

Cold Plasma Sanitation System

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BAE 4023

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Intro

Problem Statement:

“CCC (Cold Case Cleaners) will research, design, build, and test a cold plasma sanitation system for use on commercially available pecans.”

Statement of Work:

Statement of Work

Date	[5/2/19]
Client	[Oklahoma Department of Agriculture]
Job Name	[Cold Plasma Sanitation System Design]
Requested by	[Oklahoma State University]
From	[Derek Clinton, Nicholas Holden, Sarah Riley, and Calvin Wynn]

Summary

According to Sections 310:260 -3-2 through 310:620-3-5 of Oklahoma state law, all pecan growers must sanitize their pecans to a certain extent before selling them on the market. Many small-scale pecan growers have been sanitizing their products with chlorine solution. However, in order to reduce both the cost and the usage of chemicals, research has been conducted into sanitizing pecan shells via cold plasma. Our objective is to create a cold plasma sanitation system that can sanitize 25-50 lbs. of pecans at a time. Each batch of pecans must be sanitized for at least two minutes. Furthermore, the distance between the pecans and the plasma source must be adjustable, and the materials used to create the system should be resistant to oxidation. Finally, the design itself should be hygienic, affordable, and compatible with current equipment. As our group is tasked solely with designing the containment system, we will test the mechanics of the system to ensure the pecans are processed correctly. It's anticipated that the final result will give all of the required deliverables.

Project Scope

Our objective is to create a cold plasma sanitation system that can sanitize 25-50 lbs. of pecans in batches that must be sanitized for at least two minutes (each) at a time. The system must be designed in a way that is both hygienic (cleanable) and compatible with current equipment. It must be resistant to oxidation as well. Additionally, the distance between the pecans and the sensors must be adjustable. Finally, the system will utilize trays vertically stacked next to each other in order to create vertical columns. Gravity will be used to dump the pecans into the top of

these columns, and after they have been processed they will simply be released from the bottom of the system (think tic-tac-toe). We will perform tests for the experimental design in OSU's BAEL and FAPC.

Schedule

Tentative Schedule	
Tasks	Date Accomplished
Final Design Due	11/16/2018
Final Client Meeting	11/30/2018
Fall Presentation	12/7/2018
Evaluations	12/7/2018
Finalize Parts List	1/21/2019
Submit Design to Manufacturer	3/11/2019
Test First Design	4/3/2019
Submit Design Second Draft to Manufacturer	N/A
Finalize Spring Presentation	5/1/2019

Table #1: Task List

Key Assumptions

- In addition to the assumptions listed above, we must also make the design ubiquitous so that it may be able to process differently shaped food as well. The food being processed will be relatively dry, and close to the electrodes. A log reduction of 2-5 must be used, and air will be used for plasma generation. Ozone produced by the system can't be directly released into the atmosphere.

WBS:

