings of wall shielding. Leveling is achieved through the use of a VeriShield™ Grout leveling course every 5th course of wall shielding.

VeriShield™ Grout leveling bed should not exceed 1/2". Bearing plate level tolerance should not exceed 1/2". Any bearing plate level variance is generally based upon the finish of the steel plate. Minimum cut size for filler block is 1 1/2". There is no maximum size for grout cells or "filler grout".

Visual inspections of blocks are perfo rmed prior to block placement. If the visual inspection determines that the block has more than 10% mass reduction, then the block is not utilized where the installation drawings call for a full block. It is important to note that these blocks are not discarded. Rather, they are instead fashioned into make half-size filler block as well as filler grout..