RCRA INSPECTIONS & ENFORCEMENT AT COMMERCIAL LABS

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WHAT ARE COMMERCIAL LABS?

LABORATORY TYPES - MOST LABS ARE SPECIFIC TO AN INDUSTRY (E.G. PHARMACEUTICAL, CHEMICAL), OR TO AN ACTIVITY (E.G. SMALL VOLUME MANUFACTURE OF HIGH POTENT PRODUCTS, WORK WITH BIOLOGICAL AGENTS).

ANALYTICAL AND QUALITY LABORATORIES - PRODUCTS AND MATERIALS ARE TESTED AGAINST CONFORMITY TO SPECIFICATIONS AND THE ABSENCE OF IMPURITIES. THESE LABORATORIES FORM AN ESSENTIAL COMPONENT WITHIN THE PRODUCTION AND THE SUPPLY CHAIN.

BIOSAFETY LABORATORIES - INVOLVE THE CONTAINMENT OF POTENTIALLY HARMFUL BIOLOGICAL AGENTS. THE CONTAINMENT IS ACHIEVED THROUGH A THOUGHTFUL COMBINATION OF METHODS, FACILITIES AND EQUIPMENT. THE LEVELS OF CONTAINMENT GO FROM BSL1 TO THE HIGHEST LEVEL OF BSL4.

CLEANROOMS – CONTROL THE NUMBER OF DUST PARTICLES PERMITTED PER VOLUME OF AIR DEFINES THE CLASSIFICATION OF THE CLEAN ROOM.

CLINICAL AND MEDICAL LABORATORIES - THESE LABORATORIES ARE EQUIPPED FOR DIAGNOSTIC TESTS ON TISSUE, BLOOD AND OTHER PATIENT SAMPLES. THEY CAN BE SUBDIVIDED INTO VARIOUS PROCESSES SUCH AS PATHOLOGY, SEROLOGY, HISTOLOGY, VIROLOGY, BACTERIOLOGY AND MOLECULAR BIOLOGY.

INCUBATOR LABORATORIES - LABORATORIES CONDUCTING MICROBIOLOGICAL, AND CELL OR TISSUE CULTURE WORK REQUIRE INCUBATORS TO PROTECT THESE CULTURES FROM THE ENVIRONMENT.

PRODUCTION LABORATORIES - PILOT PRODUCTION OR SMALL VOLUME LABORATORIES AS A SCALE-UP BETWEEN R&D AND COMMERCIAL PRODUCTION, OR FOR THE PRODUCTION FOR CLINICAL TRIALS, FORM A CATEGORY ON THEIR OWN. SUCH LABORATORIES CAN BE FOUND IN THE PHARMACEUTICAL, BIOTECH, AND THE SCIENCE AND TECHNOLOGY SECTORS.

RESEARCH & DEVELOPMENT (R&D) LABORATORIES - THIS CATEGORY COVERS A BROAD SPECTRUM OF LABORATORIES DEPENDENT ON THE INDUSTRY BEING SUPPORTED



WHAT DOES THIS TELL YOU?

JUST AS THERE ARE NUMEROUS TYPES OF LABORATORIES OUT THERE, THIS ALSO MEANS THERE ARE NUMEROUS TYPES OF RAW MATERIALS / CHEMICALS BEING USED IN THESE LABS.

THIS DIRECTLY CORRESPONDS WITH THE VARIOUS TYPES OF HAZARDOUS & NON-HAZARDOUS WASTE STREAMS THAT COULD EVENTUALLY BE GENERATED INSIDE OF A LABORATORY AS WELL.

AGAIN, PROBABLY ONE OF THE MOST UNIQUE ASPECTS OF OPERATING A LABORATORY – THE LARGE POSSIBLE VARIETY OF RAW MATERIALS BEING UTILIZED AND WASTE STREAMS BEING GENERATED.

THE RCRA RULES APPLY TO EVERYONE IN THE SAME MANNER, BASED UPON THEIR GENERATOR STATUS – VSQG, SQG, LQG AND EVEN TSDF'S!