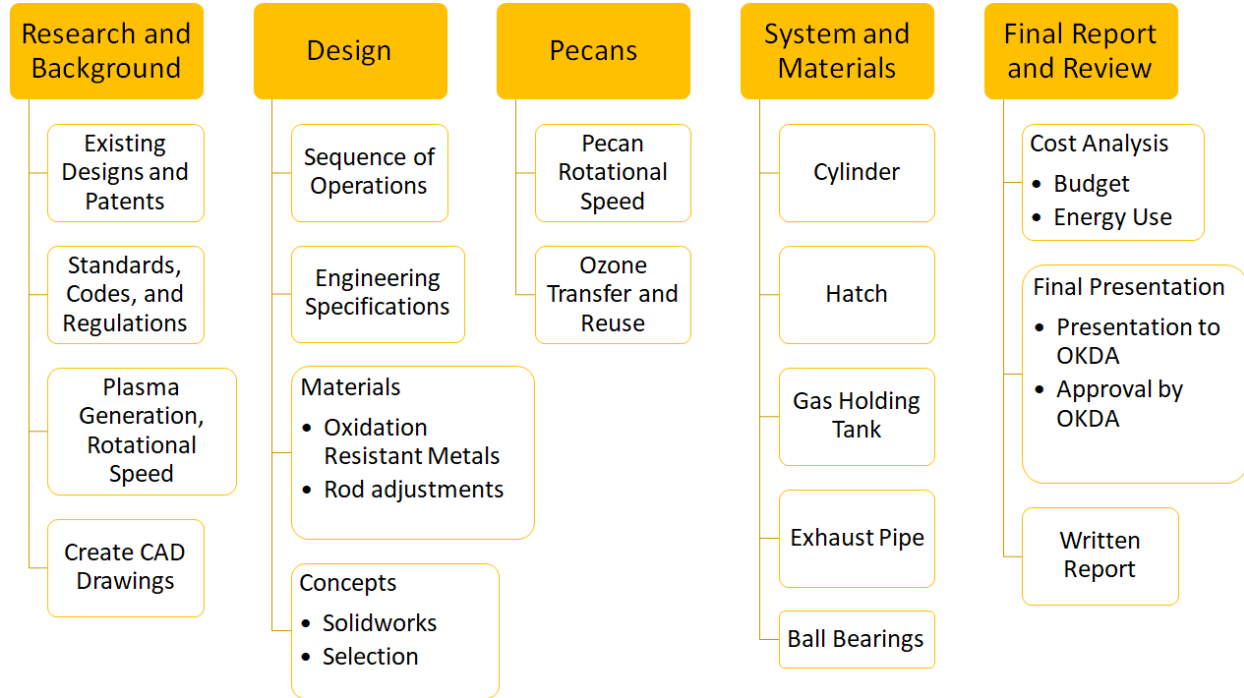


Figure #1: WBS

Task List:

- Research
 - Designs
 - Patents
 - Standards
 - Codes
 - Regulations
 - Plasma Generation
- Design and Setup:
 - Sequence of operations

- Engineering Specifications
- Acquisition of Parts
- Concept Selection
- Solidworks
- Testing:
 - Structure
 - Pecan Processing
 - Determination of Dimensions
 - Calculations
- Function:
 - Construction
 - Efficiency Estimation
 - Sanitation Verification
- Final Review
 - Cost Analysis
 - Final Presentation
 - Written Report

Revised Technical Analysis

To begin, our area of concern is with the disinfection of pecans. This is important due to the common presence of *Salmonella*, *E. coli*, and various fungi, on shells post-harvest. There are multiple techniques for disinfecting the surface of pecans and although these methods are not products, it is vital to understand how other disinfection methods function. This should give an idea as to the functionality of our own design, and let us see better the pros and cons we may

have to balance in order to create a best-fit for the Oklahoma Department of Agriculture Food and Forestry.

Before shelling, pecans must be conditioned. This important step moistens the pecans which increases the kernel moisture from 4 percent, to 8 percent. This increases the flexibility of the kernel and prevents breakage during deshelling. This step is also used to deactivate any pathogens (such as *Salmonella*). (Beuchat, 2010) *Salmonella* is normally not a thermophile, however when embedded on the surface of a low water activity nut, the *Salmonella* become very heat resistant and can thus be harder to deactivate with heat (Beuchat, 2011). Therefore, other methods of deactivation could potentially be more effective.

