

LEAD CONTAMINATION RISKS FROM IMPORTED CANDIES: DEVELOPING A  
PROTOCOL TO TEST FOR LEAD IN CANDY PRODUCTS USING  
THE X-RAY FLOURESENCE INSTRUMENT

by

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## ABSTRACT

### **Lead Contamination Risks From Imported Candies: Developing A Protocol To Test For Lead In Candy Products Using The X-Ray Fluorescence Instrument.**

by

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The problem of lead in candies imported from Latin America and or Thailand is an important public health issue. These candies come from a number of sources, with lead often being present when tamarind or chili pepper is used as an ingredient. Currently, it is expensive and time consuming for health protection agencies to test candy that has entered the consumer market in the United States. Hence children may potentially be exposed to lead contamination. If community health agencies had access to XRF technology, health agencies could quickly determine if specific candies contain lead. To date, there has not been a protocol developed using the XRF instrument to test candies. Herein, are details of the newly developed XRF procedure for testing candies and comparing the XRF results against EPA Graphite Furnace results. Additionally a comparison of candy collected from a local Las Vegas middle school against the current California toxic treat index list is provided. Details of a community health lead education program which includes the results of a student candy consumption survey are presented. The protocol explained herein will provide an important resource for both researchers and

public health officials collaborating in the effort to protect their communities from exposure to lead contamination.

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## CHAPTER 1

### INTRODUCTION

In 2002, there was an estimated 890,000 children in the United States with unsafe levels of lead in their blood (CDC, 2006). Although it is widely known that the majority of lead contamination cases come from exposure to lead from old paint, there is growing evidence that points to candy as a major contributor to this health crisis. Local health departments are often short on the funding needed to address this issue of imported candy containing lead, which is sold in local markets, corporate chain stores and from ice cream trucks. To address this growing problem, local governments need a quick and reliable source to screen candies. Helping local officials quickly and efficiently regulate the sale of imported candy that might contain lead.

Currently the graphite furnace atomic absorption spectrophotometry (GRAAS) is the most cost effective FDA approved testing modality used to screen candies for lead. The price of screening one piece of the candy is approximately twenty-five dollars. Depending upon how each sample is prepared for testing. Usually a sample will include at least one piece of candy, a wrapper, and often one other candy related item (straw, spoon, stick, and container). Each item tested will increase the cost of the analysis. Local and State governments responsible of the control and safety of food items might find it difficult to afford both the cost of an appropriate testing sample size to regulate candy, and the time to pay a staff member to collect candy items and prepare samples for the

laboratory- along with the high cost, the amount of time between collecting samples, preparation for analysis and the reporting of results could be quite lengthy. Both time and money issues put children at risk for lead contamination from imported candy items.

A number of studies have shown how x-ray fluorescence (XRF) can be used for paint, soil, dust wipes, and testing in-vivo for bone lead levels. To date, there has not been a published paper addressing how to use x-ray fluorescence as an effective screening tool for testing candy, wrappers, straws, spoons and other candy related materials for lead contamination. One published article discusses the results of their XRF study testing candies for lead, yet does not discuss the methodology used (Lynch et al., 2000).

This research will include discussions on the development of an x-ray fluorescence protocol to screen candy, wrappers, straws, spoons and other candy related materials for lead contamination. Along with comparing the XRF against the GRAAS results to determine the reporting accuracy of the XRF candy testing protocol.

Finally a discussion of the study protocol used at a local middle school to sample candy consumption patterns of Mexican/ leaded type candies. This will include the study design, along with the results detailing the amount of Mexican type candies collected. This paper will also include details on how one might collect samples from children and how to best work within the public school setting.

## CHAPTER 2

### REVIEW OF RELATED LITERATURE

Lead (Pb) is a blue/grey metallic element that has always been around the human population. Modernization and industrialized activities over many centuries have brought lead even closer to our direct surroundings (UHL, 2006). Lead possesses some characteristics that make it useful in the production of a wide variety of products. It is malleable, resists weathering, and heat exposure along with being a good conductor. These characteristics, paired with other properties, have allowed lead to be used in products that eventually get linked back to human consumption through air, water, or food products (Landsdown & Yule, 1986). Like many metals, lead has long been recognized as a serious poison. Yet it was not until 1970 that the U.S. Legislature banned the use of leaded gasoline in automobiles and other vehicles. This alone has made considerable impact on the reduction of environmental lead exposure in the United States (UHL, 2006). The Legislature in 1977 also set the lead in paint limit at 0.06%. Followed by the Food and Drug Administration's (FDA) ban on lead based paints being used in homes and schools (Lynch et al., 2000).

Even today with all that is known about the health effects of lead exposure in children, society has not solved the lead exposure problem and may see a rise in exposures from unlikely sources such as imported candies and wrappers, mini-blinds and lunch boxes (Schaller, & Arreola, 1999; Schardt, 2005).

### Lead in the environment

Lead is a naturally occurring non-nutrient metal that follows environmental pathways similar to those of nutrient metals such as calcium (Landsdown & Yule, 1986). In the human environment, these pathways of exposure transfer lead from sources such as soil, dust, air, food and drinking water to the human body by means of ingestion or inhalation (Landsdown & Yule, 1986). The biological behavior of lead through both the environment and living tissue are important topics to consider as scientists begin to build a lead poisoning prevention model to protect human health (EPA, 1994).

### Lead in soil

Lead is found in soil naturally from dust, industry and from car emissions (Landsdown & Yule, 1986). The deterioration of lead based paint, building materials and playground equipment are also sources of contamination (Oregon DHS, 2005).

Lead in soils and dust is relatively unavailable biologically as lead reacts with soil to form insoluble salts (Landsdown & Yule, 1986). Yet, one can not predict the movement of lead in soils due to many variables, including soil pH and organic content. Studies have shown that soil uptake by plants is limited, with the main Pb concentration resting on the part of the plant exposed to an air source (Landsdown & Yule, 1986). The general conclusion is that the lead content of edible plants is not a measurable source of lead contamination. Yet, new sources are starting to connect the lead found on chili peppers or tamarind fruit, along with lead from gasoline emissions (Gerstenberger, Cross, Donnelly & Fels, 2005).

A more common exposure risk is due to children playing in soil, eating candy dropped in soil, and basic hand to mouth activities performed with dirty hands (Landsdown & Yule,

1986). Soil also poses a problem when fine leaded soil and dust particles are tracked into the house and settle on household surfaces, carpets, toys and other objects (Oregon. DHS, 2005).

#### Lead in air

Lead in air comes naturally from dusts, volcanic output, forest fires and even sea spray. Anthropogenic sources are mining, primary lead production, primary non-ferrous production, secondary smelting, iron and steel production, industrial uses, coal combustion and waste incineration. Where the lead half-life in soils is long, the half-life in air is short (Landsdown & Yule, 1986). Lead is more likely to be absorbed when the particles are small, increasing the biologic effect and half-life (Landsdown & Yule, 1986).

The greatest atmospheric lead pollution is from automotive vehicle emissions. Tetra methyl, tetra-ethyl and a mix of alkyl lead compounds are used in anti-knock automotive fuel and have a long half-life in soils and dusts. After combustion about seventy five percent of lead is emitted from exhaust as inorganic salts of lead. These small particles (10µg or less) are the most harmful and they predominate in the early phase of exhaust emission (Landsdown & Yule, 1986).

#### Lead in water

The bulk of lead salts found in the ocean come from global weathering patterns as these solutions travel from eroded areas with naturally leaded geologic formations (Landsdown & Yule, 1986). Other factors to lead in water include soil and road run-off (Landsdown & Yule, 1986). Water pH is of primary importance because it dictates the movement of these dissolved lead salts (Landsdown & Yule, 1986).



Most well or city water does not naturally contain lead. Lead gets into the water from the corrosion of lead solder that connects the pipes or brass faucets (brass is 5 to 7% lead). Lead from solder is most commonly found in homes built between 1970 and 1985 (Oregon DHS, 2005). This problem encompasses over three quarters of the homes in the United States (Schardt, 2005). The Clean Drinking Water Act restricted the use of lead in pipes, solder and other plumbing components. Yet, older homes still put families at risk (Oregon DHS, 2005). Compounding this serious issue is that when the chlorination level of water increases the acidity also increases, as does the dissolvability of lead. An even more serious risk is found in households where babies are drinking formula made from water contaminated with lead (Landsdown & Yule, 1986).

#### Lead in paint

Lead is used in paint to inhibit corrosion on steel structures, allowing them to withstand weathering. Lead increases paint longevity but this weathering causes dust and lead debris to enter the environment. A very small flake of paint may contain over 1mg of lead, which would be ten times the daily mean intake from all other sources (Landsdown & Yule, 1986).

Lead was used in common house paint until 1978. Many buildings built before 1978 have lead based paint inside and out. Nationwide, lead remains in approximately seventy eight percent of these homes (Landsdown & Yule, 1986). The older the house, the more likely it is to contain lead paint. In places where the paint is in good condition there is a lower exposure risk. The main risk is found in places where lead painted surfaces rub against each other making small paint chips or dust (Oregon DHS, 2005).

### Lead in ink and wrappers

Printing ink can also contain lead and poses a health hazard. This risk is generated through the leaching of lead from the wrapper into the food item. Another risk is created when a leaded candy wrapper is used as chewing paper. Leaded ink can contaminate the candy, especially if these products are acidic like tamarind, chili pepper, and tejocote fruit (Oregon DHS, 2005). It has been found that even simple every day bread bags and grocery store vegetable bags may contain lead in the ink and should not be turned inside out for reuse (Weisle, Demak & Glodstein, 1991). The lead- based inks for labeling candy wrappers have been a regulatory issue for the past decade. Recently the U.S. Consumer Product Safety Commission sent letters to candy producers in Mexico and to candy importers in the United States asking them to halt future imports of candy. Stating they should allow the import of goods only when they could ensure that the candy wrappers did not contain lead or use ink containing lead (Wagner, Hughes, & Sobsey, 2005). This leaching of Pb from ink pigments can also be found in pottery or earthenware glazed with lead containing paints. With an increased risk of exposure when acidic food is served from these dishes (Landsdown & Yule, 1986).

### Lead in food supply

As the alimentary canal is the major route for lead absorption, food can play a major part in lead poisoning (Landsdown & Yule, 1986). Luckily lead is no longer used in the processing of canned food in the United States, but foreign manufactures still use lead solder in cans (Oregon DHS, 2005). Again the risk of lead leaching into food increases the more acidic the food item. In fact, it is possible that as much as ten to forty percent of lead exposure comes from cans. Increasing the exposure risk is when food is

cooked in water with Pb, the lead is then taken up by the food (Landsdown & Yule, 1986). Another area of concern comes from imported food products sold in ethnic markets, at swap meets, and other popular sources (Oregon DHS, 2005). Further sources of lead in food may come from lead based pesticides used on the crops (Oregon DHS, 2005).

One more area of concern is when a lactating mother has been exposed to lead, her breast milk can also contain Pb, allowing for the easy transfer of maternal lead, to her child (Landsdown & Yule, 1986). The concentration in her milk would be about the same as her serum lead concentration. This risk is much greater to the infant than is the risk to the mother, as the baby does not yet have the blood brain barrier to help protect lead from reaching the brain and nervous system (Landsdown & Yule, 1986).

#### Foodstuffs adulteration

As late as 1968, manufactures were still using lead to color curry powder. Another unusual lead source can be found in calcium supplements purchased in health foods as they contain contaminated bone products (Landsdown & Yule, 1986). The FDA has also found high lead levels in food coloring (lozeena) from Iraq, prune concentrate from France, duck eggs from Taiwan, and raisins from Turkey (Lynch, Boatright & Moss, 2000). A food source one would least likely suspect to contain lead is imported candy from Mexico, Brazil, Philippines and other South American Countries (Wagner et al., 2005).

The FDA's level of concern for lead in imported food varies. For example, the action limit has been set at 0.25 mg/kg for raisins and 0.50 mg/kg for tamarind candy (Lynch, et al., 2000). Although many States began to notice an increase in Blood lead

levels (BLL's), the California Department of Health and Human Services during May 2001 to January 2002, identified Mexican candy as a possible exposure source for approximately 1,000 cases of elevated BLL's among California children (MMWR, 2002).

When children eat lead-contaminated candies, exposure can exceed FDA's provisional tolerable daily intake level (PTIL) for lead of 6  $\mu\text{g}$  in a typical 30-g food serving. FDA's PTIL corresponds to a lead intake capable of elevating the BLLs of a small child by 1  $\mu\text{g}/\text{dL}$ . In the cases described in this report, the wrappers often contained amounts of lead that could greatly exceed FDA's PTIL if the lead were to leach into the candy. In addition, a substantial quantity of the lead could be released into saliva by a child licking the wrapper (MMWR, 2002).

Because many of these candy types are sticky and can adhere to the wrapper, children are more likely to lick or eat the wrapper. An investigation is ongoing to determine which specific candy products are contaminated with lead (MMWR, 2002). The importance of this study, along with other similar research, helps to determine and understand how quickly the consumption of lead contaminated candy can affect children's health. Take as an example: if 15 micrograms of lead is found in an imported salt-based candy container, it would take a young child ingesting only four of these containers per day to increase the child's BLL by 10 micrograms per deciliter (Wagner et al., 2005). The FDA currently recommends six micrograms per day as the tolerable limit for the dietary intake of lead and the prevention of neurological and behavioral problems (Wagner et al., 2005). In addition to the concern of lead contamination, the FDA has embargoed food products

containing tamarind fruit from entry into the United States because of filth from insects, rodents, and other pests (MMWR, 2002).

The CDC has confirmed that some imported candies which include lead are associated with elevated BBL's (MMWR, 2002) In a case study done by the CDC they discovered a four year old child that had an elevated blood level of 26 mg/dL. The family had just recently moved to the United States from Mexico where they routinely used a ceramic bean pot and water jug. Yet, upon an environmental investigation of the home, it did not reveal any high lead levels from usual sources such as paint, dust and soil (MMWR, 2002). But tests done on imported candies from the home revealed a candy wrapper that measured a lead value of 16,000 ppm (MMWR, 2002). Another similar high BBL case study found the main lead exposure source of a one year old child was imported Mexican leaded candies (MMWR, 2002). A Dulmex-brand Borlirindo lollipop was show to have a lead level of 404 ppm and 21,000 ppm in the stick and wrapper respectively (MMWR, 2002).

Imported food and food related products are an ever increasing concern to the FDA and other involved agencies. One big issue surrounding imported food regulation are the large size shipments coming into US from many ports, putting the United States food supply at risk of contamination from a number of sources (Lynch et al., 2000).

Chemical contamination of imported foods can occur during growth, processing, transportation, or packaging of the product. Pesticides (some of which may be banned in this country) may be directly applied to foods during growth, processing or storage, or foods may be contaminated by the equipment or

environment in which they are processed or stored. Finally packaging materials have been shown to cause food contamination materials such as lead may leach into food products from food dyes (Lynch et al., 2000).

Tamarind products are of great concern. The fruit originates from the pulp of the tamarind tree. This product is used to make a variety of consumable goods, including drinks, jelly, sauces and candy. Tamarind often draws the attention of the FDA and has been a part of a number of product alerts (Lynch et al., 2000). Two of these concerned tamarind products packaged in ceramic containers and the other concerning tamarind suckers (Lynch et al., 2000). A number of recorded high lead levels on individual products have been found, but the large scale public health effects are not well known (Lynch et al., 2000).