BUT LIKE IN ANY RCRA INSPECTION BEING PERFORMED, IMPORTANT TO ASK THE LAB:

- a) WHAT TYPE OF LABORATORY WORK THEY PERFORM,
- b) WHAT HAZARDOUS WASTES DO THEY GENERATE, AND
- c) FROM WHAT PROCESSES/PROCEDURES/ANALYTICAL WORK BEING PERFORMED IN THE LAB, ARE THE WASTE STREAMS BEING GENERATED

THIS WILL GIVE YOU AN IDEA OF WHAT HAZARDOUS WASTES (ACUTE OR NON-ACUTE)
WILL BE ROUTINELY GENERATED ONSITE, AND HOW MANY SATELLITE ACCUMULATION
CONTAINERS TO POSSIBLY EXPECT TO BE SEEN DURING THE FACILITY TOUR.

ANOTHER IMPORTANT ASPECT TO CONSIDER IS THAT EVEN THOUGH MORE TYPES OF HAZARDOUS MATERIALS ARE BEING USED IN LAB, THE VOLUME OF NON-ACUTE HAZARDOUS WASTE BEING GENERATED TENDS TO BE SMALLER, BUT ACUTE HAZARDOUS WASTE CAN BE LARGER. THERE ARE HOWEVER A FEW EXCEPTIONS (FOR EXAMPLE HPLC & EPLC WASTE STREAMS).

THIS PRESENTS A PARTICULAR CHALLENGE FOR BOTH GENERATORS AND REGULATORS, IN ASCERTAINING THAT ANY HAZARDOUS WASTES BEING GENERATED ARE BEING PROPERLY CLASSIFIED, MANAGED/STORED ONSITE (SAA/CAA) AND ULTIMATELY SHIPPED OFFSITE.

IN MY OPINION, THERE ARE TWO AREAS WHERE LABS CONTINUOUSLY FALL SHORT:

- a) TRAINING PERSONNEL
- b) CONTAINER MANAGEMENT (SPECIFICALLY SATELLITE ACCUMULATION CONTAINERS)

WHY? MANY OF THE PEOPLE INSIDE OF THE LABS ARE FOCUSED ON THE WORK THEY ARE DOING. THEY HAVE PHD'S, GRADUATE STUDENTS, ETC.... THEY FEEL THAT THE REGULATORY REQUIREMENTS ARE REALLY NOT AS IMPORTANT AS THE WORK THEY ARE PERFORMING. CONTAINER MANAGEMENT IS AN AFTERTHOUGHT. LEAVING THE LAB, ANOTHER FACILITY EMPLOYEE USUALLY HAS BETTER CONTAINER MANAGEMENT IN CAA. (MENTION CARDINAL)

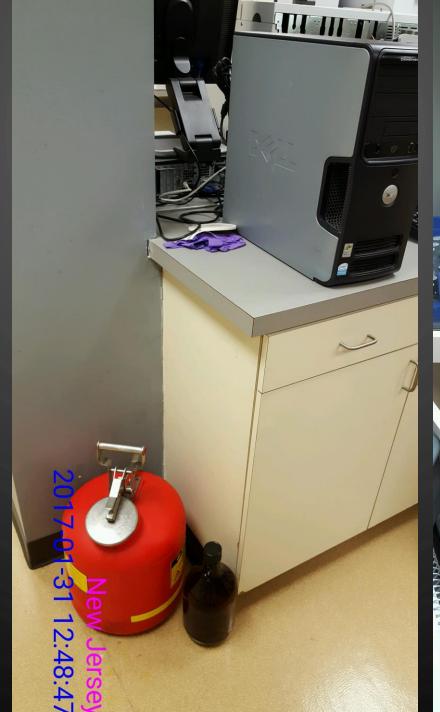
HOW DOES THIS PRESENT ITSELF DURING AN INSPECTION?