The first kind of deactivation method is heat based and utilizes hot air, and hot water baths. A heat bath has been proven to reduce CFU/g (colony forming unit) for in-shell pecans by 4 log at 99 degrees Celsius when bathed for two minutes (Beuchat, 2011). This is a quick process, however it does require the use of large tanks of water which would require the facilities to already be conformed to water readiness via drain units, lack of stagnant surfaces, and heating water can use a fair amount of energy. Moisture control can be a problem in this scenario, as the pecans soak they can absorb and may need to be monitored to make sure their moisture content is appropriate. Heat baths also pose certain dangers since automation with hot liquid may not be easy, especially if workers are required to handle the liquid which could cause safety concerns. The hot air method uses air as the main source of heat application, however this method is used after the pecans are shelled (killing salmonella that could be in the meat). The time for the hot air method was also slower, and required a higher temperature. With air being heated around 160 degrees Celsius it would take around 16 minutes for the reduction of CFU/g to reach 4 log. The time needed to reach the required reduction in CFU/g also would have adverse effects on the pecan meat itself, as the textures, structure, proteins, and color in the pecan meat could suffer due to the prolonged period of high heat.

The second kind of deactivation method is via chemicals, there are two main types, however one is utilized more often than the other. The chemical methods are the chlorine bath and PPO (Polyphenol Oxidase). The chlorine bath is a common method and involves varying amounts of chlorine in water, then rinsing the pecans for a set amount of time and removing them before shelling. The amount of time depends on the moisture content of the pecans and also the chlorine content of the water (typically in micrograms per milliliter). This method is quick, has little risk involved since chlorine is a great antimicrobial, and does not require heat (although it is possible in some instances). The water, however, must be thoroughly tested and would need to be kept at around the same chlorine level while the bath was being performed. Chlorine is also very cheap, thus chlorine is currently a good choice (Beuchat, 2013). Polyphenol Oxidase is another chemical choice, however it is not as commonly used or tested within the pecan industry, since its use is mainly commissioned by the Almond Board of California. The process involves heating a sealed compartment with a small percentage of PPO in the air to around 50 degrees Celsius, this is then sealed for two hours, then left to ventilate outside of the chamber for 2 days at 39-40 degrees Celsius or 5 days at 15 degrees Celsius. Obviously this method is very slow, however the amount of almonds processed with this method makes it noteworthy as huge pallets of almonds can be treated this way. It is relatively cheap to operate as the amount of PPO needed is miniscule since the container is sealed and injection can be controlled. (California, 2008) However, the initial cost of the machine would be much greater and this method would not lend itself well to small time farmers who do not need to process huge amounts of nuts. The chemical methods are also slightly frowned upon by the general public, and as public perception of GMOs has become more and more negative, so have chemical additives in food products. Thus even though the FDA allows the use of PPO and chlorine in food products, including them may not be what the processing facilities feel is the best option due to public opinion.

Steam treatment utilizes both heat and water to transfer heat more efficiently and affect the product as little as possible. Superheated steam on pecans needed only 20 seconds at 100

degrees Celsius to reach a 4 log reduction in CFU/g which boasts the fastest time of all methods listed here. However along with the fast treatment time, comes high moisture retention, at 120 degrees Celsius, pecans retained 15% moisture (dry basis) from the process which is around 7% higher than required by the deshelling machines. A drying process will need to be utilized after the steam treatment, unless the initial steam heat is increased to 180 degrees Celsius. At 180 degrees Celsius the superheated steam treatment caused pecans to rise to a 6% dry basis moisture content, which is much more suitable, but also requires more temperature (Ban, 2018). (Note that steam used is superheated, as the saturated steam treatment caused too much moisture and was ineffective at killing salmonella). Steam has other challenges as well, such as containment of the steam, creation of the steam, and safety hazards. Steam also could potentially cause unwanted problems with electronics, and the heat would need to be contained or a material that is a good insulator may need to be used in certain places.

Market Research

There are a multitude of different plasma sanitation systems due to the number of possible electrode configurations (geometry, number, location) (Hertwig et al., 2018). One of the two most commonly used types of plasma sanitation technology is the atmospheric pressure plasma-jet. The plasma jet transforms a particular type of process gas (ex. argon) into plasma by combining it with voltage at a high frequency. Subsequently, this plasma is expelled from the tip of the device into the surrounding area. The range of the plasma dispersed is dependent upon the amount of voltage applied to the process gas. Anything that comes into contact with the dispersed plasma is then sanitized. This sanitation occurs by the plasma electrons and ions heating the surface of the object in question, and then the surface molecules are broken apart. This technology can be used to sanitize a wide variety of biological materials such as bacterial strains, gels, and others (Baier et al., 2015). There are several potential variants of this technology. For example, there is a specialized type of this tool for bacterial treatment that

utilizes AC current. The principal behind it is that it utilizes a form of gliding arc plasma by which the electrical pulse frequency may be changed at any time (Niemira, 2012).