Chili peppers or chili pepper type products are also thought to be a potential exposure risk. Chili peppers are used in a large number of imported products. This chili gives many Mexican candies a spicy kick, and may have been contaminated out in the fields, before it is sold to candy makers (Lynch et al., 2000). There are a number of ideas on how lead makes it way into these candies putting human health at risk. But any detailed study regarding potential sources, to-date has not been published.

The University of Nevada Las Vegas Lead Laboratory, during the summer of 2005 began collecting data, which confirmed lead could be found in imported candy (Gerstenberger et al., 2005). The researchers began to see a pattern of high lead levels in tamarind and chili pepper type candies (Gerstenberger et al. 2005). They also began to notice a pattern of high lead levels in wrapper of candies that did not contain tamarind or chili pepper

type candies (Gerstenberger et al. 2005). One candy of particular interest was the Tama Roca<sup>®</sup> wrapped around a yellow straw. Lead levels were present in some of the candy tested, but every single straw contained lead (Gerstenberger et al. 2005). The researchers also began to notice a pattern with lead in spoons, wrappers and straws from different candy types (Gerstenberger et al. 2005). With a small sample size done on candies purchased in Las Vegas, it is still unknown where the exact source of lead originates, but it is clear that lead in candies are present and available for purchase locally, putting Clark County children at risk, along with all children nationally who might come across these types of candies (Gerstenberger et al. 2005).

#### Home remedies and cosmetics

Ethnic communities often have some home remedies that may contain up to one hundred percent lead. Cosmetic products are a primary source of lead in some countries. Application of Akohl (a cosmetic) results in lead exposure primarily via hand to eye to mouth movement and subsequent ingestion of particles. It is difficult to identify cultural sources of lead poisoning; in fact, sixteen percent of all cases of children with high blood lead levels are unidentified even after an in depth investigation. This most likely is due to some unidentified home remedy (Oregon DHS, 2005). As recently as May 2003, the Health and Education Leadership for Providence (HELP) Lead Safe Center investigated unexplained increases in BLL's and found that the source was litargirio (a yellow or peach colored powder). This herb is used as an antiperspirant /deodorant by Hispanic families and was found to contain thirty six percent lead (MMWR, 2005). Lead has also been found in some Chinese and homeopathic medicines. Alarcon, ghasaard, greta(is 99% lead oxide), liga, pay-loo-ay and rueda are examples of items that may also contain

lead. The source of lead is uncertain, but the use of these remedies can result in a significant rise in BLL's (MMWR, 2002).

### Absorption of lead

The two principle routes of lead exposure are: gastrointestinal absorption, which is the major entry point for lead. The average adult uptake by this route is ten to twenty percent. Most lead is not absorbed, but passed out of body unchanged in feces. The second route of lead exposure is through pulmonary absorption. Although, pulmonary absorption is the lesser of the two routes, its uptake rate is still about forty percent (Landsdown & Yule, 1986).

Even though there is great deal of lead found in the environment it must be absorbed to become toxic. The two types of absorption are carrier mediated and passive diffusion. Factors that influence absorption of lead are based on particle size with the large particles being less easily diffused than smaller particles. Food in the gut seems to decrease absorption in rat studies (Landsdown & Yule, 1986).

Age is also a factor in gut absorption. Human infants show increased absorption and retention of lead the younger they are. Water is another factor in the absorption of lead in the gut. It has been found that when the concentration of lead in drinking water is high, the actual accumulation of lead by foods from cooking water will increase the total quantity ingested in an additive manner (Landsdown & Yule, 1986). Minerals also affect the gut absorption of lead. The retention of lead varies inversely with dietary calcium content (Landsdown & Yule, 1986). It has been thought that lead and calcium share binding sites and absorptive proteins (Landsdown & Yule, 1986). It has been found that lead inhibits the transport of calcium across the duodenal walls of rats and lead will



interfere with further calcium metabolism (Landsdown & Yule, 1986). Any process that alters the tight junction between the cells will increase lead absorption. When depleted, concentrations of calcium and increased acidity affects this junction, it has been linked with an increased absorption of lead (Landsdown & Yule, 1986).

Conversely, when lead reacts with phosphate, it limits lead absorption. With the major store of phosphate found in plants and since calcium has a great affinity for lead, the combination of calcium and phosphorus in plant sources provides a natural protective factor against lead toxicity by diminishing absorption (Landsdown & Yule, 1986).

The following minerals, zinc, iron, copper, magnesium and vitamin D have been found to diminish lead absorption from the gut (Landsdown & Yule, 1986). Where higher vitamin D concentrations are found, there is an enhancement of lead absorption. However, in lead poisoned children, vitamin D deficiency is associated with high blood lead levels. It is thought that lead impairs the production of this compound or enhances its conversion into an inactive form. Scientists also found that vitamin deficiencies diminished lead excretion. A single dose of vitamin D accelerated removal of lead from the body even when the element was deposited largely in bone (Landsdown & Yule, 1986).

#### Distribution/metabolism

After lead has been absorbed it then moves into the plasma and extra cellular fluid. From this position if it is not immediately excreted, it moves to other areas of the body for retention (EPA, 2004).

Accumulation of lead can start if one is exposed in fetal life. The placenta does not limit transfer of lead from mother to baby. In fact, placental lead levels correlate with

those in maternal plasma (Ahmed et al. 2002). Increased placental lead levels are associated with congenital abnormalities as well with neonatal encephalopathy (Olmedo, Rella, Hoffman, & Nelson, 1999). When exposed lead accumulation takes place over ones lifespan with 94-95 % of accumulation found in bone. Higher bone concentrations are often found in men, sometimes being as high as 200 mg/dl (Landsdown & Yule, 1986).

Lead usually accumulates in the kidney first and then moves into the liver. This may be reflected in the fact that the body tries to quickly rid itself of the lead burden (Landsdown & Yule, 1986).

Blood concentrations of lead are found mainly in red cells. The erythrocyte is the principal transport component of lead from the gut and lungs. Lead bound to hemoglobin is rapidly distributed to other tissues (Landsdown & Yule, 1986). Lead has been found in other body fluids such as semen, sweat and breast milk in direct ratio to what is found in the blood (Ahmed et al. 2002).

A general measurement of lead in the body to some extent is meaningless as toxic effects depend on the location and concentration of lead within the body (Landsdown & Yule, 1986). The distribution of lead begins in the short-term compartment (blood) and reaches a dynamic equilibrium and half- life around sixty days. The longer- term intermediate (soft tissues) compartment reaches a dynamic equilibrium over a few months (Oliveira, Aro, Sparrow & Hu, 2002). The brain retains lead longer than blood and this may explain why the central nervous system is highly susceptible to the negative effects of this metal (Landsdown & Yule, 1986). While the long- term (bone) storage is thought to never reach this balance and continues life long uptake (Oliveira, et al., 2002).

The skeletal half-life of lead is generally less in children, due to the intensive remodeling of bone during normal growth (Landsdown & Yule, 1986). Lead after it is absorbed and distributed to all the different tissues, it is then sent to the areas where it is retained (EPA, 2004). Bone lead is a major, if not dominant lead storage, and a source of circulating lead in individuals living in the United States. Recently there has been a significant decline in environmental sources of lead contamination (Oliveira et al., 2002). Thus, the measurement of lead in the body must be interpreted in relation to the retention time of the lead in a particular tissue allowing for a clear lead treatment and abatement protocol (Landsdown & Yule, 1986).

### Excretion

After lead has been inhaled or ingested and absorbed through the lungs or gut into the blood stream where it is transferred to body tissues, it may return to the blood stream. Lead then can be transferred to other tissues or eliminated with the urine. The kidney is the principal way of lead excretion through glomerular filtration (Landsdown & Yule, 1986). Lead may also be eliminated from the body with sweat, hair, or sloughed epidermal tissue. It may also be transferred to the liver and bile ducts returning to the gut and eliminated (EPA, 1994).

Dietary components influence retention by altering rates of excretion. Chelating agent compounds function by increasing urinary excretion of lead as a chelated complex (Landsdown & Yule, 1986). Researchers, concluded that this type of therapy did not improve neuropsychological function in lead poisoning children again supporting the need for prevention over treatment (Binns, Kim & Campbell, 2001).

### Health effects of children and adults

Lead is one of the more extensively studied reproductive toxicants. It readily crosses the placenta and can cause fetal and maternal adverse outcomes. Such as low birth weight, pre-term delivery, and congenital anomalies (Sowers et al., 2002). In 2002, Sowers looked at the relation of maternal blood concentrations and found that they were closely related to negative reproductive events. The results demonstrated that lead exposure, even when the exposure ended well before pregnancy, could reduce birth weight, length, and cause hypertension in pregnancy (Sowers et al., 2002). This data also concluded that the events that take place in-utero can influence health for many years after birth. The term fetal programming is used to describe this process. In fact, there might be a link between low birth weight and hypertension in an adult (Sowers et al., 2002).

Ahmed (2002) found that a measurement of lead found in maternal trabecular bone constituted an independent risk factor for impaired mental development in infants at two months of age. This was thought to be due to the mobilization of maternal bone stores. Since lead is chemically similar to calcium, during the late stages of pregnancy, a mother's bones sometimes dissolve slightly to provide her fetus with calcium for its skeleton (Lock, 2004). These maternal lead stores were most likely a result from lead exposure earlier in life compared to an acute exposure (Gonzalez-Cossio et al., 1997).

Children's bodies are significantly more susceptible to lead poisoning than adults. This is because of an incomplete blood brain barrier in children under thirty six months (ATSDR, 2002). Because children up to age seven are more sensitive to lead's effects,

most adverse effects of lead often manifest at lower blood lead levels in children than in adult (ATSDR, 2002).

Bone serves as a repository for seventy five percent of lead in children and ninety to ninety five percent in adults (Oliveira et al., 2002). Adult bodies flush out, through waste, almost ninety nine percent of the lead taken in. Children, on the other hand, have an alarmingly low expulsion rate of thirty two percent (Oliveira et al., 2002). A child's body not only absorbs more lead than an adults, it retains more of what it absorbs. This build up of lead in a child's body could eventually cause serious and irreversible damage (EPA, 1994). Bone lead mobilization heightens during times of increased bone turnover such as rapid growth of childhood (Oliveira et al., 2002).

Because of individual differences, symptoms of lead exposure and their onset may vary. The similarities of the symptoms are often the cause for this misdiagnosis. Complicating matters further, frequently children are actually asymptomatic (ATSDR, 2002).

The Centers for Disease Control and Prevention regards lead poisoning as the number one preventable childhood illness in the United States (CDC, 2006). Between birth and age six, important developments take place in a child's brain and central nervous system. If exposed during these formative periods, lead poisoning can have a drastic, permanent affect on a child's development. Extremely high blood lead levels (>70 mg/dL) can cause severe neurological problems, which include seizures, comas, and death. However, there may be no safe threshold regarding lead's harmful effects on children's learning and behavior (Meyer et al., 2003). Children who are exposed to lead and have elevated levels of lead in their blood are at risk for other serious health

problems. Some serious health problems include attention deficit disorders, behavioral problems, decreased stature and growth, impaired hearing, neurological problems, kidney damage, major organ failure, encephalopathy, impaired peripheral nerve function (ATSDR, 2002). The absence of any overt clinical symptoms does not indicate that no lead poisoning is present, as lower levels of exposure have shown to have subtle health effects (ATSDR, 2002).

Researchers have established a relationship between early childhood lead exposure and subsequent decreases in IQ. In one study, children who were reported to have increased levels of lead in their blood were examined between the ages of two and three. These children were then given IQ tests between the ages of four and eleven. From these tests, researchers discovered that their IQ was seven to ten points lower than the national average for their age and that for every 10 micrograms of lead per deciliter of blood, the IQ deficit increased (Lead411, 2005). Understanding that sick children will put a burden on society as a whole, lead poisoning is a very important issue (Stoss, 2005).

The good news is that since the 1970's, the average BLL in children has declined significantly. In 1984, seventeen percent of children in the United States were estimated to be at risk of lead poisoning, whereas in 1991-1994 a study showed that only 4.4 percent of children ages one through five had BLL of 10 micrograms per deciliter (ASTDR, 2002).

#### Acceptable limits and standards

The Center for Disease Control has defined lead poisoning as a Pb concentration of 10mg/dL or more (Wagner, Hughes & Sobsey, 2005). According to a 2005 report based on The National Health and Nutrition Examination Surveys (NHANES), mean

blood levels have decreased by 72-77% during the past two decades. But Hispanic or black populations remained higher than non-Hispanic white or Mexican-American children (Schwemberger et al., 2005). Schwemberger (2005) believes that this is directly related to the strong regulatory policies in developed countries. Noting that lead exposure in many developing countries remains high or continues to increase.

Although lead is one of the most heavily investigated toxicants in environmental health, there are still persistent gaps and conflicting theories on the long-term effects, reversibility of effects, and potential for gene lead interactions (Oliveira et al., 2002). Responsible regulatory authorities rely on acceptable limits or standards to set policies and action limits for the protection of human health. The Environmental Research Foundation has defined five stages of lead-poisoning awareness.

1892-1914	Included a time when there was a refusal by the medical and public health communities to accept lead exposure as harmful to children.
1914-1943	They began to accept childhood lead poisoning as a valid problem, but with only two possible outcomes: death or recovery.
1944-1973	There was a continued growth of medical evidence on the impact of lead on exposed children.
1970-1994	This marked a time in history where “official levels of concern” began to take shape. The levels dropped from 60 mg/dL to the current 10 mg/dl. And finally,

1994- Present                      Continues to show increasing evidence that blood lead levels lower than 10mg/dL produce harmful, permanent health effects (Stoss, 2002).

Even a general agreement that a certain substance is harmful, does not always allow for easy to set standards and policies that all members involved can agree upon. As an example, from 1910 to 1977 there were 4,000 tons of lead pigments used in homes and products throughout the United States. This was done even though in 1921, forty other nations agreed to ban the used of lead-based paints (Lead 411, 2005). Looking back it would appear a that this should have been a quick and painless call for the United States, but regulators must weight all the pros and cons when making import decisions, effecting many participating entities.

#### National elimination goals

The United States Department of Health and Human Services (DHHS) established a national goal to eliminate blood lead levels in children, aged six months to five years to  $\leq 25$  mg/dl by 2000. This goal was not met. The current goal is the elimination of blood lead levels  $\geq 10$ mg/dL by 2010 and will require intensified efforts to target high risk populations and areas. Local, State, and Federal officials will also need to evaluate current preventive strategies and improve the quality of surveillance data before 2010 (Meyer et al. 2003).

#### Lead poisoning a health disparities issues.

Among the research and medical communities, it is accepted that lead poisoning is a socio-demographic issue rather than genetic. Even though low income and education



have been correlated with higher BLL's in white males, the majority of individuals disproportionately affected are from minority groups (Lin, Kim, Tsaih, Sparrow, & Hu, 2005). In a study done in South Central Los Angeles, researchers found that poor minority groups living in urban centers are at a higher risk. The data demonstrated that pregnant immigrants had significantly higher blood lead levels than pregnant non-immigrants. They also found an even more specific disparity among women just entering the United States from Mexico (Rothenberg et al, 1999).