FIRST OFF, IT USUALLY MEANS THAT THERE WILL BE, AND USUALLY ARE, NUMUROUS AMOUNTS OF SATELLITE ACCUMULATION AREAS/CONTAINERS. THESE SATELLITE AREAS CAN BE FOUND IN VARIOUS LOCATIONS THROUGHOUT THE LAB — IN HOODS, UNDER COUNTERS, INSIDE CABINETS. SOME FACILITIES ACTUALLY HAVE DIRECT CONNECTIONS OF THEIR LABORATORY EQUIPMENT TO AN ABOVEGROUND, AND/OR VAULTED ABOVEGROUND STORAGE TANK!

SO WHERE ARE THOSE LAB SAA'S?









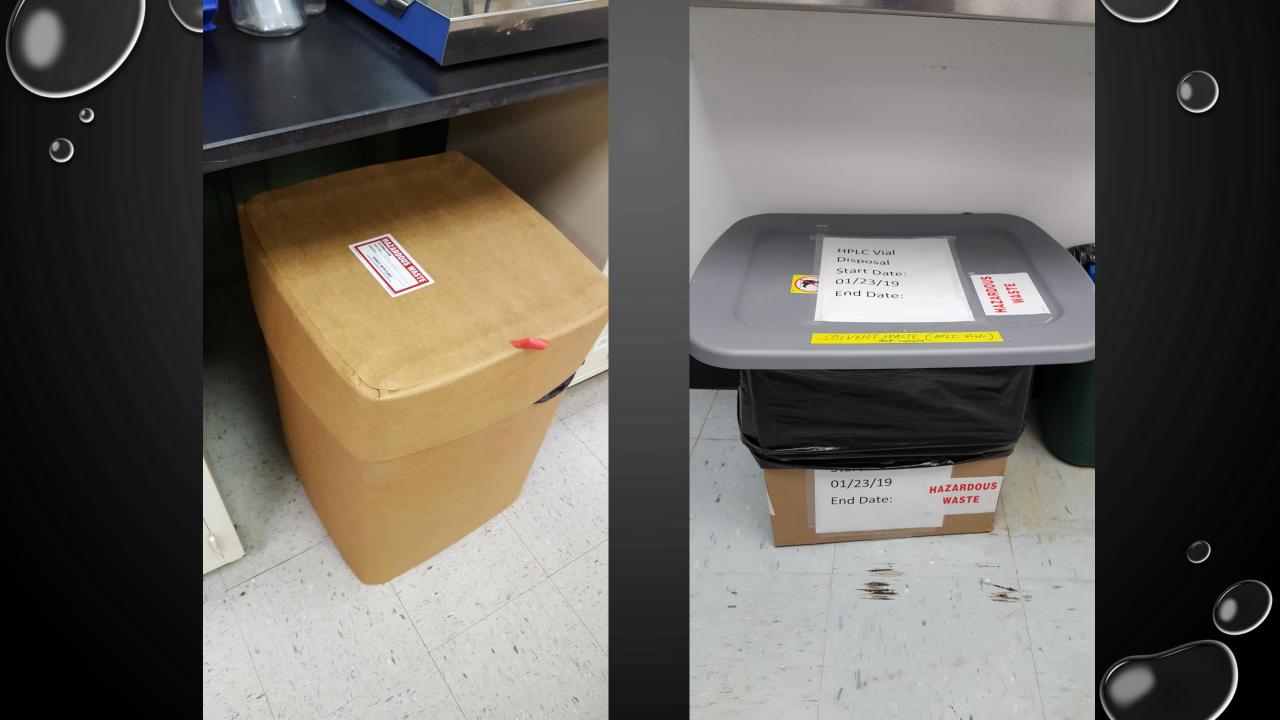


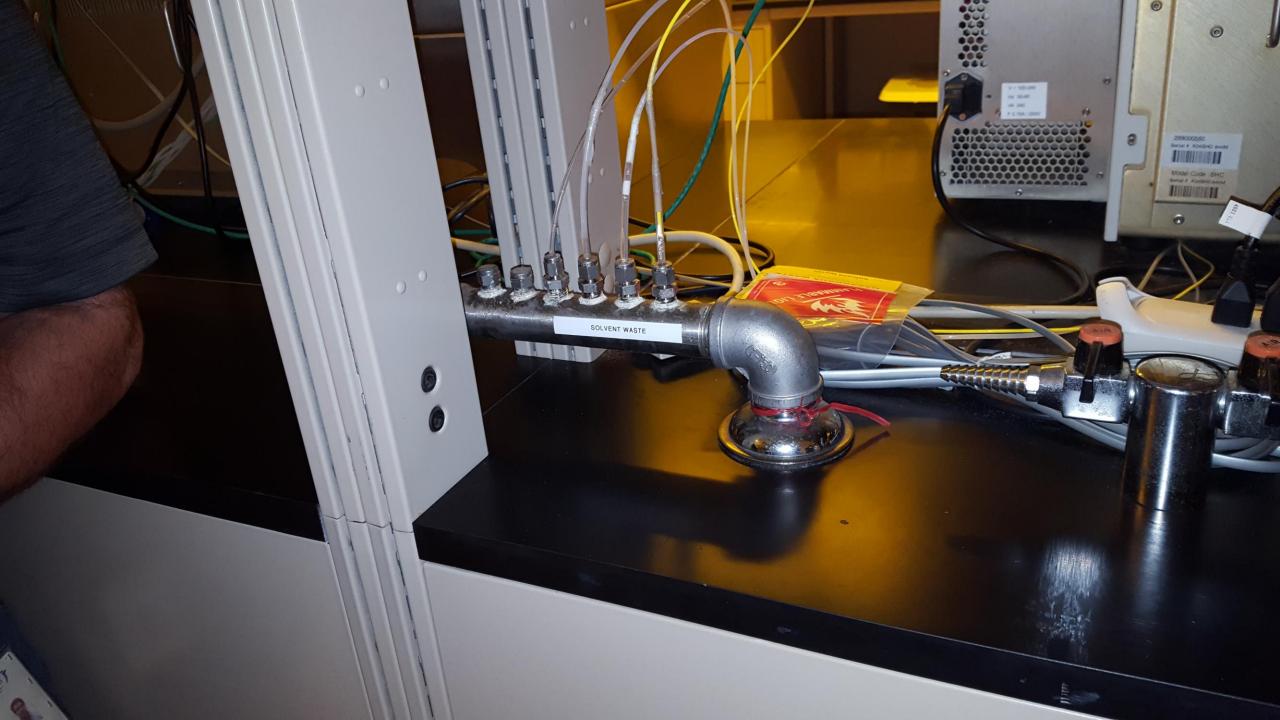






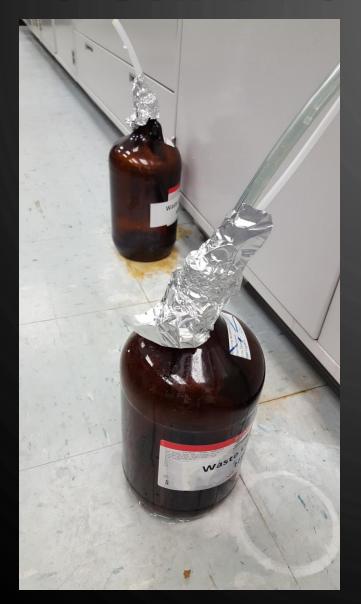
JCMC – Distillation Unit



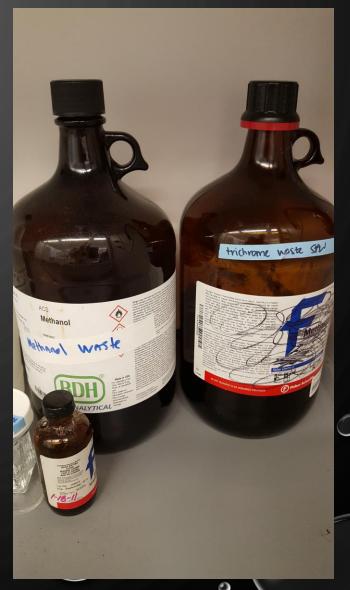




THE MARKING AND/OR LABELING REQUIREMENTS FOR THESE CONTAINERS CAN BE A DAUNTING CHALLENGE FOR THE FACILITY TO MAINTAIN, AND THE REGULATOR TO INSPECT!! THERE ARE FACILITIES OUT THERE WITH DOZENS IF NOT HUNDREDS OF LABS ONSITE.