The other most commonly used type of plasma sanitation technology is the dielectric barrier discharge (DEB) system. A DEB consists of an electrical discharge between two electrodes that is separated by an insulating dielectric barrier. The two electrodes consist of a ground electrode and high voltage electrode. The materials intended for sanitation are placed between the electrodes, and are then subjected to a plasma dispersion field. This dispersion field is generated when a process gas flows between the electrodes, and the electrodes apply a voltage to it at a certain frequency (Hertwig et al., 2018).

A less well known yet similarly useful type of plasma sanitation technology is the one atmosphere uniform glow discharge plasma (OAUGDP). One important use of this technology is the inactivation of microorganisms inoculated on various types of surfaces and commodities. Additionally, this type of plasma generating system has been used to expose fresh fruits and vegetables to antimicrobial active species produced by the OAUGDP exhaust. The OAUGDP's blower exposure unit is capable of operating at radio frequency using air or other gases. It produces uniform, steady state glow discharge plasma inside a tubular configuration that allows for the airflow to pass through the configuration. The airflow is maintained in its chamber to allow it to promote plasma uniformly. It possesses an interior and exterior electrode, and the exterior's dielectric establishes the plasma volume. These electrodes are both cooled using recirculated oil and a cold-water radiator. This radiator is mounted on the bottom of the device, and this allows for the exhaust to be maintained at a uniform temperature (25°C). Treated samples are placed into a rectangular chamber, and this chamber is placed on the radiator. This type of device creates uniform or diffuse glow charge plasma at atmospheric pressure and room temperature, without using the vacuum system and the optimum uniform glow discharge plasma can be obtained by adjusting the RF frequency or the RMS value.

An additional type of atmospheric glow discharge system is the atmospheric dielectric-barrier discharge tube jet (DBD-tube jet). It is composed of a dielectric tube wrapped in a metallic strip as both a powered electrode and sample holder (which acts as a ground electrode). It produces a plasma plume through the gas flow of the two parallel-plate electrodes. Different materials have been used for the parts of this system in order to determine its effectiveness. Subsequently, it has shown to be highly effective for inactivating microorganisms (Smeu and Nicolau, 2014).

Patent Research

A method has been developed for generating large volumes of plasma at the interface with food contact surfaces. For our system, this function will be necessary in ensuring our pecans are completely sanitized (as they will come into contact with the inside of the device). While this function is fairly ubiquitous in cold plasma devices, we must ensure our design is unique so as to not to copy the original developer's design.(US9295280B2, 2014).

A cold plasma method in which a film is created on a product after sanitization to prevent further buildup of bacteria. This is a very interesting idea, but we must be careful not to infringe upon the owners rights (US6096564A, 1999).

Patent regarding most effective angles of attack for sanitizing seeds using cold plasma. While this covers seeds, pecan sanitation may be optimized with a specific treatment angle, or perhaps a combination of multiple effective angles (US20150101082A1, 2013).

Method of sanitization regarding different wavelengths of UV light. Specific microbes are susceptible to certain wavelengths, and we may incorporate this into our design. If so, we will need to be sure not to infringe upon this patent (US6010727A, 1997).

Device using high-voltage cold plasma (HVCP) combined with Dielectric Barrier Discharge (DBD) with reactive gas transported 3 meters away (US20170112157A1, 2017) is relevant to our design as the cold plasma system will be directly attached to our apparatus. Additionally, the cold plasma treatment of seeds to remove surface materials (USOO654346OB1, 2003) and Spinning Cold Plasma Apparatus and methods (USOO7367196B2, 2008) are relevant due to the nature of our design.