Some populations of children are still at significant risk of lead poisoning. A 1991-1994 national survey found that 29.9 % of black children living in older housing had elevated BLL's, and 11.2% of all black, non-Hispanic children had elevated BLL's. 16.4 % of poor children living in older housing had elevated BLL's and 11.5% of children living in older homes in large urban areas had elevated BLL's (ASTDR, 2002). It is important to note, that no economic or racial/ethnic subgroup of children is free from the risk of have blood lead levels high enough to cause adverse often permanent health effects (ASTDR, 2002).

#### Prevention and building lead free communities

It is important to understand that lead poisoning is not just an individual or single family issue. Lead poisoning is long reaching in both scope and breadth (Stoss, 2005). A campaign for Lead-Safe America targeted twenty- five cities at highest risk for potential childhood lead poisoning. This program provided fifty million dollars in aid to cities and counties to develop programs for remediation and reducing lead exposure (Stoss, 2005).

Officials found it helpful to use a targeted screening approach for at risk populations. One new method was the use of Medicaid eligibility. By meeting this

criterion for service, the family would most likely also match the socioeconomic status that puts them at risk for high BLL's. Yet, difficulties in reaching members of the high risk group still varied from state to state and county to county. This situation is an indication that lead poisoning is still a problem at the local level and there needs to be a general prevention and treatment program at the local level addressing high BBL's (Binns, Kim & Campbell, 2001). The CDC supported and still supports the use of state and local media health alerts to direct individuals who suspect they have been exposed to seek treatment (MMWR, 2005). Community specific strategies will go a long way in the prevention and treatment of lead poisoning (MMWR, 2005).

The best method for the treatment of lead poisoning is prevention. A few simple prevention strategies are to keep the areas where children play as clean and dust free as possible. Consistently wash pacifiers and bottles when they fall to the floor, and wash stuffed animals. Make sure children wash their hands before meal- time. Mop floors and wipe down windowsills and other chewable surfaces with a solution of dishwasher detergent and tap water. Plant bushes next to an older home with painted exterior walls to help children keep away from the leaded soil source. Plant grass or another ground cover in soil that is likely to be contaminated around a home build before 1978. Have the household water supply tested. Use only water from the cold-water tap for drinking and cooking, as cold water is likely to contain lower levels of lead. If an individual works with lead either on the job or as a hobby, changing clothes before they enter the home, is important. Do not store food in open cans, especially imported cans. Do not store or serve food in pottery meant for decorative use. As community awareness and environmental controls increase, there is a direct relationship to a decrease in lead toxicity (Stoss, 2005).

It is clear that lead is an environmental toxicant. Working with local, State, and Federal officials to set reasonable standards, and continually screening for new lead sources is of the greatest importance in the field of public health. Understanding sources of exposure, how lead affects human health, along with developing target specific strategies to prevent lead poisoning will help increase global health. This thesis addresses an important lead prevention strategy focusing on the methodology for the use of XRF technology to screen candies for lead contamination.

## CHAPTER 3

### QUESTIONS, OBJECTIVES, AND HYPOTHESES

#### Questions

- Can the XRF instrument be used as a quick and effective screening tool when compared to the Graphite Furnace (GRAAS) when testing candy items for lead contamination?
- With a 2005-2006 middle school survey and candy collection, will it be found that children in Las Vegas are eating candies that contain lead in the wrapper, stick, straw or candy?
- Will candy collected from Brinley Middle School children include Mexican type candies found on the California toxic treat list?

#### Objectives

- Develop an effective protocol to using the XRF to test candies for lead.
- Survey students on purchasing and eating patterns of candy that may contain lead.
- Determine via survey if Brinley Middle school children are eating candy that may be contaminated with lead.
- Compare candy collected against candy found on the California toxic treat index list.

### Hypothesis One: XRF protocol development hypotheses

The XRF instrument can be used as a quick and effective screening tool when compared to the Graphite Furnace (GRAAS) when testing candy items for lead contamination.

- $H_0$ : The proportion of candies found to contain lead is equal when comparing XRF and GRASS methodologies.
- $H_a$ : The proportion of candies found to contain lead is not equal when comparing XRF and GRASS methodologies.

### Hypothesis Two: Middle School community and candy survey protocol hypotheses

The 2005-2006 middle school survey and candy collection will reveal that children in Las Vegas are eating candies containing lead and that consumption is equally distributed among cultures.

- $H_0$ : The observed number of students that eat imported Mexican candies is equal to the number expected by chance.
- $H_a$ : The observed number of students that eat imported Mexican candies is not equal to the number expected by chance.

### Hypothesis Three: Candy found at Brinley Middle School hypotheses

Candy collected from Brinley Middle School children includes Mexican type candies that are found on the California toxic treat list.

- $H_0$ : The Mexican-type candies found in samples from Brinley Middle School will contain equal proportions of candies listed on the California Toxic Treat index list and those not found on the list.

- $H_a$ : The Mexican-type candies found in samples from Brinley Middle School will contain unequal proportions of candies listed on the California Toxic Treat index list and those not found on this list.

## CHAPTER 4

### ANALYSIS AND METHODOLOGY

#### Hypothesis One: XRF protocol development

The development of an XRF protocol for candies began by comparing candies that contain tamarind and chili pepper ingredients, along with other candy and related items known to contain lead, against the toxic treat index list. This index was developed by the Orange County Register. This index was compiled from data collected from the California state Childhood Lead Poisoning Prevention Branch, the Food and Drug Administration, Orange County candy testing records and independent testing done by the OCRegister. This data collection started as far back in 1993 (Heisel, 2004).

This toxic treat index list (TT) was used to identify candy and related items that have been imported from foreign countries. Specifically focusing in on locally purchased candy imported from Mexico and Brazil that have been known to contain lead. Also included were imported items that did not contain tamarind and or chili pepper ingredients. Generally any candy or candy-related items that appeared to be susceptible to lead contamination were included.

Candy was purchased from local markets in Las Vegas, Nevada; Los Angeles, California; and Tijuana, Mexico. The sample size goal was a minimum of 10 candies and candy-related items from each bag or bulk purchase. Approximately 4000 candies were

screened using the XRF, and of these candies four specific brands were chosen for further evaluation these include: (1) Sponge Bob<sup>®</sup> N = 25; (2). Strawberry Filled Candy N = 25; (3) Tamarind Plastic Pots N = 10; and (4) Tama Roca<sup>®</sup> N = 15. The data collection was completed on October 11, 2005. As the XRF analysis is a non-consumptive test, these samples were then sent to Forensic Analytical CA (FACA) and analyzed using the GRAAS.

A contingency table analysis using a Chi-square statistic with McNemar p-value correction was used to compare results from the XRF lead candy testing protocol and the FDA approved GRAAS lead candy report; significance was tested against an  $\alpha = 0.05$ . Described in the results section are the detailed methods used to develop the lead candy testing protocol, including the procedure for using the XRF to test different candies, wrappers and accessories.

#### Hypothesis Two: Middle school community and candy survey protocol

When working with human subjects, IRB approval is required. The IRB protocol is presented in Appendix I. It was determined after an expedited IRB review that if the school Principal was willing to conduct and oversee the candy and survey collection. And then donate these collected items to UNLV for this project research University IRB approval was not needed. This was the course of action taken.

A three-pronged approach was taken to meet the hypothesis objectives. The first was to educate the student body on lead and the dangers of candy contamination. Second was to educate the parents' of this population on the hazards, signs, symptoms and prevention of lead contamination. The last goal was to collect a representative sample of candy exposures and students' candy eating habits, estimating the actual consumption of



potentially dangerous candies. Brinley Middle School served approximately 1,200 students during the 2005-2006 school year. These children ranged in ages from eleven to fifteen years.

The project began with the introduction of lead educational materials during the week of open house. Using the schools regular structured activities provided access to a broad school population sample. It was decided that the least restrictive way to address the student education portion of the program was during the morning announcements. Each morning the students were offered a short educational sound bite over the public announcement system. A detailed dialog of it can be found in Appendix II.

During the evening of open house a power point slide presentation, including pictures of the toxic treat candies, was conducted including an educational lecture on the risks and prevention of lead poisoning (Appendix II). Finally, during both lunch periods, candy samples and student surveys were collected from student volunteers at Brinley Middle School on Friday, September 30, 2005. The Brinley Middle School (BMS) staff conducted the collection of the candy and student surveys from any volunteer student. BMS then donated these items to UNLV for analysis. A copy of this survey is included in Appendix III.

The data from the survey was sorted based on ethnicity and consumption. A contingency table and Chi-square analysis was used to test for independence of ethnicity and consumption. Ethnicity was categorized as African American, Caucasian, Hispanic, and Asian/Pacific Islander/Indian. Consumption was categorized as never, rarely, daily, weekly, and monthly.

### Hypothesis Three: Candy found at Brinley Middle School

All candy collected was taken to the UNLV Laboratory, photographed and assigned an identification number. Appendix II provides an example of how the candy login sheet was used.

A Chi-square goodness-of-fit test was used to compare candy donated with the toxic treat list. Significance was tested at  $\alpha = 0.05$ .

## CHAPTER 5

### RESULTS

#### Hypothesis One: Introduction to the XRF protocol development

The first objective was to assess how the XRF could be used as an effective screening tool to determine if lead was present in candy and candy accessories. The EPA approved paint and soil testing methods were modified and adapted in the formation of an accurate, systematic leaded candy testing procedure. Certain types of candies have been tested by other health officials and continue to date to test positive for lead contamination using the GRAAS.

Currently, many researchers have only tested small sample sizes of tamarind and chili pepper candies, which can affect both the certainty of contamination along with accurate measures of variance. Typically lead is found in tamarind and chili pepper type candies. However it is not widely known, nor demonstrated that other candies not containing tamarind or chili pepper also tested positive for lead contamination.

With the goal of designing a quick and accurate screening tool for large quantities of potentially hazardous candy, new testing techniques were created, working to overcome some of the problems encountered by other researchers.

### The development phase of the XRF protocol

Candy is by nature dissimilar to soil, paint or dust wipes, which are the typical mediums tested by the XRF. Since each type of candy posed a different issue, a number of procedures were developed to address the specific requirements of each candy type.

Candy comes in various packaging. The candy products are found in a number of different consistencies: suckers, soft chew, hard candy with a soft center chew or gum, licorice type chews, candy bar, powder, caramel type chews, or gum. This originally was a challenge when working to find the most effective and accurate protocol to test each type.

Although candy may contain lead, candy accessories and packaging materials may also present a lead hazard. Accordingly, new measures were developed to address the issue of lead contamination in wrappers, straws, spoons or non- edible containers. Each candy type and packing materials presented unique challenges separate from the distinctive issues encountered with the candy material alone.

Although much time, effort, revision and adaptations were made along the way, this protocol represents the best possible technique based on multiple experimental designs and duplicate testing samples.

### Materials

1. Niton XLp 300A/700A Series Lead Based Paint Analyzer ( XRF).
2. Niton thin mode testing stand.
3. Niton bulk soils testing stand.
4. Testing standards (thin layer, soil, paint)
5. Plastic wrap various generic grocery store brands.
6. Niton soil testing cups and accompanying materials.
7. Niton dust wipes.
8. Various candy types purchased at local stores in Los Angeles and Las Vegas, with a few

sample items from Tijuana, Mexico.

#### Setting actions limits

Currently the FDA has set an action limit for raisins at 0.2 ppm and candy at 0.5ppm. For the purposes of this study it was decided that the action limit (when the XRF result window places a positive or negative next to the sample value) would be set at zero as lead is a non-food additive and poses a risk at any level to children. For the purpose of this protocol, a positive reading is defined as any item resulting in confirmed lead measurement on the XRF instrument.

#### Selection of measurement mode

According to the Niton manual, the XRF has three main testing modes. These modes are dependent on the total thickness of the material being tested. To determine which mode would accurately report the total amount of lead in a sample, controlled testing measures and standardized lead soil samples were used as the initial testing material. These tests lead to the discovery that using the thin layer mode for thirty seconds if the candy was less than  $\frac{3}{4}$  inches in depth reported accurate lead results in  $\mu\text{g}/\text{cm}^2$  likewise, if the candy was thicker than  $\frac{3}{4}$  inch a soil sample cup preparation was required, analyzing the sample in bulk soil mode for 60 seconds, reporting in ppm.

#### General testing and candy preparation protocol

If the candy sample is smaller than  $\frac{3}{4}$  of an inch, test in standard thin film mode for thirty seconds and if it is:

1. Sticky place a small piece of saran wrap over XRF window to prevent contamination of XRF surface. Test in thin layer mode for thirty seconds.

Note: checking the wrapping material to ensure it is lead free.

2. When candy is a powder or in a sugary/salt form, prepare in bulk sample soil cup. Using the Niton soil sample cup preparation instructions. Run sample in bulk mode for 60 seconds (see soil sample protocol below). If there is not enough sample to fill a cup and is less than  $\frac{3}{4}$  in thick, place a piece of saran wrap over window, cover XRF window with candy, running sample on the film mode for 30 seconds
3. Tamarind jelly contained in clay or plastic pots,
  - a. take a reading of pot, then
  - b. remove jelly from pot and prepare bulk soil cups.
    - i. note the specific area the tamarind was removed from (near plastic or middle of container).
4. If the candy is a liquid, prepare a bulk sample soil cup (see soil sample protocol below).
5. Assorted candy mixes are: separated by type and analyzed according to the individual category protocols.
6. If candy is sticky and attached to a spoon or stick:
  - a. first test with all parts intact; then
  - b. remove candy from accessory and run candy separately,
  - c. run accessory and the wrapper separately if there is enough material to test.
  - d. if the stick accessory contains chili pepper, cut stick away and run separately in thin film mode for 30 seconds.
7. Gum was removed from wrapper, and each part analyzed separately.

8. When dealing with a stick or wrapper, separate each part, and analyze individually.

If item was larger than  $\frac{3}{4}$  of an inch, a cheese grater was used to shred candy into a bulk solid soil sample cups. Analysis times for this type of sample in bulk mode set for 60 seconds. According to the manufactures specifications the XRF requires more time to calculate the lead content. Anything over  $\frac{3}{4}$  thick cannot be run in thin layer mode. It must be broken up and placed in soil sample cups. Unless there is uniformity to the candy sample and the proximity button will depress while testing in bulk for 60 seconds, one must use the sample cup bulk testing method. One issue with this bulk method technique is that only a small portion of the candy is analyzed, as compared to homogenizing the entire sample as done with the graphite furnace. For a more detailed description of protocol methods see Appendix IV.

#### XRF protocol development results

Below are the results from the October 11, 2005 testing done on four separate candy samples. The Tama Roca<sup>®</sup> Candy was the first candy item tested for comparison of the XRF to GRAAS. Table 1 shows the results for the Tama Roca<sup>®</sup> candy screening. The candy was removed from the straw and tested separated from all the other sample parts, then tested for thirty seconds in thin layer mode. This same sample was sent to FACA an NLAPP accredited forensics laboratory and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded similar results.