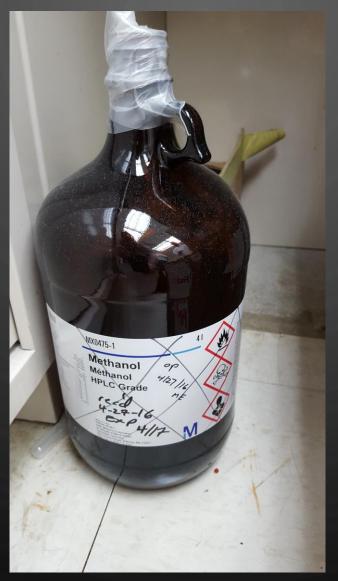




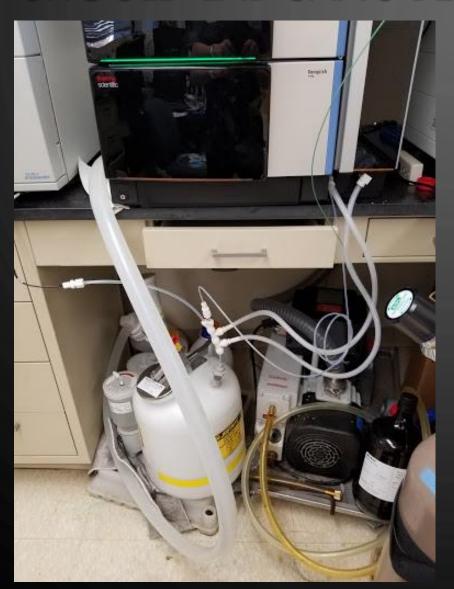














THIS IS THE PROPER WAY!!





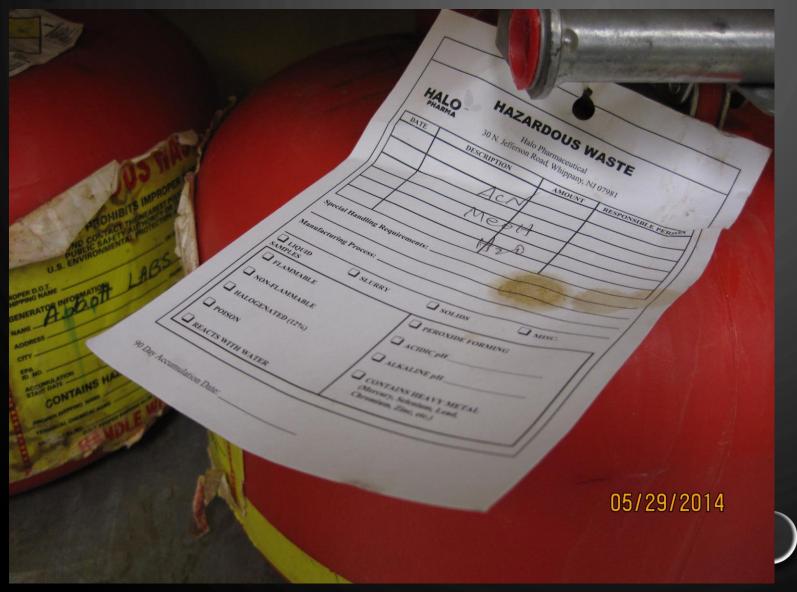


NOTE:

AS SEEN IN SOME OF THE PREVIOUS PHOTOGRAPHS, SECONDARY CONTAINMENT IS NOT REQUIRED UNDER RCRA BUT IS HIGHLY RECOMMENDED TO LIMIT THE SIZE OF THE SPILL AND REDUCE THE AMOUNT OF HAZARDOUS WASTE BEING GENERATED (REMEMBER THE MIXTURE RULE WITH LISTED HAZARDOUS WASTE). HAS TO BE COMPATIBLE WITH THE HAZARDOUS WASTE IN THE SAA.