Possible Impacts

If our system is successful on the market, then it may mark the beginning of mass utilization of cold plasma for sanitation for pecans. Additionally, part of the project involves making the design ubiquitous to the point where several different types of food can be sanitized with it. If the food industry begins utilizing cold plasma as opposed to chemicals for sanitation then environmental health could be significantly improved. Additionally, it could quicken the time certain foodstuffs reach the market globally. Furthermore,

Customer Requirements & Engineering Specifications

- Batch size: 25-50 lbs.
- Batch time: 2 minutes or less
- Adjustable plasma height
- Hygienic design
- Affordability
- Compatibility with current equipment
- Resistance to oxidation

Design Concepts

Engineering Calculations:

Measuring

- Dimensions of different commercial pecan varieties.
- Calculating
 - Sphericity - S_c
 - $S_c > 50\%$ tends to roll
 - Aspect Ratio - R_a
 - $R_a > 50\%$ tends to roll.

- $$S_c = \frac{(abc)^{1/3}}{a}$$

- $$R_a = \left(\frac{b}{a}\right) * 100$$

Volume of the Drum

- Thickness of Pecan Layer, Time to Sanitize, and Rotation Speed are all correlated.

Given: 50 lb Pecans, ~3.8 cups=1 lb pecan₁

Thus: 190.5 Cup >> 1.59 ft³

These 1.59 ft³ will be dispersed along the bottom of the cylinder.

Design Concepts:

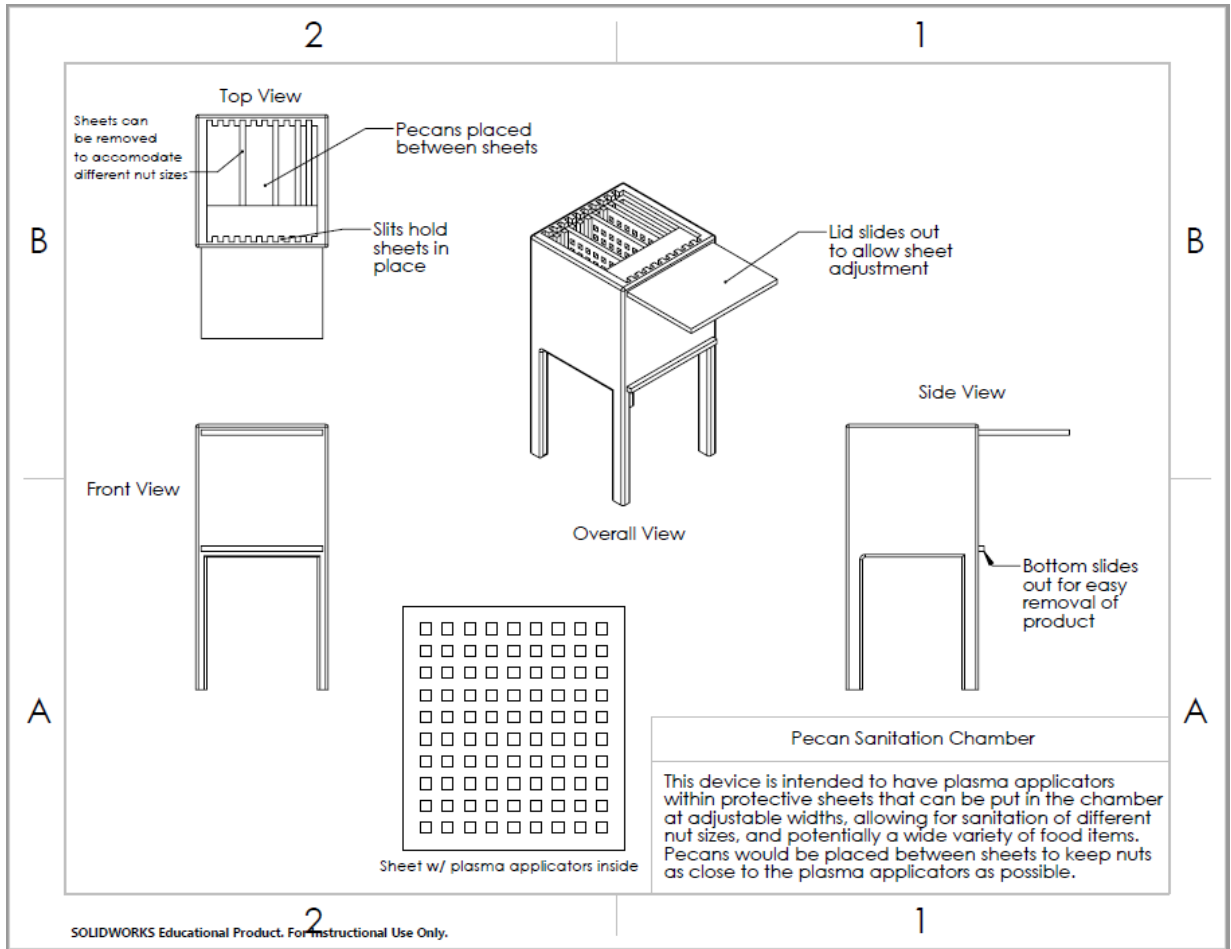


Figure #3: Design 2: Can be easily filled with pecans of all sizes. Keeps plasma near pecans, without direct contact

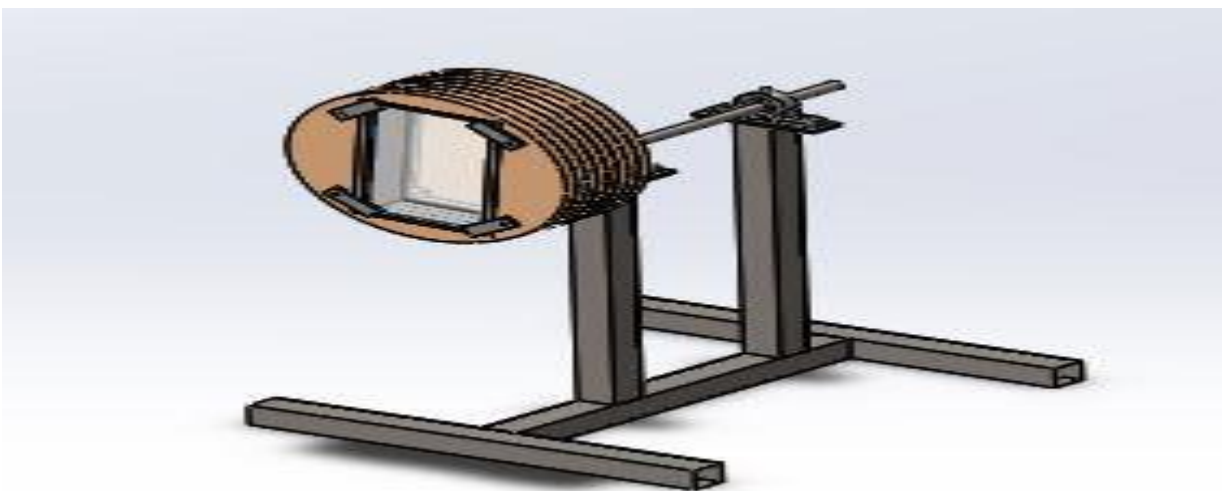


Figure #4: Design 3: Updated design that prevents the possibility of pecans packing. Sanitizes a small number of pecans in each container while it's spinning.