**Table 1 Presence of Lead In Tama Roca® Candy as Determined by XRF and GRAAS Technique**

	Positive for lead candy	Negative for lead candy
XRF	0	15
GRAAS	0	15
	N=15	X <sup>2</sup> =Undefined

Using the Chi square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, X<sup>2</sup> was undefined. As represented in Table 1 these data show an equal proportion of negative for lead readings from both testing modalities.

Table 2 represents the results for the Tama Roca® straw. The straw was removed from the candy and tested separately from all the other sample parts. Tested for thirty seconds in thin layer mode, this same sample was then sent to an FACA and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded similar results.

**Table 2 Presence of Lead In Tama Roca® Straw as Determined by XRF and GRAAS Technique**

	Positive for lead straw	Negative for lead straw
XRF	15	0
GRAAS	15	0
	N=15	X <sup>2</sup> =Undefined

Using the Chi square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, X<sup>2</sup> was undefined. As represented in Table 2 these data show an equal proportion of positive for lead results from both testing modalities.



Table 3 represents the results for the Tama Roca® wrapper. The wrapper was removed from the candy and tested separated from all the other sample parts, tested for thirty seconds in thin layer mode. This same sample was sent to FACA and run through the GRAAS. When comparing the XRF results against the GRAAS.

**Table 3 Presence of Lead In Tama Roca® Wrapper as Determined by XRF and GRAAS Technique**

	Positive for lead wrapper	Negative for lead wrapper
XRF	6	9
GRAAS	10	5

N=15

$\chi^2 = 2.14$  ; M<sup>c</sup>Nemar p=  
1.0  
Fail to reject

These results indicate that the null hypothesis should not be rejected, and hence that the proportion positive for lead measurements between the Tama Roca® wrapper verses the GRAAS wrapper result is equal. Even though the results were not significant it brings up issues of false positive and false negative rates.

The Bob Esponja® lollipop candy was the second candy item tested for comparison between the XRF and GRAAS (Table 4), The hard candy was removed from the wrapper and analyzed separated from all the other sample parts, analyzed for thirty seconds in thin layer mode. This same sample was sent to FACA and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded similar results.

**Table 4 Presence of Lead In Bob Esponja<sup>®</sup> Candy as Determined by XRF and GRAAS Technique**

	Positive for lead candy	Negative for lead candy
XRF	0	25
GRAAS	0	25

N=25 X<sup>2</sup>=Undefined

Using the Chi square statistic, and the predetermined alpha level of 0.05 and the degrees of freedom set at one, X<sup>2</sup> was undefined. As represented in Table 4 these data show an equal proportion of negative for lead results from both testing modalities.

Table 5 shows the results for the Bob Esponja<sup>®</sup> wrapper. The wrapper was removed from the candy and analyzed separated from all the other sample parts. Wrappers were analyzed for thirty seconds in thin layer mode, and then sent to FACA and analyzed with the GRAAS. When comparing the XRF results against the GRAAS with the following results.

**Table 5 Presence of Lead In Bob Esponja<sup>®</sup> Wrapper as Determined by XRF and GRAAS Technique**

	Positive for lead wrapper	Negative for lead wrapper
XRF	20	5
GRAAS	0	25

N=25 X<sup>2</sup> = 39.56; McNemar P=.031 reject the null

The test supports that the null is rejected and conclude that the proportion of positive for lead measurement between the Bob Esponja<sup>®</sup> wrapper verses the GRAAS wrapper results are not equal.

The tamarind jelly filled plastic pots were the third candy items tested for comparison of the XRF to GRAAS (Table 6). The outside of the pot was tested with the XRF and analyzed for thirty seconds in thin layer mode. This same sample was then sent to FACA and analyzed through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded similar results.

**Table 6 Presence of Lead In Tamarind Plastic Pot as Determined by XRF and GRAAS Technique**

	Positive for lead plastic pot	Negative for lead plastic pot
XRF	10	0
GRAAS	10	0
	N=10	$X^2 = \text{Undefined}$

Using the Chi square statistic, and the predetermined alpha level of 0.05 and the degrees of freedom set at one,  $X^2$  was undefined. As represented in the table these data show an equal proportion of positive for lead results from both testing modalities.

Table 7 shows the results for the tamarind plastic pot candy only. The candy was taken out of the pot, prepared in a soil testing cup, and tested with the XRF, analyzed for sixty seconds in bulk layer mode. This same sample was then sent to FACA and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded similar results.

**Table 7 Presence of Lead In Tamarind Plastic Pot Candy Only as Determined by XRF and GRAAS Technique**

	Positive for lead candy	Negative for lead candy
XRF	0	10
GRAAS	0	10
	N=10	X <sup>2</sup> =Undefined

Using the Chi square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, X<sup>2</sup> was undefined. As represented in Table 7 these data show an equal proportion of negative for lead results from both testing modalities.

Table 8 shows the results for the tamarind plastic pot spoon only. The spoon was removed from the top wrapper, held in place by a rubber band and tested with the XRF for thirty seconds in thin layer mode. This same sample was then sent to FACA and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded the results shown below.

**Table 8 Presence of Lead In Tamarind Plastic Pot Spoon Only as Determined by XRF and GRAAS Technique**

	Positive for lead spoon	Negative for lead spoon
XRF	4	3
GRAAS	4	3
	N=7	X <sup>2</sup> = 0 ; McNemar p= 1.0 Fail to reject

Using the Chi-square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, it can be concluded that we fail to reject the null hypothesis and conclude that the two results are equal to one another.

The strawberry filled hard candies were the fourth candy item tested for comparison of the XRF to GRAAS. Table 9 shows the results for the strawberry filled hard candies. The candy was removed from the wrapper. Using the XRF the candy was tested for thirty seconds in thin layer mode. This same sample was then sent to FACA and run through the GRAAS. When comparing the XRF results against the GRAAS, both testing modalities yielded equal results.

**Table 9 Presence of Lead In Strawberry Filled Candy Determined by XRF and GRAAS Technique**

	Positive for lead candy	Negative for lead candy
XRF	0	25
GRAAS	0	25
	N=25	X <sup>2</sup> =Undefined

Using the Chi square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, X<sup>2</sup> was undefined. As represented in the Table 9 these data show an equal proportion of negative for lead readings from both testing modalities.

Table 10 shows the results for the strawberry filled hard candy wrappers. The wrapper was removed from the candy. Using the XRF the candy was tested for thirty seconds in thin layer mode. This same sample was then sent to FACA and run through the GRAAS.

**Table 10 Presence of Lead In Strawberry Filled Candy Wrapper Only Determined by XRF and GRAAS Technique**

	Positive for lead wrapper	Negative for lead wrapper
XRF	11	14
GRAAS	24	1

N=25

$X^2 = 16.10$  ; McNemar  $p = 0.143$  Fail to reject the null

Using the Chi square statistic, and the predetermined alpha level of .05 and the degrees of freedom set at one, this formula concluded that we fail to reject the null and conclude that the two results are equal to one another.

Hypothesis Two: Middle School candy consumption results from survey

Survey sample size was 201 students. The reported demographic information found in the Brinley Middle School 2004-2005 accountability report was: Males 51.6 %, Females 48.4 %, American Indian/ Alaskan Native 0.7 %, Asian/ Pacific Islander 6.2 %, Hispanic 36.1 %, Black/ African American 26.9 %, White 30.1 % (Clark County School District, 2004-2005). Using a Chi-square contingency (as reported in Table 11) the data from the each survey were sorted based on race verses consumption.

**Table 11 Reported Consumption of Potentially Lead Contaminated Candy by Ethnicity**

Race	Daily	Weekly	Monthly	Rarely	Never	Row Total
African American	3	12	6	26	6	53
Caucasian	1	10	3	14	3	31
Hispanic	6	13	10	35	4	68
Asian/P. Islander/Indian	1	1	5	10	3	20
Row Total	11	36	24	82	16	
				Grand Total		172

N=201

$G^2 = 10.74$ ;  $p = 0.552$  Fail to reject the null

Using the log-likelihood statistic and the predetermined alpha level of 0.05, We conclude that we fail to reject the null and conclude that all students eat imported Mexican candies at the same rate.

Hypothesis Three: Candy found at Brinley Middle School

After the candy collection took place, each students' candy sample bag was opened and compared to items known to contain lead. These comparisons were found on this 2004 California Toxic Treat index list. If the candy was found on this list it was counted as a "yes" result and if the candy was not found on the list it was counting as a "no" result. A Chi-square goodness of fit test to test was used this hypothesis.

**Table 12 Comparison of California Toxic Treat Candy List verses Brinley Middle School Candy Collection Samples**

	Yes Found On The Toxic Treat List	Not Found On The Toxic Treat List
Candy Collected From Survey	23	23
N=46	$X^2 = 0; P = 1$	Fail to reject the null

Using these results one can conclude that the candy collected from Brinley Middle school students included candies that were found on the California Toxic Treat list.

Using the data from Table 12 sorting data set based on race verses if the candy donated was found toxic treat list. These results are represented in Table 13.

**Table 13 Race \*Toxic-Treat Ledged Candy Consumption Rates Crosstabulation**

			Toxic Treat		Total
			No	Yes	
Race	Af. Am.	Count	8	5	13
		Expected Count	6	7	13
	Cauc	Count	7	2	9
		Expected Count	4.1	4.8	9
	Hisp	Count	3	11	14
		Expected Count	6.4	7.5	14
	Asian	Count	0	3	3
		Expected Count	1.3	1.6	3
Total		Count	18	21	39
		Expected Count	18	21	39

$$G^2 = 12.43 ; p = 0.006$$

We reject the null and conclude that the distributions are not equal. There is a relationship between the consumption of candy and race. There is an increase consumption rate found among this Hispanic student population.



## CHAPTER 6

### CONCLUSIONS AND DISCUSSION

#### Hypothesis One: XRF protocol development

XRF technology provides a method to determine the content of lead in various candy items. During the first phases of protocol development it was unclear if the XRF was reporting lead levels when lead was present in a sample. Unfortunately after running approximately 1000 samples, very few samples were identified with a positive for lead reading, even in candies known to contain lead. Observing that this might be due to the thickness of the candy sample, a number of testing methods were investigated to test this hypothesis. Subsequently this resulted in the discovery when the candy and wrapper were tested separately, lead was present. Following this discovery all candy samples were retested using the new protocol. These new reported results were more consistent and reproducible compared to previous variations of the protocol and all candy components were analyzed individually. These results were used as the basis for the development of the XRF lead candy testing protocol.

#### Effectiveness of XRF as a screening tool

As shown in Table 1, 2, 3, 4, and 6 through 9 the XRF was just as effective for measuring the presence of lead in the candy and or candy accessories as the GRAAS. For the purpose of this comparison when the candy reported zero with the XRF and was

below the detection- reporting limit of the GRAAS it was considered to be negative for lead contamination.

The XRF instrument is accurate when screening for lead content in candy and candy accessories. When comparing the two methods one advantage that the XRF has over the GRAAS is the ability to screen a large number of samples quickly. Generally, the total analysis time for candy and accessories (after samples have been prepared) is approximately one minute. This of course is dependent on the thickness of sample and the number of separate parts to be tested. However, this is much faster than other conventional methods. Another advantage to the XRF is the field portability. Testing items quickly and effectively without requiring the time to collect, transport and test items in a laboratory allows for more timely results and public health action if needed.

#### Weakness of XRF protocol

One methodological issue encountered was the inconsistent candy wrapper measurements. Although In Tables 3, 5 and 10 the data show the measurements as equal. This might be a function of sample size and as the sample size grows, this might become an unequal measurement. The wrapper problem was even more evident when the XRF measurements were not in agreement with the GRAAS data, as demonstrated in Table 5. This inconsistency issue was found when testing various wrappers. Yet, some wrappers always positive when removed from the candy, even though these samples were not tested against GRAAS, it appeared that these wrappers did contain lead. When sampling these four different candy types and candy accessories, four different comparison classifications emerged: 1. positive for lead, 2. false positive, 3. false

negative and 4. undetermined (due to detection limit issues) when comparing the XRF reading against the GRASS reading of the same sample.

Undetermined due to detection limit issues was reported 100% of the time when testing all four candy samples and 43% of the time when testing plastic spoons. This is due to a zero report of lead when using the XRF, and GRAAS reporting limit set at a range of <0.2 up to <0.4 mg/kg. It is thought that if the GRAAS reporting limit would have been set lower, it too would have reported zero for lead. Either way the FDA sets the food action limit for lead at 0.5 mg/kg and all candies tested with both modalities were below the lead contamination action limit (Lynch et al., 2000).

False positives occurred with two different wrappers at the rate of 29%. One in the wrapper from the strawberry filled candies where the XRF reported  $0.72\mu\text{g}/\text{kg}^2$  and the GRAAS reported at <0.5 mg/kg with the report limit of 0.5 mg/kg. The other false positive was found in the Bob Esponja candy wrapper. The XRF identified one sample at  $.53\mu\text{g}/\text{kg}^2$  and the other at  $.91\mu\text{g}/\text{kg}^2$ . The reporting limit for the GRAAS was at a range of <0.3 to <0.5 mg/kg. These false positive results are most likely due to a detection limit issue. Comparing area verse mass, or possibly laboratory testing issues. If the reporting limits were set lower, it most likely would have shown that lead was present when testing with both modalities.

False negatives occurred 24% of the time when testing wrappers. It was consistently found that if the wrapper was put back into the approximate shape before the candy was removed, a more accurate lead reading occurred, as compared to spreading the wrapper flat on the shutter. It was often noted that while the XRF was running, the wrapper would begin to unravel and move farther way from the shutter. This gradual

increasing distance might have been part of the reading inconsistencies found between the two methods. It is thought that when the wrapper distance from the shutter increases as the XRF is reading the x-ray backscatter, less of the x-rays would fall back on the shutter and those particles of lead would not be included in the overall lead measurement. This could result in either a false negative or show a lower lead level than is actually present. The XRF screened candies correctly 66% of the time. The accuracy rate would be 93% if one were to disregard the reading inconsistencies when working with the wrappers and focus on candy and accessories. The false negatives, undetermined values and false positives found in the wrapper samples are the only reason the positive for lead reporting rate was 66%.

The sample sizes for the comparisons of XRF to GRAAS were not as large as preferred with this type of study. This was in part due to monetary constraints. Each GRAAS sample was sent to FACA and cost about \$25 dollars for each part. Highlighting one of the main reasons the development of this protocol is important. The use of the XRF allows one to test larger sample sizes of a various candies, quickly and accurately and can be more cost effective.

The detection limits differ between the two testing methods. The GRAAS has the ability to detect smaller amounts of lead than the XRF. As the level of lead contamination is reduced, the XRF has a more difficult time reading the lead level, resulting in false negatives. It is still unclear where the exact detection limit of the XRF is for this type of measurement. This is another project needed to help clarify this measurement issue. The XRF demonstrated 93% accuracy when examining candy and candy accessories and proves to be a promising tool for candy screening. However, some caution should be

exercised and confirming results pursued when working with candy wrappers that contain low levels of lead as false readings did occur.