BUT WHAT ABOUT THESE HAZARD MARKINGS?







LET'S REVIEW:

- * VERY RARELY WILL YOU SEE A LARGE SATELLITE ACCUMULATION CONTAINER INSIDE OF A LAB LARGER THAN 5-GALLONS. THEY ARE USUALLY SMALLER.
- * AS PER THE GENERATOR IMPROVEMENT RULE, ALL SATELLITE ACCUMULATION AREAS/CONTAINERS MUST BE MARKED AND/OR LABELED WITH THE WORDS "HAZARDOUS WASTE" AND THE HAZARDS ASSOCIATED WITH THE WASTE BEING ACCUMULATED INSIDE OF THE CONTAINER.
- * THE CONTAINER MUST BE COMPATIBLE WITH THE MATERIALS BEING PLACED INSIDE OF THE SATELLITE CONTAINER
- * THE CONTAINER MUST BE SECURELY CLOSED WHEN ADDING, REMOVING, OR CONSOLIDATING WASTE; OR WHEN TEMPORARY VENTING OF A CONTAINER IS NECESSARY
- * INCOMPATIBLE WASTES MUST NOT BE MIXED TOGETHER IN THE SAME CONTAINER

SPEAKING OF INCOMPATIBLE HAZARDOUS WASTE:

WHEN ACCUMULATING HAZARDOUS WASTE IN THESE SATELLITE ACCUMULATION AREAS IT IS SO IMPORTANT TO ASCERTAIN THAT INCOMPATIBLES ARE NOT STORED NEXT TO ONE ANOTHER.

ALSO CONSIDER THAT BESIDES THE ROUTINE HAZARDOUS WASTE THAT MIGHT BE GENERATED OFFSITE, ANY UN-USED AND OFF-SPECIFICATION HAZARDOUS CHEMICALS MAY EVENTUALLY BE GENERATED OFFSITE. THIS COULD LEAD TO THE FACILITY BECOMING AN EPISODIC GENERATOR OF HAZARDOUS WASTE IF THEY ARE A VSQG OR SQG.

2007 PATERSON AND NEWARK HIGH SCHOOL LAB INSPECTIONS CONDUCTED

- IN 2007 CONDUCTED INSPECTIONS OF 13 HIGH SCHOOLS IN PATERSON & NEWARK, IN SEVERAL HUNDRED LABS. ALSO INCLUDED SEVERAL GRAMMAR SCHOOLS AS WELL.
- MANY OF THE LABS HAD HUNDREDS OF OLD & EXPIRED CHEMICALS FOUND IN THE LABS. THESE OLD CHEMICALS WERE SIMPLY LEFT THERE AS TEACHERS RETIRED, AND NEW TEACHERS JUST ADDED NEW CHEMICALS IN THE SCHOOL LABS.
- AFTER TWO (2) WEEKS OF INSPECTIONS IN NEWARK, THE NEWARK BOARD OF EDUCATION GENERATED THREE (3) TRACTOR TRAILER LOADS OF HAZARDOUS WASTE OFFSITE FOR DISPOSAL.





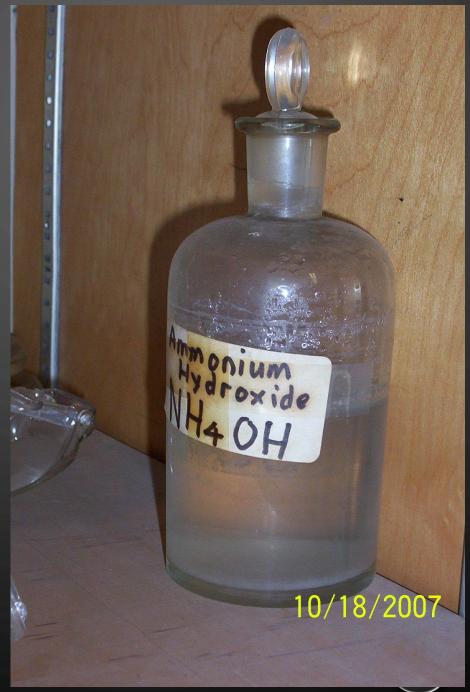












INCOMPATIBLES

AND JUST VERY OLD CONTAINERS!