Prototype Fabrication and Validation

Our initial prototype has been successfully fabricated by members of the Biosystems & Agricultural Engineering (BAEL). However, mistakes were made during the manufacturing, and these mistakes had to be corrected. As a result, our testing of the prototype was delayed. However, upon the correction of these mistakes we began testing. We filled the acrylic box in our system with each variety of pecan in our possession (four total). For each variety, we performed three tests. For each test, we added an increasing number of thickness plates (1 to 3 plates) in order to see if the pecans packed at all. No packing was observed for any test we performed.

Results

		Variety														
		#1			#2			#3			#4			Mixed		
		Mount			Kanza			Pawnee			Oconee			All		
		0.5	5.5	10.5	0.5	5.5	10.5	0.5	5.5	10.5	0.5	5.5	10.5	0.5	5.5	10.5
Width (in.)	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	1.5	6	N	2	N	5	N	8	N	3	N	N	N	N	5	2
	2	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	2.5	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

CAP treatment time	Log reduction
2 min	0.59 ± 0.15
2 min with 30 sec rotation	0.77 ± 0.19
5 min	0.87 ± 0.21
5 min with 30 sec rotation	1.14 ± 0.12

CONCLUSIONS

We have determined that packing is a slight issue when the width of the containment box is 1.5 inches. Therefore, for our finalized design we will not utilize this exact width. Additionally, we have definitively proven that rotating pecans while subjecting them to cold plasma improves sanitation.

RECCOMENDATIONS FOR FUTURE WORK

When we have attached the cold plasma apparatus, we will program the rotation of our device to where it makes half turns so that the wires won't twist around one another.

Project Schedule

Figure #5: Gantt Chart

Proposed Budget

To determine a rough budget a look at materials that may be used is important. Part 211.65 FDA states "equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements." The complete FDA regulations on food equipment is in the appendices. Table 2 shows a pros and cons list of a selection of materials. Table 3 then shows some of these products priced on McMaster Carr. Right now the option we are leaning towards is stainless steel 316. High density polyethylene (HDPE) also looks to be a good alternative. Assuming the current design is a 2' x 2' x 2' box with four 1.5' legs the stainless steel box comes out to a total of \$332.59 with every stainless mesh 2' x 2' sheet costing \$55.44. The HDPE box would cost \$202.56 and each HDPE 2' x 2' sheet that would be machined to have holes would cost \$9.72 each.

To further solidify our budget a strengths analysis must be done with all the materials to make that they can stand the weight of the process over an extended time. Different steel alloys should also be looked at to see if cost can be reduced. Different alloys can combine strengths of

different metals. The stainless mesh is expensive per sheet and with many sheets needed for the design another steel alloy will hopefully reduce the cost. Other costs will include labor and any travel that may occur in the future.

Actual Budget

Actual Cost	
Part (Quantity)	Total Cost
HDPE Block 1 (2)	\$10.00
HDPE Block 2 (2)	\$20.00
Plexiglass 1 (2)	\$20.00
Plexiglass 2 (4)	\$63.00
Plywood (1)	\$50.00
Bearing (2)	\$80.00
Screws (12)	\$6.00
Nuts/Bolts (4)	\$2.00
Steel Rod (1)	\$0.00
Steel Beam (5)	\$0.00
Steel Plates (3)	\$0.00
Overall Cost	\$251

Product Comparison		
Product	Pros	Cons
Stainless Steel	<ul style="list-style-type: none"> ● resistant to corrosion and rust ● versatile and machinable ● opaque ● food grade available 	<ul style="list-style-type: none"> ● more expensive the more corrosion resistant
Acrylic Plastic	<ul style="list-style-type: none"> ● can withstand great force the thicker it is ● insulates 	<ul style="list-style-type: none"> ● melt from direct flame ● see through ● can crack
High density polyethylene (HDPE)	<ul style="list-style-type: none"> ● inexpensive ● chemically resistant ● food grade available ● durable 	<ul style="list-style-type: none"> ● pliable
Aluminum	<ul style="list-style-type: none"> ● corrosion resistant ● lightweight ● strong 	<ul style="list-style-type: none"> ● more rare and expensive than steel ● abrasive to tools ● special processes for welding ● conducts electricity
Chrome	<ul style="list-style-type: none"> ● corrosion resistant 	<ul style="list-style-type: none"> ● usually only a coating or in an alloy
Titanium	<ul style="list-style-type: none"> ● corrosion and rust resistant ● high strength 	<ul style="list-style-type: none"> ● expensive ● cannot be cast