#### Leaching of lead into candy from accessories

Another important issue needing attention is the leaching of lead from the accessories into the candy. Does lead leach into the candy? Can certain temperatures increase leaching rates? Do certain candy types accelerate the leaching of lead? Are certain candy types naturally protected from the leaching of lead from the wrapper? Although these questions were not studied with the detail and attention paid to XRF protocol development, it was found that some parts of the Tama Roca candy often tested positive when the portion closest to the straw was tested, this event was consistently found, but not examined statistically. Yet, when one section of the Tama Roca candy tested positive, another section might test negative even if the two samples were only inches apart. This project is in need of further study, helping to reduce the risks of lead contamination found in imported candy.

#### XRF/GRAAS data discussion

Based on the data, the lead candy testing protocol developed for the XRF instrument can be used as a quick and effective screening tool when compared to the GRAAS.

The Chi-square formula was unable to be calculated as shown in Table 1 and Table 2. The actual data shows that the XRF and the GRAAS tested equally, indicating that lead was not present in the Tama Roca candy sample and that lead was present in Tama Roca straw, demonstrating that both testing modalities analyzed the lead content even when the Chi-square formula remained undefined. As a side note: during this entire

process the candy and wrapper lead measurements varied from sample to sample yet, regardless of the sample lead measurement for the candy or wrapper, the straw always tested positive.

Table 3, represents the Tama Roca wrapper and demonstrated that there was an issue when comparing the two methods with respect to wrappers. These wrapper measurements lacked repeatability and consistency. One reason might be due to the XRF's ability to test only small portions of the wrapper during each reading which is a homogeneity issue as compared to the GRAAS which digests and measures the entire wrapper. The XRF is analyzing a two dimension square area and the GRAAS measurement is analyzing a homogenized sample. One way to minimize this error is to measure a number of different sites when folding wrapper, unfolding, measuring it in separate quadrants. In fact, this methodology would be similar to the proposed technique of analyzing dust wipes using XRF technology. Each reading would record a unique lead measurement as it is only testing the area that is covering the shutter. Where as the GRAAS completely digests the entire wrapper and measures the volume of lead present in the entire sample. The GRAAS is the gold standard when measuring lead contamination and has the ability to detect lower levels of lead than the XRF. With that said, the XRF detected lead when lead was present at a rate of 93% in all the candy related matrices (wrapper excluded). There was only one time that the XRF reported a positive lead measurement when the GRAAS was unable to detect lead, this is most likely due to the FACA reporting limit, which is limited by the wrapper weight. If the GRAAS detection limit had had been set below  $<0.5$  mg/kg, lead most likely would have

been detected by the GRAAS. One might use the ICP-MS analysis for this type of accuracy comparison, as the detection limit may be slightly lower than the GRAAS.

Sponge Bob lollipops (Bob Esponja) in Table 4 supported that the XRF was able to accurately report the absence of lead when compared to the GRAAS. Yet, again as shown in Table 5 wrappers were an issue, as these two methods did not yield similar results, allowing for the conclusion is that there is a difference between the two testing modalities. The issue again must have been either the movement of the wrapper away from the shutter during the reading, or the function of the placement of the wrapper over the shutter, with the specific area that was tested being of a different concentration of lead as compared to another wrapper. Comparing the volume of an entire wrapper verses the area at one specific site of a wrapper, along with each wrapper tested on the XRF not being the exact same area tested as the sample before, is a serious issue needing further attention.

The tamarind plastic pots examined were designed to replace the highly leaded clay pots. Yet, the plastic pots lead content was also extremely high. This was an interesting discovery, as one theory on the high lead levels in tamarind candy has focused on the pottery glaze creating the lead issue. However the ability of the lead to actually leach from the plastic is not known at this time and should be explored. A leaching study between clay verses plastic pots and other accessory items is needed.

When testing for lead in the candy, there was not a positive lead reading in the candy from either the plastic pots or the one ceramic pot tested. Even when the candy was scraped from the inside wall of the pot, which one might suspect would contain lead. Whether lead is present in this tamarind jelly is still unresolved. However, caution should

be exercised when evaluating this finding as only one ceramic pot was examined. There needs to be a larger sample size tested to better answer this question.

The plastic pots containing tamarind jam was covered with plastic wrap, serving as a lid, and rubber band held the lid in place. A small plastic spoon was attached to the rubber band in some of the samples. These attached spoons came in various colors and often tested positive for lead. In Table 8 the Chi- square statistic shows that these results are equal to one another. An issue needing further attention is determining when the color, size or shape of the plastic spoon appear visually to be an exact replica, why one would test positive and the other negative?

The observed data of the strawberry filled hard candies shows that both the XRF and GRAAS indicated that the candy did not contain lead (Table 9). Again the wrappers were an issue as were in all other samples with wrappers. When looking at Table 10 using the Chi-square formula concluding that the two methods are equal to one another. Yet, looking closely at the actual numbers, if there had been a larger sample size it might have shown a difference between the methods.

A number of different strawberry type candies were tested during the protocol development phase, and it was found that the majority of these wrappers did test positive for lead when using the XRF protocol. Throughout the testing it was observed that metallic wrappers usually tested positive for lead and this issue should also be addressed, once the general wrapper protocol discrepancy is solved. Looking at wrapper types, clear, some color, yellow color or metallic, as there seems to be a difference between these types and the lead content.



### Detection limits

When comparing the data between the XRF and the GRAAS it appears that the XRF can detect lead below 0.5ppm. In fact, the GRAAS technique detected lead in a number of samples with a reported detection limit as low as 0.2ppm. Using, GRAAS we could measure lead concentrations as low as 0.2ppm, the XRF was able to also detect lead at these very low concentrations. This is an important finding supporting the reliability of the XRF instrument to detect lead at very low detection limit, making it suitable for screening for lead in candies consistent with detection limits at or below the current FDA action limit of 0.5ppm.

### Hypothesis Two: Middle school community candy survey protocol

This survey and community education project successfully reached the overall goals and objectives by providing education to both students and families on the risks of eating imported candy. The collection of a student survey, showing the consumption rates of imported candy and collecting candy samples from the students', allowed for the assessment of the potential hazards associated with leaded candy consumption.

Only a small group of parents attended the special educational session due to other family obligations. Yet, the response from the families in attendance was positive as they expressed their gratitude for the information. Lead poisoning prevention fliers were provided by the Southern Nevada Health District and many parents took one as they offered their apologies for not being able to attend. This portion of the project might have been more successful if there had been time to present the candy slideshow at the opening ceremonies for the evening. This might have sparked more interest, as parents might have

noticed candies they had seen their children eat or perhaps they had eaten themselves.

Using their individual experiences as motivation to attend a quick informational seminar.

#### School community education program protocol

This part of the program was successful as it sparked a school wide dialog about healthy eating habits and the risks associated with choosing unhealthy food items, including leaded candy. The quick sound bites were reflective in nature, allowing students to consider the consequences of their personal eating habits. The original order of the speech topics changed at the last minute, as the UNLV IRB committee felt the candy collection, with prizes as a motivation, if discussed each day might encourage children to purchase potentially hazardous candy solely for this project. It was decided that the only mention of the candy collection would occur on Thursday morning. This strategy would give students a limited time to purchase candy, as that night was open house, and most kids would be back at school within 3 hours of leaving campus.

#### Discussion on the logistics of candy and survey collection

The organization of the candy collection at lunch exceeded expectations in terms of organization and time limit concerns. This included approximately 600 teenagers during each lunch period in the cafeteria. Students' preferred not to spend a great deal of time waiting in line and this system allowed for a quick turn over rate at each independent station. More students were willing to fill out the survey, as many of the kids stated they had forgotten their candy. The only item that one might change is to have one long table per station, allowing for one student to finish taking the survey, as the candy collector began the collection procedures with the next student in-line.

### Discussion of the issues found with student survey

BMS students are from low-income families. This population has many cultural disadvantages which factor into the way they respond to certain social situations. This might account for the difficulty that all ages levels encountered when completing the survey. Many of the students were unable to select the race they most identified with. Maybe this survey should have included less politically correct words and instead listed choices such as: White, Black, and Indian. This may not have been appropriate, but when their peers stepped into help, they described race in this fashion.

Students experienced difficulty when answering how often they ate this type of candy. Many of the students that brought Mexican type candies stated they rarely ate this type of candy. Leaving the strong impression that they may have misunderstood the meaning of rarely. When developing a new survey one might use better age appropriate descriptors for each category. A few students acted as survey development test models during the development phase, but this strategy unfortunately did not eliminate the confusion.

### Data discussion on race verses consumption

The decision was made to collapse three of the race columns into one due to a low representation for each individual group. This new group includes: Asian, P. Islander, and Indian. It was also decided to excluding student surveys that left race blank or choose not to respond? This choice did not negatively impact the data set as the question was regarding race and consumption. This blank sample was unable to offer any information in regards to this question. The consumption rates were also reduced into five categories

instead of eight, cleaning up the appearance and offering a more linear representation of consumption patterns.

Forty-six students brought candy to donate. As shown in Table 11 there were more Hispanic children that filled out the survey, with African American being second in survey participation. The Chi-square analysis shows that all students eat imported Mexican candies at the same rate, with 89% of the survey participants reporting eating potentially lead contaminated candy at least once within their lifetime. It would appear from this small survey sample size of 201 students that the focus for prevention should target both the Hispanic and African American communities. This finding is representative of the school enrollment, which reported these groups as the majority populations at Brinley middle school.

Surprisingly, the results in Table 11 concluding that each race ate the candy equally, this might be due in part to the misunderstanding by students as to what each category meant. Again, recall bias might have played a major role when picking how often they ate this type of candy. Another rationale for the equal consumption rate might be due to these students having similar family income levels, creating a climate by which the purchase of candy items are drawn from a limited or small geographical area. Creating a climate in which an African American might not choose to eat this candy if they were not exposed to these type candies from Hispanic friends from their small geographical area. Another factor might be a small selection of candy choices at the local markets. And finally a larger sample size might have shown more of a variance between the groups.

### Hypothesis Three: Discussion of the candy collected at Brinley Middle School

Brinley Middle School students' were eating candy found on the California Toxic Treat index list. Many of the children claimed they had forgotten the candy items at home on the collection day and said that they had hoped the collection would have continued through Monday. If this project collected candy for at least two days, both in the morning and at lunch the sample sizes would have been larger. One potential problem with this candy collection is the possibility that one student actually brought many of the single candy samples and distributed their candy to a number of friends. If this was actually the case it would reduce the sample size to less than 46. There appears to be no clear way to limit this type of interference when working a young population like this, however future studies should indicate that these behaviors would skew study results and are discouraged.

It was noted when a child brought in Mexican type candies it usually included a number of candy items, rather than just one piece. As found in the case of student sample S1 a Hispanic male donated 6 different Mexican candies all of which were found on the toxic treat list; compared to S10 an African American female, donating approximately 5 butter scotch, candies which were not found on toxic treat list. Appendix IV lists specific data. Leading one to consider that Hispanic children might eat this type of candy on a regular basis and possibly eat more than one candy item at a time. This type of consumption behavior might put a child at an even higher risk of lead poisoning and could use further study.

### Data discussion for candy collection results

About half of the candy collected from the Brinley Middle School students was found on the Toxic Treat list and pose a potential threat to children who eat these candies on a regular basis these data shown in Table 12.

One interesting finding was that the expected count of Caucasian students was 4.8, yet the observed count was 2. Compared to Hispanic children, were the expected value was 7.5 and the observed was a count of 11. Clearly Hispanic children are purchasing more of this imported candy than expected, with the Caucasian children buying less. There was not any significant conclusion among the other races. African American children did mirror closer to the observed expected values. This issue could use further study to determine the factors that increase the risk from one group, verses another.

### Closing thoughts on project

The data reported within this thesis project indicates that the XRF can be used as a quick and effective tool for screening for lead in candy products and candy accessories. This new XRF protocol is thought to be user friendly, along with being very accurate when screening candies and candy accessories for lead.

The unique survey and candy collection protocol determined that BMS children are purchasing and eating candies that are known to contain lead. However, the procedures on how to effectively regulate these hazardous items have yet to be determined.

Valuable experiences were gained from this project. After the October GRAAS results returned from the FACA, the Southern Nevada Health (SNHD) district recognized

the need for a swift public health intervention. Using the results from this study, the SNHD set in motion a cease and desist order requiring that all tamarind and chili pepper type candies removed from approximately 1600 Clark County store shelves. This action was the first of its kind in both Nevada and the United States. Using the data reported herein as basis for a major public health intervention. This research was useful in the protection of Clark County families and community members. The protocol for the collection of candy consumption data can be a useful tool to other public health officials, using this approach as a framework to improve lead prevention in the public school or community setting.

One suggested direction this candy and survey collection protocol should take is to design and implement a CCSD district-wide candy collection, detailing the consumption patterns across the Las Vegas valley. This would not only help Nevada protect their children, but would ensure that these children would be free of the consequences of early lead exposure. These efforts translating into a healthier Nevada population and create healthier children, ready to learn without IQ and attention deficit barriers. These efforts are also in conjunction with allowing Nevada to stay aligned with the Goals of Healthy People 2010.

Society does not want children to be exposed to any level of harmful environmental toxicants. And when this type of risk can be found in a simple lollipop, there should be public outcry encouraging food safety regulations and corporate responsibility. If society can not trust manufactures to provide a food product free of lead, then what else might we be risking in other areas of our daily lives? In public health circles the mantra “prevention is the cure” is widely accepted truth. With the XRF

protocol in the hands of public health officials, large batches of potentially poisonous candy can be kept from the market place, serving to increase the quality of health across the nation.



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APPENDIX I

UNLV RESEARCH PROTOCOL PROPOSAL FORM

For Research Involving Human Subjects

**Evidence of CITI certification ([www.citiprogram.org](http://www.citiprogram.org)) must be submitted with this protocol proposal form.**

**1. Submittal Date:** 5/29/2005

**2. Duration of Study**

Anticipated Start Date: 9/09/2005

Anticipated Termination Date: 5/29/2006

NOTE: Research Studies may not begin until you have received notification of IRB approval. All research proposals are

Approved for a maximum of 1 year and can be re-reviewed at any time within that year at the discretion of the IRB.

**3. Research Protocol Title** (Research Protocol Title must match the funding/proposed funding application or proposal):

**4. Investigator(s) Contact Information**

*(One person must be designated as the PI. The PI must be a UNLV faculty or professional staff member in all cases involving studies carried out by students or fellows.)*

**A. Principal Investigator (Name and Credentials):** \_\_\_\_\_

Faculty     Faculty Advisor     Professional Staff

School/College/Center: \_\_\_\_\_

Department: \_\_\_\_\_

Mail Stop: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

**B. Student/Fellow Investigator (Name and Credentials):** \_\_\_\_\_

School/College/Center: \_\_\_\_\_

Department: \_\_\_\_\_

Mail Stop: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

*NOTE: All student/fellow initiated research must be submitted as an independent project with the Faculty Advisor listed as the Principal Investigator. The Faculty Advisor must sign the Faculty Advisor Assurance statement in Section 27B. The Student/Fellow Investigator must sign the Student/Fellow Investigator Assurance statement in Section 27C.*

**C. PLEASE COMPLETE ONLY IF APPLICABLE**

**Co-Principal Investigator (Name and Credentials):** \_\_\_\_\_

Faculty     Professional Staff

School/College/Center: \_\_\_\_\_

Department: \_\_\_\_\_

Mail Stop: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

**5. Authorized Personnel:** List all research team members who will be involved in this research project. This list will be updated yearly during periodic review unless there is a major change in personnel. Major changes in personnel (e.g. change of PI) must be reported on a Modification Form and the change must be noted on a revised Informed Consent Form.