DATE OF

MANUFACTURE IS

UNKNOWN!





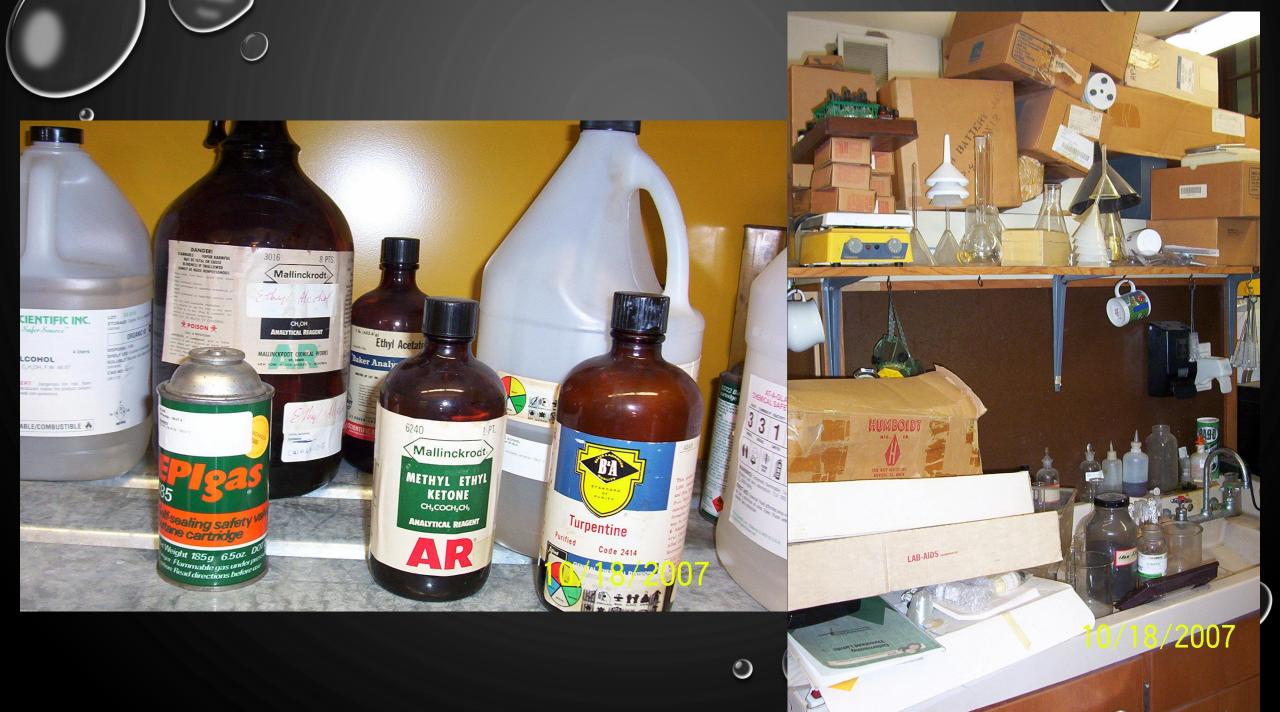












JUST REMEMBER, THESE OLD CHEMICALS CAN LEAD THE GENERATOR
TO BE AN EPISODIC GENERATOR. IMPORTANT TO REMEMBER IF
GENERATOR IS A VSQG OR AN SQG OF HAZARDOUS.

OTHER WASTES YOU MIGHT ENCOUNTER IN LABS IS REGULATED MEDICAL WASTE......BUT THAT'S ANOTHER TRAINING SESSION.