Table 2: Product Comparison



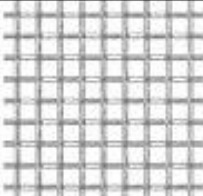







Product Pricing			
Item Name Product Number on McMaster	Number Needed	Picture	Total Price
88885K101 Highly Corrosion-Resistant 316 Stainless Steel Sheet 24" x 48", 0.024" Thick	3		\$244.11
1321T41 Highly Corrosion-Resistant 316 Stainless Steel 90 Degree Angle 1/4" Wall Thickness, 1" x 1" Outside Length 6'	1		\$88.48
9319T128 316 Stainless Steel Wire Cloth Sheets, 8 x 8 Mesh Size, 0.097" Opening Size Sheet Size 2' x 2'	1		\$55.44
9319T111 316 Stainless Steel Wire Cloth Sheets, 2 x 2 Mesh Size, 0.420" Opening Size Sheet Size 2' x 2'	1		\$74.99
8560K437 Clear Cast Acrylic Sheet 48" x 96" x 1/4"	1		\$323.56
8619K116 HDPE Sheet 48" x 96" x 1/4"	1		\$117.36
8671K43 HDPE Bar 2" Wide, 2" Thick Length 3 ft.	2		\$85.20
8619K64 HDPE Sheet 24" x 24" x 1/32"	1		\$9.72
9785T162 Marine-Grade HDPE Black, 48" x 96" x 1/4"	1		\$125.94
88685K99 Easy-to-Form Corrosion-Resistant 1100 Aluminum Sheet 15000 PSI Yield Strength, 3/8" Thick Sheet Size 48" x 96"	1		\$2325.65

Table 3 Product Pricing

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Appendix

[Code of Federal
Regulations]

[Title 21, Volume 4]

[Revised as of April 1,
2018]

[CITE: 21CFR211]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER C--DRUGS: GENERAL

PART CURRENT GOOD MANUFACTURING
211 PRACTICE FOR FINISHED
 PHARMACEUTICALS

Subpart D--Equipment

Sec. 211.63 Equipment design, size, and location.

Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

Sec. 211.65 Equipment construction.

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Sec. 211.67 Equipment cleaning and maintenance.

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use.

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in 211.180 and 211.182.

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51931, Sept. 8, 2008]

Sec. 211.68 Automatic, mechanical, and electronic equipment.

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

(c) Such automated equipment used for performance of operations addressed by 211.101(c) or (d), 211.103, 211.182, or 211.188(b) (11) can satisfy the requirements included in those sections relating to the performance of an operation by one person and checking by another person if such equipment is used in conformity with this section, and one person checks that the equipment properly performed the operation.

[43 FR 45077, Sept. 29, 1978, as amended at 60 FR 4091, Jan. 20, 1995; 73 FR 51932, Sept. 8, 2008]

Sec. 211.72
Filters.

Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters. If use of a fiber-releasing filter is necessary, an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. The use of an asbestos-containing filter is prohibited.

[73 FR 51932, Sept. 8, 2008]

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

Source: 43 FR 45077, Sept. 29, 1978, unless otherwise noted.

Acceptance

The client named below verifies that the terms of this Statement of Work is acceptable. The parties hereto are each acting with proper authority by their respective companies.

Oklahoma Department of Agriculture

Company name

N/A

Full name

N/A

Title

Signature

5/2/18

Date