NAME and DEPARTMENT	ROLE IN PROTOCOL	ROLE IN CONSENT PROCESS	SPECIFIC EXPERIENCE WITH ROLE IN PROTOCOL

**6. Project Site(s)** (Check all boxes indicating where the study is conducted.)

University of Nevada, Las Vegas (UNLV)

Maryland Campus (main)

Paradise Campus

Shadow Lane Campus

UNLV leased property. Explain:

Other: (Specify and Explain):



NOTE: If the project site is other than UNLV, Facility Authorization Letter must be submitted.

**7. Research Terms**

Provide up to three terms, keywords, or short phrases that describes the research to be performed using the guidelines below:

- 1. Research area (biomedical, social behavioral): \_\_\_\_\_
- 2. Study topic area (e.g., physical therapy, psychology): \_\_\_\_\_
- 3. Subject class (e.g., healthy adults, prisoners): \_\_\_\_\_

**8. Proposal Summary**

Summarize the proposed research project. The summary should be written in non-technical language that can be understood by non-scientific individuals. The summary must not exceed 200 words.

8.1 A brief statement of the research question (hypothesis) and related theory supporting the reason for the study.

\_\_\_\_\_

8.2 A brief description of the procedure(s) involving human subjects.

\_\_\_\_\_

**PLEASE NOTE: Complete description of the study procedure(s) must be specified in Section 26.**

**9. Number of Research Subjects**

Total number of subjects: \_\_\_\_\_

**10. Research Subject Classification**

10.1 Check all applicable boxes

- |  |                                    |
|--|------------------------------------|
| <input type="checkbox"/> UNLV Students (general student body)                | <input type="checkbox"/> Elderly   |
| <input type="checkbox"/> Student Subject Pool (Dept.): _____                 | <input type="checkbox"/> Prisoners |
| <input type="checkbox"/> Healthy Adults - Age range: _____                   | <input type="checkbox"/> Healthy   |
| <input checked="" type="checkbox"/> Minors (under age 18) - Age range: _____ | <input type="checkbox"/> Pregnant  |
- Subjects  
or Parolees  
Control Group  
Women

Clark County School District Students

UNLV

Employees

Cognitively or Psychologically Impaired (See consent form guidelines)

Institutionalized Residents

Non-English Speaking (Include consents in the appropriate language)

Other - Describe: \_\_\_\_\_

10.2 Summarize the inclusion and exclusion criteria that must be met in order for a person to participate in the study.

Inclusion: \_\_\_\_\_

Exclusion: \_\_\_\_\_

10.3  
Male  Female

What is the gender of subjects?

Both

10.4 Are there any enrollment restrictions based on gender, pregnancy or childbearing potential?

Yes  No

If yes, please explain the nature of the restriction(s) and provide justification.

\_\_\_\_\_

10.5 enrollment restrictions based on race or ethnic origins?

Are there any  
 Yes  No

If yes, please explain the nature of the restriction(s) and provide justification.

\_\_\_\_\_

## 11. Purpose of Study

## 12. Privacy and Confidentiality

*Privacy refers to a person's desire to control the access of others to themselves.*

*Privacy concerns people.*

*Confidentiality refers to the researcher's agreement with the subject about how the subject's identifiable private*

*information will be handled, managed, and disseminated. Confidentiality concerns data.*

12.1 What are the methods used to ensure confidentiality of participation and data obtained?

\_\_\_\_\_

12.2 What safeguards are used to protect against identifying, directly or indirectly, the subject involved in the study? \_\_\_\_\_

12.3 What safeguards are used to protect the information from disclosure?  
\_\_\_\_\_

12.4 What provisions exist for controls over access to data?  
\_\_\_\_\_

12.5 Are subjects asked to fill out any materials that are shared with other groups (e.g. voluntary health organizations, advocacy groups) that provide identifiers?  
 Yes  No  
If yes, describe: \_\_\_\_\_

12.6 Will the subjects' data be coded?  Yes  No  
If yes, how? \_\_\_\_\_

12.7 Will data generated be used for purposes other than this research project?  
 Yes  No  
If yes, how? \_\_\_\_\_

12.8 Where will the data be stored? \_\_\_\_\_

12.9 How long will the data be stored? \_\_\_\_\_

12.10 What are the plans for the final disposition or destruction of the data? \_\_\_\_\_

### 13. Recruitment Procedures

13.1 Describe below the processes used for selecting subjects and the methods of recruitment, including use of letters and/or advertising. Include, when, how and by whom the subjects will be recruited. Do not include inclusion and exclusion criteria which were already listed in Section 10.2.  
\_\_\_\_\_

13.2 Will subjects be recruited from one or more schools, community centers, organizations, trade groups etc.?  Yes  No  
If yes, please specify the source(s): \_\_\_\_\_

NOTE: Provide a Facility Authorization Letter from the performance site facility giving the PI permission to perform the study at that site.

13.3 Indicate the types of recruitment materials to be used below (check all that apply). Attach copies of all recruitment materials to this application.

Advertisements  Newsletters  Internet

Brochures       Radio       Contact letters (Physician Letters, Teacher Letters)

Flyers/Posters       Television       Other (Describe) \_\_\_\_\_

This research study will not be using any of the above information.

13.4      Will subjects be recruited from a non-public registry?       Yes       No

If yes, specify the source: \_\_\_\_\_

NOTE: Provide a letter from the director of the registry authorizing your access to the identifiable data for the purpose of this study. The letter needs to clearly describe how access to the identifiable information is ethically possible, (i.e. it confirms that subjects have given permission for contact and authorized the distribution of their names and address).

13.5      Are you studying pre-existing data? (e.g. academic records, medical records or specimens)       Yes       No

If yes, specify the source: \_\_\_\_\_

13.6      Do you or any member of the research team have an authoritative role (i.e. Instructor, Counselor, etc.) over the research subjects?       Yes       No

If yes, please explain: \_\_\_\_\_

**14. Research Activities (Part A)**

14.1 Please check any/all that apply to the proposed research study.

Collection of data is through **non-invasive procedures** routinely employed in clinical settings, excluding x-rays or microwaves (e.g., physical sensors that do not shock or invade the subject's privacy, weighing or testing sensory acuity, magnetic resonance imaging, EEG, EKG, moderate exercise or strength testing with healthy non-pregnant subjects).

Collection of data involves review of data, documents, records or specimens that were originally collected for non-research purposes (e.g., medical records).

Existing human biological specimens will be used.\*

Prospectively collected human biological specimens will be used.

\*\*

Indicate source and dates when the data were collected: \_\_\_\_\_

\* Specimens must be "on the shelf" at the time of the submission of the application.

\*\* Specimens will be collected after the study has started.

Collection of data is from audio or visual recordings.

Research activities involve observing individual or group characteristics when considering the subject's own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or behavior) or research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research.

Research activities involve medical devices that have been approved for marketing and are used as prescribed.

Identify device(s): \_\_\_\_\_

Blood samples are collected by finger stick or venipuncture only from non-pregnant healthy adults in amounts less than 550 ml in an eight-week period and no more than twice per week.

Provide a brief description of blood collection methods. \_\_\_\_\_

Prospective collection of biological specimens by non-invasive means (e.g., hair and nail clippings, extracted teeth, excreta and external secretions, uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at rupture of membrane prior to or during delivery, dental plaque and calculus, mucosal and skin cells collected by swab and sputum collected after saline mist nebulization).

None of the above categories apply to the proposed research study.

### 15. Research Activities (Part B)

15.1 Please check any/all that apply to the proposed research study

False or misleading information to subjects (deceptive studies)

Procedures for debriefing subjects: \_\_\_\_\_

Invasive biomedical procedures

Explain procedure: \_\_\_\_\_

Are provisions for medical care necessary?

Yes, please explain: \_\_\_\_\_

No, please explain: \_\_\_\_\_

Has a qualified UNLV affiliated Faculty Member participated in planning the study?

Yes, please identify by name and qualifying credential:

No

\_\_\_\_\_

sound, etc.?

Will the study involve drugs, radiation, lasers, high-intensity

Yes, please identify: \_\_\_\_\_

No

Sensitive questions will be asked about personal issues

The study involves use of potentially hazardous materials (Explain):

\_\_\_\_\_

The research includes collection/storage of data/biological specimens for future research analysis. If yes, the consent document must address the possibility of future use.

Procedures are novel or not accepted practice (if this category applies, explain in the Informed Consent Form how provisions are made to correct, treat or manage unexpected adverse effects)

Risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information or information creating legal vulnerability (if this category applies, explain in the *Informed Consent Forms* how harmful effects will be addressed and how benefits outweigh risks)

#### 15.2 Dissemination and Storage of Research Information

Will the research test results be provided to the research subject?  Yes

No

If yes, please explain: \_\_\_\_\_

Will the research be part of the subject's permanent record (e.g. medical)?

Yes

No

If yes, please explain: \_\_\_\_\_

15.3 Quantitative Design Elements (if applicable)

Describe the statistical procedures that will be used and specify the following:

Statistical design: \_\_\_\_\_

Dependent variables: \_\_\_\_\_

Independent variables: \_\_\_\_\_

**16. Medical Devices**

16.1 Are you using a medical device?  Yes  
 No

If no, then continue to section 17. If yes, please complete the answers below.

16.2 Is this a  
**SIGNIFICANT RISK (SR) or NON-SIGNIFICANT RISK (NSR) device?**  
 SR  NSR

16.3 Is this an  
**INVESTIGATIONAL MEDICAL DEVICE**  Yes  No

**APPROVED MEDICAL DEVICE FOR AN UNAPPROVED USE.**   
Yes  No

If yes, indicate DEVICE name: \_\_\_\_\_

IDE number: \_\_\_\_\_

Sponsor/Manufacturer: \_\_\_\_\_

NOTE: Please provide the investigator's brochure when using an investigational device.

**FDA APPROVED MEDICAL DEVICE FOR AN APPROVED USE:**  
 Yes  No

If yes, indicate DEVICE name: \_\_\_\_\_

Sponsor/Manufacturer: \_\_\_\_\_

NOTE: Please provide the package insert when using an approved device.

16.4 Is the IDE  
(Investigational Device Exemption) held by the sponsor or by the investigator?  
 Sponsor (Please forward copies of the annual report from the sponsor to the IRB.)  
 Investigator (Please provide a copy of the original IDE application and copies of the annual reports at the time of periodic review)

**17. Risks**

17.1 Summarize the nature and amount of risk (including side effects) or substantial stress or discomfort involved. \_\_\_\_\_

17.2 What are the potential risks/discomforts associated with each intervention or research procedure? \_\_\_\_\_

17.3 Estimate the probability that a given harm will occur, its severity, and its potential reversibility. \_\_\_\_\_

17.4 What procedure(s) will be utilized to prevent/minimize any potential risks or discomfort? Examples of risk include physical risks, psychological risks (such as substantial stress, discomfort, or invasion of privacy) and social risks (such as jeopardy to insurability or employability). \_\_\_\_\_

17.5 What is the overall risk classification of the research?

- Minimal     Greater than minimal     Significant  
 If unknown, please explain: \_\_\_\_\_

**18. Benefits**

18.1 Describe the probable benefits of the research for the individual subject(s).  
\_\_\_\_\_

18.2 Describe the probable benefits of the knowledge gained for society. Societal benefits generally refer to the advancement of scientific knowledge and/or possible benefit to future subjects.  
\_\_\_\_\_

**19. Risk-Benefit Ratio** (Explain how the potential benefits of the research outweigh the potential risks and how these risks are justified.)  
\_\_\_\_\_

**20. Cost to Subjects** (Do not include financial costs in this section. See Section 22)

20.1 Briefly describe the activity (i.e. laboratory testing, survey completion, travel time) that involves participation time: \_\_\_\_\_

20.2 Amount of participation time: \_\_\_\_\_ minutes per day for 1 day(s)

20.3 Describe any additional costs: \_\_\_\_\_

**21. Project Funding**



21.1 Funding Status:  Funded       Pending       None (go to section 22)  
*Note: If funded/pending funding, please submit a copy of the application or proposal.*

21.2 Funding Source:  
 Federal/State  
     NIH     NSF     NASA     BRIN     DOE        
Other: \_\_\_\_\_  
 UNLV Internal Grants  
     SITE     NIA     URA     ARI                        
Other: \_\_\_\_\_  
 Other: \_\_\_\_\_  
 Self-funded

21.3 Are there any other contributions or support (e.g. device, drugs, etc.) provided by a company/sponsor/granting agency?  
 Yes     No      If yes, explain: \_\_\_\_\_

21.4 Is any other type of contribution (aside from devices or monetary funds) being made by a company/sponsor/granting agency?  
 Yes     No      If yes, explain: \_\_\_\_\_

21.5 Has this project been submitted to the Office of Sponsored Projects (OSP)?  
 Yes     No      Submission date: \_\_\_\_\_  
If no, explain: \_\_\_\_\_

21.6 Sponsor: \_\_\_\_\_ Contract or Grant Number: \_\_\_\_\_

## 22. Financial Information

22.1 What are the financial costs involved (see sample form) as a result of participation in the research study. \_\_\_\_\_

22.2 Are there additional expenses for the subject related to this protocol?   
Yes     No  
If yes, please describe and include details in the Informed Consent Form. \_\_\_\_\_

22.3 Will subjects be paid or otherwise compensated for research participation?   
Yes     No

If yes, please respond to the following questions and include details in the Informed Consent Form:

- a) Describe the nature of any compensation to subjects. Include cash, gifts, travel reimbursements, etc. \_\_\_\_\_
- b) Provide a dollar amount, if applicable, and indicate cash or check.  
 Cash  
 Check
- c) When and how is the compensation provided to the subject? \_\_\_\_\_
- d) Schedule of payments: \_\_\_\_\_

**23. Consent**

*Refer to the UNLV Informed Consent Guidelines and Template to ensure that your submission follows the current standard consent format. Attach a copy of all consent form(s) and/or informational letter(s) used to describe the research study to potential subjects.*

*Note: Consent must be obtained from subjects prior to enrollment in the research study.*

23.1 Describe the consent process for enrolling subjects into this study. \_\_\_\_\_

23.2 Where will the consenting process take place? \_\_\_\_\_

23.3 Will there be an opportunity for the subject to take the consent form home to discuss their participation?

Yes  No If no, explain why. \_\_\_\_\_

23.4 What method(s) will be used to educate and increase the potential research subjects' knowledge of the research project and their rights as a subject? \_\_\_\_\_

23.5 What method(s) will be used to evaluate the understanding of the potential research subject's comprehension about the research project and their rights as a subject? *(Check all that apply)*

Verbal feedback of information

Pre and Post-test

Other (describe): \_\_\_\_\_

23.6 Please provide a numbered list of all consent forms used for this study listing the title and purpose of each document.

Title of Consent Form

Purpose

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_

*Readability: In an effort to assess that consent forms are not too difficult for potential subjects, investigators are requested to perform a readability measure on the consent form. Information about readability scores is available in the Microsoft Word Application Help Topics. Most consent forms should be written at the 8<sup>th</sup> grade reading level.*

23.7 Debriefing: If the study includes a debriefing script or information given to subjects, please attach with the submission.

Is a debriefing script necessary?     Yes     No

23.8                      Is a waiver of documentation of informed consent or waiver of informed consent appropriate for this study?                       Yes     No

No

(If you believe that a waiver of consent is appropriate for this study please submit the Waiver of Documentation of Consent or the Waiver of Informed Consent Form.)

**24. Conflict of Interest (COI)**

Conflict of interest refers to any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual's professional judgment in designing, conducting, analyzing, or reporting research.

Does a conflict of interest exist with this study?

Yes     No

(If yes, complete the COI Form)

**25. Project Enclosures** (Check all appropriate boxes and include the items with the Proposal Form)

- |   |  |
|---|--|
| <input type="checkbox"/> Informed Consent Form(s) | <input type="checkbox"/> Grant/Contract                |
| Application/Proposal                              |  |
| <input type="checkbox"/> Child/Youth Assent Form  | <input type="checkbox"/> Facility Authorization Letter |

<input type="checkbox"/> Debriefing Script (Surveys, Questionnaires, etc.)	<input type="checkbox"/> Research Instruments
<input type="checkbox"/> Waiver of Documentation of Consent Web postings, letters, etc.)	<input type="checkbox"/> Recruitment Information (Ads,
<input type="checkbox"/> Waiver of Informed Consent	<input type="checkbox"/> Other items: _____

**26. Complete Description of the Study Procedures**

\_\_\_\_\_

**27. Investigator/Faculty Advisor/Student/Fellow Assurance**

**A. Investigator's Assurance:**

I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.
- Not changing the approved protocol or consent form with out prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to OPRS in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

Principal Investigator's Name

Principal Investigator's Signature

\_\_\_\_\_  
Co-Principal Investigator's Name

\_\_\_\_\_  
Co-Principal Investigator's Signature

**B. Faculty Advisor Assurance: (if applicable)**

By my signature as advisor on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.
- I assure that the student/fellow investigator will promptly report adverse events to OPRS according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.

\_\_\_\_\_  
Faculty Advisor's Name

\_\_\_\_\_  
Faculty Advisor's Signature

(The faculty advisor must be a member of UNLV faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.)

**C. Student/Fellow Investigator Assurance: (if applicable)**

By my signature as Student/Fellow Investigator on this research application, I certify that I am knowledgeable about the regulations and policies governing research with human subjects and agree to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to meet with my faculty advisor on a regular basis to discuss the progress of the study.
- I agree to meet with my faculty advisor to solve protocol issues, as they arise.
- I will promptly report adverse events to OPRS and my faculty advisor according to IRB guidelines.

\_\_\_\_\_  
Student/Fellow Investigator Name

\_\_\_\_\_  
Student/Fellow Investigator Signature

## APPENDIX II

### DESCRIPTION OF CANDY COLLECTION PROTOCOL METHODS

#### Parents/open house night speech

Below is the speech that I gave after the conclusion of the open house activities. Parents were encouraged at the beginning of the open house program to return to the gym after the planned proceedings had concluded. I arranged for our Spanish translator to be available to interpret, as some of the target population might not have the ability to understand the message in English. Will Townsend had made available a SNHD lead poisoning prevention flyer.

Hello my name is Tracy Donnelly. I teach health education here at Brinley Middle School. As you might know we are very privileged to have a principal here at Brinley that is concerned not only about creating an environment that supports our students' efforts to achieve a high level of success. Mrs. Gibson along with other members of the staff are also concerned about the over all health and well being of our students and their families. The FDA has issued a warning concerning children eating candies that contain lead. Mrs. Gibson and I are now working to promote an awareness campaign to stop children from being exposed to lead. As part of our campaign I would like to share with you some of the highlights concerning lead contamination in candy. The potential for children to be exposed to lead from imported candy from Mexico, Brazil and other Countries has

prompted the U.S. Food and Drug Administration to issue warnings on the availability of lead-contaminated candy. Certain candy ingredients such as chili powder and tamarind may be a source of lead exposure. But preliminary studies have shown that imported candies other than the tamarind or chili pepper also contain lead. Lead sometimes gets into the candy when processes such as drying, storing, and grinding the ingredients are done improperly. Also, lead has been found in the wrappers, straws or spoons of some imported candies. The ink of these plastic or paper wrappers may contain lead that leaches into the candy. People selling these items may not know whether the candy contains lead. And you cannot tell by just looking at or tasting the candy. For a confirmation of lead content it must be sent to a lab and tested. Lead poisoning from candies can cause illness. Consuming even small amounts of lead can be harmful. When too much lead accumulates in the body, this process generally occurs slowly, it results in a gradual build up in bone and tissue after repeated exposure to the lead source. It is important to note that children absorb lead far more easily and quickly than adults, with children under the age of three being at greatest risk. You most likely are wondering what happens when lead gets into the body of children? Symptoms of lead poisoning are: Anemia, abdominal pain constipation, decreased appetite, diarrhea, learning problems, lowered IQ sleeplessness, tiredness, vomiting, and sometimes kids are symptom free. Most adults and children with elevated blood lead levels do not have any symptoms. As blood lead levels increase so does lead's effects on health. What can you do if you believe you or your child may have eaten candies that contain lead? See your health care provider. He or she can

perform a blood test to see whether you or your child has been exposed to lead, and if so, recommend treatment options. The FDA advises that parents, care providers, and others not allow children or pregnant women to eat candy imported from Mexico at this time. Finally this Friday at lunch there will be a candy collection project. The candies do not need to be on the toxic treat list, but the focus is on imported candies. For each piece of candy donated your child will receive a raffle ticket. This project is completely voluntary and you are not required to participate. If the student does not have any candy to donate- they can come up to the table and answer a few questions (where might you buy this candy- how often do you eat it). When both lunches are done we will draw for 5 prize packages, which include 4 all day passes for the adventure dome at Circus Circus. We will be giving this candy to The UNLV School of Public Health. They plan to test each candy item. This research team will then start working to build a complete list of candies which can be purchased locally, that contain lead. As well as creating a model of what type of candies Clark county children are actually eating. In the letter that was sent home it may have appeared that UNLV will actually be involved in the candy collection process. Please note their role is in the testing of candy once it has been collected. California conducted a similar study and tested many of the same types of candies shown on the screen along with other imported candies. Mr. Townsend- from SNHD and Dr. Shaw Gerstenberger the head Lead Analyzer from the UNLV School of Public health, along with myself are available for any questions. Thank you for your time.



### Week long morning announcement schedule

Announcements were given each morning from September 26- 30<sup>th</sup> 2005. The following details what was read each morning, this educational program reaching all classrooms for entire school population of approximately 1200 students'.

On Monday September 26<sup>th</sup> 2005 this was the announcement read over the school intercom.

Eat Healthy, Stay away from junk food. I know that you hear that statement all the time from the adults in your lives. Most teens turn their ears off when they hear someone say eat healthy. Did you ever think that maybe there is a reason you keep hearing that message from a variety people in your life. Maybe they know that making healthy choices will help you in all parts of your life. Have you ever heard the phrase- you are what you eat? What that means is that the food you put into your body is the fuel that runs your cells. If you eat junk food, your body can only use that food to run all your body systems (breathing, heart beating, learning). I am sure you have felt tired and sluggish a little while after you have eaten some candy. I am sure you have felt energized or more alert after you have made healthy food choices. Today take a little time and notice how you feel after you have eaten. Do you still feel full of energy about an hour after you eat or are you tired and want to take a nap? Tomorrow we are going to talk about candy. Have a great day and healthy eating to you.

Tuesday September 27, 2005 this was the announcement read over the school intercom.

Candy- Candy- Candy. I know that most teens love candy. Even adults have their favorite candy. I love peanut butter M&M's. There is nothing wrong with eating

like this once in awhile, but often teens think that a watermelon jolly rancher counts for a daily serving of fruit. Fact is – candy is just a quick fuel that burns fast and leaves you tired and craving more. Now we have another reason to be worried about candy. Scientists have found that some imported candy- that means the candy comes from other countries, like Thailand, Brazil and Mexico- actually contain a non- food product called lead. Since lead is not usually found in food, we are concerned as to what the lead will actually do to the health of the people that unknowingly eat it. What makes matters worse is that you can't tell that your candy has lead in it. It looks like a regular piece of candy. The only way to tell is if you send it to a lab and they test for lead. Much of the candies that contain tamarind and chili peppers are on the list of candies you should avoid. If you want to look at the posters (Toxic Treat posters) hanging in the cafeteria for a list of candies that might contain lead, you will have a better idea of some of the candies that are a health risk. Tomorrow we are going to talk about why lead is not healthy for people to eat. Have a great day and healthy eating to you.

Wednesday September 28 this was the announcement read over the school intercom.

What can eating lead contaminated candy do to healthy bodies? Lead can cause headaches, stomachaches, and problems concentrating at school, along with feeling extra tired. If you eat a lot of lead it can make you very sick. Don't panic if you have eaten some of the candies that might contain lead. You are not going to all of sudden get sick. Instead of focusing on what you have eaten, switch gears and start thinking about what you are going to eat. Going back to Monday when we talked about choosing healthy snacks, here is another reason that choosing a

handful of pretzels or an apple or orange is a better idea than a piece of candy when you are hungry.

Thursday September 29<sup>th</sup> this was the announcement read over the school intercom.

Did you make healthy food choices this morning? How about yesterday? I know it is hard to change overnight, but little by little if you reach for a handful of grapes instead of a grape sucker or eat a peanut butter and jelly sandwich instead of a bag of Doritos, you will begin to notice that you feel healthier. Today during 7<sup>th</sup> period we are going to hand out a flyer. This explains that On Friday -UNLV is going to have a team of scientists here to help collect any type of imported candy you want to donate. They are going to take the candy back to their lab and test it. They hope to make a list of all the candies that have lead in them. But they need your help. On Friday, at lunch you can give any type of candy that you want to donate to the researchers. For each piece of candy you donate you will receive a raffle ticket. Each ticket will enter you into a drawing for 4 all day passes to the adventure dome. If you don't have any candy to donate, you can fill out a questionnaire and get a ticket for that as well. You do not have to participate in the activity. This is completely voluntary. This means that you choose- if you want to participate- or you can choose not to participate. Go home tonight and show your parents the flyer, and pack in your school bag any candies that you would like to donate to the study. Bring them to school, put them in your locker until lunch, at lunch you can go to your locker and get them, then you can walk up to the table and hand the researchers your candy. Again this is voluntary- you do not have to participate in this study. Your participation in this project will be

helping this group of researchers' help children all over the valley and the world. So you can take pride helping the planet. Have a great day and healthy eating to you.

Friday September 30<sup>th</sup> this was the announcement read over the school intercom.

Today is the day that we will collect any candy that you have. At lunch you can quickly go to your locker. Then come up to the collection table in the cafeteria. For each piece of candy that you donate you will get a raffle ticket, this will enter you into the drawing and you might be the winner of four all day passes to the Circus -Circus Adventure Dome. Remember that this is voluntary- you do not have to participate. If you choose to participate- at lunch bring up your candy to the collection table in the cafeteria. This is the only time you can donate your candy. They will take your candy, ask you a few questions and give you your raffle tickets. Then wait for the 7<sup>th</sup> hour announcement for the prize winners. If you have any questions this year about what candy might have lead in it, you can always stop by room 304 and Mrs. Donnelly will be happy to talk with you.

Thanks again, for your help. Have a great day and healthy eating to you.

#### Design of candy collection

At lunch, on the day of the collection the custodians set up three long tables. Four chairs for the candy collectors, which were four UNLV graduate assistant students (GA). There were signs at each GA station stating: "Donating your candy and answering the survey questions is completely voluntary- you are not required to participate."

At each station the GA had a large pile of surveys, pencils, collection sacs, rubber bands to close sample, raffle tickets. The students' stood in- line and waited until a

collection station was open. They brought up their candy, the GA collected the candy and while she counted items, the student filled out the survey. Before the student began this process the GA they stated: "any questions you do not feel comfortable answering feel free to leave blank. If you do not want to answer any portion of the survey- but would like to donate the candy, this is acceptable also". The GA then counted the candy, when the student was done the GA collected the survey and put this along with the candy into a collection bag. Using a rubber band to close the sample, the GA then handed the student a raffle ticket for each candy item donated or one ticket for a survey. The student put their student number or name on each ticket and placed ticket in the collection box. If the student did not have any candy to donate they waited until a collection station was available, filled out the survey and was given one raffle ticket to place in the box after they put their student number on ticket. This survey was put into the file for surveys only. This procedure was followed for the duration of each 27 minutes lunch period. The Dean of Students had a microphone, and announced a student reminder of procedure, to encourage students to participate if they would like too. At the end of the second collection session, the GA's cleanup, helped to pack all candy samples and surveys into large moving boxes. The middle school donated these candy sample boxes to UNLV and they were taken back to the UNLV Lead lab for analysis. Four tickets were drawn from the ticket collection box, and the student numbers were announced at the end of seventh hour over the school intercom. These students were given four raffle tickets to the local Circus- Circus Adventure Dome theme park to use at their leisure. All other raffle tickets were thrown away in the school trash.

APPENDIX III

STUDENT SURVEY

Date 9/30/05

School: Brinley 433

Taken by: Heather Tracy Eleana

**Circle the correct answer to each question.**

1. Male Female  
2. **Your Age** 7 8 9 10 11 12 13 14 15 16

3. **Ethnicity (circle one)**

- African-American/ Black
- Asian
- American Indian
- Alaskan Native
- Caucasian
- Hispanic
- Pacific Islander
- Choose not to respond

4. **Circle the name that best matches the places you get Mexican candy. (circle all that apply)**

- a. Parents.
- b. Family or friends/and or Party.
- c Mexico Trip.
- d. AM/PM store or other convenience store/ Gas station.
- e. Mall.
- f. Grocery store.
- g. Mexican or Asian grocery store.
- h. Other/ or I don't buy this type of candy.

5. **How often do you eat this type of candy? (circle one)**

- Everyday
- 2-4 Times a week.
- 5-7 Times a week-
- 2-4 Times a month
- 5 or more times a month
- Once every other month
- Once or twice a year
- Rarely

APPENDIX IV

DESCRIPTION OF XRF TESTING PROTOCOL METHODS

Example of data sheet for XRF testing

XRF AND ATOMIC ABSORPTION DATA SHEET.

Test date	Candy ID#	Candy Name	Candy Type	Candy Description	Date and Place Purchased
10/1/05	103-0331	None	Tamarind plastic pot	Tamarind jelly in a plastic pot	Jasmin's

Manufacturer	Manufacturer location	lot #	Distributor	Distributor Location	English/Spanish
None	None	None	None	None	english

Sample #	XRF ug/cm2	GRAAS mg/kg	Report limit	XRF ug/cm2	GRAAS mg/kg	Report limit	mg/kg	GRAAS mg/kg	Report limit
	plastic container	plastic container		spoon	spoon		candy/bulk	candy/bulk	
1	21.7	0.4	0.3	54.83	2	1	0	<0.2	0.2
2	26.88	0.5	0.3	0	<0.2	0.2	0	<0.2	0.2
3	21.93	0.5	0.3	64.55	1.9	0.9	0	<0.2	0.2
4	21.29	0.5	0.2				0	<0.2	0.2
5	21.6	0.5	0.2	78.09	4	1	0	<0.2	0.2
6	23.95	0.5	0.2	0	<0.2	0.2	0	<0.2	0.2
7	20.58	0.6	0.2	0	<0.2	0.2	0	<0.2	0.2
8	19.01	0.4	0.3				0	<0.2	0.2
9	positive hit	1.1	0.2				0	<0.2	0.2
10	21.53	0.5	0.3	20.36	0.6	0.2	0	<0.4	0.4

### UNLV lead lab candy log in protocol and XRF candy testing instructions

Put on your dosimeter. Get XRF out of locked cabinet. Open box and attach battery turn on XRF and log in (use stylus for best results). Let the system calibrate. It will run through the spectra and cool down. This can take up to 10 minutes or longer. While it is cooling down, turn on other computer pull up data log in sheets. Find the data log in sheet that matches your batch log in number. Open this spreadsheet and have it sitting on desk top for use when running samples. Connect XRF to fire wire cord and connecting to computer. From the start menu open up on screen data icon

### Thin layer protocol

Run the testing standards as detailed in Niton instructions: Run bulk standards (blank- medium-high) Access the mode menu by selecting the mode icon from the main menu screen. Select bulk mode. You will need to change the testing time to 60 second, by accessing the utilities menu and selecting the utilities icon from the main menu screen. The utilities menu enables you to view instrument specifications, select the time screen and change testing time parameters When complete, select the blank soil standards cup and place in soil testing stand drawer close drawer. Run each standard (blank, medium, high) three times to ensure that the XRF is running within acceptable limits. Next run the paint standards, switching the mode to standard paint, via the main menu screen. Run the three standards on the left of paint standards sheet, three times each to ensure they are within acceptable range limits. Finally run the thin film standards, looping through the main menu to change testing mode. Working in this fashion is the most effective as this is the most frequent mode used to test the candy. Run each standard three times ensuring that the XRF is testing within the acceptable range limit. You will need to loop back



through the main menu and into the utilities menu and change the time from 60 seconds to 30 seconds. You are now ready to run your candy samples in thin film mode- using the film stand. When testing bulk items see bulk items directions- First you must enter candy identification data into the XRF data screen. To access the data menu, select the data icon from the main menu display, enter data into each section using the computer keyboard. Also as a cross data reference technique you will enter all the candy data into computer spreadsheet.

You are now ready to put your test sample onto thin film stand. When the XRF is set up according to the protocol for the specific candy type, open the shutter by clicking the stop light icon. The XRF will take reading for 30 seconds as long as that is what you set it for. It shut its self off after 30 seconds, if you have to stop it for any reason just click stop sign icon again. When done record results on spreadsheet log, found on other computer, do this before you move to the next piece of candy. This reading will also be automatically recorded and saved in the XRF. The separate spreadsheet acts as a quick data reference and another back up method.

Begin with a new sample and repeat above steps for items starting after the instructions on how to run standards. Every four hours run all your standards again to ensure accuracy also run standards when you are ready to end the testing for the day. Run in reverse - thin- paint- bulk. The XRF remembers the last time you had it set and it will be ready to start on bulk setting next testing session. When standards are run, shut testing screen. But keep the XRF connected to computer. Open up the icon that says NDT (Niton Data Transfer). Then download your sample data. You can select from list the items you did today or all items if you need too. If you do not select your items it will down load all

data in the XRF. Save this downloaded information to the blue pin drive on computer top and send to Dr. Gerstenberger via lotus notes. Important note: when the XRF data is full- someone will need to reset to zero- this should be done approximately every 2000 samples, usually Dr. Gerstenberger will do this to ensure back up safety. Finally turn off the XRF remove the battery and plug into charger. Place XRF and standards in case and lock this case and then lock up box in cabinet.

#### Bulk sample mode

When candy is thicker than  $\frac{3}{4}$  inch use the bulk sample mode. Start up XRF and run the standards the same as detailed in thin layer protocol. The only difference is that you can run standards so that bulk is the last standard run. The XRF will be ready to run in bulk, mode if done this way, if not remember to change the time to 60 seconds. You will need to have your sample cups prepared or you can prepare on the spot. Enter data into XRF and computer spreadsheet as detailed in thin layer mode. Place candy in soil cup and then the cup into bulk stand. Start test by selecting the stop light icon. XRF will run for time specified as long as proximity sensor is depressed (when the drawer is closed properly it automatically is depressed). If you get a message that it not depressed. Open drawer and reposition the cup and try shutting the drawer better. This drawer is tricky- just be patient it will work when you get it positioned properly. Put your test results into the spreadsheet. Follow regular shutdown procedures.

#### Data entry protocol

Take a picture of candy with digital camera. Use photo number as number for identification Use these screen photo numbers as this candies identification log in number. Fill out information on the data information master data sheet as thoroughly as

possible, as this information is very important. Save the data with this log in data on the computer use current date when saving document, saving on pin drive, when you are done with testing print out your data sheets put in binder.

Parting out candy for testing

Use the following symbols for parting out candy the candy.

C=Candy Strw= Straw Stk= Stick W= Wrapper Spn= spoon Cntr= container/jar

Using whirl packs® write candy id number on the whirl packs® then part out candy (candy, wrapper, accessory). Write on the whirl pack® the candy identification number and symbol for that specific part of candy. Rubber band these whirl packs together if possible. Repeat this process for the entire bag or sample size of candy.

These directions are very specific to the UNLV lead lab. I have included these details as a courtesy for others who are setting up a lead lab, hoping this will help others develop a system for their specific lab needs.

## APPENDIX V

### RAW CONDENSED SURVEY CONSUMPTION DATA

**Sample Codes Key:**

- A. Sample numbers column: S= candy sample and survey, NC= only survey no candy.
- B. Student gender column: F= female and M= male. If cell is empty this response was not answered.
- C. Student age column: Ages ranges from 11-14.
- D. Condensed race column: 1= African American, 2= Caucasian, 3= Hispanic, 4=Asian, Pacific Islander, Native Indian or Pacific Islander, 5= choose not to respond or left blank.
- E. Eating patterns column: 1= every day 2= 2-7 times a week 3= 2-5 times a month 4= once every other month or one or twice a year or rarely 5=never
- F. Found on California toxic treat list: N= no the candy was not on list. Y=yes candy sample was found on list.

Sample Number	Students' Gender	Students' Age	Condensed Race Categories	Eating Patterns	Found on the California Toxic Treat List
NC123	F	12	1	1	
S10	F	12	1	1	N
NC148	F	12	1	1	
S20	M	13	1	2	Y
NC145	M	12	1	2	

NC20	F	11	1	2	
S11	F		1	2	N
S21		13	1	2	N
NC69	M	13	1	2	
S18	M	13	1	2	Y
NC133	F	12	1	2	
S32	M	12	1	2	N
NC84	F	13	1	2	
NC17	M	11	1	2	
NC8	F	12	1	2	
NC131	F	13	1	3	
NC140	F	12	1	3	
S36	F	13	1	3	Y
NC27	M	12	1	3	
NC130	F	13	1	3	
NC135	F	13	1	3	
NC66	M	13	1	4	
NC12	M	12	1	4	
NC117	F	12	1	4	
NC19	F	13	1	4	
NC73	F	12	1	4	
NC26	F	11	1	4	
NC116	F	12	1	4	
S9	F	13	1	4	Y
S28	F	13	1	4	N
NC1	F	13	1	4	
NC68	F	12	1	4	
S37	M	11	1	4	N
NC134	F	12	1	4	
NC153	F	12	1	4	
S4	F	12	1	4	N
NC118	F	12	1	4	
NC15	F	12	1	4	
NC60	F	13	1	4	
NC86	F	14	1	4	
NC119	F	12	1	4	
NC154	M	12	1	4	
NC36	F	13	1	4	
NC42	M	13	1	4	
NC70	M	12	1	4	
S27	F	12	1	4	N
NC82	F	11	1	4	
NC75	F	12	1	5	
NC107	F	13	1	5	
NC28	M	12	1	5	
S5	M	14	1	5	Y
NC64	M	12	1	5	
NC92	M	12	1	5	
S13	F	13	2	1	N
NC7	F	12	2	2	
NC122	M	13	2	2	

NC129	F	12	2	2	
NC150	F	12	2	2	
S22	F	13	2	2	N
NC72	M	12	2	2	
NC30	M	12	2	2	
NC77	F	13	2	2	
NC21	F	13	2	2	
NC18	F	12	2	2	
NC2	F	12	2	3	
S6	F	13	2	3	Y
NC125	F	12	2	3	
S8	M	13	2	4	N
S38	F	13	2	4	N
NC127	F	12	2	4	
NC139	F	12	2	4	
NC141	F	12	2	4	
S3	F	12	2	4	N
NC6	M	12	2	4	
S41	F	13	2	4	N
NC61	F	13	2	4	
S44	F	11	2	4	Y
NC29	M	12	2	4	
NC38	M	12	2	4	
NC59	F	12	2	4	
S24	M	11	2	4	N
NC50	F	13	2	5	
NC132	F	12	2	5	
NC16	M	13	2	5	
NC128	F	12	3	1	
NC149	F	12	3	1	
NC71	F	13	3	1	
NC144	M	14	3	1	
NC23	F	12	3	1	
NC146	F	12	3	1	
NC44	M	11	3	2	
NC48	F	11	3	2	
NC51	F	11	3	2	
NC74	F	12	3	2	
NC76	F	12	3	2	
NC89	F	12	3	2	
NC90	F	12	3	2	
S39	F	11	3	2	Y
NC65	F	13	3	2	
S31	M	12	3	2	Y
NC64	F	12	3	2	
NC155	M	11	3	2	
S16	F	14	3	2	Y
NC39	F	12	3	3	
NC142	F	13	3	3	
S35	F	13	3	3	Y
NC24	M	11	3	3	

NC3	M	13	3	3	
NC99	F	12	3	3	
NC35	M	11	3	3	
NC103	M	12	3	3	
NC115	F	12	3	3	
NC37	F	11	3	3	
NC47	F	11	3	4	
NC105	F	11	3	4	
S25	F	14	3	4	N
NC33	F	13	3	4	
NC75	M	11	3	4	
NC5		13	3	4	
NC143	F	13	3	4	
NC56	M	11	3	4	
NC121	F	12	3	4	
NC109		13	3	4	
NC34	F	13	3	4	
NC104	M	14	3	4	
S46	M	11	3	4	N
NC79	M	12	3	4	
NC25	M	11	3	4	
NC52	M	11	3	4	
NC102	F	12	3	4	
S26	M	12	3	4	Y
NC9	M	12	3	4	
NC45	M	11	3	4	
NC101		12	3	4	
NC124	M	12	3	4	
NC147	M	13	3	4	
S7	M	13	3	4	Y
S15	M	13	3	4	N
S43	F	13	3	4	Y
NC113	M	12	3	4	
NC80	M	12	3	4	
S19	M	12	3	4	Y
NC10	M	13	3	4	
NC54	F	11	3	4	
NC151	F	11	3	4	
NC83	M	12	3	4	
NC100	M	12	3	4	
S29	M	11	3	4	Y
S45	F	14	3	5	Y
NC14	F	12	3	5	
NC53	M	12	3	5	
S1	M	11	3	5	Y
NC67	F	14	4	1	
NC126	F	12	4	2	
NC58	M	13	4	3	
NC94	M	14	4	3	
NC152	F		4	3	
NC63	F	12	4	3	

S40	F	13	4	3	Y
NC4	F	13	4	4	
NC55	F	11	4	4	
NC46	F	11	4	4	
NC120	F	12	4	4	
NC96	F	11	4	4	
S30	F	11	4	4	Y
NC136		13	4	4	
S14	M	14	4	4	Y
NC11	M	13	4	4	
NC32	M	12	4	4	
NC31	F	11	4	5	
NC49	F	12	4	5	
NC110	M	12	4	5	
NC138	M	11	5	1	
NC88	F	13	5	1	
NC112	F	12	5	1	
NC57	M	11	5	1	
S33	F	12	5	2	N
NC95	M	12	5	2	
NC93	M	12	5	2	
NC111		12	5	2	
NC137	F	13	5	2	
S34	M	13	5	2	N
NC22	M	12	5	2	
NC85	F	13	5	2	
NC106	M	11	5	3	
S17	M	12	5	3	N
NC97	F	13	5	3	
NC114	M	13	5	4	
NC81	M	13	5	4	
S23	F	12	5	4	N
NC43	F	11	5	4	
NC13	M	13	5	4	
NC91		13	5	4	
NC40	F	11	5	4	
S2	M	11	5	4	Y
S12	F	12	5	4	N
NC41	F	11	5	4	
NC108	F	13	5	4	
S42	F	13	5	4	Y
NC87	F	13	5	5	
NC62	F	11	5	5	
NC98	M	11	5	5	



APPENDIX VI

LETTER HOME TO PARENTS

J. Harold Brinley Middle School  
2480 Maverick Street  
Las Vegas, Nevada 89108

Telephone (702) 799-4550

Fax (702) 799-4549

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Rosalind Gibson, Principal

Jason Zona, Assistant Principal

Chris Hermes, Dean of Students

Dear Parents,

September 29, 2005

Currently, in Clark County, some of the candies that are available for purchase have been found to contain the metal, lead. This metal is not normally found in food and can cause lead poisoning in both children and adults. The University of Nevada, Las Vegas is working on a public health study of Lead in Candies. This project has a number of goals, of which one is to understand what types of candies children are currently eating, how often they are eating the different types of candies and finally, which of these candies actually contain lead.

The UNLV School of Public Health research team will be on campus the evening of open house. When the activities of the night have ended, UNLV will offer a short presentation on the issues surrounding lead found in candies along with the effects of lead on children. The research team will return to campus during lunch on September 30, 2005. They will be collecting any candy that you and your child would like to donate, to their Lead in Candy Research Project. For each piece of candy donated students will receive a raffle ticket and be entered into a drawing for four all day passes to the Circus Circus Adventure Dome. If students do not wish to donate candy for this Research Project, they will receive a raffle ticket for filling out a candy survey.

When the team is done with this collection, the candy will be taken back to the laboratory and tested for lead contamination. The results will be published at a later date. We appreciate your effort in helping our school community prevent lead poisoning and in educating our students on the effects from lead tainted candies.

Sincerely Rosalind Gibson Brinley Middle School Principal

VITA

Graduate College  
University of Nevada, Las Vegas

Tracy L. Donnelly

Local Address:

8273 Gulf Star Lane East Flamingo Road  
Las Vegas, Nevada 89147

Degree:

Bachelor of Science, Athletic Training, Health Education.  
Southern Oregon State University

Special Honors and Awards:

UNLV Lead Prevention Award 2007

Thesis Examination Committee:

Chairperson Dr. Shawn Gerstenberger, Ph.D.  
Committee Member, Dr. Chad Cross, Ph.D.  
Committee Member, Dr. Michelle Chino, Ph.D.  
Graduate Faculty Representative, Dr. Timothy Farnham, Ph.D.